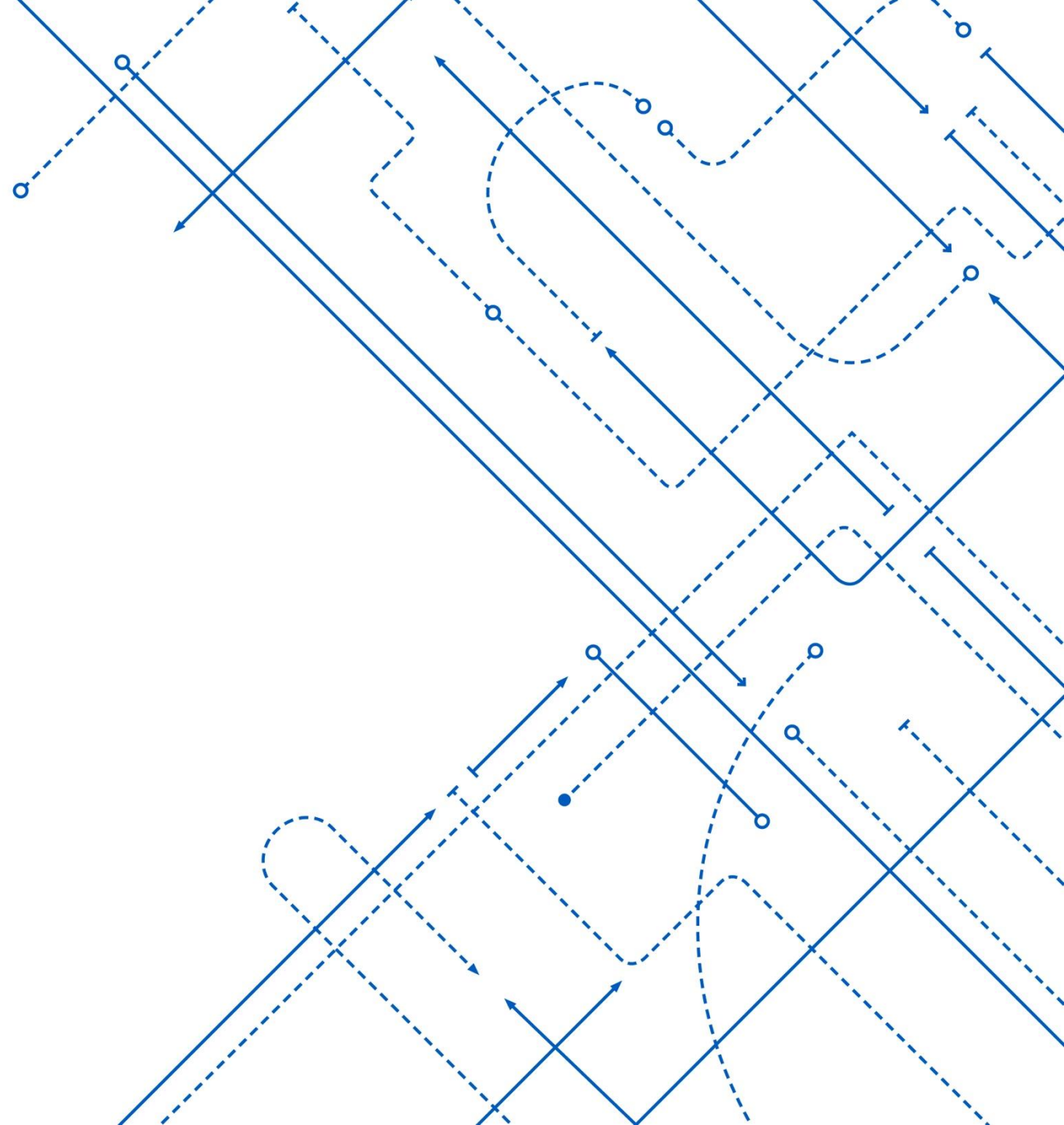
UBIRB SUBMISSION PROCESS



University at Buffalo
Office of Research Compliance
Research and Economic Development

When reviewing human subjects research, the Institutional Review Board (IRB) must consider applicable regulations and requirements from the following:

