A. Purpose

The Houghton College Institutional Review Board (IRB) exists to ensure that people who participate in research are treated ethically. The IRB protects the rights and welfare of participant volunteers in research projects that fall under the auspices of any department within the college. It is not the review board’s purpose to determine the goodness of a proposal or its efficacy. Approval is solely based on safeguarding those involved, including principally the participants, but also the researchers and their institutions.

Houghton College recognizes and accepts the responsibility to protect the rights and human welfare of research participants. As such, the college’s IRB policy* complies with the Code of Federal Regulations, (http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html), Title 45, Subtitle A–Department of Health and Human Services, Part 46–Protection of Human Subjects.

Houghton’s IRB serves in an advisory capacity to the president of the college. Although it remains the prerogative of the institution to determine its own policies regarding all aspects of the research program, we acknowledge that all research involving human participants will require the full review and prior approval by the IRB, unless the project is eligible for exemption or expedited review as described below. As stated in the federal guidelines (see 45 CFR 46.112), a college official cannot unilaterally approve a previously IRB disapproved research proposal.

To accomplish permission to proceed with the research, an application should be sent to the IRB through its chair for approval before any participants are recruited or data is gathered. Researchers should complete the “Application for IRB Review and Approval of Research Involving Human Participants.”

B. Guiding Principles

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the National Research Act of 1974. The commission identified basic ethical principles that should underlie research with human participants. Commission members were from a wide variety of disciplines including medicine, law, bioethics, religion, and other social science disciplines. Their report was published as the

*This policy statement (including the IRB application form) draws liberally from the federal regulations and from the IRB materials associated with Kennesaw State University, Pennsylvania State University, Roberts Wesleyan College, and St. Bonaventure University.
“Ethical Principles and Guidelines for the Protection of Human Subjects of Research” and commonly known as the *Belmont Report*. The following three basic principles undergird the research ethics involving human participants.

1. **Respect for Persons.** The principle asserts that persons should be respected for their individual autonomy and right to make personal decisions regarding self. Participation in research should be voluntary and participants should be provided enough information to make informed decisions about their participation. Further, the *Belmont Report* specifies that persons with diminished autonomy or capacity (e.g., children, impaired individuals) are entitled to additional protections. The principle of informed consent is rooted in accurate information, personal comprehension, and voluntariness. According to the *Belmont Report*, “... to show lack of respect for an autonomous agent is to repudiate that person’s considered judgments” and it would “deny an individual the freedom to act on those considered judgments.”

2. **Beneficence.** The principle of beneficence requires the researcher to protect individuals from harm and make every effort to secure their well-being. Such a value includes maximizing possible benefits while minimizing possible harms. Risk is evaluated by considering both the chance or probability of harm and the severity or magnitude of the possible harm. Again, the *Belmont Report* explains: “The risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects’ rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.”

3. **Justice.** The benefits and burdens of the research should be fairly distributed. It is a violation of the principle of justice to select a class of participants (e.g., welfare patients, institutionalized persons) simply because of easy availability rather than for reasons directly related to the problem being studied. Justice requires that there be fair procedures and outcomes in the selection of participants. “Individual justice in the selection of subjects would require that researchers exhibit fairness...Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons” (*Belmont Report*).

**C. Scope of the Institutional Review Board’s Responsibility**

These policies apply to all research activities conducted under the auspices of Houghton College that to any degree involve using humans as research participants. The institution is guided by the ethical principles of the *Belmont Report* and will comply with federal regulations (45 Code of Federal Regulations, Part 46, or simply, 45 CFR 46) for all human participant research regardless of funding. These federal regulations require the establishment of an IRB to review and approve human participant research prior to its initiation. Specific points of information must be included in the informed consent process and in most cases, the consent process itself shall be documented in writing.
Before a research study involving human participants is initiated, it must be reviewed and approved by our IRB. All human participant research must be reviewed when the research:

- is sponsored by the college;
- is conducted by or under the direction of any employee or agent of this college (including students) in connection with his or her institutional responsibilities;
- is conducted by or under the direction of any employee or agent of this institution using any property or facility of this college; or
- involves the use of this college’s non-public information to identify or contact human participants.

