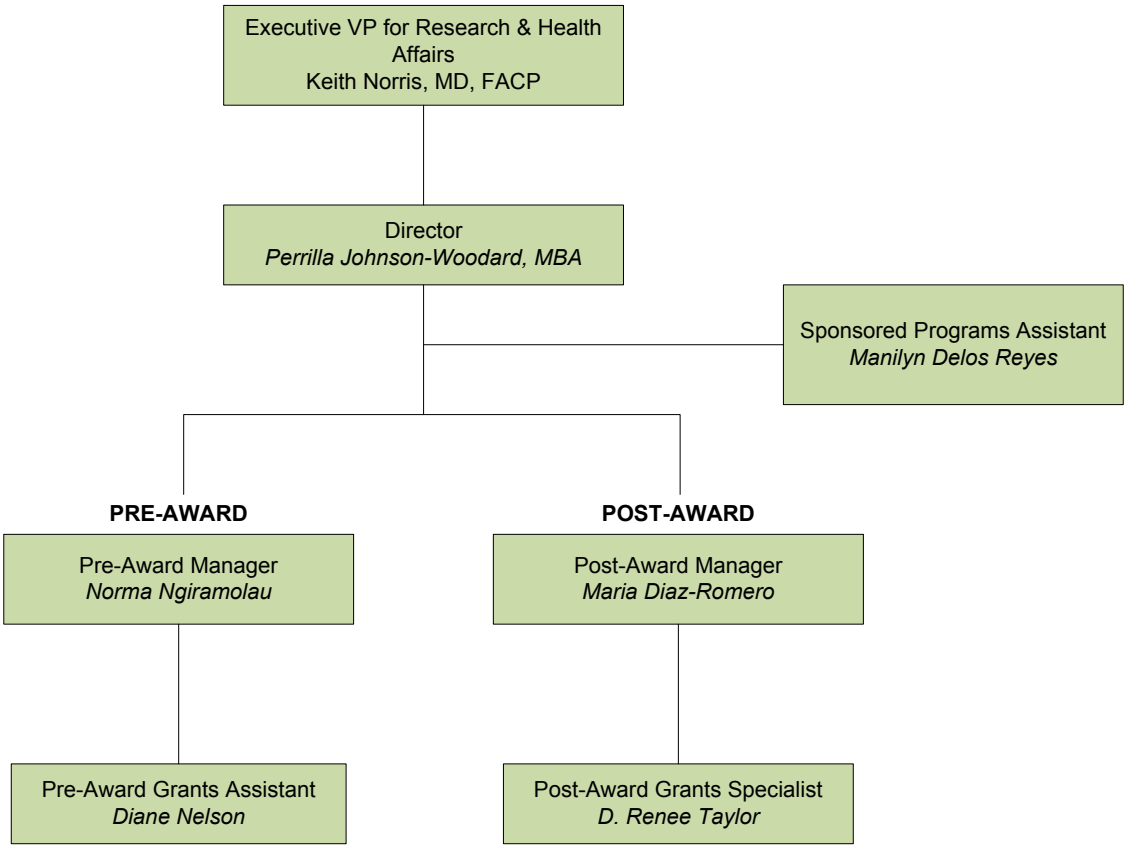
CHARLES DREW UNIVERSITY OF MEDICINE AND SCIENCE

Office of Sponsored Programs

Pre-Award Manual

Table of Content

Office of Sponsored Programs (OSP)
Organizational Chart



This manual has been designed as a tool to assist new and established researchers in the conduct of research. The handbook seeks to support the University's research effort by providing guidance regarding the development and administration of sponsored projects; informing investigators of their roles and responsibilities in research administration and compliance; and collecting and organizing information pertinent to sponsored project administration in a single document that makes this information accessible to the University community.

Mission

The Office of Sponsored Programs (OSP) is to support the University's efforts to identify mission-appropriate sources of external support, establish productive business relationships with those sponsors and to manage those grants and contracts effectively.

Vision

The vision of the Office of Sponsored Program is to be a premier sponsored program office that guarantees a high level of credibility, financial integrity, and regulatory compliance. OSP fosters proposal development for research, education, and service throughout the University thereby promoting and sustaining sound business practices and provides the highest quality of administrative management and financial services to support the University mission.

Values

The OSP staff strives to create an ideal work environment by sharing and maintaining

- honesty
- compliance
- integrity
- competent
- responsibility
- open communication
- dedication
- discipline
- courtesy

Goals

Improve grants management by recruiting and retaining quality personnel and to support their efforts by providing adequate resources for them to succeed in meeting their requirements for accountability.

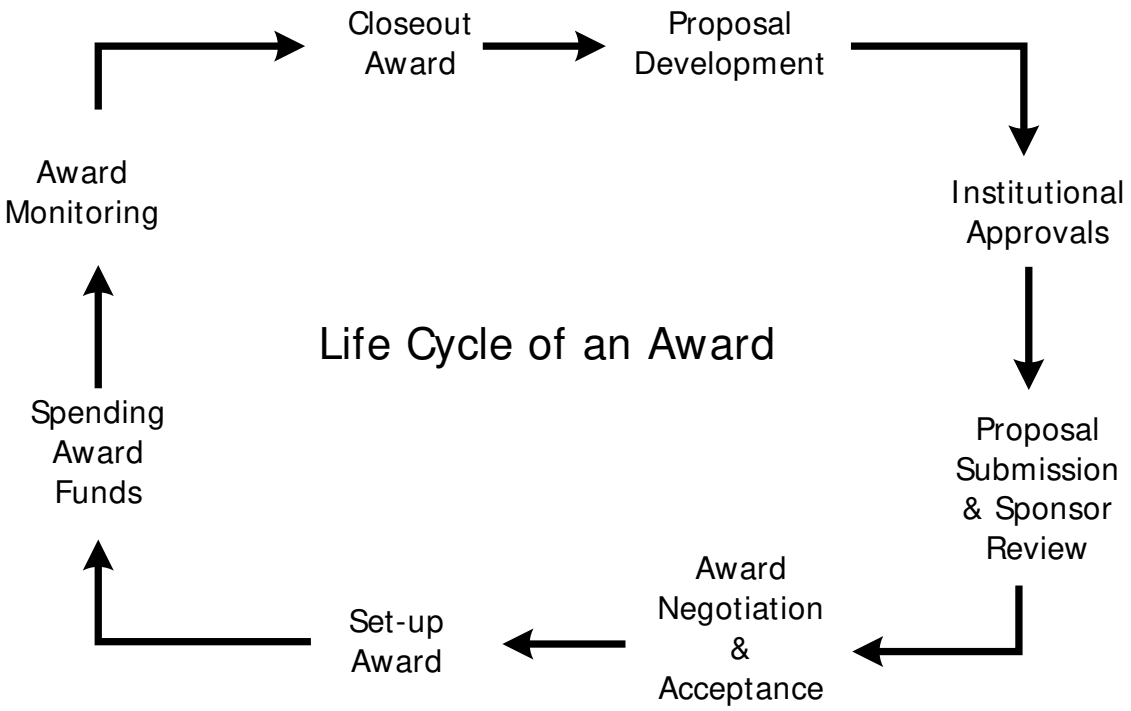
Develop and implement an effective training program for efficient utilization of administrative tools and processes to most efficiently conduct sponsored projects.

Increase the efficiency of research administration by assisting faculty in the number and quality of grant proposals submitted, thereby potentially increasing CDU overall extramural funding.

Promote management excellence with an environment of financial accountability and integrity, regulatory compliance, and internal controls.

Develop a model sponsored program administration that generates a high level of customer satisfaction.

Strengthen understanding of the integrated grants management office service role by increasing and improving communication between OSP, faculty, staff, administration and sponsors.


Life Cycle of an Award
Closeout Award
Proposal Development
Institutional Approvals
Proposal Submission & Sponsor Review
Award Negotiation & Acceptance
Set-up Award
Spending Award Funds
Award Monitoring

Section

1

Pre-Award Services

The Pre-Award Office assists faculty and other university personnel with all aspects of securing support for research and other scholarly activities from external sponsors. All requests for externally funded sponsored projects should have, and in most cases require, the review and approval of OSP. Once a project is approved, the University and the PI have a shared responsibility to make sure that a project is performed as proposed, that funding is used in accordance with sponsor terms and conditions, and that all required reports and closing documents are provided in a timely manner.

The following services provided by the pre-award office include the following:

- Identify and disseminate funding opportunities and notifying the University community about these opportunities as well as sponsor policies and application guidelines
- Obtain sponsor guidelines/instructions and applications forms from the sponsors
- Review and Assist faculty with proposal and budget development in according with sponsoring agencies guidelines and requirements
- Update faculty and staff on funding opportunities and sponsor policies
- Review proposals to ensure compliance with sponsor and institutional requirements
- Provide assurances, representations and certifications
- Advise the University community regarding Federal, State and Local Government agency rules, regulations and procedures
- Review and submit all university endorsed applications for external sponsored funding
- Provide grant management training to administration, faculty and related staff in areas of compliance such as OMB Circulars, proposal development, locating and searching for funding opportunities
- proposal submission and grant administration training;
- Review, negotiate, and accept awards on behalf of the University;
- Serve as the liaison between the University, the principal investigator and sponsors
- Maintain a database for proposals and other relevant information that provides University administration, colleges, departments and others with critical management information
- Produce proposal reports upon request

Section

2

Office of Sponsored Programs Review and Approval Process

All Proposals that are submitted to external sponsors whether new, continuation, supplemental, renewal, or revision must be reviewed and approved by OSP. If the proposal is a hard copy or paper submission, OSP will review, approve and return the proposal to the principal investigator for forwarding to the sponsor. All electronic proposal submissions will be submitted by OSP, unless a sponsor specifically requires that the proposal be submitted directly by the PI.

The review/approval process also applies to pre-proposals or other preliminary applications, e.g. concept papers, if they involve detailed budget figures or a commitment of university resources.

OSP Pre-Award Unit is available to assist the Principal Investigator and/or their staff in any phase of proposal preparation. Proposals are carefully reviewed to ensure that they comply with University and Sponsor requirements. Proposals are reviewed for institutional commitments and include the following criteria:

- Review of the Request for Proposal Approval and Submission (RPAS) Form for appropriate signatures and compliance with applicable research protection policies;
- Verification of Principal Investigator eligibility;
- Verification of the correct use of institutional identifiers;
- Verification that proposed costs are consistent with the University's and the sponsor's cost principles;
- Verification that the correct Facilities & Administrative rate is used for the proposed activity and location of activities;
- Verification of cost-share commitments;
- Verification of documentation for subcontractors and/or consultants;
- Review and signature of certifications and representations.
- Ensure regulatory approvals are obtained.

Investigators should notify OSP as soon as possible when preparing to submit a proposal. The review and institutional approval of a proposal requires time and cannot be left to the last minute.

What to Submit

For institutional approval by OSP, one copy of the proposal must be submitted for review. At minimum, the following elements of the proposal must be provided:

- Request for Proposal Approval and Submission (RPAS) Form
- Copy of the Sponsor's Program Announcement (FOA, RFP, RFA, BAA)
- Conflict of Interest Form(s), if applicable
- Original Application Pages Requiring Institutional Endorsement
- Draft Abstract
- Draft Budget and Budget Justification
- Draft Statement of Work
- Draft Biographical Sketches
- Draft Other Support
- Draft Facilities and Resources
- Additional Attachments, when applicable
- Additional Attachments, when applicable:
    - Cost Sharing Commitment Letter(s)
    - Consultant Commitment Letter(s)
    - Subcontract Commitment Letter(s) and proposal, signed by an authorized institutional representative
    - Request for Exception to Principal Investigator Eligibility
    - Request for an Facilities & Administrative Costs Waiver
    - Certifications and Representations

When submitting a proposal in draft form for review and approval, OSP requires a final copy of the proposal submitted to the sponsor be forwarded to the OSP within three to five business days.

Clinical Trial Proposals Supported by For-Profit Sponsors

The institutional review and approval of clinical trial protocols to for-profit sponsors also requires the submission of a proposal to OSP. One copy of the proposal must be submitted and the following elements must be included:

- Request for Proposal Approval and Submission (RPAS) Form
- Financial Disclosure Form(s)
- Final Budget, as approved by the sponsor
- Clinical Trial Protocol
- Clinical Trial Questionnaire
- Draft Clinical Trial Agreement, if provided by sponsor
- Additional Attachments, when applicable
- Request for Exception to Principal Investigator Eligibility

Investigators should notify OSP as soon as possible when initiating a clinical trial supported by a for-profit sponsor. The review of the proposal and negotiation of the clinical trial agreement requires time and cannot be left to the last minute.

OSP can begin to negotiate a clinical trial agreement prior to IRB approval. However, the clinical trial cannot commence until the IRB approves the protocol and OSP has signed the clinical trial agreement.

Electronic Submissions

Many sponsors are developing and implementing electronic systems that allow the University to submit proposals electronically either through the internet or via e-mail.

Each sponsor may impose different registration requirements and procedures. OSP is responsible for institutional registration and maintaining institutional profiles. Many systems also require individual registration which will be handled in accordance with each sponsor's guidelines. A list of sponsors that currently have information available regarding applicable electronic research systems is available from OSP.

Despite the method of submission, OSP review and approval of proposals requesting extramural funding is required prior to submission to the sponsor.

Normal internal requirements and review are necessary for all proposals submitted electronically. A selection of electronic proposal submission web sites is listed below.

- American Heart Association (AHA)
- GRANTS.GOV
- Health Resources and Services Administration (HRSA)
- NIH Commons (Applicable Progress Report and Just-in-Time information submission)
- NSF Fastlane
- Proposal Central
- U.S. Department of Defense / Congressionally Directed Medical Research Programs
- U.S. Department of Education (e-Grants.ed.gov)

If a specific sponsor is not included in the list above but submission by an authorized organizational representative is required by the sponsor, contact Office of Sponsored Programs, Pre-Award Office.

Please note that Central Contractor Registration (CCR) is required in the federal proposal submission systems, and registration is handled centrally. Do not register in CCR separately. In addition, do not register in grants.gov separately. Access to grants.gov proposal opportunities and forms does not require registration. Other systems may require that passwords for individual researchers be set by an institution’s primary organizational user. For such systems, contact the Office of Sponsored Programs.

Section

3

Eligibility to Submit Proposals for Extramural Support

Solicitation Authority

No solicitation or application for extramural support of research, training or public service programs or projects shall be made officially in the name of the University without the prior approval of an authorized officer or official of the University. This review should be based on an adequately prepared written proposal, submitted by an individual authorized to do so as stated below.

Academic Policy

A research proposal may be submitted only by academic appointees (singly or jointly) who will personally direct the research effort and also serve as the Principal Investigator or Co-Investigator. (Note: Not all funding agencies allow Co-Investigators).

A proposal for a training or public service may be submitted only by an academic appointee who will personally direct the project to a significant degree and also serve as the project director. A proposal for a research, training or public service program involving numerous programs may be submitted only by an academic appointee who will personally oversee the programs in his/her capacity as the program director.

A director of a sub-project of a multi-unit program must qualify by academic appointment.

Whenever a form or other document calls for the use of a University employee's title in any official way, the correct payroll title must be used. Therefore, since proposals are official University documents, the academic appointee's title must be given in full. For example, Adjunct Professor, Assistant Professor or Associate Professor, etc., may not be designated solely as a "Professor". Titles of research appointees should specify Research Scientist or Project Scientist etc. In addition, the proper payroll title must also be used for staff employees. If an employee has a different working title, that title may be shown in addition to the payroll title.

In addition, when referring to an individual in charge of a particular department, division etc., the proper title, as it specifically related to the academic unit or departmental (or equivalent)

sub-unit, should be used: e.g. Professor John H. Doe, Chair, Department of Surgery, or Associate Professor, Jane L. Smith, M.D., Head, Division of Physiology.

Eligible Appointees and Exceptions

On or before the start date of a proposed project, the Principal Investigator and, if applicable, the Co-Investigator(s) must have formally accepted an appointment at the University in an eligible title, or qualify by exception approved by the Vice President for Research as noted below.

- **Eligible Academic Appointees**

  Academic appointees who currently hold a title in the following groups are automatically eligible by virtue of appointment to submit proposals for extramural support of research, training or public service contracts or grants, subject to conditions, restrictions, and review procedures established by the University:

  Members of the Academic Senate:

  - Career Academic – all ranks
  - Adjunct Academic – all ranks
  - Clinical – all ranks

- **Exceptions**

  By exception, the Executive Vice President for Research & Health Affairs may approve the submission of a grant or contract proposal by other appointees or candidates for appointments, in special circumstances when the individual is highly qualified, when such action is in the best interest of the University, and provided that space and facilities can be assigned without detriment to the regular research, instructional and public service responsibilities of the University.

  Previous approval of an exception of the principal investigator status is not a guarantee of approval of subsequent requests for exceptions. An exception is required for renewal of an existing project for which an exception was originally required and the PI still does not have a qualified title.

  Listed below are appointment series which require exceptions. Questions regarding qualifications of Principal Investigators should be referred to the Executive Vice President for Research & Health Affairs and/or the Office of Sponsored Programs.

  1. Staff (Administrators/Coordinators)
  2. Postdoctoral Fellow
  3. Research Associate
  4. Lecturer
  5. Resident
  6. Undergraduate/Graduate Students

7. Visiting

"Visiting" appointments are normally for short-term periods up to one or two years and are subject to annual reappointment. Therefore, appointees to Visiting titles should submit proposals for a period of support that coincides with their current term of appointment. If the proposal end date exceeds the end date of the Visiting appointee's current appointment, the proposal should stipulate, by name, a qualifying Co-Principal Investigator who is willing and able to assume the functions as the Principal Investigator and devote adequate time to head the work should the Visiting appointee sever connections with the University prior to the proposal termination

- **Exceptions**

To request an exception, a written justification must be submitted by the Executive Vice President for Research & Health Affairs. In order to insure timely review and final decision, requests should be received **ten (10) business days** prior to the agency due date for proposal submittal. The written justification must include the PI Exception Form and a current curriculum vitae or bio-bibliography.

Section

4

Basic Responsibilities

Completion of a successful proposal involves the cooperation and interaction of numerous University faculty/staff. It is critical that faculty/staff keep one another informed and involved in proposal processing.

Principal Investigator's/ Project Director's Responsibilities

The University assumes legal responsibility for funded projects and the PI is responsible for the management, activities and technical reporting activities.

The PI/PD must maintain contact with the sponsor's technical monitor and comply with all technical reporting requirements. The PI/PD must also initiate correspondence with the sponsor's administrative or contract monitor to request programmatic or budgetary changes. All such requested revisions should be routed through OSP for appropriate approval signatures.

- Notifies Office of Sponsored Programs (OSP) of intent to submit
- Coordinates with OSP during proposal development
- Researches and develops proposal information and components
- Produces and types each draft and the final proposal in electronic format
- Complies with sponsor guidelines and requirements
- Verifies of University and other resource availability
- Develops detailed budget
- Identifies animal care, human subject protection, DNA, or other relevant research issues
- Identifies potential intellectual property products
- Identifies and secures approval of desired space use
- Obtains Letters of support
- Notifies OSP of collaborating institution(s) and provides business contact

- Completes text and any other necessary agency forms in compliance with agency guidelines. May include checklist, biosketch, budget justification, current and pending, etc.
- Solicits and secures all cost sharing commitments
- Completes and obtains all required signatures for Request for Proposal Approval and Submission Form (RPAS)
- Forwards completed proposal to OSP for final review and submission

Principal Investigator's Administrator (if applicable)

- Works with PI on budget
- Consults with other departments, when necessary
- Prepares internal budget papers for proposal
- Reviews budget and checks budget justification
- Checks proposal text for budget related statements
- Consults with other institutions if subcontracts are involved
- Reviews cost sharing commitments and prepares necessary cost share forms
- Reviews proposal format requirements, page limits, font size, etc.
- Assures original RPAS is completed and routed for signatures

Cluster Leader

- Reviews text to make sure research is within CDU's mission, scientifically valid
- Reviews and agrees on release time
- Reviews and agrees on cost sharing commitment
- Signs RPAS to indicate approval of proposal for transmission to sponsor

Dean (COM/ COSH/ SON)

- Reviews and agrees on cost sharing commitment
- Reviews and space commitment
- Signs RPAS to indicate approval of proposal for transmission to sponsor

Executive Vice President for Research & Health Affairs

- Reviews and agrees on cost sharing commitment
- Reviews and space commitment
- Signs RPAS to indicate approval of proposal for transmission to sponsor

Office of Sponsored Programs

- Identifies potential sponsors
- Reviews format and content
- Assists with development of the proposals
- Assists, reviews and approves budget proposal
- Reviews and approves Request for Proposal & Approval Form (RPAS)
- Processes Certification and Assurances
- Performs final review for all CDU proposal submissions
- Completes electronic submission of proposals
- Provides Pre-Award training (e.g., proposal development, budget development, locating funding opportunities, etc.)
- Provides administrative oversight for University sponsored programs
- Serves as official University's negotiator for sponsored program agreements
- Serves as final approval point for sponsored program activity
- Serves as official University's contact for government and other sponsors for all sponsored program activity
- Serves as official reviewer of sponsored program agreements
- Monitors program compliance issues for sponsored programs
- Review reports to sponsors, prior to submissions by principal investigators/program directors
- Coordinates between sponsors and principal investigators/program directors interactions on program matters

Section

5

Identification of Funding Opportunities

Funding can be identified through various sources. The Office of Sponsored Projects (OSP) is available to assist you in identifying funding sources for your externally sponsored project by performing a funding search or registering you to receive funding alerts via email. In addition, OSP maintains a comprehensive electronic collection of sponsor guidelines.

Funding Opportunity Announcements (FOAs)

FOAs are publicly available documents by which agencies or other sponsor organizations make known their intentions to award funding, usually as a result of a competitive process. Funding opportunities (or solicitations) may be called by a number of names, including: Request for Proposals (RFP); Request for Applications (RFA); Funding Opportunity Announcements (FOA); Proposal Announcements (PA); or any other name the sponsor decides to use. It is important to check for new funding opportunities frequently. In addition, you should check periodically to see if a sponsor has revised an existing FOA.

Understanding Funding Opportunity Guidelines

- **Overview of Steps**

  The basic steps for understanding the sponsor's proposal submission guidelines and instructions are the same regardless of what the funding agency calls the announcement.

- **Download and print ALL of the announcement/ guidelines/ instructions from the appropriate agency's website.**

  Each funding opportunity has a specific set of instructions, or guidelines associated with it. Be sure to download the most recent version of the sponsor's guidelines and look for any associated updates to the opportunity (i.e., deadline extensions, format changes, etc.) to ensure you have a complete set of instructions before proceeding to the application. Most federal funding for basic assistance requires that a proposal be prepared using agency specific formats. Therefore, be sure to download the most current application form packets for each submission. This is of particular importance because **all of the sponsoring agencies which submit through Grants.gov also**

use the basic SF424RR form. However, each agency can add their own particular form(s) to the basic SF424RR application set, or they can ask that certain information be loaded into sections of the application where it may not seem to fit intuitively.

