Castleton University
Human Subjects Institutional Review Board (HSIRB)
Policies and Procedures

I. Purpose of the Policy

This policy's purpose is to protect human subjects of original research conducted at Castleton University. It is intended to ensure that subjects of research are aware of their rights and protections. All research and review of human subjects research at Castleton is guided by the ethical principles of the Belmont Report.

Title 45 of the Code of Federal Regulations (CFR) Part 46 of the Code of Federal Regulations requires an institution engaged in human subjects research supported by certain federal agencies to establish an Human Subjects Institutional Review Board (HSIRB). These policies and procedures are written to satisfy the requirement for written procedures that adhere to federal regulations for ethical conduct of human subjects research. Although these policies are influenced by the guidelines of numerous federal regulatory agencies, the Castleton University Institutional Review Board is ultimately the committee for creating and overseeing them.

In accordance with federal regulations, the HSIRB has the authority to approve, require modifications in (to secure approval), or disapprove human subjects research. The purpose of HSIRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. To accomplish this purpose, HSIRBs review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of humans participating in research.

The Castleton HSIRB directly reports to the Chief Academic Officer (CAO), who serves as the Institutional Official for human subjects research. As Institutional Official, the CAO acts and speaks for the University and oversees the operation of and resources provided for the HSIRB.

The responsibilities of the Castleton HSIRB include:

1. Providing education and training for Castleton faculty, staff, and students in the ethical and legal requirements for conducting research with human subjects.
2. Following the written procedures in this document and in Title 45 of the Code of Federal Regulations (CFR) Part 46.103(b)(4) and to the extent required by 46.103(b)(5)
3. Review research proposals from Castleton students, faculty and staff
4. Consultation with researchers on-campus, as needed
5. Consultation with members of the community who might have an interest or concerns about human subjects research conducted by Castleton faculty, staff, or students.

These policies and procedures are written in accordance with the Federalwide Assurance process. Federalwide Assurance (FWA) is a binding written agreement between Castleton University and Department of Health and Human Services (DHHS). The FWA describes the responsibilities of the institution, the Institutional Official, the Institutional Review Boards, and the investigator. The University is required to enter into this agreement because it receives or intends to receive federal funding for research involving human subjects. The FWA covers all non-exempt human subjects research at Castleton that is DHHS-conducted or -supported or funded by any other federal department or agency that has adopted the Common Rule and relies upon the FWA. It is not project specific. Castleton does not extend our FWA to cover all human subjects research. However, in most cases, the Castleton HSIRB will apply the same ethical standards to all human subjects research activities and the standards and protections described in the Common Rule (45 CFR 46) will be applied.

The regulations in this document are not intended to be definitive. Depending upon the nature, sponsorship, or funding source of the research and the participants involved, Castleton University, its HSIRB, and/or various governmental agencies may impose different or additional requirements not contained in these regulations as permitted or required by law. Moreover, the laws governing human subject research are subject to change, which may require changes to these regulations without prior notice.

In some cases human subjects research conducted at Castleton University or by a Castleton University principal investigator may also be subject to review by another IRB, Castleton HSIRB may rely on another appropriately constituted IRB for the review of the research, including determinations of Exemption. If the other IRB is part of an AAHRPP-accredited HRPP, then it will be presumed that Castleton University standards are being met and Castleton's HSIRB will defer review and decisions about the research to that institution's IRB. If the other institution's HSIRB is not part of an AAHRPP-accredited HRPP, then the HSIRB Chair will make the determination about whether or not to delegate authority. This decision will be made in writing.

Castleton's HSIRB primarily reviews social and behavioral research proposal. In cases where the protocol exceeds the HSIRB members' expertise, and appropriate consultants are unavailable, the HSIRB Chair may decline to review the protocol and request the principal investigators seek review by an external IRB. This decision will be made in writing.

II. Who Must Complete A Request for Review of Human Subjects Research?

Anyone formally affiliated with Castleton University (faculty, staff, students) who engages in scholarly research involving human subjects, either on- or off-campus, must apply for HSIRB approval.

The definition of "human subjects research" in this context is a systematic investigation that collects data from humans through intervention, interaction, or uses identifiable private information for the purposes of contributing to generalizable knowledge. Many forms of surveys, interviews, observations, and experiments led by faculty, staff, and students at Castleton meet this definition. Please see Section III, Definitions, for additional markers of research that falls under the purview of this committee. Any scholarly discipline may involve human subject

research. Sociological, anthropological, and psychological studies often involve human subjects; biological studies sometimes involve human subjects. Increasingly, research in the humanities involves human subjects.