1. **Definition of Research.** Federal regulations define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration). Activities that do not meet this definition would be course evaluations, college-wide assessment (such as the Student Satisfaction Survey and the National Survey of Student Engagement), end-of-course outcomes assessments, pedagogical demonstrations, and in-class activities. If there is some question regarding the research status of an activity, any party may refer it to the IRB chair for clarification.

2. **Definition of Human Participant.** Federal regulations define such as a living individual about whom an investigator conducting research obtains:

   a. data through intervention or interaction with the individual; or
   b. identifiable private information.

Intervention includes both physical and invasive procedures (e.g., drawing blood) and manipulation of the environment for research purposes. Interaction includes communication or interpersonal contact between researcher and participant. 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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical record information).

**D. Structure of the IRB**

1. **Membership.** Federal regulations describe specific responsibilities for the “authorized institutional official” (AIO). The AIO (the vice president and academic dean of Houghton College) has responsibility for oversight of research and IRB functions. The AIO has the legal authority to act and speak for the college, and shall appoint the chair of the IRB. However, the AIO cannot serve as chair of the IRB.

Houghton’s IRB will consist of six members and is structured to include:
a. the authorized institutional official, or designee, for purposes of federal assurance,
b. the IRB chair, appointed by the authorized institutional official,
c. three faculty members elected by the faculty, one in each category of the social sciences, natural sciences, and the faculty-at-large,
d. one individual from the community, appointed by the AIO. Neither this person nor a member of his or her immediate family should be affiliated with Houghton College.

The three elected faculty members of the IRB shall serve staggered, three year terms, and may be re-elected for not more than two consecutive terms. The AIO is a permanently-appointed member of the IRB, according to federal guidelines, and may be represented by a designee who serves any length term at the pleasure of the AIO. The chair of the IRB is appointed by the AIO and serves a two-year term as chair. Business may be conducted with a quorum of any four members.

2. IRB Meetings. The IRB shall meet at least once each academic term, on the call of its chair. Meetings will usually be scheduled monthly to evaluate submitted proposals in a timely fashion. Meetings shall be open and shall be conducted under Roberts Rules of Order. Any decision may be enacted by a majority vote of the members present, providing that at least a quorum of four members is present. IRB members shall not participate in any decision involving their own research or presenting other conflicts of interest. Minutes of meetings shall be kept and shall include the names of members attending, summaries of discussions, actions taken and a numerical vote on these actions, dissenting reports and opinions, and the basis for any required change in or approval of a proposal. Records shall be maintained for at least three years.

E. Researcher Responsibilities

Researchers are obligated to fulfill the following responsibilities when conducting research with human participants at Houghton College.

- Researchers are responsible for protecting the rights and welfare of human participants and for complying with all applicable federal regulations.

- Researchers are responsible for preparing and submitting the appropriate IRB forms. A written approval must be obtained from the IRB prior to commencing any research project. If the project is part of a proposal or application for funding from external sources, the proposal must be approved prior to submission of the proposal or application to the funding agency.

- Researchers are responsible for obtaining informed consent from all human participants according to the procedure approved by the IRB, unless the IRB has specifically waived this requirement.

- Researchers are responsible for providing a copy of the IRB approved and signed Informed Consent Form to each participant at the time of consent, unless the IRB has
specifically waived this requirement. All signed consent forms must be retained in a manner approved by the IRB.

- Researchers will promptly report proposed changes in previously approved research to the IRB.

- Researchers will promptly report to the IRB any injuries or other unanticipated problems involving risks to participants or others.

- Researchers are responsible for seeking the advice of the IRB as necessary concerning research involving human participants not covered in these policies.

- Research conducted by non-faculty staff should be done in cooperation with a faculty member.

- Researchers who are students or non-faculty staff at the college carrying out projects involving human participants must conform to the policies and procedures of these policies. Since students are in a learning role, the faculty advisor under whose direction they are working also bears the responsibility to ensure that the student’s responsibilities are fulfilled.

F. Methods of Proposal Review

Houghton College has adopted three basic methods to review and approve research proposals that involve human participants. In all cases, written notice of the action of the IRB is delivered to the submitter of the IRB approval request and maintained for IRB records.

