



Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

**Institutional
Review Board**

Human Research Seminar Series

Grant Submission & Private Industry Sponsored Research: Guidelines/Requirements

Thursday, November 4, 2010

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Einstein Institutional Review Board (IRB)

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Overview

- What is the Office of Grant Accounting (GA)?
- What is the Einstein Institutional Review Board (IRB)?
- GA and Einstein IRB grant processes.



The Role of the Office of Grant Accounting

- Grant Accounting...
 - > Provides management oversight for the pre-award and post-award process.
 - > Checks transactions and activity for completeness.
 - > Checks for proper authorization and approval as required.



What is the Institutional Review Board (IRB)?

- The Einstein IRB is the Institutional Review Board 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 Einstein IRB is also the IRB for all YU schools, Montefiore Medical Center, North Bronx Hospital Network (NBHN) consisting of Jacobi Medical Center (JMC) and the North Central Bronx Hospital (NCB).



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
- > Drugs
- > Devices
- > Supplies or Equipment



What's This I Hear About a Merger of the Einstein and Montefiore IRBs?

- Until recently, Einstein and Montefiore each had their own IRB.
 - > Einstein's IRB was known as the Committee on Clinical Investigations (CCI).
 - > Montefiore's IRB was called the MMC IRB.
- Late last year Einstein and Montefiore signed an affiliation agreement to merge their research infrastructures.
- Going forward both will be known as the Einstein IRB.
 - > The CCI will be known as the East Campus IRB.
 - > The MMC IRB will be known as the West Campus IRB.

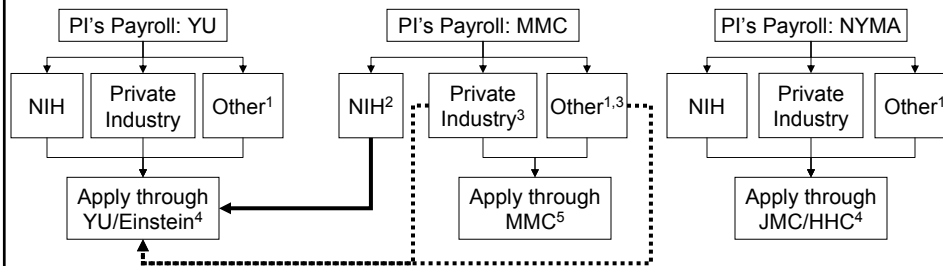


What Does the Merger Mean to Me?

- At the moment, not much has changed.
- The most noticeable changes will occur after new IRB software is implemented – expected sometime in 2011. Changes include:
 - > Electronic signatures
 - > Two IRBs available for review
 - > Mac (and PC) compatibility
- Until then, the submission rules remain as follows:
 - > IRB (East vs. West) is determined per the rules on the following slide.
 - > East Campus IRB Submissions: Through PATS
 - > West Campus IRB Submissions: MS-Word forms



Which IRB Should Review is Tied to... Which Institution Should be the Grantee?



1. The term "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 IRB (East Campus)
5. Project to be reviewed by Einstein IRB (West Campus)



What About New Grants on MMC IRB Approved Studies?

- Submit through Cayuse, route to the Einstein IRB.
- Instead of a CCI #, specify the MMC IRB #.
- Once a fundable score or JIT request is received, submit the grant to the East Campus IRB.
- The East Campus IRB will verify that the grant matches the MMC IRB approved study and issue grant approval.



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

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

> Complete the NBHN Research Form:

http://www.einstein.yu.edu/uploadedFiles/CCI/NBHN_Research_Form.doc



Categories of Supporting Agencies

- University Funding (e.g. start-up funds, slush funds, etc.)
- Federal Agency Grants (e.g., NIH, NCI, etc.)
 - > Research Grant or Fellowship
 - > Umbrella Grant: Program Project; Center Grant
 - > Training Grants, e.g., T32
- 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., Pfizer, Roche, etc.)



Four Processes for Four Types of Support

- Administrative – Applies to University Funds.
- 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 (CTAs) – Applies to research governed by a contract with a company.



