Tips for Preparing Successful IRB Submissions

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Objectives

• Tips and Common Issues for New Study Submissions
  – Things to consider before you submit a new study
  – Things to consider for specific study activities/content

• Tips and Common Issues for Post-Initial Approval
  – Things to consider when submitting RNIs for events at Northwestern or relying sites
  – Things to consider when acquiring other institutional approvals

• Tips and Common Issues for Modifications and Continuing Reviews
  – Things to consider when re-submitting (ex: clarifications, modifications, panel reviews)
  – Things to consider at continuing review
  – Things to consider after a panel review
Tips and Common Issues for New Study Submissions
Before You Submit

• Single IRB Pre-Consultation is required when Northwestern will serve as Single IRB
  – This process is *recommended* when ceding review to an external Single IRB
  – Please submit at least 5 weeks prior to the grant application due date

• Do not assume that Northwestern is willing to serve or cede IRB review
  – We must consider if reliance is appropriate, feasible, and if there are any federal/sponsor requirements
Preparing the Application

• Know what you are trying to submit
  – Human Research Determinations
  – Data/Specimen only Analysis
  – Research activities involving human participants
• Know what office will review your submission
• Use current IRB templates
  – Access templates directly from the IRB website
  – Do NOT use old documents from previous applications
  – Read all instructional text and delete all instructions in the final protocol/consent templates
• Submit for IRB review via the eIRB+ system
Protocol Tips

• Submit **one** protocol per application for review
  – A single study may have multiple conditions or phases, but a protocol should not describe “multiple studies” or “versions of studies”

• Provide specific details about the participants and how you plan to protect them
  – Go light on the background/literature review

• Present each section in a narrative-like format
  – Don’t just answer bullet point prompts from instructions
Include a Reliance Plan

• Is reliance federally required?
  – Will sites do a local review or cede review?
• Who is the IRB of Record?
  – Is there a Single IRB Letter of Support?
• What sites are involved?
  – What activities will each site participate in?
  – How will information be shared between sites?
• What reliance agreement/path will be utilized?
  – When will reliance be executed?

If Single IRB fees apply, relying sites should be added after the initial review.
Choosing a Reliance Agreement

• The most common reliance agreements are:
  – SMART IRB Online Reliance Platform or LOA

• When an External IRB is the proposed IRB of Record, they can dictate the reliance method.

• Reliance agreements are typically executed after initial review and approval, in a subsequent modification
Funding

• Every study is required to list a funding source
  – If internally funded, list the PI’s department
  – If externally funded, link the grant information
    • This will populate in IRB approval letters
Study Team Members

Section #1: Individuals with an NU NetID who will interact with participants, perform study-specific procedures, and/or have access to identifiable data

Section #2: Individuals for whom NU IRB will have oversight responsibility

- HR approved interns, volunteers, or research staff covered by a reliance agreement.
- **DO NOT** list research staff from other institutions that have their own IRB approval.
Study Team Training

- The NU IRB accepts CITI Training (Basic Course SBS/BIO, Basic Course Refresher), NIH Training, and Investigator 101 Training
  - CIRT training is accepted for community researchers only
  - RCR and GCP Training **DO NOT** fulfill IRB training requirements
  - If a training does not populate, email a copy of the training certificate (within last 3 years) to irbtraining@northwestern.edu
- DOA log as tool to keep track of training dates (Biomed / sBER DOA)

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<tr>
<th>Name</th>
<th>Training Type</th>
<th>Certification Date</th>
<th>Other Description/Notes</th>
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<tr>
<td>Kim Rowan</td>
<td>CITI Biomedical</td>
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Recruitment

• For every recruitment method mentioned in the protocol, the associated material must be uploaded in the "Recruitment Materials" section of the eIRB+ application
  – Emails, phone scripts, flyers, social media posts
  – Consider whether Public or private locations

• Guidance on required elements for recruitment materials is available on our website:
  – Webpage: Recruitment Materials and Guidelines
  – Worksheet: HRP-315 Advertisements (Recruitment Materials)
Consent

• Use of **IRB approved consent templates** ensures compliance with federal regulations
  – Detail key information of the study
  – Detail study duration and all procedures listed in the protocol (in layman’s terms)
  – Detail compensation amount/form/and timing
  – HIPAA/FERPA/MHDDCA

• Studies that include optional elements **must have a clearly-labeled “Optional Elements” section** where participants can opt-in or opt-out

• The **signature block** in consent documents must align with what is described in the protocol
  – One signature block per form
Debriefing

• Studies involving incomplete disclosure or deception should end with a debrief process that fully informs participants about elements that were obscured or falsely represented in the consent process
  – Coercion may be utilized in Exempt studies only if there is a prospective agreement detailed in the consent process, with debriefing after.

