Guidance to Connect Grants and IRB Approved Protocols

In order for the IRB to approve a new grant for an existing approved study, you must explain how the grant relates to the protocol.

See an example below:

Example – The research grant R01-CA456321-03 attached is relevant to three IRB-approved protocols. 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 highlights 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.

Please provide the following to secure approval via an amendment:

- Attach and highlight 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.
- If the study has a consent form, ensure that the funding statement is accurate and reflects this grant in the heading, 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.
- Ensure that the funding sources are added accurately in the funding section of the IRB file, with attachments that include the entire grant application (or subcontract/subaward that includes the scope of work for Emory, if applicable) – not just the “Notice of Award.”
- If adding a Career Development (K) Awards – If the (K) Award grant proposal contains any aims/analysis that are not in the already approved protocol, the new aims/analysis will either need to be (1) added to the existing protocol, (2) a sub-study protocol should be added, or (3) just explain that the detailed aims/analyses fall under the description of the already approved protocol because the protocol is more general.

In Amendment Applications “Description of Changes section, please attest to 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.
- Explain what changes are being made to the consent form, smartform, and/or protocol to align with the grant. Be sure the IRB application includes ‘Changes to Protocol’ and not just ‘Changes to Funding’

Remember to add information about changes to consent and protocol, if applicable (the protocol and consent have been modified as follows: ....)
Background Information about the requirements regarding grant funding and human subjects’ protocols

Federal regulations [45 CFR 46.103(f)] require that the institution certify for each federally-supported grant application or proposal that the human subjects research was reviewed and approved by an IRB. This means that an IRB must review all human subjects’ activities of every grant application – not via simply receiving the grant application, but by having all activities submitted as part of a protocol(s) that follows IRB protocol guidelines.

The IRB must be able to verify to the Sponsored Programs office that the grant application matches adequately with any IRB-approved protocols. The PI should therefore include the award/grant number and title of the award/grant to ensure that the appropriate award/grant is referenced in the IRB approval. No assumptions should be made regarding IRB approval of a specific award/grant without that information identified specifically within the funding section of the IRB application.

When should a 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 of the protocol or, if the IRB already has approved the research study, a modification should be submitted to add the grant. The modification will include edits to the actual application as well as the relevant documents such as the protocol and consent(s).
- 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 or any other indications that that funding is likely), the research team can handle these one of two ways:
  - If the research is greater than minimal risk, requiring full committee review, then the research proposal and documents (e.g., IRB application, consent, advertisements, etc.) must be fully developed and ready for IRB review. Without fully developed documents the convened IRB cannot grant approval. The grant must be attached in the funding section of the application for review and approval. OR
  - If the research qualifies for expedited review and the research plan and corresponding documents are complete, with the exception of participant-facing documents (e.g., consent form, recruitment materials, etc.), and IRB approval is needed for the release of funds, then the IRB application should be submitted for review and approval. As long as the grant is attached in the funding section of the application and sufficient information is provided, the participant-facing documents can be submitted when available before enrollment of human participants. Note: In your approval letter, you will receive specific instructions that no enrollment may occur prior to IRB review and approval of all participant-facing documents.
### Relevant exemptions from human subject research requirements

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation</th>
<th>Description</th>
<th>IRB interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>104(d)(4)</td>
<td>Consent not required for biospecimen that has been collected for some other ‘primary’ or ‘initial’ activity if the sample is de-identified and the research proposed is not prohibited by a consent signed by the patient.</td>
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</tr>
<tr>
<td>7</td>
<td>104(d)(7)</td>
<td>Tissue bank</td>
<td>All ‘broad consent’ elements were included in the study consent for a well-defined set of patients</td>
</tr>
<tr>
<td>8</td>
<td>104(d)(8)</td>
<td>Secondary research of tissue bank specimens with no plan to return research results</td>
<td></td>
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### Relevant definitions

- **Clinical trial**: a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

- **Human subject**: a living individual about whom an investigator: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.