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Committee on Clinical Investigations

Human Research Seminar Series:

Grant Submission & Private Industry Sponsored Research: Guidelines/Requirements

Thursday, September 17, 2009

Presented by:
David Wallach, CIP
Manager, Committee on Clinical Investigations
Bob Ness
Associate Director, Office of Grant Accounting

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Human Research Education Program
Grant Submission & Private Industry Sponsored Research: Guidelines and Requirements

Presented by:
David Wallach, CIP, Manager
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Bob Ness, Associate Director
Office of Grant Accounting

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Overview

- What is the Office of Grant Accounting (GA)?
- What is the Committee on Clinical Investigations (CCI)?
- GA and CCI grant processes

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Grant Management at YU/Einstein

- There are three administrative components that provide assurance that there is an ongoing, multilevel internal control and review process.
  - > **Department Administrators** assist PIs in the preparation of applications and obtain proper internal authorization, where necessary.
  - > **Senior Management** provides an oversight review and approval of activity relative to the goals and strategic needs of Einstein.
  - > **Grant Accounting** coordinates the review of financial and related activity for completeness and proper authorization.

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The Role of the Office of Grant Accounting

- Grant Accounting provides internal control assurance
- Key in the process is that the likelihood of errors are diminished:
  - > Dual review and assessment reduces the likelihood that errors occur.
  - > When errors occur, they are identified and corrected in a timely manner.

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Grant Accounting: A Provider of Specific Oversight and Assurance

- Grant Accounting
  - > Provides management oversight for the pre-award and post-award process.
  - > Checks transactions and activity for completeness and proper authorization.
  - > Checks for completeness in terms of assurance that proper documentation has been marshaled to allow for service department review and approval.
  - > Checks for proper authorization and approval as required.

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What is the Committee on Clinical Investigations (CCI)?

- The CCI is the Institutional Review Board (IRB) of Yeshiva University
  - > An IRB is a body of members appointed by institutional officials to review research and determine if the rights and welfare of human subjects involved in research are adequately protected.
- The CCI is also the IRB for the North Bronx Hospital Network (NBHN) consisting of Jacobi Medical Center (JMC) and the North Central Bronx Hospital (NCBH).
- Montefiore Medical Center (MMC) has its own IRB.

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When Is A Study Considered Supported?

- A study is considered supported when a sponsor provides any of the following, directly or through a sub-contract:
  - > Financial support
  - > Drug
  - > Device
  - > Supplies or Equipment

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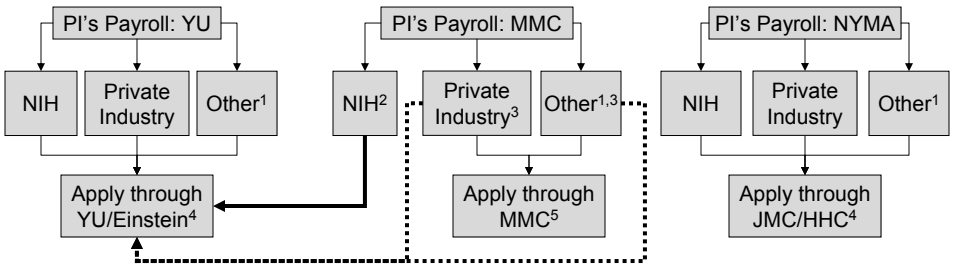
Which Institution Should be the Grantee?



1. "Other" includes Non-Governmental Awards and non-NIH Federal Agency Grants.
2. NEW: MMC PIs applying for new NIH grants apply through Einstein.
3. MMC PIs applying for Private Industry and non-NIH grants continue to do so through MMC, for now. This may change in the near future.
4. Project to be reviewed by Einstein CCI
5. Project to be reviewed by MMC IRB

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Externally Supported Research Conducted at the North Bronx Health Network (NBHN)

- The NBHN includes Jacobi Medical Center (JMC) and the North Central Bronx Hospital (NCBH).
- Researchers must consider financial reimbursement/ subcontract for research conducted at NBHN.
- YU/Einstein researchers are required to contact Barbara Levy to discuss all financial arrangements prior to beginning discussions with the NBHN Research Office or NBHN collaborating departments.

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Categories of Supporting Agencies

- Federal Agency Grants (e.g., NIH, NCI, etc.)
  - > Research Grant or Fellowship
  - > Umbrella Grant: Program Project; Center Grant
  - > Training Grants, e.g., T32, K12
- Non-Governmental Awards
  - > Private Foundations (e.g. Ford, Rockefeller)
  - > Voluntary Health Organizations (e.g. American Heart Association, etc.)
  - > Scholar's Award (all submitted through YU/Einstein)
- Private Industry (e.g., drug, device)

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Three Processes for Three Types of Support

- Just-in-Time – Applies to most grants and awards, including sub-contracts.
  - > Examples: R01 and Program Project grants.
- Training Grants – Applies to T32 grants only
  - > Federal grants that provide a stipend to fellows or post-docs to train with researchers with approved human research protocols. No new human research protocols will be developed.
- Private Industry Contracts – Applies to research governed by a contract with a company.
  - > Example: Pharmaceutical drug study

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"Just-In-Time" Procedure (For Federal Grants & Non-Governmental Awards)

- Just-In-Time (JIT) is the name of the process that allows/requires researchers to submit certain application materials after initial review by the agency.
- Grant Accounting works in conjunction with other service departments (Safety, Animal Institute, and CCI) and the PI's departmental administrative personnel to provide the required documentation.
- Just-In-Time efforts have expanded while the timeline has shrunk.

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"Just-In-Time" Procedure (For Federal Grants & Non-Governmental Awards): IRB Approval

- Agencies do NOT require IRB approval until the grant application has received a fundable score (or JIT request).
- To avoid duplicative or unnecessary work, researchers should only submit the CCI application and grant for review after receipt of a fundable score (or JIT request).
  - > Exception: If the research will be carried out without funding, the CCI application may be submitted prior to receipt of a fundable score. However, once a fundable score is received, the grant must be submitted to CCI as an amendment.

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CCI's Dual Involvement in the Grants Process

- Pre-Submission
  - > CCI administratively reviews and signs "Pending" on all grant applications that involve human subjects before they leave the institution.
- Post-Submission
  - > Once a grant is awarded (or a JIT request/fundable score is received), CCI reviews and approves the grant.

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Cayuse and the Internal Review Mechanism

- The Pre-Award Process is documented through the use of an Internal Grant Approval routing mechanism:
  - > Old system: Internal Grant Approval Form 6743 (AKA the “Internal packet”).
  - > New System: Cayuse424 (AKA Cayuse)
- In either case any research proposals that have or expect to have Human Subjects are flagged and await the award process.

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Grant Accounting Systems: Old System

- Internal Grant Approval Form 6743 (AKA the “Internal packet”)
  - > Paper-based system
  - > The Internal packet has as its goal to provide internal control assurance that the proposal to be submitted satisfies Einstein requirements.