- **Types of Sponsors**

  Support for research and scholarly activities can come from diverse sources. Before submitting a proposal to a potential sponsor, it is important to understand the characteristics of sponsors in general as well as specifics about the sponsor you are considering. There are three broad categories of external sponsors:

  - Government: Federal, State and Local Programs
  - Nonprofit Organizations: Foundations and Other Nonprofit Organizations
  - For Profit Organizations: Business & Industry

- **SPINPlus (Sponsored Programs Information Network)**

  SPINPlus is an online database of funding information that is updated regularly with new sponsor announcements. CDU has purchased a license agreement for SPINPlus that is renewed annually which provides access for members to a database of funding opportunities. Members can search for funding opportunities, signup for email notifications and create a Genius Profile. SPIN allows networking and collaboration with other investigators interested in the same research via the Genius Profile. This site is restricted to CDU employees. Contact OSP Pre-Award Division at 5843 to assist you in registering for SPINPlus.

- **Grants.gov**

  Grants.gov acts as a central portal to finding and applying for federal government grants. grants.gov. The 26 grant-making DHHS agencies can be accessed through this system and the viewer can see what grant and contract opportunities are available.

  To search for grants on Grants.gov, go to:

  www.grants.gov/applicants/find_grant_opportunities.jsp

  In order to find out who might provide future opportunities, it is beneficial to view DHHS grant opportunities that have not been announced but are in the planning stage.

  To search for future funding opportunities, go to:

  www.hhs.gov/grantsforecast/index.html

- **Substance Abuse & Mental Health Services Association** (SAMHSA)

  www.samhsa.gov/grants

- **Centers for Disease Control and Prevention** (CDC)

  The CDC awards nearly 85 percent of its budget through grants and contracts to help accomplish its mission to promote health and quality of life by preventing and controlling disease, injury, and disability. Contracts procure goods and services used directly by the agency, and grants assist other health-related and research organizations that contribute to CDC's mission through health information dissemination, preparedness, prevention, research, and surveillance.

  Each year, the CDC awards approximately $7 billion in over 14,000 separate grant and contract actions, including simplified acquisitions

  www.cdc.gov/od/pgo/funding/grantmain.htm

- **Health Resource Services Association** (HRSA)

  Health Professions grants improve access to health care by helping health professions training programs address some of the most pressing needs across the U.S. health workforce. Most health professions grants are made to colleges and universities which use the funds to build programs that enroll diverse students, including those from disadvantaged backgrounds, and produce graduates who make careers in primary care. Each grant program has specific eligibility requirements, but generally, public or nonprofit private hospitals, accredited health professions schools, and other public or private nonprofit organizations that meet the requirements are eligible to apply

  www.hrsa.gov/grants/default.htm.gov

- **Agency for HealthCare Research & Quality** (AHRQ)

  The Agency for Healthcare Research and Quality (AHRQ) is the health services research arm of the U.S. Department of Health and Human Services (HHS), complementing the biomedical research mission of its sister agency, the National Institutes of Health. AHRQ is a home to research centers that specialize in major areas of health care research such as quality improvement and patient safety, outcomes and effectiveness of care, clinical practice and technology assessment, and health care organization and delivery systems. It is also a major source of funding and technical assistance for health services research and research training at leading U.S. universities and other institutions, as well as a science partner, working with the public and private sectors to build the knowledge base for what works—and does not work—in health and health care and to translate this knowledge into everyday practice and policymaking.

  www.ahrq.gov/fund/

- **National Institutes of Health (NIH), Centers and Offices**

  To stay current on upcoming NIH opportunities, it is recommended that the Principal Investigator explore the NIH site.

  Browse the NIH Institutes, Centers and Offices website for specific areas of interest, upcoming solicitations and recently cleared concepts. This website offers key information, including objectives, descriptions for future solicitations and has a link to NIH staff personnel. Potential applicants can view listings of future initiatives meant to provide early possible alerts. For a listing of NIH Institutes, Centers and Offices, go to: www.nih.gov/icd to look for recently cleared concepts.

  NIH's Funding Opportunities and Notices Search Page:

  www.grants.nih.gov/grants/guide/listserv.htm

  Sign up for the NIH Guide to Grants and Contracts for weekly announcements of new NIH grant opportunities and for NIH email LISTSERV:

  www.grants.nih.gov/grants/guide/listserve.htm

- **National Science Foundation (NSF)**

  The NSF aids scientific progress in the United States by competitively awarding grants and cooperative agreements for research and education in engineering, mathematics and science.

  To search for NSF opportunities, go to: www.nsf.gov/funding
  To browse NSF programs, go to: www.nsf.gov/fundign/browse_all_funding.jsp

- **Department of Defense (DoD)**

  The Defense Advanced Research Projects Agency (DARPA) is the central research and development organization for the DoD. It functions as the manager and director of selected basic and applied research and development projects for the DoD.

  To search for DARPA opportunities, go to: www.darpa.mil/baa

  The Office of Naval Research (ONR) is the technology and science provider of the Department of the Navy.

  To search for ONR opportunities, go to: www.onr.navy.mil/o2/baa

  To search for DoD's Congressionally Directed Medical Research Programs, go to:

  www.cdmrp.army.mil/funding/default.htm

- **To search for The DoD SBIR & STTR Programs opportunities, go to:**

  http://www.acq.osd.mil/osbp/sbir/

  The **Department of Defense** (DoD) **SBIR** and **STTR** programs fund a billion dollars each year in early-stage R&D projects at small technology companies -- projects that serve a DoD need and have commercial applications.

  The **SBIR Program** provides up to $850,000 in early-stage R&D funding directly to small technology companies (or individual entrepreneurs who form a company).

  The **STTR Program** provides up to $850,000 in early-stage R&D funding directly to small companies working cooperatively with researchers at universities and other research institutions.

Other Federal Resources

The Catalog of Federal Domestic Assistance

Currently there are 15 types of assistance available, including guaranteed loans and grants, training and surplus equipment. The online CFDA gives you access to a database of all the Federal programs. Note that this comprehensive listing of all legislated programs will include programs for which funds may not have been allocated during a single federal budget period. Thus it is important to contact the program office for current information about the availability of funds. https://www.cfda.gov

Federal Business Opportunities (FedBizOpps)

Lists notices of proposed government procurement actions, contract awards, sales of government property, and other procurement information over $25,000 (updated daily). Commercial vendors can use this system to search federal markets for products and services, monitor and retrieve opportunities sought by the entire federal contracting community. https://www.fbo.gov

U.S. Small Business Administration (SBA) Office of Technology

The SBA Office of Technology oversees the Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program. The SBA, through these two programs, ensures the nation's efforts in small, high-tech; innovative businesses are a huge part of the federal government's research and development.

Federal grants, such as those available through the Small Business Innovation Research (SBIR) or Strategic Technology Transfer (STTR) programs offer significant funds for early-stage companies to assist with development research. These grants are extremely attractive because unlike loans they do not bear interest or require payback, and unlike equity they do not require the founders to give up ownership. The disadvantage of SBIR/STTR grants is the

uncertainty of funding given the competitive nature of the federal award process and the relatively long amount of time from grant submittal to approval.

To view current SBIR/STTR opportunities, go to: www.sbir.gov/solicitations/

Federal Register (FR)

The FR is the official daily publication for rules, proposed rules, and notices about Federal agencies and organizations, as well as executive orders and other presidential documents. It is available to the campus community in a variety of formats, using varied search engines as well.

To view the federal register, go to: www.gpoaccess.gov/fr/index.html

The Foundation Center

The Foundation Centers also provides information about foundations and corporations that offer grants. The Center has a Foundation Finder that offers basic information on sponsors in the United States. Private foundations, community foundations, public charities and corporate giving programs are also included.

To search the Foundation Finder, go to: www.foundationcenter.org/findfunders/foundfinder/

GrantsNet.org

GrantsNet.org is a searchable database that can be accessed, to include an email alert module of funding opportunities from federal agencies and non-profit organizations. The database contains specific training support programs for postdocs, graduate students and junior faculty members in the sciences. It is supported by the American Association for the Advancement of Science (AAAS) and the Howard Hughes Medical Institute (HHMI). Access is completely free!

To search GrantsNet.org, go to: http://www.grantsnet.org

GrantsAlert

GrantsAlert is a searchable database that includes educational programs, agencies and grant writers from across the nation. The only national professional organization of grantmakers active in the field. http://www.grantsalert.com

Grantmakers In Aging (GIA)

GIA is dedicated to promoting and strengthening grantmaking for an aging society. GIA's membership includes leading staff and trustees from all sizes and types of foundations involved directly or indirectly with aging. GIA's greatest asset is its network of expert funders and leaders in the nonprofit and government world involved in aging. http://www.giaging.org/links/

Guidestar

This searchable database provides information on U.S. non-profit organizations, including financial data from the IRS form 990. Free registration is required to access certain data.
http://www2.guidestar.org

Code of Federal Regulations (CFR)

The CFR contains the rules and regulations that govern federal grants and awards. The CFR online provides access to current and archived copies of these regulations. The CFR is updated once each calendar year and issued on a quarterly basis.
http://www.access.gpo.gov/nara/cfr/waisidx/cfr-table-search.html

Funds Net Service

Government funding resources section is a collection of resources where you will find grants, contracts and other sources of funds by federal and state agencies.
http://www.fundsnetservices.com/gov01.htm

Section

6

Pre-Proposal Contact with Sponsors

In limited circumstances, some solicitations require or restrict certain pre-proposal communications and activities. It is especially important for the Principal Investigator to contact OSP to determine the most appropriate approach for addressing any such pre-proposal submission requirements even if the Principal Investigator has had previous experience with a particular sponsor, or the program announcement or proposal solicitation states a specific course of action. The reason for this is that only certain individuals are authorized to commit the University to a research proposal/program, and care must be taken to verify that any pre-proposal contacts or activities do not commit the University to proceed with a proposal/program.

These pre-proposal activities may take a number of forms as follows.

1. *Letter of inquiry*

   A "Letter of Inquiry" is a general presentation of a program idea designed to elicit feedback from a potential sponsor. No commitments should be made in the letter. Letters of inquiry do not require OSP review and no formal routing is required. It is recommended, however, that a copy of any such correspondence be forwarded to the Pre-Award Office in order to be prepared for the proposal development effort or agency inquiries that may result from the letter.

2. *Concept papers*

   The prospective sponsor may request concept papers. Concept papers tend to be approximately two-to-four pages in length, and they highlight key features of the anticipated proposal. Normally, these are sent to the program officer after telephone conversation requesting permission to submit a concept paper. The program officer may comment on areas to highlight, what should be avoided, and activities that should be included. Generally, in shortened form, these would include:

a) Project title.
b) Statement of need - with relevance to sponsor's mission.
c) Goals and objectives - overall goal, specific objectives, quantifiable.
d) Methodology - related to objects, anticipates questions, objections, snags.
e) Resources and personnel.
f) Generalized budget - with cost sharing (if required) and F&A, which should be coordinated with the Pre-Award Office which verifies it does not commit the University and the information is accurate. Cost sharing is strongly discourage, however, if cost sharing is required by the sponsor, the PI is required to complete a cost sharing request form along with a one page summary of the proposed research project. Send form and all relevant information to the Office of Sponsored Programs (OSP) at least *three weeks prior* to the date the proposal is due at the agency.

3. *Letter of intent.*

A "Letter of Intent" expresses the intention to submit a proposal in response to a particular program announcement or request for proposals. Letters of intent are generally solicited by the sponsor in conjunction with an announcement that is expected to generate widespread interest. Agencies generally require that such letters present only a general statement of the intended program theme. If the letter of intent contains budget estimates or representations, it should be reviewed and approved by the appropriate OSP Pre-Award Office prior to submission. The OSP Director will sign the letter as an indication of the institution's concurrence with the planned submission.

4. *Preliminary proposals (pre-proposals)*

Preliminary proposals, like letters of intent, are generally solicited by the sponsor. A preliminary proposal usually includes a one- to five-page program description. It may also require a draft budget and some indication of the university's willingness to support the program through a commitment of resources. Any document that mentions budget figures or commits university personnel, facilities, and/or other resources requires OSP review and signature approval.

Personal contacts with sponsors

Whether, when and how to make contact with sponsors (phone, e-mail, visit) may be determined by timing - before, during, or after proposal submission.

Before Proposal Submission: Prior to proposal development and/or submission, Principal Investigators may establish contact with program official, especially if there is a need to clarify unclear areas in the guidelines for a particular program. Program officers in federal agencies can be extremely helpful. It may be advisable to initiate contact via e-mail to establish a time for a personal visit or a telephone call. Program officers prefer to talk to the Principal Investigator, especially when the issues relate to the content of the proposal.

Sponsors may have guidelines for such contacts to protect fairness in the process and the appearance of impartiality in granting awards.

During Proposal Development: Some sponsors, while not requiring pre-proposals, will review drafts or comment on concept papers. Such feedback gives agency perspective and helps to establish rapport with a program official who, in some cases, can be the deciding factor in whether a program is funded

After Proposal Submission: Many sponsors have a set schedule for when proposals are reviewed and when funding decisions are supposed to be made.

1. For those agencies with internal review processes, the Principal Investigator may call the program officer concerning the proposal's status.

2. For sponsors with a grant and contract staff, call the Grants or Contracts Office to see where the proposal is in the process. Although grants officers rarely make funding decisions, they are good people with whom to establish a relationship. They have detailed knowledge on agency requirements, upcoming deadlines, new programs, etc.

3. For NIH, status checks on proposal via eRA Commons

4. For NSF, status checks on proposals are commonly done on-line.

Section

7

Request for Proposal and Submission (RPAS) Form Policy

Request for Proposal and Submission (RPAS) Form is to be completed by the PI/PD and routed with a copy of the full proposal to appropriate administrative personnel for an internal review and approval recommendation by signature prior to submission. Signatures are required from the PI, Chair/Cluster Leader, Dean and Vice President for Research and Health Affairs, additional signatures (i.e. Human Subjects-IRB, Animal Use-IACUC etc.) may be required. Be aware of signatories' travel and other absences that may interfere in collecting signatures on time.

A project <u>needs</u> a new RPAS Form if

- The original project period is extended beyond the initial project period, and additional funding and/or a new scope of work is awarded that was not previously anticipated;
- It was proposed/submitted as a multi-year project and the next anticipated funding increment is being awarded.

A project <u>does not</u> need a new RPAS if

- The project period is extended by the sponsor
- Additional funds are provided by the sponsor, but there is no change in scope of work or budget

Section

8

Proposal Submission Deadline Policy

The university policy is that all completed proposals must be received by the Charles Drew University, Office of Sponsored Programs (OSP) five (5) business days prior to the sponsor's deadline. Submitting your proposal to us five (5) business days in advance of the sponsor's deadline allows our office adequate time to conduct a thorough review of your proposal and budget, and to make corrections and/or provide recommended changes to PI, if necessary. This time also allows us to transmit the proposal before the last day of a deadline, thus avoiding transmission problems that could prevent the successful submission of your proposal.

The OSP's timeline is as follows:

- Proposals that are received five (5) business days before the sponsor's deadline will be processed first and will receive a full review (consistent with solicitation, format, compliance, etc.)

- Proposals received three (3) business days prior to the deadline will be reviewed for compliance only.

- Proposals received one (1) business day prior to the deadline may be submitted without review, subject to subsequent withdrawal if content of the proposal is later determined to be in error. We discourage departments and investigators from submitting proposals on such short notice.

- **Same-day proposals will not be submitted. Same-day proposals are defined as those for which OSP has not received prior notice that a proposal is in development and arrive in OSP on the same day they have to be sent to the sponsor to meet the sponsor's due date.**

Because most proposals are now submitted electronically, we are dependent on the reliability of CDU IS and/or sponsor systems. However, our systems and/or the sponsors' sometimes experience slowdowns or system failures. In our experience, these situations typically occur on the day proposals are due (last minute submissions). A system slow down/system failure can result in delayed notification by the sponsor if there is an error in your application and a revision is required before it will be accepted could result in a missed deadline. The best way to avoid these problems is to submit your proposal to us as early as possible.

In addition, keep in mind that insufficient reviews increase the possibility of a proposal being rejected due to non-compliance. Because of the increased volume of submissions, increased complexities with submission requirements, and our stewardship obligation to provide a complete and timely review of all proposals, it is important that all PIs conform to these deadlines.

Section

9

Proposal Development Process

A proposal is a request for funding to support a research, training, instruction, or service program that is an appropriate undertaking for members of the CDU community. Proposals describe the work to be undertaken, its significance, the qualifications of the proposer(s) to carry out the tasks, and the resources available to support the program. They usually include an estimate of the costs that will be incurred. Because successful proposals result in awards that are legally binding agreements on the University, care must be taken in their preparation to verify that:

- The information presented is accurate and complete;
- The program meets with the goals of the department, school, and University;
- The sponsor policies and requirements are acceptable to the University;
- The proposal text complies with University policies and procedures; and
- The required approvals are documented prior to submission.

For a quick, interactive reference and guide to all the major steps involved in submitting proposals for sponsored research at CDU, please contact the OSP's website as well as our latest forms and checklists to facilitate the whole process.

PRELIMINARY/ PRE-PROPOSAL PLANNING - Steps for Successfully Proposing and Performing Sponsored Research at CDU

For anyone contemplating conducting research at CDU, the first thing to verify is eligibility to conduct research. This provides early and effective communication within the prospective researcher's department, school or college and the kinds of coordination that should occur with CDU departments dedicated to supporting and facilitating research to better enable the proposal process to proceed smoothly.

Increasing Chances for Successful Research

This handbook serves as a resource too for researchers and the research support team in their efforts to successfully propose and conduct research at CDU.

1. **Importance of Early Coordination**

   It is very important for Principal Investigators to recognize the advantages of early feasibility discussions with the appropriate Dean/Executive Vice President for Research & Health Affairs to ascertain initial information as to whether a proposed

program is consistent with the University's mission and resources. This is particularly true for proposed programs that will require any costs, space, equipment or other services to be provided by CDU. Principal Investigators should gather general information early in the process to verify that there are adequate resources, space and facilities for pursuing the proposed line of research.

Additionally, it is also very important to plan for early and close coordination with and among the University's core offices that support research. By touching base early, the Principal Investigator alerts the appropriate people who will become instrumental later in helping the Principal Investigator to verify that the proposal is properly prepared and submitted and that any resulting award is effectively established and executed. In any event, the Principal Investigator should advise the OSP office at least 25-30 days before proposal submission is due.

The Office of Sponsored Programs can assist in budget preparation and review guidelines with Principal Investigators to point out any obstacles to be dealt with early in the process (cost sharing requirements, consortia or subcontract documentation, etc.). Where appropriate, the OSP will provide applicable Facilities and Administration rates, Fringe Benefit rates, or other applicable rates as well as other basic information needed in the proposal. Additionally, the OSP can explain whether advance coordination with other organizations for any compliance reviews would be appropriate given the nature and purpose of the proposed research endeavor.

As a further note, Principal Investigators should be aware that if other individuals, including those employed at CDU, and/or outside organizations will be included in the proposed research, it is the Principal Investigator's responsibility to obtain their agreement to participate as well as the approval of their respective departments or organizations. Doing this as early in the process as appropriate, and communicating these requirements to OSP from the beginning, will better enable the proposal submission deadlines to be met in a timely and efficient manner.

2. **Proposal Limitations/ Solicitation Limits on Number of Applicants**

Occasionally, proposal guidelines state that there is a limit to the number of proposals an institution can submit. If you note such a limitation for a competition you are interested in, please send an e-mail right away to the Office of Sponsored Programs, notifying us of your interest to submit an application to that competition.

3. **Proposal Preparation Costs**

Another important reason for early coordination with limited exceptions such as non-competing continuations, time spent on proposal preparation is University compensated time within the meaning of CDU's applicable Effort Certification Policy. In accordance with the applicable regulations and our CDU Policy, Principal Investigators can not charge one sponsor for competing continuations or new

proposal work for that sponsor or another sponsor, even if similar work or work in the same field is involved.

4. **Lobbying Restrictions and Certifications**

In accordance with the University's Policy on use of federal funds for lobbying, it is CDU's Policy to comply with applicable law that federal funds may not be used to influence or attempt to influence any member of the Executive or Legislative branches of Government (including any agency employee) for the purpose of securing a grant, contract or cooperative agreement or any extension, renewal or modification of any of these. The Office of Sponsored Programs routinely certifies on federal awards that the University will abide by these restrictions, so if there is any reason to believe that the certification would be inaccurate for any reason, contact the OSP.

5. **Special Proposal Planning Considerations Requiring Additional Compliance Reviews**

CDU promotes, through policy and process, the highest standards of regulatory compliance in all areas of sponsored projects, including but not limited to: protection of human subjects (IRB); appropriate use of animals in research (IACUC); appropriate handling of radioactive, hazardous and toxic materials and wastes; biosafety; conflict of interests and integrity in research. In addition, the reporting of research results, compliance with federal and international laws, assurance that charges to sponsored projects are allowable and allocable, and documentation of cost sharing are critical issues in university audits.

Early coordination and consultation with CDU will greatly facilitate any special approvals that may be required due to anticipated involvement of compliance-related subject matter as further described in our Manual. Special approvals are required for research involving one or more of the following:

6. **Human Subjects**

The Office for the Protection of Human Subjects (OPHS) is the University's compliance with federal regulations regarding the protection of human research subjects. Federal regulations require that all research involving human subjects or analysis of data gathered from human subjects, regardless of funding status, be reviewed by the prior to the implementation of any research activity. Faculty, students or staff planning to conduct any kind of research involving human subjects (surveys, clinical studies, basic research, chart reviews, etc.) must get approval from the Institutional Review Board (IRB) to comply with Federal Regulations (45 CFR 46).

The Human Subjects Protection Committee, as required by Federal law, acts as the institutional review board for research on human subjects at CDU regardless of the

source of funds. See Guidelines for Submitting Protocols to the Institutional Review Board (IRB) on CDU website.

No human subject research may be started if the IRB has not approved a project or if the one-year renewal has not been approved.

The Charles R. Drew University of Medicine & Science Human Subject Assurance ID Number is: FWA-00002736

7. **Use of Animals in Research**

Any project involving the use of an animal, in particular vertebrate animals must have the approval of the IACUC Committee. This committee is charged with ensuring the humane use of animals in research and compliance with national policies, procedures and regulations. The services provided include review of animal use protocols, assistance in ensuring appropriate housing and facilities for animals, and training of investigators and other individuals involved with housing a research involving animals.

The Vivarium provides space, equipment, and care for laboratory animals used for research and teaching purposes. Various federal agencies and private research foundations regulate the use of vertebrate animals used or intended for use in research. Working closely with the Institutional Animal Care and Use Committee (IACUC), provides the highest standards of humane care and use of laboratory animals and assures compliance with University and federal regulations. They share responsibility to ensure that the use of animals in research programs are necessary, that the investigator has included in the protocol measures to eliminate any unnecessary pain and discomfort to the animals, and that alternatives to the use of live animals have been considered.

The use of animals, either for research or instruction, must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). Some sponsors require that approval be obtained prior to submission of a proposal, or within a specified time after submission. If required by a sponsor, OSP will forward animal protocol to the IACUC Committee for action. In no case may animals be purchased, utilized, or handled without formal prior IACUC approval. See Institutional Animal Care and Use Committee Policy on CDU website.

The Charles R. Drew University of Medicine & Science Animal Welfare Assurance ID Number is: A3190-01

8. **Lab Safety/ Hazardous Materials**

The Institutional Biosafety Committee (IBC) is responsible for occupational and environmental health and safety for the research activities in CDU. The primary

focus is the safe management of biological and chemical hazards associated with research and teaching.