All faculty, staff, and students are urged to evaluate their research agendas in light of this policy. The HSIRB should be consulted to determine whether or not their research qualifies as "human subjects research," even if human subjects or concerns regarding human subjects are traditionally not common in their disciplines.

III. Definitions

anonymous data: data that by virtue of the method of collection can *never* reasonably be connected with the person providing them. Anonymous data can be obtained by using questionnaires that are returned by mail (in envelopes with no return address or other identifying markers), questionnaires that are collected by one of a group of subjects and returned to the researcher, or internet surveys (with software that renders it virtually impossible to connect answers with respondents). Questionnaires that collect data anonymously do not require separate written consent; consent to use the data is implied when the respondent completes the questionnaire (a statement that explains this principle should be printed at the beginning of any such survey). *See also non-anonymous data.*

confidential data: non-anonymous data that a human subject gives an investigator with the understanding or assumption that the human subject's privacy will be honored. Divulging the source of non-anonymous data to an outside party, or failing to ensure that no outside parties will be able to connect data with their source, normally constitutes a violation of confidentiality. This HSIRB presumes that all data collected from human subjects is properly considered confidential, unless subjects have explicitly waived their presumption of confidentiality in writing.

deception: intentionally misleading or providing untruthful information; any concealment or withholding of information from a participant; use of trickery or deceit.

generalizable knowledge: knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts: Knowledge that contributes to a theoretical framework of an established body of knowledge; the primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study; dissemination of the results is intended to inform the field of study (though this alone does not make an activity constitute research contribute to generalizable knowledge); the results are expected to be generalized to a larger population beyond the site of data collection; the results are intended to be replicated in other settings.

human subject: a living individual about whom an investigator (whether professional or student) conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's

environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Experts sharing facts or professional opinions in the area of their expertise are *not* considered human subjects for the purposes of this policy.

HSIRB: the Institutional Review Board. Castleton's HSIRB is responsible for the ethical oversight of all research involving human subjects conducted by Castleton faculty, students, or staff, as well as such research conducted on the Castleton campus by outside investigators.

non-anonymous data: data that, by virtue of how it is collected or the nature of the information, can be connected at some point, no matter how brief, to the person providing them. This category includes questionnaires that the researcher collects personally from a group of subjects (unless a ballot box or envelopes are used). It also may include cases in which the researcher can recognize the handwriting of one or more of his or her subjects and could therefore potentially match the data with a specific respondent. *See also anonymous data.*

oral history: a method of gathering and preserving historical information through interviews with participants about past events and ways of life. Oral history is not subject to HSIRB review if the researcher does not seek to generalize to a larger population beyond the oral history case study. Researchers using oral history methods should follow the ethical guidelines of the Oral History Association, available at http://www.oralhistory.org/do-oral-history/principles-and-practices/

research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (i.e. designed to draw general conclusions, inform policy, or generalizable findings beyond the people, programs, or organizations being studied). Research using human subjects, even if it is done simply to verify existing hypotheses, theses, theories, or ideas, is considered original research.

For the purposes of this policy, the following are *not* considered "research" and thus do not fall under the purview of the HSIRB:

- 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 only on the specific individuals about whom the information is collected
- works that deal entirely with secondary sources (public data sets are considered such secondary sources)

- activities in which human subjects perform exclusively for instructional purposes (though the intent or effort to publish data from such activities—at any time—converts these activities to original research involving human subjects)
- data gathering for the purposes of fundraising by the external affairs offices; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; statistical data collected for the management of institutional affairs; and attitudinal research of alumni, students, or parents
- information collected for entertainment purposes
- data collected as a class assignment only for the strict purposes of fulfilling course requirements and the findings will not be shared beyond the coursework (i.e., cannot be published or presented in a colloquium, symposium, publication, conference, or other public venue.)

Individual student research projects, even if conducted as part of the institutional curriculum, are subject to the same guidelines as other scholarship (i.e., are original research) and require review.

principal investigator (PI): the primary person conducting the research. The principal investigator can be a professional or a student. However, student projects must be overseen by a faculty or staff advisor.

risk: potential for physical, psychological, social, or financial harm. Anonymous surveys often constitute no-risk research. By contrast, *minimal risk* means that some potential for harm exists, but that the probability and magnitude of harm 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 tests.

unreasonable harm: any physical, psychological, social, or financial damage or injury that can be avoided without sacrificing the goals of the research. Unreasonable harm also includes any damage or injury so extensive that it cannot be justified by any contribution the research might make to human understanding.