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Grant Accounting Systems: New System

- Cayuse424 (AKA Cayuse)
  - > Electronic paperless system for administrative routing and approval.
  - > Much of the completeness check documented in the Internal is initiated in the Cayuse routing and up front checking by the Office of Grant Support.
  - > The Cayuse assists in the electronic application submission process.
  - > Subsequent years of an ongoing project initiated in Cayuse continue to be processed using the Internal Packet (at this time).

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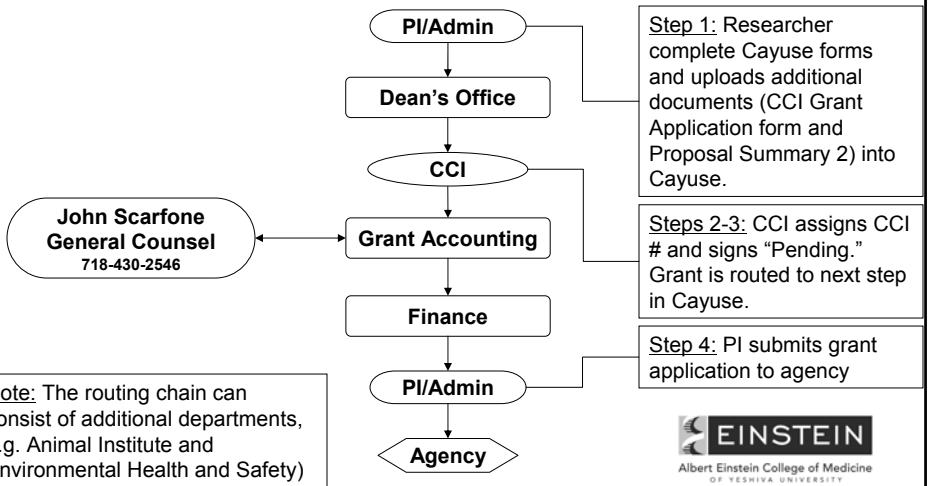
The Life Cycle of Federal/Foundation Grants Part 1: Pre-Submission Process (Cayuse)



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Just-in-Time – Step 1: Pre-Submission: CCI Process/Requirements

- CCI Process is different for Internal Packet vs. Cayuse based applications. This presentation focuses on the latter. For information on the former, see the CCI "Just-in-Time" Grant Approval Guide.
- Properly complete then upload into Cayuse these forms/sections for CCI:
  - > CCI Grant Application Form
  - > Proposal Summary Part Two (Human Subjects Section)

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Just-in-Time – Step 1: Pre-Submission: CCI Grant Application Form

- Available on CCI's website at: http://www.einstein.yu.edu/uploadedFiles/CCI/cci_grant.pdf
- PI must determine the Application Type (see next slide).
- For grants on existing protocols, the PI must provide the correct currently approved CCI number to which the new grant applies.
  - > If the CCI number belongs to a different PI than the applicant, provide an explanation to CCI to avoid delays in processing.

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CCI Application Types

- **Exempt Application:** See the definition of Exempt Research at http://www.einstein.yu.edu/cci/page.aspx?ID=9780
- **Chart Review/Database Study Application:** Study Examples: Medical Records review, Hospital Databases, Public Database, Data Analysis, etc.
- **Behavioral/Observational Study Application:** Study Examples: School based research, or research using Focus Groups or questionnaires, etc.
- **Specimen Study Application:** No direct research intervention by PI. Study Examples: research on leftover specimens, identifiable previously collected specimens, prospective specimens, etc.
- **Clinical Research Study Application:** Direct research intervention by PI. Study Examples: blood drawing, MRI's, radioisotopes, drugs, or devices, etc.

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CCI Review Options for Specimen/Data Analysis

- Most data analysis (e.g. chart reviews) and specimen analysis studies qualify for "Exempt-style" review.
- Always needs to be de-identified and not collected for the currently proposed project.
  - > Exempt Category 4 – allows the researcher to de-identify existing (at the time of application) data/specimens.
  - > Not Human Subjects Research – allows use of prospective (not available/existing at the time of application) data/specimens but must be obtained de-identified.
  - > Not Engaged – allows the researcher to analyze data/specimens for an external researcher. "We" cannot be the primary grantee. Specimens may be coded, but an agreement not to release the key is required.

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Just-in-Time – Step 1: Pre-Award: Proposal Summary Part Two (Human Subjects Section)

- Available on OGS's website at: http://www.einstein.yu.edu/ogs/Gg/ProposalSummary2.pdf
- Complete both questions to avoid delays in processing.
- Note that YU/Einstein's definition of Human Subjects is broader than NIH's.
  - > In addition to any interaction or intervention with humans for research purposes, CCI includes any data/specimens of human origin.
  - > Exception: Non-hESC, commercially available cell lines do not require CCI review.

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Just-in-Time – Steps 2-3: Pre-Award: CCI's Process

- CCI conducts an administrative audit.
- CCI links the new grant application to the existing study or assigns a new CCI Number when there is not an existing CCI approved protocol.
- CCI signs off in Cayuse and the grant continues to the next step.
- CCI sends an email with instructions on how to apply for full CCI approval once a grant is awarded (or a JIT request/fundable score is received).
  - > The email is sent to the PI, coordinator/submitted of the grant.
  - > Save this email! It contains the CCI # assigned to your grant which you should use when you apply for CCI approval.

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Education Requirement

- The NIH requires that the institution have mandatory human subjects education.
- Completion of the CITI course satisfies this requirement for 5 years. Details and registraitno information is available at: http://www.einstein.yu.edu/cci/page.aspx?id=9746
- The CITI refresher course is required every 5 years thereafter.
  - > Instructions on registering for the refresher course are available at: http://www.einstein.yu.edu/cci/forms/CITI_Refresher_Registration.pdf

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Education Requirement (Cont'd)

- Investigators are required to submit to the NIH:
  - > Copies of the CITI certificates or Einstein letters for applicable Key Personnel, together with a cover memo. Suggested wording is:
    - The following Key Personnel have successfully completed the required CITI Education Program. The program satisfies the education requirements concerning the protection of human subjects in research, and is described in the attached certification letters.
      (List applicable Key Personnel.)
- Investigators must include a similar commentary, and copies of the certification letters when submitting a Continuation Progress Report to the agency.
- Contact Carmen Garcia (Carmen.Garcia@Einstein.yu.edu or 718-430-2211) for replacement letters.