9. **Research Involving Recombinant DNA/ Gene Therapy**

By federal law, every biomedical research facility performing publicly funded research must have an Institutional Recombinant DNA Advisory Committee. As such, CDU is required to review each and every funded or proposed protocol and/or grant, which utilizes recombinant DNA technologies.

Section

10

Components of a Proposal

A. **Format and Content**

Most federal sponsors publish guidelines that list proposal requirements and instructions on how to prepare a proposal. They also require the use of specific forms, most of which can be obtained from the OSP website or by contacting the pre-award division.

Sponsors frequently revise proposal guidelines and other requirements (e.g., page limits, font sizes, margins, number of copies). Guidelines can vary not only between sponsors, but also among programs within an agency. Questions concerning proposal requirements that are not addressed in the sponsor's guidelines can usually be answered by OSP pre-award staff. In general, both federal and non-federal sponsors require the following:

B. **Cover or Title Page**

The cover or title page should include the title of the proposed project, name(s) and title(s) of the principal investigator and co-investigators (if any), proposed project period, dollar amount, sponsor, the date, and any required school or department signatures. As the legal entity submitting the proposal on behalf of the investigator, CDU, with OSP's address, should be used for the institutional address.

C. **Introduction**

A brief description of the proposed project's objectives, any direct or closely related work which may be in progress, and any other pertinent background information as required by the sponsor.

D. **Table of Contents** or index with page references (not required for NIH electronic proposal submissions via grants.gov).

E. **Detailed Program Description,** including an explanation of the objectives in clear and concise terms, and a description of the procedures to be followed in carrying out the objectives.

F. **Description of Current Facilities and Equipment,** and the percentage of time it will be available for the proposed project.

G. **List of Personnel**

Include the names and titles of all professional personnel.

H. **The Biographical sketch of Key Personnel**

Include only professional and academic essentials and avoid personal background information.

I. **List of Principal Investigator's Publications**

Include only those that are relevant or significant to the proposed project. The list should include items such as publications being printed.

J. **Budget with Justifications and Supporting Documentation,** where appropriate.

K. **Concurrent submissions**

When the same proposal is being submitted to other sponsors a statement should appear in each proposal indicating that it is a concurrent submission.

L. **List of Personnel's Current or Pending Support**

Indicate:

a. the source of support
b. project title
c. percent of effort
d. dates of project period
e. annual costs, and
f. how this project does not overlap or duplicate projects supported by other funds.

The statement "No overlap" is considered insufficient by most sponsors.

M. **If required, include letters of collaboration, endorsement letters subcontractor proposals, and other supporting documentation.**

N. **Special requests or justifications**

These could include: a change of principal investigator on renewal or continuation proposals, use of unexpected funds from a prior budget period, or the temporary absence of the principal investigator.

O. **Certifications and representations and other forms that may be required.**

These should be prepared by the department for signature by OSP.

P. **Estimating Your Budget**

It is crucial for investigators to closely follow the sponsor's instructions when preparing a budget. A competitive budget is one that will provide the sponsor with a complete financial picture of the proposed project. Budget should be allowable, allocable and reasonable.

A budget is reviewed by the sponsor to verify if the costs are reasonable and necessary to carry out the proposed project, and if it conforms to the sponsor's instructions. During award negotiations a budget is sometimes subjected to further analysis by the sponsor's audit staff. Investigators and department administrators should refer questions to the OSP staff.

Q. **Direct Costs**

Typical budget categories include personnel, employee benefits, equipment, travel, materials and supplies (refer to OMB Circulars A-21 and A-133). Some budgets may need categories for publication costs, consultants, or subcontracts. In most instances the direct costs should be reflected by major budget categories with an attached narrative detailing how the costs were calculated. The budget narrative should contain enough detail for the sponsor to verify the appropriateness of the costs.

Certain costs are unallowable on projects. Unallowable costs, along with allowable costs, are explained in detail in Agency Guidelines.

a) **Salary** compensation should be based on the percent of time the employee will spend on the project. Example: (monthly salary rate) x___% of effort x number of months. If the project is multi-year include a 3% annual increase. Check with OSP for forward projections of increases. Salary requests for non-University people should be listed under the category of "Consultants". Consultant payments are not salary or wage payments and should be listed as a separate line item under consultants.

b) **Hours** and/or rates and/or hourly rates are occasionally a requirement for proposals. Always include the following note when reporting hours:

Hours – The estimate of hours and/or hourly rates are furnished solely for the purpose of this proposal. It is understood that the University will be required to maintain a record of hours of effort under any resultant award.

A similar note should be included in proposals that require a cost by task or project breakdown.

c) **Fringe Benefits** are expenses directly associated with employment and are applicable to ***all*** University salaries and wages. All full-time staff, part-time staff, and wage payroll personnel carry a fringe benefit rate of 26.4%.

The following budget note may be used:

R. **Facilities and Administrative Costs (Indirect Costs)** are those costs that benefit common or joint objectives and cannot be identified readily and specifically with a particular sponsored program, instructional activity or other institutional activity.

In addition to direct costs, sponsored projects are also charged **facilities and administrative costs**. Facilities and administrative costs are charged to a project by applying a percentage (the facilities and administrative cost rate) to the total direct costs of the project minus certain exclusions. Facilities and administrative costs rates are proposed annually by CDU to the Department of Health & Human Services using the federal cost principles detailed in OMB Circular A-21 (Cost Principles for Educational Institutions).

The proposed rates are then audited by the federal government and negotiated by the University Controller with the government's representative. The calculation results in a facilities and administrative cost rate that is applied to certain direct costs, in order to arrive at the indirect costs that are charged to a project.

The fixed rate for Charles R. Drew University of Medicine and Science is as follows:

Effective Period	Applicable To	On Campus	Off Campus
07/01/08 – 06/30/11	Organized Research	41.0%	26.0%
07/01/06 – 06/30/11	Instruction	32.6%	26.0%
07/01/06 – 06/30/11	Other Spon Act	34.6%	25.3%
07/01/11 Until Amended	Use same rates conditions as those cited for fiscal year ending 06/30/11		

CDU's F&A base is Modified Total Direct Costs (MTDC)

Modification includes equipment of $5,000 or more per unit cost, patient care, tuition and fees, alterations, renovations, rent and utilities, and amounts over $25,000 for each subcontract.

S. **Cost-sharing**

Under certain circumstances it may be appropriate or required for CDU to share the costs of a project although it is strongly discourage. Cost-sharing under a federal program is subject to Office Management and Budget (OMB) Circular A-110 (Grants and

Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations: Uniform Administrative Requirements).

A-110 stipulates that the cost-sharing must come from non-federal sources and contribute directly to the proposed project. Proposals listing cost-sharing should explain how the cost-sharing commitments will be met. The actual cost-sharing is auditable and subject to verification. Cost-share commitments should be discussed with OSP and department head well in advance of the proposal deadline.

T. Sponsored Program Responsibilities

OSP is available to assist as needed the investigator/director and/or unit in any phase of proposal preparation. Proposals are carefully reviewed to ensure that they comply with all University, sponsor, and/or State requirements, and are prepared in such a way as to meet with favorable reviews during competition. Proposals are reviewed for the following criteria:

- Proposal format and content must comply with sponsor guidelines;
- Budget must reflect adequate resources and costing detail to accomplish the project and complies with sponsor, University and State guidelines;
- Review of RPAS for appropriate signatures and investigator compliance with relevant special reviews;
- Verification of cost-share commitments and/or matching funds;
- Verification of documentation for subcontractor and/or consultants; and
- Review and signature of certifications and representations, OSP then prepares a transmittal letter and forwards the proposal as appropriate.

U. Non-Disclosure Agreement

In instances where confidentiality is an issue a confidentiality agreement, also known as non-disclosure agreement (NDA) is needed. NDAs are agreements by which one or more parties, standing in a confidential relationship to each other, promises to keep secret certain information acknowledged by the parties to be confidential or trade secrets. A non-disclosure agreement shows a recipient's rights and obligations in respect to confidential information.

V. Consultants

Consultants are independent contractors and not employees or agents of the University. Special review and approval procedures are required if a project anticipates using consultants. Designation of independent contractor status is governed by the Internal Revenue's Code of Common Law. In addition, contracting with an independent contractor may expose the University to significant financial risk if the consultant has limited net worth or inadequate insurance coverage.

W. Contracts

Investigators who are aware of special sponsor requirements should discuss them with their OSP well in advance of the proposal deadline. CDU will normally only enter into agreements that adhere to the following principles: the research is conducted on a best-efforts basis without guarantee of success and without financial risk or liability to the University; costs are fully reimbursed unless cost-sharing has been approved; and there are no restrictions on the dissemination of the research results except:

- those that relate to the protection of a sponsor's proprietary information;
- the rights of privacy of individuals; or
- establishing rights in patentable inventions and other intellectual property.

X. Limited Proposal Submissions

Some sponsors limit the number of nominations or proposals that CDU may submit to a particular program. When this situation occurs OSP will determine who gets to submit based on the following criteria: the order in which the proposals were submitted to OSP, the quality of the submissions, and input from appropriate Deans and/or Vice Presidents.

Y. SPECIAL REVIEWS

A number of internal review and approval procedures may be required before proposal submissions, or before an award can be accepted by the university. All necessary reviews and approvals should be initiated before OSP's proposal review process, thereby avoiding last minute delays.

a) Intellectual Property

Intellectual property is addressed in the terms and conditions negotiated by OSP when accepting an award. For most awards CDU will retain ownership of intellectual property developed on sponsored projects in order to avoid conflicting commitments to various sponsors.

Z. Scientific Misconduct

In compliance with PHS regulation (42 C.F.R. Part 50, Subpart A) the CDU has in place procedures for responding to allegations of scientific misconduct. Scientific misconduct means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. See the Research Integrity Policy in the CDU Office of Research Integrity and Compliance.

Section

11

Developing Proposals

The format or presentation of a particular proposal will depend on the requirements of the sponsor. Most sponsors have developed policies and procedures for the submission of proposals and may require the use of specific application forms or electronic web-based systems. Other sponsors may have less stringent format requirements. In any case, PIs should obtain the most recent version of the sponsor's application guidelines and should follow the required proposal format. Guidelines or links to guidelines should be forwarded to OSP along with the application for review well. OSP reserves the right to withdraw the application if the terms of the grantor do not meet University standards.

It is a good idea to start the writing process months in advance of any expected due date. Estimates of the total time devoted to producing a new application may range from two to three months or longer. Revised applications and renewals usually take less time, but are still a major effort and should not be under estimated.

An effective proposal conveys the substance of the planned research in a clear, comprehensive and persuasive manner with contents that meets University submission requirements and sponsor expectations. In an increasingly competitive environment, the challenges of writing winning proposals are considerable. Doing the proposal planning discussed above will save time and effort later when the pressures increase as the submission deadline approaches. The coordination discussed in the proposal planning phase allows others to provide support and conduct reviews concurrently with the Investigator's efforts to complete the technical proposal. Then all elements of the proposal will come together and be ready in a timely manner for proceeding to the Proposal submission.

Types of Proposals

A proposal is a request for support of sponsored research, instruction, or extension projects, and generally consists of a cover page, brief project summary, technical or narrative section, biographical sketches of the key personnel, and a detailed budget. Common proposal types include:

a) New Proposals

A new proposal is one that is being submitted to a sponsor for the first time.

b) **Solicited Proposals**

A solicited proposal submitted in response to a specific solicitation issued by a sponsor. Such solicitations, typically called Funding Opportunity Announcement (FOA), Program Announcement (PA), Request for Proposals (RFP), Request for Quotations (RFQ), Broad Agency Announcements (BAA), NASA Research Announcements (NRA), or Requests for Bids (RFB), are usually specific in their requirements regarding format and technical content, and may stipulate certain award terms and conditions.

A solicited proposal is a proposal submitted in response to a request by a sponsoring agency for research or other services on a specified subject. Solicitations are generally in the form of a request for proposal (RFP) or funding opportunities announcement (FOA) or program announcement (PA). Solicited proposals can be either competitive or sole-source. While most solicitations are formal – that is, they are presented in writing and in detail – some agencies request proposals informally. Writing a solicited proposal is generally a straightforward process since most solicitations are specific in their requirements on format, technical content and budget. This is usually true in the case of informally solicited proposals as well.

c) **Unsolicited Proposals**

An unsolicited proposal submitted to a sponsor that has not issued a specific solicitation but is believed by the investigator to have an interest in the subject.

An unsolicited proposal is submitted to a sponsor that generally funds research of the type being proposed. In developing an unsolicited proposal, a formal request to a sponsor is usually subject to factors and criteria that should be explored. The PI should ascertain, primarily through preliminary inquiries, the degree of interest sponsors have in supporting the proposed work and the extent to which they can do so financially and determine if the sponsor has specific forms and instructions that need to be used. Check to see if the sponsor has a set deadline for submittal of unsolicited proposals.

d) **Pre-proposals**

A pre-proposal is requested when a sponsor wishes to minimize an applicant's effort in preparing a full proposal. Pre-proposals are usually in the form of a letter of intent or brief abstract. After the pre-proposal is reviewed, the sponsor notifies the investigator if a full proposal is warranted.

e) **Competing Proposals**

A competing continuation or renewal is a request for continued funding of a project that is ending. They are usually prepared in the same format as the new proposals and will be reviewed competitively.

f) **Continuation or Non-Competing Proposals**

Continuation or non-competing proposals confirm the original proposal and funding requirements of a multi-year project for which the sponsor has already provided funding for an initial period (normally one-year). Continued support is usually contingent on satisfactory work progress and the availability of funds.

An annual non-competing Continuation or Progress Report for continued support of a funded grant through National Institutes of Health does not go through a competitive peer review process, but is administratively reviewed by the Institute/Center and will receive an award based on prior award commitments.

eSNAP – Electronic Streamlined Non-Competing Award Process

NIH is the only agency that currently uses eSNAP for the submission of progress reports, offering information and guidelines through the following websites:

- PHS 2590 instructions and forms (for eSNAP or paper submission)
- eSNAP Fact Sheet
  http://era.nih.gov/services_for_applicants/reports_and_closeout/esnap.cfm
- eRA Commons
  https://commons.era.nih.gov/commons/index.jsp?menu_itemPath=Home
- eSNAP User Guide
  http://era.nih.gov/

The National Institutes of Health (NIH) developed an Electronic Streamlined Non-Competing Award Process (eSNAP) to enable Principal Investigators with eligible grants to submit streamlined annual progress reports, simplifying the non-competitive renewal award process. The electronic version of SNAP "the eSNAP module" enables PIs to submit these streamlined progress reports electronically, through the eRA Commons.

Beginning with SNAP progress reports due on/after August 1, 2010, paper progress reports will not be accepted. All progress reports for awards subject to SNAP must be submitted electronically using the eRA Commons eSNAP module. The purpose of this firm implementation date is to electronically capture all SNAP Progress Reports eligible for funding in FY2011. Paper submissions will be considered noncompliant and will not be accepted or used for consideration for funding and will not become part of the official grant file. Grantees who incorrectly submit a paper progress report will be required to resubmit the progress report electronically using eSNAP. Note that late progress reports may delay a noncompeting award.

eSNAP Features and Benefits

- eSNAP allow PIs an extra 2 weeks to complete the progress report (eSNAPs are due 45 days before the renewal budget start date, while paper reports are due a full 2 months in advance). PI can delegate eSNAP access to an individual assigned an Assistant (ASST) role in the eRA Commons, enabling the delegate to work on the report. (This individual will need to complete a **NIH eRA COMMONS REGISTRATION REQUEST FORM**. This form is provided by the Office of Sponsored Programs, please contact OSP director or the Pre-Award Manager to obtain a copy of this form.
  - System retains key personnel data and publication data from previous submissions for easy updating.
  - Publication citations are linked to information stored in the PI's Person Profile.
  - eSNAP offers the ability to save and route progress report in a work-in-progress state.
  - System generates a PDF of progress report, which is stored in an electronic grant folder.

  There are several tools available to confirm whether your grant is eligible:
  1. Web queries – NIH provides 2 ways to query and gather information on progress reports: by Institutional Profile Number (See IPF Definition) and by Institution Name.
  2. eRA Commons Status Function –Use the Status Function to see whether NIH is providing an eSNAP link.
  3. Notice of Grant Award: If the NGA includes the statement This grant is subject to Streamlined Noncompeting Award Procedures, the progress report is eligible for submission via eSNAP.

CDU Process for eSNAP Submission:

1. PI or delegated Assistant prepares the eSNAP progress report on the eRA Commons. Email perrillajohnson@cdrewu.edu to request an Assistant account.
2. PI must route the progress report electronically OSP Pre-Award Office. Since this electronic routing constitutes the PI's approval of and signature on the report, the PI, rather than a delegated Assistant, must e-route the application along with a copy of a completed and signed Request for Proposal and Submission (RPAS) form to OSP.
3. OSP reviews the progress report and submits electronically to NIH if acceptable.

g) **Competitive Renewals**

Competitive renewals are requests for continued support for an existing project that is about to terminate, and, from the sponsor's viewpoint, generally have the same status as an unsolicited proposal.

h) **Revised Proposals**

If you send a proposal to a sponsor and the sponsor asks you to make changes and send it again, the second version of your proposal is usually called a revision.

i) **Supplemental Proposals**

Supplemental proposals request additional support to make sure the original scope of work can be done adequately.

j) **Collaborative/ Consortium/ Joint Proposals and Subcontracts**

When a proposed project involves investigators from two or more institutions, a collaborative proposal is submitted to the sponsor. Various funding agencies use different terms for describing collaborative projects. For example, NIH awards "Consortium Grants" and has established a set of guidelines for awards that must be acknowledged by the collaborating organizations and CDU solicits "Collaborative Proposals". The terms "subcontractor", "sub-recipient", "sub-grantee", "sub-awardee", and "lower tier recipient" are often used interchangeably.

The collaborative proposal requires that one institution be designated as the "lead" for the purpose of submitting the lead proposal. It's important to determine which institution will be the lead and which will be the non-leads. Lead institutions are typically those whose faculty are doing the bulk of the work in terms of writing the proposal and/or those who will manage the largest portion of the funds should the proposal be awarded.

Submission of a collaborative proposal should be coordinated by the institution designated as the lead. The usual method for submitting a collaborative proposal is for the lead institution to prepare a proposal that includes the collaborating organization as a subcontractor or sub-grantee. If an award results from the proposal, a single grant or contract is awarded to the lead institution, and the lead in turn, issues a sub-award agreement to the collaborator. The sub-award agreement will contain terms and conditions required by the lead as well as relevant terms and conditions of the funding agency. Most federal agencies prefer this method since it makes one institution solely responsible to the sponsor for administration of and reporting on the project.

Types of Sponsored Projects

a) **Grant**

A type of financial assistance awarded to the University, on behalf of an individual, for the conduct of research or other program as specified in an approved proposal. A grant is used whenever the awarding office anticipates no substantial programmatic involvement with the recipient during the performance of the activities. The statement of work allows the principal investigator some freedom to change emphasis within the general area of work as the project progresses. A grant is a contractual document but does not carry the specific terms and conditions denoted in a "contract."

b) **Cooperative Agreement**

A funding mechanism which can be used by federal agencies when a program requires more agency involvement and restrictions than a grant but requires less agency supervision than a contract. The principal purpose of the relationship is the transfer of money, property, services, or anything of value to the University in order to accomplish a public purpose of support or stimulation authorized by federal statute.

c) **Contracts**

A mechanism for procurement of a product or service with specific obligations for both sponsor and recipient. Typically, the sponsor specifies a research topic or a service and the methods for conducting the research/service in detail, although some sponsors award contracts in response to unsolicited proposals. There is an expectation of specific deliverables within a specified time frame. There is generally less flexibility in the method used for carrying out the plan of action.

- **Cost Reimbursement Contracts:**

  This is the preferred type of contract for University research and service. This contract provides for payment of actual costs both direct and facility and administrative (F&A), for performance toward contract objectives as specified in the statement of work. This type of contract offers less risk to the University as it implies best efforts toward the completion of the task but offers no guarantee of specific outcomes.

- **Fixed Price Contracts:**

This type of contract provides a total-sum payment or lump sum payment schedule for performance of specific tasks or delivery of a certain number of products or services. Fixed price contracts should only be used when costs for quantity and/or delivery are readily and easily definable. This type of contract offers more risk to the University and the Principal Investigator because the delivery of the product or service is still required even if there are additional costs over the contracted amount.

The Principal Investigator may move unexpended funds from a fixed price contract to a departmental operation or a development activity at the conclusion of the sponsored project. These residual funds should normally not exceed fifty percent of the total value of the fixed price contract. F&A costs will be removed from the residual amount prior to the transfer of funds.

If the residual funds exceed fifty percent of the total value of the contract, the Principal Investigator will provide to OSP a written explanation as to how the project was accomplished using less than the budgeted amount. This memo will protect the University and the Principal Investigator from Unrelated Business Income Tax implications and alleviate any perception regarding the University Kickback policy.

The Principal Investigator is responsible for accurate expenditures charged to a project. Over expenditures for cost reimbursement contracts and fixed price contracts are the responsibility of the Principal Investigator. Any funds not expended on a cost reimbursable project would be returned to the agency if not required to complete the project. Under no circumstances may the Principal Investigator use residual funds from one sponsored project to help pay expenses for another sponsored project without the explicit approval of the agency.

In general, the criteria for identifying a contract are the same as those for a grant, except that:

1. The award is subject to formal conditions outlined in a contractual instrument signed by both parties.
2. The sponsor often places more restrictions upon expenditures allowed in the pursuit of the activity (e.g., clauses concerning "Buy American", ceiling on certain spending, etc).
3. Financing may be on a cost-reimbursable basis, although the University tries to arrange some method of advance funding where necessary. Some fixed-price contracts may provide for lump sum or incremental payments as work progresses.
4. The sponsor requires periodic progress reports and some array of others including invention reports, royalty reports, financial status reports, equipment inventory reports, etc.

5. Often there is intellectual property, confidentiality, and/or publication conditions associated with receipt of the funds.
6. A closing audit is sometimes required.

The University has developed various contracts or agreements to meet the needs of the wide variety of research interests and service commitments of the faculty. These agreements are good starting points to develop contracts with various agencies. Also, agencies may have their own agreements and wish to use those as starting points for negotiations.

It is important to remember that no two projects are the same and there will be some differences in specific agreements. The University has some flexibility in terms and conditions, but there are some specific requirements, which are governed by certain laws, that cannot be altered. The Office of Sponsored Projects (OSP) will negotiate terms, conditions, and language depending on the circumstances of the each specific project.

- **Memorandum of Understanding (MOU)**

An MOU is an informal agreement that serves as the basis of a future formal contract or deed and/or a brief written statement outlining the terms of an agreement or transaction. The word memorandum implies something less than a complete contract. The memorandum functions only as evidence of the contract and need not contain every term, so that a letter may be a sufficient memorandum to take an agreement out of the statute of frauds. Under the statute of frauds, the memorandum must be such, as to disclose the parties, the nature and substance of the contract, the consideration and promise, and be signed by the party to be bound by the agreement.

- **Material Transfer Agreements (MTA)**

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even some types of software.

Request for Proposal and Submission (RPAS)

Once you have completed your proposal you should complete a Request for Proposal and Submission (RPAS) including appropriate signatures. The RPAS Form can be downloaded from the OSP webpage or a copy can be obtained from OSP by requesting a copy via email.

