INSTITUTIONAL REVIEW BOARD

Policy for the Protection of Human Participants

Originally Based on protocols from Antioch College, Oberlin College, Otterbein College, and Ohio Northern University

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Statement of Purpose for the Institutional Review Board

Heidelberg University recognizes the need for investigations in which human beings may serve as research subjects. The University also acknowledges its responsibility for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected. Consequently, Heidelberg University has established the Institutional Review Board committee to review and approve the adequacy of human subject protection. The IRB may approve, disapprove or state conditions for the conduct of human subject research. The ethical principles and guidelines utilized are primarily drawn from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Belmont Report).

Purpose of the Policy Regarding the Protection of Human Participants

The purpose of this policy is to clearly detail the definitions, procedures, and regulations governing any research done at Heidelberg University, which involves human participants. These procedures and regulations are intended to function both as a systematic means to protect the welfare, rights and privacy of human participants, as well as to assure the federal government that these measures are in place. This policy applies to ALL research involving human participants at Heidelberg University or under the auspice of Heidelberg University, regardless of the source of funding. This includes research conducted by individuals outside of the University either using human participants or pre-existing or unpublished data gathered from Heidelberg University. The intended audience for this policy includes research administrators, principal investigators (faculty, staff, and students), and IRB members. The policy describes the review process as well as the requirements and processes of submitting protocols.

Human Participant Research Defined

Human Participant Research is most broadly defined as a process of inquiry, observation or systematic investigation that collects data about individuals who can be individually identified, and that seeks to draw generalizations from the effort. Whether you wish to conduct research resulting in data that individually identifies your participants, or research with confidentiality or anonymity assurances in place, federal law provides participants certain rights and places certain responsibilities on researchers.

The following definitions of human research are derived from the Title 45 Code of Federal Regulations, part 46 ("The Common Rule"):

- **Research** is a systematic investigation designed to contribute to generalizable knowledge.
- **Human participants** are living individuals about whom an investigator obtains data, either through an intervention, interaction or identifiable private information.
- **Intervention** includes both physical procedures by which data are gathered and manipulation of the participant or the participant's environment that are performed for research purposes.
- **Interaction** includes communication or interpersonal contact between the investigator and the participant (e.g., use of interviews or collection of survey data).
- **Identifiable private information** includes information about behavior that occurs in a

context in which an individual can reasonably expect that no observation or recording is taking place, as well as information provided by an individual which they can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

- **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test).
- **Informed Consent** is a process facilitated by researchers that ensures participation in a research study is voluntary and based on (1) a disclosure of the information needed to make an informed decision; (2) an understanding of what has been disclosed (accounting for age and language barriers or ensuring the rights of vulnerable populations; and (3) promoting the voluntariness of the decision about whether or not to participate in the research (or to continue participating).

Who Must Submit Protocols to the IRB

At Heidelberg University, all **faculty, staff, and student research** that conforms to the definitions in the Common Rule must submit protocols for review by the IRB regardless of funding source (federal, state, local, private, or unsponsored) or curricular integration. The Heidelberg University IRB reviews protocol applications from all disciplines. The actions of Heidelberg University officials, researchers, staff, and students must conform to all applicable federal, state, and local laws and regulations.

All individuals conducting human subjects research must submit proposals for approval by the Institutional Review Board (IRB). The IRB must receive such proposals if the research:

- is in any way sponsored by the University;
- is conducted by, or under the direction of, any employee or agent of the University as part of their institutional responsibilities;
- is conducted by, or under the direction of, any employee or agent of the University using University facilities or properties;
- involves the use of the institution's non-public information to contact or identify participants or prospective participants.

Independent Faculty research involving human participants conducted at research sites must have approval before research begins. Human participant research includes any research that involves identifiable human participants intended to result in generalizable knowledge, including interview-based research. IRB approval from a previous institution does not constitute IRB approval at Heidelberg University.

Faculty-Student Collaborative Research, whether on or off-campus, requires IRB approval.

Student research involving identifiable human participants intended to result in generalizable knowledge OR any research gleaning information from identifiable human participants that may

be shared outside the classroom learning environment **must** be submitted for review at Heidelberg University. For example, a student project on diversity presenting aggregate survey data at a research conference or public symposium **must** submit protocols and gain approval prior to engaging in research activities.

Please note that class assignments and honor's project research involving information gleaned from human participants are typically subject to IRB approval as laid out in the Common Rule.

Please consult the Office of Human Participant Protection charts at the end of this document to assess the likely status of your research project.

Types of Research Reviews by the Institutional Review Board

There are three types of review of proposed research protocols which investigators can submit to the Institutional Review Board: 1) Full Review which requires review by the Institutional Review Board at a convened meeting, 2) Expedited Review where the review is conducted by a Subcommittee of the Institutional Review Board, and 3) Exempt Review where the investigator submits a modified protocol under the exempt category which is then treated as an expedited review. It is the responsibility of the IRB to determine if the proposal requires full committee review, expedited review, or is exempt from review.

Full Review

Full review is required for all human subjects research involving more than minimal risk to subjects/participants and for research involving vulnerable populations (e.g. children, mentally or physically handicapped people, prisoners). Research in which the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing must be submitted for full review.

