Human Subjects Review Board

Policies and Procedures

Hendrix College

Conway, Arkansas

With acknowledgements to Hope College and the University of Central Arkansas.
Updated January 2018.

PURPOSE

Hendrix College is committed to the ethical treatment of all human participants in research conducted by its faculty, staff, and students. The Hendrix College Human Subjects Review Board (HSRB) is responsible for reviewing all research done under the auspices of the college and to ensure that, in each project, human participants are treated in a just and ethical manner. Hendrix College will comply with the regulations of the United States Department of Health and Human Services for the Protection of Human Research Subjects (Part 46 of Title 45 of the Code of Federal Regulations, as amended) and with the principles 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* (also know as the *Belmont Report*). Copies of both documents are available in the offices of the Donald W. Reynolds Center for Life Sciences. The three basic principles of the Belmont Report are **respect for persons** (acknowledging autonomy and protecting those with diminished autonomy), **beneficence** (maximizing possible benefits while minimizing possible harm), and **justice** (sharing equitably the burdens and benefits in the population). For each research project conducted at Hendrix College, the HSRB shall be responsible for ensuring the following:

- Any costs and risks to participants will be outweighed by the sum of the benefit to the participants and the importance of the knowledge to be gained in order to warrant approval of the proposed project.
- The rights and welfare of all participants will be adequately protected.
- Informed consent will be obtained from all participants in accordance with HSRB policies.
- On-going projects will be reviewed at timely intervals (at least once a year).

The HSRB shall have jurisdiction over the collection and analysis of data that utilize the participation of human participants and are intended primarily for research purposes.

NEW CHANGES TO THESE POLICIES AND PROCEDURES

As of January 19, 2018, amendments to the Common Rule, known as the Final Rule, will be adopted by the Hendrix College Human Subjects Review Board. These changes include:

- the addition of a "concise summary" on informed consent forms;
- the expansion of categories of research that qualify as exempt from HSRB review and require only minimal HSRB monitoring;
- the reduction of oversight of research that spans multiple institutions to a single review board; and
- changes to post-approval monitoring of research projects.

Thus, if you have conducted research under our previous Policies and Procedures, we encourage you to direct your attention to the sections of this document that address the above issues.

At this time, Hendrix College is not implementing procedural changes related to Broad Consent, as detailed in the Final Rule. Full information about the Final Rule can be found here: https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf

DEFINITIONS

Research: A systematic investigation, including preliminary research (pilot studies) designed to develop or contribute to generalized knowledge, whether or not funded or supported.

> ***Note***. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected are not termed "research" per the Final Rule and, thus, are not subjected to the Policies and Procedures of the Human Subjects Review Board.

Human subject: A living individual about whom an investigator conducting research obtains

(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

> **Note:** Data that is already in existence, publicly available, and free of all identifiers prior to the research study is considered ***secondary data*** and does not involve human subjects; therefore, research involving analysis of secondary data is not subject to HSRB oversight.

Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

Identifiers: Any material that would allow an individual to identify a subject in a research study either directly or through identifiers linked to the subjects. When possible, researchers should not record identifying information about subjects.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Intervention: Both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Benign behavioral intervention: Interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Clinical trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

> ***Note.*** If your research meets the definition of a clinical trial and is supported by federal funding, you must register your research as a clinical trial via https://clinicaltrials.gov

Private information: Information about a person or behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information provided by an individual for specific purposes which the individual can reasonably expect will not be

made public. When recording private information, ***coding precautions*** should be used to protect individual identities. The codes should be kept in a separate location from the data.