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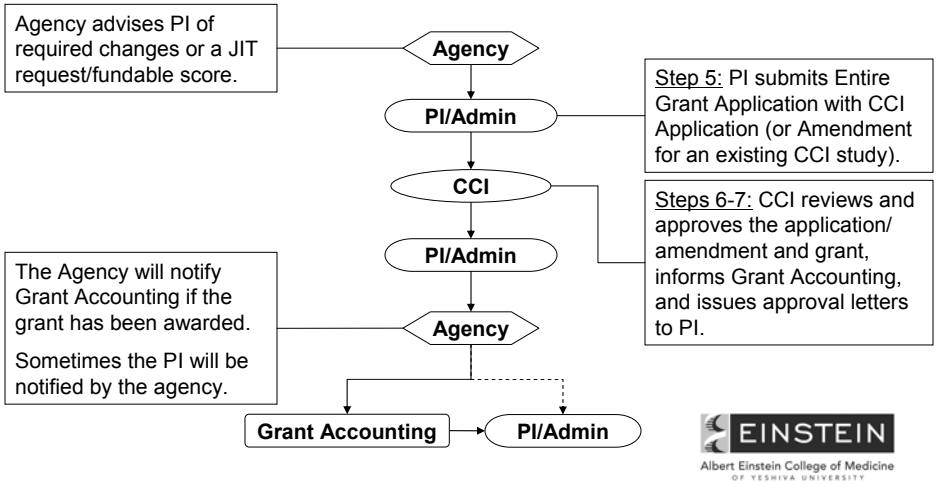
The Life Cycle of Federal/Foundation Grants Part 2: Post-Submission Process (Cayuse)



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Just-in-Time – Step 5: Researcher Submits Grant to CCI for Approval

After receipt of a fundable score, PI submits the following to CCI:

- Complete (and final) grant application, plus
- For a grant on a new protocol:
  - > CCI application and consents
    - NOTE: You must use the CCI Number assigned by the CCI when the "PENDING" signature was issued. (Do not start a new application in PATS.)
  - > PI determines the review type. Guidelines are found at: http://www.einstein.yu.edu/cci/page.aspx?ID=9792
- For a grant on an approved protocol:
  - > CCI amendment (adding the grant and updating the protocol as necessary) and revised consents (identifying the new sponsor, as applicable).
  - > A bulleted summary of previously approved amendments.

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Just-in-Time – Step 5: Researcher Submits Grant to CCI for Approval

Review Requirements

- Full Review: Materials (including 3 complete copies of the grant) must be submitted no later than deadline dates. Schedule is found at http://www.einstein.yu.edu/cci/page.aspx?ID=9670
- Exempt or Expedited Review: Materials (including 1 complete copy of the grant) may be submitted at any time.

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New Grant Application Or Competing Renewal (Renewal) For Currently Approved CCI Protocol

- When the research in the grant is identical to the CCI approved protocol, the statement, "There have been no changes in the human subject protocol, the investigators and key personnel, collaborating institutions or the resources utilized for this project," must be included in the amendment.
- When the research in the grant is different from the CCI approved protocol, the changes must be reported in the amendment.

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Just-in-Time – Step 6-7: CCI Reviews & Approves

- CCI reviews the submission
- CCI may require changes to the protocol and/or consent.
- When all CCI and institutional requirements have been met, CCI:
  - > informs Grant Accounting
  - > Issues the following to the PI:
    - Protocol/amendment/grant approval letter(s)
    - Stamped consents (when applicable)

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Grant Accounting: Post-Award 1

- The Post Award process utilizes the accounting and other transaction systems to manage and record financial and other activity.
  - > Award is received.
  - > Application is matched to the award.
  - > CCI Approval and other pending documentation are obtained.
    - You won't get started in your staffing and ordering and expenditure efforts until you can get a grant in which to charge them.
    - You won't get a grant until you receive CCI Approval.
  - > Collectability is reasonably assured. Otherwise its pay as you go.
  - > Renewal of Approvals obtained if necessary.
  - > Grant account and budget is established.

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Grant Accounting: Post-Award 2

- Ongoing Monitoring
  - > General ledger and support systems capability
  - > Budget and expenditures – reasonable agreement with expectations and activity
- Annual reporting and renewal
  - > Non-competing continuation and competing renewal
  - > Assurance of overall criteria and identification of change
  - > NIH Management by exception – three questions, etc.

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Program Projects: Center Grants, Master Protocols, K12 Training Grants, etc.

- Grant Consisting of Multiple Projects
- The entire grant application requires CCI review and approval.
- Processed as all other grants.
- Referred to as an “umbrella” grant, is assigned a CCI Number and is identified as the “administrative file.”
  - > Despite the administrative status of “umbrella” projects, progress reports are required annually. Minimal data is required unless there is a research component included in the “administrative file.”

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Program Projects: Center Grants, Master Protocols, K12 Training Grants, etc. (Cont'd)

- Each separate human research project under the grant requires review and approval on its own merits, and will be assigned a separate CCI Number which is linked back to the administrative file.
- For purposes of the CCI Grant Application Form, the administrative file is to be categorized as 'Chart Review,' so the least amount of data entry is required.
  - > Contact the CCI for guidance.
- However, models that contain a single human subject project or if screening may be included in the 'administrative' portion of the file, specify "Clinical Research Study Application."

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T32 Training Grants: Process 1

- Federal grants that provide a stipend to fellows or post-docs to train with researchers with approved human research protocols. No new human research protocols will be developed.
- Dept. sends CCI (and the MMC IRB, when applicable) a memo listing all trainers/mentors.
- CCI and IRB send the PI/department a report of active research protocols for each trainer/mentor, including the approval period for each protocol.
- The department includes the information, in table form, within the grant, and includes the current CCI/IRB recertification/expiration dates of each protocol.

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T32 Training Grants: Process 2

To obtain CCI sign-off, the department must submit:

- Internal Grant Approval Form – CCI will sign and date the approval. A CCI Number is not assigned.
  - > The page number listing all the trainers and approved protocols should be referenced, or "See attached List" written.
- NIH Grant Application
  - > The Institution's Federal Wide Assurance Number, FWA00000140.
- Report listing the names of trainers, research protocols, and CCI/IRB approval/expiration date.

