Cleveland Clinic Akron General

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

Institutional Research Review Board Akron General Medical Center
Continuing Review / Interim Report of Human 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 to the Institutional Research Review Board IRRB@akrongeneral.org. Questions regarding IRRB submissions can be directed to (330) 344-6947, or by emailing IRRB@akrongeneral.org.

Project Title:

Estimated Completion Date:

Principal Investigator

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

Study Contact Person

Name: Department:
Email: Phone:
Address:

Research Personnel (use additional sheet if necessary)

Are there any changes to the study personnel? ☐ Yes ☐ No If 'yes', please complete table below.

Name/Degree	Research Role	IronKey #	Department	Add	Remove
	Other Key Study Personn			☐	☐
	Other Key Study Personn			☐	☐
	Other Key Study Personn			☐	☐
	Other Key Study Personn			☐	☐

Conflict of Interest Determination

1. Have any new significant financial interests* or conflicts of interest been identified since the last review?
   ☐ Yes ☐ No
   If 'yes', a revised Conflict of Interest Disclosure form must be on-file with the Department of Research.
2. Do all members of the research team (investigators and key study personnel) have an up-to-date Conflict of Interest Disclosure Form on file in the Department of Research?
   ☐ Yes ☐ No

*Significant Financial Interest means an Investigator's monetary interest or other relationship related to his/her Institutional responsibilities including, but not limited to: salary or paymentfor services (e.g. consulting fees or honoraria), equity interest, excessive reimbursement for conducting a research study, any reimbursed travelorsponsored travel related to Institutional responsibilities (refers to travel, which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be determined by Investigator).

If you answered 'no', please attach a Conflict of Interest Disclosure Form for each member of the research team, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

FUNDING

What is the current funding status of the research? ☐ None ☐ Funded
If 'yes', list the funding source(s):

Is there a new, revised, or renewal grant/contract application since the last IRB review? ☐ Yes ☐ No

If 'yes', please forward any contracts and budgets related to sponsored or funded research to the Director, Office of Sponsored Programs/Associate Legal Counsel Office for Sponsored Programs. Any changes in the contract or funding status should be reviewed by the Office of Sponsored Programs as soon as the change in status occurs.

RESEARCH STATUS

☐ No research participants have been enrolled

Please explain if no participants have been enrolled:

- ☐ Research study is closed.
- ☐ Recruitment is ongoing

☐ Research participants have been enrolled

If participants have been enrolled, check all that apply:

- ☐ Recruitment is ongoing
- ☐ Recruitment has been completed (choose one of the following)
  - ☐ Participants have not completed the research interventions
  - ☐ Participants have completed all research interventions
  - ☐ Research remains open only for long-term follow-up and data analysis
  - ☐ Research remains active only for data analysis
- ☐ Research study is closed. Study activity is limited to data analysis and all data is de-identified.

****IF STUDY RECRUITMENT IS ON-GOING, THEN 'STAMPED' AND 'UNSTAMPED' COPIES OF THE CURRENT INFORMED CONSENT(S) MUST BE SUBMITTED WITH THIS DOCUMENT.****

RECRUITMENT AND INFORMED CONSENT

Have the recruitment materials changed since the last IRRB review?
☐ Yes ☐ No ☐ N/a If 'yes', please attach the updated recruitment materials for studies still enrolling.

Have there been any changes in the consent/assent process since the last IRRB review?
☐ Yes ☐ No ☐ N/a
For studies still enrolling, please attach the most recent consent/assent document(s).

STUDY PROGRESS

Summarize the progress of the research thus far. Describe any obstacles that may have impacted recruitment. Provide a summary of the preliminary results if applicable, including information regarding results that have been published in journals or presented at a professional conference(s).

ENROLLMENT

Number of participants enrolled at Akron General Medical Center:
Number of participants enrolled at other sites:
Total number of participants enrolled:
IRRB approved number of participants:

Are you requesting an increase in the approved number of participants enrolled? ☐ Yes ☐ No
If 'yes', provide a rationale for increasing enrollment:

COMPLAINTS AND WITHDRAWALS

Have any participants submitted a complaint regarding the study since the last IRRB review?
☐ Yes ☐ No
If 'yes', please list the complaints and explain how they were resolved:

Have any participants voluntarily withdrawn (do not include subjects lost to follow-up or investigator initiated withdrawals) from the study since the last IRRB review?
☐ Yes ☐ No
If 'yes', please list withdrawal reasons and any actions taken:

RISK ASSESSMENT

Have any unanticipated problems or serious adverse events occurred since the last IRRB review, which have not been reported previously?
☐ Yes ☐ No **If 'yes', please attach an Unanticipated/Serious Adverse Event report.**

Is the research subject to Data and Safety Monitoring Board review or any other committee/board review for safety and monitoring?
☐ Yes ☐ No **If 'yes', please attach the latest report if not previously submitted.**

Summarize any relevant literature or information obtained since the last review that may impact the risk or benefit associated with the study.

Describe any significant findings, if any, which could influence the subjects' willingness to participate or remain in the study, and how participants have been or will be informed.

Are you requesting any changes in the research (i.e. design, methods, personnel) or consent/assent process?
☐ Yes ☐ No **If 'yes', complete the Amendment form.**

Investigator Assurance

I certify that the information provided in this continuing review/interim report 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 the Department of Research.

_____ _____
Principal Investigator Signature Date

_____ _____
Printed Name of Principal Investigator Title

DOCUMENT SUBMISSION CHECKLIST

Submitted	N/a	Document	Appendix
☐		Continuing Review / Interim Report	
☐	☐	Informed Consent (If enrollment is on-going)	
☐	☐	Assent form (If enrollment is on-going)	
☐	☐	Research Participant Information Sheet (If enrollment is on-going)	
☐	☐	HIPAA Authorization (If enrollment is on-going)	
☐	☐	Recruitment Materials (If changed since last review)	
☐	☐	Request for Amendment or Change in Human Subjects' Research (If not previously submitted)	
☐	☐	Unanticipated/Serious Adverse Event Report (If not previously submitted)	
☐	☐	COI Disclosure Form (Only for those whom a COI exists)	
☐	☐	Contract/Budget for Funded Research (Submit to Office of Sponsored Programs if changes have occurred since the last review)	