AVOID COMMON ERRORS
ON THE NIH COMMONS

1. Use correct institutional DUNS number, EIN number on cover form
2. Provide correct Type of Submission (box #1) and Type of Application (box #8) on cover form
3. Include correct NIH Commons ID for PI(s)
4. Include correct email address for PI(s)
5. Make sure an institution is listed for each Senior/Key Personnel
6. If this is a Multiple PI proposal
    a. Include NIH Commons ID for all named PI's
    b. Designate all named PIs as "PD/PI" in the Senior/Key Personnel and Budget sections
    c. Include a Multiple PI plan in the Research Plan section of the application
7. Make sure all required files are included and attached in PDF form
8. Follow page limits specified in the Funding Opportunity Announcement (FOA)
9. Include effort > 0 for all Senior/Key Personnel listed on the Budget form
10. Be sure to use correct and consistent dates on the budget and the SF424 cover page
11. Upload a consistent Budget Justification
12. Follow any special instructions noted in Section IV. Application and Submission of the FOA

Guide for assembling Adobe Forms B Version of the PHS SF424 (R&R) Application* For Applications due January 25, 2010 or later

*All page references included in this guide are from the Adobe Forms B Version of the SF424 – Grants.gov Application Guide; Part I: Instructions for Preparing and Submitting an Application and Part II: Human Subjects (dated December 22, 2009). The Application Guide can be downloaded from http://grants2.nih.gov/grants/funding/424/index.htm.

- In order to open the PHS SF424 (R&R) Adobe Application, you must download a compatible version of Adobe Reader onto your computer. This can be done by going to http://www.grants.gov/applicants/apply_for_grants.jsp. Compatible versions are currently Adobe Reader versions 8.1.1 through 8.1.7 and 9.0, 9.1.1, 9.1.2 and 9.2. ***Versions 8.1.6 or 9.2 are recommended.*** Adobe Professional versions 8.0 and 9.0 are also compatible.
- Full details on compatibility with grants.gov and specific operating systems are available at: http://www.grants.gov/help/download_software.jsp#adobe811
- To check that your version of Adobe Reader is compatible please go to: http://www.grants.gov/applicants/AdobeVersioningTestOnly.jsp. Follow the instructions to verify that you have a compatible version.
- NIH & other PHS agencies **require** all text attachments to the Adobe forms to be submitted as **PDF files**. This can be done easily by clicking on the Acrobat icon on the Word toolbar, OR, if you do not have the icon on your toolbar, going through the Print menu to convert. Click on File, Print, and then click on Printer Name and highlight Acrobat Distiller. When submitting to NIH, all text attachments must follow NIH formatting instructions, i.e., font requirements, margins, page limitations.
- When naming PDF files for electronic submissions use only standard characters in file names: i.e. A through Z, a through z, 0 through 9, and underscore (_). Do not use any special characters (example: "&", "$", "-", "*", "%", "/", and "#") or spacing in the file name. For word separation use underscore (example: "My_Attached_File.pdf").
- **Find** a Funding Opportunity Announcement (FOA), **download** application instructions (one time only), and **download** Grant Application Package to your desktop. Note that on the download page you can enter your email address to receive automatic updates pertaining to that particular FOA. We recommend that you do this only for applications to FOAs other than the parent FOAs. For NIH submissions - if you know your FOA number - the easiest way to download Grant Applications is through the NIH Guide at http://grants1.nih.gov/grants/guide/index.html . If you are not responding to a specific FOA, you must download the appropriate parent grant application at http://grants1.nih.gov/grants/guide/parent_announcements.htm .
    - For NIH R03s, the parent FOA is PA-10-064
    - For NIH R21s, the parent FOA is PA-10-069
    - For NIH R01s, the parent FOA is PA-10-067
- For those of you who are planning to work on NIH Grants.gov submissions using a shared drive or folder, please be aware that several people have experienced file corruption errors resulting in a loss of all work. To avoid these errors, Grants.gov and ITS recommend copying the file onto your own desktop to work on and then pushing it out when finished onto the shared drive/folder. Do not work on the application on that shared drive or within that folder at all. Be sure to communicate with others working on the drive/folder when changes have been made to avoid saving over someone else's work.

Grant Application Package

- Once downloaded, verify the Grant Application screen corresponds with the FOA.
- **To ensure that you have the current version of the application package, the Competition ID should list "ADOBE FORMS-B".**
- In the first required box to complete, **"*Application Filing Name,"** enter a name for the application use the following format: **Sponsor initials, PI last name, partial title of project: example: <u>NIHJonesFlightofBumbleBee</u>**
- **Open** and complete all **Mandatory Documents. If the documents to be completed (mandatory and optional) are moved to the "Mandatory (or Optional) Documents for Submission" box the forms will appear as a continuous document under the Application face page. In this way each form can be accessed by scrolling up or down, rather than constantly closing and opening file.** Most documents consist of more than one page. Be sure to look for the "Next" button at the top of the page or scroll down to ensure all information is completed. Work logically and complete the forms as they are laid out in the SF424 (R&R) Adobe Forms B Application Guide. Remember to continuously save documents as you work on them. As each page is completed, scroll up and click the **"save"** button on the top of the Grant Application Package form page. Any time the "save" button is clicked a statement will appear "*One or more of the items in this form contains an invalid value. Do you want to proceed anyway?"* Always check the Yes box.
- Do **not** use the "Save & Submit" button to save your application. Only your ORPA RA can submit the application.
- Under the **Optional Documents,** for NIH submissions, either the Modular Budget or the Research & Related Budget will need to be selected and completed. The FOA will indicate which budget format is required.