The RPAS form must accompany every proposal submitted to OSP. The RPAS provides OSP with information on where to submit the proposal and identifies what compliance issues exist and what institutional resources are required for the project. Investigators are responsible for completing the RPAS and, by signing it, accept full responsibility for the project. The RPAS along with your proposal should be submitted to the Office of Sponsored Programs at least five days prior to proposal due.

Occasionally a sponsor may require an institutional cover letter or letter of support from the President. These letter requests should be received by OSP at least ten business days before the deadline. In addition to the required internal review, additional time is necessary to obtain a signature due to the President's extensive travel schedules. Investigators are strongly urged to coordinate their proposal schedule with the OSP as soon as the proposal deadline is known.

All proposals should be submitted to the OSP electronically via email, on a CD, flash drive or other USB mass storage device.

Proposal forms and guidelines are available on the Office of Sponsored Programs web page.

Helpful Hints for Proposal Writing

Your plans or goals should be written in a clear and concise manner.

- Be original and innovative.
- Explain the significance of the work to be undertaken.
- Be sure that what you propose is possible and plausible.
- Follow instructions. Reviewers notice if you use a 10 point font when the instruction requires a 12 point font, it is imperative that sponsor guides be explicitly followed.
- Stay within the page limitations.
- Be sure that your budget is well-justified and that it adds properly.
- Proofread several times for errors and be sure to execute a spell check.

Section

12

NIH MULTIPLE PRINCIPAL INVESTIGATOR SUBMISSION

ESTABLISHMENT OF MULTIPLE PRINCIPAL INVESTIGATOR AWARDS FOR THE SUPPORT OF TEAM SCIENCE PROJECTS

NIH has announced the Establishment of Multiple Principal Investigators (PI) Awards for the Support of Team Science Project. The announcement is posted to the NIH Multiple PI website at: http://grants.nih.gov/grants/multi_pi/index.htm . The Multiple PI policy allows investigators to choose either a single or multiple PI approach for virtually all NIH programs. Key features and aspects of the policy include: multiple PIs share responsibility and authority for the project; all PIs will be listed in the summary statement, Notice of Award, and listed in CRISP. All PIs have access to status information through eRA Commons. The first PI listed must be affiliated with the applicant institution and will serve as the contact for NIH.

Implementation of the Multiple Principal Investigator Policy:

Beginning with applications submitted in February 2007, the Multiple PI option will be extended to most research grant applications submitted electronically through Grants.gov when they transition to an electronic format. Some paper applications submitted on PHS 398 application forms also will allow inclusion of more than one PI, but only when the multiple PI option is clearly specified in the soliciting Request for Applications or Program Announcement. Grant applications that will accommodate more than one PI beginning in February will include the R01, R03, and R21. Grant mechanisms that ***will not*** accommodate more than a single PI include individual career K awards, individual fellowships (Fs), Director's Pioneer Awards (DP1), Construction Grants, and Shared Instrumentation Grants.

Decision to Use the Multiple PI Option:

The decision to apply for a single PI/PD or multiple PI/PD grant is the responsibility of the investigators and the applicant organization and should be determined by the scientific goals of the project. It is important to note that NIH expects the availability of the Multiple PI option to encourage interdisciplinary and other team science approaches to biomedical research. When considering multiple PI/PDs, please be aware that the organizational structure and governance of the PI/PD leadership team as well as the knowledge, skills and experience of the individual PI/PDs will be factored into the assessment of the overall scientific merit of the application.

Multiple PI/PD Leadership Plan:
Multiple PI/PDs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. For applications designating multiple PI/PDs, a new section of the research plan, entitled "Multiple PI/PD Leadership Plan" must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PI/PDs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PI/PDs must be delineated in the Leadership Plan. In the event of an award, the requested allocation may be reflected in a footnote on the Notice of Grant Award.

Criteria for using the Multiple PI/PD Option:

The multiple PD/PI option will be exercised for applications in which an interdisciplinary "team science" approach will best achieve the aims of the research. Each PD/PI is scientifically considered equal for merit in achieving the project outcome. For all Charles Drew University applications that propose the Multiple PD/PI option, the following criteria must be met prior to submission:

- All proposed PIs must have PI status as defined in the Charles Drew University's Policy and Procedures or from their home institution.

- Each identified PD/PI must complete and sign a separate Request for Proposal Approval and Submission (RPAS) form.

- The Multiple PI/PD Leadership Plan must be included in the proposal sent to Office of Sponsored Programs. The grants management staff will review the plan to determine whether the planned multiple PD/PI submission is consistent with agency and University requirements.

- If separate budget allocations are desired for each PI/PD, discrete internal budgets for each PD/PI will be required with the application materials. These budgets will not be sent to NIH, but the amounts should be reflected in the portion of the Multiple PI/PD Leadership Plan addressing resource allocation. If awarded, the funds will be allocated into separate accounts for each PI.

The first PI/PD named in the proposal (typically on the application face page) will be the designated Contact PI/PD. Review of the proposal and signature approval by the appropriate department head(s) for each PI must be secured prior to submission. Each multiple PI/PD has equal responsibility for leading and directing the project; each is equally accountable for the proper conduct of the program including fiscal oversight and submission of all required reports. It is important that each department head is aware of the commitments of his/her PIs.

Awards Involving More Than One Institution

Awards involving PIs at different institutions will be managed using subawards until options involving linked awards have been developed.

New Investigator Policies

- NIH policies related to New Investigators will be applied to applications only when all PIs involved are classified as New Investigators.

- The New Investigator Box on the application may be checked only when all PIs involved are classified as New Investigators.

- For the purpose of classification as a New Investigator, serving as a PI on a multiple PI grant will be equivalent to serving as a PI on a single PI grant.

Examples of Project Leadership Plans for Multiple PI Grant Applications

For Multiple PI applications, a new section for Leadership Plans (PHS 398, Section I) must be included, unless the RFA/PA announcement requests the information be provided in another section. There are no page limitations for Section I. Leadership Plans should address the following administrative processes and PI/PD responsibilities:

- Roles/areas of responsibility of the PIs
- Fiscal and management coordination
- Process for making decisions on scientific direction and allocation of resources
- Data sharing and communication among investigators
- Publication and intellectual property (if needed) policies
- Procedures for resolving conflicts

Examples of Single Project Leadership Plans

Examples of Leadership Plans for single project applications are provided below. (Applicants should follow any special instructions in the specific RFA/PA to ensure the requested information and format is included.)

Example 1 (Same Institution)

PI#1 and PI#2 will provide oversight of the entire Program and development and implementation of all policies, procedures and processes. In these roles, PI#1 and PI#2 will be responsible for the implementation of the Scientific Agenda, the Leadership Plan and the specific aims and ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including biosafety, human and animal research, data and facilities. Specifically, PI#1 will oversee aim 1 and be responsible for all animal research approvals. PI#2 is responsible for aims 2, 3, and 4 including the implementation of all human subjects' research and approvals. PI#1 will serve as contact PI and will assume fiscal

and administrative management including maintaining communication among PI s and key personnel through monthly meetings. He will be responsible for communication with NIH and submission of annual reports. The responsibilities of the contact PI will be rotated to PI #2 in even years of the grant award. Publication authorship will be based on the relative scientific contributions of the PIs and key personnel.

Conflict Resolution
If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of impartial senior faculty officials. No members of the arbitration committee will be directly involved in the research grant or disagreement.

Change in PI Location
If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

Example 2 (Different Institutions)
PI#1 at Institution A will be responsible for the oversight and coordination of project management for aim 1 involving the molecular design and production of vectors expressing tumor specific antigens. PI#2 at Institution B will be responsible for aims 2 and 3 including the in vivo and in vitro testing of vaccines. Each PI will be responsible for his own fiscal and research administration.

The PIs will communicate weekly, either by phone, e-mail, or in person, to discuss experimental design, data analysis, and all administrative responsibilities. All PIs will share their respective research results with other PIs, key personnel, and consultants. They will work together to discuss any changes in the direction of the research projects and the reprogramming of funds, if necessary. A publication policy will be established based on the relative scientific contributions of the PIs and key personnel. PI#1 will serve as contact PI and be responsible for submission of progress reports to NIH and all communication.

Intellectual Property
The Technology Transfer Offices at Institutions A and B will be responsible for preparing and negotiating an agreement for the conduct of the research, including any intellectual property. An Intellectual Property Committee composed of representatives from each institution that is part of the grant award, will be formed to work together to ensure the intellectually property developed by the PIs is protected according to the policies established in the agreement.

Change in PI Location
If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

Section

13

Budget Development

The Principal Investigator (PI) should ensure the project is carefully planned to include all costs necessary for successfully conducting the project. The budget should account for the costs of personnel, equipment, supplies, collaborations, subcontracts, travel, and other specific research needs.

The PI should include only costs that relate specifically to the work that will be performed on the project. The PI should avoid the temptation to include contingencies (i.e., padding the budget) and include only those costs that can be justified in a budget narrative or in response to a sponsor inquiry.

Known or predictable cost increases should also be included (e.g., annual inflation increase). In order to ensure that the budget contains sufficient direct costs, it is important for the Investigator to:

- Obtain up-to-date, realistic price estimates;
- Allow for expected inflation and/or possible salary increases (3% or 4%);
- Review the technical effort carefully so nothing is overlooked that could be a potential cost to the project; and
- Accurately estimate what kinds of funds will be needed.

Proposal budgets include two basic categories: direct costs of the proposed project, and indirect costs or facilities & administration (F&A) expenses.

Cost Accounting Standards

The majority of externally sponsored funding at the University is provided by the federal government. Cost accounting principles for higher education grantees are established by the federal Office of Management and Budget (OMB). The OMB circulars that are most relevant to universities include OMB Circular A-21, OMB Circular A-110, and OMB Circular A-133.

As you begin to develop a budget for your research grant application and put all of the relevant costs down on paper, many questions may arise. Your best resources for answering these questions are the grants or sponsored programs office within your own

institution, your departmental administrative officials, and your peers. They can answer questions such as:

- What should be considered a direct cost or indirect cost?
- What is the fringe benefit rate?
- What Facilities and Administrative (F&A) costs rate should I use?

Provided below are some additional tips and reminders we have found to be helpful for preparing a research grant application, mainly geared towards the SF424 (R&R) application. (Note: these tips do not supersede the budget instructions found in the relevant application instruction guides: http://grants.nih.gov/grants/forms.htm).

Cost Considerations

An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

Information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in the NIH Grants Policy Statement under Cost Considerations http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600115. In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600117.

The cost principles address four tests that NIH follows in determining the allowability of costs. Costs charged to awards must be allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

"The fact that a cost requested in a budget is awarded, as requested, does not ensure a determination of allowability. The organization is responsible for presenting costs consistently and must not include costs associated with their F&A rate as directs".

Budgets: Getting Started

- Carefully read the Funding Opportunity Announcement (FOA) for budget criteria. You should look for limits on the types of expenses (e.g. no construction allowed), spending caps on certain expenses (e.g. travel limited to $10,000), and overall funding limits (e.g. total costs cannot exceed $300,000 per year). Relevant FOA sections include:

    1. Mechanism of Support
    2. Funds Available
    3. Cost Sharing or Matching
    4. Funding Restrictions

- Identify all the costs that are ***necessary*** and ***reasonable*** to complete the work described in your proposal.
- Throughout the budgeting process, round to whole dollars and use only U.S. dollars.
- The best strategy is to request a reasonable amount money to do the work, not more and not less because:

    1. Reviewers look for reasonable costs and will judge whether your request is justified by your aims and methods.
    2. Reviewers will consider the person months you've listed for each of the senior/key personnel and will judge whether the figures are in sync with reviewer expectations, based on the research proposed.
    3. Significant over- or under-estimating suggests you may not understand the scope of the work.
    4. Despite popular myth, proposing a cost-sharing (matching) arrangement where you only request that NIH support some of the funding while your organization funds the remainder does not normally impact the evaluation of your proposal. Only a few select programs require cost-sharing, and these programs will address cost-sharing in the FOA.

What is the difference between allowable direct costs and allowable facilities & administrative (F&A) costs?

Direct Costs: Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.

F&A Costs: Costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. These costs also are known as "indirect costs."

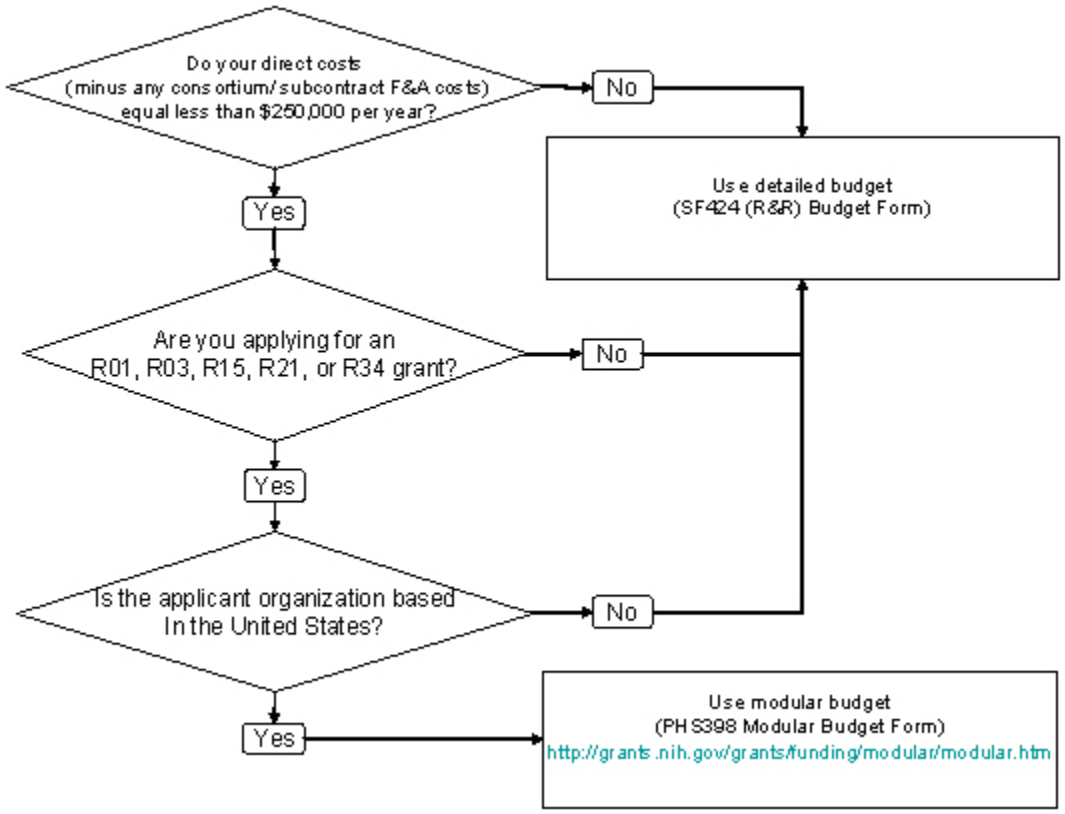
- The total costs requested in your budget will include allowable direct costs (related to the performance of the grant) plus allowable F&A costs. If awarded, each budget period of the Notice of Award will reflect direct costs, applicable F&A
- F&A costs are determined by applying CDU's negotiated F&A rate to the direct cost base. Most educational, hospital, or non-profit organizations have negotiated their rates with other Federal (cognizant) agencies such as the Department of Health and Human Services.
- What is your direct cost base?
    - For most institutions the negotiated F&A rate will use a modified total direct cost (MTDC) base, which excludes items such as: equipment, student tuition, research patient care costs, rent, and sub-recipient charges (after the first $25,000).
    - When calculating whether your direct cost per year is $500,000 or greater, do not include any sub-recipient F&A in the base but do include all other direct costs as well as any equipment costs. NOTE: Direct cost requests **equal to or greater than $500,000 require prior approval** from the NIH Institute/Center before application submission.

Modular versus Detailed Budgets

The NIH uses 2 different formats for budget submission depending on the total direct costs requested and the activity code used.

The SF424 (R&R) Application Guide includes two optional budget components—(1) R&R Budget Component requesting detailed budget information; and, (2) the "simplified" PHS398 Modular Budget Component. Note: NIH applications will include either the R&R Budget Component or the PHS398 Modular Budget Component, but not both.

To determine whether to use a detailed versus modular budget for your NIH application, see the flowchart below.



Modular Budgets

NIH uses a modular budget format (applicants request funds in lump sums of $25,000 intervals) for some applications, rather than requiring a full detailed budget. The modular budget format is not accepted for SBIR and STTR grant applications. SBIR and STTR applicants must complete and submit budget requests using the SF424 Research and Related (R&R) Budget component. Applications from foreign (non-U.S.) institutions must include only detailed (non-modular) budgets (see NIH Guide Notice NOT-OD-06-096).

- Creating a modular budget:
  - Select the PHS398 Modular Budget Component form for your submission package, and use the appropriate set of instructions from the electronic application user's guide. You do not need to submit the SF424 (R&R) Budget Component form if you submit the PHS398 Modular Budget form.

- Consider creating a detailed budget for your own institution's use including salaries, equipment, supplies, graduate student tuition, etc. for every year of funds requested. While the NIH will not ask for these details, they are important for you to have on hand when calculating your F&A costs base and writing your justification, and for audit purposes.
- In order to determine how many modules you should request, subtract any consortium F&A from the total direct costs, and then round to the nearest $25,000 increment.

- A modular budget justification should include:
  - **Personnel Justification:** The Personnel Justification should include the name, role, and number of person-months devoted to this project for every person on the project. Do not include salary and fringe benefit rate in the justification, but keep in mind the legislatively mandated salary cap when calculating your budget. [When preparing a modular budget, you are instructed to use the current cap when determining the appropriate number of modules.]
  - **Consortium Justification**: If you have a consortium/subcontract, include the total costs (direct costs plus F&A costs), rounded to the nearest $1,000, for each consortium/subcontract. Additionally, any personnel should include their roles and person months; if the consortium is foreign, that should be stated as well.
  - **Additional Narrative Justification**: Additional justification should include explanations for any variations in the number of modules requested annually. Also, this section should describe any direct costs that were excluded from the total direct costs (such as equipment, tuition remission) and any work being conducted off-site, especially if it involves a foreign study site or an off-site F&A rate.

Detailed Budget: Personnel (Sections A & B)

Personnel make up sections A and B of the SF424 (R&R) Budget form. *All personnel from the applicant organization dedicating effort to the project should be listed on the personnel budget with their base salary and effort, even if they are not requesting salary support.*

- **Effort**: Effort must be reported in person months. For help converting percent effort to person months, see: http://grants.nih.gov/grants/policy/person_months_faqs.htm.
- **Salary Caps**: NIH will not pay requested salary above the annual salary cap, which can be found at http://grants.nih.gov/grants/policy/salcap_summary.htm. If salary is requested above the salary cap, NIH will reduce that line item to the salary cap, resulting in a reduced total award amount. In future years, if the salary cap increases, grantees may rebudget to pay investigator salaries up to the new salary cap, but NIH will not increase the total award amount. If you are preparing a detailed budget, you are instructed to base your request on actual institutional base salaries (not the cap) so that NIH staff has the most current information in hand at the time of award and can apply the appropriate salary cap at that time.
- **Fringe Benefits**: The fringe benefits rate is based on CDU institution's policy; the NIH does not have a pre-set limit on fringe benefits. More information on what is included as fringe benefits can be found in the Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm#Fringe_Benefits. If you have questions about what rate to use, consult OSP.

- **Senior/ Key Personnel:** The Senior/Key Personnel section should include any senior or key personnel *from the applicant organization* who are dedicating effort to this project. "Other Significant Contributors" who dedicate negligible effort should not be included. Some common significant contributors include: 1) CEOs of companies who provide overall leadership, but no direct contribution to the research; and 2) mentors for K awardees, who provide advice and guidance to the candidate but do not work on the project. Likewise, any consultants or collaborators who are not employed by the applicant organization should not be included in section A, but rather should be included in section F.3 of the budget (for consultants) or in section A of the consortium/subaward budget page (for collaborators).
- **Postdoctoral Associates:** Postdocs can be listed in either section A or B depending on their level of involvement in project design and execution. If listed in section B, include the individuals' names and level of effort in the budget justification section.
- **Graduate Students**: Graduate students can be listed in either section A or B, but if listed in section B, includes the individuals' names and level of effort in the budget justification section. Tuition remission is included in section F.8 (not section A), but is included in the graduate student compensation limits. For more about the graduate student compensation limit, see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html. For current NRSA stipend levels, see the NRSA help page at: http://grants.nih.gov/training/nrsa.htm.
- **Other Personnel:** Other personnel can be listed by project role. If multiple people share the same role such as "lab technician", indicate the number of personnel to the left of the role description, add their person months together, and add their requested salaries together. The salaries of secretarial/clerical staff should normally be treated as F&A costs. Direct charging of these costs may be appropriate where a major project or activity explicitly budgets for administrative or clerical services and individuals involved can be specifically identified with the project or activity [see Exhibit C of OMB Circular A-21 (relocated to 2 CFR, Part 220)]. Be specific in your budget justifications when describing other personnel's roles and responsibilities.

Detailed Budget: Equipment, Travel, and Trainee Costs (Sections C, D, and E)

- **Equipment:** Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. Tips:
  - Generally equipment is excluded from the F&A base, so if you have something with a short service life (< 1 year), even if it costs more than $5,000, you are better off including it under "supplies".
  - If you request equipment that is already available (listed in the Facilities & Other Resources section, for example), the narrative justification must explain why the current equipment is insufficient to accomplish the proposed research and how the new equipment's use will be allocated specifically to the proposed research. Otherwise, NIH may disallow this cost.
  - General purpose equipment, such as desktop computers and laptops, that will be used on multiple projects or for personal use should not be listed as a direct cost but should come out of the F&A costs, unless primarily or exclusively used in the actual conduct of the proposed scientific research.

- While the application does not require you to have a price quote for new equipment, including price quotes in your budget justification can aid in the evaluation of the equipment cost to support the project.

- **Travel:** In the budget justification, include the destination, number of people traveling and dates or duration of your stay for all anticipated travel. As with the equipment justification, it is important that you clearly state how the travel is directly related to your proposed research (e.g., you can go to a conference to present your research, but not just for the purpose of staying current in your field). You should refer to your institution's travel policy for guidance on how you should arrange the travel, but if your institution lacks a policy, it is expected that you will follow the U.S. federal government policy found here: http://www.gsa.gov/federaltravelregulation.
- **Trainee Costs**: Leave this section blank unless otherwise stated in the FOA. Graduate student tuition remission can be entered in section F.8.

Detailed Budget: Other Direct Costs (Section F)

- **Materials and Supplies**: In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories that include costs less than $1,000 do not have to be itemized.
- **Animal Costs**: While included under "materials and supplies", it is often helpful to include more specific details about how you developed your estimate for animal costs. Include the number of animals you expect to use, the purchase price for the animals (if you need to purchase any), and your animal facility's per diem care rate, if available. Details are especially helpful if your animal care costs are unusually large or small. For example, if you plan to follow your animals for an abnormally long time period and do not include per diem rates, the reviewers may think you have budgeted too much for animal costs and may recommend a budget cut.
- **Publication Costs**: You may include the costs associated with helping you disseminate your research findings from the proposed research. If this is a new application, you may want to delay publication costs until the later budget periods, once you have actually obtained data to share.
- **Consultant Services**: Consultants differ from Consortiums in that they may provide advice, but should not be making decisions for the direction of the research. Typically, consultants will charge a fixed rate for their services that includes both their direct and F&A costs. You do not need to report separate direct and F&A costs for consultants; however, you should report how much of the total estimated costs will be spent on travel. Consultants are not subject to the salary cap restriction; however, any consultant charges should meet your institution's definition of "reasonableness".
- **ADP/ Computer Services**: The services you include here should be research specific computer services- such as reserving computing time on supercomputers or getting specialized software to help run your statistics. This section should not include your standard desktop office computer, laptop, or the standard tech support provided by your institution. Those types of charges should come out of the F&A costs.
- **Alterations and Renovations (A&R)**: A&R does not include general maintenance projects (normally handled under F&A) or projects exceeding $500,000 (considered "construction" projects). A&R can be used for projects such as altering a room to make space for a new grant-related piece of equipment. If applicable:

- Justify basis for costs, itemize by category.
- Enter the total funds requested for alterations and renovations. Where applicable, provide the square footage and costs.
- If A&R costs are in excess of $300,000 further limitations apply and additional documentation will be required.