- Title 45 CFR 46 (HHS)
  - revised common rule
- Title 21 CFR Parts 50, 56, 312, 812 (FDA)
- NYS Mental Hygiene laws
- HIPAA
- AAHRPP
- UB HRPP FWA (OHRP)
- Local laws and guidelines
- Institutional requirements
- Sponsor requirements

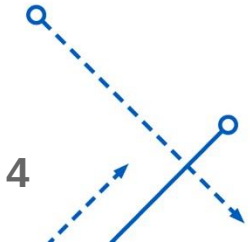
Today's Topics

- How and where to submit your research study
- Common documents and templates
- I've submitted my study to the IRB. Now what happens?
- Differences in Study Review level
- Modifications and Continuing Reviews
- Questions

The Institutional Review Board (IRB)

The University at Buffalo IRB reviews every research study conducted by university personnel in order to comply with government regulations (45 CFR 46), otherwise known as the “Common Rule.”

We are on your side! The IRB is happy to assist you as much as possible throughout your submission process. But hopefully this presentation will give you a head start on some basics and frequently asked questions that come our way.



Click

- UB uses the Click software platform for submitting and review research studies.
- The best way to log in is to access this website: http://www.buffalo.edu/research/research-services/compliance/irb/click-irb.html and then click on “Login to Click.”
- If you do not already have a Click account, please contact the IRB and we will send you instructions on how to register for an account.

Central Study Registration

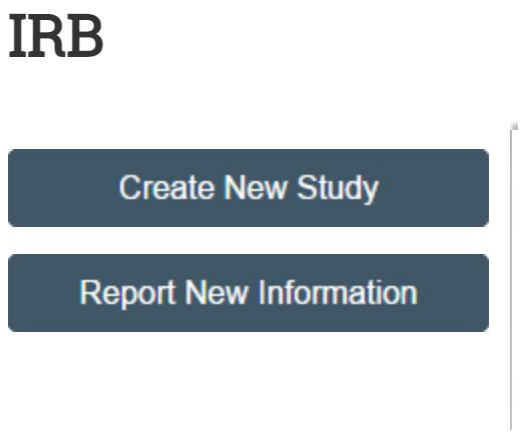
- Most clinical studies submitted to the IRB must first go through Central Study Registration (CSR) as the single point of entry for various processes, workflows, and software platforms for clinical research at UB. Ideally, you will do this process before your IRB submission, as a submission will be created in Click automatically for you.

Central Study Registration

- CSR does not apply if:
  - If you are submitting your protocol to the IRB for determination of 'Not Human Subjects Research' or are seeking “Exempt Status’
  - If your research does not meet the definition of clinical research (Chart reviews are required to be submitted).
  - If your research is originating from a non-health science school at UB and is not a clinical trial
- For questions on Central Study Registration, please contact Kim Brunton at kbrunton@buffalo.edu or Pamela Andersen at pka2@buffalo.edu

Submitting Your Study in Click

- If your study does not require CSR, you can choose “Create New Study” in the IRB tab of Click after logging in. This should also be accessible from the “My Inbox” tab. From there, you would answer the questions and upload documents in the appropriate Click Smart Form pages and sections.

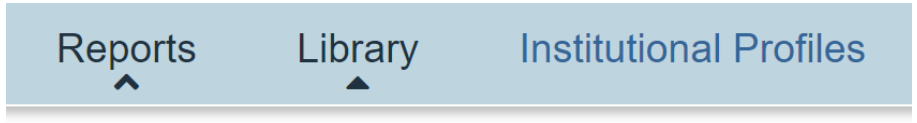


Commonly Used Documents and IRB Templates

- HRP-503 Study Protocol
- HRP-508 Site Supplement to Sponsor Protocol
- HRP-502 Consent Form and all other applicable Consent and Assent Forms.
- HRP-612 HIPAA Waiver, HRP-611 Partial HIPAA Waiver for Recruitment
- Data collection sheets, code keys
- Study questionnaires, surveys
- Recruitment documents, such as flyers or recruitment scripts

Click Library

- UBIRB-required templates are available in the Click Library under the "Templates" tab.
- The "General" tab in the Library includes helpful documents such as an "Intro to Click" PowerPoint, a list of Research Training Requirements, and "Tips from the IRB" on specific topics.
- We are working on adding more guidance documents as part of the "Tips from the IRB" series.