- **<u>SF424 (R&R)- Cover Component (pages I-38 to I-51)</u>**
  - **Open** and **complete** document **SF424 (R&R)** **<u>first</u>** as this page will pre-populate information on pages where the same information is requested;
    - **Box 1** – Type of Submission:
      - Pre-application – unless specified in a program announcement this field is NOT used by NIH/PHS
      - ***Application*** – check **new** application (all applications are new; the type of application – New, Resubmission, Renewal or Revision is identified in box 8).
      - ***Changed/Corrected Application*** - this box used only by ORPA if submitting a corrected application (i.e. the grant was submitted to grants.gov but errors or warnings needing correction were identified).
    - **Box 2 –** Date Submitted and Applicant Identifier
      - **Leave** the "Date Submitted" box **blank**.
      - Applicant Identifier – initials of funding agency, PI's last name, brief version of title, such as NIHJonesFlightBumbleBee (identical entry to information entered on initial page of the application package).
    - **Box 3** – Date Received by State and State Application Identifier
      - for **NIH/PHS submissions – leave blank**
    - **Box 4a** Federal Identifier
      - **<u>New</u>** projects – leave blank,

- if application will be a **<u>Resubmission</u>, <u>Renewal</u>** or **<u>Revision</u>** as denoted in Box 8, in Box 4 enter the ***previously assigned grant number, i.e. CA123456* (please use this format).**
- If submitting after the submission date (for any reason) include a **Cover Letter component** (see Application guide pages I-89 to 90).

▪ **Box 4b** Agency Routing Number
- To be entered only if agency specific instructions indicate. For NIH, leave blank.

▪ **Box 5 –** Applicant Information
- **Organizational DUNS Number <u>041294109</u>**;
  Legal Name**: University of Rochester,** Department: **ORPA,** Street 1: **518 Hylan Building,** City: **Rochester,** State: **NY** Zip Code: **146270140. Note that the nine digit zip code is required.**
  This address will pre-populate addresses for both PI (box 15 and ORPA RA (box 19) – PI will need to change address to his/her own mailing address in box 15. Note that the nine digit zip code is required.
- "Person to be contacted on matters involving this application" – ORPA RA – make sure email address is correct **(ORPA addresses do NOT use underscore or URMC in the address)**
  - donna.beyea@rochester.edu
  - anne.corriveau@rochester.edu
  - gayle.elledge@rochester.edu
  - tammie.martin@rochester.edu
  - laurie.naber@rochester.edu
  - cwilliam@orpa.rochester.edu
  - bkavanaugh@orpa.rochester.edu

▪ **Box 6 –** Employer Identification **<u>160743209</u>** or if submitting to NIH or any PHS agency, use **<u>1160743209A1</u>**.

▪ **Box 7 –** Type of Applicant. From the drop down menu choose **<u>O. Private Institution of Higher Education</u>**

▪ **Box 8 –** Type of Application
- **New** - application being submitted for the <u>first time</u>
- **Resubmission** - application was previously submitted and not funded, is being resubmitted ***(previously known as a revised application)***
- **Renewal** - application requesting continued funding ***(previously known as competing continuation)***
- **Continuation** - non-competing application (***previously known as* Progress Report**) - **DO NOT** use for NIH/PHS awards
- **Revision** - is checked if application is either requesting a change in financial obligations or in the terms and conditions. If requesting a change in the financial obligations, check appropriate box(s); i.e.,
  - **Increase Award**
  - **Decrease Award**
  - **Increase duration**
  - **Decrease duration**
  - **Other** - provide written explanation, i.e., any other change in the terms and conditions of the existing award

- Indicate whether this application is being submitted to other agencies. If, yes, indicate the agency name.
- **Box 9** - Name of Federal Agency - will be pre-filled
- **Box 10** - **Do not complete**. Catalog of Federal Domestic Assistance Number (CFDA) - will be pre-filled or left blank.
- **Box 11** - Descriptive Title of Applicant's Project - fill in with the **Project Title (remember if submitting to NIH the title is limited to 81 characters– including spaces and punctuation).**
- **Box 12** - Enter proposed start and end dates – use format: **MM/DD/YYYY.** For NIH submissions under a parent FOA, use the dates found at: http://grants1.nih.gov/grants/funding/submissionschedule.htm
- **Box 13** - Congressional district of the Applicant Organization - Enter **NY-028.**
- **Box 14** - Project Director/Principal Investigator – complete all boxes in this section. **The PI's email address must be included to ensure proper processing by NIH.** For Medical Center Departments, "Division" will be School of Medicine & Dentistry (please use this format). **Note that the nine digit zip code is required.**
- **Box 15** - Estimated Project Funding
  - a) Total Federal Funds Requested: enter **total Federal funds** (direct and indirect/F&A) requested for entire project period
  - b) Total Non-Federal Funds: enter total non-federal funds for the entire project period. For NIH enter "0" unless cost-sharing is required.
  - c) Total Federal & Non-Federal Funds: enter total estimated funds for entire project period - including both Federal and non-Federal funds. **For NIH/PHS applicants - 16a and 16c should be the same**, unless the FOA indicates cost sharing is a requirement.
  - d) Estimated Program income - identify any Program Income for the project period. If no program income, enter "0". For further guidance, please see the University's program income policy at http://www.rochester.edu/ORPA/policies/proginc1.pdf.
- **Box 16** - for NIH/PHS submissions - check **No**, Program is not covered by EO 12372.
- **Box 17** - Certification - **be sure to click on the "I agree" button.** Although this box is for the AO to certify, if this box is not checked, an error message will result.
- **Box 18** - If applicable, attach the SFLLL (Standard Form LLL, Disclosure of Lobbying Activities). It is unlikely this will be required. Please contact your ORPA RA with questions.
- **Box 19** - Authorized Organizational Representative (AO) - Also known as Signing Official, this is your ORPA Research Administrator.
- **Box 20** - Pre-Applications - Unless specifically noted in a program announcement, **NIH/PHS** do not use pre-applications - leave blank