- **Patient Care Costs**: Few budgets contain patient care expenses, however if inpatient and/or outpatient costs are requested, the following information should be provided:
  - The names of any hospitals and/or clinics and the amounts requested for each.
  - If both inpatient and outpatient costs are requested, provide information for each separately.
  - Provide cost breakdown, number of days, number of patients, costs of tests/treatments.
  - Justify the costs associated with standard care or research care. (Note: If these costs are associated with patient accrual, restrictions may be justified in the Notice of Award.)
    (See NIH Grants Policy Statement, Research Patient Care Costs)
- **Tuition**: In your budget justification, for any graduate students on your project, include what your school's tuition rates are. You may have to report both an in-state and out-of-state tuition rate. Depending on your school stipend and tuition levels, you may have to budget less than your school's full tuition rate in order to meet the graduate student compensation limit (equivalent to the NRSA zero-level postdoctorate stipend level).
- **Other:** Some types of costs, such as entertainment costs, are not allowed under federal grants. NIH has included a list of the most common questionable items in the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm). If NIH discovers an unallowable cost in your budget, generally we will discount that cost from your total award amount, so it is in your best interest to avoid requesting unallowable costs. If you have any question over whether a cost is allowable, contact your sponsored programs office or the grants management specialist listed on the funding opportunity announcement.

Consortiums/ Subawards

If you are using the detailed budget format, each consortium you include must have an independent budget form filled out.

- **Direct costs**:
  - In the rare case of third tier subawards, "subawards/consortium/contractual" costs should include the total cost of the subaward, and the entire third tier award is considered part of the direct costs of the consortium for the purposes of calculating the primary applicant's direct costs.
  - Cost Principles. Regardless of what cost principles apply to the parent grantee, the consortium is held to the standards of their respective set of cost principles.
- **F&A:**
  - Consortium F&A costs are NOT included as part of the direct cost base when determining whether the application can use the modular format (direct costs < $250,000 per year), or determining whether prior approval is needed to submit an application (direct costs > $500,000 for any year).

- F&A costs for the first $25,000 of each consortium may be included in the modified total direct cost base, when calculating the overall F&A rate, as long as your institution's negotiated F&A rate agreement does not express prohibit it.
- If the consortium is a foreign institution or international organization, F&A for the consortium is limited to 8%.
- If the consortium is with a for-profit entity, such as a small business, the organization must have a negotiated F&A rate before they can charge F&A costs. The default small business rate of 40% is only applicable to SBIR (R43 &R44) and STTR (R41 & R42) applications. See the Division of Financial and Accounting Services (DFAS) at NIH to set up a rate: http://oamp.od.nih.gov/dfas/IdCSubmission.asp

- **Justification:**
  - Consortiums should each provide a budget justification following their detailed budget. The justification should be separate from the primary grantee's justification and address just those items that pertain to the consortium.

Understanding the Out Years

- We do not expect your budget to predict perfectly how you will spend your money four to five years down the road. However, we do expect a reasonable approximation of what you intend to spend. Be thorough enough to convince the reviewers that you have a good sense of the overall costs.
- You may request an escalation factor for recurring costs in accordance with your institution's policy, depending on NIH's budget appropriation. NIH will generally provide up to a 3% escalation factor for recurring costs each future year. Consistent with the FY 2009 appropriation, the FY 2008 average cost of competing grants is allowed to increase by 3 percent over FY 2008 (see NIH Guide Notice NOT-OD-09-066). The adjustment on salaries cannot exceed the salary cap.
- Any large year-to-year variation should be described in your budget justification. For example, if you have money set aside for consultants only in the final year of your budget, be sure to explain why in your justification (e.g. the consultants are intended to help you with the statistical interpretation of the data and therefore are not needed before the final year).
- In general, NIH grantees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the grantee's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a grantee makes certain budget modifications or undertakes particular activities (such as change in scope). See NIH Grants Policy Statement - Changes in Project and Budget.

Section

14

Procedures for the Submission of Proposal

Submission of Grant Proposals

The Office of Sponsored Projects (OSP) reviews applications and proposals after the internal routing process is completed.

5-Day Grant Submission Deadline

Because of the volume of proposals and the technical and administrative requirements that increase the processing time for each application, the University requires that a complete and final proposal be submitted to OSP five (5) business days prior to the sponsor's submission deadline.

Submitting your proposal to us five (5) business days in advance of the sponsor's deadline allows our office adequate time to conduct a thorough review of your proposal and budget, and to make corrections and/or provide recommended changes to PI, if necessary. This time also allows us to transmit the proposal before the last day of a deadline, thus avoiding transmission problems that could prevent the successful submission of your proposal.

Proposals that are incomplete or contain inappropriate information or which do not follow University policies or procedure will need to be corrected and resubmitted to OSP before the proposal may be sent to the sponsoring agency.

The OSP's timeline is as follows:

- Proposals that are received five (5) business days before the sponsor's deadline will be processed first and will receive a full review (consistent with solicitation, format, compliance, etc.)

- Proposals received three (3) business days prior to the deadline will be reviewed for compliance only.

- Proposals received one (1) business day prior to the deadline may be submitted without review, subject to subsequent withdrawal if content of the proposal is later determined to be in error. We discourage departments and investigators from submitting proposals

on such short notice.

- Same-day proposals will not be submitted. Same-day proposals are defined as those for which OSP has not received prior notice that a proposal is in development and arrive in OSP on the same day they have to be sent to the sponsor to meet the sponsor's due date.

Electronic Submission

Proposals that must be sent via the Internet will be handled in a manner differently from proposals that are submitted via mail. A primary difference is the advance time the Office of Sponsored Programs (OSP) staff need for access to the electronic version of the application. If these timing requirements are followed, all of the review aspects will be met in addition to additional electronic checks and submission.

The electronic version and the paper version must be made available to OSP staff by noon, 3 business days prior to the launching time. This will allow for barriers unique to proposal submission via the Internet. Proposals to be delivered to a sponsor electronically need to be ready to launch no later than 5 pm of the day prior to due. This timeframe provides an opportunity to review necessary files, repair corrupted files, and overcome Internet service interruptions that may otherwise result in failure to get the proposal to the sponsor on time.

Specific provisions of OSP as it relates to electronic submissions:

1. Launch Deadline: The complete electronic version of proposals for Grants.gov, FastLane or any other electronic submission process must be ready for launching to the sponsor no later than noon of the deadline day. This will allow the OSP staff to avoid sponsor overload and Internet malfunction.

2. OSP Deadline: To facilitate this launching, access to the electronic version and paper version, if needed, and the Request for Proposal Submission and Review form (RPAS) must be given **to OSP staff by noon, 3 business days prior to the launching time**. For example, a proposal due to the sponsor by 5:00 P.M. on a Thursday would need to be launched by noon (or before) of that Thursday. Access to the electronic version and the paper copy, including the fully signed RPAS, would need to be given to OSP by noon on Monday. Saturdays and Sundays do not count in this calculation. Thus, proposals that must launch at noon on Tuesday need to be at OSP by noon the preceding Thursday. If time to work on the proposal over the weekend is need, the Principal Investigator should make arrangements with OSP.

3. Order of Launch: OSP staff will review and launch the proposals in the order they are received. Once OSP has processed and launched all proposals that arrived at OSP within the three days before launch time, proposals that arrive later will be handled to the best of the staff's ability. Every effort will be made to handle proposals arriving late. Note that problems beyond OSP control such as corrupted files or Internet interruptions may result in proposals not being launched in a timely fashion. It might well be possible that OSP staff cannot correct or even send a late proposal.

4. Review and Processing: Proposals received within the timeframe of this Electronic Submission Policy will be reviewed online by OSP staff. Online administrative changes will be made as needed. Due to the extra workload imposed by sponsor electronic requirements, OSP staff will not be able to scan files, convert text to PDF files, nor do other large scale proposal corrections in the few days prior to deadlines.

5. Proposal Preparation: Up to a week before a deadline, OSP will happily help prepare proposals for electronic submission, provided they are not involved in the submissions of another deadline. Departments or colleges without the necessary equipment to complete the requirements for electronic submission must contact the OSP staff well in advance of the particular deadline for any help that is needed. As always, OSP staffs are available for questions, budgetary review, and other administrative help during the proposal preparation period in the weeks prior to the deadline.

Rationale:

Government imposed restrictions are making firm deadlines a necessity. Proposals that must be sent by OSP to a sponsor via the Internet require much extra processing. Electronic submissions are subject to barriers to submission of files that do not occur in traditional paper submissions. Therefore, we must adopt a fairly strict policy for such applications. We feel we have created a timeline for electronic submissions that builds in an opportunity to address complications in this process but allows maximum time possible to the researcher for proposal development. We hope that we will be able to ease these deadlines when the NIH, NSF and other sponsors that require electronic submission have developed sufficient capacity to permit easier access to their submission systems.

In order to ensure success for Grants.gov, Fastlane and all other electronic proposal submissions, it is crucial that OSP receives the proposal a minimum of five working days prior to the agency receipt deadline. **If the final proposal is not submitted to OSP five days before the Grants.gov receipt date, OSP cannot guarantee review and successful submission of the application**.

One should understand that electronic submissions become more complicated in that although we have hit the send button on our end, we are not assured that the application will be accepted by the sponsor, be it NIH or any other sponsor, there are VALIDATIONS that need to take place at the Grants.gov level as well as from the sponsor. If we are submitting at the last minute even as late as the morning of the deadline, due to heavy internet traffic, the validations or non-validations may not be received until it is too late to re-submit.

Section

15

Signature Authority on Grants and Contracts

A Principal Investigator (PI), Department Chair, Dean, or other Charles Drew University employee should never sign a sponsored projects proposal, contract or grant on behalf of the University unless they have been given actual authority to do so by someone with statutory authority to delegate such power to them. This policy specifically designates the Office of the Vice President for Research as the signatory authority on all contracts, grants, agreements and/or proposals and applications for sponsored projects. The Vice President for Research has delegated this signatory authority to the Director of Sponsored Programs. While this policy does not preclude PI's, Department Chairs, Deans, and other individuals from signing internal processing documents, the Director of Sponsored Programs must sign actual sponsored project contracts and grants for the University.

Before an agreement can be enforced, it must be signed by a person with specific statutory authority to sign on behalf of the University. Authority must be ACTUAL authority and cannot be delegated unless the University allows such delegation. As described above, for research grants and contracts, this authority has been delegated to the Director of Sponsored Programs. Therefore, if a sponsored project proposal or award is NOT signed by the Director of Sponsored Programs, the Vice President for Research, President or the Board of Trustees, the contract or grant is void and unenforceable against the University.

Key reasons behind the policies relating to signatory authority include:

- protecting the University and individual University employees from legal liabilities; and
- maintaining University compliance with University, State, Federal, and private contract regulations and requirements while performing research and services inherent in sponsored projects.

Any Principal Investigator or other University employee who contemplates signing a research proposal or agreement on behalf of the University without actual authority to do so assumes extensive personal legal liability. The Principal Investigator or employee should remember the following potential consequences of signing without authority:

1. Because the individual does not have the signatory authority to bind the University to a contract, the University is not bound by that agreement and is not obligated to provide lab or office space, personnel, or any other support to the PI in carrying out the work described in the sponsored agreement.
2. If the University employee uses University facilities and personnel to conduct research or other sponsored activities not otherwise approved through proper University procedures, the employee may be subject to discipline for misappropriation of governmental property and/or resources.
3. Without an authorized signature, only the individual who signed the agreement is personally liable for performance of the agreement and adherence to all of the laws, rules and regulations relating to the agreement, including, but not limited to, the Internal Revenue Code and state tax laws. If signed without authority, taxes may be imposed on the entire amount of research funding as the personal income of the individual.
4. A PI or other employee who signs a proposal or agreement without authority to do so may be subject to claims by the sponsor of the project or the University for fraud or misrepresentation if the PI led the sponsor to believe that he/she did indeed have the authority to sign on behalf of the University.

The professional reputation of a PI may suffer if a PI is required to go back to an organization after an unauthorized signature has been given and explain that the sponsor does not have a legally binding agreement with the University.

Section

16

Guidance for Review of Proposals by Deans and Department Chairs

This guidance is provided to assist deans, and department chairs in review of proposals for extramurally sponsored grants, contracts, and other agreements and to explain the purpose of their signature approving such proposals.

By reviewing an extramural proposal and signing the accompanying Request for Proposal Approval and Submission (RPAS) form, the dean, or department chair certifies that the arrangements proposed are compatible with the activities and resources of the unit and school or college, and also authorizes acceptance, within University policies, of an award that may result from the proposal.

These responsibilities are not to be delegated to staff. If the dean or department chair is unavailable to review and approve proposals, another academic member of the unit should be delegated to do so.

If the dean or department chair has a personal financial interest in the proposed sponsor of a project, someone else with appropriate authority must review the proposal and sign the RPAS.

Review of extramural proposals should cover all areas of University activities affected by a proposed project. The questions below are exemplary but not inclusive of those to be considered in each particular case.

Financial Resources

Are the resources required to carry out the project currently available? Are there cost sharing or matching requirements? If so, are those resources available for commitment to that purpose? If two or more units are involved, are the cost sharing responsibilities of each clearly understood?

Space

Is the space needed for the project adequate and available for the full project period? If additional space or facilities will be required, have appropriate commitments been made to assure their availability for the project? Have the deans and chairs of other involved units been consulted?

Faculty and Staff Time

Are the time commitments proposed by the faculty reasonable to achieve the goals of the project in light of teaching and other University responsibilities? Is release time likely to be required? If so, can it be approved? Will the principal investigator/project director and other key personnel be available throughout the proposed term of the project? If the project involves staff employees, are they available and properly funded for the entire project period?

PI Status

If the principal investigator or project director will lead the project does he/she have a faculty appointment? Is the commitment of time of the PI/PD reasonable considering other awards or pending proposals?

Appropriateness

Is the proposed project acceptable under the mission of the University? Is the proposed project appropriate for the principal investigator/project director(s), the administering unit, and the University to undertake? Does it serve the University missions of expanding knowledge and educating students? Is there significant graduate student involvement? If not, why? If the project involves other departments in the University have the chairs of those departments been consulted?

For assistance in evaluating administrative commitments in proposals, please contact the Office of Sponsored Programs.

Section

17

Guidance for Establishing Memoranda of Understandings

From time to time the Charles Drew University enters into a Memorandum of Understanding (MOU) with one or more other entities. In the vast majority of cases, these MOUs are legally binding contracts which impose significant duties and liabilities on the University. Accordingly, it is extremely important that no MOU be executed on behalf of the University--or any subdivision of the University--without full compliance with this guidance.

Step One: Departmental Approval

The first step toward approval of an MOU is written approval from the department chair with whom the MOU originates.

Step Two: Collateral Review

Any MOU involving one or more of the following elements must also be reviewed by the appropriate department(s).

- Any MOU involving research must be reviewed by the Office of Research
- Any MOU involving a domestic state or federal government agency must be reviewed by the Office of Research and the Office of Sponsored Programs.
- Any MOU involving a commitment of resources from one or more departments other than the originating department must be reviewed by the other department(s).

Every MOU must be approved by the Executive Vice President of Research. The Executive Vice President of Research reviews the MOU to determine if the MOU involves the commitment of substantial University resources.

Criteria for Review

Review of each MOU shall include (but not be limited to) the following factors:

a) consistency with the education and research mission of the University;
b) consistency with current academic priorities;
c) avoidance of conflict of interest;
d) comparison of long term costs and benefits;
e) character of the other party to the MOU;
f) coverage of indirect costs; and
g) detailed specification of responsibilities.

Violations of Policy

Because an MOU can have legal implications for the University even if the person signing the MOU is not properly authorized, the University must regard it as a serious violation for any official or employee of the University to execute such a document without specific authorization from the Executive Vice President of Research & Health Affairs.

Section

18

NIH Salary Cap Guidelines & Procedures

The National Institute of Health (NIH) salary cap is a limitation on the rate of pay directly chargeable to grants and contracts issued by NIH. It is indexed to Executive Level 1 and is usually updated each January 1. Effective January 1, 2010, the salary cap increased to $199,700. On January 1, 2009 it was $196,700.

For the purposes of the salary limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are exclusive of fringe benefits and facilities and administrative (F&A) expenses, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization.

NIH grant/contract awards for applications/proposals that request direct salaries of individuals in excess of the applicable RATE per year will be adjusted in accordance with the legislative salary limitation and will include a notification such as the following: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap.

The salary cap summary with links to the full text of the NIH guidelines can be found at the following web site:

http://www.grants.nih.gov/grants/policy/salcap_summary.htm

When an individual's institutional base salary exceeds the salary cap, the difference between that individual's actual salary and the maximum amount allowed under the cap for their percent of effort is an unallowable cost on NIH awards and must be charged to a non-sponsored account. Institutional base salary is the annual compensation an individual receives, whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes incidental pay and any income that an individual is permitted to earn outside of duties for the institution. However, in no event will total salary charged to sponsored projects (which include grant accounts, cost sharing accounts

and the salary cap accounts) exceed the individual's CDU salary. The salary cap applies to both grants and contracts received directly from NIH and indirectly from NIH through another institution. It also applies to salaries being charged to cost sharing accounts associated with NIH projects. The unallowable portion of salary over the cap may not be charged to a regular cost sharing account.

COMPETING grant applications and contract proposals that include a categorical breakdown in the budget figures/business proposal should continue to reflect the actual institutional base salary of all individuals for whom reimbursement is requested. In lieu of actual base salary, however, applicants/offerors may elect to provide an explanation indicating that actual institutional base salary exceeds the current salary limitation. When this information is provided, NIH staff will make necessary adjustments to requested salaries prior to award.

Guidelines & Procedure Statement

Effective July 1, 2008, the university began requiring departments/colleges (COM/COSH) to track in accounting the salary amount that cannot be directly charged to an NIH grant or contract due to the NIH salary cap. As a result, all unallowable costs attributable to salary cap must be charged to another non-federal account.

The salary cap is normally updated each January 1st. Additional funds are not provided by NIH, but re-budgeting is allowed to accommodate the current Executive Level I salary. The university does encourage the use of the salary cap in effect for each budget period of an award.

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Section

19

Glossary

http://grants.nih.gov/grants/glossary.htm retrieved 08/10/10

Term	Definition
Academic Research Enhancement Award (AREA - R15)	Grant award stimulating research at health professional academic institutions with less than $3 million of NIH support in total costs in four or more of the last seven years. Go to AREA
Accession Number	Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.
Commons Account	As used by the NIH eRA Commons, a personal account an individual uses to log into the NIH eRA Commons which is identified by a unique combination of username and password.
Active Grant	A grant meeting the following criteria: 1. Today's date is between the budget start and end dates. 2. The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."
Activity Code	A 3-character code used to identify a specific category of extramural research activity, applied to various funding mechanisms. NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts. Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes may be found on the Types of Grant Programs Web page.
Administrative Expenses	Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and

	activities of the National Institutes of Health.
Administrative I/C	The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.
Administrative Supplement	Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.
Amendment (amended or revised applications)	Resubmission of an unfunded application revised in response to a prior review.
Animal Welfare Assurance	Document an institution and all performance sites involving animals in research must have on file with the Office of Laboratory Animal Welfare before a PHS Agency may award a grant or contract.
Animals in Research	Any live, vertebrate animal used for research, research training, biological testing, or related purposes. See PHS Policy on Humane Care and Use of Laboratory Animals for information and links to legislation and the Office of Laboratory Animal Welfare Animal Welfare Regulations tutorial.
Application	A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. [For detailed information about the application process (including an explanation of the types of applications), go to Application and Review Processes.]
Application Identification Numbers	The application number identifies: • type of application (1) • activity code (R01) • organization to which it is assigned (AI) • serial number assigned by the Center for Scientific Review (CSR) (183723), • suffix showing the support year for the grant (-01) • other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. **Sample Application Identification Number** 1 R01 AI 183723 -01 A1 S1

<table>
<tr><td>Application Types</td><td>
<table>
<tr><td>Type I</td><td>New</td></tr>
<tr><td>Type 2</td><td>Competing continuation (a.k.a. renewal, re-competing)</td></tr>
<tr><td>Type 3</td><td>Application for additional (supplemental) support</td></tr>
<tr><td>Type 4</td><td>Competing extension for an R37 award or first non competing year of a Fast Track SBIR/STTR award</td></tr>
<tr><td>Type 5</td><td>Non-competing continuation</td></tr>
<tr><td>Type 7</td><td>Change of grantee institution</td></tr>
<tr><td>Type 9</td><td>Change of NIH awarding Institute or Division (competing continuation)</td></tr>
</table>
Amended - See Resubmission
Contract types - See Contract Transaction Types
</td></tr>
<tr><td>Approved Budget</td><td>The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.</td></tr>
<tr><td>Assistance</td><td>The award of money, property, or services to a recipient to accomplish a public purpose as authorized by Federal statute. Assistance relationships (e.g., grants) are expressed in less detail than are acquisition relationships (contracts), and responsibilities for ensuring performance rest largely with the recipient or are shared with the Government.</td></tr>
<tr><td>Average Programmatic Reduction</td><td>The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.</td></tr>
<tr><td>Award</td><td>The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.</td></tr>
</table>

- B -

Term	Definition
Bridge	Provides one year of funding so investigators can continue research while

Awards	reapplying for an R01 grant or enables new investigators to gather preliminary data to improve their applications. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R21 with one year of funding, which the PI can choose to spend over a two-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R21 mechanism.
Budget Mechanism	Identifies the sub-mechanism category of the award for reporting purposes.
Budget Period	The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

- C -

Term	Definition
Catalog of Federal Domestic Assistance (CFDA)	A database which helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the Catalog of Federal Domestic Assistance (CFDA) which is referred to as the "CFDA number."
Capital Expenditure	The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds. Go to Administrative Requirements—Changes in Project and Budget —Prior-Approval Requirements—Capital Expenditures.
Carryover	As indicated by the Notice of Award (NoA), carryover authority provides grantees permission to carry over funds unobligated at the end of a budget period to the next budget period. For awards under the Streamlined Non-Competing Award Process (SNAP), funds are automatically carried over and are available for expenditure during the entire project period. However, under those awards, the grantee will be required to indicate, as part of its non-competing continuation request, whether its estimated un-obligated balance (including prior year carryover) is expected to be greater than 25 percent of the current year's total budget. If so, the grantee must provide an explanation and indicate plans for expenditure of those funds if

	carried forward.
Center for Scientific Review (CSR)	The NIH component responsible for the receipt and referral of applications to the PHS, as well as the initial review for scientific merit of most applications submitted to the NIH.
Center Grants	Center grants are awarded to institutions on behalf of program directors and groups of collaborating investigators. They support long-term, multi-disciplinary programs of research and development.
Central Contractor Registration (CCR) Database	The main vendor database for the U.S. Federal Government. Grant-applicant institutions need to register with the CCR to apply for a grant through Grants.gov. The CCR stores organizational information, allowing Grants.gov to verify the organization's identity and to pre-fill organizational information on its grant application. Institutions must have a DUNS number to register in the CCR.
Citation ID	The number used when citing papers falling under the Public Access Policy on applications, proposals, or progress reports. The citation ID will be a PMCID or an alternative when the PMCID has not been assigned yet.
Clinical Research	Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual. Studies falling under 45 CFR 46.101(b)(4) are not considered clinical research for purposes of this definition.
Clinical Trial	A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy in large groups of people (from

	several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use. Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
Close Out	A procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy. This includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.
Code of Federal Regulations (CFR)	An annually revised codification of the general and permanent rules published in the Federal Register.
Co-funding	Funding arrangement through which two or more Institutes or Centers pay for a grant.
Co-Investigator	An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS).
Commons	The NIH eRA Commons is a web-based system for applicants and institutions to participate in the electronic grant administration process. (see Electronic Research Administration).
Competing Applications	Either new or re-competing applications that must undergo initial peer review.
Competing Continuation	An application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)
Competing Research Project Grant	An application for a Research Project Grant requiring competitive peer review. Also, a number of obligations which serve as an input for determining success rates.

