CHANGES IN STUDY PROCEDURES OR FUNDING: IS A NEW STUDY NEEDED?

PROTOCOL REVISIONS, FUNDING, AND SECONDARY ANALYSIS CONSIDERATIONS

Emory University IRB
August 10, 2017
Topics to be covered

• When you are required to submit a new study when changing or adding protocol elements
• When it’s best to instead submit an amendment to an approved protocol
• How new funding sources should be submitted to the IRB
• IRB review of secondary analyses of existing data/specimens
• Example cases
When you may need to submit a new study - not an amendment

- If you are making *unforeseen* substantial changes to the protocol that significantly alter the study. Examples:
  - Changing an observational study to an interventional study, especially if a new research aim resembles a clinical trial
  - Adding aims that require enrollment of new cohorts
Why does the IRB care?

- Not an intent to increase bureaucracy
- Keeping IRB submissions streamlined reduces potential for regulatory headaches, IRB confusion, and review delays
- IRB experience with allowing multiple new investigators and their grants to be added to existing IRBs: Saves time for investigators but hard for IRB to track status of various substudies, consent considerations, enrollment numbers...
- Different IRB and ancillary review requirements for different substudies: causes confusion
- Can lead to inadequate IRB review when new grant/investigators added but rest of smartform/protocol not updated
But when is it **okay** to submit an amendment?

- Submit an amendment if the changes fall almost completely under the originally proposed aims, same/similar cohort and investigator team, *and* there are only minor changes (if any) to study procedures
  - Examples: adding an additional blood draw, additional related assays
  - Adding procedures that become required/integral to the existing study in order to achieve existing aims
What to do with funding from a new grant

- In general, expect new grants to require a new study submission
- Confirm with IRB in advance - be prepared to submit to IRB at Just In Time (JIT) stage
Exceptions for new funding

• One member of study staff is awarded a grant for minor expansion to existing IRB-approved study
  – The protocol must be revised accordingly; PI must agree. May be done via adding an ancillary/substudy document instead of revising existing main protocol
  – If the new grant’s aims require too drastic of a change to the approved study, it’s still best to submit a new study

• When a single grant supports multiple projects
  – NIH may require a standalone submission for the grant as well, but the grant should be added via an amendment to the projects it supports

• When a new grant proposal matches up exactly with the existing study protocol, and just adds new support
Secondary Data or Specimen Analyses

- When obtaining and analyzing data or specimens from an IRB-approved registry or repository, submit a new study unless there is no way to link data or samples to identifiers (in which case, not “human subjects” research)
  - Repository IRBs are generally only for collection and storage, not use in specific research studies
- When obtaining and analyzing data/specimens collected under another specific research study: consult with IRB
  - Depends on whether aims are closely aligned; whether new analyses will be integrated with the existing study results (vs being done independently); and whether PI of existing study agrees to take responsibility for the new analyses (if not PI for new analyses as well)
A study is administering a survey that is designed to measure quality of life in Alzheimer's patients. The same study team wants to add an imaging component (MRI) to identify shrinkage in specific brain areas.
Case 1 Answer

It depends:

-If the imagining component is still supposed to relate to quality of life of Alzheimer’s patients, this could be submitted as an amendment

-If the imaging component is meant to support a different aim, for example, if the study team were researching how a new MRI sequence detects brain volume changes over time, the study team should submit a new study
Case 2

The PI of a study that is evaluating patient samples for certain biomarkers of a disease is awarded a grant to do genetic analyses on the same type of samples, for the same disease.
Case 2 Answer

The team may submit an amendment for the additional genetic analysis of patient samples.

The team may need to update the consent form to ensure that language relevant to genetic research is included; reconsent may be required (or only post-amendment samples used for the new analyses).

Additional language regarding data sharing may need to be added to the consent form if the data or samples may be shared per NIH genomic data sharing policies.
Case 3

One co-investigator works on an approved biorepository study collecting human samples from patients with a certain disease. The co-investigator is awarded funding to research a new assay, and these samples would be perfect.
Case 3 Answer

Submit a new study – biorepositories are almost always for collection and storage only
WHEN IN DOUBT…

Check with the IRB!
# Contact Us

<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maria Davila, MD, CCRC, CIP</td>
<td><a href="mailto:maria.davila@emory.edu">maria.davila@emory.edu</a></td>
<td>(404) 712-0724</td>
</tr>
<tr>
<td>Shara Karlebach, WHNP-BC, CIP</td>
<td><a href="mailto:swilli7@emory.edu">swilli7@emory.edu</a></td>
<td>(404) 712-0727</td>
</tr>
<tr>
<td>Jessica Baker, BS</td>
<td><a href="mailto:jessica.baker@emory.edu">jessica.baker@emory.edu</a></td>
<td>(404) 712-9698</td>
</tr>
<tr>
<td>Clarissa Dupree, BS</td>
<td><a href="mailto:cdupree@emory.edu">cdupree@emory.edu</a></td>
<td>(404) 727-8864</td>
</tr>
</tbody>
</table>