- Once all data have been entered, scroll up and click the "Save" button – on the top left corner of the first page of the Grant Application Package.

- **Project/Performance Site Locations Component (pages I-52 to I-55)**
  - Project/Performance Site Primary Location. List applicant organization i.e., University of Rochester's address. If the Primary site is an offsite facility, i.e. Rochester General Hospital, Family Medicine, etc., that site should be listed.
  - Do **NOT** check the "I am submitting…" box. The applicant will always be UR, not an individual.
  - Enter the DUNS number for the primary performance site. This is **041294109** (providing the University of Rochester is the primary performance site).
  - **Note that the nine digit zip code is required for the Primary performance site. Every attempt should be made to include this information. *If the four digit extender is not available, enter the five digit zip code followed by four zeros (e.g. 123450000).***
  - Enter the Project/ Performance Site Congressional District for the primary performance site. This is **NY-028** (providing the University of Rochester is the primary performance site).
  - Up to thirty (30) additional sites can be added; after completing each site screen – click "next site" button. If more than 30 additional sites are needed enter the information in a separate file and upload to the Additional Locations box. For further guidance follow instructions in the Adobe Forms Application Guide (pages I-52 to I-55). A sample Additional Performance Sites format page can be viewed at: http://grants.nih.gov/grants/funding/424/index.htm
  - The DUNS number is required for all performance sites.
  - **Note that the nine digit zip code is required for all performance sites. *If the four digit extender is not available, enter the five digit zip code followed by four zeros (123450000).***
  - The congressional district is required for all performance sites. This should be entered in the format 2 character State Abbreviation-3 character District number (i.e. NY-028). If all districts in a state are affected, enter all for the district number (i.e. NY-all). If nationwide (all districts in all states), enter US-all. If the program project is outside the US, enter 00-0000.

- **Other Project Information Component (pages I-56 to I-62)**
  1. **Are Human Subjects Involved?** Check yes if activities involving human subjects are planned at any time during the proposed project period at any performance site.
     1a - If Yes to Humans Subjects:
     - Is the project exempt from Federal regulations? Answer Yes or No.
     - If yes, check the appropriate exemption number (1-6).
     - If No, is IRB review pending? If using human subjects and you do not yet have approval, you must check yes.
     - Enter the IRB approval date if already approved (if entered provide a copy of the approval letter to ORPA RA)
     - Enter the Human subjects assurance number: **0000009386** - ***all 6 zeroes must be entered***
  2. **Are Vertebrate Animals Used?** Check yes if activities involving animals are planned at any time during the proposed project period at any performance site.
     2a- If Yes to Vertebrate Animals:
     - Is IACUC review pending? If using animals and you do not yet have approval, you must check yes.

- IACUC approval date - either enter the approval date (if entered provide a copy of the approval letter to ORPA RA) or *leave blank if Pending*.
- Animal Welfare Assurance number: **A329201**

3. **Proprietary Information** included? If yes is checked, clearly identify all proprietary information throughout the text and include a statement on each page stating: "*The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.*"
4. **Environmental impact**? Unless the FOA indicates that the National Environmental Policy Act (NEPA) applies - check **No**
5. **Historic Site?** Is the research site designated, or eligible to be designated, as a historic place? If yes is checked an explanation must be provided in box 5a.
6. **Will there be activities outside the US?** Will there be partnerships with International Collaborators? If the project includes a foreign component this box must be checked yes. For clarification see Adobe Forms Application Guide page I-59
    - Check yes if the project involves activities outside the U.S. or partnerships with international collaborators.
    - If 6a is yes, identify countries involved
    - A brief (optional) explanation may be added in item 6b
    - Applicants to NIH or PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. This information should be attached in a separate file in item 12, Other Attachments. In the body of the text, begin the section with a heading indicating "Foreign Justification." The PDF file uploaded to item 12 should be named "Foreign_Justification.pdf".
7. **Project Summary/Abstract:** No more than 30 lines of text – following all font and margin specifications – must be converted to ***PDF format.*** Note that the 30 line limit includes any title listed and any line spaces between paragraphs (or between title and text).
8. **Project Narrative:** Relevance to public health statement: No more than 2 or 3 sentences in lay language. Convert to ***PDF format***
9. **Bibliography & References Cited:** (Literature Cited) ***PDF format.*** When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant PI and arose from NIH funding provide the NIH Manuscript Submission Number (NIHMS#) or PubMed Central reference number (PMC ID#) for each article. If the PMCID# is not yet available because the journal submits articles directly to PMC on behalf of authors, indicate "PMC Journal – In Process"
10. **Facilities & Other Resources: PDF format.** DO NOT LIST MAJOR EQUIPMENT UNDER THIS SECTION.
    - As before, identify the facilities to be used and describe the resources available to the project.
    - ***For the new Adobe B applications additional information is required:*** Describe how the scientific environment contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will