1. Exempted Review. The IRB chair shall designate members of the IRB to serve as representatives of each of the Academic Areas of the college. Research proposals involving human participants that are in exempted review categories should be submitted directly to the appropriate IRB representative, who may then approve the proposal without further review. Research in the following categories will be eligible for such IRB approval without detailed review (see 45 CFR 46.101).

   a. Research on educational practices conducted in normal educational settings (e.g., educational strategies, instructional techniques, curriculum, classroom management).
   b. Research involving the use of aptitude, achievement, or diagnostic tests in which the identity of the participant is protected.
   c. Research involving surveys, interviews, or the observation of public behavior unless one of the following applies:

      (1) The results of the research can be directly linked to a participant;
      (2) The results can place the participant at risk of criminal or civil liability;
(3) The results can be damaging to the participant’s financial standing or employment;
(4) The research involves sensitive areas such as drug use, illegal behavior, or sexual behavior.

d. Research involving the collection or study of existing data, documents, records, or specimens, as long as these are publicly available.

2. Expedited Review. If the IRB chair determines that a submitted research proposal meets the eligibility requirements for expedited review, the chair or designee may approve the proposal or require modifications before granting approval via an expedited review. The entire IRB will be notified of all proposals approved through the expedited review process, and by majority vote may reconsider the proposal at the next IRB meeting.

The chair, or the chair’s designee, is the sole authority for determining whether the research meets the expedited review criteria based on review and approval of the researcher’s application to the IRB. The chair or designee retains the discretionary right to require full board review, even when the study appears to meet the criteria for expedited review.

Expedited review is limited to research involving no more than minimal risk which involves human participants in one or more of the following ten categories:

a. Collection of hair, nails, or teeth in a non-disfiguring manner
b. Collection of excreta or external secretions (e.g., saliva, sweat, placenta at birth)
c. Non-invasive data recorded from participants over 18 years of age during routine medical/clinical practice (e.g., weighing, visual tests, EEG, EKG)
d. Collection of blood samples from healthy, non-pregnant participants over 18 years of age. The amount should not exceed 450 ml in an eight week period.
e. Collection of dental plaque and calculus during routine prophylactic scaling
f. Voice recording for research purposes
g. Moderate exercise by healthy volunteer participants
h. The study of existing records or medical specimens
i. Research on individual or group behavior or characteristics that does not involve manipulation of behavior or stress to the participant
j. Research on drugs or devices that does not require an investigational new drug or investigational device exemption

3. Full Board Review. Human participant research not classified as exempt or expedited requires review by the IRB at a convened meeting. The IRB may approve, require modifications before approval, or disapprove any proposal. IRB meetings are scheduled regularly and proposals to be considered should be submitted to the IRB chair two weeks prior to the meeting. A period of approximately 2-3 weeks may be expected for IRB response to the researcher, depending on the college calendar.
G. Criteria for Approval

The IRB (or IRB chair or the chair’s designee in the case of expedited studies) requires the following to be satisfied prior to approval:

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be reasonably expected to result.
- Selection of participants is equitable. The IRB should take into account the purposes and setting of the research and should be particularly cognizant of the special problems of research involving vulnerable populations such as children, pregnant women, mentally challenged persons, or educationally disadvantaged persons.
- Informed consent will be sought from each prospective participant or the participant’s legally authorized representative, in accordance with, and to the extent required by, 45 CFR 46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by, 45 CFR 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

H. Notification of Approval

The period that begins the IRB review, a period normally lasting two to three weeks, starts when the researcher receives an email from the IRB chair indicating receipt of the proposal. If the principal researcher is a student, the faculty advisor also receives a copy of the receipt-of-proposal memo. Following action of approval, disapproval, or modification by the IRB, the principal researcher as well as any co-researchers will receive notification via email from the IRB chair. It is the principal researcher’s responsibility to maintain accurate files of IRB correspondence, approvals, and research records for three years following the close of the study. For studies that involve protected health information and are subject to the Health Insurance Portability and Accountability Act (HIPAA), research records must be kept for six years after the close of the study. The approval notification includes a memo from the IRB chair, the principal researcher’s name, the study title, approval date, type of application (new, continuing review, modification), and level of review (exempt, expedited, or full board).