Research Training Requirements

- Before your submission can be approved, all members of the study team must complete the appropriate CITI training courses. For all biomedical/clinical studies, the required courses are as follows:
- **Biomedical Research Investigators**
- **CITI Good Clinical Practice**
- **CITI Conflicts of Interest**
- You can log in and/or create an account here: https://www.citiprogram.org/index.cfm?pageID=14

Conflict of Interest

- All submissions to the UBIRB also go through a Conflict of Interest (COI) review. Research personnel are required to complete an annual COI disclosure, which can also be done in the Click system under the COI tab near the top of the page.
- Similar to CITI training, studies with team members who have not completed their annual COI disclosures cannot be approved until all have done so.
- Please contact the COI Administrator, Kyle Mann with any questions or concerns at 716-645-0311 or klmann@buffalo.edu

So I've Submitted My Research Study

- What happens next?

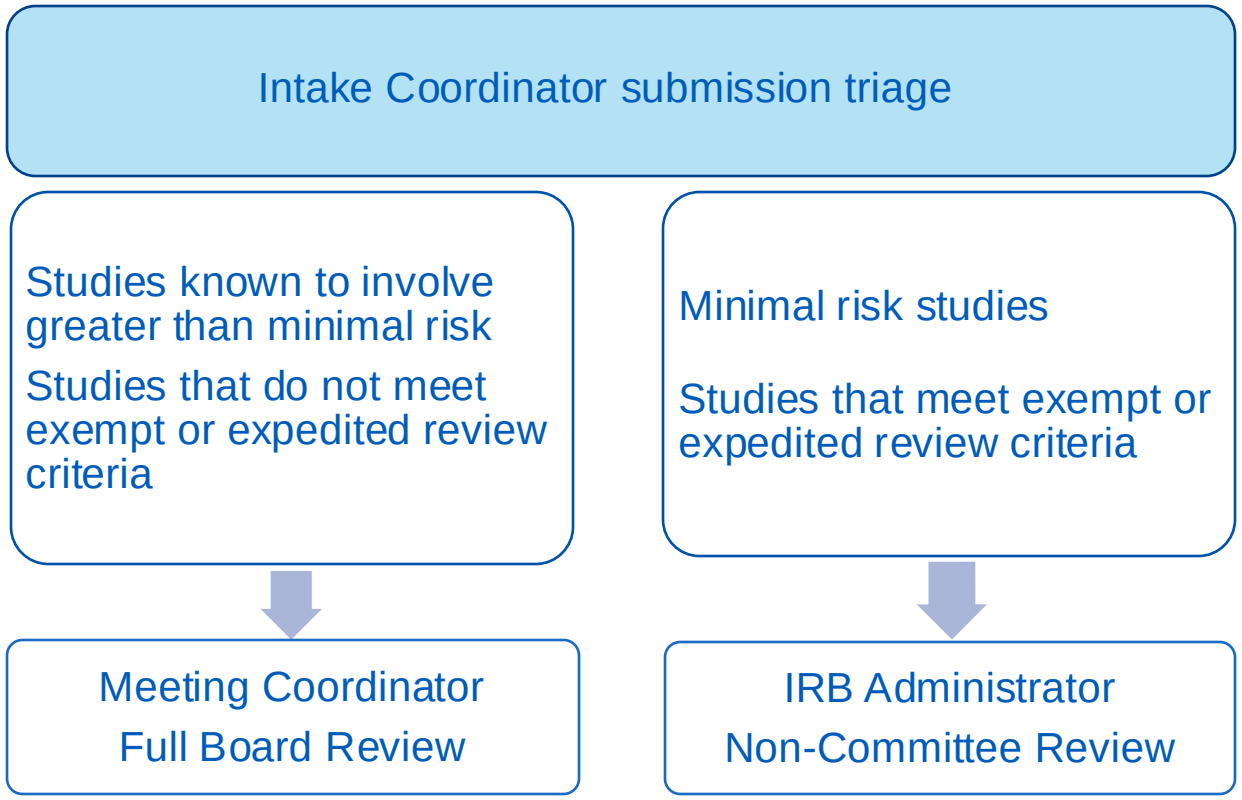
IRB Pre-Review

Once the initial triage takes place, the IRB Intake or Meeting Coordinator will:

- Check that all required documents are submitted using current templates and in their correct location in Click
- Assign a Conflict of Interest (COI) review
- Verify CITI course completion for all study team members, and note members who have unmet requirements
- Send Full Board studies and expedited studies with participant interaction to a CTSI Clinical Research Facilitator

IRB Pre-Review

- After a study is submitted in Click, an IRB Intake Coordinator will make an initial assessment of the **study risk level** based on submitted materials.