Administrative Approval Process for University Funds

- Since there is no grant to review, the Einstein IRB does not track University Funds. (However, any research done needs Einstein IRB approval, regardless of funding.)
- Researchers with start-up funds or other slush funds that will be used for human research studies will need to link a particular CCI # to the slush fund.
 - > If they want to use the funds for additional human subjects projects (with different CCI #s), the other projects should be noted as sub-project.
- Documentation of Einstein IRB approval of the particular project(s) needs to be provided to Grant Accounting office.



“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 IRB) and the PI’s departmental administrative personnel to provide the required documentation.
- Just-In-Time efforts have expanded while the timeline has shrunk.



“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 Einstein IRB application/ amendment and grant for review after receipt of a fundable score (or JIT request).
 - > Exception: If the research will be carried out without funding, the Einstein IRB application may be submitted prior to receipt of a fundable score. However, once a fundable score is received, the grant must be submitted to the Einstein IRB as an amendment.



The East Campus IRB’s Dual Involvement in the Grants Process

- Pre-Submission
 - > The East Campus IRB 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), the East Campus IRB reviews and approves the grant.



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 6744 (AKA the “Internal packet”).
 - > New System: Cayuse424 (AKA Cayuse)
- In either case any research proposals that will involve Human Subjects are flagged – funds will not be released with Einstein IRB approval.



Grant Accounting Systems: Old System

- Internal Grant Approval Form 6744 (AKA the “Internal packet”)
 - > Paper-based system
 - > The Internal packet provides internal control assurance that the proposal to be submitted satisfies Einstein requirements.

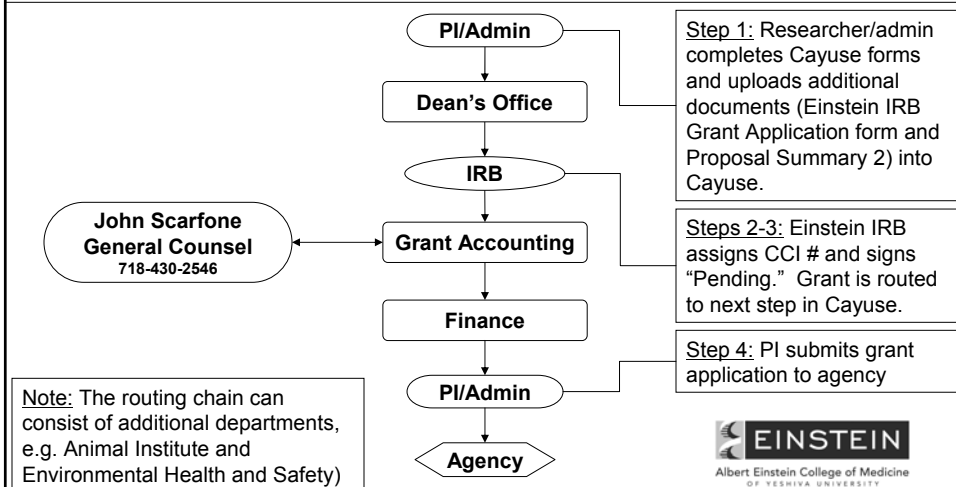


Grant Accounting Systems: New System

- Cayuse424 (AKA Cayuse)
 - > Electronic paperless system for administrative routing and approval.
 - > Much of the completeness check documented in the Internal packet is initiated in the Cayuse routing and up front checking by the Office of Grant Support.
 - > Cayuse assists in the electronic application submission process.
 - > Subsequent years of an ongoing project initiated in Cayuse are now processed using Cayuse (generally).



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



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

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



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

- Available on the Einstein IRB 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 Einstein IRB number to which the new grant applies.
 - > If the number belongs to a different PI than the applicant, provide an explanation to avoid delays in processing.



PATS Application Types

- **Exempt Application:** See next slide and 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.



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 existing or 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 research project. "We" cannot be the primary grantee. Specimens may be coded, but an agreement not to release the key is required.



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

- Available on OGS's website at:
<http://www.einstein.yu.edu/ogs/Gg/ProposalSummary2a.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, we include any use of data/specimens of human origin.
 - > Exception: Non-hESC, commercially available cell lines do not require Einstein IRB review.