I. Approval Period and Appeal Procedure

A research project will be approved for a period for no longer than one year. Any project requiring an extension beyond a year, or involving any changes in the original procedures once started, must be resubmitted to the IRB for review and approval.
Researchers whose proposals have been disapproved may submit to the IRB a written request for reconsideration, including their reasons for disagreement with the IRB decision, within 30 days after written notification of the disapproval. The IRB will then meet within 14 days to consider the appeal, as long as the college is in session. If not, an appropriate period of time will be agreed upon by the parties. If the IRB still disapproves of the proposal, the chair may, upon written request of the researcher, appoint a special and separate “appeal IRB” to reconsider the proposal. The appeal IRB shall have access to all information concerning the proposal. The decision of the appeal IRB shall be made within 14 days and will be final in the case of a second disapproval.

IRB decisions may be reviewed by college administrators including the president, any vice president, who may themselves request reconsideration of any proposal, whether approved or disapproved. The IRB will then meet within 14 days to reconsider the specified proposal. As noted elsewhere, and stated in the federal guidelines (see 45 CFR 46.112), a college official cannot unilaterally approve a previously IRB-disapproved research proposal.

**J. Consent, Assent, and Confidentiality**

The process of obtaining informed consent is a basic ethical obligation for the researcher. The potential participants are provided with information about the research study that is understandable and permits the participant to make an informed and voluntary decision about whether to participate or not. The amount of information and the manner of presentation is generally related to the complexity and risk involved in the research study. Consent should be viewed as an ongoing educational interaction between the investigator and participant throughout the study.

Except in certain minimal risk studies, the Informed Consent Form is typically signed after the investigator has verbally explained the purpose and procedures involved in the study, answered questions, and otherwise provided information that permits the participant to make an informed decision. The form serves as a written source of information for the participant and documents the fact that the process of consent occurred. A copy shall be provided to the participant.

1. **Contents of Informed Consent.** The informed consent process should provide the potential participant with a full understanding of the research and its consequences, and an opportunity to carefully consider whether or not to participate. Informed consent should be obtained using a written form containing the following items:

   a. A statement that the project involves research, a brief explanation of the research and the expected duration of involvement, and a description of the procedures to be followed, especially any procedures that are experimental.
   b. A description of any potential risks or discomforts for the participants.
   c. A description of any alternative treatments or procedures, if any, that might be advantageous to the participant.
d. A disclosure of any alternative treatments or procedures, if any, that might be advantageous to the participant.

e. A statement as to how the participant’s anonymity and confidentiality will be maintained.

f. For research involving more than minimal risk, an explanation of whether and in what manner any compensation or medical treatment will be made available to the participant in the case of injury.

g. Who to contact concerning further information about the research and who to contact in the case of a research-related injury.

h. A statement that participation in the research is voluntary and that refusal to participate will involve no penalty to or prejudice toward the participant. In addition, a statement should be included indicating that the participant may withdraw from the research project at any time without any penalty, including the participant’s data.

i. Informed consent should contain no exculpatory language through which the participant is made to waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or its agents from liability or negligence.

j. Additional information may be required by the IRB in the informed consent in certain cases, such as a statement about possible circumstances in which the participant’s involvement may be terminated by the researcher regardless of the participant’s willingness to continue, any additional costs resulting from their involvement, or any consequences of a participant’s decision to withdraw from the research, including the participant’s right to withdraw his or her data.

2. Nature of Assent. Consent is a legal concept and as such, may be obtained only through a legally competent adult giving legally informed consent. Minors and those individuals who are not competent to provide consent should be given the opportunity to assent to participate in the research study. Assent is a knowledgeable agreement to participate in the study. Adequate provisions should be made for soliciting the independent, non-coerced assent from minors or cognitively impaired persons who are, nevertheless, still capable of knowledgeable agreement. In general, children about age 6 or older should be given the opportunity to assent. In cases where assent is obtained from a minor or impaired participant, permission must also be obtained from the legally authorized representative (e.g., parent, legal guardian). If the person from whom assent is sought refuses, the person should not be enrolled in the research, even if the parent or legally authorized representative gives permission. On the other hand, if the person from whom assent is sought agrees to participate, the person may not be enrolled if the parent or legally authorized representative does not give permission.