At-risk research: Research that places a subject in a position with greater potential for physical, mental, social, legal, or financial harm than would be expected for that individual in their normal occupation or daily activities. **At-risk research requires HSRB review.**

Minimal-risk research: Research that places a subject in a position where the probability and magnitude of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. **Minimal-risk research requires HSRB review.**

Exempt research: Research that falls under one or more categories of exemption (see Pages 5-6 of this document) and does *not* involve any of the following:

- Undisclosed deception (i.e., participants are unaware that deception will be occurring)
- Physiological measures (data collected from a FitBit, EEG, etc.)
- Personally identifiable information that could connect subjects' data back to them
- The use of the following vulnerable populations: children, pregnant women, prisoners, individuals with cognitive impairments, elderly participants, economically- or educationally-disadvantaged individuals
- More emotional, physical, legal, social, mental, or financial risk than the average person would experience in everyday life

Informed consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research.

Permission: The agreement of the parent(s) or guardian(s) to the participation of their child or ward in research.

Children: Persons who have not attained the legal age of or consent (under 18 years of age). Research involving participants under the age of 18 requires the consent of a legal guardian.

Emancipated minor: A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they had by virtue of assuming adult responsibilities, such as self-support, marriage, or procreation.

COMMITTEE STRUCTURE

The Associate Provost of the College is responsible to ensure that the HSRB is completing its duties in a timely and appropriate manner. The co-chairs of the HSRB shall submit an annual report detailing the activities of the board to the Associate Provost.

The members of the HSRB shall be appointed annually by the President of Hendrix College. The composition of the board shall adhere to the following guidelines:

- Have at least five members, with the diversity of the institution represented in terms of race, gender, cultural background, and disciplinary expertise.
- Include two faculty members from different departments in the Social Science Area, one of whom will serve as a chair. The chairs shall provide board members with copies of pertinent

federal guidelines, the Belmont Report, and any other materials that might be useful to them in their deliberations.

- Include two student members with research experience
- Include a person from on- or off-campus with an advanced degree in a health-related profession.
- Include a community member who is not currently affiliated with Hendrix College and has no immediate family member currently affiliated with Hendrix College.

The board may, at its discretion, 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 HSRB, but these individuals shall not be considered HSRB members and shall not vote on the issue of approval of any projects.

Any HSRB member with a vested interest in a project being reviewed must be disqualified from participating in the decision.

PROCEDURES

Determination of Review

The first task of a researcher is to determine their project's need for HSRB review. **If a researcher believes their project to qualify for exemption (please see below and the document, "Is my research exempt from review?" on the HSRB website), the researcher need only submit a Self-Determination Form to the HSRB.** For minimal risk and at-risk projects (see DEFINITIONS), a full proposal must be submitted to the HSRB.

Exemption from HSRB Review. Research that falls under one of the below categories may qualify for exempt status.

Note. Other, less common categories of exemption are available for review on page 7262 of https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf)

1. **Educational research:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are **not likely to adversely impact students' opportunity to learn** required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. **Surveys, interviews, educational tests, and observation of public behavior:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording). Oral history research is included in this category.

3. **Benign behavioral interventions:** Research involving benign behavioral interventions (see DEFINITIONS) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

4. **Secondary research:** Secondary research (see DEFINITIONS) uses of identifiable private information or identifiable biospecimens, **if at least one of the following criteria is met:**
    a. The identifiable private information or identifiable biospecimens are publicly available; OR
    b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

In addition, exempt research **must not** involve any of the following:

- Undisclosed deception (i.e., participants are unaware that deception will be occurring)
- Physiological measures (data collected from a FitBit, EEG, etc.)
- Personally identifiable information that could connect subjects' data back to them (see exception above for publicly-available secondary data)
- The use of the following vulnerable populations: children, pregnant women, prisoners, individuals with cognitive impairments, elderly participants, economically- or educationally-disadvantaged individuals
- More emotional, physical, legal, social, mental, or financial risk than the average person would experience in everyday life

Research projects that are conducted for pedagogical purposes, are not intended to add to generalized knowledge, and present no more than minimal risk to the subjects do NOT need to submit a Self-Determination form to the HSRB. This includes all student research conducted for course credit that is not intended to be presented at a professional conference or published. **Instead, for these projects, the professor for that course has the responsibility to review the student's research proposal**. If he or she deems the research to place participants at risk or if the student wishes to conduct research involving vulnerable populations, the professor must submit that proposal to the HSRB for a full committee review. Anytime professors wish to obtain HSRB approval for student research, they should feel welcome to submit the research for review.