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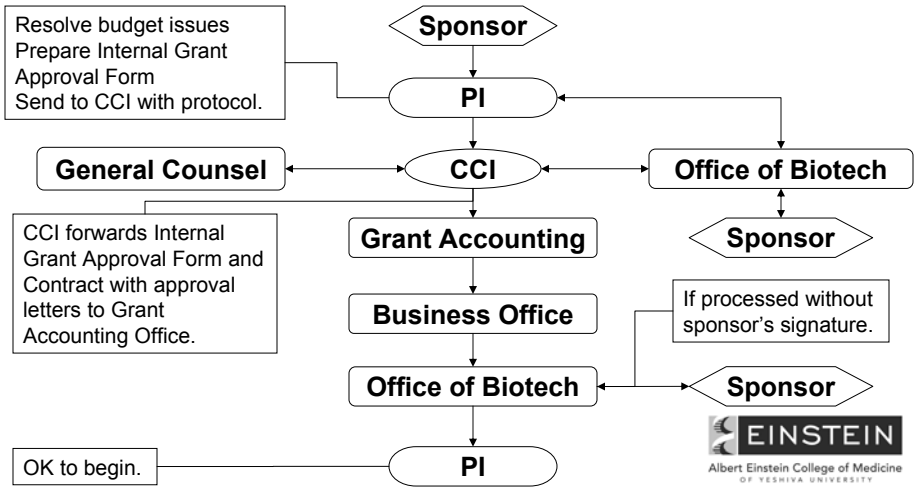
The Life Cycle of a Private Industry Research Contract and Internal Grant Approval Form



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Private Industry Sponsored Research: Contract Submission Process

- The contract process is different from the grant process.
- Contracts cannot be signed "Pending".
- Contracts require review and approval by YU General Counsel.
- Protocol approval is contingent on contract approval.
  - > The Office of Biotechnology (OB) and the Office of General Counsel are responsible for all contract negotiations for clinical studies and for 'basic science' research that involves the use of human specimens.
  - > Contact John Harb, Assistant Dean for Scientific Operations at 718-430-3357 or John.Harb@Einstein.yu.edu.

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Private Industry Sponsored Research: Non-Disclosure Agreements (NDAs)

- On occasion, the protocol sponsor may send a "Non-Disclosure Agreement" to the PI to be signed by Einstein in order for the PI to receive the protocol. Such an agreement should be submitted to the Office of Biotechnology for review and approval.

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Private Industry Sponsored Research: Protocol Submission

- Submit to CCI:
  - > CCI Application, protocol, consents, investigator's brochure, etc.
  - > Contract (and final budget).
    - NOTE: The CCI Research Application may be submitted before the contract is received.
  - > CCI forwards the contract to General Counsel and OB for review.

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Private Industry Sponsored Research: Budget

- Negotiate the budget early in the process.
- Remember to include overhead and CCI fee ($2000) before sending the contract to CCI.
- If HHC space, resources, or patients are used, HHC reimbursement must be budgeted accordingly.
  - > PI should contact Barbara Levy to assist in the HHC budget development and negotiation.
  - > HHC overhead expenses must also be budgeted.
- Prepare the Einstein Internal Grant Approval (IGA) form as soon as the budget has been finalized.
- Obtain all institutional signatures and submit the IGA form and budget to CCI.

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Private Industry Sponsored Research: Contract Not Executed by the Sponsor

- When all human subject issues are resolved, CCI sends the PI an approval letter with a proviso stating the study may not be initiated until institutional approval is obtained.
- Approved contracts executed by Einstein prior to execution by the sponsor are tracked by the OB.
- Upon receipt of the fully executed contract from the sponsor, OB sends the PI a memo indicating that the contract has been signed and the research may begin.

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Private Industry Sponsored Research: Contract Executed by the Sponsor (rare)

- The Office of Biotechnology (OB) sends the CCI the approved contract.
- When all human subject issues are resolved, CCI approves the research and sends the approved contract to Grant Accounting (GA) for processing.
- GA returns the contract to the OB for signature.
- OB informs the PI that the contract has been signed.

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Protocol Application & Tracking System (PATS)

- CCI holds 2-3 PATS Trainings for researchers and staff each month.
- The PATS Training schedule and registration information is available at: http://www.einstein.yu.edu/cci/page.aspx?ID=9650
- Contact Jacqueline Smith (718-430-2237 or Jacqueline.Smith@Einstein.yu.edu) if you have any registration questions.

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Useful Contacts: Administrative Offices

- CCI Administrative Office
  - David Wallach, Manager
  - 718-430-2237
  - David.Wallach@Einstein.yu.edu
- Office of Grant Accounting
  - Bob Ness, Associate Director
  - 718-430-3712
  - Robert.Ness@Einstein.yu.edu
- Office of Biotechnology (OB)
  - John Harb, Asst. Dean for Scientific Affairs
  - 718-430-3357
  - John.Harb@Einstein.yu.edu
- Office of Grant Support
  - Charles B. Hathaway, Director
  - 718-430-3642
  - Charles.Hathaway@Einstein.yu.edu
- YU General Counsel
  - John Scarfone, Esq.
  - 718-430-2546
  - scarfone@yu.edu
- Office of the Executive Dean
  - Barbara Levy, Asst. Dean of Academic Affairs
  - 718-430-2211
  - Barbara.Levy@Einstein.yu.edu

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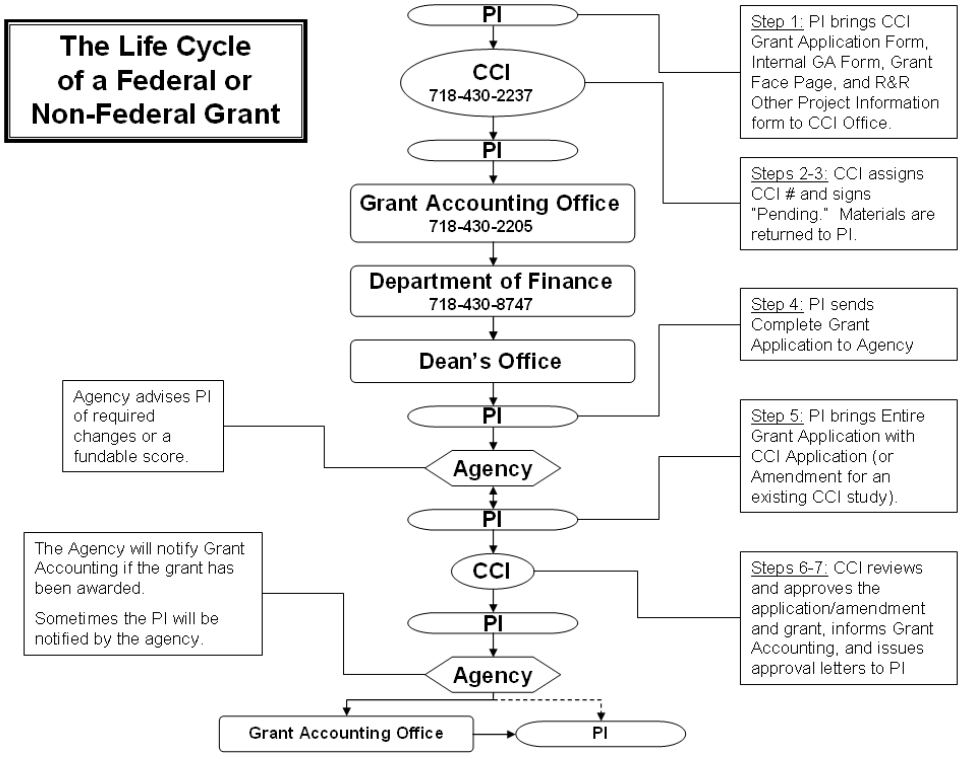
CCI "Just-in-Time" Grant Approval Guide – Internal Packet (non-Cayuse) Grants

