CWRU IRB OVERVIEW

The CWRU Institutional Review Board (IRB) is responsible for reviewing and approving IRB protocols submitted by all faculty, staff, and students for the University. The CWRU IRB's portfolio includes over 1200 active protocols and averages 110 protocol submissions each month. In addition to the review and approval of new studies, the IRB is responsible for review and approval of modifications, continuing reviews, study closures, and the reliant review process of studies that have multiple sites and are required to rely on one IRB of record (either the CWRU IRB or an external IRB). We are committed to performing a thorough and timely review of submitted protocols.

Processing and Timeline Information

The current guidelines to submit IRB submissions are posted below as a general guide only. Submissions that are underlineincomplete or do not adhere to IRB submission guidelines will require additional time for review and approval.

- It is strongly recommended to submit at least 8-12 weeks in advance of the proposed start date of the study whenever practicable to avoid delays in the onset of human subjects' research.
- IRB approval is dependent on meeting the regulatory criteria, institutional policies and procedures, and the cooperation of the investigator(s) in responding to the IRB's requests for clarifications and modifications promptly.
- IRB approval will be delayed if all study team members are not CREC certified and do not have a Conflict of Interests disclosure form on file.
- Completion of Ancillary Committee Reviews and meeting additional FDA requirements, if applicable, can delay IRB approval.
- **NIH Grants or Submissions Requiring Just-In-Time Review**
  To ensure that the NIH's timelines are met, the IRB Office encourages investigators to start working on the study submission in the SpartaIRB system as soon as a fundable score is received.

Studies are reviewed in the order in which they are received.
- When investigators request that the IRB prioritize a review, it effects our ability to perform a timely review of those protocols already in the queue. This may cause a delay in the start of human subjects research of your colleague.
- Investigators who believe that their submission requires immediate processing due to delays, which adversely affect study subjects, should contact the Executive Director for Research Compliance, Kim Volarcik (kav6@case.edu) and provide justification and a description of the specific circumstances.

Timelines by Type of Submission

<u>New Protocol:</u>
- Submission for a **not human subjects research determination** requires up to 2 weeks for an affirmation that the research falls under this category. This can be longer if additional information is needed from the researchers. Typically, NHR is used for research that does not meet the federal definition of human subjects and research, such as quality improvement/program evaluations and using publically available databases.
- Review time can vary depending on the review type determined by the IRB Office.
    - Review of **exempt** studies can take 6 weeks to process.
    - Review of **expedited** studies can take 8 weeks to process.
    - Review of studies by the **full committee** can take 12 weeks to process.
        - When a study protocol has a greater than minimal risk, is a device study, or involves certain vulnerable populations, it will require full committee review.
        - After it is determined the new protocol has all of the components required for the full board to review, it will be assigned to the next monthly meeting. The CWRU IRB Committee typically meets during the first week of each month.
- Anticipate interactions through the SpartaIRB system to address clarifications or modifications. Approval of new studies is a multi-step process; at each point in the review process, clarifications may be requested and modifications required before progressing towards approval.

<u>Modifications:</u>
- Submit modifications for exempt, expedited and full board protocols at least 4-6 weeks ahead of the implementation of the change.
- Ensure newly added study team members have completed CREC certification. Study team modifications can generally be approved more quickly when this step is done in advance of submitting modifications.
- Recognize that modifications go through a similar review process as a new protocol, dependent on the type of review previously determined for the parent study.
- Be aware that changes to non-personnel parts of the study could need a higher type of review (e.g., Exempt to Expedited Review).

<u>Continuing Reviews:</u>
- Submit continuing reviews at least 6-8 weeks before the expiration date to give the IRB ample time to review and request any clarifications or modifications.
- Anticipate that migrating documents out of iRIS to SpartaIRB and updating consent forms will require more rather than less time to address all issues.
- Ensure all study team members have updated CREC certification.

Types of IRB Review

- The IRB administrators determine the type of review: Not Human Subjects Research (NHR), Exempt, Expedited (non-committee), or Full Board (committee).
- The anticipated type of review may change based on the IRB Chair, Vice Chairs, or IRB member's recommendations.

Detailed Review & Explanation of Steps:

STEPS	Not Human Research	EXEMPT	EXPEDITED	FULL BOARD
1	Pre-review	Pre-review	Pre-Review	Pre-review
2	Approval/confirmation made by IRB Coordinator	Approval/confirmation made by IRB Coordinator	Non-committee Review: by IRB member	Non-committee Review: by IRB members
3			Approval by IRB member	Reviewed by Full Committee
4				Approval by Full Committee

The flow of IRB submissions through the SpartaIRB system

Pre-submission: In this state, all types of protocol submissions are initiated.
- Submission is created by the PI and the study team
- Department Chair/Dean for Department Scientific Sign-off is required for new studies
- The protocol has not been submitted to the IRB.

Pre-Review: In this state, all types of protocol submissions are reviewed by the IRB Office.
- The CWRU IRB has successfully received the submission.
- An IRB coordinator is assigned to a protocol and begins their pre-review.

- *Protocols determined to be NHR or Exempt will be processed to the approval status after all clarifications have been addressed.*

  o **Clarification Requested**: The submission has been returned to the study team by the IRB coordinator requesting changes or clarifications by the PI and study team.

When the PI sends back their responses to the clarifications, the submission goes back to the Pre-review state.
Pre-review protocols only proceed to IRB review when all clarifications and changes have been addressed.

IRB Review: This step occurs for all submissions requiring an Expedited or Full Board Review
- A single IRB member reviews submissions that fall under the Expedited Review criteria.
- The full committee reviews the submission that meets the Full Board criteria.

Post-Review: This step occurs for all submissions requiring an Expedited or Full Board Review
- A single IRB member submits their decision to the IRB for the Expedited Review process.
- The IRB committee vote is recorded in this state for the Full Board Review process.
- One of the following decisions is made:
  o Approved
  o Modifications required to secure approval
  o Deferred
- A letter detailing the decision/vote will be sent to the PI through the SpartaIRB system.

  o **Modifications Required to secure approval**: The submission has been returned to the study team requesting changes that are required for approval of study. This may or may not need to be returned to the IRB reviewer (Expedited) or IRB (Full Committee).

Review Complete= Determination/Approval: All protocol submissions move through the system to this state.
- Determination of Not Human Research or Exempt
- Approval of Expedited or Full Board
- A determination or approval letter is generated and sent to the PI and the protocol is moved to the Approved state