# Initial Submission Guidance

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**Brief protocol and submission summary:**

Members are expected to come to the meeting as “informed discussants”, therefore, you do not need to reiterate the study design and methodology in detail. Rather, mention any notable features about the research that you think are important to frame the conversation at the convened meeting. This may include the study purpose, key eligibility criteria, design, study products, other study required procedures, any connection to prior studies that the UNC IRB has approved, etc. 3-5 sentence summary will generally be sufficient (see example below).

Example: This is a single/multi-site double-blind study in which 100 (XX at UNC) participants ages (range) with (major inclusion criteria) but without (major exclusion criteria) are randomized 1:1 to 6 weeks of X (active intervention) or Y (placebo, waitlist, etc.) and undergo (list key assessments) while completing (weekly, monthly, etc.) study visits (in person, virtually, both). The study drug/intervention/manipulation is intended to improve XX or reduce YY, etc. The primary outcome(s) of the study is/are efficacy at week X based on (name the measures, test, variables), safety (with a focus on A, B such as risks to liver, heart, etc.). Mention if Scientific Review Committee (SRC), Lineberger Protocol Review Committee (PRC), or other external review of a Master Protocol and/or grant.

**Criteria of Approval (111): provide justification for how each criterion is met or identify additional steps or measures needed for each to be satisfied.**

1. Risks to subjects have been minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (Sections. A.1, A.4, A.2.A, A.6, A.8)
   1. Describe the main physical, psychological, and other risk(s), including those associated with drugs and/or devices. State which of the risks are greater than minimal risk (GTMR).
   2. Explain what measures the study team is taking to minimize risk.
   3. Identify any additional measures or steps needed to minimize risk OR state that the measures, in your opinion, are adequate to protect participants (note, stipulate for additional measures).
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result. (Sections A.1, A.2.A, A.5, A.6)
   1. State the benefit to society (what new knowledge will be gained and how will it help?)
   2. State the direct benefit to the participant or indicate there is no direct benefit.
   3. State why you think the risks are reasonable (e.g., given the refractory nature of the disease, given the privacy protections, given the exclusion of severely ill/vulnerable persons because of Exclusion Criterion #).
3. Selection of subjects is equitable. (Sections A.2, A.2.A, A.3, B.1, B.2)
   1. Summarize the recruitment plan (who, by whom, where, and how) and comment on its adequacy for ensuring equitable selection of participants given the scientific aims of the study.
   2. State the scientific or otherwise reasonable justification for the exclusion of any population.
   3. If requesting a Limited HIPAA Waiver (B.2.), verify that documentation is complete and that the review and/or collection of protected health information (PHI) is limited to the minimum necessary to meet the research needs (e.g., to screen for eligibility) (compare B.2. to A.3).
4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative as outlined in 45 CFR 46.116. (Sections D.1, D.2, D.3)
   1. Summarize the steps of the consent process and comment on its adequacy (e.g., adequate time for the process and for the individual to consider participation, opportunity to ask questions, confirm that the individual is provided with a copy of the consent document).
   2. Describe measures for mitigating potential coercion and undue influence.
   3. Indicate whether the investigator will seek the assent of children and/or individuals with impaired decision-making capacity.
   4. If any consent waivers are requested, explain the rationale for the waiver(s) and provide your assessment regarding the appropriateness of the request.
5. Informed consent will be documented appropriately as outlined in 45 CFR 46.117. (Section D.1)
   1. State the method(s) by which consent will be documented, e.g., electronic, paper/pen, verbal.
   2. If children and/or individuals with impaired decision-making capacity will assent, indicate how it will be documented (written, verbal).
   3. State whether all required elements for consent are included in the consent form(s) and identify any shortcomings that need to be addressed through stipulations (e.g., cost of non-research activities is missing, the study drug is not described as investigational /experimental, the risk of X is missing and this must be included because . . . ).
   4. State whether the consent and/or assent form(s) is/are appropriately written for the target population(s) and identify any shortcomings that need to be addressed through stipulations (e.g., medical or other complex terms that require insertion of lay language for participant understanding).
   5. Indicate whether the consent/assent forms include the correct signature lines.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (Section A.7)
   1. Summarize the plan for monitoring data for safety (including scale for monitoring AEs), including the person (e.g., PI) or entity (e.g., DSMB) and frequency.
   2. Describe key discontinuation, pausing, and/or stopping rules for both individual subjects and the entire study.
   3. Explain why, in your assessment, the plan is appropriately calibrated to the study risk level.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (A.6, A.9, A.10, A.11, A.12, B.1, B.2, B.3)
   1. State how privacy is protected during in-person and/or virtual interactions and whether these measures are adequate.
   2. State the main data protection strategies and whether these strategies are adequate.
8. When some or all the subjects are likely to be vulnerable to coercion or undue influence (i.e., children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons) describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects. (Sections A.2, A.2.A, B.4, D.1)
   1. State what vulnerable population(s) is/are included.
   2. State whether the specific study risks and overall study risk level are different for vulnerable participants and, if so, why.
   3. State the additional safeguards employed in the study to protect their rights and welfare.
   4. Provide the regulatory determination for the inclusion of the vulnerable population(s) based on the risks and benefits of the study activities and their participation (e.g., 45 CFR 46.404, 5, 6, or 7 for children; refer to [OHRE SOP 1201](https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=132228) re: pregnant women, fetuses, neonates; prisoners).