Just-in-Time – Steps 2-3: Pre-Submission: Einstein IRB's Process

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



Education Requirement

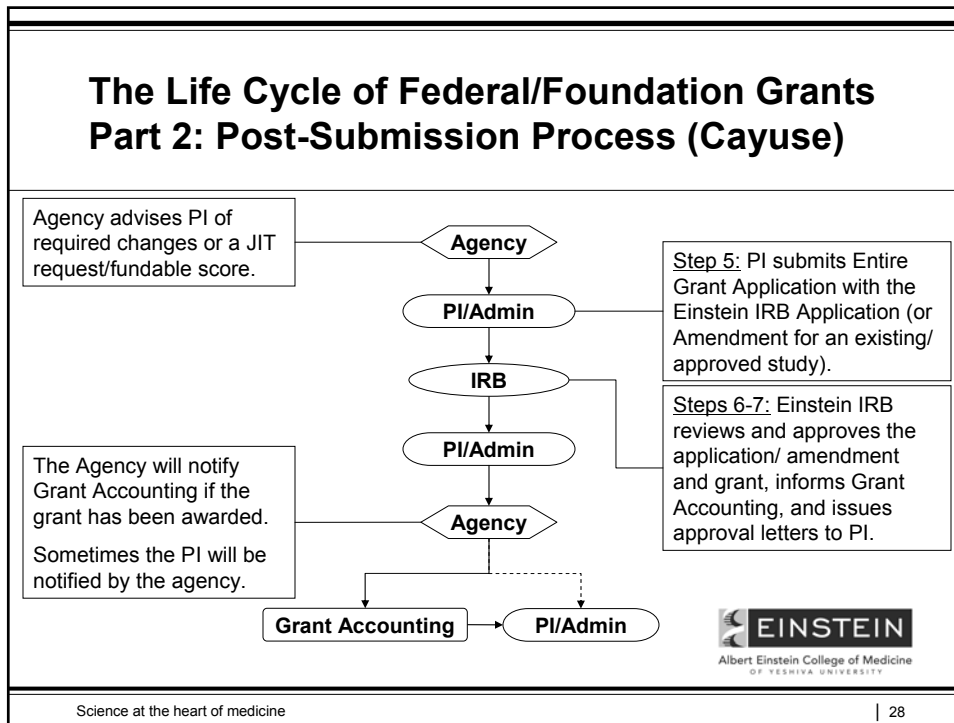
- The NIH requires that the institution have mandatory human subjects education.
- Completion of the CITI course satisfies this requirement for 5 years. Details and registration information is available at:
<http://www.einstein.yu.edu/cci/page.aspx?id=9746>
- The CITI refresher course is required every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



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.






Just-in-Time – Step 5: Researcher Submits Grant to the Einstein IRB for Approval

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

- Complete (and final) grant application, plus
- For a grant on a new protocol:
 - > Einstein IRB application and consents
 - NOTE: You must use the CCI # assigned by the Einstein IRB 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:
 - > Einstein IRB 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 the Einstein IRB 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.



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

- When the research in the grant is identical to the Einstein IRB 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 Einstein IRB approved protocol, the changes must be reported in the amendment.



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

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



Grant Accounting: Post-Award

- The Post-Award process utilizes the accounting and other transaction systems to manage financial and other activity.
 - > Award is received.
 - > Application is matched to the award.
 - > Einstein IRB approval and other pending documentation are obtained.
 - You won't get a grant # until you receive Einstein IRB approval.
 - Without a grant # you can't get started in your staffing, ordering, or expenditure efforts.
 - > Grant account and budget is established.



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

- Grant Consisting of Multiple Projects
- The entire grant application requires Einstein IRB review and approval.
- Processed as all other grants.
- Referred to as an “umbrella” grant, is assigned a CCI # 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.”



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 # which is linked back to the administrative file.
- For purposes of the Einstein IRB Grant Application Form, the administrative file is to be categorized as ‘Chart Review,’ so the least amount of data entry is required.
 - > Contact the Einstein IRB 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 either “Clinical Research Study Application” or “Behavioral/Observational study.”