Step	Who	Materials	New Protocol	Existing Protocol
1	Researcher submits to CCI	CCI Grant Application Form	✓	✓
		CCI Number of Approved Protocol to which this grant will apply		✓
		Internal Grant Approval Form	✓	✓
		Consortium Agreement (for sub-contracts)	✓	✓
		Grant Application Face Page (NIH: SF 424 and R&R Other Proj. Info)	✓	✓
2	CCI	Signs "Pending" on the Internal Grant Approval Form.		
3	CCI provides to researcher	Instructions for submitting grant to CCI for approval once a fundable score is received.	✓	✓
		CCI Number	✓	
		IGA with "Pending" signature	✓	✓
4	Researcher	Works with Grant Accounting to submit grant application to agency, then waits for "Fundable Score."		
5	Researcher submits to CCI	CCI Application & Consents	✓	
		Amendment & Revised Consents		✓
		Complete (final) grant application	✓	✓
6	CCI	Reviews and approves the application/amendment and grant, then informs Grant Accounting of the approval.		
7	CCI provides to researcher	Application/Amendment/Grant Approval Letter	✓	✓
		Stamped Consents	✓	✓



FOR INTERNAL USE ONLY

SEE INSTRUCTIONS ON PAGE 4

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THIS FORM MUST ACCOMPANY ALL GRANT AND CONTRACT APPLICATIONS

Gt. Pgm # _____ Deadline Due Date _____

Ex: Ro1, T32, K08

Electronic Application: No ☐ Yes ☐

By PI ☐ By AECOM ☐

APPLICATION TO: _____

PROJECT TITLE: _____

APPLICANT NAME: _____ BUILDING AND ROOM # _____ TEL. NO. _____

DEPARTMENT NAME : _____ APPLICANT SIGNATUR _____

A. This Application is for a: ☐ Grant ☐ Contract ☐ Sub-Contract:

Modular Application Yes ☐ No ☐

Federal Sub-Contract Yes ☐ No ☐

This Budget Period: *From:* _____ *To:* _____ *EOPP Yr.:* _____

B. Type of Application

1 ☐	Laboratory Research	9 ☐	Equipment
2 ☐	Clinical Research	10 ☐	Conference
3 ☐	Program Project	11 ☐	Drug Trial / Device
4 ☐	Center	12 ☐	Scholar Award
5 ☐	Training	13 ☐	Sub-contract
6 ☐	Clinical Service	14 ☐	EPH Research
7 ☐	Salary Award	15 ☐	Other (specify) _____
8 ☐	Fellowship		

C. Classification

	Traditional/Hd Cy Terms	Electronic Terms
1 ☐	New	New
* 2 ☐	Non-competing Renewal (Continuation)*	Not yet to be used - eSNAP Alternative
* 3 ☐	Competing Renewal *	Renewal
* 4 ☐	Supplemental Request *	--- Revision (Sup/Chgs)
5 ☐	Revision	Resubmission
6 ☐	Other	<-- Not yet to be used

* Enter current agency and AECOM award numbers:

AECOM Number: 9526-

AGENCY Number: _____

D. Research Protocols Requiring Pre-Award Approvals

1. **Vertebrate Animals** ☐ Yes * ☐ No**

Protocol # _____ Protocol Approval Date _____

Signature for Animal Institute / or attach an AA1 _____

* If Yes, Animal Institute (AI) signature is required on all applications except revisions or non-competing renewals with no changes. For revisions or non-competing renewals with
Use
Rene
requ

** If No
Sign

Always check "Yes" if any human data or specimens will be studied, whether or not the sources of the specimens are alive and/or identified.

STATEMENT NO. 1 -- NO LIVE VERTEBRATE ANIMALS

"Live vertebrate animals will not be involved in this proposal."

Principal Investigator (Signature) _____ Date _____

2. **Human Subjects** ☒ Yes* ☐ No**

CCI # _____

* If Yes and a Non-Competing Renewal, without any Human Subject change, then STATEMENT NO.2 (below) must be signed by PI. CCI signature is not required.
* All others checked "Yes" require CCI signature.
** If No, then STATEMENT NO. 3 (below) must be signed by PI.

Signature for Committee on Clinical Investigations (CCI) _____

STATEMENT NO. 2 - HUMAN SUBJECTS - FOR NON-COMPETING APPLICATIONS ONLY

"There have been no changes in the Human Subject Protocol, the investigators and key personnel, collaborating institutions, or the resources utilized for this project since the last approval or recertification letter (a copy of which is attached) dated _____."

Remember To Attach a CCI Copy

Principal Investigator (Signature) _____ Date _____

STATEMENT NO. 3 -- NO HUMAN SUBJECTS

"No human subjects will be involved in this proposal, including the use of data or organs, tissues, body fluids, DNA, or other materials from Human Subjects."

Principal Investigator (Signature) _____ Date _____

Proposal Summary

Proposal Number **Proposal Status:**

Sponsor Deadline **Submission Method:**

INVESTIGATOR DATA

PROJECT DIRECTOR / PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: * First Name: Middle Name: * Last Name: Suffix:

Position/Title: Organization:

Department: Division:

Street1: Street2:

City: County:

State: Zip Code:

Country: Employee ID:

Phone:

Fax:

Email:

First Budget Period Effort

Calendar Academic Summer

Status of PI: Status Waiver Required? Yes No

Signed Intellectual Property Waiver Attached? Yes No

Signed Conflict of Interest Disclosure Attached? Yes No

Agency Certification Documentation Attached? Yes No

Cost Sharing Authorization Form Attached? Yes No

All attachments should be uploaded to the Document Upload Area

SPONSOR DATA

Agency:

Proposal Type:

Sponsor Mechanism:

Sponsor Type:

Sponsor Name/ID:

SubDivision 1:

SubDivision 2:

PROJECT DATA

Title of Project:

Is This a Subcontract? Yes No

If Yes, who is prime?

Type of Proposal:	Kind of Application:	Type of Project:
(•) Grant ( ) Contract ( ) Fellowship Type of Agency: (•) Federal ( ) Association ( ) State ( ) Foundation ( ) Industry ( ) Other	(•) New ( ) Resubmission ( ) Renewal ( ) Continuation ( ) Revision/supplemental Previous Grant # or Federal Identifier: [ ] Change in grantee institution	( ) Basic research ( ) Equipment (•) Clinical/applied research ( ) Clinical trial ( ) Research training ( ) Service ( ) Instructional research ( ) Other

PROJECT ADMINISTRATION

Who is responsible for this research?