**Investigational Devices (IDE; Section A.4.A.5):** Provide rationale for device(s) risk level(s) based on the IDE Worksheet, Device Description, etc.

1. If Significant Risk (SR) device, indicate where IDE number is documented.
2. If applicable, present the rationale for IDE Exemption or NSR.

**Investigational Drugs (IND; Section A.4.A.4):** Provide rationale for drug(s) risk level(s) based on the IND Worksheet, Drug Inserts/Brochures, etc.

1. If a study has an IND, indicate where the IND number is documented.
2. Present rationale for IND Exemption, if applicable. Be sure to include your assessment of increased risks or decreased acceptability of risks based on changes in route, dosage, or study population.

**Conflict of Interest determinations:**

State what conflicts, if any, have been identified.

Confirm acceptance of conflict management plan(s) or provide recommendations for modifications to conflict management plan(s).

**Additional Considerations for Federal Sponsors** (Complete Additional Considerations checklists as needed; checklists available in IRBIS alongside the Committee Review list of submissions)

DoD, DoN, DoE, DoEd, DoJ, EPA; confirm all requirements are met.

**Overall Study Risk Level** State the overall risk level for the study (Minimal Risk OR GTMR)

If Minimal Risk, identify the applicable expedited category for each study procedure:

Category 1: clinical study involving drugs or devices

Category 2: blood sampling

Category 3: non-invasive collection of biological samples

Category 4: non-invasive clinical procedures

Category 5: data and samples not collected for this research study

Category 6: audio, video, and image recordings

Category 7: survey, interview, questionnaire, observations

Category 9: study procedures do not fit into 2-7.

If Minimal Risk, identify the annual review type:

Administrative Review (standard default type).

Expedited Continuing Review: provide rationale.

Continuing Review by a convened board: provide rationale.

If GTMR, refer back to section 1.a. and briefly restate the GTMR elements of the study

**Recommendation:**

Approval / Approval with stipulations. The default approval period is 12 months. If shorter review cycle, provide justification.

Deferral. If Deferral, cite which of the 111 criteria are not met and why.

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2. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative as outlined in 45 CFR 46.116.
5. Informed consent will be documented appropriately as outlined in 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all the subjects are likely to be vulnerable to coercion or undue influence (i.e., children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons) describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects.

**Investigational Devices (IDE; Section A.4.A.5):**

**Investigational Drugs (IND; Section A.4.A.4):**

**Conflict of Interest determinations:**

**Additional Considerations for Federal Sponsors:**

**Overall Study Risk Level**

**Recommendation:**