Tips & Tricks for Preparing Successful IRB Submissions

Presented by:
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Today’s Agenda

• Common Issues with the IRB Application
• Common Issues with Modifications and Continuing Reviews
• Other Common Issues
• Reportable New Information (RNI)
• Q & A
Common Issues with the IRB Application
Templates are your friends!

- Don’t count on an “old” protocol or consent to serve as your template. *IRB Templates change occasionally,* so the best way to “get it right” is to grab a template directly from our website.

- **Protocol:** Read all instructional text as you complete each section of the protocol, then delete the instructions in the final protocol.

- **Consent:** Make sure you prepare the right kind of consent for your study. The Templates page includes several different templates, as well as some example consents that show how the templates can be adapted.
Protocol

- A single protocol must represent **one study only**. A single study may have multiple conditions or phases, but a protocol should not describe “multiple studies” or “versions of studies”
- Always err on the side of giving us *more* detail about what you are doing with participants (you can go light on the background/literature review)
- Each section of the protocol should be presented in a narrative-like format. Do not just fill in the information that each bullet point describes. The information in the bullet points is intended to provide you with guidance; the bullet points are not intended to be the outline of the protocol/protocol section.
The Funding Page

• Every study is required to list a funding source.
  – If the study is internally funded, list the PI’s department.
• If the study is externally funded, you must upload the grant. The IRB is charged with making sure the protocol and grant are consistent with each other.
Study Team Members

• Anyone with an NU NetID who will interact with participants or have access to identifiable data belong in #1.

• Anyone who will interact with participants or have access to identifiable data for whom NU IRB will have oversight responsibility, such as Interns/Volunteers, research staff covered by an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA), belong in Section 2. Do not list research staff from other institutions that have their own IRB approval.

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Study Team Members

1. Identify each internal person who will interact with participants or have access to identifiable data:

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beth Irwin</td>
<td>Co-Investigator</td>
<td>yes</td>
<td><a href="mailto:bethirwin@northwestern.edu">bethirwin@northwestern.edu</a></td>
<td></td>
</tr>
</tbody>
</table>

Add

2. Identify each external person who will interact with participants or have access to identifiable data for whom NU IRB will have oversight responsibility such as interns/volunteers, research staff covered by an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA). Do not list research staff from other institutions that have their own IRB approval.

Add

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>Roles</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
<th>Training Date</th>
</tr>
</thead>
</table>

There are no items to display
Study Team Training

- When adding new study staff, please check to see if their human research training is populating in the system. If the “Certification Date” field is empty, you may need to email a copy of their training certificate to the IRB. ([irbtraining@northwestern.edu](mailto:irbtraining@northwestern.edu))
- The NU IRB only accepts CITI Training (Basic Course SBS/BIO, Basic Course Refresher), NIH Training, and Investigator 101 Training
  - RCR and GCP Training DO NOT fulfill the IRB’s training requirements
Recruitment

• For every recruitment method mentioned in the protocol, be sure to upload the associated material in the Recruitment Materials section.
• Look for the list of **required elements for recruitment materials** on our website.

<table>
<thead>
<tr>
<th>Required Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Study title and IRB study number.</td>
</tr>
<tr>
<td>• The word &quot;research.&quot; Make it clear that this is a research study.</td>
</tr>
<tr>
<td>• &quot;Northwestern University&quot;</td>
</tr>
<tr>
<td>• The PI’s name.</td>
</tr>
<tr>
<td>• A contact name with either a phone number or e-mail address.</td>
</tr>
</tbody>
</table>
Consent

• Consents must **specify all procedures** listed in the protocol.
• Consents must identify the **study duration**.
• Consents must include the **amount, the form, and the timing of study compensation**. If there is something that could impact a participant’s compensation, the consent needs to identify what that is.
• Consents for studies that include optional elements **must have a clearly-labeled “Optional Elements” section** where participants can opt-in or opt-out.
Sites

- This page is specifically for information about other institutions that will be engaged in the research. Pay no attention to the instructional “help” text that says otherwise.
- Northwestern University (NU) – Chicago/Evanston is almost always a “Site”, even if the study is taking place on the other side of the world.
Sites, Continued

If this is "yes", there must be an IRB approval letter uploaded in Supporting Docs

If this is "yes", there must be an IAA letter uploaded in Supporting Docs
Supporting Documents

• **Q**: What belongs in Supporting Documents? **A**: *Everything!* (that is, everything that doesn’t show up in other sections of the application)

• The IRB generally needs to see everything a participant will see over the course of study participation.

• Supporting Documents can include: survey instruments, interview guides, images/video clips, letters of support, relevant permission/approval letters, training documents for any external personnel, certificates of translation, and debriefing forms.
Common Issues with Modifications
Choosing the type of Modification to submit

- If you are only adding/removing NU staff, choose “Study team member information.” This will give you access to the Study Team Members page of the application.
- If you are adding non-NU staff, click “Study team member information” and “Other parts of the study.” You must click both because you will need to upload their CITI Training certificate.
- If you need to modify anything unrelated to study team members, choose “Other parts of the study.”
- If you need to add/remove study staff and modify a study document, choose both “Study team member information” and “Other parts of the study.”

**Alert!** Once you choose an option and click “Continue” to move to the next page of the modification, you will not be able to change the type of modification.
Providing a rationale for the Modification

A rationale for each change must be provided.

