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Special points of interest:

1. NIH will provide a RPPR training webinar on October 17th.
2. Insight on Penn's policy on providing information on FCOIs
3. Helpful hints on submitting proposals with human subjects.
4. All the latest NIH updates.

Determining if a Project Involves Human Subject Research

When completing an application for funding assistance, the principal investigator often has to answer a question about whether human subjects are involved in the research. The answer will determine what other forms and documents must be included with the application and what information may be requested during the agency review of the application. Sometimes, the answer is not clear cut, especially when the principal investigator is working solely with human subjects' private information or specimens but not personally interacting with the human subjects.

Is it Human Subject Research?

Penn's Institutional Review Board (IRB) Web site has a guidance document that discusses when IRB Review is required. Since IRB review is usually a requirement of human subject research, this document can help principal investigators decide how to complete applications. The IRB is available to review research plans to determine whether a project is human subject research, and, if it is human subject research, whether it is exempt from IRB review.

From the Guidance, the threshold question for human subject research is whether the research involves obtaining from human subjects identifiable private information or identifiable specimens for research purposes. Obtaining includes "using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source [or] . . . identifiable private information or identifiable specimens that were already in the possession of the investigator."

Research does not involve human subjects, if (1) the information or specimens cannot be linked by any investigators conducting the research to specific individuals, (2) the information or specimens were not collected specifically for the project through an interaction with living individuals, and (3) the investigator cannot readily ascertain the identity of individuals whose coded information or specimens are used in the project. The latter condition can be met if (a) the code-key holder agrees not to disclose the key to the investigators, until the individuals are deceased, (b) IRB-approved policies and procedures exist to prohibit release of the key to investigators, until the individuals are deceased, or (c) there are other legal requirements prohibiting release of the key, until the individuals are deceased.

Please see *IRB* on page 2

PennERA Had an Upgrade!

The PennERA System recently underwent an upgrade to the database and application software. While most of the changes have been to "behind the scenes" functions, there are a few noticeable changes to proposal users.

The most obvious of these changes is a completely new **Review Dashboard** for Approvers in the internal proposal routing process. These changes are documented in the Reviewer & Approver Reference Guide and on pages 79-81 of the newly revised Proposal Development User's Guide.

There have also been some changes to entry of Subcontractor/Consortium Budget Items. Please refer to pages 54-56 of the newly revised Proposal Development User's Guide.

The Proposal Mechanisms for System-to-System (S2S) submission reference document has also been updated. These updated reference materials, as well as all other PennERA reference materials are available through links on both on the Research Services website at www.upenn.edu/researchservices/PennERA.html and the **Proposals Reference Materials** section of the PennERA website.

NIH implementation also includes the following PHS agencies that use existing progress reports maintained by NIH:

Food and Drug Administration (FDA)

Agency for Healthcare Research and Quality (AHRQ)

Centers for Disease Control and Prevention (CDC)

Q&A with Pre-Award on PHS implementation of RPPR

What is RPPR?

Research Performance Progress Report (RPPR) is a federal-wide uniform progress report format for use by all federal agencies that provide sponsored funding. RPPR will end up replacing other interim performance progress report formats currently used.

PHS Implementation

NIH will implement the RPPR as a new module in the eRA Commons.

Implementation of the RPPR will replace the:

- PHS Non-competing Continuation Progress Report (PHS 2590)
- eSNAP module in the eRA Commons
- NIH and AHRQ Ruth L. Kirschstein National Research Service Award Individual Fellowship Progress Report for Continuation Support (PHS 416-9).

When will NIH expect grantees to use the RPPR?

Training for all grantees on the use of the new NIH RPPR will be provided via webinar on October 17, 2012. Implementation for complex mechanisms and non-SNAP awards has not been determined and further guidance will be provided at a later date. NIH will update the grantee community of the RPPR rollout plans, and provide informational and training resources.

When I begin my progress report in eRA Commons, what should I do?

When clicking on the "eSNAP" tab in eRA Commons, the PI will have two choices: to click on the RPPR link or the eSNAP. Once the RPPR link is chosen, the PI is taken into the fields to complete the RPPR and route to the Signing Official.

What if I start the RPPR in eRA Commons and decide I would rather use the eSNAP format?

According to NIH, once the RPPR link is chosen, the user cannot click cancel and start over with an eSNAP format. If you begin an RPPR, and decide to start the progress report over again via eSNAP, please contact the eRA Commons helpdesk. Only NIH can re-set the eRA Commons system to allow you to start over using the eSNAP format.

