PRINCIPAL INVESTIGATOR ASSURANCES AND APPLICABLE REFERENCES

Institutional Review Board and Human Subjects Office

All University of Iowa Principal Investigators agree to the following at the time of submission of a HawkIRB application:

I am ultimately responsible for the conduct of the study.

Office of Human Research Protections (OHRP) FAQ – Investigator Responsibilities

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I agree to comply with all applicable UI policies and procedures, and applicable federal, state and local laws.

Department of Health & Human Services (DHHS): Basic HHS Policy for Protection of Human Research Subjects 45 CFR 46 – Pre 2018 Requirements and 2018 Requirements

OHRP Guidance

OHRP FAQS

Food & Drug Administration (FDA) Policy 21 CFR 50

Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors

University of Iowa (UI) Operations Manual:

27.4 General Policy and Procedures for Review of Research Projects Involving Use of Human Subjects

27.6 Ethics in Research

University of Iowa IRB Policies and University of Iowa Investigator's Guide (UI Guide)

ClinicalTrials.gov Regulations and Requirements

ClinicalTrials.gov Investigator's Guide

The application is consistent with proposal(s) submitted to external funding agencies.

45 CFR 46.103 Assuring compliance with this policy – research conducted or supported by any Federal Department or Agency

UI Investigator's Guide:

Section I, Part 2.A: Division of Sponsored Programs

Section I, Part 15: Overall Approval

Section II, Part 1.A: Beginning the IRB New Project Application

Section II, Part 4: HawkIRB Section III Funding/Support

Section II, Part 19.A: Modifications

The research will only be performed by qualified personnel.
All persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

OHRP FAQs

21 CFR 56.102(h) FDA Definition of an Investigator

21 CFR 312.53(a) Selecting Investigators and 21 CFR 312.53(d) Selecting monitors

21 CFR 812.43(a) Selecting Investigators and 21 CFR 812.43(d) Selecting monitors

IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed

45 CFR 46.116 General Requirements for Informed Consent

FDA Information Sheet – Recruiting Study Subjects

FDA Information Sheet – Screening Tests Prior to Study Enrollment

FDA Information Sheet – A Guide to Informed Consent

University of Iowa Record of Consent Frequently Asked Questions

I will not implement any changes in the approved IRB application, study protocol, or informed consent process without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of a human participant).

OHRP FAQ – What should investigators do if they want to revise an IRB-approved research study?

Human Subjects Office (HSO) FAQs – Modifying an Approved IRB Application or Materials

UI Guide Section II, Part 19.A Modifications

If unavailable to conduct this research personally, as when on sabbatical leave, I will arrange for another investigator to assume direct responsibility for the study. Either this person is named as another investigator in this application, or I will notify the IRB of such arrangements.

OHRP FAQs

UI Guide Section II, Part 19.A Modifications

I will obtain Continuing Review approval prior to 12:01 am on the date the approval for the study expires. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all study activity must cease until IRB approval is granted.

Department of Health & Human Services (DHHS): Basic HHS Policy for Protection of Human Research Subjects 45 CFR 46 – Pre 2018 Requirements and 2018 Requirements

OHRP Guidance on IRB Continuing Review of Research - for on-going studies approved under pre-2018 regulation

FDA Guidance – IRB Continuing Review after Clinical Investigation Approval

HSO FAQs – Continuing Review of IRB-Approved Research

UI Guide Section II, Part 20: Continuing Review

If protected health information is used or created as part of this research project, the research

team agrees NOT to reuse or disclose the information to any other person or entity (beyond the named research team) except as required by law, for authorized oversight of the research project, or unless subsequent IRB approval is obtained for such reuse or disclosure.

HIPAA Privacy Rule

If members of the research team access protected health information from a covered component in order to seek consent and authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered component.

UI Guide Section II, Part 5.D – HIPAA

Neither I nor any member of the research team has a significant financial interest, as defined by the University of Iowa Operations Manual, whereby the value of the interest to me or any member of the research team could be influenced by the outcome of the study.

University of Iowa Conflict of Interest in Research

FDA - What is a Conflict of Interest?

OHRP Guidance – Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

PCORI Applicant Resources -- Policy on Conflict of Interest

NIH Grants & Funding - Financial Conflict of Interest

NSF Grants & Funding – Chapter V Grantee Standards

UI Guide Section I, Part 2.G: Conflict of Interest in Research Committee

UI Human Subjects Office - Conflict of Interest in Research Committee

UI Operations Manual: 18.6 – Conflict of Interest in Research

UI Operations Manual: 18.7 - Institutional Conflict of Interest in Human Subjects Research

If the above stated research study has a plan to compensate the research subjects participating in this project, I acknowledge that our unit has a Cash Handling Procedure that has been approved by Accounting Services.

UI Guide Section II 12.G: Subject Compensation

Research Subject Compensation Policy & Procedures

UI Accounting and Financial Reporting - Research Subject Compensation

UI Accounting and Financial Reporting - Cash Handling Deposits Policies and Procedures

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I assure that the proposed research is not currently being conducted and will not begin until IRB approval has been obtained.

HSO FAQs - IRB Approval

OHRP FAQs - Investigator's Responsibilities - Must investigators obtain IRB approval before involving human subject in nonexempt research?

UI Guide Section I, Part 19: Notification of Approval

- **FDA references are applicable to studies involving drugs, devices and biologics. Studies that do not involve drugs, devices and biologics are not subject to FDA regulations.**