**Modification Information**

1. **Study enrollment status:**
   - [ ] No subjects have been enrolled to date
   - [ ] Subjects are currently enrolled
   - [ ] Study is permanently closed to enrollment
   - [ ] All subjects have completed all study-related interventions
   - [ ] Collection of private identifiable information is complete

2. **Notification of subjects:** (check all that apply)
   - [ ] Current subjects will be notified of these changes
   - [ ] Former subjects will be notified of these changes

**Attach files:** If notifying subjects, add a description of how they will be notified to the Supp

3. **Please provide a rationale for the modification you are requesting:**
Revising Study Documents

• Revised documents **must** be uploaded with all changes tracked. If you don’t know how to use Microsoft Word’s “track changes” feature, Google it!
  – Please do not **highlight** the changes; we will send the modification back to you!
• Don’t forget to remove any previously tracked changes in a study document before starting to work on the new changes.
• Remember to consider all possible study documents that might be affected by the change to the study.
Common Issues with Continuing Reviews
Enrollment Totals

- “Subjects enrolled” = the total number of signed consent forms (including online and verbal consenting).
  - Waiver of Consent

- “Total” = how many signed consents since the beginning of the study.

- “Since Last Approval” = number of participants enrolled since the last CR. If it’s the first CR, input the # of participants since the study started.

- If your study is multi-site, the two boxes on the top row are for NU totals, and the “Study-wide” box is total consented participants at all study sites, including NU.

### Continuing Review / Study Closure Information

1. Specify enrollment totals:

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At this investigator’s sites:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-wide:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Research Milestones

• You may check 0, 1, or multiple boxes in this section.
• If you think you \textit{may} want to enroll more participants at some point, leave all of these checkboxes blank.
• If any of these boxes are selected, we will expect the first box ("Study is permanently closed...") to be selected as well.

\begin{itemize}
  \item \textit{Note: If you would like to close your study, select the first four checkboxes.}
  \item Study is permanently closed to enrollment OR was never open for enrollment
  \item All subjects have completed all study-related interventions OR not applicable (e.g. study drug not given)
  \item Collection of private identifiable information is complete OR not applicable (no subjects enrolled)
  \item Analysis of private identifiable information is complete OR not applicable (no subjects enrolled)
  \item Remaining study activities are limited to data analysis
  \item Study remains active only for long-term follow-up of subjects
\end{itemize}
Continuing Review Question #3

• If anything is left *un*-checked in item #3, a corresponding document needs to be uploaded in item #4.

3. Check the items that are true since the last IRB continuing review for all sites involved in the study:
   - NO subjects experienced unexpected harm (that wasn’t previously reported to the IRB).
   - Anticipated Adverse Events have NOT taken place with greater frequency or severity than expected.
   - NO subjects have withdrawn from the study after initial screening procedures, if any.
   - There have been NO unreported unanticipated problems involving risks to subjects or others.
   - There have been NO complaints about the study.
   - There have been NO publications in the literature relevant to risks or potential benefits that would indicate a need.
   - There have been NO interim findings (if this study involves interim analysis).
   - There have been NO multi-center trial reports (if this study is part of a multi-center trial).
   - There have been NO data safety monitoring reports (if a monitoring plan was required for approval of this study).
   - There have been NO regulatory actions that could affect safety and risk assessments (e.g. FDA drug recall).
   - There has been NO other relevant information regarding this study, especially information about risks.
   - In the opinion of the principal investigator, the risks and potential benefits are unchanged.
   - There have been NO modifications to the study that have not been submitted to or approved by the IRB.
   - All other problems that require prompt reporting to the IRB have been submitted.

4. Attach supporting documents: (for each item left unchecked above, include an explanation or a document from an ext
Name
There are no items to display
Other Common Issues
Screening

• Screening activity is different from research activity, as it often takes place *before* consent
• Screening procedures must be clearly described in the study’s protocol
• If screening procedures are extensive or involve collecting sensitive personal information, the study may need a screening consent
• Unlike research data, the IRB generally expects screening data to be discarded
Debriefing

• Any study that involves incomplete disclosure or deception must end with a debrief process that fully informs participants about any elements that were obscured or falsely represented in the consent.

• The debriefing process must include:
  – Complete disclosure of the deceptive/incomplete disclosure aspect(s) of the study.
  – An explanation of the reasons for the deception/incomplete disclosure.
  – An opportunity for the participant to ask questions.
  – An opportunity for the participant to withdraw the provided data (in some instances).
Review Turnaround Time

• Every project is reviewed on its own merit!
• There are many factors that impact how long it takes for a study to get approved:
  – IRB work load
  – Type of IRB review
  – Involvement of vulnerable populations
  – Procedures that require the use of a consultant
  – Submission quality
  – Conflict of Interest Office review
  – Reliance Agreements (IRB Authorization Agreements, Individual Investigator Agreements, etc.)
Reportable New Information (RNI)

• RNIs are how you let us know when something has gone wrong or gone differently than expected
• The most important part of the RNI is the prompt that asks you to briefly describe the new information
  – This will include: How many participants were affected, steps that have been taken to address the issue, and steps that have been taken to ensure that the issue does not come up again
• Don’t be afraid to report! The purpose is to identify something that went wrong, then figure out a way to make sure it doesn’t happen again.
Questions?

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Or

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