Assessing Minimal Risk

- The definition of “Minimal Risk” in human subjects research is: the probability and magnitude of harm or discomfort anticipated in the research are **not greater than those ordinarily encountered in daily life** or during the performance of routine physical or psychological examinations or tests *(45.CFR.46.102(j)).*

- Consideration is given to privacy and confidentiality risks as well. Identification of research participants or their responses cannot reasonably place them at risk of liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing.

Exempt Research

Basic Criteria

- The research involves no more than Minimal Risk to subjects, including risk of identification of participants or their responses
- **All** research activities in the study must fall under exempt categories

Common categories at UB (HRP-312)

- 1: Educational research using normal educational practices
- 2: Survey and interview studies with adult participants
- 3: Non-medical benign behavioral interventions and data collection with cognitively capable adults
- 4: Secondary research on existing data where no identifiers are recorded including a code or link to identifiers

Exempt Research – Review Workflow

Submission

- Submit completed Protocol and supporting documents directly into Click (bypass Central Study Registration)
- Add a comment to the Study History stating that you are seeking Exempt status.

IRB Review

- Pre-Review will take place as noted on prior slide
- Study will be reviewed by an IRB Administrator. If modifications are required, these will be requested directly in the Click system.
- If the IRB determines upon review that the study does not meet criteria for exemption, you will be asked to go back and submit in CSR.
- When all clarifications are addressed to meet criteria for approval, including CITI and COI requirements, a determination of exempt will be recorded.

Expedited Review

Basic Criteria

- The research involves no more than Minimal Risk to subjects, including risk of identification of participants or their responses
- **All** research activities in the study must fall under expedited categories

Common Categories at UB (HRP-313)

- 2: Blood collection within specified frequency and volume limits by age and health
- 4: Data collection through non-invasive means routinely employed in clinical practice, such as non-contrast MRI, ECG, and ultrasound
- 5: Records review from routine, non-research procedures, such as medical or administrative records
- 7: Research on individual or group characteristics or behavior, such as observation, focus groups, interviews, or personality surveys

Expedited Review - Workflow

Submission

- Submit study into CSR. When CSR is complete, the study will be automatically ported into Click. You will need to click Submit.

IRB Review

- Pre-Review will take place as noted on prior slide
- Study will be reviewed by an IRB Administrator (“Non-Committee Review”). They may consult with another IRB member or expert or refer the study to the Full Board.
- If reviewing themselves, the Administrator may request modifications to the submission directly in the Click system. When all clarifications are addressed to meet criteria for approval, including CITI and COI requirements, they will approve the study.

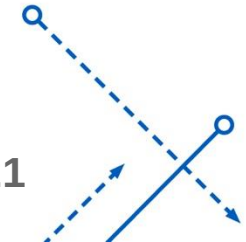
Full Board Review

Basic Criteria

- Any human research that does not qualify for exempt or expedited review is referred to the Full Board.

Examples of procedures considered greater than minimal risk

- X-rays, including DEXA scans
- MRIs when contrast media and/or sedation are used for research purposes
- Randomized treatment studies
- Studies using investigational drugs and/or devices, or off-label use of approved drugs
- Behavioral studies involving risky interventions, observations of illegal or stigmatizing behavior, or collection of highly sensitive data



Full Board Review – Workflow

Submission

- Submit study into CSR. When CSR is complete, the study will be automatically ported into Click IRB. You will need to click Submit.

IRB Review

- Pre-Review will take place as noted on prior slide

Assignment to agenda

- Conflict of Interest review must be complete before being assigned to an agenda.
- Submission is assigned to an agenda two weeks in advance to provide IRB members time for review.
- Meetings are typically the first Monday, second Tuesday, third Wednesday, and fourth Thursday of each month.