employ useful collaborative arrangements. For further details see page I-61.

- If there are multiple performance sites, describe the facilities and resources at each site.
- **For Early Stage Investigators,** describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support (such as administrative management and oversight and best practices training); and financial support (such as protected time for research with salary support).

11. **Equipment:** list major items of equipment already available for project. **PDF format**
12. **Other Attachments:** Do not use unless specified in FOA or unless a foreign component is included (see #6 above).

- **<u>Senior/Key Person Profile(s) Component (pages I-63 to I-71)</u>**
  - Project Director/Principal Investigator - will pre-populate from SF424 R&R page. **Important - Mandatory - DO NOT forget as an error will result at submission! *Fill in* Credential, e.g. agency log in - <u>NIH user Commons name is required</u> – *exactly as listed in Commons profile.*** *The Commons profile must be affiliated with the applicant organization. Make sure it is. Check with your ORPA RA if unsure.* Attach Biographical sketch as a PDF and use the **new biographical sketch format**. The SF424 biosketch template is available at: http://grants1.nih.gov/grants/funding/424/SF424R-R_biosketch_VerB.doc. Do NOT include Current & Pending support for NIH/PHS – this is required Just In Time (JIT).
  - Note that the nine digit zip code is required as part of the address for all senior/key personnel. Every attempt should be made to include this information. If the four digit extender is not available, enter the five digit zip code followed by four zeros (e.g. 123450000).
  - **The new Biographical Sketch format must be used**. Four page limit to include the information listed below (Education plus sections A-D). A sample biographical sketch is available at: http://grants1.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerB.doc
    - **Education Block** - complete as for previous biographical sketch format
    - **Personal Statement (A)** - Briefly describe why the individual's experience and qualifications make this individual particularly well-suited for the role (e.g., PD/PI, mentor) in the project that is the subject of the application.
    - **Positions and Honors (B)** - List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.
    - **Peer-reviewed publications or manuscripts in press (in chronological order) (C)** - NIH encourages applicants to limit the list to fifteen (15) publications. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number or the Pubmed Central (PMC) reference number for each article.

- **Research Support (D)** - List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key Person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

- The remaining Senior/Key Person Profiles should be listed in alphabetical order. Senior/key personnel are defined as individuals who contribute to the project in a substantive way. Complete all requested information. For NIH submissions in the box Project Role - **DO NOT use Co-PD/PI**. Choose "Faculty" to designate Co-Investigators or other efforted Key Personnel. Choose "Other" to designate non-efforted "Other Significant Contributors (OSC)". Choosing "Other" will activate the "Other Project Role Category" box and allow a descriptor to be entered. Choose "Consultants" for external consultants. Do not use the role "consultant" for University of Rochester employees – by definition, a consultant is an individual not employed by the applicant organization. To add the next key personnel – click "Next Person" button. Attach Biographical Sketch in the PDF format for each person. Do NOT include Current & Pending support for NIH/PHS – this is required JIT.
- For NIH and PHS agency submissions, unless required in FOA, DO NOT upload Current and Pending support documentation – this will be requested JIT.
- Forty individuals (39 + the PI) can be added in this manner. If more than 40 need to be added, use the "Additional Senior/Key Person Profile". This will become available once the first 40 profiles have been entered. For additional entries, use the sample "Additional Senior/Key Person Profile" format page found at http://grants1.nih.gov/grants/funding/424/index.htm. Additional biographical sketches (and current and pending support, if requested) must be included for each additional senior/key personnel.
- It is not necessary to include the credential (or NIH Commons User name) for anyone other than the PI (or PIs if the multiple PI model is used).
- **Multiple Principal Investigators** All named PI's must be registered on the NIH Commons and identified as PD/PI in the application. Use of Multiple Principal Investigators will require a Leadership Plan describing the roles, responsibilities, and working relationship of the PI's in the proposal. Please read NIH Notice NOT-OD-07-017 for more information at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html.

- **<u>Modular Budget</u> Component (pages I-97 to I-105)**
  - Must be used if the NIH proposal is being submitted as a R01, R03, R15, R21, or R34 <u>AND</u> if the average direct costs per year do NOT exceed $250,000. See modular budget instruction pages SF 424 (R&R) Application Guide pages I-97 to I-105, or contact your ORPA RA for help.
  - Only one budget justification is required and all years' justifications will be included in this one document. This PDF document will be included on the "PHS Modular Budget, Period 5 and Cumulative" page, and will be appended under Cumulative Budget Information Box 2.
  - Note that different F&A rates may apply within one budget period (this is dependent on the budget period start date). In these cases, the F&A calculation must reflect the F&A rate in effect for each portion of the budget period. For assistance with this calculation contact your department CLASP administrator or your ORPA RA.

