CHAPTER 1: INTRODUCTION
I. Ethical Principles in Research; Role of IRB
Heritage University’s Institutional Review Board (IRB) has institutional responsibility for all use of human subjects under the auspices of, or utilizing the students, personnel or facilities of, Heritage University. All research projects must be accomplished in accord with this policy, and all research projects covered by this policy may be undertaken only after appropriate approval and may continue only so long as that approval remains in effect.

Heritage University recognizes, and affirms, the need for academic freedom in the conduct of research, and the value of well-designed, responsible activities that involve human subjects. At the same time, Heritage University recognizes and accepts its responsibility to assure the protection of any human subjects involved in research. It is the policy of Heritage University to adhere to the generally accepted ethical and professional standards for the protection of human subjects of research that are described in The Belmont Report, the Declaration of Helsinki, and the Nuremberg Code. The three Belmont Principles have been summarized by the Office for Protection from Research Risks, National Institutes of Health, as follows:

1. “Respect for Persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy….Required by the moral principle of respect for persons, informed consent contains three elements: information, comprehension, and voluntariness…Institutional Review Boards (IRB) should be especially sensitive to these factors when particularly vulnerable subjects are involved.”

2. “Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks or harm…The Report recommends the Institutional Review Board’s insistence upon precise answers to direct questions. The IRB should:
   a. Determine the ‘validity of the presuppositions of the research’
   b. Distinguish the ‘nature, probability, and magnitude of risk with as much clarity as possible,’ and
   c. ‘determine whether the investigator’s estimates of the probability of harm or benefits are reasonable, as judges by known facts or other available studies.’

3. “Justice requires that the benefits and burdens of research be distributed fairly. The principles of justice mandate that the selection of research subjects must be the result of fair selection procedures and must also result in fair selection outcomes. The ‘justness’ of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, or ethnic groups.”

II. Applicability of Policies & Procedures
The Authorized Institutional Official (AIO) is charged with the responsibility of protecting human participants in research. The AIO empowers the IRB to suspend or terminate any study previously approved by the IRB or to require additional reviews. Suspension or termination may be due to serious and/or unexpected increased risks to
participants, or continuing or serious noncompliance of the investigator(s) or other factors that the IRB deems warrant suspension or termination. The AIO cannot influence the decision of the IRB or approve a study that has not been approved by the IRB. The AIO also empowers the IRB to create and implement policy that will serve to protect human participants.

The authority to create, change and implement policy is shared by the IRB and AIO. New policies or changes to policies may be presented to the IRB to solicit input from the committee members. At the discretion of the IRB, input may also be sought from those parties that would be affected by the policy.

The AIO at HU may elect to rely on the IRB of other institutions for review and approval of a study. In order to do so, that IRB must be officially designated on HU’s Federalwide Assurance and a written agreement must be in place between the two institutions. This is generally used when a study involves HU and a facility with which a close working relationship exists. In such an event, the IRB of the other institution, referred to as the IRB of Record, holds the same rights, authority, and responsibility as the IRB of HU. The President or Provost are designees of the AIO to sign these documents.

Every three years, the AIO and IRB will review all policies that are posted on its website, regardless of the date on which the policy was implemented. Such review will include an assessment of the accuracy and relevancy of the policies, a determination as to whether the policies are in-line with institutional policies and whether there is a need for new policies to be developed. Within this document and posted on the IRB website, if an individual policy has been revised, it will show a revision date.

The institution provides support to the IRB and the IRB members in terms of staffing, office space and an operating budget, including educational opportunities. The AIO reviews the ORB/IRB budget annually with the IRB to ensure adequate resources continue to be available.

It is the policy of Heritage University (HU) that all research involving human participants conducted by the faculty, students and staff of HU, or research conducted using HU facilities, is conducted in accordance with federal regulations, regardless of the funding source. Those regulations include, but are not limited to, the following: 1) Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, National Institutes of Health Office for Protection from Research Risks, Part 46, Protection of Human Participants; 2) Code of Federal Regulations, 21 CFR 50, 56, 312, 812, as established by the Food and Drug Administration.

Per 45 CFR 46.103, because Heritage University is engaged in human subjects research (not otherwise exempt) that may be conducted or supported by an agency of the U.S. Department of Health and Human Services (HHS), Heritage University has an Office of Human Research Protections (OHRP)-approved Federalwide Assurance (FWA) whereby the University agrees to conduct all human subjects research in compliance with the HHS regulations. The Heritage University FWA number is FWA00009054.