3. Protection of Confidentiality. One crucial issue of importance is the protection of confidentiality, especially in a wide range of social and behavioral studies. These studies may include personality inventories, interviews, questionnaires, the use of observation, photographs and film, taped records, or stored data. The investigator must take precautions to protect the participant’s identity as well as the confidentiality of the research records. The devised mechanisms to care for research information should be carefully explained and be safely locked in private offices. Further, the researcher should describe who has access to that data and under
what circumstances. A special situation arises for video and taped data and photographs, since these media provide additional potential means for participant identification. Investigators must secure participant consent explicitly mentioning these practices. Researchers should also explain plans for final disposition or destruction of such records.

K. Special Considerations

1. Course Related Student Projects. In accordance with federal regulations, Houghton College requires that all human participant research be prospectively reviewed by the designated IRB. Accordingly, course-related research, honors theses, research practica, and masters’ theses involving human participants must be submitted for IRB review and approval. The college recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might be viewed as research. As a general rule, when those activities are conducted solely to fulfill a course requirement, an element of the definition of research (that the intent is to develop or contribute to generalizable knowledge) is lacking. Nevertheless, it is also the case that some classroom research assignments could place participants at risk. When full IRB review and approval are not needed, the instructor of the course bears responsibility for the conduct of the study.

2. Students as Research Participants. Researchers should take particular caution to avoid the unintentional or subliminal coercion that may occur when a potential research participant is also a student. Researchers are encouraged to avoid using their own students as research participants, if possible. Researchers who wish to use their own students should be able to provide a good scientific reason, rather than convenience, for selecting those students as research participants. The study should be relevant to the topic of the class, and participation should be part of the learning experience for the students.

In instances where investigators can provide a good reason for using their own students in their research, the IRB generally requires that someone other than the investigator (instructor) obtain informed consent and collect the data. When this is not possible, the IRB will consider other methods for obtaining consent and collecting data that would not be revealed to the instructor whether or not a student participated in the research study, until after final grades have been determined. The student should be informed of what these procedures are in the Informed Consent Form.

3. Surveys, Questionnaires, and Interview Studies. Not all survey, questionnaire, or interview research is minimal risk. A survey or interview that asks questions about sensitive topics (e.g., childhood abuse, sexual functioning) may cause emotional stress or discomfort to participants and require full IRB review. Some survey research may be classified as exempt from the regulations if the information obtained is recorded in a way that the participant cannot be identified (either directly or through a code number or link). That is, the research data must be anonymous. The term anonymous is sometimes confused with the term confidential. In human participant research, anonymous means that at no time during the data collection could someone determine who provided the information. If a link existed at any time, even if the link is subsequently destroyed, the IRB cannot consider the information anonymous.
A survey or interview study may also be considered exempt from the regulations even when data is not anonymous and if it could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant’s financial standing, employability, or reputation.

The most common classification for survey, questionnaire, or interview research is expedited approval. If the study is not anonymous and contains information that, if known, could be damaging as described above, but it does not rise to the level of more than minimal risk, it may be given expedited approval.

For minimal risk mail-out or web-based surveys or questionnaires, it may be appropriate to request that the chair or the chair’s designee waive the requirement for the participant’s signature on an Informed Consent Form. When the participant’s signature requirement is waived, generally the investigator provides all the required elements of consent in a cover letter, with a statement that returning the survey or questionnaire will be considered voluntary agreement to participate.

L. Handling Allegations of Non-Compliance

Under institutional authority and federal regulations, the Institutional Review Boards are responsible to oversee the safety of research participants and may suspend or terminate human research that (1) is not being conducted in accordance with the federal and institutional requirements, (including not being duly reported for review), or (2) has been associated with unexpected serious harm to participants. Anyone who believes an activity meets the criteria for the definition of research may refer it to the IRB chair. IRBs are supported in this process by the governmental Office of Research Protections (ORP) and the Human Subjects Protection Office (HSPO), as provided in the 45 CFR 46.

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