Connecting Grants with Existing IRB-Approved Protocols

IRB review is needed for all federal grants that involve human subjects research

By default, **a new human subjects grant requires a new IRB submission**. But if you believe there is an ongoing IRB-approved protocol that aligns with the new grant, an amendment may be submitted. (It's best to consult with the IRB first.)

Instructions for Amendments to Add New Funding

1. **In the Amendment Narrative, i**nclude one of the following:
   - "I have reviewed the current protocol and consent and smartform and found they did not require any changes to match the research highlighted in the grant." (Note: the IRB will thoroughly verify this.)

   Or…

   - An explanation of what changes are being made to the consent form, smartform, and/or protocol to align with the grant. (Be sure the amendment smartform includes 'Changes to Protocol' and not just 'Changes to Funding')
     - For example: The protocol and consent form(s) have been modified as follows:"

   Also, explain how the grant relates to the clinical protocol and why it makes sense to include it in an existing IRB record, instead of starting a new one. (Generally, only minimal changes should be needed to an existing IRB record; if not, it might suggest the need for a separate, new IRB submission for the new grant work.)

   Example – The research grant R01-CA456321-03 attached is relevant to three IRB-approved protocols because: research described in specific aim 1 describes prospective treatment of patients on a phase 1 clinical protocol W1234-18. Specific aim 2b proposes the use of de-identified specimens collected as part of W5678-18. Finally, specific aim 3a proposes obtaining samples from tissue bank W5555-15 for genomic characterization of response that has inherent risks covered by the GINA language and other paragraphs in the consent for W5555-15. This amendment is to associate specific aim 1 of this grant to IRB study [number], which involves the same treatment plan as described in that aim of the new grant, and involves the same team of researchers and the same study population.

   We have highlighted relevant sections from specific aim 1 in the attached grant and protocol W1234-18. Details of the translational science group established at Emory is included in the attached Facilities document from this R01.

2. **In the Amendment History, attach and highlight** (via logged comment): relevant sections of **both** the grant (e.g. specific aims, approach, "Human Subjects" section, facilities) and the clinical protocol that clearly demonstrate overlap for the IRB reviewer.

3. If the study has **consent form(s):**
   - Ensure that the funding information in the consent form(s) is accurate, i.e. in the **heading, and HIPAA and/or confidentiality sections**.
   - If the grant is federal, **OHRP** needs to be added to the Confidentiality or HIPAA sections, if not yet present.
   - If **NIH** funding is being added for the first time, **Certificate of Confidentiality** language should be added (and old language about subpoena removed), if the study didn't already have a Certificate of Confidentiality.

4. Update the "Funding" section of eIRB smartform
   - Add new entry and attach the ***entire grant application*** (or subaward that includes the **scope of work** for Emory, if applicable) – not just the "Notice of Award."

Why Does This Matter?

- Funding agencies (including NIH) require that the institution **certify** that the human subjects research was reviewed and approved by an IRB.

- The Emory Office of Sponsored Programs must verify that the grant application matches adequately with any IRB-approved protocols. They rely on the IRB to evaluate this.

- Thus an IRB must review **all human subjects activities of every grant application** in the form of a protocol that follows IRB protocol guidelines (*not* just a copy of the grant application)

- The **grant number** and title must be included in the IRB submission. The grant number will then be listed in the IRB approval documents as well.

- Linking IRB submissions and grant records (via EPEX number) is important for linking information across the University.

When should a grant be submitted to the IRB (either via amendment or as a new study)?

- When the research team has been informed that it is *likely* to receive the award (e.g., Just-in-Time [JIT] notification), unless funding agency requests a different timeframe