- At the end of each year's modular budget page, enter "MTDC" for indirect cost type and use the current approved rate in effect. In the box requesting the Cognizant Federal Agency, enter "DHHS, Robert Aaronson, 212-264-2069." This information must be entered for each year of the budget. In the box requesting the Indirect Cost Rate Agreement Date, enter the date of the current F&A rate agreement. If you do not know this date, please contact your department CLASP administrator or ORPA RA.
- If a subaward or consortium is proposed, a consortium justification must be included. Provide an estimate of total costs (direct plus facilities and administrative) for each year, rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, along with all personnel, including percent of effort (in person months) and roles on the project. Do not provide individual salary information. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the **total** consortium/contractual costs must be included in the overall requested modular direct cost amount. For grants submitted in the modular format, the R&R subaward budget is not required.
- If the requested budget requires additional justification, such as variation on the number of modules requested, this attachment should be uploaded.
- **As with paper submissions, a detailed internal budget is required for ALL modular submissions at the time of University sign-off.**

- **R&R Budget Component - For non- Modular Budgets (pages I-72 to I-88)**
  - <u>A separate detailed budget must be completed for each year of requested support</u>
  - All required fields must be completed before the system will allow for progression into the next budget period***, including the attachment for the Budget Justification field. Only one budget justification is required and all years' justifications will be included in this one document.*** *This PDF document will be attached to section K. of the Research & Related Budget before the "Next Budget" button will become active on the top right corner of that specific page.*
  - If no funds are requested for a required field - enter "0"
  - DUNS number and name of Organization will pre-populate from SF 424 R&R. Check appropriate box if primary applicant or subaward applicant.
  - Start and end dates, use format: MM/DD/YYYY. Start date must be the same as the project start date (as indicated on SF 424 (R&R) Cover Component box 12).

A. Senior/Key Personnel

- Start with PI information. **PD/PI** must be the same as **PD/PI** designated for the application. In all subsequent years, be consistent in "Project role" title for **PD/PI**. ***Person months*** are being used instead of percent effort. **To calculate standard person months: multiply %effort X 12, 9, or 3** (these are the appointment types; I.e. 12 = calendar appt., 9 = academic appt., 3 = summer comp. For assistance in calculating person months use this form: http://www.rochester.edu/orpa/eRA/CalculatingPersonMonths.xls
  - Requested Salary: indicate the amount of salary being requested ($ will generally be based on the % effort times the institutional base salary). For NIH grants, the salary cap should be used for salaries in excess of the current cap.

  - Fringe Benefits should be calculated using the current benefit rate associated with the actual institutional base salary (current fringe rates are available at: http://www.rochester.edu/ORPA/PropInfo/fy10bene.htm).
  - The PI must have a listed effort. Entering zero effort for the PI will result in a submission error.
- Continue to add all Key personnel. Note: if there are more than 8 (7 + the PI) key personnel, attach a document in the same format as the Key personnel budget category and enter the total additional salary in the 2nd to last box under the "Funds Requested" column (right hand column).
- Do NOT include consultants in the salary fields – they are added in Section F. Other Direct Costs.

B. Other Personnel

- Number of personnel: for each area identify the number of personnel proposed.
  - Enter the number of months devoted to the project for each project role category.
  - Requested Salary: indicate the amount of salary being requested ($ will generally be based on the % effort times the institutional base salary).
  - Fringe benefits: enter applicable benefits (use the rate associated with the actual institutional base salary) associated with salary requested

C. Equipment

- List equipment and associated costs – UR Indirect cost rate agreement defines equipment as having an acquisition price of $1,000 and greater and a life expectancy of greater than one year.
- If space provided does not accommodate all the equipment needed, in an attached PDF document (use "Additional Equipment field for upload) list the additional equipment and add the total dollars requested for this additional equipment to the box opposite line 11 - *"Total funds requested for all equipment listed in the attached file"*

D. Travel

- List funds separately for domestic and foreign travel.

E. Participant/Trainee Support Costs

- ***Unless specifically indicated in the FOA, NIH/PHS proposals DO NOT utilize this space – leave blank***
- If requesting tuition remission for graduate students on NIH/PHS proposal include the funds requested in Section F. Other Direct Costs

F. Other Direct Costs

- Request funds for categories listed
- Subaward/consortium Costs – enter total funds for all subaward/consortium organizations proposed. ***Separate budgets and justifications will be attached under R&R Subaward Budget Attachment(s) Form.***
- Sections 8-10, if requesting inpatient and outpatient costs, list these costs on separate lines. Also include tuition for graduate students in this area, and other costs, if applicable. If additional space is needed for other direct costs combine all other

direct costs and include in the last box. Description of these and all other direct costs should be described in the budget justification.
- For further clarification, see pages I-83 to I-85.

