A tip on the new Personnel Changes Process

Not only can you add, remove and replace study coordinators in real time, you can add or replace co-Investigators in real time too!

A regulatory binder for each study should include a delegation log, log of research staff, a copy of their CV and any necessary certificates, licenses or other documentation of qualifications (CITI certificates of training completion do not need to be stored).

The delegation of authority should include details such as interaction with subjects, obtaining consent, writing orders for Pharmacy fulfillment, etc.

It is the responsibility of the PI to ensure that all education requirements, training on the protocol, disclosure of potential financial conflicts of interest, etc. have been completed before any new personnel can begin work on the project.

Remember to keep your files current and let us know of any changes at the time of continuation (in your progress report memo. HRP-213 is not required).

If you have any questions about this policy, please call us at 212-824-8200.

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Is your project “Exempt”? EXEMPT CATEGORY 4:

Exempt category 4 (45 CFR 46.101(b)(4)): Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

There are key terms worthy of a brief explanation to help with your understanding of whether your project fits this category:

1. “Existing”— this means in existence at the time the paperwork submission is received by the PPHS to get the determination.
2. “Recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject”—this means that if you have coded the data and have a code sheet somewhere that will let you link back to name, MRN, etc. once data collection has been completed this criteria cannot apply.

If you are planning research using data or specimens from Mount Sinai and you are applying for exempt status, you need to have systems in place that allow you to collect the data you need without linking back to any identifiers. Your plan should include how many data sources you are collecting information from and how you are doing so while keeping the code sheet for as short a time as possible (up to 1 day). The code sheet cannot be retained after data collection. The dataset cannot include any identifiers under this category.

If you are proposing research under exempt category 4, it is important to understand that OHRP’s interpretation of retrospective is that all materials/specimens/data to be used in the research are already in existence. If the data or specimens to be used for research purposes will be collected in the future, even for clinical use or discard, OHRP considers that to be prospective and not eligible for an exempt determination.

If you are accessing Protected Health Information (PHI), even if you are not recording it, HIPAA will apply. Please submit a Request for HIPAA Waiver form in addition to the Exempt Determination Form to IRB@mssm.edu

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STEP RIGHT UP:

Step Right Up and have your questions answered on your way to or from lunch:

Every Thursday from 12-1pm outside the cafeteria in GP Atrium
ARE YOU USING THE CURRENT PPHS FORMS?

The PPHS office recommends that you check the website frequently to ensure that you are using the current version of all forms and templates. To assist the research community in this regard, the PPHS office maintains a document (PDF) named PPHS Forms and Documents Version Revision History. This document is stored on the website in the PPHS Form and Document Kiosk. If you maintain a library of PPHS forms locally, rather than downloading forms from the website each time, this document may be valuable in ensuring that you are using the current version. This document also informs the research community of what revisions have been made and on what date the changes were implemented. When a form or template is revised in a manner that requires immediate implementation, the PPHS office communicates the changes and rationale via our newsletters and/or the CRC and Research Faculty listservs. To be added to the CRCList, send an email request to Liz.Carroll@mssm.edu.

EXEMPT Research:
January—November 2012

Determinations of Exempt Research by category

Category 1 : 24
Category 2 : 89
Category 4 : 24
Total Exempt Determinations: 137

BACK BY POPULAR DEMAND

NEW!

Submission Checklists:
Based on feedback from the research community, the PPHS office has released a new E-Submissions Checklist for study teams to utilize. This checklist includes what to submit for new studies, continuing studies and modifications to approved research.

PPHS Submission Tips:
Guidance from the PPHS office on submission materials (based on common mistakes).

Submissions and IRB Approvals:

OCTOBER 2012

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NOVEMBER 2012

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PPHS Suggestion Box
Submit your suggestions, comments, feedback, questions and concerns to IRB@mssm.edu

Happy Holidays from the PPHS Office