Submission Tips & Avoiding Common Mistakes

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New Projects

- Funding Section – Always use the drop down menu to choose the funding source.

- Special Studies Consideration – Only check Chart Review box if that is the only procedure in the protocol.

- Drugs/Device Sections – If NU holds the IND or IDE, then provide FDA correspondence.
Consent Process Description

Inadequate Response:
- The research team will explain the details and collect the signed consent form.

Adequate Response:
- The PI or Co-I will approach potential subjects during their clinic visit. They will review the consent form document with the subject and discuss the possible risks and benefits of participation, as well as alternatives. There will be adequate time for the subject to consider participation and have all their questions answered. Once the subject decides to participate, they will be asked to sign the consent form and a signed copy will be provided to them. The consent process will be documented in the medical record and the original signed document will be stored with the study record in a locked cabinet.
Consent Form

Follow the template, especially the following sections:

- Financial Information
- Research-Related Injury *(Get OSR Email if it Deviates)*
- Questions and Concerns
- Subject Rights
- Confidentiality
- Consent Summary & Signature
Consent Form

- Always use a clean footer and do not enter any information in the footer or delete fields.

- Use lay language and simple sentence structures.

- Do not include risks of standard of care procedures.
Consent Waivers

Why is it not feasible to conduct the research without a waiver of consent:

Inadequate Response:
• This is a retrospective chart review

Adequate Response:
• Due to the retrospective nature of the study, many subjects may be deceased or may no longer be being seen at Northwestern. It would be near impossible to contact patients for consent.
Revisions

- Always upload tracked versions of amended consent forms, recruitment materials and questionnaires into question 6.0.
- Always provide summary of changes for protocols, investigator’s brochures and any sponsor correspondence.
- In the description of the event provide the current status of the study and how these changes will affect NU subjects.
Safety/Others

- Review reporting criteria to determine if the event even needs to be reported:
  - Unanticipated Problem involving Risk to Subjects or others
  - Non-compliance that compromised the rights and welfare of subjects or compromised the integrity or interpretability of the data.
- In the description of the event provide the current status of the project and how these changes will affect NU subjects.
Safety/Others – Corrective Action Plans

**Inadequate Plan:**
- The person responsible for this event has left the university.

**Adequate Plan:**
- To avoid dosing errors in the future, the PI has re-educated all co-investigators on protocol drug dosing and when dose modifications are necessary. Once the investigator writes the prescription, the research nurse will review it to confirm that it is compliant with the protocol, before it is filled by the pharmacy.
Responses

- Always include a point by point response to IRB comments.
- Always use tracked changes to show edits that have been addressed. Never use highlights.
- If there is a change you do not wish to make, please include your reasoning.
Questions