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.
- Administrator sends a memo listing all trainers/mentors to the Einstein IRB (East and West Campus offices, as applicable).
- The Einstein IRB sends a report of active research protocols for each trainer/mentor, including the approval period for each protocol to the administrator.
- The department includes the information, in table form, within the grant, and includes the current Einstein IRB recertification/expiration dates of each protocol.



T32 Training Grants: Process 2

To obtain Einstein IRB sign-off, the department must submit:

- Internal Grant Approval Form – the Einstein IRB will sign and date the approval. A CCI # 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 Federalwide Assurance Number, FWA00000140.
- Report listing the names of trainers, research protocols, and Einstein IRB approval/expiration date.



Common Errors: Pre-Submission

- Leaving out the Einstein IRB Grant Application form
- Incomplete Einstein IRB Grant Application form:
 - > Missing CCI # (for grants on existing studies)
 - > Missing NIH institute (e.g. NIA, NCI, etc.)
 - > Missing Application Type
- Incomplete Proposal Summary Two:
 - > Question 1 (Human Subjects?) marked no, but grant routed to Einstein IRB
 - > Question 2 (Are A-C true?) left blank
 - > Question 2 (Are A-C true?) contradicts human subjects answer in the grant.



Common Errors: Post-Submission

- Waiting too long to apply to the Einstein IRB for approval.
- Not including:
 - > paperwork for sub-contracts – we need the Grant Accounting paperwork (Internal Packet or Cayuse) at least the portion of the grant that relates to our researchers' work.
 - > a full copy of the complete grant.
 - > for research involving NBHN (JMC/NCB): The HHC-641 and the NBHN Research Form (for YU payroll PIs).



Common Errors: Post-Submission (cont'd)

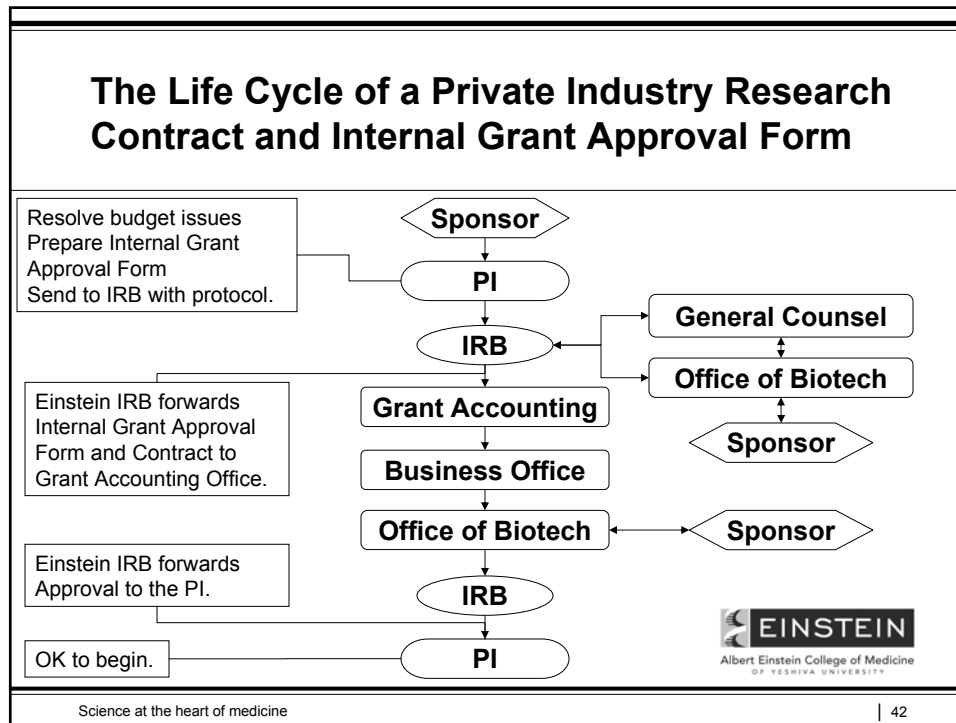
- **Grants on New Studies**
(Submitted via PATS Application)
 - > Starting a new PATS application (resulting in a change of CCI #) instead of using the one assigned at Pending sign-off.
 - > Not using the grant title on the PATS application and/or consents.
- **Grants on Approved Studies**
(Submitted via Amendment)
 - > Not adding the funding source in PATS.
 - > Discrepancies in the grant title.
 - > Adding Supplies even though they are not receiving.