IV. General Principles

All researchers conducting original research are responsible for protecting their subjects from the risk of unreasonable harm. The principal investigator has initial responsibility for determining whether such a risk exists. A faculty member is responsible for supervising research undertaken by students in the context of his/her courses or departmental/program curriculum. If there is any doubt about risks, the principal investigator should contact the HSIRB chair or a member of the HSIRB.

All researchers, including the principal investigator and any collaborators or research assistants must complete training in the ethics of research with human subjects using a training program that the HSIRB deems acceptable. All Principal Investigators and Co-Investigators will need to complete this training prior to requesting review of their project by the HSIRB. Evidence of completion of the training (certificate, etc.) must be submitted with the Request for Review Form. PIs should follow the guidelines of the relevant professional organizations and, where

appropriate, those of governmental funding and regulatory agencies. Faculty members supervising student research are responsible for introducing the students to Castleton's guidelines.

At a minimum, research activities at Castleton should conform to the following standards:

Informed consent: The principal investigator must explain to subjects before participation, in language and manner that is clear and understandable to the subjects, the objectives of the research, the procedures to be followed, the associated risks, and the potential benefits. Investigators must not use individuals as subjects unless they are satisfied that the subjects, or others legally responsible for the subjects' well-being, freely consent to participating and fully understand the consequences. The consent process should allow for subjects to have questions answered by the principal investigator.

Elements of Consent:

The basic requirements for informed consent (as dictated by federal regulations) are quoted below. The HSIRB requires that the basic elements, required by regulation, be provided to human participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects. These elements must appear within the consent form for both expedited and full board review Note that element #6 below applies only to research that is greater than minimal risk and is therefore not applicable to inclusion in a consent form for expedited review research. 45 CFR 46.116(d) allows for waiver of some elements or all elements of informed consent in some circumstances and most typically involves research that is very low risk and certainly no greater than minimal risk.

BASIC ELEMENTS 45 CFR 46.116(a):

§46.116(a) General requirements for informed consent.Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of any benefits to the subject or to others which may reasonably be expected from the research;
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are

available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

In general, subjects should signal their agreement to participate by signing a *written* consent form, though a researcher may make the case for using oral consent or waiving the need for a signature instead. The requirement for signed, written consent *may* be waived under one of the following conditions:

- the research is not greater than minimal risk
- the consent form will be the only evidence linking the subject and the research, and the primary risk of harm is to the subject's privacy

Anonymous surveys do *not* require written consent, though the explanations of the research protocol that are standard on a written consent form should be included at the beginning of the survey. Consent to participate is implied when a subject completes and returns the survey.

Research involving *deception* compromises a subject's ability to give truly informed consent. The Institutional Review Board will consider requests to waive some of the requirements for informed consent for research that intentionally involves deception, but only if *all* of the following criteria are met:

- The research cannot be done without the deception.
- The potential value of the research outweighs any potential risks to the subject.
- The subjects are informed of the true nature of the research as soon as possible.
- The research involves no more than minimal risk.

2. Confidentiality: Investigators must respect the privacy of their subjects. Investigators must protect confidential information given to them and must advise subjects in advance of any limits on their ability to ensure that the information will remain confidential.

If the data gathered by a student researcher is not anonymous, the HSIRB recommends that the data be turned over to the faculty sponsor, who then becomes responsible for either ensuring that it is destroyed or archiving it with his or her data.

3. Coercion: Subjects, including students who are participating in classroom experiments or faculty scholarship, must not be induced to participate by means or in circumstances that might affect their ability to decide freely.

When course credit is offered for participating in research, some other mechanism to earn that credit must also be made available to those students who choose not to participate as human subjects. Rewards for participating should be in line with the burden imposed by participating, to avoid presenting an undue influence on a person's ability to freely choose to participate (or not).

Researchers must inform subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw will be allowed to do so promptly and without penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this condition must be clearly stated as part of the informed consent statement.