Submission of Self-Determination Forms

Before any exempt research activity involving humans as participants may be undertaken at Hendrix College, the Principal Investigator must submit to the HSRB **one** paper copy (with original signatures) and **one** electronic copy (sent to HSRB@hendrix.edu) of the Self-Determination Form. **A researcher will be notified by an HSRB Co-Chair within 24 hours if their project does not qualify for exemption;** if a project is determined by an HSRB Co-Chair to not meet the criteria for exemption, then a full proposal must be submitted and approved before research activities may begin.

Submission of Minimal-Risk and At-Risk Proposals

Before any non-exempt research activity involving humans as participants may be undertaken at Hendrix College, the Principal Investigator must submit to the HSRB **one** signed paper copy (with original signatures) and **one** electronic copy of the plan of investigation to the HSRB chair (sent to HSRB@hendrix.edu). The plan must include each of the following:

- A completed *Application for Review of Research Involving Human Subjects*, called the **HSRB Application** on the HSRB website. The application includes a question that asks investigators to

assess whether or not their project puts participants at minimal risk (see definitions above) and includes a brief description of the project.
- Copies of any materials to be used, including interview protocols, survey instruments, and any text used in the recruitment of participants.
- A copy of the informed consent form (see detailed description below and the sample informed consent document in the Appendix as a template) or a request for a waiver of informed consent documentation or waiver of traditional informed consent.

In addition, students who are serving as the primary investigators of research must also include the following with their HSRB proposal:
- Certificate(s) of completion for the National Institutes of Health Protecting Human Research Participants course.
- **NOTE**: This course replaces CITI training. If you previously completed CITI training through Hendrix College, you DO NOT have to complete the NIH course. Instead, please indicate your prior completion on your HSRB application and the chairs will confirm your completion in our CITI database.

Informed Consent Form

Participants should sign a copy of the informed consent form for the investigator's files and should receive a copy of the form for their own use. A sample informed consent form is provided in the Appendix.

The informed consent form should:
- Begin with a concise summary of the most important information (see the Appendix for more detailed information);
- Clearly state that the study involves research and describe the purposes of the research;
- Describe the activities in which the participants will be engaged;
- Describe any benefits to the participants or to others which may be reasonably expected from the research;
- State whether data will be collected from the participants anonymously and whether those data will be held in confidence;
- Advise participants that they are free to withdraw from the study at any time without penalty;
- Describe any reasonably foreseeable risks or discomforts the participant may experience;
- Tell participants whom to contact for answers to questions about the research, about their rights as subjects, and about any research-related stress or injuries.

Waiver of Informed Consent Documentation. Under some circumstances, researchers may not need to obtain signed consent forms. Researchers can request a waiver of informed consent documentation if:
- The only record linking a participant and the research would be the consent document (i.e., no personally-identifying information is collected) and the primary risk would be a breach of confidentiality;
- The research presents no more than minimal risk and no procedures for which written consent is typically required outside of the research contexts;
- When surveys are administered on-line, through the mail, or over the telephone, it will not be necessary to ask participants to return a signed copy of the informed consent form unless the HSRB makes doing so a condition of approval.

Waiver of Informed Consent. Under some circumstances, researchers can request a waiver of informed consent if

- The research involves no more than minimal risk;
- The waiver will not adversely affect the rights or welfare of the participants;
- The research could not be practically be conducted without the waiver (e.g., informed consent to observe a public event);
- Participants will be provided with additional pertinent information *after* participation.

Please note that *the justification for either type of waiver* – either one requesting a waiver of informed consent or one requesting a waiver of informed consent documentation – *must be provided in the HSRB proposal* for the waiver to be considered.

