IRB Submission Guidebook

Best Practices and Resources

Office of Institutional Review Board (OIRB)
UNIVERSITY OF ALABAMA AT BIRMINGHAM

SUPPORT AND RESOURCES FOR SUCCESS

This guidebook provides researchers with essential best practices and actionable guidance for developing research protocols involving human subjects. Compiled by the UAB Office of the Institutional Review Board (OIRB), it highlights key considerations for ensuring ethical compliance, regulatory adherence, and submission success.

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Introduction

Purpose of the Guide:

This guidebook provides researchers with clear directions to navigate the IRB submission process. It outlines key requirements, best practices, and resources to help ensure a smooth and timely submission. The goal is to make the process easier by offering practical advice on documentation, approval, and common challenges. By following this guide, researchers can ensure their initial application meets IRB expectations and avoid unnecessary delays.

This guidebook serves as a **living document**, regularly updated to reflect the most current processes and requirements. Additionally, utilize the trainings, links, and resources provided here, as they offer further detailed guidance and support to help you succeed in preparing your submission efficiently.

Importance of IRB Submissions:

The IRB submission process is critical for ensuring ethical research practices and protecting the rights and welfare of human subjects, as outlined in the Federal Policy for the Protection of Human Subjects, commonly known as the **Common Rule (§46.101-§46.124)**. IRB approval confirms that research complies with legal, ethical, and safety standards established under federal regulations, including **45 CFR 46** and, for FDA-regulated studies, **21 CFR 50 and 56**. This process upholds the integrity of both the study and the institution. Submitting a complete and accurate application is essential to avoid delays, ensuring your research aligns with the highest ethical and regulatory standards. To approve a study, the IRB evaluates it against specific criteria to ensure compliance with federal regulations and ethical principles:

- **Minimization of Risks**: The research design must minimize potential risks to participants through careful planning and implementation.
- **Risk-Benefit Analysis**: Risks must be reasonable in relation to the anticipated benefits to participants, if any, and the importance of the knowledge to be gained.
- **Equitable Subject Selection**: Participant selection must be fair and appropriate, considering the purpose and setting of the research.
- **Informed Consent**: Consent must be sought from participants in accordance with §46.116, ensuring they are fully informed about the study's purpose, procedures, and risks.
- **Documentation of Consent**: Informed consent must be properly documented in alignment with regulatory standards.

- **Data Monitoring**: Adequate provisions must be in place to monitor collected data to protect the safety and well-being of participants.
- **Privacy and Confidentiality**: Measures must be implemented to safeguard the privacy of participants and the confidentiality of research data.

Understanding Integrated Research Administration Portal (IRAP)

The IRB submission process at UAB is managed through IRAP, the university's electronic research administration platform. IRAP facilitates various research-related activities, including compliance management, training, and document tracking. This platform also includes tools such as the ePortfolio research application and Personnel eForm, which are essential for submitting and managing IRB protocols. Specific training is available to help researchers understand how to navigate IRAP effectively, including guidance on its components like the ePortfolio. For details on this training and other trainings to ensure a successful submission, refer to the section **'Getting Started: Essential Training'** below. Gaining proficiency with IRAP ensures researchers can streamline their submission process and meet compliance requirements efficiently.

When to Submit:

It is important to submit your IRB application well in advance of your intended research start date. While approval times can vary, early submission allows for thorough review and any necessary revisions. Allowing sufficient time for submission helps ensure a smoother approval process and minimizes the risk of delays that could disrupt your research timeline.

Keep in mind that IRB submissions are categorized as exempt, expedited, or convened/full, but these labels reflect the nature of the review and **not the time required for approval**. Planning ahead ensures you're ready to start your research on time, regardless of the review type.

Access Expert Support Through Virtual Office Hours:

The Office of the Institutional Review Board (IRB) offers virtual office hours to provide direct access to experienced OIRB staff members for assistance with your submission. These sessions are held bi-weekly on Thursdays from 11:00 AM to 12:30 PM, offering a valuable opportunity to clarify any questions or issues. Whether you're navigating the submission process or need guidance on your protocol, our staff is available to provide support. For Zoom meeting details, please visit the UAB Campus Calendar at https://calendar.uab.edu/event/oirb_virtual_office_hours_6879 or join the OIRB Listserv for updated information. Sign up for the IRB ListServ: https://forms.uab.edu/186

Special Considerations Before Proceeding with the Guidebook

Before diving into the full application process, it is important to evaluate specific factors that could affect how you proceed with the IRB submission. Depending on the classification of your study—whether it is human subjects research, falls under Single IRB review, or is determined to be outside the scope of research—certain procedures and requirements may differ.