4. Disclosure: An investigator must disclose to a subject, upon request, the source of support for the research.

V. Composition of the HSIRB and Member Roles and Responsibilities

A. Composition of the HSIRB

The Institutional Review Board is a standing committee with a minimum of seven members. The members are appointed by the Institutional Official (IO). The IO at Castleton is the Chief Academic Officer.

The Institutional Official is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Federalwide Assurance (FWA). The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO cannot serve as a member or chair of the HSIRB nor can the IO approve research that has been disapproved (or not yet approved) by the HSIRB.

The general administrative obligations of the IO are:

- Providing sufficient resources, space, and staff to support the HSIRB's review and record keeping duties;
- Providing training and educational opportunities for the IRB and investigators;
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Serving as a knowledgeable point of contact for OHRP and other federal agencies, or delegating this responsibility to another appropriate individual.

HSIRB members (and alternates), appointed by the Institutional Officer, should have a diverse experience and expertise and with the professional competence and background necessary to

adequately review research activities at Castleton. In identifying and appointing the members of the HSIRB, the Institutional Officer, HSIRB Chairperson, and HSIRB Administrator will ensure that the HSIRB is composed of a set of scientists and non-scientists who are diverse both in terms of expertise and background. The HSIRB will include at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in non-scientific areas. The HSIRB will not be composed of only one gender. The HSIRB will include one member who is not otherwise affiliated with Castleton University and is not part of the immediate family of someone affiliated with Castleton University. The HSIRB may invite individuals with competence in special areas to assist in the review of protocols that require expertise beyond or in addition to that available on the HSIRB. These individuals (consultants) may not vote with the HSIRB. All HSIRB members will receive training related to the federal regulations for human subjects research and HSIRB review procedures.

Rosters for each HSIRB contain the following information for each member and alternate:

- Name
- Earned degree(s)
- Chief anticipated contribution (board certifications, licenses, etc.)
- Special representation
- Scientist status (physician, other, or non-scientist)
- Affiliation (yes or no)
- Employment or other relationship with the university

The chair of the committee is appointed by the IO. Records of the committee are stored electronically. The HSIRB is staffed by the HSIRB Administrator who may also serve as a member of the HSIRB. As circumstances warrant, the HSIRB Chair may also fulfill the role of the HSIRB Administrator.

B. Member Roles and Responsibilities

1. HSIRB Chair

The HSIRB Chair is appointed by the IO. The Chair typically convenes HSIRB meetings. The Chair is also responsible for reviewing and approving protocols that do not require full HSIRB review (e.g., expedited). The Chair is ultimately responsible for communicating approvals, disapprovals, and revisions of full board reviewed projects. The Chair is also responsible for and investigating problem reports and noncompliance, including the decision to suspend research until the HSIRB is convened for further review of problems. The HSIRB Chair may designate their duties to the HSIRB Administrator or another HSIRB member.

2. HSIRB Administrator

The HSIRB Administrator is responsible for keeping HSIRB minutes and HSIRB documents as required by federal law. The HSIRB Administrator typically provides the determination of level of review, review of exempt protocols, and provides pre-review and consultation with investigators. In cases where a determination cannot be made or when problems are reported to

the HSIRB, the Administrator will inform the Chair. The duties of the HSIRB Administrator can be designated to the Chair or any other HSIRB member.

3. HSIRB Members

Each member of the HSIRB will serve a 3 year renewable term of service. HSIRB member responsibilities include:

- Attending HSIRB meetings and participating in review of research
- Completing initial training in human subjects research for HSIRB members
- Understanding and applying the Belmont Report, the guiding document for this HSIRB, and the federal regulations in 45 CFR 46, as they apply to research submitted for review
- Reviewing research submitted for review when requested by the HSIRB Administrator or Chair
- Maintaining confidentiality of all HSIRB-related information and documents, including requests for review
- Participating in efforts to educate the Castleton community about ethical and legal requirements for the conduct of research with human subjects

VI. Quorum

The HSIRB Administrator attending HSIRB meetings is responsible for determining that the meeting is appropriately convened with a quorum prior to discussion and voting for each review. Attendance may be in-person or via telephone or other similar voice connection. A quorum is defined as:

1. At least half of HSIRB members listed on the roster are present
2. At least one member is present whose primary concerns are scientific
3. At least one member is present whose primary concerns are non-scientific

If quorum is not met, voting cannot take place and all agenda items are tabled until the next meeting. If quorum is lost during a meeting due to a member leaving, no more voting will take place. HSIRB members with potential conflicts of interest must not participate in the discussion of the research and shall not be counted toward quorum or be permitted to vote on the review for which a possible conflict of interest exists.