Private Industry Research

(The preceding portion of the presentation applied to grants. The upcoming portion applies to CTAs from private industry. The processes have some elements in common, but also have significant differences!)





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 Ece Auffarth, Contract and Licensing Administrator, at 718-430-3357 or ece.auffarth@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.



Private Industry Sponsored Research: Protocol Submission

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



Private Industry Sponsored Research: Budget

- Negotiate the budget early in the process.
 - > Include overhead and the IRB fee (\$2000 now, increasing on 1/1/2011 to \$3000).
- 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, then submit the IGA form and budget to the Einstein IRB.



Private Industry Sponsored Research: Contract Execution

- Approved contracts are generally executed by Einstein prior to execution by the sponsor.
- Upon receipt of the fully executed contract from the sponsor, the Office of Biotechnology notifies the Einstein IRB.
- The Einstein IRB sends the approval letter and the Office of Biotechnology's authorization to commence the study to the PI.
- The research may begin.



Protocol Application & Tracking System (PATS)

- The Einstein IRB 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.



Useful Contacts: Administrative Offices

- Einstein IRB (East Campus) 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)
 - > Ece Auffarth, Contract and Licensing Administrator
 - > 718-430-3357
 - > ece.auffarth@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 for Academic Affairs
 - > 718-430-2211
 - > barbara.levy@einstein.yu.edu



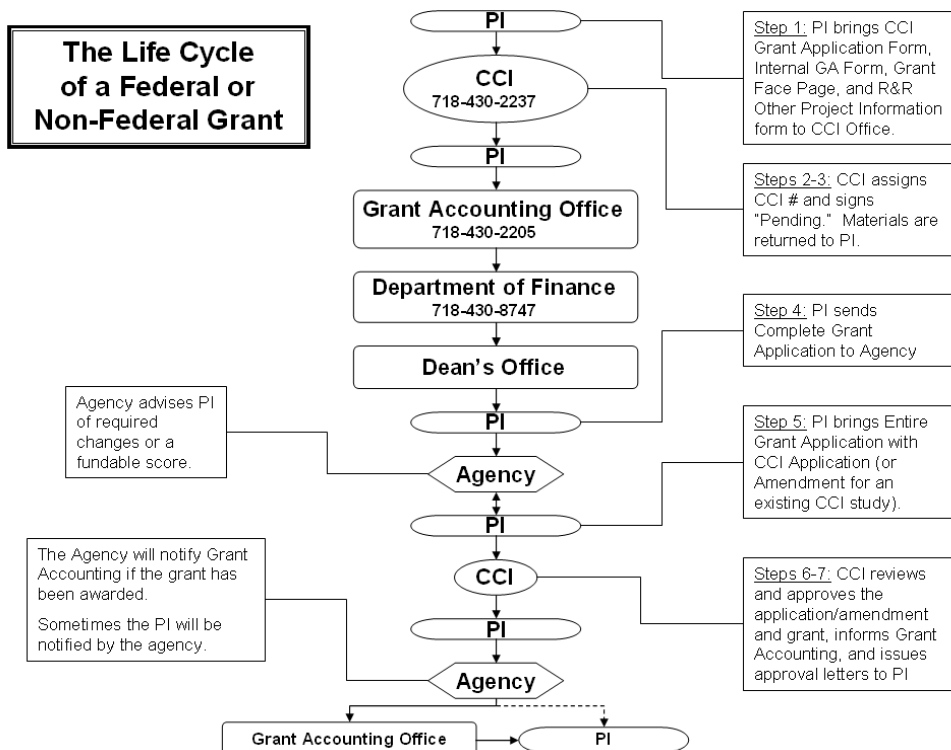
Einstein IRB Contact Information

- East Campus IRB (CCI)
 - > Einstein IRB
 - Belfer Building, Room 1002
 - 1300 Morris Park Avenue
 - Bronx, NY 10461
- Phone: 718-430-2237
- Fax: 718-430-8817
- Website:
<http://www.einstein.yu.edu/cci>
 - > Including: Policies and Procedures, Submission Guidelines, and Educational Materials
- West Campus IRB (MMC IRB)
 - > 3308 Rochambeau Ave
 - Bronx, NY 10467
 - Tel: 718-798-0406
- Phone: 718-798-0406
- Fax: 718-798-5687
- Website:
<http://www.montefiore.org/prof/research/IRB/>