Full Board Review

Study will be reviewed by a Committee of IRB members at a convened meeting. You may be invited to call into the meeting.

The review will result in IRB approval, “Modifications Required to secure approval”, or Deferral of the submission, which will be communicated via letter in Click.

- Modifications Required – The study will meet criteria for approval if minor, prescriptive modifications are made. These changes will be submitted in Click and reviewed by an IRB Administrator. If addressed as requested, the Administrator may process final IRB approval.
  NOTE: If changes are made other than those prescribed, subsequent Full Board review will be required.
- Deferral – Board is unable to approve the study as currently written, and major changes are required before further review will occur. Subsequent Full Board review is required.

Modifications, Continuing Reviews, and Reportable New Information (RNI)

Modifications and renewal applications will typically follow the same pathway as the initial study review with the following exceptions:

- Studies determined by the Full Board to be no greater than Minimal Risk can be reviewed on an expedited basis at renewal
- Greater than minimal risk studies can be expedited at renewal when they are permanently closed to enrollment, research interventions are complete, AND only long-term follow up remains (8a); OR, when only data analysis remains (8c).
- A proposed modification may impact the study risk level

Reports of adverse events or noncompliance are reviewed at a level commensurate with their severity.

Typical Timelines for IRB Review

Investigators are advised to begin the submission process as early as possible.

- The IRB recommends allowing **2 months** for a study to complete the process of approval within Click.
- Prior to workflow through Click, most studies need to complete Central Study Registration as previously mentioned.
- Submissions are typically reviewed in the order they are received.

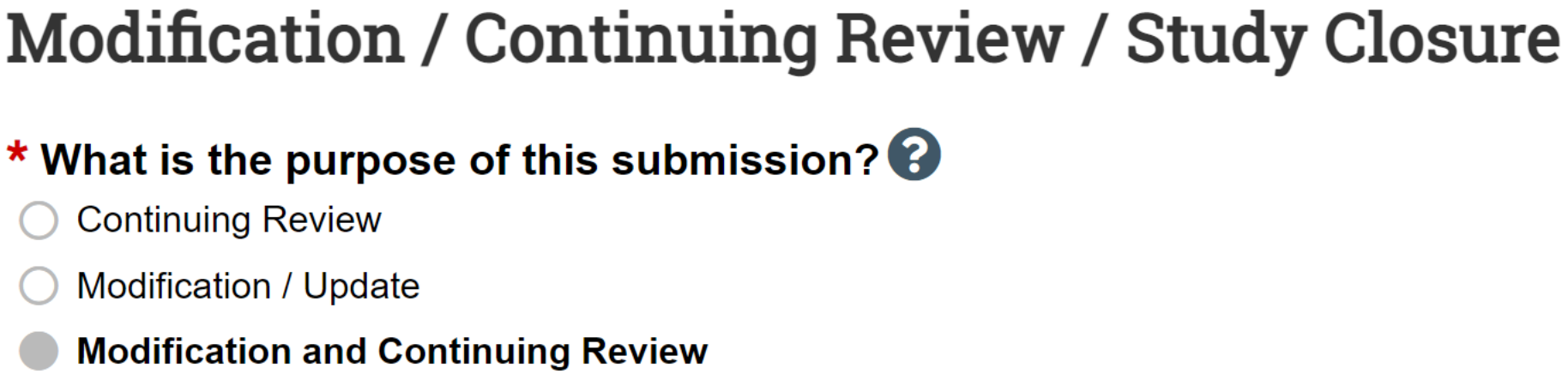
If you have a **"Just In Time"** submission for the NIH or NSF, contact the IRB. These reviews are performed on a more immediate basis to satisfy requirements for potential funding.

Submitting Continuing Reviews or Modifications

- On your main study page and under “Next Steps” you will have the option to choose “Create Modification/CR”.
- **IMPORTANT**: The first page of these submissions is very important, and cannot be edited after it is completed.
- Under “What is the purpose of this submission”, for a Modification, choose “Modification,” for a Continuing Review of an ongoing study, choose “Modification and Continuing Review,” and if you are planning on closing the study ONLY, choose “Continuing Review”.