<table>
<tr><td>Competitive Range</td><td>A contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.</td></tr>
<tr><td>Competitive Segment</td><td>The initial project period recommended for support (in general, up to 5 years) or each extension of a project period resulting from a competing continuation award.</td></tr>
<tr><td>Conflict of Interest</td><td>Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.</td></tr>
<tr><td>Congressional District</td><td>A territorial division of a state from which a member of the United States House of Representatives is elected.</td></tr>
<tr><td>Consortium Agreement</td><td>A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. Go to Consortium Agreements.</td></tr>
<tr><td>Consultant</td><td>An individual providing professional advice or services on the basis of a written agreement for a fee. These individuals are not normally employees of the organization receiving the services. Consultants also include firms providing professional advice or services. Go to Allowability of Costs/Activities—Selected Items of Cost—Consultant Services.</td></tr>
<tr><td>Contract Transaction Types</td><td><table>
<tr><td>Type 1</td><td>New contract</td></tr>
<tr><td>Type 2</td><td>Renewal</td></tr>
<tr><td>Type 3</td><td>Modification</td></tr>
<tr><td>Type 4</td><td>Letter contract</td></tr>
<tr><td>Type 5</td><td>Continuation of an incrementally (typically, in one year increments) funded contract</td></tr>
<tr><td>Type 6</td><td>Task orders and subsequent modifications relating to existing ordering agreements</td></tr>
<tr><td>Type 7</td><td>Exercise of option</td></tr>
</table></td></tr>
<tr><td>Contract Under a Grant</td><td>A written agreement between a grantee and a third party to acquire routine goods and services. Go to Office of Acquisition Management and Policy (OAMP) Web site for information on contracts and contract opportunities.</td></tr>
<tr><td>Cooperative Agreement (U</td><td>A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means</td></tr>
</table>

Series)	that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.
Cost Overrun	Any amount charged in excess of the Federal share of costs for the project period (competitive segment).
Cost Sharing	See Matching or Cost Sharing.
Council/ Board, Advisory	National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.
Critique	An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at the meeting.
Current Dollars	Actual dollars awarded, without adjustment for inflation.

- D -

Term	Definition
Data Universal Numbering System (DUNS)	The DUNS number is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is recognized as the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in Commons.
Deferred	Refers to the delay in the review of an application by a scientific review group, usually to the next review cycle, due to insufficient information.
Department of Health and Human Services (HHS)	Federal Executive Department of which the U.S. Public Health Service (PHS) is a component and the NIH is an agency of the PHS. Go to HHS. Previously DHHS.
Direct Costs	Costs that can be specifically identified with a particular project or activity.
Direct Operations	Funds for salary and other administrative costs.
Domestic Organization	A public (including a State or other Governmental Agency) or private non-profit or for-profit organization located in the United

	States or its territories which is subject to U.S. laws and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.
Dual Review System	Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.
DUNS Number	See Data Universal Numbering System.

- E -

Term	Definition
Early Stage Investigator (ESI)	A New Investigator within 10 years of completing his/her terminal research degree or medical residency. A traditional NIH research grant (R01) application from an ESI will be identified and the career stage of the applicant will be considered at the time of review and award.
Earmark	A requirement by Congress that a Federal Agency spend a specified amount of money for a stated purpose (e.g. to establish a centers program or conduct a clinical trial).
Electronic Research Administration (eRA)	The NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required. Go to eRA.
Employer Identification Number (EIN)	Identification of a business to the U.S. Internal Revenue Service; also known as a Federal tax identification number. Entered on the SF 424 form of a grant application.
Enrollment Data	Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.
Equipment	An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.
eRA Commons	A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants.

	Registration is required. At this site: • Applicants access the status of their applications. • Grantees access the status of their awards, submit reports and make requests electronically. Go to eRA Commons.
Error	Any condition causing an electronically-submitted application to be deemed unacceptable for further consideration. Generally, errors will indicate significant inaccuracies, inconsistencies, omissions or incorrect formatting. The error needs to be corrected by the applicant and the application submitted again as a changed/corrected application via Grants.gov.
Error Correction Window	During the process of submitting a grant application electronically, applicants may receive a notification from the eRA Commons regarding errors or warnings that need to be corrected to complete the application process. NIH currently allows applicants to correct errors or warnings during the two (2) business days after the submission deadline. This time is referred to as the "error correction window." To make any corrections, the original application submission must have been submitted on time with all appropriate registrations in place. Note: Errors stop applications from processing and must be corrected. However, warnings do not stop application submission and are corrected at the discretion of the applicant.
Electronic Streamlined Non-competing Award Process (eSNAP)	Process allowing an institution to review non-competing grant data and submit a progress report online.
Expanded Authorities (EA)	Operating authorities provided to grantees that waive the requirement for NIH prior approval for specified actions. Go to Administrative Requirements—Changes in Project and Budget—Expanded Authorities.
Expiration Date	The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

- F -

Term	Definition
Facilities and Administrative Costs (F&A)	Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."
Federal Demonstration Partnership (FDP)	A cooperative initiative among some Federal Agencies (including NIH) and select organizations receiving Federal funding for research and certain professional organizations. Its efforts include a variety of demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.
Federal Register	An official, daily publication communicating proposed and final regulations and legal notices issued by federal agencies, including announcements of the availability of funds for financial assistance. Go to Federal Register.
Federal-Wide Assurance (FWA)	Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections--HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.
Fee	An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as “profit.” Go to Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee.
Fellowship	An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.
Final Peer-reviewed Manuscript	The author’s final manuscript of a peer-reviewed article accepted for journal publication, including all modifications from the peer review process.
Final Proposal Revision (FPR)	After completion of negotiations, offerors are asked to submit a final proposal revision which documents all cost and technical agreements reached during negotiations.
Final Published Article	The journal’s authoritative copy of the article, including all modifications from the publishing peer review process, copyediting and stylistic edits, and formatting changes.
Financial Status Report (FSR)	A financial report due 90 days after the end of each budget period for those awards not under SNAP, and at the end of the competitive

	segment for those awards under SNAP, showing the status of awarded funds for that period. The report is mandatory for continued funding of the grant. The form numbers for FSRs are SR 269 and SF 269A.
Fiscal Year (FY)	The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2007 – Started October 1, 2006 and ends September 30, 2007.
Foreign Component	The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities meeting this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the grantee having an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Foreign travel for consultation is not considered a foreign component. Go to Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components.
Foreign Institution	An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI.
Full-Time Appointment	The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.
Funding Opportunity Announcement (FOA)	A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program. Funding opportunity announcements can be found at Grants.gov/FIND and in the NIH Guide for Grants and Contracts.

- G -

Term	Definition

Government Accountability (GAO)	An oversight organization reporting to Congress. Go to GAO.
Grant	Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH Institute or Center anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.
Grant Appeals	A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.
Grant Closeout	A procedure to officially conclude a grant. Institute staff must assure that necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy. This includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.
Grant Compliance Review	An evaluation by grants management staff to assess an institution's business and financial management systems to ensure that regulations and policies are being followed.
Grant Project Period	Total period a project has been recommended for support which may include more than one competitive segment. For example, a project period for a grant begun in 1990 can be divided into competitive segments 1990 to 1994, 1994 to 1998, etc.
Grant Re-budgeting	With the advent of modular grants, grantees no longer have to request permission from NIH for re-budgeting (formerly moving money from one budget category to another). For non-modular grants, permission is still needed for some items.
Grant Start Date	Official date a grant award begins; same as the first day of the first budget period.
Grant Type	See Application Types.
Grantee	The organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to

	NIH for the performance and financial aspects of the grant-supported project or activity.
Grants Management Officer (GMO)	An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.
Grants Management Specialist (GMS)	A NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.
Grants Process	Go to Grants Process At-A Glance. (http://grants1.nih.gov/grants/grants_process.htm)
Grants.gov	An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (HHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to Grants.gov (http://www.grants.gov).
Grant-Supported Project/ Activities	Those programmatic activities specified or described in a grant application or in a subsequent submission(s) approved by an NIH Institute or Center for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.

- H -

Term	Definition
Health Insurance Portability and Accountability Act (HIPAA)	Law from 1996 that amends the Internal Revenue Code to improve portability of health insurance coverage, promote medical savings accounts, improve access to long-term care services and coverage, and simplify administration of health insurance. Go to

	HIPAA. (http://www.hhs.gov/ocr/privacy)
High Risk/ High Impact (HR/ HI)	A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.
Historically Black College or University(HBCU)	Any historically black college or university established prior to 1964 whose principal mission was and is the education of black Americans, and is accredited by a nationally recognized accrediting Agency or Association determined by the Secretary [of Education] to be a reliable authority as to the quality of training offered or is, according to such an Agency or Association, making reasonable progress toward accreditation.
Human Subject	A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. Go to Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects.
Human Subjects Assurance	A document filed by an institution conducting research on human subjects with the Office for Human Research Protections--HHS which formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

- I -

Term	Definition
IACUC	See Institutional Animal Care & Use Committee.
Identifier	Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.
Indirect Costs	See Facilities and Administrative Costs (F&A).
Initial Peer Review Criteria	**Significance** - Is the topic important? Will it advance Scientific Knowledge? **Approach** - Are the hypothesis, design, and methods well

	developed and appropriate? Are potential problems addressed? **Innovation** - Does the proposal involve new ideas or methods; does it challenge existing paradigms? **Investigator** - Does the investigator and collaborators have the training and experience to do the work? **Environment** - Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations?
Initial Review Group (IRG)	See Scientific Review Group.
Initiative	A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not.
Institute/ Center (IC)	The NIH organizational component responsible for a particular grant program or set of activities.

Acronym	Full Name	Organizational Code
CLC	Clinical Center	CL
CSR	Center for Scientific Review	RG
FIC	John E. Fogarty International Center	TW
NCCAM	National Center for Complementary and Alternative Medicine	AT
NCI	National Cancer Institute	CA
NCMHD	National Center on Minority Health and Health Disparities	MD
NCRR	National Center for Research Resources	RR
NEI	National Eye Institute	EY
NHGRI	National Human Genome Research Institute	HG

	NHLBI	National Heart, Lung, and Blood Institute	HL
	NIA	National Institute on Aging	AG
	NIAAA	National Institute on Alcohol Abuse and Alcoholism	AA
	NIAID	N National Institute of Allergy and Infectious Diseases	AI
	NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	AR
	NIBIB	National Institute of Biomedical Imaging and Bioengineering	EB
	NICHD	National Institute of Child Health and Human Development	HD
	NIDA	National Institute on Drug Abuse	DA
	NIDCD	National Institute on Deafness and Other Communication Disorders	DC
	NIDCR	National Institute of Dental and Craniofacial Research	DE
	NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	DK
	NIEHS	National Institute of Environmental Health Sciences	ES
	NIGMS	National Institute of General Medical Sciences	GM

	NIMH	National Institute of Mental Health	MH
	NINDS	National Institute of Neurological Disorders and Stroke	NS
	NINR	National Institute of Nursing Research	NR
	NLM	National Library of Medicine	LM
	OD	Office of the Director	OD
Institutional Base Salary	The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. Go to Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages.		
Institutional Business Official	Person working in a research organization's business office who has signature or other authority. That person is the same as Grants.gov's Authorized Organizational Representative (AOR) and the Commons' Signing Official (SO).		
Interagency Agreement	Formal agreement among government agencies to collaborate on and fund research; Y series activity code.		
Integrated Review Group (IRG)	A cluster of study sections responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.		
Internet Assisted Review (IAR)	Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SRAs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRA or GTA.		
Investigator-Initiated Research	Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research. See Targeted Research.		

- J -

Term	Definition
Just-In-Time	Within the Status module of the eRA Commons, users will find a

	feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

- K -

Term	Definition
Key Personnel	The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.

- M -

Term	Definition
Matching or Cost Sharing	The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.
Material Transfer Agreement (MTA)	A legal document defining the conditions under which research or other materials can be transferred and used among research laboratories.
Mechanism	Extramural research awards are divided into three main funding mechanisms: grants, cooperative agreements and contracts. A funding mechanism is the type of funded application or transaction used at the NIH. Programs are areas within the funding mechanisms. Activity codes identify categories applied to the various funding mechanisms. Also known as award mechanism or

	financial assistance mechanism or support mechanism.
Minority Group	Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.
Modified Summary Statement	Former term for a summary statement containing reviewer critiques, which is now standard practice. See Summary Statement.
Modular Application	A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award. Go to Modular.
Multiple Principal Investigator	Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution. Go to Multiple Principal Investigators.

- N -

Term	Definition
New Application (award, grant)	Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.
New Investigator	A new investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: • Pathway to Independence Award-Research Phase (R00) • Small Grant (R03) • Academic Research Enhancement Award (R15) • Exploratory/Developmental Grant (R21) • Clinical Trial Planning Grant (R34) • Dissertation Award (R36) • Small Business Technology Transfer Grant-Phase I (R41) • Small Business Innovation Research Grant-Phase I (R43)

	• Shannon Award (R55) • NIH High Priority, Short-Term Project Award (R56) Additionally, an individual is not excluded from consideration as a "New Investigator" if he/she has received an award from the following classes of awards: • Training-Related and Mentored Career Awards • Fellowships (F05, F30, F31, F32, F34, F37, F38) • Mentored-career awards (K01, K08, K22, K23, K25, K99-R00) • Other mentored career awards (developmental K02 as used by NINDS and the developmental K07) • Loan repayment contracts (L30, L32, L40, L50, L60) Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. Instrumentation, Construction, Education, or Meeting Awards • G07, G08, G11, G13, G20 • S10, S15 • X01, X02 • R25 • C06, UC6 • R13, U13 Also see Resources for New Investigators for more information.
NIH eRA Commons	Systems enabling the electronic transmission of information between NIH and the research community. See eRA Commons.
NIH Guide for Grants and Contracts	The official publication for NIH's medical and behavioral research grants policies, guidelines and funding opportunities. Go to Funding Opportunities and Notices.
No Score(NS)	Lower 50 percent of applications in the study section--no priority score is assigned to those applications.
No-Cost Extension	Within Status, users will find a feature to automatically extend grants eligible for a one-time extension of the final budget period of a project period without additional NIH funds through the eRA Commons. The system will automatically change the end date for the grant and notify the appropriate NIH staff.
Non-Competing Continuation	A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are

	administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.
Non-Competing Grant	An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.
Notice of Award (NoA)	The legally binding document • notifying the grantee and others that an award has been made • contains or references all terms and conditions of the award • documenting the obligation of Federal funds may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA). Previously known as Notice of Grant Award (NGA).

- O -

Term	Definition
Obligation	Data based on NIH funds that have been awarded by an NIH Institute/Center.
On-time Submission	For an application to be on time, all registrations must be completed prior to initial submission. Submission must be accepted by Grants.gov with a timestamp on or before 5:00 p.m. local time of submitting organization on submission deadline date. Additionally, errors or warnings must be corrected within the two-business day error correction window. **NOTE** • For both paper and electronic submissions, when these dates fall on a weekend or holiday, they are extended to the next business day. • Requests for Applications (RFAs) and Program Announcements with Special Referral Considerations (PARs) with special receipt dates always must be received (by Grants.gov for electronic applications and the Center for Scientific Review for paper applications) on the dates designated in the announcement to be on time. Go to NIH Policy on Late Submission of Grant Applications.

Organization	A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.
Organizational Code	A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. **Grant Number** 3 R01 CA 12921(9) -04 S1A1 In the example above, "CA" refers to the National Cancer Institute. For certain activities, DHHS organizations having Bureau status may use a Division-level code. An interagency agreement awarded by NCI, for instance, may be coded 1Y01CM00999-00, where CM refers to NCI's Division of Cancer Treatment. Also referred to as an I/C Code or Admin PHS Org Code.
Other Support	Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.
Overlap of Support	Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months. See Scientific Overlap.

- P -

Term	Definition
Program Announcement Reviewed in an Institute (PAR)	Program Announcement with special receipt, referral and/or review considerations.
Parent Announcement	NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism, e.g., Research Project Grant (Parent R01). Go to Parent Announcements for Unsolicited or Investigator-Initiated Applications.
Program	Program Announcement with set-aside funds

Announcement with Set-Aside Funds (PAS)	
Peer Review	A system for evaluating research applications using reviewers who are the professional equals of the applicant. See Dual Review System.
Peer Review Criteria	See Initial Peer Review Criteria.
Percentile	Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.
Person Months	Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort. Go to Frequently Asked Questions Regarding the Usage of Person Months.
Pre-application	A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.
Principal Investigator (PI)	An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.
Prior Approval	Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds. Go to Administrative Requirements—Changes in Project and Budget—Prior-Approval Requirements.
Priority Score	A numerical rating of an application reflecting the scientific merit of the proposed research relative to stated evaluation criteria.
Program Announcement (PA)	An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts. Go to Program Announcements.

Program Balance	The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.
Program Income	Gross income earned by a grantee directly generated by the grant-supported project or activity or earned as a result of the award. Go to Administrative Requirements—Management Systems and Procedures—Program Income.
Program Official (PO)	The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.
Project Number	Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.
Progress Report	Periodic, usually annual, report submitted by the grantee and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report.
Project Officer	An Institute staff member who coordinates the substantive aspects of a contract from planning the request for proposal to oversight.
Project Period	The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.
Protocol	Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

- R -

Term	Definition
Rating Criteria	See Initial Peer Review Criteria.
Receipt, Referral, and Assignment of	Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a

Applications	scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self assign.
Recipient	Organizational entity or individual receiving a grant or cooperative agreement. See Grantee.
Re-Competing	Grant whose term (e.g., four years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.
Renewal	See Competing Continuation and Application Types--Type 2.
Request for Application (RFA)	The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.
Request for Proposals (RFP)	Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.
Research	A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”
Research Grants	Extramural awards made for Other Research Grants, Research Centers , Research Projects, and SBIR/STTRs. Includes the following: • R,P,M,S,K,U series (excluding UC6) • DP1, DP2, D42, G12.
Research Misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. • Fabrication is making up data or results and recording or reporting them. • Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that

	research is not accurately represented in the research record. • Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.
Research Portfolio	The cohort of grants supported by a given NIH organization.
Research Projects	Includes the following selected Research Grant and Cooperative Agreement activities: • R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41. Exceptions: • In 1980 & 1981 activity code, U01 was not a research project • From 1989 until 1992 activity code, R55 was not a research project • In 1986 NINR did not have any research projects • From 1984 until 1989 NCRR did not have any research projects • FIC did not have any research projects until 1994 • From 1991 until 1996 NCRR did not consider R21's research projects • NLM never had any research projects • In FY 2002, P41s not RPG for NIGMS.
Research Project Grant (RPG)	Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. See Research Project s.
Research Supplement	Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.
Restriction	Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.
Resubmission	Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term

	was "revision." A resubmission has an entry in its application identification number, e.g., A1. See Resubmission Policy.
Review Cycle	Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review. See Standard Receipt Dates.
Revision	Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now “resubmission” in Grants.gov.

- S -

Term	Definition
Salary Cap/ Limitation	A legislatively-mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts. For current and historical salary cap levels, go to Salary Cap Summary.
Scientific Overlap	Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.
Scientific Review Officer (SRO)	A Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.
Scientific Review Group (SRG)	The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. See also Dual Review System. Also known as Study Section.
Scored	In the peer review process, applications judged by a study

	section to be competitive, i.e., generally in the upper half of the applications reviewed. These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.
Significant Rebudgeting	A threshold reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant re-budgeting is one indicator of change in scope.
Signing Official (SO)	A Signing Official (SO) has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The label, "Signing Official," is used in conjunction with the NIH eRA Commons. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Streamlined Non-Competing Award Process (SNAP)	Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP.
	
	• Routinely applied to:
	  ○ all R series grant mechanisms except for Outstanding Investigator Grants (R35s), Phase 1 Small Business Innovation Research Grants (R43) and Phase 1 Small Business Technology Transfer Grants (R41).
	
	  NOTE: For Phase I SBIR/STTR awards that *exceed* one year, grantees should review the Notice of Grant Award to determine if their project is subject to or excluded from the SNAP provisions.
	  ○ Career award mechanisms (Ks)
	• Not routinely applied to:
	  ○ those mechanisms not having the authority to automatically carry over un-obligated balances (centers, cooperative agreements, Kirschstein-NRSA institutional training grants, non-Fast Track Phase I SBIR and STTR awards)
	  ○ clinical trials (regardless of mechanism)

	○ Program Project Grants (P01s) ○ and Outstanding Investigator Grants (R35s)
Specific Aims	A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).
Scientific Review and Evaluation Award (SREA)	Scientific Review and Evaluation Award is a payment made to a Scientific Review Group (SRG) reviewer. SREA funds are used to reimburse travel, lodging, per diem and honoraria for review group members. Also refers to the process by which the award is generated.
Statement of Work (SOW)	In a contract proposal, the detailed description of the work to be performed under the contract.
Status	Allows Principal Investigators to review the current status of all their grant applications and review detailed information associated with their grants. Institution Officials [i.e., Signing Official (SO) or Administrative Official (AO) associated with the institution] can see a summary view of grant applications, review the Notice of Grant Award, and access the Progress Report face page.
Stipend	A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.
Study Section	See Initial Review Group.
Subaward	Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.
Subproject	A subproject may include a scientific investigation, the provision of a service or resource, or a combination of

	activities and receives a specific review assignment and assessment (score and/or descriptor). Most commonly, subprojects are part of the M, P, S, and U mechanisms.
Success Rate	Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers. NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.
Success Rate Base	The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.
Summary Statement	A combination of the reviewers' written comments and the SRA's summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.
Supplement	A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3 application or award, a supplement can be either non-competing (administrative) or competing (subject to peer review).
Suspension	Temporary withdrawal of a grantee's authority to obligate grant funds, pending either corrective action by the grantee, as specified by NIH, or a decision by NIH to terminate the award. This meaning of the term "suspension" differs from that used in conjunction with the debarment and suspension process. Go to Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Debarment and Suspension and Administrative Requirements—Enforcement Actions.
System Issue	Most system issues are technical problems with federal systems used for electronic submission of grant applications (Grants.gov or eRA Commons) that keep an applicant from

	successfully submitting their grant application on time. Please note: Problems with computer systems at the applicant organization are not considered system issues nor is a failure to complete any required registration by the submission deadline. System issues must be reported to the eRA Helpdesk on or before the deadline and will be investigated on a case by case basis.