Departmental Identification Number: Primary Secondary

Departmental Name: Primary Secondary

Primary Dept. Contact Info:

Account Classification: Primary Secondary

Other Institutional Code:

NAICS Code:

COMPLIANCE DATA

Animal Subjects	Human Subjects	Does this project involve use of any of the following?
Are animal subjects used? ( ) Yes (•) No Is IACUC review pending? ( ) Yes ( ) No IACUC Protocol # Approval Date:	Are human subjects used? (•) Yes ( ) No Is IRB review pending? (•) Yes ( ) No IRB Protocol # Approval Date:	Radioactive Material(s), Radiation Producing Devices(s), Recombinant DNA, Biohazardous Chemical(s), Class IIIb or IV Lasers, Other certifications of health, safety and/or environmental compliance. ( ) Yes (•) No If Yes, Explain in attachment

BUDGET DATA

Performance Dates	Begin Date	End Date	Cost Sharing Information:
First Budget Period:			Mandatory Committed ( ) Yes (•) No Amount: Source:

Cumulative Budget Period:			Voluntary Committed ○ Yes ◉ No Amount: Source:

Budget Period	Period 1	Period 2	Period 3	Period 4	Period 5	Total
Direct Cost						
Indirect Cost						
Total Cost						

AWARD DATA

Award #: Contract #: Date:

Budget Period	Period 1	Period 2	Period 3	Period 4	Period 5	Total
Direct Cost						
Indirect Cost						
Total Cost						

EXPORT CONTROL

1. Will the project involve participation, collaboration or access to information by foreign nationals, defined as: individuals with foreign citizenship, foreign governments, foreign associations and corporations, or foreign political parties? ○ Yes ◉ No

Note: Foreign nationals granted US citizenship, or permanent residence "green card" or granted status as a "protected individual," e.g., political refugees and political asylum holders are "EXEMPT" from deemed export rule.

2. Will the project involve the shipment of equipment, technology, software, materials data or other information? ○ Yes ◉ No

3. Will the project involve a foreign subcontract or other foreign contractual agreement? ○ Yes ◉ No

If you answered "yes" to any of the above questions, please attach documentation to the Generic Upload Area describing the details of these issues for this proposal.

COMMENTS AND EXPLANATIONS

PLEASE INDICATE ANY SPECIAL INSTRUCTIONS BELOW:

NIH GRANT APPLICATION SAMPLES
"RESEARCH & RELATED Other Project Information"

EXAMPLE #1: Exempt (Category 4) Research

1. * Are Human Subjects Involved? [X] Yes [ ] No

1.a If YES to Human Subjects

Is the IRB review Pending? [X] Yes [ ] No

IRB Approval Date:

Check one

Exemption Number: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6

Human Subject Assurance Number: FWA00000140

EXAMPLE #2: Not Human Subject Research
(Human research that does not meet the federal definition)

1. * Are Human Subjects Involved? [ ] Yes [X] No

1.a If YES to Human Subjects

Is the IRB review Pending? [ ] Yes [ ] No

IRB Approval Date:

Exemption Number: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6

Human Subject Assurance Number:

EXAMPLE #3: Research Requiring Full or Expedited Review
or Not Engaged Research

1. * Are Human Subjects Involved? [X] Yes [ ] No

1.a If YES to Human Subjects

Is the IRB review Pending? [X] Yes [ ] No

IRB Approval Date:

Exemption Number: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6

Human Subject Assurance Number: FWA00000140

Yeshiva University Grant Application Electronic Approval Form

Proposal Summary Part Two

This form must be completed for all applications.

Answer all numbered questions unless instructed otherwise.

Location of Project

Building, room number (if not on a Yeshiva University campus, also provide street address.)

_____

_____

1) Will the research proposed in this application require

Structural Change ☐ No. ☐ Yes.

Additional Space ☐ No. ☐ Yes.

Participation of Other Departments or Institutions

1) Are personnel from other Yeshiva University departments budgeted or listed as Key Personnel on this proposal?

☐ No. ☐ Yes. Other Departments Approval Form is attached to the Cayuse application file under Proposal Summary, Documents.

2) Are personnel from other institutions budgeted or listed as Key Personnel on this proposal?

☐ No. ☐ Yes. Other Institutions Approval Form is attached to the Cayuse application file under Proposal Summary, Documents.

****

Compliance Data (Part Two)

Human Subjects

1. Does the research proposed in this application involve the use of human subjects (INCLUDING use of de-identified data or specimens of human origin)?

☐ No. (Review by Committee on Clinical Investigations is NOT required. Do not answer Question 2.)

☐ Yes. (Review by Committee on Clinical Investigations is required. Continue with Question 2.) CCI Grant Application Form is attached to the Cayuse application file under Proposal Summary, Documents.

2. The Federal (NIH) definition of human subjects excludes projects in which ALL of the following are true:

A) There is no direct intervention with the human subjects;
B) The human data/specimens are not collected specifically for the currently proposed research project;
C) The human data/specimens received by the investigator do not contain a code derived from individual personal information (e.g. name, medical record #, date of birth, etc.)

☐ A, B, and C are all true. (Mark "No" to human subjects on the NIH application. However, institutional policy requires that the Committee on Clinical Investigations review this application. And for NIH applications, justification for your claim that no human subjects are involved should be attached in line 8 of the PHS 398 Research Plan.)
[Note: Checking "No" to human subjects on the application will result in the Cayuse-generated Proposal Summary also indicating NO involvement of human subjects. This inconsistency with your answer Yes to Question 2 above is unfortunate but must be tolerated.

☐ A, B, and C are not all true. (Mark "Yes" to human subjects on the NIH application. CCI review is required.)

CCI Use Only: _____

Vertebrate Animals

1) Does the research proposed in this application involve the use of vertebrate animals?

☐ No. (Review by Animal Institute is NOT required. Do not answer Question 2.)

☐ Yes. (Review by Animal Institute is required. Continue with Question 2.)

2. A protocol for the research proposed in this application (check one):

☐ has been approved and is on file in the Animal Institute.

☐ has been submitted to the Animal Institute.

☐ will be submitted to the Animal Institute.

Note: For NIH applications the "Vertebrate Animals" attachment (Item 12) to the Research Plan must be completed and attached to the application package.

Hazards in Research

1) Does the research proposed in this application involve the use of 1) infectious agents known to cause or suspected of causing disease, 2) hazardous chemicals known to cause or suspected of causing illness or disease including cancer, or 3) certain recombinant products?

☐ No. (Review by Environmental Health and Safety is NOT required. Do not answer Question 2.)

☐ Yes. (Review by Environmental Health and Safety is required. Continue with Question 2.)

2. Which of the following hazardous materials are to be used (specify below):

a) Infectious Agents	☐ Yes	☐ No
b) Bloodborne Pathogens	☐ Yes	☐ No
c) Recombinant DNA	☐ Yes	☐ No
d) Hazardous Chemicals	☐ Yes	☐ No
e) Carcinogens	☐ Yes	☐ No
f) Radionuclides	☐ Yes	☐ No
g) Other (specify) _____	☐ Yes	☐ No

Note:
1) An up-to-date Environmental Health and Safety Evaluation Form (signed in current calendar year) must be on file in EH&S or attached to the Cayuse application file under Proposal Summary, Documents.

