Guidance Regarding Federal Requirements for IRB Review of Grants

Version Date: December 15, 2011; Updated: November 14, 2012

What is the basis of the requirement for IRBs to review federal grants?

Federal regulations (45 CFR 46.103(f)) require that each grant application or proposal for most federally supported human subjects research be reviewed and approved by an IRB. As part of this review, IRBs are required to ensure that the activities described in the grant are consistent with the proposed or IRB-approved protocol. The University of Wisconsin-Madison also requires an IRB to review and approve a federal grant that involves human subjects in order for an account to be set up by Research and Sponsored Programs (RSP) and funds to be released.

Does the title of my grant need to match the title of my IRB protocol?

Although most funding agencies and RSP prefer for the grant title to match the IRB protocol title, this is not always possible because some IRB protocols cover multiple projects and multiple grants. As long as the funding agency and RSP can connect an IRB approval to a particular grant, the titles of the IRB protocol and grant are not required to match. If you need additional documentation from the IRB to demonstrate the link between an IRB approval and a particular grant, contact the IRB Director.

What if the grant does not match the IRB application?

Any discrepancies between the IRB protocol and grant must be resolved or accounted for before the grant can be approved. The IRB may request a research team revise an IRB application to reconcile discrepancies (e.g., to add new procedures described in the grant that will be conducted), submit a new initial review application (e.g., when the grant appears to describe a new study), or provide clarification regarding the reason for the differences (e.g., when only part of the grant appears to support the IRB-approved application).

What if a single grant supports several IRB protocols?

If a grant supports more than one research study approved by the IRB, the research team should submit the grant for review for each protocol it supports and clarify which components of the grant apply to each protocol.

When should a federal grant be submitted to the IRB for review?

- If a federal grant has been awarded it should be provided to the IRB for review at the time of initial review or the protocol or, if the IRB already has approved the research study, a change of protocol should be submitted to add the grant.
• If the human subjects research has been reviewed by the IRB Office and determined to be exempt human subjects research, the research team should submit a change of protocol to the previously approved exempt to request the addition of the grant to the project. Contact the IRB Office to request confirmation that the grant is consistent with the existing exemption application. Please contact the staff reviewer who originally handled your exemption to request this review and provide a copy of the grant for the reviewer [LINK to CONTACT PAGE] to compare to the exemption. If the staff reviewer is no longer with the IRB Office, please send your request to irbreview@medicine.wisc.edu.

• If the grant has not been awarded but the research team has been informed that it is likely to receive the award (e.g., Just-in-Time, JIT, notification), the research team can handle this one of two ways.
  o If the research has not been approved by the IRB already, submit an Application for Protocol Development Activities (PDA) to the IRB if the research study has not yet been approved by the IRB. The PDA is a simplified application that allows the IRB to quickly review and approve the grant in concept or those activities described in the grant that do not involve human subjects while the research team prepares its application for IRB review or responds to IRB requests. Additionally, approval of a PDA allows Research and Sponsored Programs (RSP) to release funds.
  o If the research team plans on adding the grant will be used to support research that is an already approved by IRB protocol, do not use the PDA mechanism and instead submit a change of protocol when the grant has been awarded. If you need additional documentation for the funding agency or RSP, contact the IRB Director Nichelle Cobb (nlc@medicine.wisc.edu or 608-262-1980) who can provide further guidance assistance in these cases.

What sections of the grant application does the IRB need to review?

The IRB is expected to review a copy of the entire proposal in order understand the scope of a project, including any potential collaborations outside the institution that may be planned. Appendices do not need to be submitted for review.

What do I do if there are not immediate plans to conduct human subjects research (e.g., the grant includes a planning stage or a component that involves non-human animal research)?

There are cases for certain types of grants that research involving human subjects may be planned, but would not occur until some time in the future during the proposed period of support. These include activities such as projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. In these cases, the research team should submit an Application for Protocol Development Activities (PDA) to the IRB. The PDA is a simplified application that allows the research team to provide Research and Sponsored Programs with the documentation that office needs to release funds for the components
of the grant that do not involve human subjects.

**Do training grants or core grants require IRB review?**
If a grant does not directly support human subjects research, IRB review and approval is not needed unless required by the funding agency. Any human subjects research studies that receive funds from the grant do require IRB review and approval.

**Where do I include the grant in the electronic system used by the Health Sciences IRBs, ARROW?**

The ARROW application includes a section on funding. For studies that have funding administered through UW-Madison, study teams are asked in ARROW to select a funding source from the RSP database and to upload a grant application in the UW-Madison Funding Detail section of the application. In the case of studies that have funding administered through the Madison VA or UWHC, the ARROW application will prompt study teams to upload a copy of the grant in the VA/UWHC Funding Detail section.