See link below for more information on the differences between eSNAP and RPPR

http://grants.nih.gov/grants/rppr/rppr_vs_esnap.htm. In addition, if you have any questions please contact your Pre-award contact.

Training

On October 17, 2012, the NIH Office of Extramural Research will provide training for grantees on use of the NIH RPPR eRA module. This webinar is designed for those who are responsible for completing and/or submitting progress reports to NIH through the eRA Commons.

The webinar is limited to 1,000 log-ins and interested participants should register early. To maximize participation NIH strongly encourages institutions to promote classroom style viewing whereby groups of viewers can participate via one log-in. This event will be recorded and accessible 3-5 business days following the webinar on the RPPR webpage should staff wish to view it at a later date.

NIH RPPR Training Webinar for all Grantees
Wednesday, October 17, 2012 – Live Broadcast
Time: 1:30pm-3:00pm EDT
Registration Required!
Reserve your webinar slot at www3.gotomeeting.com/register/647997446

After registering, you will receive a confirmation email containing additional information about joining the webinar.

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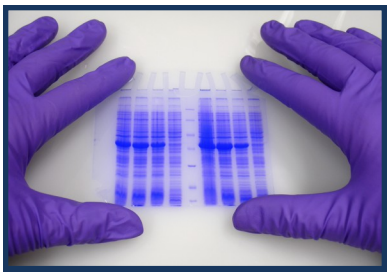
Human Subject Research Exempt from IRB Review, per Exemption 4

If the project is human subject research, it may still be exempt from IRB review, under 45 CFR 46.101 (b)(4), commonly known as Exemption 4. This research involves "the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if [the] sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects."



The difference between projects that involve private information or specimens that are not human subject research and projects that involve private information or specimens that are human subject research has to do with whether the identity of particular individuals are known to the investigator.

For additional information please visit the Office of Regulatory Affair's Institutional Review Board website.

New FCOI Requirement for PHS Funded Researchers

The Office of Research Services has received varying requests for certification of compliance since the implementation of the new federal regulations governing financial conflicts of interest (FCOI) went into effect on August 24, 2012.

Please be advised that The University of Pennsylvania maintains an enforced PHS-compliant Financial Conflict of Interest Policy (FCOI Policy) entitled: "University of Pennsylvania Policy on Conflicts of Interest Related to Research".

Penn is also listed in the Federal Demonstration Partnership (FDP) Clearinghouse, which provides a listing of FCOI compliant institutions.

When Penn is the recipient of a subaward:

- The Prime institution should utilize the FDP Clearinghouse to verify that Penn has a compliant FCOI policy in place. Please note that Penn will not agree to provide disclosures of significant financial interests to any outside institutions or entities, as such disclosures will be handled internally via *The Office of the Vice Provost for Research*, and in accordance with Penn's policy requirements.
- Penn will respond that it has a compliant FCOI policy and will report to the Prime any identified FCOIs and whether they have been managed or eliminated.
- If at the point of proposal the Prime requests additional certification that all disclosures have been made, Penn will need to comply with the requirements, including confirmation that we have obtained all required disclosures.

Any request for written certification of Penn's FCOI policy should be directed to your Pre-award contact in the Office of Research Services, or for PSOM, to ORSS, for official institutional signature.

Please see our website for additional information.

Human Subject Requirements When Completing Proposals.

The IRB has a "Guides" tab what provides links to guidance documents, policies, and forms, as well as contact information for personnel who can help with a given topic.

Understanding whether or not research involves human subjects dictates how you complete proposals in PennERA and what information is placed on SF424 and PHS298 forms.

If a project is not human subject research, then the line in the PennERA Proposal Development Setup Questions screen for human subjects should be answered, "No". For applications to HHS, if private information or human biological specimens are used in the research, then an explanation of why the project does not involve human subjects is required. The HHS SF424 (R&R) Application Guide for NIH and Other PHS Agencies, Part II, Sec. 3, Scenario A, instructs applicants to attach to line 6 of the PHS398 Research Plan (for K applicants, line 14 of the PHS 398 Career Development Award Supplemental Form) a PDF file containing an explanation of why the proposed study is not human subject research. The explanation could include: "a description of the source of the data/biological specimens, and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected."

