Cleveland Clinic Akron General

Standard Operating Procedure
Request for Amendment / Change in Human Subjects Research

PURPOSE

To provide investigator guidance on the documentation and reporting of amendments to previously approved human subjects research.

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

It is the Principal Investigator's responsibility to submit a Request for Amendment / Change in Human Subjects Research to the IRRB Office anytime there is a proposed change to a protocol, procedure, or informed consent/assent document(s) prior to implementation of the change.

The IRRB Office must also be notified of changes in the Prinicipal Investigator and/or addition of sub-investigators or key research personnel in order for them to actively be involved in the research.

Change to Investigator(s) or Key Research Personnel

Any time a new investigator or key personnel are added to a study, a Request for Amendment / Change in Human Subjects Research form is required to be submitted to the IRRB Office prior to the personnel actively participating in research related activities.

All new study personnel are required to have the following complete prior to being approved to perform research:

- Current Curriculum Vitae
- Confidential Information Acknowledgement Form
- Conflict of Interest Disclosure
- Completion of Human Subjects' Research Training (www.citiprogram.org; updated every 3-years)
- Completion of Conflict of Interest Training (www.citiprogram.org; updated every 3-years)

Change in Principal Investigator

If a change in the Principal Investigator is requested, then a Request for Amendment / Change in Human Subjects Research form is required to be submitted to the IRRB Office prior to the change occurring.

The proposed Principal Investigator is required to have the following complete prior to being approved to perform research:

- Current Curriculum Vitae on file in IRRB Office
- Confidential Information Acknowledgement Form on file in IRRB Office
- Conflict of Interest Disclosure on file in IRRB Office
- Completion of Human Subjects Research Training (www.citiprogram.org; updated every 3-years)
- Completion of Conflict of Interest Training (www.citiprogram.org; updated every 3-years)

Change(s) to Research

If a change to the research design, procedures, and/or consent process is proposed, then a Request for Amendment / Change in Human Subjects Research form is required to be submitted to the IRRB office. No changes may be implemented without the approval of the IRRB Office.

If the change results in a change in the protocol, informed consent/assent document, HIPAA Authorization, or recruitment materials, then both a tracked change copy and a clean copy of the document(s) should be submitted with the request. The revision number and date should be changed in the footer of the document to reflect that the effected forms have been updated.

While most changes can undergo an expedited review, a full board review may be requested if the change involves a possible increase in risk to the human subjects.

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 that include 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. No changes may be implemented until the approval letter has been received.