Is This Research?

The Quality Improvement (QI) Self-Determination Tool is designed to help researchers determine if a project falls outside the scope of IRB review by not meeting the federal definition of human subjects research under 45 CFR 46. This tool is intended for projects aimed at quality improvement or program evaluation. While the tool aids in self-determination, it does not constitute IRB review, approval, or exemption, and users must ensure their responses are accurate.

Projects determined to be QI using this tool can include a statement in publications indicating that they do not constitute human subjects research. However, the tool is not suitable for all Not Human Subjects Research projects, such as public health surveillance projects, which require submission with the UAB IRB Office.

For further details and to access the tool, visit the QI Self-Determination Tool at https://uab.co1.qualtrics.com/jfe/form/SV_6FJOgRxg81Eqge2.

Is This Human Subject Research?

Certain research activities may qualify for the designation of "Not Human Subjects Research" (NHSR) if they do not meet the federal definitions of research or human subjects as outlined by HHS and FDA regulations. Examples of NHSR activities include using data or specimens that have been de-identified prior to receipt by the investigators, outdated blood products, cadaveric materials, or publicly available data. Additionally, specific scholarly, public health, criminal investigative activities, and national security activities, as described in 45 CFR 46.102(l) (1-4), are not considered human subjects research.

It is important to note that **only the OIRB can make the official determination of NHSR status**. Investigators must submit an application through IRAP using the IRB ePortfolio to request this designation **before conducting research**. NHSR determinations cannot be issued retroactively for research that has already been conducted.

To assist with the submission of your NHSR determination request, refer to the NHSR fact sheet available here: https://uab365.sharepoint.com/:b:/s/research/EZOA-1N_p4hBsaxznNvbNSUBVLZwhFPWcB9XYaRBNoj1pA?e=AdW4gc

For further details, visit the NHSR Designation page at https://www.uab.edu/research/home/nhsr-designation.

Single IRB

The Single IRB (sIRB) model is designed to streamline the review process for NIH funded multi-site studies by allowing multiple sites conducting the same protocol to use a single IRB for review, rather than having each site undergo separate reviews by different IRBs. Depending on whether UAB is the prime institution or a site on the study, and whether the review is conducted by UAB's IRB, an independent IRB, or an external IRB, different procedures, and requirements, and forms may apply when submitting an application for review. It is important to understand these variations to ensure compliance and avoid delays.

For more detailed information on Single IRB procedures and requirements, visit the Single IRB page at https://www.uab.edu/research/home/single-irb.

Getting Started: Essential Training

Required Personnel Training for Human Subjects Research:

At UAB, **key personnel** refers to anyone directly involved in the design, conduct, or reporting of research involving human subjects. This includes principal investigators, co-investigators, faculty advisors, and research staff. UAB requires all key personnel to complete specific training in human subjects protections to ensure compliance with ethical and regulatory standards. **Failure to complete these trainings is one of the most common reasons applications are returned or delayed**.

- **IRB Training**: All involved research staff must complete the initial IRB training, with refresher training required every 3 years. Accepted training options include CITI Online Training, UAB's GRD 717 course, or the CCTS Research Training Program.
- **Good Clinical Practice (GCP) Training**: Required for all personnel involved in clinical trials, with refresher training every 3 years. Clinical trials must also be registered on clinicaltrials.gov before IRB approval is granted.
- **Financial Conflicts of Interest (FCOI) Training**: Required for individuals responsible for the design, conduct, or reporting of research. Initial training is required, followed by refresher training every 4 years. All key personnel must also submit an annual Disclosure of Financial Interests.

Make sure that all personnel complete the necessary training before submitting your application to avoid unnecessary delays in the approval process. For details on key personnel, refer to the section **'Personnel eForm Overview'** below.

Currently, the OIRB is automatically notified of courses completed through CITI or UAB WebCT. All other online training options, including UAB's GRD 717 course, require verification by submitting certificate of completion with the application.

How to Check & Verify Trainings

- Visit the Office of Research E-Reports website at https://research-bi.ad.uab.edu/reportserver?/default.html&rs:Command=GetResourceContents.
- Click on "Office of Institutional Review Board (OIRB)."
- Scroll down and select "IRB Investigator Training by Name" to confirm up-to-date training for all key personnel involved in your research.
- If a name or training does not appear (e.g., due to outside training or use of a different email), attach confirmation of the training in the ePortfolio under Section 31.