2) If "Yes" is checked for a), b), or c) above, an up-to-date Document of Registration (signed in last 3 years) must be on file in EH&S or attached to the Cayuse application file under Proposal Summary, Documents.

****

Federal Monitoring Requirements

Patent Policy

1) Has a Patent Policy Acceptance Agreement been signed and sent to the Office of Biotechnology for all Yeshiva University-paid individuals (faculty, postdocs, students, visiting scientists, technicians, and other research staff) who are budgeted or listed as key personnel on this application?

☐ Yes. ☐ No. All those who have not signed the Patent Policy Acceptance Agreement are listed below and will submit a signed agreement.

_____ _____

_____ _____

Conflict of Interest

1) Does any aspect of this proposal raise issues of conflict of interest as defined by the Conflict of Interest Policy for Faculty (http://www.aecom.yu.edu/home/policies2/conflict_of_interest.htm)?

☐ No. ☐ Yes. All disclosure provisions of the conflict of interest policy are being followed.

Independent Contractors

1) Are consultant costs budgeted in this application?

☐ No. ☐ Yes. Independent Contractor Questionnaire (GA Form 101) is attached to the Cayuse application file under Proposal Summary, Documents.).

Clerical and Administrative Salary and Office Supplies

1) Is this an application to a DHHS agency requesting clerical/administrative salaries or office supplies?

☐ No.

☐ Yes. Clerical/Administrative Form (GA Form 105B) and/or Office Supplies Form (GA Form 105C) are attached to the Cayuse application file under Proposal Summary, Documents.).

Albert Einstein College of Medicine of Yeshiva University
Committee on Clinical Investigations
CCI Grant Application Form

FOR CCI USE ONLY:
CCI # Assigned:
200__ – __ __ __ – 000
Transaction Type:
☐ PATS ☐ Paper

Complete and submit this form with the Internal Grant Accounting Form and the Face Sheet of the Grant Application to the CCI.

1. Investigator Name*: _____
2. For a new grant without an approved protocol, indicate the type of application will you need.
   NOTE: Check only one (1) box. Choose carefully – application types cannot be changed after they are assigned. If you are uncertain, call the CCI at 718-430-2237.
   - ☐ **Exempt Application:** See the definition of Exempt Research at http://www.einstein.yu.edu/cci/page.aspx?ID=9780
   - ☐ **Chart Review/Database Study Application:** Study Examples: Medical Records review, Hospital Databases, Public Database, Data Analysis, etc.
   - ☐ **Behavioral/Observational Study Application:** Study Examples: School based research, or research using Focus Groups or questionnaires, etc.
   - ☐ **Specimen Study Application:** No direct research intervention by PI. Study Examples: research on leftover specimens, identifiable previously collected specimens, prospective specimens, etc.
   - ☐ **Clinical Research Study Application:** Direct research intervention by PI. Study Examples: blood drawing, MRI's, radioisotopes, drugs, or devices, etc.
3. For a new grant on an approved protocol, provide the CCI #: _____
4. If the Grantor is the NIH, specify the institute(s): _____
5. Name of person completing this form: _____ Date: _____
6. All researchers who do not currently have any approved protocols must complete the "PATS Access Request Form," below. The PI and/or designated staff must register for PATS training. See http://www.einstein.yu.edu/cci/page.aspx?ID=9650 for more information.

PATS Access Request Form

Last Name*: _____ First Name*: _____ M.I.: ____
Title*: _____
Department*: _____

Phone*: _____ Extension: _____
Fax*: _____ Email*: _____

Address 1*: _____
Address 2: _____
City*: _____ State*: _____ Zip*: _____

Payroll*: _____ YU School*: _____
Degree(s)*: _____ Academic Rank*: _____

Training: _____
See **http://www.einstein.yu.edu/cci/page.aspx?ID=9650** for the schedule of training.

***Required**	CCI Use Only: ☒ New Researcher ☒ PI Username: _____

What to Do After You Get a Fundable Score – PATS Transactions

For a grant on a New Protocol:

1. If application type is wrong, alert the CCI immediately.
2. Access the PATS application using the Application Type and CCI # listed on page 1.
3. Complete the application. NOTE: If there are multiple pending grants assigned to this CCI #, delete those that have not (yet) received fundable scores from your PATS application.
4. Submit the following items to the CCI:
   a. CCI Research Application. (See http://www.einstein.yu.edu/cci/page.aspx?ID=9672 for guidelines and instructions.)
   b. One of the following:
      - 3 complete copies of the grant when Full Review is required **or**
      - 1 complete copy of the grant when Expedited or Exempt Review is permitted.

For a grant on an Existing Protocol:

1. Create an amendment to the approved protocol in PATS, adding the new "External Source" and modifying the Informed Consent Documents to include the sponsor.
2. Submit the following items to the CCI:
   a. One of the following:
      - 3 complete copies of the grant when the original protocol required Full Review **or**
      - 1 complete copy of the grant when the original protocol received Expedited or Exempt Review.
   b. A bulleted summary of previously approved amendments.
   c. A copy of the current CCI approved informed consent document(s), when applicable.
   d. One of the following:
      - When the grant is unchanged from the approved protocol, add the grant to the CCI approved protocol in PATS and include the statement, "There have been no changes in the human subject protocol, the investigators and key personnel, collaborating institutions or the resources utilized for this project" in the amendment **or**
      - When the grant contains an amendment, indicate the changes to the CCI approved protocol and/or consent in the PATS amendment.

What to Do After You Get a Fundable Score – Paper Transactions

For a grant on a New Protocol:

1. If application type is wrong, alert the CCI immediately.
2. Download and complete a CCI Research Application from http://www.einstein.yu.edu/cci/page.aspx?ID=9676.
3. Make sure to include the CCI # listed on page 1.
4. Submit the following items to the CCI:
   a. CCI Research Application. (See http://www.einstein.yu.edu/cci/page.aspx?ID=9672 for guidelines and instructions.)
   b. One of the following:
      - 3 complete copies of the grant when Full Review is required **or**
      - 1 complete copy of the grant when Expedited or Exempt Review is permitted.