Submitting Continuing Reviews or Modifications Example

- Here is an example of the available options

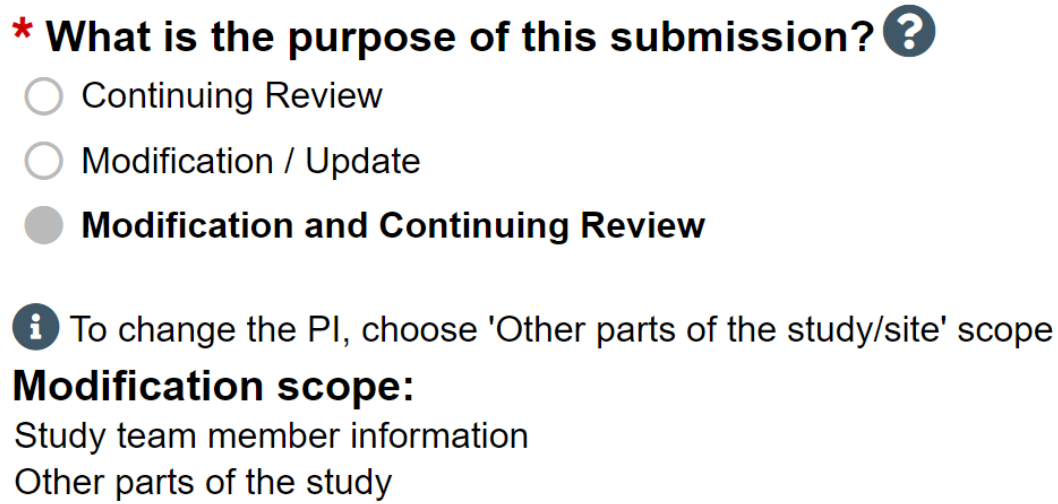


Submitting Continuing Reviews or Modifications

- Equally important is the second question on this page: the Modification Scope
- For all “Modification and Continuing Review” submissions, “Other parts of the study” **must be selected.** We also recommend choosing “Study team members as well even if you are not adding or removing personnel, in case you need to remove someone who has not completed CITI or COI requirements during the review. Otherwise you will need to do another submission.
- For “Modification” submissions, you may choose “Study team members”, “Other parts of the study” or both. Only one modification of each scope can be open at one time.

Submitting Continuing Reviews or Modifications Example

- Here is an example of the Modification Scope. Both scopes are chosen in this example.



Reportable New Information (RNI)

An RNI is to be submitted to the IRB when an adverse event or unanticipated problem occurs within a study and meets one of these parameters:

- An increased or new **risk** to the study
- Any **harm** that is unexpected and related or **probably related** to the research procedures
- **Non-compliance**, which includes protocol deviations
- **Audits** by a federal agency
- **Reports** from a study monitor (not including DSMB reports, these can be submitted as part of a Modification or Continuing Review)
- Researcher error
- Confidentiality breach
- Unreviewed change
- Incarceration of participant
- Complaint
- Study suspension for any reason
- Unanticipated adverse device effect

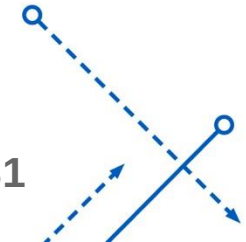
Reportable New Information (RNI)

All RNIs must be submitted to the UBIRB within 5 business days of being aware of the event.

Please include in the body of your RNI:

- What happened
- Why it happened
- When and where it happened
- What was done to address the issue
- An action plan to prevent the event from occurring again.

You should see the option to “Report New Information” under “Next Steps” from your home page or your study page.



What studies need to be submitted to the IRB?

- It is recommended that ALL proposals be submitted for review and approval.
- Studies that do not meet human research requirements, such as Quality Improvement Projects, do not require approval however:

  Journals often ask for IRB approval or acknowledgment letters when results are published.

  If your study was not submitted and is later determined to be human research, the IRB cannot give retroactive approval which would be considered serious non-compliance and reportable to the government.

- It is recommended to submit a completed HRP-503 to the UBIRB, though many sections of the protocol will not apply.

Questions

University at Buffalo
Research and Economic Development

For questions, please contact:

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