For more information and access to training courses, visit the UAB IRB Training page at https://www.uab.edu/research/home/irb-training-page.

Additional Essential Trainings:

To enhance your understanding of the IRB review process and submission procedures, UAB offers three **highly recommended** training courses. These optional but valuable resources provide specific guidance on using the ePortfolio system and navigating protocol submissions effectively.

1. **IRB Initial Application Course**
   This course offers a comprehensive overview of the IRB, the lifecycle of a protocol submission, and step-by-step guidance for using ePortfolio to submit an initial application. Participants will learn to utilize IRAP, successfully submit IRB applications, and access IRAP support.

2. **IRAP Basics Training Course**
   Designed for both new and experienced users, this course explains how to navigate the IRAP system, including configuring the Enable portal and locating module records. Completing this training ensures a thorough understanding of IRAP functionality.

3. **IRAP Delegate Training Course**
   This course clarifies the role of delegates in the IRAP system and provides detailed instructions on assigning or requesting delegation for records. Participants will learn how to view records and manage delegation access effectively. Additionally, the training emphasizes the importance of setting up correspondence permissions. By default, all IRB-related correspondence is sent to the Principal Investigator (PI). However, delegates must be explicitly designated in IRAP to receive these communications. This training ensures researchers understand how to assign these permissions, reducing delays and improving the efficiency of the submission and review process.

How to Access These Trainings

- Visit the UAB Campus Learning Management System (LMS) at https://www.uab.edu/campuslms
- Log in with your BlazerID credentials and search for the desired course (e.g., "IRB Initial Application Training").
- Enroll in the course to begin training.

Preparing for Application Submission: Forms, Disclosures, and Special Approvals

Before the IRB can review your application, specific steps must be completed, including special approvals, disclosures, and additional forms that may apply depending on the nature of your research. These requirements ensure compliance with both IRB and institutional policies. Certain approvals or disclosures, such as financial conflict of interest disclosures or departmental reviews, may be necessary alongside standard forms. Failing to address these aspects thoroughly can lead to delays or hinder the review process.

It may be helpful to review previous submissions from your department if applicable to familiarize yourself with the materials and processes.

Using Updated Forms

To ensure your IRB submission is complete and accurate, it is essential to use the most recent sample forms provided by UAB. Outdated templates or forms previously approved for other studies may not meet current requirements and could lead to delays in the review

process. All required and updated forms and documents must be accessed, completed, and uploaded into the ePortfolio system as part of your submission. This includes forms such as the Protocol Oversight Review Form (PORF), consent forms, and any necessary ancillary approvals.

- **How to Access Forms:**
  Visit the UAB Forms Website at **https://www.uab.edu/research/home/irb-forms** to download the latest forms and ensure your submission complies with current guidelines.

Protocol Oversight Review Forms (PORF)

The Protocol Oversight Review Form (PORF) is a **required document for all Expedited and Full Board/Convened IRB** applications and serves as a critical step in ensuring scientific integrity and quality control for the proposed research. The form must be signed by both the Principal Investigator (PI) and appropriate designee of the dean. UAB policy relies on deans of the schools and the college to ensure a robust scientific review, quality control, and departmental approvals have been obtained and that the study's hypothesis and procedures align with generally accepted scientific principles within the discipline. For this reason, the PI must seek review and approval from the department where their primary appointment is held.

Form 205 is a sample PORF template provided for documenting departmental approval. It is found on the UAB Forms website mentioned earlier in this guide. However, some departments may have their own approved versions of the Protocol Oversight Review Form. Investigators must confirm and use the appropriate form required by their department to document this approval. To avoid unnecessary setbacks, ensure the PORF is completed, signed, and uploaded as part of your IRB submission.

Conflict of Interest

UAB policy requires that the Conflict-of-Interest Review Board (CIRB) review any nonexempt research in which the principal investigator or any individual involved in the study (including their immediate family) has financial or proprietary interests. These include:

- Ownership interests, stock options, or other financial interests.
- Compensation of $5,000 or more in the past year or any amount influenced by the research outcome.
- Proprietary interests such as patents or licensing agreements.
- Board or executive roles related to the research.

The CIRB provides information to the IRB to assist in determining whether financial interests are managed adequately to protect participants, minimize risks, and disclose conflicts to participants. The IRB may require additional measures beyond those recommended by the CIRB. For more details, visit the UAB CIRB website at https://www.uab.edu/cirb.

