IRB SUBMISSION TIPS AND BEST PRACTICES

The Office of the Institutional Review Board (OIRB) has identified best practices and guidance for researchers to take into consideration when developing a research protocol involving human subjects.

Contents

1. When in doubt, come to the OIRB Virtual Office Hours.

- The Office of the Institutional Review Board (IRB) holds virtual office hours to augment current services as an opportunity for members of the UAB research community to have direct access to an experienced OIRB staff member.
    - Held bi-weekly on Thursdays.
    - 11:00 AM to 1:00 PM
- For Zoom meeting information, search UAB Campus Calendar for "**Office of the IRB Virtual Office Hours"** or join the OIRB Listserv for Zoom information.

2. Use the most recent IRB sample forms.

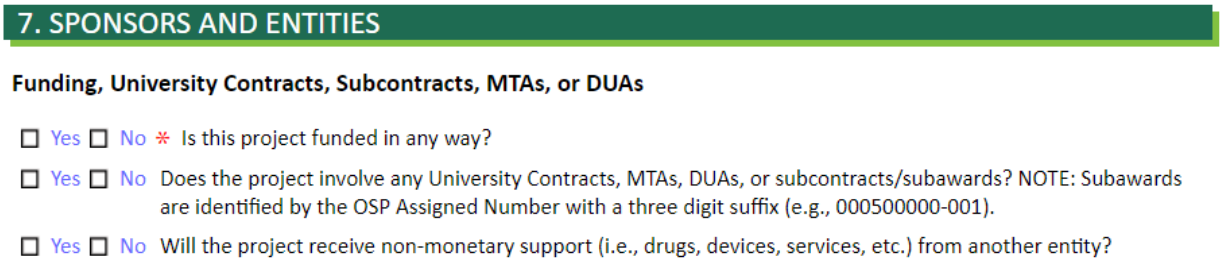
- Current sample forms are available here.
- Don't try to reinvent the wheel or assume that a previously approved form is the best template for all studies.
- Pay special attention to HIPAA Authorization language. Instead of using the standalone authorization form, use the most recent sample consent form with the HIPAA Authorization language imbedded in the document.

3. Ensure all ancillary reviews and/or related content language relevant to other UAB regulatory or compliance offices are included in the submission.

- UAB Radiation Safety Program - Review and approval should be done before IRB submission.
    - Submissions should be made for studies that involve x-rays and scans.
    - The IRB submission should include the appropriate language in the consent form.
    - For more information, visit: https://www.uab.edu/research/home/radiation-safety
- Institutional Biosafety Committee (IBC) - Review and approval should be done before IRB submission, if applicable.
    - Submissions should be made for studies that involve all research (regardless of funding) involving:
        - recombinant or synthetic nucleic acid research classified as non-exempt by the *NIH Guidelines*,
        - all agents capable of causing illness in man (designated Risk Group 2 and above)
        - the use of toxins.
    - For more information, visit: https://www.uab.edu/research/home/rsc/rsc-ibc

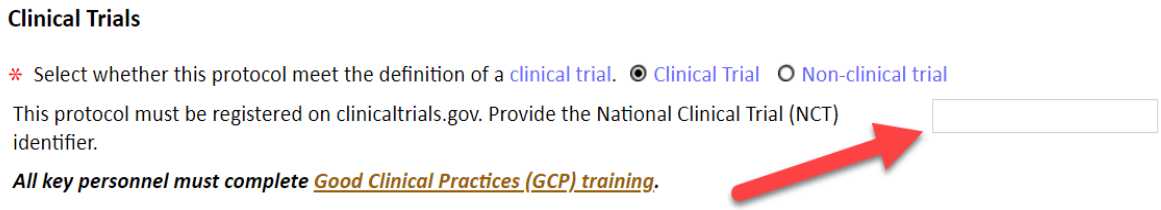
4. Provide sponsor and funding information with your submission.