• The debriefing process should 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)

• See IRB Office Guidelines for Research Involving Deception and Incomplete Disclosure for more information
# Research Sites

**Sites**

1. **Please specify study site(s):**
   - [ ] Northwestern University (NU) – Evanston
   - [ ] Northwestern University (NU) – Chicago
   - [ ] Northwestern University (NU) – Qatar
   - [ ] Ann & Robert H. Lurie Children’s Hospital of Chicago (Lurie Childrens)
   - [ ] Clinical Research Unit (CRIU)
   - [ ] Northwestern Memorial Healthcare (NMHC) and/or its affiliates (NMH, NMG, NLF)
   - [ ] Shirley Ryan AbilityLab (GRALab)
   - [ ] Robert H. Lurie Comprehensive Cancer Center and/or its affiliate
   - [ ] The Family Institute

2. **Other Sites:**
   
   This section should only include sites engaged in human research. A site is engaged in the conduct of human research when the following are taking place by agents of the institution (see: HRP-101 – Human Research Protection Program Plan):
   - Informed consent
   - Interaction or intervention with participants as part of the research
   - Obtain or analyze personally-identifiable subject data
   - Funding (awardees/institutions)

   Guidance from OHRP on engagement in human subjects research can be found at the following link:

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**Please select NMHC locations:**

- [ ] Northwestern Memorial Hospital
- [ ] Northwestern Medical Group
- [ ] Marianjoy Rehabilitation Hospital
- [ ] NM Central DuPage Hospital
- [ ] NM Lake Forest Hospital
- [ ] NM Delnor Hospital
- [ ] NM Northwest Region (Huntley, McHenry, Woodstock)
- [ ] NM Kishwaukee Hospital & NM Valley West
- [ ] NM Regional Medical Group
Other Research Sites

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- Informed consent
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Guidance from OHRP on engagement in human subjects research can be found at the following link: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

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<th>Phone</th>
<th>Email</th>
<th>External IRB Review</th>
<th>Rely on NU IRB</th>
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There are no items to display

- If an external site received external IRB review, they can be included once the external IRB’s approval or determination is available.
- If an external site will rely on NU IRB, they should be included when reliance agreements are fully executed.
Supporting Documents

• The IRB generally needs to see all research-related material 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
  – Debriefing forms.
Children as Research Participants

• Detail your plan for recruiting and documenting assent/consent/parent permission from all participants and parents involved

• New assent templates have been built/revised to align with developmental considerations
  – 12+ years should be combined with the parent permission form
  – 7-11 years should include a separate assent document with language appropriate to the youngest child
  – Documentation of assent is not required for under 7, but the protocol should still detail a plan for assessing the child’s comfort level/desire to be in the research

• Depending on the age range of participants you plan to recruit, multiple documents may be needed
  – Guidance on Children as Research Participants, Parental Permission, and Child Assent
Review Turnaround Time

• Every project is reviewed on its own merit and when it enters the queue

• There are many factors that impact how long it takes for a study to get approved:
  – IRB work load/ Panel Assignments
  – Type of IRB review (e.g. Exempt, Expedited or Convened Panel)
  – 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.)
Tips and Common Issues for Post-Initial Approval
IRB is Not the Only “Review”

- All studies must undergo institutional reviews
  - Where applicable, review/approval must be obtained from: COI Office, Radiation Safety Office, Cancer Center Scientific Review Committee, NMH Device Committee, etc.

- Ensure that reporting/submitting requirements for all sites are followed
  - When submitting modifications or RNIs to an external IRB of Record, you may need to submit to NU for our acknowledgement too
Reportable New Information (RNI)

- During the course of a research study UPIRSOs and Non-compliance may occur and need to be reported to the IRB
  - Submit RNI in eIRB+
  - Don’t be afraid to report!
  - The purpose is to identify, evaluate, & take action to prevent recurrence

- Perform Root Cause Analysis (RCA)
  - Focus on identifying underlying problems that contribute to the error rather than mistakes made by individuals.
  - Identify the cause/source of a deviation or problem so that it can be resolved and prevent recurrence

- Prepare Corrective and Preventive Action (CAPA) Plans
  - Specific: Identify actions to address the root cause, the individual (role) responsible for taking actions, and where documentation of actions will be kept
  - Timely: Include the date(s) when the actions were/will be completed
  - Measurable: Include a process of assessment of the action plan effectiveness and a process by which the plan will be amended if it is found to be ineffective.
Compliance Tips & Tricks