Subcontracts

When human subjects research involves subcontracts with non-UAB collaborators, the following are required:

- IRB approval from the subcontractor's institution.
- Evidence that the subcontracting institution has a Federalwide Assurance (FWA) with DHHS. If no FWA exists, an Individual Investigator Agreement (IIA) or Memorandum of Understanding (MOU) must be obtained.
- Certification of human subjects protection training for subcontract investigators.

Coordination of subcontracts is facilitated by UAB's Office of Sponsored Programs (OSP). For details, visit the OSP website at https://www.uab.edu/research/home/osp.

Material Transfer Agreements (MTAs)

Material Transfer Agreements (MTAs) govern the transfer of tangible research materials, such as cell lines, plasmids, and proteins, between institutions. These agreements outline ownership, usage rights, confidentiality, and liability.

- UAB requires MTAs for inbound and outbound material transfers to ensure compliance with institutional and legal obligations.
- Intangible research materials, like data or software, are typically handled through Confidentiality Agreements (CDAs).

For more information, visit the UAB Research Foundation (UABRF) at https://www.uab.edu/uabrf or the OSP website at https://www.uab.edu/research/home/osp.

Devices, Inventions, and Patents

If research involves investigator-developed devices or inventions, researchers must contact the UAB Research Foundation (UABRF) for guidance. The UABRF assists with patenting and protecting intellectual property. Learn more at the UABRF website at https://www.uab.edu/uabrf.

Advertisements

Recruitment advertisements for studies must adhere to IRB guidelines to ensure ethical and accurate representation. Key elements include:

- Investigator name, research purpose, and eligibility criteria.
- Description of benefits and compensation.
- Contact information and location of the study.

Ensure the email used for communication and recruitment materials is HIPAA-compliant if applicable, such as a UABMC email address. Using a secure email system helps maintain patient confidentiality and aligns with privacy regulations.

Avoid claims that a therapy or device is safe, effective, or superior, and do not use phrases like “free medical treatment” if this is not accurate. Compensation should not be overemphasized. **All recruitment advertisements must be included and uploaded as part of your application submission.**

Data Safety Monitoring Plans (DSMPs) and Boards (DSMBs)

Data and safety monitoring ensures participant safety and scientific validity.

- DSMPs: Sufficient for most low-risk studies and detail how the investigator and monitoring personnel will oversee safety, report toxicities, and implement stopping rules.
- DSMBs: Required for federally funded Phase III studies and high-risk trials. DSMBs consist of qualified experts, including statisticians, ethicists, and clinical professionals.

Common Ancillary Approvals and Their Requirements

Certain types of research may require additional approvals from UAB regulatory or compliance offices. Examples include approvals for Radiation Safety, and Biosafety. These ancillary reviews must be completed before submitting your IRB application to avoid delays. It is essential to include all relevant language and documentation in your submission to ensure compliance with UAB requirements. The necessary approval forms can be found on the **Forms website** listed above.

- **Where to Check**:
  Visit the Special Approvals Website at **https://www.uab.edu/research/home/special-approvals** to determine which approvals may apply to your study.

Research Involving Special Populations

Research involving certain populations requires adherence to additional regulations and documentation within the application to ensure compliance with federal and institutional policies. These populations include:

- Pregnant Women, Fetuses, and Neonates
- Children/Minors
- Prisoners

For detailed information about research involving special populations, visit the Participant Populations page at https://www.uab.edu/research/home/participant-populations.

Creating a Strong Initial Application

Understanding the ePortfolio

The ePortfolio is an advanced tool designed to consolidate all IRB submission forms into a single electronic format, simplifying the application process. Using branching logic, the system guides users to complete only the questions relevant to their specific applications, streamlining submissions for efficiency and accuracy.

As a single-threaded, "Living Document," the ePortfolio retains responses from the initial application and carries them forward for amendments or continuing reviews. This feature allows researchers to update only the necessary sections, ensuring that information remains consistent and up to date throughout the lifecycle of the study. Processes within the ePortfolio must be completed sequentially.

- **Where to Access Step-by-Step Guidance:**
  Visit the ePortfolio Guidance Documents at http://go.uab.edu/eportfolio for detailed, step-by-step instructions on completing the ePortfolio.