- Information related to your funding or sponsor should be included on your IRB submission application.
- Missing funding information will likely result in delays in your review and/or release of funds.



5. NCT identifier requirement for clinical trials

- All clinical trials, regardless of funding, must be registered on clinicaltrials.gov, and the NCT number must be provided in the ePortfolio.
- **NOTE:** NCT identifiers are **required** for IRB approval of a clinical trial; however, if all other information is complete and accurate, pending NCT identifiers can be obtained in parallel with the IRB's review of the submission.



6. Ensure all applicable initial/basic training and refresher training is up-to-date, as applicable.

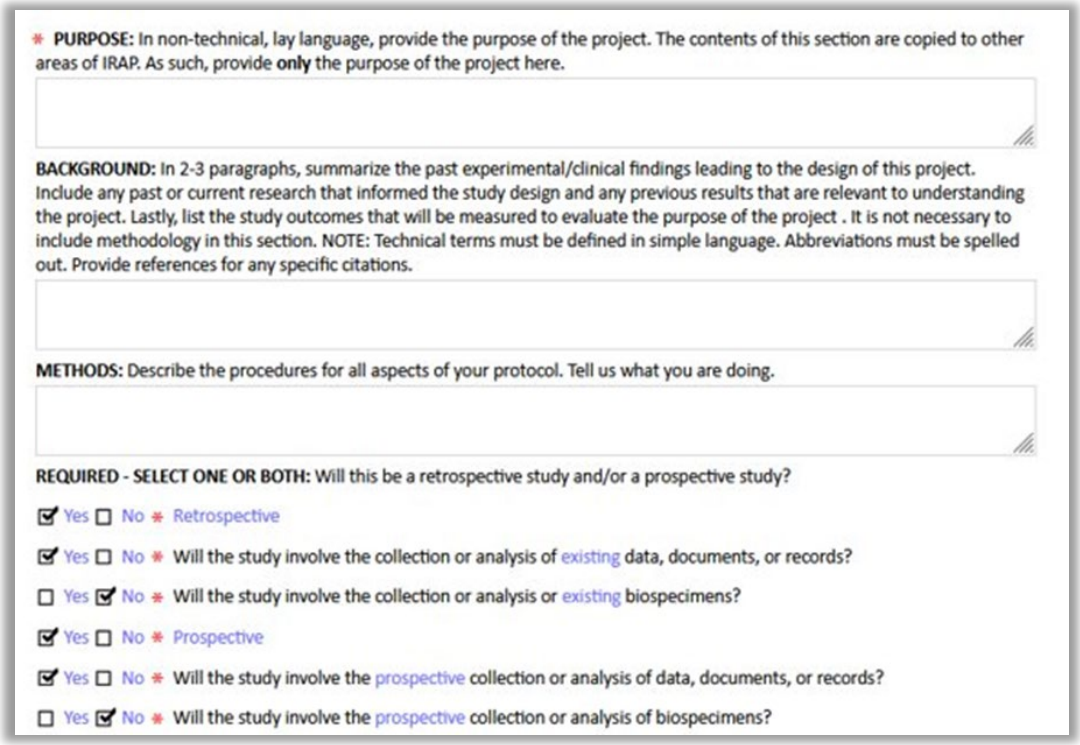
- IRB Training
  - All research staff, including the Faculty Advisor, are expected to have current IRB training prior to conducting research.
  - Any one (1) of the following options listed below may be completed to fulfill the Initial IRB training requirement.
    - CITI Online Training (https://www.citiprogram.org)
    - "IRB Training – Biomedical"
    - "IRB Training - Social and Behavioral"
    - UAB Course: GRD 717: Principles of Scientific Integrity