G. Indirect Costs

- List the indirect cost type. For UR, that will be MTDC – Modified Total Direct Costs.
- If Off-site rate will be used - list that here as well as the fact that it also is MTDC
- List indirect cost rate % - using the current rates in effect at the time of application.
- Note that different F&A rates may apply within one budget period (this is dependent on the budget period start date). In these cases, the F&A calculation must reflect the F&A rate in effect for each portion of the budget period. For assistance with this calculation contact your department CLASP administrator or your ORPA RA.
- List MTDC as the indirect cost type
- Multiply MTDC base x the rate listed and add to the Funds Requested box.
- **In the box requesting the Cognizant Federal Agency, enter "DHHS, Robert Aaronson, 212-264-2069." This information must be entered for each year of the budget. In the box requesting the Indirect Cost Rate Agreement Date, enter the date of the current F&A rate agreement. If you do not know this date, please contact your department CLASP administrator or your ORPA RA.**

H. Budget Justification - Budget justification is uploaded only once, in year 1 **and is for all years**. Remember, personnel must now be justified in "person months" not percent effort. *This PDF document must be attached in section K. of the year 1 Research & Related Budget before the "Next Budget" button will become active on the top right corner of that specific page.*

Budget Periods 2 - 5 If requesting funds for more than the one budget period, a separate detailed budget for each year of support is required. Each budget year consists of 3 screens. On the 3rd screen the "Next Period" button will be activated once all the required fields in all the screens have been entered. The system automatically calculates the cumulative budget page.

Submitting Budgets with more than five budget periods: When authorized or requested by the appropriate NIH IC, applicants may submit applications with more than 5 budget periods. In these situations complete the detailed budget for periods 1-5 as usual. However, include the same level of detail for Period 6 in the Budget Justification along with an explanation of the situation. Also, be sure to include a cover letter that addresses these extra budget periods, and include the IC Program Official's preapproval as part of the Cover Letter.

R&R Subaward Budget Attachment(s) (see pages I-88 to I-90 for details)**:** Inclusion of subawards in an application using a detailed budget requires completion of a Subaward Budget Attachment Form (PDF format). E-mail the form to the subaward site to complete and return. Save the file using the first 10 letters of the subaward site organization name. The "Subaward Budget Attachment Form" can be found by clicking the Click here to extract the R&R Subaward Budget Attachment button. IMPORTANT: A DUNS NUMBER IS REQUIRED FOR EACH SUBAWARDEE AND MUST BE INCLUDED ON THE BUDGET PAGES. If the subawardee is a foreign site or the DUNS number is not accessible enter nine zeros.

Submitting Subaward Budgets that are not active for all Periods of the Prime Grant: When submitting subaward budgets that are not active for all periods of the prime grant, fill out the subaward R&R Budget form and include only the number of periods for which the subaward is active. The budget period start/end dates reflected in each period should reflect the corresponding prime budget period start/end dates. This approach is the most workable solution to the limitations in existing forms that do not allow an "empty" budget period and do not allow submission of a subaward budget with zero effort to skip a budget period.

Note that if the subaward is not active for the entire project period, an explanation must be included in the cover letter.

This subaward budget attachment is not required if the modular budget format is being used.

- <u>Cover Page Supplement Component (pages I-93 to I-97)</u>
  - **Box 1** – Project Director/Principal Investigator box will be pre-populated from SF424 (R&R)
  - **Box 2** – Clinical Trial? Check yes or no. Agency-Defined Phase III Clinical Trial? Check Yes or No. Note that Public Law 110-85, enacted 09/27/2007, mandates registration and results reporting of applicable clinical trials in ClinicalTrials.gov (see SF424 – Grants.gov Application Guide; Part II: Human Subjects and Part III: Policies, Assurances, Definitions and Other Information.
  - **Box 3** – The first section of the Applicant Organization Contact will be pre-populated from SF424 (R&R) with ORPA RA's information. Complete the second section to reflect the title of the ORPA RA, ORPA, 518 Hylan Building, Rochester, NY 146270140
  - **Box 4**. Human Embryonic Stem Cells? Check yes or no. If yes, complete information on cell line(s).

- **<u>Research Plan Component</u> (pages I-106 to I-117)**
- **Please note the new structure and page limits for the Research Plan**
- ALL attachments must be converted to PDF prior to uploading into each section.
  - **Box 1** - Application Type – will pre-populate from SF 424 (R&R).
  - **Box 2** – Research Plan attachments. The Research Plan consists of multiple attachments. It is not submitted as one single file but is broken up into sections. However, the page limit for section 3 (Research Strategy) must be reflective of each grant mechanism – six (6) pages for an R03, six (6) pages for an R21 and twelve (12) pages for an R01. Further details on page limits can be found in table 2.6-1 (page I-22) of the SF424 instructions. Note that the FOA instructions always take precedence over the general instructions.

    1. **Introduction to application:** Include for Resubmissions or Revision Applications only. **The introduction is limited to one (1) page for all applications except the R25 or as indicated in the FOA.** For R25 applications, the introduction is limited to three (3) pages. If the FOA specifies different page limits for the introduction the FOA takes precedence over the general instructions.

The introduction must indicate how changes to the application are identified or state that changes are so extensive as to include most of the text.