• View the protocol as source of truth
  – Submit changes prior to implementation via a Modification
  – Ex: increase enrollment numbers, update the dates for chart review

• Emphasize the importance of Version Control

• Use required template language

• Opening a chart = enrolling a participant, HIPAA authorization or waiver required

• The PI must maintain regulatory documentation for their study outside the eIRB+ system
  – eIRB+ and Legacy systems do not meet requirements for PI’s Regulatory Binder or Research Records

• Close out your inactive studies!
  – Principal Investigator Transfer of Responsibility Guidelines
Compliance Resources

• **Post-Approval Monitoring Program:** Proactively identify and address potential compliance concerns through monitoring and targeted education
  – Checklists help PIs evaluate their research and identify potential noncompliance issues before they become serious
  – Template checklists are available on the website [IRB’s Checklists Page](#)

• **Resources Available**
  – [Study Support Resources and Templates](#)
  – [Post-Approval Monitoring & For-Cause Audits](#)
Tips and Common Issues for Modifications & Continuing Reviews
Choosing the Type of Modification

- 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.
Provide Rationale for Modifications

**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 (provide a plan of how you will notify subjects in section 3 below)
   - [ ] Former subjects will be notified of these changes (provide a plan of how you will notify subjects in section 3 below)
   - [ ] No subjects will be notified (provide a reason why subjects will not be notified in section 3 below)

Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. **Please provide a brief summary and rationale for the modifications, including any plan to notify participants of changes (if applicable).**

   If there are updates to the IB (Investigator Brochure), please indicate if the updated IB:
   - a. affects the risk-to-benefit ratio of the study thereby requiring a change to the study documents;
   - b. affects alternatives available to study participants; and/or
   - c. represents new information that should be provided to participants.
Revised/Updated Study Documents

- Revised documents (e.g. consent, protocol, questionnaires) **must** be uploaded with all changes tracked.
  - Please **do not highlight** the changes; we will send the modification back to you!
- Remove all previously tracked changes in a study document before starting to work on the new changes, **including** the previous approval stamped header.
- Remember to consider all possible study documents that might be affected by the change to the study, such as:
  - Updated IBs impacting risk
  - Documents for relying sites or training certificates for external members
  - Radiation Safety form for updated activities involving radiation
  - New or updated recruitment materials
  - Revised Data Collection tools
  - Updated Investigators Brochures, package inserts, or FDA letters
Enrollment Totals – CR Q#1

- “Subjects enrolled” = the total number of consented participants (# of consent forms, including online and verbal consent)
  - If data review only study, include the number of records utilized in the research
  - Please do not include screening failures in subjects enrolled
- “Total” = number of consented participants (# of consents) since the beginning of the study
- “Since Last Approval” = number of consented participants (# of consents) since the last CR. If it’s the first CR, input the # of consented 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.
Research Milestones- CR Q#2

- If any of these boxes are selected, we will expect the first box ("Study is permanently closed...") to be selected as well.

2. Research milestones: (select all that apply)
   Note: The first four checkboxes are sequential and describe the milestones of the overall study. If the first four milestones have been met and are checked, then the study will be closed.
   NEW: If your study is closed to enrollment, the IRB will not finalize your consent form(s) with a new expiration date. Please provide a justification in section 4 if you do need the consent form(s) finalized with a new expiration date.

   - [ ] Study is permanently closed to enrollment OR was never open for enrollment
   - [ ] All participants have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no participants were enrolled)
   - [ ] Collection of private identifiable information is complete OR not applicable (no participants were enrolled)
   - [ ] Analysis of private identifiable information is complete OR not applicable (no participants were enrolled)
   - [ ] Remaining study activities are limited to data analysis only
   - [ ] Study remains active only for long-term follow-up of participants.*

* Note: Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a participant for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.
Resources
Resources and Guidance

• Please visit our website for further guidance
  – Templates and Forms includes required protocol, consent, and supporting documents templates
  – SOPs, Checklists, Worksheets, Policies, and Guidance Documents are also available

• Sign-up to attend office and drop-in hours
  – Social Behavioral Drop-In Hours
  – Reliance Office Hours
Thank you for your time!

Biomedical: irb@northwestern.edu
Social Behavioral: sbsirb@northwestern.edu
Compliance: irbcompliance@northwestern.edu
Training: irbtraining@northwestern.edu
Reliance: irbreliance@northwestern.edu