        - CCTS Research Training Program (offered twice a year)
        - For New UAB Researchers: Transferred Human Subjects Protection Training from previous institution
    - IRB Training is valid for 3 years from the date of completion. After training expires, a refresher course, below, must be taken.
        - IRB Refresher Training – Biomedical
        - IRB Refresher Training – Social, Behavioral, Educational (SBE)
    - Note that investigators should only complete one refresher course.
- <u>Good Clinical Practice (GCP) Training</u>
    - All key personnel on a study considered a clinical trial must complete GCP training.
        - Clinical Trial (NIH definition):
            - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
    - GCP Training is valid for 3 years from the date of completion. After training expires, the Good Clinical Practices (GCP) Refresher course must be taken.
- <u>Financial Conflicts of Interest (FCOI) Training and Disclosures of Financial Interests</u>
    - All individuals responsible for the design, conduct, or reporting of research are required, by federal regulation and UAB Enterprise Policy, to complete training on conflicts of interest prior to engaging in research and charging effort to a federally-sponsored program.
    - FCOI training is valid for 4 years from the date of completion.
    - FCOI Courses are available through the Campus Learning System (Docebo LMS).
    - Additionally, all responsible Key Personnel must complete an annual Disclosure of Financial Interests.
    - For more information on submitting a disclosure, visit the following page: https://www.uab.edu/research/home/cirb/submit-a-disclosure-of-financial-interests.
    - **NOTE:** While the IRB ensures that responsible personnel have taken the appropriate FCOI course and completed a disclosure, the course and disclosures are required and maintained by the Conflict of Interest Review Board (CIRB). For more information, please visit CIRB's website at https://www.uab.edu/research/home/cirb.

7. Provide thorough Methods information.

- On Page 1 of the ePortfolio (General Questions), the Purpose, Background, and Methods questions must be completed clearly and accurately for the IRB staff reviewer to apply the appropriate review category.

- Methods should be in chronological order and should include all aspects of the participant's experience from recruitment to completion.
- Tell us what you are doing in lay language.



* **PURPOSE:** In non-technical, lay language, provide the purpose of the project. The contents of this section are copied to other areas of IRAP. As such, provide **only** the purpose of the project here.

BACKGROUND: In 2-3 paragraphs, summarize the past experimental/clinical findings leading to the design of this project. Include any past or current research that informed the study design and any previous results that are relevant to understanding the project. Lastly, list the study outcomes that will be measured to evaluate the purpose of the project . It is not necessary to include methodology in this section. NOTE: Technical terms must be defined in simple language. Abbreviations must be spelled out. Provide references for any specific citations.

METHODS: Describe the procedures for all aspects of your protocol. Tell us what you are doing.

REQUIRED - SELECT ONE OR BOTH: Will this be a retrospective study and/or a prospective study?

☑ Yes ☐ No * Retrospective

☑ Yes ☐ No * Will the study involve the collection or analysis of existing data, documents, or records?

☐ Yes ☑ No * Will the study involve the collection or analysis or existing biospecimens?

☑ Yes ☐ No * Prospective

☑ Yes ☐ No * Will the study involve the prospective collection or analysis of data, documents, or records?

☐ Yes ☑ No * Will the study involve the prospective collection or analysis of biospecimens?

8. Ensure all documents/forms have consistent information.

- IRB Submissions involve various types of documents submitted within the ePortfolio. For example:
    - Letters of Support: required for off site use of facilities. They may also be necessary from your work unit if you are using resources or data or are implementing a new standard of care process. Letters of support are also required for the use of other's research data.
    - Recruitment Tools: All tools to be utilized (e.g., surveys, educational materials, recruitment materials, postcards, scripts, release forms, etc.) submitted and properly described by name.
    - Consent forms and information sheets
- Ensure these documents contain concordant information. For example:
    - Number of subjects in the ePortfolio vs the consent form
    - Duration of participation stated in the ePorftolio vs the consent form
    - Procedures described in the ePortfolio vs the consent form
- To summarize, be thorough and be consistent.

