Children's Hospital of Wisconsin

Human Research Newsletter

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Protected Health Information on IRB Forms

Forms submitted to the IRB must no longer contain PHI. The Continuing Report and Reportable Events forms have been revised to eliminate requests for name or medical record number. Any IRB submission that that contains PHI will be returned to the study team to remove.

Federal Grants Directly Awarded to Investigators Require IRB Review

Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(f) require that each application or proposal for HHS-supported human subject research be reviewed and approved by the IRB. Accordingly, IRBs must review the grant to ensure the information is entirely consistent with any corresponding protocols.

Investigators directly awarded federal funds should remember to:

- **Upload grants in IRBNet**. The CHW IRB does not have access to grants in the MCW eBRIDGE system.
- **Notify the IRB any time new federal funding is secured** for a study by submitting an amendment.

Common areas of non-congruence between grants and protocols include:

- Data collection procedures that are proposed in the grant application but are not described in the IRB-approved protocol.
- Descriptions of the study population(s) and number of participants to be recruited.
- Descriptions of collaborating institutions and listed research sites that are proposed in the grant application but are not described in the IRB-approved protocol.
- Co-investigators and/or research personnel listed in the grant application but not in the IRB protocol (or vice-versa).

If the IRB comparison identifies material discrepancies, the MCW Grants & Contracts Office cannot process the award for full release until those discrepancies have been resolved either by clarification or an amendment to the IRB protocol or the grant proposal, as appropriate to the research project. For more information, please call the IRB Office or see *IRB Review of Proposals for HHS Support* at http://www.hhs.gov/ohrp/policy/aplrev.html.

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Collaborators Engaged in CHW Research

CHW Investigators who **engage** other performance sites in CHW human subject research must ensure additional regulatory requirements are met. Any collaborating institutions/investigators engaged in CHW research must be named in the IRB application.

Engagement in Research
Generally, an institution/investigator is engaged in research upon obtaining:

- Data about research subjects through intervention or interaction with them;
- Identifiable private information about research subjects; or
- Informed consent of human subjects for research.

For details, see OHRP Guidance on Engagement at:
http://www.hhs.gov/ohrp/policy/engage08.html.

Institutions receiving financial support for a study may also be considered engaged in research, even when activities involving human subjects are conducted elsewhere.

Federal-Wide Assurance
When a collaborating institution/investigator is engaged in CHW human subjects research and the project is federally funded, CHW requires one of the following:

- The institution must be covered under its own Federal-Wide Assurance (FWA); or
- The individual investigators engaged in the research must have an agreement (Individual Investigator Agreement) to be covered under the FWA of another institution.

For details, please see OHRP Assurance FAQs at:
http://www.hhs.gov/ohrp/policy/faq/assurance-process/index.html

IRB Review
Some general principles to be aware of:

- Each institution/investigator, domestic and foreign, engaged in a CHW research project must ensure IRB/IEC review for at least the portion of the research project in which it is engaged.

- CHW will determine appropriate IRB review arrangements with collaborating institutions on a case by case basis, considering the nature of CHW's involvement, the possible risks to subjects, how the study is funded, and any other relevant factors. IRB review of collaborative research may occur in the following ways:
  - Each institution conducts its own IRB review;
  - CHW agrees to rely on IRB review of the collaborating institution;
  - A collaborating institution agrees to rely on the CHW IRB review;
  - A CHW-approved third-party IRB provides review.

- CHW researchers who function as the lead investigator, prime grant holder or serve as a coordinating center for a multi-center study are responsible for:
  - Obtaining CHW IRB review for the overall project,
  - Ensuring that other sites receive IRB review at their respective institutions, and
  - Ensuring that relevant safety information is appropriately recorded and shared between engaged sites.

Notice of Proposed Rulemaking (NPRM)

The U.S. Department of Health and Human Services has issued a Notice of Proposed Rulemaking (NPRM) with the purpose of modernizing, strengthening and making more effective the federal policy for the protection of human subjects. The NPRM includes rationale for changes, revised regulation and questions for additional comment.

This Office for Human Research Protections (OHRP) has also developed six short webinars covering key topics to help the public better understand the proposals.

- Overview of the NPRM
- Exclusions and Exemptions
- Informed Consent
- IRB Review and Operations
- Research with Biospecimens
- Secondary Research Use of Data

To watch now, go to:
http://www.hhs.gov/ohrp/education/training/nprmwebinars.html

IRB Member Reviewer Checklists

Did you know that IRB Members are using new checklists as tools to assist in the IRB review process? These checklists help assure that the federal and local requirements for IRB review and approval are met.

Individual researchers may also wish to review these checklists so that they understand what the requirements are for IRB approval.

Current checklists are posted in the IRBNet Document Library.

- IRB - Full Board Amendment Reviewer Checklist
- IRB - Full Board New Study Reviewer Checklist

Q&A

The IRB Office, TRU, and Research Compliance Office would like to share answers to some frequently asked questions. If you have recommendations for other topics to address in the future, please let us know!

Q: If an IRB application for a chart review study states that records from 20 subjects will be reviewed, does the IRB application need to be amended in order to review records from 30 subjects?
A: Yes. Prior to enrolling additional subjects, an amendment must be submitted to update the IRB application.

IRBNet Document Library

The IRB Office is reviewing and updating the submission forms posted in IRBNet. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission. Changes to documents will also be announced in this newsletter.

Documents recently updated:

- IRB – Continuing Report Form
- IRB – Reportable Events Form

New documents available:

- Prior issues of this newsletter have been posted under Research Newsletter.
- IRB - Full Board Amendment Reviewer Checklist*
- IRB - Full Board New Study Reviewer Checklist*

**Reviewer checklists used by IRB Members*

The IRBNet Document Library houses submission forms, templates, policies and guidance documents. To access, log on to IRBNet. On the left navigation bar click "Forms and Templates". Then click the dropdown menu on top of the page and choose the second option "CHW IRB Milwaukee, WI Documents for Researchers".

Questions, Comments, or Suggestions

Your thoughts and recommendations for future newsletter topics are much appreciated! Please send your ideas and feedback to Julia Kennedy at jkennedy@chw.org.