Review of Proposals

Full Board Review. An HSRB chairperson will distribute copies of the plan of investigation to four board members and will schedule a meeting for the following circumstances:

- If the investigator indicates on the *Application for Review of Research Involving Human Subjects* that the proposed project involves putting the participants at risk or if an HSRB chair disagrees with the investigator's assessment that the project involves minimal risk to participants.
- If the research is conducted with a vulnerable population (e.g., children, cognitively impaired persons, prisoners, and elderly/aged persons).
- If a board member disapproves of a project sent through Expedited Review (see below).

All reviewing members of the HSRB shall be sent materials pertaining to the proposal and shall be given timely notice of all meetings. No meeting can be held with fewer than four members present.

The HSRB shall strive to arrive at a consensus in its decision, and all projects must be approved by a majority of the attending members. Decisions of the HSRB can be appealed to the Associate Provost.

Expedited Review. If the investigator indicates on the *Application for Review of Research Involving Human Subjects* that the proposed project involves minimal risk to participants, and if a chair of the HSRB agrees with that assessment, then the review will be carried out by an HSRB chair or will be conducted by an experienced committee member who is designated by a chair.

The HSRB chair or committee member conducting the review may offer approval with the provision that minor procedural changes be made in the protocol. If the investigator agrees to implement the suggestions, it will not be necessary to convene the board to discuss them. However, the investigator should resubmit his or her proposal incorporating those changes for the purpose of a permanent record.

Requests for a waiver of informed consent documentation or a waiver of informed consent can be considered in both full board reviews and expedited reviews by the members of the HSRB.

Timeline Regarding Proposal Review

For projects that pose minimal risk to participants and can be evaluated using Expedited Review, it will typically take ***five business days*** for researchers to receive feedback. If the HSRB suggests any changes,

researchers will typically need to respond to the suggested changes within one week of receiving the HSRB feedback.

For projects that place participants at risk, a Full Board Review will have to be conducted. Typically, this will take ***five to ten business day***. If the HSRB suggests any changes, researchers will typically need to respond to the suggested changes within one week of receiving the HSRB feedback.

These timelines are the time for review ***after*** all required materials are submitted. If an initial proposal does not include all required materials, the committee will wait until all materials have been submitted for review before the beginning of this timeline.

Decisions Regarding Proposals

An HSRB chair shall notify all investigators of the board's decision regarding their applications. Approval of at-risk applications will last for twelve months; investigators will be given an expiration date when they receive approval. Approval of minimal risk applications will not expire. In the event that the HSRB did not approve an application, the chair will explain to the investigator why approval was not granted and will specify the changes that would be necessary for the application to be approved. The chair will also shall notify investigators of their right to appeal HSRB decisions to the Associate Provost.

The chairs shall place all correspondence with board members, correspondence with investigators, and minutes of all meetings (including discussions of substantive issues, the resolution of those issues, and any vote counts) in a permanent file. All records shall be retained for at least three years.

HSRB Monitoring of Ongoing Research Activity

Exempt research. If your Self-Determination Form was accepted by the HSRB, your project will be subject to minimal oversight by the HSRB.

- For record-keeping purposes, the HSRB will email the Primary Investigator every two years to determine whether or not the project is still active.
- Researchers do not need to inform the HSRB about modifications to research protocols, ***so long as the modifications do not change the exempt status of the research.*** If a change to a research protocol changes the status of a research project from exempt to minimal risk or at risk, a full proposal must be submitted to the Board.
- Exempt research projects do not carry approval expirations dates.

Minimal risk (expedited) research. If your project was approved as a minimal risk project, your project will be subject to minimal post-approval oversight by the HSRB.

- For record-keeping purposes, the HSRB will email the Primary Investigator every two years to determine whether or not the project is still active.
- When a project is no longer active, researchers are expected to submit the **HSRB Final Report form**. This report communicates to us that your research has concluded properly. Research for which a Final Report has not been received may be considered non-compliant.

- If there are substantive changes to a research proposal, researchers will need to complete and submit the **HSRB Modification form** to request approval for these changes, with changes highlighted in all supporting documents (e.g., questionnaires, etc.). These changes may be implemented as soon as they are approved by the HSRB.
- Minimal risk projects do not carry approval expiration dates and, thus, do not need to apply for continuing review.