2. **Specific Aims:** Limited to one (1) page. Save in a single file, convert to PDF.
3. **Research Strategy:** Organize the Research Strategy in the specified order and using the instructions provided on pages I-109 to I-110. Start each section with the appropriate section heading – Significance, Innovation, Approach. The Research Strategy should be a single file conforming to the page limits for the grant mechanism. As applicable, also include the information on Preliminary Studies for new applications or the Progress Report for renewal and revision application as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach).
4. **Inclusion Enrollment Report:** Upload only if submitting a competitive renewal or revision and the previous project period involved the enrollment of human subjects – must report distribution by race, ethnicity, and gender.
5. **Progress Report Publication List:** upload only if submitting a competitive renewal.
   - List publications, etc. that have resulted from the project since it was last reviewed competitively
   - When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant PI and arose from NIH funding provide the NIH Manuscript Submission Number (NIHMS#) or PubMed Central reference number (PMC ID#) for each article. If the PMCID# is not yet available because the journal submits articles directly to PMC on behalf of authors, indicate "PMC Journal - In Process".
   - Manuscripts accepted for publication, but not yet published - submit entire article in PDF format in Appendix (but note Appendix limitations).
   - Published manuscripts without an online journal link - may be submitted in PDF format in the Appendix (note Appendix limitations).

<u>Human Subject Sections</u>: For help in completing sections 8 - 11, refer to SF424 Adobe Forms Application Guide, Part II, Supplemental Instructions for Preparing the Human subjects Section of the Research Plan:

6. **Protection of Human Subjects**
7. **Inclusion of Women and Minorities**
8. **Targeted /Planned Enrollment Table**
9. **Inclusion of Children**

<u>Other Research Plan Sections:</u> (see pages I-112 to I-117 in the Adobe Forms Application Guide):

10. **Vertebrate Animals:** include if vertebrate animal use is planned. For detailed instructions see pages I-112 and I-113
11. **Select Agents:** include if select agent use is proposed
12. **Multiple PD/PI Leadership Plan:** For applications designating multiple PDs/PIs, a 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 PDs/PIs and other collaborators.

13. **Consortium/Contractual Arrangements**: Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the authorized organizational official on the SF424 (R&R) cover component (Item 18) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

    The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium *agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy*.

While the letter of intent (LOI) to establish a consortium agreement is no longer required by NIH, ORPA requires an LOI or signed face page on file for each subaward proposed in the application.

14. **Letters of Support:** Save letters as a single file and upload as a PDF
15. **Resource Sharing Plan(s):** (1) *Data Sharing Plan,* and (2) *Sharing Model Organisms.* A **data sharing plan** must be included if the applicant requests more than $500,000 in direct costs in any single year, or if the FOA requires the inclusion of a data sharing plan (regardless of funds requested). Please review the FOA for this requirement. A plan to **share model organisms** must be included if development of model organisms is anticipated (regardless of funds requested). Applicants seeking funding for a **genome-wide association study** (GWAS) are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible.
16. **Appendix:** A maximum of ten (10) PDF attachments is allowed. Note that this is the total number of PDF attachments, not the total number of items. If more than ten (10) items are needed in the appendix, combine the remaining information in attachment # 10. When allowed there is a **limit of three publications that are not publicly available** (see below for further details and check the FOA for any specific instructions), though not all grant mechanisms allow publications to be included in the appendix. Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process. For further details, please refer to NIH Guide Notice, NOT- OD-07-018.

Password protected documents cannot be used as NIH Commons does not have access to the password and therefore cannot utilize them. Keep the new guidelines in mind regarding publications when uploading Appendices. Photographs or color images of gels, micrographs, etc. are no longer accepted as

appendix material. See pages I-116 to I-117 in the Adobe Forms Application Guide for additional information.

- **PHS 398 Cover Letter File Component (pages I-91 to I-92)**
  Found under the Optional Documents on the Grant Application Package page. This component can be used to upload a cover letter requesting assignment to a specific institute or study section. Potential reviewers with conflicts may also be identified. Note the suggested format provided by NIH (see page I-92).
    - Must be used if submitting an application requesting 500K or more in direct costs in any given year. Upload the letter from the Institute accepting the application for review.
    - For late applications an explanation for the delay must be included.
    - Explanation of any subaward budget components that are not active for all periods of the proposed grant must be included.
    - Must upload a justification letter when submitting a changed/corrected application AFTER the deadline/submission date because of Commons validation errors or due to issues with the conversion from Grants.gov to the Commons.

- **Checklist Component (pages I-118 to I-122)**
    - **Box 1** - Application Type**:** pre-populated
    - **Box 2** - Change of Investigator/Change of Institution Questions: complete as necessary
    - **Box 3** - Inventions and Patents: **For Renewal Applications only (formerly a Competing continuation) this section must be completed.**
    - **Box 4** - Program Income – complete only if program income is anticipated
    - **Box 5** - Disclosure Permission Statement – check Yes or No. In the case this application does not result in an award, check "Yes" to provide permission for the government to disclose the title of the proposed project, and the name, address, telephone number, and email address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment). Check "No" if you do not provide this permission.

NIH electronic submissions through Grants.gov

Required PDF Attachments for Each Component

Mandatory Documents

SF 424 (R&R)

- None for NIH. If submitting to other agencies that use the Grants.gov application package and require a pre-application, the pre-application may be uploaded under this component.
- SF LLL (Standard Form LLL, Disclosure of Lobbying Activities) (unlikely that this will be required; contact your ORPA RA with questions).