9. Beware of typos.

- The purpose of the consent form is to *aid* in providing prospective subjects adequate information for them to make a decision regarding whether or not to participate in research. Thus, keep in mind the information presented by the consent form must be clear and understandable.
- The consent form should be free of the following:
    - Spelling errors
    - Content that is separated, bolded, indented or has odd page breaks and spacing.
    - Odd font types and sizes
- Such errors may cause the review process do be delayed due to the need of verifying whether edits were, in fact, typographical errors, issues of inconsistent information or something of greater significance.

10. Updating Consent Form Version Dates

- Version dates allow the IRB to quickly assess current versus outdated forms and are important for version control, especially after initial submission.
- Each time a consent form is updated, the version date must also be updated.

11. Use Lay Language in Consent Forms (and Other Documents)

- The use of lay language is important to ensure participants understand the information presented to them in consent forms, scripts, and other recruitment materials.
- While you are an expert in your field, the IRB includes members from all walks of life that might not have a great understanding of the jargon used in your field. Please make sure you complete all forms in non-technical, lay language as much as possible.

12. Consent Form Signature Lines

- Ensure all consent forms have appropriate signature lines. For example:
    - Legally authorized representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(c)).
        - This is different from the requirement to obtain parental consent for minor participants. Be sure to include a Parental/Guardian signature line if enrolling minors.

13. Other Things to Remember for the Consent Process

- Consent is a must if interacting with participants in a study involving human subjects, though the requirement for consent might be less if the project is exempt.
    - If Full or Expedited, use the sample consent form here, if HIPAA applies, or here, if HIPAA does not apply.
    - If Exempt, use the sample information sheet here.
- Consent is a *process*, not just a form, and it can involve many tools:
    - Oral script, cover letter or information sheet
    - Recruitment ads, notices, or invitations
    - Parent/guardian consent forms
    - Child Assent forms
- Ensure that the process of consent is thoroughly described and that any documents include:
    - All required and any applicable additional elements
    - Language at an 8th grade reading level
    - No jargon or exculpatory language
    - Consistency with information in the ePortfolio (as applicable)
- Clearly state the difference between activities that are “standard of care” and “research”.
- All information that will be shown or provided to participants is considered to be a part of the process of informed consent and requires IRB approval.

- For more information the “Informed Consent FAQs” on the HHS.gov website: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

14. Application of HIPAA

- If you are a member of a HIPAA covered entity and accessing identifiable private health information, the HIPAA Privacy Rule applies, and you must either:
    - Obtain written authorization; or
    - Request a waiver of authorization if not “practicable” to obtain a signature. If requesting a waiver, be sure to provide justification that it is not practicable to obtain authorization and fulfill any additional requirements necessary for a waiver of authorization. For more information, visit the IRB Policies and Procedures tool here, and review POL012/PRO112.

15. Include all participant facing materials.

- Recruitment materials, including flyers, phone scripts, and email templates
- Intervention materials (i.e., presentations for an educational study)
- All surveys/questionnaires
- Focus group/interview guides

16. If using an FDA regulated test article (drug or device), or if the project will support a submission to the FDA, the protocol must be expedited or full.

- FDA does not recognize the OHRP exempt categories.
- **NOTE:** Software can be considered a medical device.

17. Be very clear in your purpose statement.

- The Purpose should always imply a research question (i.e., does x affect y?) or specify a quality improvement intent (i.e., implementing an already proven practice at a specific UAB location).
- Your purpose is never “to collect data…” Collecting data is *what* you are proposing to do, not *why*.
- *Why* you are conducting this project is often just as important as what you are doing.

18. Take the application questions at face value.

- Answer the only the question being asked in the field provided (i.e., recruitment questions should not detail the full protocol methods.).

19. Use the Microsoft Word Track Changes feature when possible.

- Any time a previously reviewed document changes, whether in a Response to Info/Mod Request or in a Revision/Amendment, be sure to include both a “tracked” copy showing the individual changes and a “clean” copy with the changes accepted.

20. Answer questions in the IRB ePortfolio as they appear.

- The ePortfolio relies heavily on branching logic, which means that the answer to one question may trigger other questions/sections/pages. If you skip around in the form, you will likely miss questions.