Any member of the Institutional Review Board may request a Full Review of a research protocol. The review must be conducted by a majority of the members present at a convened meeting, including at least one member whose primary concerns are in nonscientific areas. Approval of research is by a majority vote of this quorum. Research protocols or activities may be disapproved only after a Full Review.

Investigators should submit their completed IRB proposal packet using the Moodle site at: https://numu3.heidelberg.edu/moodle/. A complete packet includes the IRB form, abstract, informed consent, any study materials (surveys, questionnaires, etc.) to be completed by participants, and a certificate of completion from the National Institutes of Health (NIH) "Protecting Human Research Participants" for all faculty or staff mentors on the project. To complete this training, researchers must register with the NIH and proceed through the online tutorial available at https://phrp.nihtraining.com/users/login.php. The packet must be submitted by the deadlines published on Moodle (usually at least 7 days prior to the IRB meeting).

Though substantial efforts should be made to minimize risks, any unanticipated problems involving risks to subjects or others must be reported the IRB immediately.

Expedited Review

Expedited reviews may be carried out for:

- Some or all of the categories of research then currently established by federal regulations as being eligible for an expedited review procedure if the research involves no more than minimal risk (e.g.,45 CFR 46, Subpart A. 46.110 available at http://www.hhs.gov/ohrp/policy/expedited98.html)
- Minor changes in previously approved research during the period for which approval is authorized;
- Projects that have been previously approved by the IRB and whose approval date exceeds one year;
- Determination of whether research involving human subjects is exempt from this policy.

Under the Expedited Review procedure, the review may be carried out by the Institutional Review Board Chair and a rotating regular member(s) who will comprise a Subcommittee of the Institutional Review Board. The reviewer(s) of the Subcommittee may exercise all of the authorities of the Institutional Review Board except they may not disapprove the research. The Institutional Review Board shall keep all members advised of research protocols which are pending, have been approved, or determined to be exempt under this expedited procedure by notifying the full committee of review status of each proposal through email. All documents for each study protocol will be available to all committee members via Moodle.

To apply for expedited review, ***the standard protocol form must be submitted*** for review by the chair of the IRB. Protocols that do not fit the expedited review category will be sent to the full committee for review.

Research Eligible for Exemption

An investigator may submit a research protocol to the Institutional Review Board for Exempt Review if the research involving human subjects will be in one or more of the following exempt categories:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the preceding paragraph of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Except as may be provided by law (e.g., research funded by the United States Department of Health and Human Services), the Institutional Review Board has final authority to determine whether particular research is subject to this policy or exempt under one of the categories stated above. An investigator who believes his or her research is exempt under one of the stated categories shall submit his or her written protocol to the Institutional Review Board together with a statement that he or she believes it to be exempt and the reasons for his or her belief; the format of the protocol will be supplied by the Institutional Review Board. The determination of exempt status shall be made by means of the expedited review set forth in this policy.

Resubmissions to the IRB

IRB approval is valid for one year. For multi-year studies, the researcher must resubmit an IRB proposal annually. If significant changes are made to the study anytime during the research process, the research proposal must be resubmitted to the IRB for a new review.

Required Training

Before commencing research or sponsoring student research projects, all University faculty and staff must complete the training in human participant research module provided by the National Institutes of Health (NIH). To complete this training, researchers must register with the NIH and proceed through the online tutorial available at https://phrp.nihtraining.com/users/login.php. All members of the IRB must also complete this training. Each individual must renew their training

at least once yearly following initial completion of the course.

Duties of the IRB

The IRB is charged with protecting human research participants. To carry out its duties, the IRB will:

a) Determine what activities constitute research that involves the use of human participants
b) Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by the policy prior to the commencement of such research.
c) Require that voluntary informed consent is obtained from all human participants, and that the information provided to participants as part of informed consent is in accordance with all appropriate regulations and standards.
d) Notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. IRB approval means that the research has been reviewed and may be conducted within the constraints set forth by the IRB and other appropriate requirements. If research is disapproved, the IRB will include a statement of reasons for its decisions and give the investigator an opportunity to respond in writing or in person.
e) Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and have authority to observe or have a third party observe the consent process and the research.
f) Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unanticipated harm to participants. Any suspension of termination of approval shall include a statement of reasons for its decisions and shall be reported promptly to the investigator and appropriate institutional officials.

IRB Membership and Infrastructure

The Heidelberg University Institutional Review Board for Human Participants consists of 5 members. As required by Title 45 Code of Federal Regulations, part 46 ("The Common Rule"), these members consist of:

a) Both men and women
b) One faculty member with a decidedly scientific interest
c) One faculty member with a decidedly non-scientific interest
d) One member who is not affiliated with Heidelberg University nor is a family member of anyone affiliated with Heidelberg University

By discretion, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. However, these individuals may not vote with the IRB.

Members will be elected by the general Faculty for two-year terms.

Additional Resources

The Office of Human Research Participant Decision Charts are an invaluable resource for investigators. They are available online at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html. Further resources, including info on Informed Consent, can be accessed from the Office for Human Research Protections of the Department of Health and Human Services at http://www.hhs.gov/ohrp/policy/consent/index.html.