- T -

Term	Definition
Targeted/ Planned Enrollment Data	Provides race and ethnicity data for projected number of human subject participants to be enrolled in an NIH-funded clinical research study. The data is provided in competing applications and annual progress reports.
Targeted Research	Research funded as a result of an Institute set aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research .
Technology Transfer	Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local Governments. Go to NIH Office of Technology Transfer .
Termination	Permanent withdrawal by NIH of a grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the grantee.
Terms and Conditions of Award	All legal requirements imposed on a grant by NIH, whether based on statue, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.
Tethered Application/ Grant	When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are

	associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the collaborative project. All applications are linked by a common project title and by cross-references within each application.
Total Project Costs	The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.
Training Awards	Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F). Go to NIH Research Training Opportunities.
Translational Research	Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

- U -

Term	Definition
Underrepresented Group	Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs. Also see human subjects and minority group.
Un-obligated Balance	Funds not used by the completion of a grant's project period. Grantees must report un-obligated balances over 25 percent of total costs to the grants management specialist. Grants awarded under expanded authorities may carry over un-

	obligated funds from one budget period to another within an approved project period without prior approval, as stated in the Notice of Award.
Unscored	In the Center for Scientific Review peer review process, applications judged by a study section to be noncompetitive are generally in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed and applicants receive a summary statement. Between FY 1992 and FY 1995 the term "Not Recommended for Further Consideration" (NRFC) referred to noncompetitive applications.

- V -

Term	Definition
Validation	The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

- W -

Term	Definition
Warning	Any condition in an electronically-submitted grant application acceptable but worthy of bringing to the applicant's attention. It is left to the applicant's discretion to take any corrective action. The application goes forward even if the warnings are not corrected. NOTE: Some warnings may need to be addressed later in the process or the review stages.
Withholding of Support	A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Section

20

APPENDICES - RESOURCES

CHARLES R. DREW UNIVERSITY OF MEDICINE AND SCIENCE

INSTITUTIONAL DATA SHEET

<table>
<tr><td>Applicant Organization
Address
Phone
Website</td><td>Charles R. Drew University of Medicine and Science
1731 East 120th Street • Los Angeles, California 90059-3051
323-563-4800
www.cdrewu.edu</td></tr>
<tr><td>Organization Type</td><td>Private, non-profit higher educational institution</td></tr>
<tr><td>Federal Tax Exempt Status</td><td>Issued under 501(c)(3) of the Internal Revenue Service (IRS) code</td></tr>
<tr><td>Congressional District</td><td>CA-037</td></tr>
<tr><td>Dunn & Bradstreet Number (DUN)</td><td>785877408</td></tr>
<tr><td>EIN</td><td>1 956151774 A1</td></tr>
<tr><td>California Tax ID # (TIN)</td><td>21614078</td></tr>
<tr><td>Tax ID #</td><td>95-6151774</td></tr>
<tr><td>Cage Code</td><td>3GZ36</td></tr>
<tr><td>IPEDS ID</td><td>111966</td></tr>
<tr><td>Federal Interagency Committee Education (FICE) Code</td><td>010365</td></tr>
<tr><td>Human Subject Assurance ID No.</td><td>FWA-00002736</td></tr>
<tr><td>Animal Welfare Assurance ID No.</td><td>A3190-01</td></tr>
<tr><td>Institutional Profile (IPF) No. (NIH)</td><td>489501</td></tr>
<tr><td>AAALAC Date</td><td>May 9, 2009</td></tr>
<tr><td>Institutional Signing Officials</td><td>Perrilla Johnson-Woodard, MBA, Interim Director, Sponsored Programs
323-563-5973 / 323-563-5967 (f)
perrillajohnson@cdrewu.edu

Keith Norris, MD, FACP, Interim President
323-563-4987 / 323-563-5987 (f)
keithnorris@cdrewu.edu</td></tr>
<tr><td>Financial Official</td><td>Ron Lau, Ed.D, Chief Financial Officer
323-563-5860 / 323-563-1953 (f)
ronlau@cdrewu.edu</td></tr>
<tr><td>NIH Salary Cap</td><td>$199,700 (2010)
$196,700 (2009)</td></tr>
<tr><td>Cognizant Federal Agency</td><td>Department of Health Human Services (DHHS)</td></tr>
<tr><td>Date of Federal Negotiated Rate Agreement & Contact</td><td>September 2, 2009
(POC) Wallace Chan 415-437-7820</td></tr>
<tr><td>Fringe Benefit Rate</td><td>
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<tr><th>Effective Period</th><th>Applicable To</th><th>Type</th><th>Rate</th></tr>
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<tr><td>Federal Facilities & Administrative Rate (F&A)</td><td>
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<tr><td>07/01/08 – 06/30/11</td><td>Organized Research</td><td>41.0%</td><td>26.0%</td></tr>
<tr><td>07/01/06 – 06/30/11</td><td>Instruction</td><td>32.6%</td><td>26.0%</td></tr>
<tr><td>07/01/06 – 06/30/11</td><td>Other Spon Act</td><td>34.6%</td><td>25.3%</td></tr>
<tr><td>07/01/11
Until Amended</td><td colspan="3">Use same rates conditions as those cited for fiscal year ending 06/30/11</td></tr>
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<tr><td>F&A BASE</td><td>Modified Total Direct Costs (MTDC)
Modification includes equipment of $5,000 or more per unit cost, patient care, tuition and fees, alterations, renovations, rent and utilities, and amounts over $25,000 for each subcontract.</td></tr>
<tr><td>Award Notification</td><td>Same as signing officials</td></tr>
<tr><td>Award/Check Payable to</td><td>Charles R. Drew University of Medicine and Science</td></tr>
</table>

A Step by Step: Checklist for Proposal Preparation
Getting Started- Required Documents
☐Download and print the Sponsor's Request for Funding Opportunity and Proposals (FOA) or Proposal Guidelines and the application forms
☐Notify Office of Sponsored Programs
☐Read them thoroughly!
☐If you are the administrator, discuss the project and the budget with the Principal Investigator
☐Questions to ask:
☐Is this a HRSA proposal? If so, are you set up to use HRSA Electronic Handbook?
☐Is this a NSF proposal? If so, are you set up to use Fastlane?
☐Is this an NIH proposal? Is the budget ☐modular or ☐regular?
Is it ☐new or a ☐renewal? ☐eRACommons?
☐Make sure the PI can be a PI, and confirm PI eligibility status if not sure. Faculty appointment,
Yes or No
☐Confirm the current indirect cost and fringe benefit rates
Preparing the proposal – Required Documents
☐Prepare the budget using the guidelines and the budget forms
☐Prepare the budget justification and Scope
☐Prepare other required forms such as the biosketches, "Other" support, a description of available facilities for the project, etc.
☐Make sure you use current forms, updated 398 version
☐Include CDU RPAS with Grant Submission
Institutional Approval
☐Fill out and print a RPAS Proposal Approval Form (This is a requirement for OSP)
☐Circulate the form with the abstract and budget for all the required signatures
☐PI
☐Cluster or Dean of the PI or Vice President of Research
☐co-PIs, if included on the project
☐If lower F&A, Do F&A rate exception form☐☐If the project requires the use of
vertebrate animals, an approved protocol from the Institutional Animal Care
and Use Committee (IACUC) (this can be pending)
☐☐If the project requires the use of human subjects, an approved protocol from the Institutional
Review Board (IRB) (this can be pending)
☐☐If hazardous materials are to be used, OESO approval for the use of such materials (recombinant
DNA, radioactive materials, etc)
☐☐If the sponsor is a corporation or foundation, clearance from the University Development Office
Other Approval if applicable
☐☐If cost sharing is required, letters of commitment and a cost sharing form with signature
☐☐If subcontractors are part of the project, proposals from each subcontractor; subrecipient documents
Submitting to OSP
☐One week before the due date
☐ abstract, budget and budget justification at a minimum)
☐A completed and signed RPAS
☐If needed, a completed and signed Cost Share Form with letters of commitment.

☐If needed, subcontractors' proposals, reviewed and signed by their institutions
(Prior to bringing a completed proposal to us, we can start reviewing sections of a proposal and give you feedback as you are working on them. Call or email us and we will arrange to work along with you so the final preparations and submission go smoothly.)
Submission
☐OSP Submit Grants

To provide an initial orientation to the process of proposal preparation and to facilitate advance planning, the following chart presents the main steps in the Preliminary/Pre-proposal Process.

1. Locate appropriate internal and/or sponsored funding source(s).
2. Review applicable program and/or sponsor information and guidelines.
3. Early feasibility consultations help ensure efficiency and success of proposal effort.

If matching or cost sharing is required, or if the program will involve allocation of department or university's resources, consult with Dean and Executive Vice President for Research & Health Affairs before beginning to write the proposal.

CHARLES DREW UNIVERSITY OF MEDICINE AND SCIENCE
Office of Sponsored Programs

REQUEST FOR PROPOSAL APPROVAL AND SUBMISSION (RPAS)

Internal Due Date: _____ Sponsor Due Date: _____ Submission Method _____ OSP #: _____

Proposal Purpose: _____ Proposal Type: _____ Proposal Action: _____

Lead PI/Contact PI: _____ Dept/Div: _____ Phone: _____ Email: _____

Dept/Div Contact: _____ Dept/Div: _____ Phone: _____ Email: _____

Sponsor Name: _____ Prime Sponsor *(if applicable)*: _____

Contact Name: _____ Phone: _____ Email: _____

FOA/RFA/RFP/Program Title: _____

FOA #: _____ Grant Title: _____

Grant/Contract #: _____

Initial/Current yr: From: _____ To: _____ Direct Cost: $ _____ F&A Cost: $ _____ Total Amount: $ _____

Entire proposal: From: _____ To: _____ Total Direct Cost: $ _____ Total F&A: $ _____ Total Project Amount: $ _____

F&A Rate Exception Request Form Required: ☐ Yes ☐ No *(If Yes, approved waiver must be attached)* F&A Rate: _____ %

PROJECT LOCATION(S) Building: _____ Room: _____ Other: _____

YES NO

☐ ☐ Is all of the above space assigned to you or otherwise approved for your use? *(If not, attach explanation from Dean (COM/COSH/SON))*

☐ ☐ Is rental space, construction or renovation required to house project? *(New rental space or renovations must be approved by the Research Space Committee)*

ADMINISTRATION

YES NO or N/A

☐ ☐ NIH Salary Cap applies

☐ ☐ NIH Commons User Name: _____

☐ ☐ Subawards/consortia agreements included in this proposal

☐ ☐ Limited Submission by Sponsor

☐ ☐ Cost Sharing _____ *(If Yes, approved cost share document must be attached)* *If Yes, cover by Account #:* _____

☐ ☐ This is a Major Project as defined by A-21 allowing specific administrative and clerical expenses to be charged (Federally-Funded Projects only).

☐ ☐ American Recovery & Reinvestment Act (ARRA) Funds

RESOURCES

YES NO or N/A

☐ ☐ Research is International in scope or location

☐ ☐ This submission requires coordination with the Office of Development/Advancement *If Yes, approval has been obtained. Additional information at www.cdrewu.edu*

☐ ☐ Does project involve commitment of facilities, services, patient care, or FTE support from MACC or others? *See approval below. For example AXIS-PCIR, etc..*

☐ ☐ Export Control - Do you anticipate transporting or shipping any research materials or equipment related to this project outside the United States?

REGULATORY *(Approval from the below regulatory offices must be obtained.)*:

YES NO

☐ ☐ Human Subjects *(If Yes, all required CDU personnel must complete **Human Subjects Training** before an award is made.)* ☐ Pending

☐ ☐ Vertebrate Animals ☐ Pending

☐ ☐ Institutional Biosafety Issue(s) including biological and chemical agents / Recombinant DNA Molecules (IBC) ☐ Pending

☐ ☐ Radioactive materials/radiation-generating machines ☐ Pending

☐ ☐ Proposal/project includes the use of propriety information or carries restrictions on participation, access to data or dissemination of results

☐ ☐ Has an invention disclosure on any new invention, process or discovery from work in the scope of this project ever been filed?

FOCUS (Check only if highly relevant to the proposed in this application. Check maximum of two.)

☐ Aging ☐ Cancer ☐ Cardio-Metabolic ☐ Global Health ☐ HIV/AIDS ☐ Mental Health ☐ Substance Abuse

☐ Other *(Please specify)*: _____

REQUEST FOR PROPOSAL APPROVAL AND SUBMISSION (RPAS)

Lead PI/Contact PI: _____ Sponsor Due Date: _____

Grant Title: _____

CONFLICT OF INTEREST

YES ☐ NO ☐ Do you* OR *anyone** involved in this research who has responsibility for the design, conduct or reporting of the research have a relationship or receive payment for services or have stock or stock options in the proposed sponsor, vendor(s), or subcontractor(s) or in a company that would be interested in the study results but is not sponsoring the study?

How to Determine Disclosure Requirements

1. Any relationship such as unpaid consultant, founder, or employee;
2. Payment for services such as consulting, service on an advisory board, or giving talks;
3. Stock or stock options;
4. Gift Funds

Who must disclose?

1. Principal investigator*
2. Any other participant* in the research who has responsibility for design, conduct, or reporting of the research, or in other words any one who has independent responsibility for the research or research results;

(this includes spouse/domestic partner, and dependent child(ren));

When must it be disclosed?

1. When the relationship or financial interest is related to the company sponsoring the study (i.e. consulting for a company sponsoring the research;
2. When the relationship or financial interest is indirectly related to the study:
   a. the company is supplying a product being studied;
   b. the study will be purchasing materials, supplies or equipment from a company in which there in is a relationship;
   c. or the results of the research would be of interest to the company in which there is a relationship;
3. At application or renewal, or when there is a new reportable interest.

What happens?

All reported financial interests will be reviewed by CDU's Auditor's office or designated committee to determine whether action is necessary to manage, reduce or eliminate a conflict of interest. Additional information at www.cdrewu.edu.

CHECKLIST OF REQUIRED DOCUMENTS THAT MUST BE ATTACHED WITH THIS RPAS *(Please check each that apply)*:

_____ Abstract _____ Budget Justification _____ Cost Share document (if applicable)

_____ Detailed Budget _____ F&A Rate Exception Request Form (if applicable)

PI CERTIFICATION/ASSURANCE

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Furthermore, I certify that I will direct this project in compliance with CDU policies, with the terms and conditions of CDU's agreement with the sponsor and with all applicable laws and regulations, and I will uphold the responsibilities of PIship.

Signature: _____ Date: _____

IF MULTIPLE PI: PI CERTIFICATION/ASSURANCE

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. Furthermore, I certify that I will direct this project in compliance with CDU policies, with the terms and conditions of CDU's agreement with the sponsor and with all applicable laws and regulations, and I will uphold the responsibilities of PIship.

Signature: _____ Date: _____

CLUSTER/DEPARTMENT APPROVALS (if applicable)

I have reviewed and approve the financial commitments for this proposal, including any cost sharing, any salary in excess of the sponsor's salary cap, or infrastructure charges. I have also reviewed and approve the space commitments. I have reviewed the proposed/reported effort and confirm it is accurate.

Cluster Leader/Dept. Chair: _____ Date: _____

COLLEGE APPROVALS (if applicable)

Dean (COM/COSH/SON): _____ Date: _____

EXECUTIVE VICE PRESIDENT OF RESEARCH (if applicable)

Signature _____ Date: _____

INSTITUTIONAL REVIEW BOARD (IRB) (if applicable)

Chair/Designee: _____ Date: _____

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) / VIVARIUM (if applicable)

Chair/Designee: _____ Date: _____

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) (if applicable)

Chair/Designee: _____ Date: _____

RADIATION SAFETY COMMITTEE (if applicable)

Chair/Designee: _____ Date: _____

OFFICE OF SPONSORED PROGRAMS (OSP)

(The signature of the Office of Sponsored Programs represents the assurance that all administrative requirements for the submission of this proposal have been addressed.)

Signature _____ Date: _____

NIH eRA COMMONS

Overview:

- The NIH eRA Commons is a Web interface where NIH and the grantee community are able to conduct their extramural research administration business electronically.
- For further information, please visit the NIH eRA Commons Web site (https://commons.era.nih.gov/commons/).

Functions of the Commons:

Status:

- This section lets the Principal Investigators (PIs) review the current status of all their proposals and review detailed information associated with the grant. PIs will be able to access their own priority scores, percentiles, and summary statements via the Commons a couple of weeks before they receive them in the mail. In addition, PIs will be able to review the Notice of Grant Award and access the Progress Report face page.

eSNAP:

- In the future, the electronic Simplified Non-competing Award Process (eSNAP) section will let CDU submit electronic versions of SNAP Continuation applications to NIH. The Office of Sponsored Programs (OSP) has already been implementing this.

How to Register:

- To be able to use the NIH eRA Commons **you must be registered as a user**.
- OSP is currently registering PIs and Assistants (Asst). PIs can delegate data entry responsibilities to Assts.
- To register, please complete the following request form or contact OSP at 323-563-5829 or via email at cdugrants@cdrewu.edu. Allow up to 5 days for account validation and activation.
- After the account is registered, you will receive email from NIH with a link to a website where you can activate the account.

eRA Commons Roles:

PI Role:

A Principal Investigator (PI) is designated by the grantee organization to direct the project or activity being supported by the grant. The PI is responsible and accountable to the grantee for the proper conduct of the project or activity. The role of the PI within the NIH eRA Commons is to complete the grant process, either by completing the required forms via the NIH eRA Commons or by delegating this responsibility to another individual. The PI can view information for all his/her grants and applications at NIH, including access to the Summary Statement and Notice of Grant Award (NGA).

ASST Role:

The Assistant (ASST) role has been designated to allow PIs to delegate certain responsibilities for data entry of grant information (eSNAP) and upkeep of their personal profiles. The ASST does not have any other functions in the system.

Additional Resources:

- The NIH Commons Help site provides information about how to log on to the Commons and how to access the various components (https://ithelpdesk.nih.gov/eRA
- The NIH Commons Demo site allows you to assume various roles in order to practice using the various components of the Commons with sample proposals and grants provided by NIH (https://commonsdemo.era.nih.gov/commons-demo/).
- The NIH Commons Support page has user' guides for some of the components and technical information about various versions of the program that have, or will be, released (http://era.nih.gov/commons/index.cfm).

NIH eRA COMMONS REGISTRATION REQUEST FORM

First name:

Last name:

User name *(6-20 characters, must be unique within Commons)*:

Email address:

Role: ☐ Principal Investigator (PI) ☐ Assistant (ASST) ☐ Other (FSR, AA etc..)

Note: If Assistant role has been checked, signature of PI must be obtained.

If necessary, the Office of Sponsored Programs (OSP) will contact those who register for the following information:

- Birth date *(PI only)*
- Social Security number *(PI only)*
- **Please note:** NIH will use these 2 personal items to match a PI's registration to all the other grants and committee memberships he or she already has with NIH.

Once registration information has been submitted by the Office of Sponsored Programs, NIH will contact the newly registered user and provide a password.

SIGNATURES

Principal Investigator

Assistant Role

Other: Office of Finance

Office of Sponsored Programs

Date entered into Commons: _____

MATERIAL TRANSFER AGREEMENT (MTA) QUESTIONNAIRE

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even some types of software.

1. Principal Investigator Information:

Name: _____ Phone #: _____

Department: _____ E-mail: _____

Primary Researcher who will use the material, if not Principal Investigator:

Name: _____ Phone #: _____

Department: _____ E-mail: _____

2. Identify the Sponsor(s) that will be funding, in whole or in part, your research with the Material(s)

☐ Government funding (NIH, CDC, etc)

Sponsor(s): _____

Project Title: _____

Grant Number: _____

☐ Discretionary Funds

☐ Other: _____

3. Provider Information:

Provider Organization: _____

☐ For Profit ☐ Non-Profit

Contact Information:

Name: _____ Address 1: _____

Phone #: _____ Address 2: _____

E-mail: _____ City: _____ Zip Code: _____

4. Name and Description of Material(s):

5. How will the Material(s) be used (please provide or attach a detailed description of your research involving the Material)

MATERIAL TRANSFER AGREEMENT (MTA) QUESTIONNAIRE

6. Requested Material Information:

Material is

☐ Animal ☐ Antibody ☐ Chemical Compound ☐ Nucleic Acid ☐ Software ☐ Tissue

☐ Other: _____

Origin of Material

☐ Human (Provide IRB Approval)

☐ Animal (Provide IACUC Approval)

☐ Radioactive Materials (Provide Approval from Safety Officer)

☐ Other: _____

Does the Material include any of the following (check all that apply):

☐ Recombinant DNA listed as "covered" experiments in the NIH Guidelines

☐ Transgenic animals

☐ Transgenic plants

☐ Biological toxins

☐ Infectious agents

7. Where will your research using Material(s) be performed?

8. Where will the Material(s) be stored?

Required Signatures

Principal Investigator	Date
Edward Assanah, Research Operations Director	Date
Executive Vice President for Research and Health Affairs	Date
Office of Sponsored Programs	Date

Grants.gov Submission Tips

- **Start early!** Especially if you are using Grants.gov for the first time.
- Principal investigators (PIs) and university faculty and staff do not create Grants.gov accounts. The only account holders are OSP administrators who submit applications with Grants.gov.
- The Data Universal Number System (DUNS) number for the Drew University is 785877408. Drew University is already in the Central Contractor Registry (CCR); ***do not*** ***re-register the institution.***
- Principal investigators and university faculty and staff do not submit the application. The Office of Sponsored Programs (OSP) submits applications via Grants.gov. PIs must submit a printed proposal copy to OSP for review along with the signed Request for Proposal Approval and Submission Form (RPAS). After OSP reviews the printed proposal and the RPAS, the completed and checked final application package is sent to OSP as an email attachment or on a CD. OSP then submits the application.
- The Grants.gov Customer Support section has some good resources for learning and using the system: Training Demonstration, Tutorial, and User Guide.

Steps for using Grants.gov "Apply":

1. **Identify and Download the Application Package**
   - Each application package is specific to a specific grant program and deadline and cannot be used for other grant programs.
   - Use Grants.gov "Find" to search for and identify the grant program you want to apply for, and click the "Apply for Grant Electronically" button at the bottom of the page.
   - Or, if you know the program-specific Catalog of Federal Domestic Assistance (CFDA) number or Funding Opportunity Number, go to https://apply.grants.gov/forms_apps_idx.html, type in the number, and download the application package and instructions. You can search for CFDA numbers on the CFDA web site.

2. **Complete the Application Package**
   - Application instructions provide guidance on how to complete the application. The steps below should be sufficient to have your application accepted by Grants.gov. However, the agency may reject it in a later step if you do not follow all of the program application instructions.
   - Complete all fields that are yellow, or the application package will not be validated.
   - For the SF424(R&R) form, the DUNS for Drew University is 785877408, the Employer Identification number (EIN) is 1956151774A1, and the Congressional District is 37th.
   - Open and complete all the forms listed in the mandatory box.
   - Move all the forms in the mandatory box to the "Completed Documents for Submission" box.
   - Move all optional completed forms and/or documents to the "Optional Completed Documents for Submission" box.