Avoiding Common Pitfalls for a Successful ePortfolio Submission

Submitting an ePortfolio successfully requires careful attention to detail and adherence to IRB requirements. **Many issues arise from incomplete or inaccurate responses, skipped sections, or missing documents, which can delay approval**. The following outlines common pitfalls in completing the ePortfolio and offers actionable guidance for addressing specific sections to ensure a successful submission.

Section 1: General Questions

- Clearly and accurately answer the Purpose, Background, and Methods questions on Page 1 to allow IRB staff reviewers to apply the appropriate review category.
- Methods need be written in **chronological order and thoroughly**, including all aspects of the participant's experience, from recruitment to completion.
- Carefully review and accurately answer the questions regarding **Prospective** and **Retrospective** research. Misclassification can prevent Section 8 (Retrospective) and/or 9 (Prospective) from populating, delaying the pre-review process.
    - **Retrospective Data:** Refers to existing data or biospecimens recorded or collected for purposes other than the current research study.
    - **Prospective Data:** Refers to data or biospecimens that will be collected specifically for the current research study after the research has been approved and begins.
- Use lay language to clearly explain the study's purpose, focusing on why the project is being conducted rather than describing the actions (e.g., "to study how X affects Y" rather than "to collect data").

Section 5: Research Determination and Risk Level

- This section requires you to specify the type of research (e.g., exempt, expedited, or convened/full board) and its associated risk level**. Understanding the classification of your research is crucial, as the ePortfolio's branching logic and questions are tailored to the selected classification**.
- To assist you in determining the appropriate review category, **UAB provides an IRB Review Category Self-Determination Tool.** This Microsoft Form guides you through a series of questions to help you identify the correct classification and directs you to the appropriate fact sheet for completing your application.
    - **Access the IRB Review Category Self-Determination Tool here:** https://forms.office.com/r/RCdy0FMFcq?origin=lprLink
- Research involving an FDA-regulated test article (e.g., drug or device) or studies intended to support an FDA submission must be categorized as expedited or convened/full.

Section 7: Sponsor and Funding Details

- Provide accurate information about the funding source(s) or sponsor in your application. Missing or incomplete details in this section can delay the review process and the release of funds.

Section 9: Prospective

- All clinical trials, regardless of funding, must be registered on clinicaltrials.gov, and the NCT number must be included in the ePortfolio.
- Note: While an NCT identifier is required for IRB approval, it can be obtained concurrently with the IRB review if all other submission details are complete and accurate.

Section 25: Cost and Payment

- Ensure compliance with the UAB Policy for forms of payment to research participants. Gift cards and Greenphire Clincards are not interchangeable terms; confirm the correct payment method to avoid confusion and potential delays. Including clear language about the payment type will help streamline the review process. For more information, visit the UAB Participant Incentives at https://www.uab.edu/financialaffairs/accounting/subject-participant-incentives.

Sections 28-29: Consent, Privacy, and Confidentiality

- Questions about consent, privacy, and confidentiality are critically important and must be answered accurately in the ePortfolio.
- These elements are essential for ensuring compliance and protecting participants. For further details, refer to the section devoted to this topic later in this guidebook called “Consent and HIPAA.”
- Attach all consent forms to the application

Sections 30: Info Sheet

Section 30 of the application will automatically appear when the research has been marked as exempt. In this section, you must indicate whether consent will be obtained by selecting "Yes" or "No."

- Exempt Research Information Sheet Requirements: Informing participants of their rights in the study is required for exempt research, with the exception of studies classified under Category 4 (retrospective data review).
- Use of the Information Sheet: For exempt research (excluding Category 4), the required form is referred to as an "Information Sheet." This simplified form has fewer requirements compared to consent forms for convened/full board or expedited reviews.

Researchers must complete and attach the **" SAMPLE CONSENT/INFORMATION SHEET FOR EXEMPT RESEARCH (with HIPAA Authorization)"** to their application. A sample of this form can be found on the **UAB Forms Website**, as mentioned earlier, or in the Resources section of this guidebook.

Section 31: Attachments

- Upload all participant-facing materials as required in this section. Examples include:
  - Recruitment materials (flyers, phone scripts, email templates).
  - Intervention materials (e.g., presentations for educational studies).
  - Surveys or questionnaires.
  - Focus group and interview guides.
  - Key personnel training verification *(if the Personnel eForm does not show completed required trainings)*

Personnel eForm Overview

The IRB Personnel eForm is a crucial tool for identifying and documenting key personnel involved in human subjects research. All key personnel must not only complete the required training in human subjects protections but also be listed within the eForm. This ensures compliance with UAB policies and provides the IRB with essential information about study contributors.