If a project is human subject research, but falls under Exemption 4, then the line in the Setup Questions screen for human subjects should be answered, "Yes." On the Other Project Info screen, human subject research should be indicated, as well as the exemption. On the PHS398 Research Plan screen, line 6 (for K applicants, line 14 of the PHS 398 Career Development Award Supplemental Form) should have the statement, "This Human Subjects Research falls under Exemption 4", and a justification of how the project meets the criteria of Exemption 4, see Scenario C of the SF424 Application Guide, Part II, Sec. 3. Please note that when Exemption 4 is claimed on an application, lines 7, 8, and 9 (for K applicants, line 15, 16, and 17 of the PHS 398 Career Development Award Supplemental Form) do not require attachments.

Penn's Office of Regulatory Affairs, Institutional Review Board, can help principal investigators determine whether the proposed project constitutes human subjects research, and, if it does, whether Exemption 4 applies. The IRB has a "Guides" tab what provides links to guidance documents, policies, and forms, as well as contact information for personnel who can help with a given topic.

Recommendations for future newsletter articles or questions that you would like addressed can be sent to Yvette M. Wilmoth at ywilmoth@upenn.edu.

NIH Updates

Change in NIAID Salary Caps and Research Support for the K08 and K23 Career Development Awards

NIAID salary caps will change to $90,000 and Research Support to $50,000 for both K08 and K23 awards. All other budgetary items and policies for NIAID Career Development Awards remain unchanged. grants.nih.gov/grants/guide/notice-files/NOT-AI-12-053.html

Clarification: Time Limit on NIH Resubmission Applications

NIH policy allows a thirty-seven month window for resubmissions (A1 applications) following the submission of a New, Renewal, or Revision application (A0 application). The initial submission of a new, renewal or revision application constitutes the starting point for the thirty-seven month policy. After thirty-seven months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the thirty-seven month time period. grants.nih.gov/grants/guide/notice-files/NOT-OD-12-128.html

Updated Grants.gov Filename Restrictions

Beginning August 15, 2012, applicants are now limited to using the following characters in all attachment file names.

Valid file names may only include the following UTF-8 characters:

A-Z, a-z, 0-9, underscore (_), hyphen (-), space, period.

If applicants use any other characters when naming their attachment files their applications will be rejected.

NIH Announces Revised Pre- and Post-Award Forms and Instructions

NIH has announced the availability of newly revised forms and instructions used to submit interim and final progress reports, and other post-award documents associated the monitoring, oversight, and closeout of an award.

Revised Pre- and Post-Award Forms and Instructions Available (NOT-OD-12-152) National Institutes of Health.

NIH Announces the Publication of their Revised Grants Policy Statement

Publication of the Revised NIH Grants Policy Statement (Rev. 10/1/2012): Policy Changes and Clarifications Notice (NOT-OD-12-157) National Institutes of Health

While this revision does not introduce any new material for the first time, it incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated 10/1/2011. The document is available in the following electronic formats: HTML and PDF (http://grants.nih.gov/grants/policy/nihgps_2012/index.htm).

NIH Announces Plans to Transition to Electronic Submission of Multi-Project Applications

(NOT-OD-12-161) National Institutes of Health

Our office will provide further guidance on this transition plan.

ORS Staff Updates

Welcome to Pooja Agarwal, our Newest Associate Director in Corporate Contracts

Pooja Agarwal joined Research Services in early September as an Associate Director in the corporate contracts group and is responsible for negotiating clinical trial and other research agreements. Pooja brings with her a wealth of experience, having practiced transactional law in New York and Philadelphia, most recently with Morgan Lewis & Bockius. Pooja also practiced pro bono immigration law as a Mintz Levin Fellow for the Hebrew Immigrant Aid Society of Philadelphia and served as a financial analyst for Columbia Investment Management Co., LLC.

In her spare time, Pooja is an active member on the Board of Directors of the Pennsylvania Immigration and Citizenship Coalition, which advocates on behalf of immigrants, migrants, refugees and other new Americans to policy makers, and the Friends of the Free Library of Philadelphia which advocates for library services and access for all.

Pooja's email address is poojaa@upenn.edu and her phone number is 215-573-8807.

Congratulations to our Newest Team Leaders in Post Award

Please join our office in celebrating the promotions of Robert Lucas and Marissa McGeehan. Rob has worked within Post Award for the last four years. Marissa has been with our office for two years.

They will be instrumental in the training of new accountants and the development of their teams. Rob's email address is lucasr@upenn.edu and Marissa can be reached at mmcgeeh@upenn.edu.