At-risk (full board) research. If your project was approved as an at-risk project, your project will be subject to the following post-approval oversight by the HSRB.

- For record-keeping purposes, the HSRB will email the Primary Investigator every year to determine whether or not the project is still active.
- When a project is no longer active, researchers are expected to submit the **HSRB Final Report form**. This report communicates to us that your research has concluded properly. Research for which a Final Report has not been received may be considered non-compliant.
- If there are substantive changes to a research proposal, researchers will need to complete and submit the **HSRB Modification form** to request approval for these changes, with changes highlighted in all supporting documents (e.g., questionnaires, etc.). These changes may be implemented as soon as they are approved by the HSRB.
- **At-risk projects may not continue past their approval expiration date** (one year after approval). The date on which your project's HSRB approval expires can be found on the HSRB approval memo. If you are unsure of your project's approval expiration date, please e-mail HSRB@hendrix.edu. **If you wish to continue your research project (ongoing data collection) beyond its original approval expiration date, submit the HSRB Continuing Review form within 30 days of the project's expiration date.** Projects may be renewed twice over the course of the project, resulting in three years total project time. If modifications will be made to the study design or procedures, please submit an updated application with modifications highlighted. If there are no changes to the research as described in the original HSRB Application after a year, resubmit the most recent version of your HSRB Application.
    - *Note.* At-risk projects that are at the data analysis stage and are no longer enrolling participants do not need to submit for continuing review.

Appendix: Sample Informed Consent Document

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

CONCISE SUMMARY: The revised Common Rule requires that consent forms have a concise summary at the beginning of the document. This should include a summary of the purpose of the study, duration of participation, any requirements of the participants, and the major risks and benefits to participating. If your research involves the collection of identifiable private information or identifiable biospecimens, please also include that information here. Information may be discussed later in the form, as well, but should be presented in a shortened form here.

1. You are invited to participate in a research study conducted by **[insert primary researcher(s) and faculty supervisor's names]**. The overall purpose of this research is **[insert brief goal of the research]**.
2. a) Your research participation will involve [insert short, easy to understand description of what participants will be asked to do in the study].

   b) The amount of time involved in your participation will be **[insert time]**. For your participation, we will compensate you with **[insert any compensation or remove this sentence]**.
3. There are certain risks and discomforts that may be associated with this research, which may include **[insert description of potential risks]**.
4. The possible benefit to you from this research is **[insert description of benefits]**.
5. Your participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time. You will NOT be penalized in any way should you choose not to participate or to withdraw your consent.
6. We will do everything we can to protect your privacy. As part of this effort, your identity will not be revealed in any publication that may result from this study **[only include this sentence if it is true]**. Only the researchers will have access to your data. **[Insert any safety precautions and ways confidentiality will be maintained, if you have promised confidentiality]**.
7. **IF YOU PLAN TO TAPE AN INTERVIEW, YOU NEED TO INCLUDE THE FOLLOWING:** With your permission, I would like to **[video or audio]** tape this interview. We can stop the taping at any time (or not use the tape at all) without penalty and I will not put your name on the recording. At the end of the study, I will transcribe the tape and then erase it **[please modify this sentence to reflect any differences in what you might do with any taped information]**.
8. If you have any questions or concerns regarding this study, or if any problems arise, please feel free to contact the researchers **[insert the contact information – including email address and phone number – of researcher(s) and faculty supervisor]**. If you have any questions about the rights of research participants or any concerns about the research, feel free to contact the Co-Chairs of the Hendrix College Human Subjects Review Board, Dr. Kiril Kolev and Dr. Lindsay Kennedy (501-450-1236 and 501-505-1527; HSRB@hendrix.edu)

I have read this consent form and have been given the opportunity to ask questions. I will also be given a signed copy of this consent form for my records. I hereby consent to my participation in the research described above.

Participant's Name Printed	**Signature of Participant**	**Date**

Signature of Researcher	**Date**