The Personnel eForm enables investigators to:

- Name key personnel from UAB and affiliated organizations.
- Associate relevant degrees, certifications, and IRB training with each individual.
- Specify the roles and duties of each individual within the study.
- Address UAB's financial conflict of interest policies.

The eForm links to a flowchart to help determine who qualifies as key personnel. For each person identified, researchers must select the specific activities they will perform. Activities marked with an asterisk require special attention to ensure compliance.

Document Standards and Consistency

Ensure that all information in your application and supporting documents is fully aligned to avoid delays in the review process. Key areas to verify include:

- The number of participants listed in the ePortfolio versus the consent form.
- The duration of participation stated in both the ePortfolio and consent form.
- Procedures described in the ePortfolio that must match the details in the consent form.

Pay particular attention to recruitment tools and consent forms, as these are often scrutinized for accuracy and clarity. All documents must be free of typos, formatting errors, and inconsistencies, as these can raise concerns and require additional clarification during the review process.

Carefully read through your application and all supporting materials before submission. Ensure that every document presents accurate, consistent, and clear information. By adhering to these standards, you can help expedite the review process and avoid unnecessary revisions. **In summary: be thorough and be consistent.**

Consent and HIPAA

The process of obtaining participant consent is a cornerstone of ethical research involving human subjects and plays a critical role in the IRB review process. Ensuring participants fully understand the nature of the research, their involvement, and their rights is essential for maintaining trust, compliance, and integrity in your study. **Improperly completed consent forms or consent-related issues are among the most common reasons for delays in IRB approval.** Addressing these issues early and thoroughly can help streamline the review process and avoid setbacks. Below are key considerations and best practices for crafting consent documents and adhering to HIPAA regulations.

Lay Language in Consent Forms

Using lay language is vital for ensuring participants can comprehend the information presented in consent forms, recruitment scripts, and other materials. While researchers are experts in their fields, participants and IRB members may not be familiar with technical jargon. Consent forms and related documents must be written in simple, non-technical language, aiming for an 8th-grade reading level to promote accessibility and understanding.

Consent Form Signature Lines

Consent forms must include the appropriate signature lines based on the study's design and participant population:

- For participants unable to consent for themselves, legally authorized representatives (LARs) must sign on their behalf. A LAR is defined under applicable law as an individual or entity authorized to consent for another person (45 CFR 46.102(c)).
- Studies involving minors must include a Parental/Guardian signature line and, where applicable, a Child Assent form.

Key Elements of the Consent Process

The consent process encompasses more than just obtaining a signed form; it involves various tools and practices to ensure participants are fully informed. Depending on the study design, these may include:

- Oral scripts, cover letters, or information sheets.
- Recruitment materials, such as advertisements, notices, or invitations.
- Parent/Guardian consent forms and Child Assent forms.

All consent materials must include:

- Required and applicable additional elements as outlined by IRB guidelines.
- Clear distinctions between "standard of care" procedures and research activities.
- Consistency with the ePortfolio application and the study protocol.

For more details about the consent process, visit the Informed Consent Page at https://www.uab.edu/research/home/informed-consent.

For consent samples and updated consent forms, visit the UAB Forms Website at https://www.uab.edu/research/home/irb-forms to ensure your submission meets current guidelines.

For additional national standards and guidance on informed consent, including frequently asked questions, visit the HHS.gov Informed Consent FAQs at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html. This resource, provided by the U.S. Department of Health and Human Services, offers detailed information on the informed consent process, regulatory requirements, and best practices for compliance in human subjects research.

Application of HIPAA

If your research involves identifiable private health information and you are a member of a HIPAA-covered entity, you must comply with the HIPAA Privacy Rule. This may require either:

- **Obtaining Written Authorization**: Secure signed authorization from participants when collecting identifiable health data.

  OR

- **Requesting a Waiver of Authorization**: If it is not practicable to obtain written authorization, you must provide a justification and meet all additional waiver requirements.

