Cleveland Clinic Akron General

Standard Operating Procedure
Continuing / Interim Review of Human Subjects Research

PURPOSE

To provide investigator guidance on submitting continuing/interim review reports when conducting human subjects' research to the Institutional Research Review Board (IRRB) for review and approval.

APPLICABILITY

The procedures in this document apply to all investigator(s) and research personnel conducting human subjects research at Akron General Medical Center (AGMC) or its affiliates.

RESPONSIBILITY

It is the responsibility of all investigator(s) and research personnel conducting human subjects research at Akron General Medical Center (AGMC) and its affiliates to follow the procedures set forth in this document.

PROCEDURES

Training

It is the responsibility of the Principal Investigator to verify that the appropriate training is on file in the IRRB Office for all investigator(s) and research personnel involved with research at AGMC, and that the training is up-to-date.

All investigator(s) and research personnel are required to complete the Human Subjects' Research training prior to conducting human subjects' research at AGMC or its affiliates. The training module is located at www.citiprogram.org. ***Make sure you include AGMC as your affiliate. Training completed for other institutions may not be substituted.*** Training must be updated every 3-years.

All investigator(s) and research personnel are required to complete Conflict of Interest training prior to conducting human subjects' research at AGMC or its affiliates. The training module is located at www.citiprogram.org. ***Make sure you include AGMC as your affiliate. Training completed for other institutions may not be substituted.*** Training must be updated every 3-years.

Continuing/Interim Review

The Principal Investigator must complete the Continuing/Interim Review of Human Subjects Research form and attach the following if applicable:

- Continuing/Interim Review of Human Subjects Research (required)
- Informed consent/assent, HIPAA Authorization (required if enrollment is on-going)
- Recruitment materials (if changes made since last review)

- Request for Amendment or Change in Human Subjects Research (if not previously submitted)
- Unanticipated Problem or Serious Adverse Event Report (if not previously submitted)
- Conflict of Interest Disclosure Form (if change in COI status has occurred)

Health and Human Services federal regulations require that a continuing/interim review of human subjects research must be conducted at intervals appropriate to the degree of risk, but not less than once per year. Continuing/interim review of human subjects research must be submitted and approved before the expiration date, which is determined as follows:

- For approved submissions, the expiration date will be the date of the full board/expedited review when approval was obtained.

- For submissions approved with conditions, the expiration date will be the date when the conditions have been reviewed and accepted by the IRRB designated reviewer.

- A reminder to complete the continuing/interim review of human subjects research will be emailed to the Principal Investigator as well as the contact person on file 60-days prior to the expiration date. It is the Principal Investigator's responsibility to be cognizant of expiration dates, and to have the continuing/interim review completed and submitted to the IRRB so that it can undergo IRRB review prior to the expiration date. Please note: The full board IRRB convenes once per month, with the exception of December. Thus, if your expiration date falls in late December or in January, the continuing/interim review will need to be submitted in time for the November meeting.

Full Board Review of Continuing/Interim Report

- The IRRB posts deadlines for submission on the internet that are approximately 3-weeks prior to the convened IRRB meeting. If the original submission underwent full board review, the continuing report submission must be completed by this deadline in order to be reviewed at the convened meeting.

- If an *unanticipated problem* or *serious adverse event* has been reported since the last review, if new information has become available that changes the risk to subjects since the last review, or if you are amending the protocol, recruitment materials, investigator brochure, or informed consent/assent; then, the continuing/interim review should be submitted by the IRRB submission deadline for full board review.

Expedited Review of Continuing/Interim Report

NOTE: Most expedited studies will not need full board approval of the continuing/interim review, but there may be exceptions when it is determined that the risk to subjects have changed.

- If the original study underwent expedited review and the risk to subjects has not changed, the continuing/interim review must be submitted at least 10-days prior to the expiration date in order to ensure that it is approved by the expiration date.

SUBMISSION

The completed continuing review package is to be emailed to the IRRB Office (IRRB@akrongeneral.org). Please submit a tracked change as well as clean copy of amended protocols, informed consent/assent documents, HIPAA authorizations, or recruitment materials as a Word documents (.doc,.docx) when applicable. Other documents may be submitted as Word documents or PDFs.

When submitting the application, please verify that all signatures have been obtained (digital signatures with a time and date stamp are acceptable). The IRRB Secretary will verify that all of the necessary attachments, training, and required signatures are present prior to forwarding the application to the IRRB for review. Incomplete applications will not be reviewed.

If additional information or changes are requested, the indicated contact person and the Principal Investigator will be notified of the requests. Please submit a tracked change copy as well as a clean copy of all changes.

Once the submission has been successfully completed, the IRRB Coordinator will notify the contact person of the progress of the review. A decision to approve, approve with conditions, or disapprove will be forwarded to the contact person and the Principal Investigator in the form of a letter.