For a grant on an Existing Protocol:

1. Make sure to include the CCI # listed on page 1.
2. Modify the Informed Consent Documents to include the sponsor, when applicable.
3. Submit the following items to the CCI:
   a. One of the following:
      - 3 complete copies of the grant when the original protocol required Full Review **or**
      - 1 complete copy of the grant when the original protocol received Expedited or Exempt Review.
   b. A bulleted summary of previously approved amendments.
   c. A copy of the current CCI approved informed consent document(s), when applicable.
   d. One of the following:
      - When the grant is unchanged from the approved protocol, add the grant to the CCI approved protocol using the CCI Amendment form at http://www.einstein.yu.edu/cci/page.aspx?ID=9676#other and include the statement, "There have been no changes in the human subject protocol, the investigators and key personnel, collaborating institutions or the resources utilized for this project" in the amendment **or**
      - When the grant contains an amendment, indicate the changes to the CCI approved protocol and/or consent using the CCI Amendment form, available at: http://www.einstein.yu.edu/cci/page.aspx?ID=9676

Once approved, the CCI sends the investigator written approval for the grant and the protocol/amendment, when applicable. The CCI sends a copy of the letter to the Grant Accounting Office. The investigator is responsible for sending the CCI approval letter to the agency.

Routing & Approval

Routing Chain

Begin

- [x] Zimmerman, Molly () / Albert Einstein College of Medicine of Yeshiva University
- [x] Mehler, Mark F. () / Albert Einstein College of Medicine of Yeshiva University
- [x] * OFFICE OF GRANT SUPPORT, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University
- [x] Stockhausen, Angela () / Albert Einstein College of Medicine of Yeshiva University
- [x] Rohan, Thomas () / Albert Einstein College of Medicine of Yeshiva University
- [x] * DEAN'S OFFICE, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University
- [x] * CCI, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University
- [x] Cioffi, Ana M. () / Albert Einstein College of Medicine of Yeshiva University
- [ ] * GRANT ACCOUNTING, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University
- [ ] * FINANCE, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University

End

An AOR is on the routing chain, but has not yet approved this proposal. The proposal will not be submittable until an AOR has approved the proposal.

Routing History

username	person	type	date/time	comments
Cioffi	Cioffi, Ana M. () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-15 13:32	
DWallach	* CCI, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-15 13:04	
Pinzon	* DEAN'S OFFICE, [Routing Contact] () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-15 11:52	
Rohan	Rohan, Thomas () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-15 06:20	
Stockhausen	Stockhausen, Angela () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-15 05:05	
Stockhausen		Modify	2009-09-14 12:22	
hathaway	Hathaway, Charlie () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-14 12:05	
Cioffi	Cioffi, Ana M. () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-14 09:01	
Cioffi	Cioffi, Ana M. () / Albert Einstein College of Medicine of Yeshiva University	Approve	2009-09-14 09:01	
Cioffi		Modify	2009-09-14 08:43	
Cioffi		Modify	2009-09-09 05:57	

Albert Einstein College of Medicine of Yeshiva University
Grant Accounting Department

Webpage: Pre-award Guide

Description: **Just In Time**

Guide / Process: Summary and Process is provided below. Documents are marshaled, as per the JIT request, and uploaded onto the Commons. PI, Chairperson, and Central Administration sign a standard letter that clearly allows Grant Accounting to submit the notification.

Link to Document(s): Example Letter

Summary

In order to electronically submit JIT response, two things must be present:

(1) Documents and research clarifications (if any) are marshaled by the PI or Department Administration, as per the JIT request, and uploaded onto the Commons.

(2) PI, Chairperson, and Central Administration sign a standard letter that clearly allows Grant Accounting to submit the notification.

An alternative method of submission may be required by the NIH requestor. This may be either fax or standard hard copy mail. The cover letter should have a specific and full inside addressee, who shall be receiving the letter and attachments. Steps (1) and (2) (above) are completed, though the standard electronic letter can be replaced by a more individualized letter. (The "electronic cover letter", if prepared as indicated can also be used for fax or mail submission.)

Keep-In-Mind

(1) The cover letter has to have an addressee. It must be addressed to either NIH personnel, agency official identified in their request, or program official on the Grants NOGA. This will allow you to fax or mail the "electronic cover letter" should this be necessary. "To whom it may concern' is "No Good". Addressing a letter to AECOM personnel is "No Good".
(2) The cover letter should allow for easy reference of both AECOM and NIH. The reference section must identify the PI, the agency number and the AECOM 9526-XXX number if one exists, or the title of the proposal. Grant Accounting cannot

identify the source proposal without the 9526-XXX number (for grants) or the title (for pending proposals). I have sent several previous email communications regarding this requirement. The frequency of poorly referenced letters continues to grow. When departments with administrative staff submit such as document, it too will be returned for correction.

(3) Three signatures are required: PI, Chairperson, and either Dr. Spiegel or Mr. Shivers; whichever appropriate.

(4) The referenced documents in the letter should be what you have uploaded and otherwise provided on the eRA Commons. This will allow the SO to match the uploaded letter to the eRA Commons uploaded document.

Process

(1) PI or Department Administrator receives the JIT request (see above).
(2) Documents and clarification responses are marshaled for attachment to a cover letter.
(3) A JIT cover letter is prepared, signed by the PI and Department Chairperson and sent to Grant Accounting.
(4) Grant Accounting reviews and submits the letter for institution approval with a summary memo attached.
(5) Institution approval is obtained and the folder is sent back to Grant Accounting.
(6) The JIT documents are matched to the eRA Commons JIT file.
(7) When matched and complete, it is electronically submitted by Grant Accounting personnel, who is an eRA Commons Signing Official (SO) and confirmation is obtained. (At times, the SO is required to enter and save the IACUC date or other information.)
(8) NIH sends an email notification to the PI and the SO. The SO forwards the email to the Department Administrator and requests that the department pick up their folder (just outside Belfer 1108C).
(9) Department picks up the folder which has a copy of the original letter, attached documentation, and the eRA Commons confirmation.

Albert Einstein College of Medicine
Of Yeshiva University
1300 Morris Park Avenue
Bronx, New York 10461

February 21, 2007

DRAFT TO USE FOR FOLLOW UP NIH JUST-IN-TIME REQUEST. All documents are to be uploaded by PI or department personnel. Grant Accounting checks Commons JIT file for completeness and then submits.

Ms. Mollie McCree
Grants Management Officer
National Institute of Allergy and Infectious Diseases

Re: 5R01 AIXXXXXX-27
Enter here - either 9526-XXX if a grant or
the title if a pending proposal
Dr. T. Danika

Dear Ms. McCree:

In response to your request on February 17, 2007, in reference to the above, I have uploaded the following on the eRA Commons:

- IRB Approval Letter
- Other Support of Key Personnel
- Confirmation that all key personnel who are involved with human subjects, have satisfied the human subject education requirements.

This letter authorizes an electronic notification to the NIH with reference to the above via the eRA Commons as requested by NIH.

This document when signed, will allow the Grant Accounting signing official (SO) to electronically submit the above via eRA Commons.

Sincerely,

Thomas Danika
Principal Investigator

Department Chairperson Signature,
Name and Title

Allen M. Spiegel, M.D.
Dean