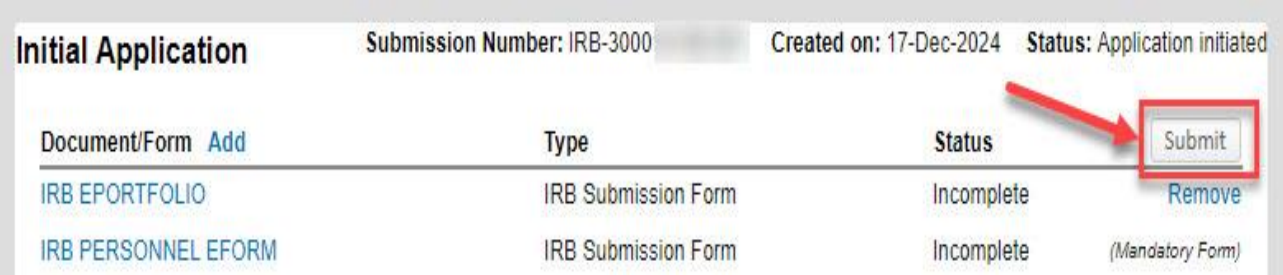
For detailed information, visit UAB's IRB Policies and Procedures at https://www.uab.edu/research/home/irb-policies-and-procedures. Under the **"IRB Policies and Procedures"** section, review policies related to **"Informed Consent"** and **"Privacy, Confidentiality."** For additional guidance, navigate to the **"IRB Guidance"** section and explore resources under **"Consent and Recruitment"** and **"HIPAA"** for tools and clarifications tailored to your research needs.

Submitting the Application: A Critical Final Step

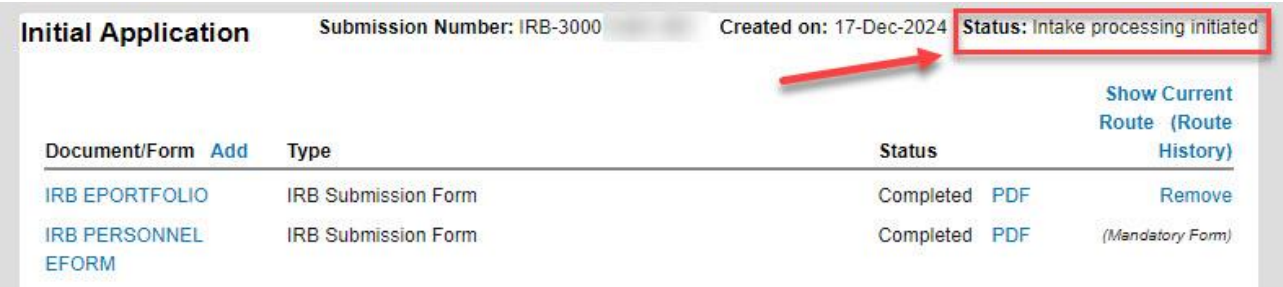
One of the most frequent issues encountered during the IRB application process is **failing to click the "Submit" button** after completing and reviewing the ePortfolio and Personnel eForm. Even though the application may appear ready on the Submission page, it will **not move forward to the IRB for review until the Submit button is clicked**. This step is critical—without formal submission, the application will remain incomplete and cannot proceed to the review stage.

To address this:

1. Review Your Application: Ensure that the ePortfolio and Personnel eForm have been thoroughly completed and all required sections are addressed.
2. Locate the Submit Button:
   - The Submit button is located inside the current submission page.
   - Refer to the provided image below for visual guidance to help you easily locate the Submit button.



3. Verify Submission: After clicking **Submit**, confirm that you receive a submission confirmation notification or email. Additionally, verify that the application status has been changed from "Application initiated" to "**Intake processing initiated**." Refer to the image below for guidance.



Post-Submission: Pre-review, Approval, and Beyond

Pre-approval

During the pre-approval stage, an OIRB staff member conducts a preliminary review of your application to ensure that all necessary information and documents are included before it is sent to the IRB board members for review. Exempt and Not Human Subjects Research (NHSR) studies may receive determinations at this stage. If the IRB staff identifies missing information or documents, you will be asked to provide additional details to complete your application.

For detailed guidance on how to respond to IRB requests for changes or locate IRAP protocol correspondence, refer to the Step-by-Step ePortfolio Guidance Documents at http://go.uab.edu/eportfolio. These resources are located in the "After You Submit" section.

When making changes to previously reviewed documents, whether in response to an IRB request or as part of a revision or amendment, it is essential to follow specific steps to

ensure clarity and maintain version control. Use the Microsoft Word **Track Changes** feature to create a "tracked" copy that highlights all individual edits made to the document. Additionally, provide a "clean" copy with all changes accepted for ease of review. For consent forms, update the version date each time changes are made. Version dates are crucial for distinguishing current forms from outdated versions, particularly after the initial submission, and enable the IRB to efficiently manage and assess the documents.

