CWRU IRB Expectations and Guidelines for Protocol Submissions:

When should you submit your IRB protocol submission?

It is important to plan ahead and submit your IRB protocol submission ahead of time so it can be reviewed, processed, and approved by the CWRU IRB.

- The PI has a significant influence on the length of time between submission and approval.
- Well prepared applications result in fewer requests for required stipulations by the IRB.
- Rapid response by the PI to the IRB issues speeds the approval process.

When you obtain a good grant score, (if you have not done so already) submit your IRB protocol. It takes time to process the new protocol application. Therefore, while waiting for the Just in Time letter to arrive, you can work with the IRB to get your protocol processed.

When working on a contract that is considered human subjects research allow time for the IRB review and approval and consider the timeline for completion of the work.

When working with the Technology Transfer Office for a Data Use Agreement (DUA) of human-related data or Material Transfer Agreement (MTA) of human-derived samples or specimens:

- The IRB protocol/modification can be started at the same time as the TTO review form.
- Please contact and work with Cal Frye (at 216.368.3769 or cxf244@case.edu), from CWUR's UTech IT Security Office, on your data security plan that will be part of:
    - Your IRB protocol and
    - Shared with TTO to match the terms of the DUA or MTA.

What are the time frames for submitting IRB protocol submissions?

During times of high CWRU IRB submission volume, these times will be required to be extended-

- Submit your new protocol submission 4-8 weeks ahead of time from your deadline.
    - If the protocol is a greater than minimal risk, device study, or risk study and would need to be reviewed by the full board, the approval time may be longer.
- Modifications need to be submitted 2-6 weeks before the required change.
    - Modifications consist of study personnel changes and changes to the research activities.
- Continuing Reviews need to be submitted 4-8 weeks before the expiration date to give the IRB time to review, process and approve them.
    - Submitting with ample time for review allows both the study team and the IRB reviewers time to address any issues found within the protocol, SmartForm, and study documents.
    - In addition to reviewing the protocol and consent forms, the IRB Administration staff will check the personnel table while processing Continuing Review applications.

What criteria do reviewers apply when looking at my project?

- Reviewers look at the purpose, methodology, adequate handling of the informed consent process, whether the research deals with high risk or sensitive issues. If so, the IRB determines whether the benefits outweigh the risks, and the degree to which confidentiality is both assured and protected.
- Federal regulations, Common Rule, state and local laws, and institutional and CWRU IRB policies and procedures.

Tricks of the Trade:

Plan early to submit your new protocol submission to give the CWRU IRB time to review, process and approve it.

Selecting the correct type of protocol template to match your research study.

- Talking with the IRB: meeting or conference call
- Review the Office of Humans Research Protections Decision Trees: https://www.hhs.gov/ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf

Review the Library tab in the SpartaIRB system to find useful information:

- Protocol templates
- Directions on how to submit protocol submissions

What delays approval of my IRB application?

Items that may delay approval of your IRB application include:

- Submitting an incomplete or incorrect protocol template application
- Listing study team members, who have not completed training of the protection of human subjects in research (CREC Program Certificate).
- Listing study team members, who have not submitted a Conflict of Interests disclosure form.
- Cross-checking information on the consent form against information in the protocol
- Proofreading the application and relevant documents.
- Submitting a Reliance Review study to rely on another institution or have another IRB rely on the CWRU IRB without prior IRB consultation and approval.
    - Reliance Reviews need to be reviewed by Research Compliance Officer (RCO).
    - In turn, the RCO informs the Institutional Official of the request to grant:
        - The CWRU IRB to be the IRB of record for another institution
        - Another institution to be the IRB of record for CWRU
- During the pandemic and the University of the President's process that is required to be followed for in-person human research activities, the Safety Plan is required to be approved and attached to the new or modification to an existing protocol.