About the Human Research Protection Program – Lawrence Campus (IRB)

I. THE INSTITUTION AUTHORITY UNDER WHICH THE IRB IS ESTABLISHED AND EMPOWERED

The Institution Authority under which this institutional review board (IRB) is established and empowered is the University of Kansas. The authorized institutional official for this IRB, known as the Human Research Protection Program (HRPP) is the Vice Provost for Research at the University of Kansas, Lawrence, Kansas. The University of Kansas has physically located the office of the Human Research Protection Program (HRPP) at the KU Center for Research, Inc.(KUCR), Youngberg Hall.

The purpose of this IRB is to protect the rights, well-being, and personal privacy of individuals; to assure a favorable climate for the conduct of scientific inquiry; and to protect the interests of the University of Kansas.

The University's Assurance

All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.

HSCL will ensure that all requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all applicable Department of Health and Human Services (DHHS)-supported research, and all other human subject research, regardless of sponsorship. 45 CFR 46 is the set of regulations under which HSCL operates. Regardless of source, no funds for which this Assurance applies may be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.

II. HRPP REVIEW DESIGNATION

HRPP designates applications as needing either Non-Committee or Committee Review.

Non-Committee Review. The IRB chair designates IRB members who can conduct Non-Committee Reviews. The HRPP Coordinator and HSCL Assistant Coordinator are Designated Reviewers for Non-Committee Review.

> *Expedited Review*: This level of review requires that the proposed research procedures fall under at least one of the criteria designated by 45 CFR 46.110. No application may receive expedited review if any research procedure presents more than minimal risk, even if it would otherwise fall within the procedures described in 46.110.
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> *Exempt Designation*: The regulations allow for some research activities to be designated "Exempt" (see 46.101 (b)). However, HRPP's agreement with the Office for Human Research Protections (OHRP) stipulates that HRPP must review all research to determine whether or not such research may be exempted from full board review. Research that falls under the definition of "Exempt" research receives Non-Committee Review.

Committee Review. This level of review requires that the proposed research be reviewed by members of the committee, and be acted upon at a convened meeting.

III. THE PRINCIPLES THAT GOVERN THE HRPP IN ASSURING THAT THE RIGHTS AND WELFARE OF SUBJECTS ARE PROTECTED

This institution is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* [the "Belmont Report"]), regardless of whether the research is subject to federal regulation or with whom conducted or source of support (i.e., sponsorship).

a. The University of Kansas and the individual members of its faculty, staff and student body recognize their responsibility for protection of the rights and welfare of human subjects.

b. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.

c. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law and university policy.

d. Minimum standards for informed consent are established by the federal government and may be augmented by the University according to 45 CFR 46.

IV. THE AUTHORITY OF THE HRPP

Scope of authority: What types of studies must be reviewed

This Assurance applies to all **research involving human subjects**, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by this institution, or
2. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.
5. The research is carried out by an organization which has a FederalWide Assurance (FWA) and which has indicated HRPP as its IRB of record.

The term "research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

Pilot studies, pre-tests, and other "preliminary" investigations are considered research and must be reviewed.

Classroom activities may include instructing students in research methodologies and techniques. If the sole

purpose of the activity is to teach students research techniques or methodology and not to develop or contribute to generalizable knowledge, it is not considered to be research. However, if students will practice research methodologies on human beings, they should be instructed in the ethical conduct of such activities and should be advised to obtain informed consent from their practice subjects.

Quality improvement and quality assurance activities conducted solely for the intent of maintaining or improving quality of services provided by an institution, likewise, are not considered research activities.

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

V. THE HRPP'S RELATIONSHIP TO THE INSTITUTION

Education of Investigators

The Human Subjects Tutorial is hosted through the CITI program. Researchers are required to complete the tutorial every three years. Additional learner modules are required when working with specific populations. The *Research and HIPAA Privacy Protections* module is required when researchers work with HIPAA of protected health information (PHI).

Communication with other institutions

Researchers at this institution do collaborate with researchers at other institutions. In such cases HRPP does require the researchers at this institution to submit an application for review by HRPP. HRPP may accept use of another institution's approved protocol and/or consent form if they meet HRPP's requirements for approval.

Institutions that are not direct signatories to this Assurance are not authorized to cite this Assurance. This institution will ensure that such other institutions and investigators not bound by the provisions of this Assurance for DHHS-sponsored research will satisfactorily assure compliance with 45 CFR 46, as required, as a prior condition for involvement in human subject research which is under the auspices of this institution.

Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Assurance must submit a Federalwide Assurance (FWA) to the Office for Human Research Protections (OHRP) of DHHS for DHHS-sponsored research, on request, when that research is not conducted under the auspices of a signatory institution to this Assurance.

HRPP does agree to be the IRB of record for organizations separate from KU when those organizations have an approved Federalwide Assurance (FWA) from the Office of Human Research Protection (OHRP) and have entered into a contractual agreement with HRPP.

VI. OPERATIONS OF THE HRPP

Research Application and Review

All submissions are managed and approved within HRPP's electronic submission system eCompliance. Submissions eligible for Non-Committee review are accepted and processed year round.

Submissions requiring full Committee Review that are received on or before the 15th of the month are reviewed by HRPP at the next monthly meeting, set for the first Thursday of each month. Submissions with missing

components, such as consent forms or debriefing procedures, are withheld from distribution to the board until the missing items are received by HRPP.

All research studies (with the exception of those designated as “exempt”) are subject to continuing review on an annual basis. Investigators receive email reminders to submit their continuing review within eCompliance at 90, 60, 30, and 15 days prior to approval. In order to maintain the study anniversary date, HRPP processes Continuing Reviews 30 days prior to expiration according to OHRP guidance.