- Click the "Verify Package" button. Make sure no errors are identified, correct any errors.
- Click the "Save" button to save the final copy of the application.
- Make sure that the "Submit" button is now active, although you will not be able to submit the application.
- If you revise the application, you must repeat the last three steps.

3. Provide a Printed Copy and RPAS to OSP for Review

- Submit a printed copy of the application to OSP for review along with the signed Request for Proposal Approval and Submission form (RPAS). This includes documentation of collaborative sub agreements.
- To allow sufficient time for review OSP requests applications five working days before the agency deadline
- After the initial review by OSP, make any recommended changes in Grants.gov application and provide OSP with the revised copy.

4. Provide the Final Copy to OSP for Submission to Grants.gov

- Submit a final electronic copy of the grant application to OSP by sending the file as an email attachment or delivering a copy on CD to OSP.
- OSP will then submit the application to Grants.gov.

5. After Submission to Grants.gov

- After the application is submitted, OSP and the PI will receive an email notification of the submission from Grants.gov
- Email from Grants.gov will confirm if the proposal was received and if it passed or failed data verification/validation.
- Lastly, email from the sponsor/agency will confirm that the agency received the application and if it passed or failed data verification/validation.
- If there are errors in the Grants.gov submission, you must correct them and email or deliver the application to OSP so that OSP can resubmit the application.(IMPORTANT: Applications with errors will not move forward, Errors MUST be corrected
- Once the proposal has been accepted by the agency, it is no longer within Grants.gov. The only way to check on its status is to query the agency (for example, the eCommons for NIH or FastLane for NSF proposals).

Resources:

- http://era.nih.gov/ElectronicReceipt/
- http://www.grants.gov/
- https://commons.era.nih.gov/commons/

Last Minute NIH-Grants.gov Checklist
Frequently Identified Problems

General Reminders

_____ **PDF Attachments-** Attached files are PDFs.

_____ **Font/ Margins-** Margins ½ inch all around; Font no smaller than 11 pt. FONT; Arial, Helvetica, Palatino Linotype or Georgia typeface and 15 characters/inch; 6 lines/inch.

SF424R&R Reminders

_____ **Revision.** If a revision of a previous submission, the "Resubmission" field is checked in Box 8 AND the **Federal Identifier** previously assigned to the application showing the institute and NIH tracking number in the listed in the Federal Identifier Field. The field should read CA123456.

_____ **Competing Continuation.** If the application is a competing continuation the **Renewal** is checked and Box 8, **Federal Identifier** reflects the institute and NIH tracking number of the prior award. The field should read CA123456.

_____ **SF424 R&R fields** reflect the following information –
Duns number-785877408
Entity Identification Number (EIN)-95-6151774
Person to be contacted: Name of Principal Investigator
EO 12372 – State has elected not to review
Authorized Representative: Perrilla Johnson-Woodard

_____ **Congressional District-** uses the CA-037 Format.

_____ **Title –** does not exceed 81 characters including spaces.

_____ **Budget Numbers –** the budget total from the budget forms matches the 424R&R 16a & b fields.

_____ **Budget Numbers –** 424R&R 16a & b fields are the same (unless there is mandatory costsharing).

R&R Key Personnel

_____ **Credential Field**-Is completed for the PI in the R&R Key Personnel form subset and reflects the PI's eRA Commons user Name.

_____ **Co-PI / PD –** Term has not been used to identify any personnel on the project.

_____ **Key Persons –** All mandatory fields have been completed and a biosketch has been attached for each person.

_____ **Biosketch Length –** Limited to 4 pages per person.

R&R Other Project Information

_____ **Human Subjects or Animals.** If human subjects or animals the appropriate assurance No. is provided.

Animal Welfare Assurance # - A3190-01
Human Subjects Assurance # - 00002736

398 Research Strategy

_____ **Two PIs.** If a second PI has been identified, verify a project Leadership plan is attached.

_____ **Human Subjects or Animals.** If Human Subjects or Vertebrate Animals were identified the required attachments are included in the 398 Research Plan.

_____ **Page limits** have been followed.

_____ **Renewal-Human Subjects & Publication List.** Ensure required reports are attached.

Budget

_____ **Budget fields** reflect the following information –

Cognizant Agency-(Agency Name, POC Name and Phone Number)
-Department of Health and Human Services, Wallace Chan,415-437-7820
Indirect Rate Agreement Type: MTDC (Modified Total Direct Cost)
Indirect Rate: depends (Research, Instruction, Other Sponsored Activities)

_____ **Budget Form Set -** Only one budget form set is attached, either Modular or R&R Budget.

If <= $250,000 in direct costs are requested in any one year the modular budget should be used.
If >$250,000 R&R budget should be used.

_____ **>$500,000 -** Cover letter indicating institute acceptance and Shared Resources Plan are attached.

_____ **R&R Subaward Budget** is only used, if a detailed budget is being prepared for the application.

DETAILED BUDGET

Any or all of the following components may be found in a typical budget. This narrative is meant to be a guide, but the PI is urged to consult the specific program guidelines or the Office of Sponsored Programs (OSP) Pre-Award Office if any question remains unanswered. You may request a budget template from the OSP Pre Award Office or download a copy from the OSP website to facilitate this process. The proposal budget should be clearly presented, and should reflect CDU appropriate budget categories. For example, major budget categories such as personnel, benefits, travel, supplies, equipment, and facility and administrative cost(s) should be clearly identified.

The following budget categories are typical. They are meant to serve as a guide rather than a template, and sponsors will vary regarding the order the budget is requested.

Personnel

Salaries for personnel are calculated based on the effort a person will devote to the project. For comparison purposes, 50% effort is approximately two and one-half days (2.5) per week, 20 hours per week or 6 person months (since CDU operates on a 12-month calendar). Because effort may vary over the life of a project, for budgeting purposes, effort should be determined based on an anticipated average over each project year. Personnel estimates of effort should describe accurately the amount of time expected to be spent by those involved with the project, along with total associated costs, including current salaries and fringe benefits (e.g., Project Director or Principal Investigator, 6 person months [pm] for one year at an annual salary of $30,000 = $15,000). Federal granting agencies now require percent effort to be expressed as person months. A calculator to convert percent effort to person months is available on the OSP website or by contacting the OSP.

Institutional Base Salary is the annual compensation that CDU pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary may not be increased as a result of replacing institutional salary funds with grant funds. **NIH has a salary cap of $199,700 for FY 2010.**

Cost Sharing, Matching, In-Kind

The terms "cost sharing," "matching," and "in-kind" refer to that portion of the total project costs not borne by the sponsor. Cost sharing should be reflected only if mandated by the sponsor or needed to accurately reflect the effort required to conduct the project. All cost sharing and matching/in-kind commitments must be verifiable through documentation and must conform to University and federal/agency policies regarding allowability, allocability, and reasonableness. Any cost sharing or matching must be approved by the department head (or designee) and appropriate officials; the Cost Sharing Approval Form is available on the OSP website or you may contact OSP for a copy.

If any individual contributes more effort to the project than the person-months being requested, this is considered cost-sharing. For example: The PI lists 3 person-months'

effort on the proposal, but requests only 1.8 months' salary. The difference (cost share) should be described in the budget justification and a supporting account (from which the 1.2 person months will be paid) must be listed in the RPAS.

Fringe Benefits
Fringe benefit rates should be calculated using CDU applicable rate. Please see OSP's website for current fringe rates.

Effective Date	Applicable To	Type	Rate
07/01/09 – 06/30/10	All employees locations	Fixed	26.7%

Consultant Costs
If outside consultants are required, a description of their role in the project should be included in the research plan and in the budget justification. For each consultant, include a biographical sketch and a letter of participation. All external consultants should be listed, even if they are not charging fees or costs.

Consultants or lecturers, along with their fees and travel costs, may be included in the budget. The consultant's services to the proposed project must be professional, short-term or intermittent, and must be solely advisory to the project. For a federal employee, consult the agency guidelines applicable to the individual in order to determine allowability.

Consultants are often confused with consortium/contractual relationships.

Consultant: A person employed on a short-term basis that provides expert advice without responsibility for a portion of the work scope; an individual hired to give professional advice or services for a fee, normally not as an employee of the hiring party. In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. In order to prevent apparent or actual conflicts of interest, grantees and consultants must establish written guidelines indicating the conditions for payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

Subcontract and consortium costs
Subcontract and consortium costs comprise part of the project that may be conducted by an organization outside of the University. List the subcontractor or contractor name(s) and total cost. If the subcontractor is a college or university, it might charge F&A (indirect) costs to CDU's budget, as well as direct expenses. Include these F&A costs as a direct cost, if applicable.

Definition - Consortium: An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's principal investigator, who must provide a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including Facilities and Administrative costs.

OSP Pre-Award Office will assist in coordinating consortium or contractual arrangements. If investigators from other institutions will participate in the project, the PI at the collaborating institution must submit the following information to CDU:

A letter of collaboration or statement of intent, co-signed by an institutional authority. NIH requires specific language, which can be obtained from the Office of Sponsored Programs.

- Subrecipient Commitment Form
- A Scope of Work
- Detailed Budget for Initial Budget Period
- Budget for Entire Proposed Period of Support
- Biographical Sketches of Key Personnel
- Subaward Checklist

Note that when using the federally negotiated rate, CDU indirect costs can be charged on only the FIRST $25,000 of each subcontract.

Equipment
Equipment is defined as items that are: 1) $5,000 or more per unit; 2) have a life expectancy of more than one year; and 3) should be tagged by CDU. Provide justification for the purchase and how it is essential to accomplish the objectives of the project. A vendor quotation is always helpful. Exceptions to these definitions of equipment are: 1) items that have a per unit cost of less than $5,000 but will be used to fabricate a piece of equipment that is valued at more than $5,000 and can be tagged. *Equipment is excluded from F&A calculation.*

Supplies
List laboratory/clinical supplies, chemicals and/or gases, animals, and similar consumable items that is required for the research. Estimates for supplies and expenses should be supported by a complete description of the supplies to be used, with the basis for computing estimates included (e.g., 100 assay kits x $25.00/kit = $2,500.00). Supply and expense estimates offered as "based on experience" are not sufficient. Estimated costs for purchases may be shown as follows:

Animal Purchases	
30 dogs x $120 ea.	= $3,600
30 rats x $3.50 ea.	= $105
Supply purchases	
100 assay kits x $25 ea.	= $2,500

Travel
Provide explanation for purpose of trips, e.g., to a professional meeting to present results of the research project. If possible, name the prospective seminars. Transportation costs and per diem rates must comply with the CDU policies. The budget or the budget narrative should include the number of persons traveling, the number of trips to be taken, and the length of stay. The estimated costs of travel, lodging, and other

subsistence should be listed separately. When combined, the subtotals for these categories should equal the estimate given for travel or per diem.

Patient Care Costs
The costs of routine and ancillary services provided by hospitals to individuals participating in research programs, including patients and volunteers, are allowable provided that the procedures are not considered standard of care and billable to an insurance provider, such as x-ray, laboratory, pharmacy, blood bank, pathology, etc. *Patient Care Costs is excluded from F&A calculation.*

The following otherwise allowable costs are not classified as research patient care costs: items for patient expense reimbursement, such as patient travel and parking; professional physician fees; and supplies, such as syringes, specimen collection kits, etc. Such costs should be included in the “Supplies” or “Other Expenses” category of the grant budget.

Alterations/Renovations. *Alterations/ Renovations excluded from F&A calculation.*

Other Expenses
These are expenses that do not fit into the categories above. Examples include: Publication cost - $400; Service contract on Electron Microscope - $600; Subject reimbursement - $10/subject X 20 subjects = $200. Also, break down all costs for animal housing. Show the nature and extent of any printing to be done. Some specific allowable expenses follow.

Animal care: Standard rates apply for charging animal care costs.

Computer services:

Equipment maintenance costs and service contracts: Costs for repair and maintenance of project equipment that is necessary to keep it operating efficiently, but does not appreciably add to its "permanent value or prolong its intended life," are allowable and should be budgeted (OMB Circular A-21).

Costs associated with the general maintenance and upkeep of a building used for research are generally considered as F&A (indirect) costs and therefore cannot be charged as direct costs. Costs of this nature include repair of light fixtures, custodial costs, unclogging drains, and other maintenance costs that cannot be directly related to a particular grant or contract.

Insurance: Costs of insurance required or approved pursuant to sponsored projects are allowable and may be charged to the federally sponsored projects.

Telephone service: Costs incurred for local telephone services, telephone equipment, cellular telephones, pagers, and fax lines are indirect costs and may not be charged to federally sponsored projects. Long distance toll charges may be charged to federally sponsored projects when a charge can be specifically identified with a project.

Photocopy Costs: Photocopy costs can be charged to federally sponsored projects only when the photocopies directly and specifically benefit the contract or grant to which the charge is made. Photocopy costs for routine administrative activities are indirect costs and may not be charged to federally sponsored projects.

Postage or Delivery/Courier Costs: Ordinary and routine postage costs may not be charged to federally sponsored projects. These costs are normally indirect cost may not be charged to federally sponsored projects. Federally sponsored projects with an extraordinary high demand for postage may be charged with these costs only if the postage is related to the specific work of the federally sponsored projects and only if the cost is included in the budget narrative and approved by the awarding agency. Delivery/courier costs can be charged to projects if approved in the project budget and justification.

Printing and Publications: Printing and publication costs are allowable and may be charged to federally sponsored programs.

Participant travel and any other direct payments to participants: Direct payments to participants, including patients, donors, subjects, and volunteers, should be listed in this category.

Tuition

Tuition for Sponsored Projects: The amount must be identified on the proposal budget. Faculty sponsorship of tuition and fees for qualifying students is handled as a form of compensation, in accordance with the sponsor's guidelines and with OMB Circular A-21. Some sponsors do not allow tuition reimbursement.

Tuition for Training Projects: The cost of tuition under training grants may be budgeted unless otherwise specified in the program guidelines. Note: If tuition is allowable under the program guidelines and indirect costs are based on Modified Total Direct Costs, tuition and fees *must be excluded* from the indirect cost base calculations. Contact your OSP Pre Award Office, if you have questions concerning any information provided in this document.

Facility & Administrative Costs

The Facility and Administrative Cost rate (F&A), also called indirect cost rate, should be included in all proposed budgets. CDU accepts published sponsor restrictions regarding the reimbursement of F&A, i.e., a sponsor may not pay F&A, or may pay at a reduced rate. NOTE: Modified Total Direct Costs (MTDC) consist of all salaries and wages, fringe benefits, materials, supplies, services, travel and subcontracts up to the first $25,000 of each subgrant or subcontract, regardless of the period covered by the subgrant or subcontract. However, MTDC excludes equipment costing more than $5,000, capital expenditures, charges for patient care, tuition remission, rental costs of off-site facilities, scholarships, and fellowships, as well as the portion of each subgrant and subcontract in excess of $25,000. Some funding agencies allow F&A on all of these categories, without exclusions, which are considered Total Direct Costs (TDC).

EXAMPLE: Budget Calculation Including Subcontract

	Year 01	Year 02	Year 03	Total Project
Direct Costs	$177,500	$184,600	$191,984	$554,084
Less Equipment	-5,000	0	0	-5,000
Less Patient Care	-5,000	0	0	-5,000
Less Subcontract	-37,000	-38,480	-40,019	-115,499
Subtotal	$130,500	$146,120	$151,965	$428,585
Plus Subcontract Base	25,000	0	0	25,000
Total Indirect Cost Base (modified total direct costs -- MTDC)	$155,500	$146,120	$151,965	$453,585
Indirect Rate	53%	53%	53%	53%
Indirect Total	$82,415	$77,444	$80,541	$240,400
TOTAL COSTS	**$259,915**	**$262,044**	**$272,525**	**$794,484**

CDU Facilities &Administrative Rates: (F/A)

Organized Research	41% MTDC (effective 7/1/08 – 6/30/11)
Instruction	32.6% MTDC (effective 7/1/08 – 6/30/11)
Clinical Trials	20% (typical this rate is utilized for most clinical trials
Off-Campus Rate	26% MTDC (effective 7/1/08 – 6/30/11)
Training Grant Rate	8 to 10 % (typical these rates are utilized for most training grant)

INCREMENTING BUDGETARY REQUESTS IN MULTI-YEAR BUDGETS: NIH POLICY IS TO GRANT UP TO 3% ANNUAL INCREASES FOR INFLATION. EXPERIENCE SHOWS THAT MOST FEDERAL AGENCIES ARE RECEPTIVE TO THIS INCREASE.

Budget Justification

Most federal sponsors require a budget justification and it's advisable to include one with all proposals, whether required or not. The justification gives the PI an opportunity to provide an explanation of budgetary requests that may not be immediately obvious to a reviewer.

For example: A $25,000 request that is described easily as "Laboratory Equipment" should be augmented to explain: “The $25,000 will be used to purchase a critically needed microscope that will serve as a dedicated tool for infectious disease research for on- and off-campus collaborators.” A clear and focused explanation helps the reviewer understand the need and benefit; a sample budget justification.

Modular Budget

The modular budget is most often used with R03, R21 and some R01 applications. With a modular budget, the amount requested must fall in increments of $25,000 (modules).

Modular budget requests are limited to $250,000 in direct costs per year for R01s, $50,000 in direct costs per year for R03s, and $275,000 in total direct costs for 2 years for R21s.

The budget justification requires only a description of the personnel who will be participating in the research, but their salaries should not be included. In fact, no budget breakdown (i.e., dollar amounts) is necessary at all. The detailed budget template that must be completed for the project is for internal review purposes only and should be submitted to OSP Pre-Award Office at the time of your submission for review. It must not be included with the grant application only for OSP.

If a difference exists in the requested amounts between one year and another, the justification must explain why. For example, $250,000 direct costs are sought for budget period 1, and $200,000 for budget periods 2-5, an explanation for this purpose is necessary (major equipment, for instance) and should be uploaded in the SF424 modular budget component “additional narrative justification” field.

Key Point

Once the budget has been prepared, you should make a final comparison of the amounts listed in the budget justification with the amounts in the budget form. Thoroughly review your budget against your budget justification. When inconsistencies exist between the budget justification and the budget form, or the total amount of the request listed elsewhere on the proposal, the amount of the request also may be in doubt. A final check of all the numbers will preclude such confusion. Budgets included in requests for external funding must be reviewed and approved by OSP. Budgets along with justification may be emailed OSP Pre-Award ahead of time.

Sample Budget Justification

The budget justification is one of the most important non-technical sections of the proposal, and it is often required by the sponsor. In this section the Principal Investigator (PI) provides additional detail for expenses within each budget category and articulates the need for the items/expenses listed. The information provided in the budget justification may be the definitive criteria used by sponsor review panels and administrative officials when determining the amount of funding to be awarded.

The following format is a sample only; not all components will apply to every proposal. Many sponsors prefer that budget justifications follow their own format. In all cases, however, it is best to present the justification for each budget category in the same order as that provided in the budget itself.

Salaries and Wages:

Note: The quantification of *unfunded* effort (e.g., "The PI will donate 5% effort...") in the proposal narrative, budget, or budget justification is considered Voluntary Committed Cost Sharing. This is a legal commitment which must be documented in the University's accounting system. Consider quantifying effort **only** for the requested salary support.

Principal Investigator: This proposal requests salary support for _____% of effort during the academic year and 100% of effort for _____months during the summer.

Other Professional Support: List title and level of effort to be proposed to be funded. Other personnel categories (Research Associates, Postdoctoral Associates, and Technicians) may be included here.

Administrative and Clerical: List the circumstances for requiring direct charging of these services, which must be readily and specifically identifiable to the project with a high degree of accuracy. Provide a brief description of actual job responsibilities, the proposed title, and the level of effort. (See note at the end of this Appendix regarding direct charging costs that are normally considered indirect.)

Graduate Students: List number and a brief description of project role. Include stipend, GRA allowance (tuition), and health insurance.

Undergraduate Students: List number and a brief description of project role.

Employee Benefits have been proposed at a rate of _____% for all non-student compensation as approved by the Department of Health and Human Services.

Capital Equipment: The following equipment will be necessary for the completion of the project: Include item description(s), estimated cost of each item, and total cost. Provide a brief statement on necessity and suitability.

Travel: For each trip, list destination, duration, purpose, relationship to the project, and total cost. Indicate any plans for foreign travel.

Technical Supplies and Materials: Include type of supplies, per unit price, quantity, and cost. When the cost is substantial, provide a brief statement justifying the necessity.

Publications: Page charges (number of pages multiplied by the per-page charge).

Services: Include type of services, cost per type, and total cost.

Consultants: Include the consultant's name, rate, number of days, total cost per consultant, and total consultant cost. Provide a brief statement outlining each individual's expertise and justifying the anticipated need for consultant services. Note: Justifying a specific consultant in the proposal may avoid the need to competitively bid consulting services.

Subcontracts: Include the subcontractor's name, amount, and total cost. Provide a brief description of the work to be performed and the basis for selection of the subcontractor. A separate budget and corresponding budget justification should be completed by the subcontractor, and is required by many agencies. Note: Justifying a specific subcontractor in the proposal may avoid the need to competitively bid subcontracted services. Post-award changes to subcontracts (additions, deletions, scope or budget modification) may require sponsor approval.

Other Expenses: May include conferences and seminars, Repair and Maintenance, Academic and User Fees.

Facilities and Administrative Costs (F&A): F&A costs have been proposed at a rate of _____% of Modified Total Direct Cost (MTDC) as approved in CDU's rate agreement with the Department of Health and Human Services. MTDC exclusions include Capital Equipment, GRA Allowance and Health Insurance, and Subcontract costs in excess of $25,000 per subcontract.

Special information for direct charging costs that are normally considered indirect. Many costs such as administrative and clerical salaries, office supplies, monthly telephone and network charges, general purpose equipment, and postage are not typically considered direct costs. These may be proposed as direct costs where "unlike and different" circumstances exist. In such cases a budget justification detailing the request must be submitted to OSP for review and approval. Please contact the Office of Sponsored Programs (OSP) for additional assistance.

Principal Investigator's Final Review and Responsibilities

The principal investigator should review the proposal to determine that agency guidelines have been followed, grammar and spelling errors have be corrected, no pages are missing, attachments are complete and copies are readable. During the final review and before submittal, consider the following:

- Is the proposal complete?
- Does the budget provide for the recovery of facilities and administrative (F&A) costs at the appropriate established rates?
- Has "Charles Drew University of Medicine and Science" been identified as the applicant's organization?
- If another campus, institution, or facility is participating, is there a letter of intent to cooperate enclosed in the proposal?
- If release time is being requested, have the department chair and dean(s) of the college been consulted?
- If another institution is involved or a subcontract being requested, has the Office Grants, Contracts and Compliance been contacted?
- Are the appropriate signatures on the cover page?
- Have the Request for Proposal Approval and Submission (RPAS) form been prepared?
- If academic personnel from other departments are involved, have signatures of approval from their department chairs and been obtained on the RPAS and proposal?
- Does the project involve the use of animals? Has a protocol been prepared?
- Does the project involve human subjects? Has a protocol been prepared?
- Does the project involve recombinant DNA? Has the Office of Research been contacted regarding a protocol?
- Does the laboratory meet environmental health and safety standards required for the project? Contact the Office of Research for information and policies.
- Have sufficient copies of the proposal been prepared for the principal investigator, co-investigators, and other project personnel, the sponsor, the department, the dean's office, and the Office of Research and the Office of Sponsored Programs?
- Have the RPAS been reviewed for correctness?