Grant Submission & Private Industry Sponsored Research: Guidelines and Requirements Page 27 of 40
Einstein IRB “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 <u>and</u> 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	✓	✓



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INTERNAL GRANT APPLICATION APPROVAL FORM
To Be Completed for Non-Cayuse Routed Proposals

Please complete page 1. Attach a detailed budget for year 1 only. A PHS398 budget or SF424 budget or the Budget page (included here) is acceptable. PI's and Chairpersons sign where indicated. Submit page 1 and a detailed budget. Attach page 2 with "sign-offs", if applicable. You need not submit the sheets named "Budget", "Instructions". These sheets are here for your reference and understanding.

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.

Department Name <input type="text"/>	Contact Name <input type="text"/>
PI Name <input type="text"/>	Contact Number <input type="text"/>
Date Submitted <input type="text"/>	Date Due <input type="text"/>

CAYUSE Name <input type="text"/>	Electronic Submission By:
Project Title <input type="text"/>	Principal Investigator <input type="checkbox"/>
Location of Project <input type="text"/>	Einstein/SO <input type="checkbox"/>

Name of Grantor

Proposal Dates: From To **End of project Period**

Please check one box in each of the four categories. Note that they are the same as in CAYUSE. PLEASE CHECK OFF BOTH (best as Possible)

Type of Proposal <u>Check One Box</u>	Type of Agency <u>Check One Box</u>	Kind of Application <u>Check One Box</u>	Type of Project <u>Check One Box</u>	<-----Old Type/Meld into? <u>Check One Box</u>
<input type="checkbox"/> Grant	<input type="checkbox"/> Federal	1 <input type="checkbox"/> New	1 <input type="checkbox"/> Lab Research (Basic)	<input type="checkbox"/> 1 Lab Research
<input type="checkbox"/> Contract	<input type="checkbox"/> State	2 <input type="checkbox"/> Resubmission (Revision)	9 <input type="checkbox"/> Capital (Equip/Construction)	<input type="checkbox"/> 2 Clinical Research
<input type="checkbox"/> Fellowship	<input type="checkbox"/> Industry	3 <input type="checkbox"/> Renewal (Competing)	3 <input type="checkbox"/> Applied Research	<input type="checkbox"/> 3 Program Project
<input type="checkbox"/> Sub-Contract (Prev "Type of Project" #13)	<input type="checkbox"/> Association	4 <input type="checkbox"/> Continuation	6 <input type="checkbox"/> Clinical Study/Trial	<input type="checkbox"/> 4 Center
	<input type="checkbox"/> Foundation	5 <input type="checkbox"/> Revision/Supplement	5 <input type="checkbox"/> Research Training	<input type="checkbox"/> 5 Training
	<input type="checkbox"/> Other (must explain): <input type="text"/>	6 <input type="checkbox"/> Change of Gtee Institution	2 <input type="checkbox"/> Research Service	<input type="checkbox"/> 6 Clinical Service
		<input type="checkbox"/> Other (must explain): <input type="text"/>	12 <input type="checkbox"/> Instructional Research	<input type="checkbox"/> 7 Salary Award
			15 <input type="checkbox"/> Other (must explain): <input type="text"/>	<input type="checkbox"/> 8 Fellowship
				<input type="checkbox"/> 9 Equipment
				<input type="checkbox"/> 10 Conference
				<input type="checkbox"/> 11 Drug Trial / Device
				<input type="checkbox"/> 12 Scholar Award
				<input type="checkbox"/> 13 Sub-Contract (Type)
				<input type="checkbox"/> 14 Ephr
				<input type="checkbox"/> 15 Other (must explain): <input type="text"/>

Research Protocols, Institution Disclosures, Federal Required Disclosures:

Yes Please check box only if "Yes" and attach page 2 of this form with appropriate "sign-off" for the checked box. Leave the box blank if your response is "No". If you do not check any box, then Page 2 is not required.