Additionally, ensure that all necessary delegates are set up to receive correspondence. By default, correspondence is sent only to the Principal Investigator unless permissions are updated during the delegation process. Proper setup of delegates can help avoid delays in responding to IRB requests.

Approval Notifications and Review Outcomes

After IRB review, investigators receive a determination letter detailing the outcome via email. Possible outcomes include Approval, Additional Information Required, Deferred for Response, or Disapproved. Approved protocols will include an IRB Approval Form and any approved consent forms, allowing research to begin immediately. For conditional approvals, the research may not proceed until all specified changes are reviewed and approved.

The IRB approval period is specified in the approval form. If informed consent documents are required, they will be returned with an IRB approval stamp and expiration date for use in the study. For more details, visit the IRB Review Outcomes and Approval Details page at https://www.uab.edu/research/home/irb-review-outcomes-and-approval-details.

Post-Approval

Once your research is approved by the IRB, it is important to maintain compliance with IRB regulations and policies. This includes ensuring proper oversight of amendments, promptly reporting any research-related problems, and adhering to compliance and monitoring requirements. Below are key post-approval considerations to help you manage your approved protocol effectively. For detailed information, refer to the resources linked under each section.

- **Amendments and Revisions**

  No protocol, informed consent process, or consent document may be modified without prior IRB approval unless the change is necessary to eliminate an immediate hazard to participants. Researchers must submit amendments or revisions to the IRB for review and approval **before** implementing changes. Use the Microsoft Word **Track Changes** feature to create a "tracked" copy that highlights all individual edits made to the document when possible.

For more details, visit the Amendments and Revisions page at https://www.uab.edu/research/home/amendments-and-revision.

- **Reporting Research-Related Problems**

  Principal Investigators and their study teams are required to promptly report any unanticipated problems involving risks to participants or others. This includes both FDA-regulated and non-FDA-regulated research, as per federal regulations and UAB IRB policy.

  For reporting guidelines, visit the Reporting Research-Related Problems page at https://www.uab.edu/research/home/reporting-research-related-problems.

- **Compliance and Post-approval Monitoring**

  All protocols reviewed by the IRB are subject to monitoring by the IRB and OIRB personnel. Monitoring maybe random or for-cause based on criteria outlined in UAB's policy for compliance with human subjects research regulations.

  For further information, visit the Compliance and Monitoring page at https://www.uab.edu/research/home/compliance-and-monitoring.

For further step-by-step guidance on these procedures, refer to the Step-by-Step ePortfolio Guidance Documents at http://go.uab.edu/eportfolio. These resources are located in the "After You Submit," "Renewing Your Study," and "Submission Guides for Pre-ePortfolio Studies" sections.

Important and Additional Resources

- Access the most **up-to-date forms and templates** by visiting the UAB Forms Website at https://www.uab.edu/research/home/irb-forms. These resources ensure your submission aligns with current IRB guidelines.
- **For step-by-step PDF guides to help navigate the application process, both pre- and post-approval, visit the Step-by-Step ePortfolio Guidance Documents at http://go.uab.edu/eportfolio.**
- For a **glossary of research-related terms** and their definitions, visit the UAB IRB Glossary at https://www.uab.edu/research/home/irb-glossary. This resource provides clear explanations of terminology used throughout the research process.

- For **frequently asked questions** and additional guidance related to the IRB process, visit the UAB IRB Guidance FAQs at **https://www.uab.edu/research/home/irb-guidance-faqs**. This resource offers answers to common queries and clarifications to assist researchers throughout their submissions.
- For the most **current UAB policies and procedures and specific IRB Guidance** regarding research, visit the IRB Policies, Procedures and Guidance page at **https://www.uab.edu/research/home/irb-policies-and-procedures**. This resource provides detailed guidelines to ensure compliance with institutional and federal research regulations.
- The Office of the Institutional Review Board (IRB) offers **virtual office hours** bi-weekly on Thursdays from 11:00 AM to 12:30 PM. These sessions provide researchers with direct access to experienced OIRB staff for assistance with submissions, protocol guidance, and navigating the review process. For Zoom meeting details, visit the UAB Campus Calendar and search for “Office of the IRB Virtual Office Hours.
- Stay informed about important updates, announcements, and resources by subscribing to the **IRB ListServ**. This newsletter ensures you receive the latest information about IRB processes and events. To sign up, visit **https://forms.uab.edu/186**.