Research & Related Other Project Information

- Project Summary/Abstract - thirty (30) lines lay summary abstract
- Project Narrative - Relevance to Public Health Statement (should be no longer than two (2) or three (3) lines). For non-NIH projects, the project narrative will usually be the actual project narrative/research plan. For NIH, the research plan is uploaded in a different component (see PHS 398 Research Plan below).
- Bibliography & References Cited (Used to be included right after the Research Plan in the paper submission).
- Facilities & Other Resources – No form page required. Include information requested by NIH. Note new content, particularly for ESI.
- Equipment - Equipment information as previously included in the 398 Resources Form.
- Other Attachments - for NIH purposes, this will not be used, unless further explanation of a foreign component is required (see Other Project Information, item #6, above for details).

Research & Related Project/Performance Site Location

- If greater than thirty (30) sites are involved in the project, complete the form found at the following link, convert to PDF and upload under "Additional Locations": http://grants.nih.gov/grants/funding/424/index.htm

Research & Related Senior/Key Personnel

- Biosketch for each Key Personnel and Other Significant Contributors. Use the Adobe B Biographical sketch form page: http://grants2.nih.gov/grants/funding/424/SF424R-R_biosketch_VerB.doc
- Current and Pending Support - for NIH purposes, leave blank (no need to upload anything) as this is part of the Just-In-Time process.
- If greater than 40 Key Personnel are proposed, enter the information in a separate file and attach the file under "Additional Senior/Key Person Profile(s). A sample format page is available at: http://grants.nih.gov/grants/funding/424/index.htm.
- If greater than 40 Key Personnel - upload Biosketch of those additional Key Personnel under "Additional Biographical Sketch(es) (Senior/Key Person)." Combine biosketches into a single PDF.

PHS 398 Cover Page Supplement

- No attachments required.

PHS 398 Research Plan

Multiple uploads are required in this component:

Research Plan:

- Introduction for revised application (if submitting a resubmission only)
- Specific Aims
- Research Strategy
- Inclusion Enrollment Report (if submitting a competing renewal only). If using 398 format page, remember to remove all headers and footers or use the revised Enrollment Report form page at: http://grants.nih.gov/grants/funding/424/index.htm
- Progress Report Publication List (only if submitting a competing renewal)

If Human Subjects will be involved, follow instructions in Part II of the Adobe Forms Application Guide or the PHS 398 Instructions and upload these files, if applicable:

- Protection of Human Subjects, including Data and Safety Monitoring Plan if applicable
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment Table. If using 398 format page, remember to remove the header and footer or use this revised Planned Enrollment form page: http://grants.nih.gov/grants/funding/424/index.htm
- Inclusion of Children

Other Research Plan Sections (upload these files if applicable):

- Vertebrate Animals
- Select Agent Research
- Multiple PI Leadership Plan - applicable only if proposing multiple PIs.
- Consortium/Contractual Arrangements
- Letters of Support - will need to scan and upload as one single file if multiple letters
- Resource Sharing Plan(s)

Appendix

- If including Appendices, follow NIH instructions contained in notice NOT-OD-07-018 for what is allowable. You may either upload each Appendix as individual files or convert them into a single file (this is strongly recommended)

PHS 398 Checklist

- No attachments required.

Optional Documents

PHS 398 Cover Letter

- If the PI wishes to request assignment to a specific NIH Institute or Study Section and/or identify possible reviewers or note reviewers to be excluded due to a conflict of interest. Include a cover letter if 500K or more in direct costs is being requested in any given year (include the letter from the NIH Institute accepting the application). If there are any subaward budget components that are not active for all periods of the grant include an explanation in the cover letter. This file will be excluded from the assembled grant image created by Commons. The assigned reviewers will not see this letter.
- If the application is rejected after the deadline date by either Grants.gov or Commons due to validation errors, a cover letter is mandatory explaining the reason for the Changed/Corrected Application.

PHS 398 Modular Budget

- Budget Justification on the third page of the Modular Budget Component for the UR Personnel.
- Budget Justification on the third page of the Modular Budget Component for Consortium (Subaward) Personnel if application includes sub-sites. If more than one subaward, it will still only be one single PDF file so will need to provide justification for each site in one file.
- Additional Narrative Justification if requesting variations in the number of modules (not required for an R21 submission as this mechanism allows for variation).

Research & Related Budget (to be used only if submitting a non-modular grant/budget)

- A. Senior/Key Personnel. If requesting salary support for more than 8 Senior Key Personnel provide requested budget information in a blank excel or word document (using same format as the R&R Budget), convert to PDF and upload under "Additional Senior Key Personnel."
- C. Equipment Description. If requesting funds for more than 10 Equipment items, provide description of additional equipment item(s) and associated cost(s) in a blank word or excel document, convert to PDF and upload under "Additional Equipment."
- K. Budget Justification. Upload a budget justification for all requested items and years as one single file at the end of Year 1 budget.

Research & Related Subaward Attachment(s) Form (to be used only if submitting a non-modular grant/budget)

- If UR budget includes requested funds for sub-awards, a PDF file of each subaward site Research & Related Budget (previously extracted and completed by each site) must be uploaded in this component. This PDF file must include the budget justification for the subaward site as well.