- 1 **Animals** :Live Vertebrate Animals are involved in this Project. Animal Institute sign-off on Page 2, Item 1
- 2 **Human Subjects** will be involved in this Project. CCI sign-off on Page 2, Item 2.
- 3 **Hazards in Research:** Hazardous agents known to cause or suspected of causing illness or disease (including cancer or hazardous recombinant DNA projects) will be involved with this Project. Safety sign-off on Page 2, Item 3
- 4 **Other Department and/or Other Institutions** - Please list any that will be involved with this project and provide the department's or institution's (whichever applicable) "sign-off" to their role in this Project on Page 2, Item 4.
- 5 **Structural Change and/or Additional Space Required:** For all but Continuations, please Check Box if this applies to the Project and obtain Executive Dean "sign-off" on Page 2, Item 5.

Federal Requirements Necessary for this Project: Check appropriate box if there are exceptions and attach page 2 of this form and/or a copy of the required document (whichever is appropriate)

- 6 Not all budgeted personnel have submitted a Patent Policy Agreement to the Office of Bio-Technology. Complete Page 2, Item 6.
- 7 There are no Issues related to Conflict of Interest except for those that have been disclosed as per Conflict of Interest Policy. Sign Page 2, Item 7, indicating acknowledgement.
- 8 Independent Contractors and/or Consultants are listed in the budget. If checked, then follow Page 2, Item 8 directive.
- 9 Clerical and Administrative Salary and/or Office Supplies are adequately justified, if involved in the project. Continuations or Modular applications have attached GA FORM 105B or C, whichever is appropriate.

PRINCIPAL INVESTIGATOR / PROGRAM DIRECTOR CERTIFICATION (and Central Administration Routing)

Do Not Complete (Below) -- For Grant Accounting Use Only			
<input type="text"/>	<input type="text"/>	<input type="text"/>	Salaries & Fringe
Principal Investigator signature	Gt Acctng Reviewer	Date	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	O.T.P.S.
Chairperson or Designee	Finance Approver	Date	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	Total Direct Cost (A)
Other: Biotech, Clinical Dean (if applicable)	Dean's Office	Date	<input type="text"/>
	(YU if applicable)		MTDC Base
			<input type="text"/>
			F&A/Indirect (B) 66.0%
			<input type="text"/>
			Total Cost Yr 1 (A)+(B)
			<input type="text"/>
			Total Cost All Years
			<input type="text"/>

GRANT APPLICATION APPROVAL FORM
Additional Review and Approval Requirements
To Be Completed for Non-Cayuse Routed Proposals

SPECIFIC INSTRUCTIONS: if you have checked off any item on Page 1, then complete the same numbered item (below), obtain signature(s) where appropriate, and attach this Page 3 to Page 1.

Research Protocols Requiring Pre-Award Approvals

1. Vertebrate Animals

 Protocol # Protocol Approval Date Signature for Animal Institute Date

2. Human Subjects

 CCI # Signature for Committee on Clinical Investigations (CCI) Date

3. Hazards in Research

PI has submitted all required information and documents Signature of Safety Officer Date

 Date

If the Yes box was checked regarding Other Departments and/or Other Institutions, then complete the following and obtain appropriate signatures

4a. Participation of Other Departments

(Approval is required if personnel from other departments are budgeted or listed as key personnel on this proposal.)

 Name of Department Name of the individual(s) involved Signature of Chairperson

 or authorized individual

4b. Participation of Other Institutions / Affiliates

 Name of participating institution Signature of authorized individual or attach a signed

 FACE Page or Consortium Agreement page Date

5 Structural Change and/or Additional Space

A written explanation was presented to Executive Dean

 Approval and Signature of Executive Dean Date

Federal Monitoring Requirements

6 A Patent Policy Acceptance Agreement must be signed and on file as per Instructions.

"All budgeted personnel have signed and submitted their Patent Policy Acceptance Agreement except for the above.

 Signature for Department or PI

7 If any aspect of this proposal raises issues of Conflict of Interest as defined by the Conflict of Interest Policy, then the PI must ensure that the disclosure provisions in the Policy are followed. Signature below indicates acknowledgement.

