PROTOCOLS INVOLVING HUMAN MATERIALS

Policy Number: 607GS

Effective Date: 6/1/16

Revised Dates: 6/26/17; 5/21/19; 11/09/2020

Scope

This Policy on Ethical Review for Protocols Involving Human Materials, Human-derived Substances, or Human Subjects applies to faculty, staff, predoctoral researchers, summer scholars and applicants ("Covered Individuals") of The Graduate School of the Stowers Institute for Medical Research ("The School").

Purpose

The purpose of this policy is to establish guidelines for Covered Individuals using human materials or human-derived substances in research or enrolling human subjects in research protocols.

The School is included in the Stowers Group of Companies ("SGC") Organizations and has adopted the following policy as its own.

Definitions

- Human materials: Primary materials such as liver, kidney, pancreas, gall bladder, brain, thyroid, and bone marrow, as well as blood and body fluids such as whole blood, blood cells serum, spinal fluid, urine, semen, and feces, and any tumorgenic material arising from a primary material.
- Human-derived substances: Proteins, RNA, and DNA derived from human materials.
- Human subjects: Individuals who volunteer to participate in a research protocol after receiving all information required for informed consent.

Policy

The School will adhere to the highest ethical standards when using human materials or human-derived substances for research purposes or when enrolling human subjects in research protocols. The ethical issues of donor privacy, informed consent, vendor trustworthiness, custody and disposal of samples, and the need for approval by the designated Institutional Review Board ("IRB") will be considered when determining whether a particular protocol should be approved or modified.

All vendors, suppliers, and sources of human materials or human-derived substances, as well as the protocol for using these materials, must be approved by the Institute Biosafety Committee ("IBC") the Senior Director of Research Operations prior to their procurement.
No Covered Individual may undertake research with human materials or human-derived substances until these approvals have been obtained.

Institute Biosafety Committee

No human materials or human-derived substances may be obtained, received, or used at SIMR until the responsible principal investigator has filed a registration with the IBC. The registration is necessary so that the IBC can make the determinations set out in IBC SOP 300 of whether the studies are excluded from classification as "human subjects research," as that term is defined in IBC SOP 300 and applicable regulations. If the IBC determines that the research involves identifiable human materials or human-derived substances, is collected for the purpose of the study outlined, or is uncertain of the classification, a protocol must be submitted to the IRB in order to obtain written approval or determination of exemption.

Institutional Review Board

The IRB is the University of Kansas Medical Center ("KUMC"), which conducts IRB review of all uses of human materials, human-derived substances, or human subjects classed as "human subjects research" conducted by Covered Individuals.

Depending on the source of the human materials or human-derived substances or the circumstances surrounding the enrollment of human subjects in research protocols and the affiliations of the individuals involved in the research, approval of other IRBs may also be required. If either the Covered Individual or a research collaborator holds a faculty appointment at an institution other than KUMC, the IRB serving that other institution may also require an opportunity to review the research.

Receipt of Human Materials and/or Human-derived Substances Classed as "Human Subjects Research"

Immediately upon receipt of any human materials and/or human-derived substances classed as "human subjects research" for use in research at SIMR, the responsible principal investigator must register it with the Histology Department.

Reporting Requirements

The responsible principal investigator must fulfill all reporting requirements of each IRB involved in review of the registration covering the use of human materials, human-derived substances, or human subjects.

This policy was approved by the GSSIMR Board of Directors on September 5, 2018.
This policy was last updated by the GSSIMR Board of Directors on November 09, 2020.
This policy will be reviewed by the GSSIMR Board of Directors in 2022.