Cleveland Clinic Akron General

FOR IRRB USE ONLY
IRRB Number:_____
IRRB Reviewer:_____
☐ Exempt ☐ Expedited ☐ Full

Institutional Research Review Board Akron General Medical Center
Request for Amendment / Change in Humans Subjects' Research

Please type all of the required information. HAND WRITTEN FORMS WILL NOT BE ACCEPTED. Submit an electronic copy of the completed and signed form with all required attachments to the Institutional Research Review Board (IRRB) IRRB@akrongeneral.org. Questions regarding IRRB submissions can be directed to (330) 344-6947, or by emailing IRRB@akrongeneral.org.

Project Title:

Revision/Version and Date of Effected Document(s) and/or Amendment(s):

Principal Investigator

Name/Degree: Department:
Email: Phone:
Address:

Study Contact Person

Name: Department:
Email: Phone:
Mailing Address:

PROPOSED CHANGE(S)

Change in Co-Investigator(s) or Key Study Personnel

Are you requesting a change in the study co-investigator(s) or key study personnel? ☐ Yes ☐ No
If 'no', go to the Change in Principal Investigator section.

☐ Co-investigator(s) and/or key study personnel are being removed from the study.
If checked, please identify the names of any co-investigator(s) or key personnel being removed.

☐ Co-investigator(s) and/or key study personnel are being added to the study.

If checked, complete the table below for each of the new co-investigator(s) and/or key study personnel.

Name/Degree	Research Role	IronKey#	Department
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		
	Other Key Study Personnel		

Do all new research personnel have an updated CV on file with Research Administration?
☐ Yes ☐ No (If 'no', then you must submit a current CV with this application)

Do all new research personnel have a Confidential Information Acknowledgement document on file with Research Administration?
☐ Yes ☐ No (If 'no', then you must submit a completed form(s) with this application)

Have all new personnel completed human subjects' research protection education in the last 3-years?
☐ Yes ☐ No (If 'no', then complete training at www.citiprogram.org)

Have all new research personnel completed conflict of interest training in the last 3-years?
☐ Yes ☐ No (If 'no', then complete training at www.citiprogram.org)

Note: All new research personnel are required to complete a Conflict of Interest Disclosure form and submit it with this document to the IRRB office.

Change in Principal Investigator

Are you requesting a change in the Principal Investigator? ☐ Yes ☐ No
If 'no', go to Changes in Research section.

Name/Degree: Department:
Email: Phone:
Address: IronKey#:

Provide a rationale for a change in the Principal Investigator:

Describe the proposed Principal Investigator's qualifications:

Will the former Principal Investigator continue to have a role in the study?
☐ Yes ☐ No If 'yes', explain:

Has the sponsor or funding source of the study been notified?
☐ Yes ☐ No ☐ N/a If 'no', explain:

Does the proposed Principal Investigator have an updated CV on file with Research Administration?
☐ Yes ☐ No (If 'no', then you must submit a current CV with this application)

Does the proposed Principal Investigator have a Confidential Information Acknowledgement document on file with Research Administration?
☐ Yes ☐ No (If 'no', then you must submit a completed form(s) with this application)

Has the proposed Principal Investigator completed human subjects' research protection education in the last 3-years?
☐ Yes ☐ No (If 'no', then complete training at www.citiprogram.org)

Has the proposed Principal Investigator completed conflict of interest training in the last 3-years?
☐ Yes ☐ No (If 'no', then complete training at www.citiprogram.org)

Note: Proposed Principal Investigators are required to submit a Conflict of Interest Disclosure form with this document to the IRRB office.

Assurance of Proposed Principle Investigator

I understand as the Principal Investigator, that I am ultimately responsible for the protection of the rights and welfare of human subjects and the ethical performance of the research. I agree to comply with all applicable AGMC policies and procedures, and applicable federal, state, and local laws. I also agree to the following:

- The research will only be performed by qualified personnel as specified in the approved research application and/or protocol;
- No changes will be made to the research protocol (accept when necessary to alleviate apparent immediate hazards to the subject), or consent forms without the prior approval of the IRRB;
- Informed consent/assent will be obtained from all human subjects, unless the consent is waived by the IRRB, using only the approved consent/assent documents and recruitment materials approved by the IRRB. The potential benefits of participation will not be overstated and the risks will not be minimized. Additionally, precautions will be taken to ensure that participants are able to comprehend the consent process;
- Unanticipated problems involving risks to the subjects or others will be reported to the IRRB office in a timely manner; and
- If applicable, all research staff will complete required training and provide appropriate documentation of conflict of interest as well as confidentiality acknowledgement to Research Administration.

_____ _____
Proposed Principal Investigator Signature Date

_____ _____
Printed Name of Proposed Principal Investigator Title

Change(s) to Research

Does this request require the addition, revision, or deletion of the following: (Check all that apply)

- ☐ Consent/Assent forms and/or scripts, parental permission forms and/or scripts, research participation information scripts
- ☐ HIPAA Authorization form(s)
- ☐ Recruitment materials
- ☐ Protocol and/or instruments
- ☐ Other: Specify
- ☐ Not applicable

For all items checked, provide an electronic copy of both the tracked changes and a clean copy. Submit the documents electronically at IRRB@akrongeneral.org.

Describe the changes and provide a rationale for each change.

Describe any changes in the risk and/or benefits to the participants as a result of this change.

If the proposed changes could affect the subjects' willingness to participate in the research, please describe how you will relay information regarding the change to current and former subjects?

RESEARCH STATUS

☐ No research participants have been enrolled.

☐ Research participants have been enrolled (or charts have been reviewed).
If participants have been enrolled or if charts have been reviewed, please indicate the number:

Investigator Assurance

I certify that the information provided in this application is complete and correct. I understand as the Principal Investigator, that I am ultimately responsible for the protection of the rights and welfare of human subjects and the ethical performance of the research. I agree to comply with all applicable AGMC policies and procedures, and applicable federal, state, and local laws. I also agree to the following:

- The research will only be performed by qualified personnel as specified in the approved research application and/or protocol;
- No changes will be made to the research protocol (accept when necessary to alleviate apparent immediate hazards to the subject), or consent forms without the prior approval of the IRRB;
- Informed consent/assent will be obtained from all human subjects, unless the consent is waived by the IRRB, using only the approved consent/assent documents and recruitment materials approved by the IRRB. The potential benefits of participation will not be overstated and the risks will not be minimized. Additionally, precautions will be taken to ensure that participants are able to comprehend the consent process;
- Unanticipated problems involving risks to the subjects or others will be reported to the IRRB office in a timely manner; and
- If applicable, all research staff will complete required training and provide appropriate documentation of conflict of interest as well as confidentiality acknowledgement to Research Administration.

I certify that the proposed changes are not underway at this time and that the proposed changes will not begin until approval has been received by the IRRB.

_____ _____

Principal Investigator Signature Date

_____ _____

Printed Name of Principal Investigator Title