 Signature of PI

8 The Internal Revenue Service requires that if consultant costs are budgeted: An Independent Contractor Questionnaire (GA FORM 101) is attached for each consultant with budgeted costs.

9 DHHS requires that Clerical and Administrative Salary and Office Supplies be adequately justified. Therefore, if a DHHS proposal is either a continuation or a modular application which includes Clerical and / or Administrative Salary or Office Supplies, a Clerical/Administrative Form (GA FORM 105B) or Office Supplies Form (GA FORM 105C) must be attached.

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: <input type="text"/>	Organization: <input type="text"/>
Department: <input type="text"/>	Division: <input type="text"/>
Street 1: <input type="text"/>	Street 2: <input type="text"/>
City: <input type="text"/>	County: <input type="text"/>
State: <input type="text"/>	Zip Code: <input type="text"/>
Country: <input type="text"/>	Employee ID: <input type="text"/>
Phone: <input type="text"/>	
Fax: <input type="text"/>	
Email: <input type="text"/>	

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

Grant Submission & Private Industry Sponsored Research: Guidelines and Requirements Page 31 of 40

If Yes, who is prime?

Type of Proposal:	Kind of Application:	Type of Project:
<input checked="" type="radio"/> Grant <input type="radio"/> Contract <input type="radio"/> Fellowship <u>Type of Agency:</u> <input checked="" type="radio"/> Federal <input type="radio"/> Association <input type="radio"/> State <input type="radio"/> Foundation <input type="radio"/> Industry <input type="radio"/> Other <input type="text"/>	<input checked="" type="radio"/> New <input type="radio"/> Resubmission <input type="radio"/> Renewal <input type="radio"/> Continuation <input type="radio"/> Revision/supplemental Previous Grant # or Federal Identifier: <input type="text"/> <input type="checkbox"/> Change in grantee institution	<input type="radio"/> Basic research <input type="radio"/> Equipment <input checked="" type="radio"/> Clinical/applied research <input type="radio"/> Clinical trial <input type="radio"/> Research training <input type="radio"/> Service <input type="radio"/> Instructional research <input type="radio"/> Other <input type="text"/>

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? 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. <input type="radio"/> Yes <input checked="" type="radio"/> No If Yes, Explain in attachment
Are animal subjects used? <input type="radio"/> Yes <input checked="" type="radio"/> No Is IACUC review pending? <input type="radio"/> Yes <input checked="" type="radio"/> No IACUC Protocol # <input type="text"/> Approval Date: <input type="text"/>	Are human subjects used? <input checked="" type="radio"/> Yes <input type="radio"/> No Is IRB review pending? <input checked="" type="radio"/> Yes <input type="radio"/> No IRB Protocol # <input type="text"/> Approval Date: <input type="text"/>	

BUDGET DATA

Performance Dates	Begin Date	End Date	Cost Sharing Information:
First Budget Period:	<input type="text"/>	<input type="text"/>	Mandatory Committed <input type="radio"/> Yes <input checked="" type="radio"/> No Amount: <input type="text"/> Source: <input type="text"/>

NIH GRANT APPLICATION SAMPLES “RESEARCH & RELATED Other Project Information”

EXAMPLE #1: Exempt (e.g. Category 4) Research

1. * Are Human Subjects Involved? Yes 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 #2: Not Human Subject Research (Human research that does not meet the federal definition)

1. * Are Human Subjects Involved? Yes 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? Yes 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:

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.)

Albert Einstein College of Medicine of Yeshiva University
 Institutional Review Board
Grant Application Form

FOR CCI USE ONLY:	
CCI # Assigned:	200__ - ____ - 000
Transaction Type:	<input type="checkbox"/> PATS <input type="checkbox"/> Paper

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

- Investigator Name*: _____
- 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.
- For a new grant on an approved protocol, provide the CCI #: _____
- If the Grantor is the NIH, specify the institute(s): _____
- Name of person completing this form: _____ Date: _____
- 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: <input checked="" type="checkbox"/> New Researcher <input checked="" type="checkbox"/> 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

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