VII. Procedures for HSIRB Review

Review Submissions and Determination of Type of Review:

All research proposals involving human subjects must be submitted for HSIRB review and approval**.** All review submissions are screened in by the HSIRB Administrator or Chair. At this initial, pre-review, one of three types of review (Exempt, Expedited and Full Board) is determined. The review type is based on the criteria outlined in 45 CFR 46 or 21 CFR 56.

The types of initial review are exempt, expedited and full.

Exempt Research is "exempted" from federal regulations outlined in 45 CFR 46; which means that the research is not subject to a formal informed consent process or to continuing review by the HSIRB.

Only projects involving no more than minimal risk are considered for Expedited review (45 CFR § 46.110). The HSIRB reviewer makes the final decision as to whether or not the protocol meets the applicability criteria and qualifies for the category or categories noted (or another one or more of the 7 categories) and can make a decision to refer the review to the full board. Investigators must submit sufficient information to ensure that the HSIRB criteria for approval are met, including but not limited to scientific rationale, research protocol, consent form and any other necessary information. The HSIRB Chair typically conducts expedited reviews, however the HSIRB Chair may designate another member of the HSIRB, including the HSIRB Administrator, to conduct the review. The reviewer may (1) approve research submitted for Expedited review (as submitted) or may (2) require modifications prior to approval. The reviewer may not disapprove projects that have been submitted for expedited review. In cases where the research cannot be approved via expedited review, the reviewer must recommend resubmission for full board approval.

Protocols that do not meet the criteria for exempt or expedited review will be reviewed by the full HSIRB.

Scope of Review

IRB review is conducted to ensure proposed research involving human subjects meets the criteria for IRB approval in accordance with 45 CFR 46.111 and 21 CFR 56.111. Specifically, to approve a study, the IRB must find:

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, people

who have physical or mental disabilities, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.
- Informed consent will be appropriately documented, in accordance with and to the extent required by 50.27.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects, such as children, prisoners, pregnant women, people who have physical or mental disabilities, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- The principal investigator is qualified to conduct the proposed research.

To submit an application for review, principal investigators must complete the Request For Review Form and email it along with the additional requested documentation to the HSIRB Administrator, for review. To prepare for review, you will need to have all instruments (e.g., survey questions), participant/subject recruitment materials, a clear description of all study-related procedures, and consent documentation ready.

No application can be submitted without the following attachments:

- the completed request for review form
- evidence of completion of human subjects research training for the principal investigator and any co-investigators
- copies of any source instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, etc.)
- a proposed informed consent document or script or appropriate waiver request
- for students, an email from the researcher’s faculty advisor certifying that the advisor has read and approved the research protocol

An application may also include these attachments as appropriate:

- evidence of permission from cooperating institutions (if any)
- any relevant grant application(s)
- non-disclosure or other agreements with owners of restricted data sets
- for renewals and extensions, a status report
- if the PI is a student, approval from a faculty/staff advisor

Applications are acknowledged by email to the PI (and the PI’s advisor, if the PI is a student). Exempt or Expedited proposals typically are reviewed within one to two weeks; full board proposals are reviewed once a month.

Applications that require full-board review are distributed to the Board by HSIRB staff before each meeting. The committee generally acts by consensus; if consensus cannot be reached, the committee decides in favor of the major opinion.

The initial approval letter sent to the principal investigator must ask the PI to promptly report to the Institutional Review Board any unanticipated problems or adverse effects that the PI encounters in the process of completing the research.

Researchers whose applications are not approved by the HSIRB will be provided a list of the concerns cited by the committee. Normally such researchers will be invited to respond, revise, and resubmit their application for a new review.

Continuing Review: Full board projects HSIRB require annual continuing review. If continuing review is required, the principal investigator must submit, before the date indicated in the approval letter, a status report of the project to date, including:

- the number of subjects accrued
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and withdrawal of subjects from the research or complaints about the research since the last review
- a summary of any relevant amendments or modifications to the research since the last review
- any other relevant information, especially information about risks associated with the research
- a copy of the current informed consent document and any newly proposed consent document

Appeals: If an application is denied because the Institutional Review Board feels the risks outweigh the benefits of the research, and the investigator disagrees with the committee's disapproval decision, the researcher may appeal the decision by re-submitting the same application form and 1) a letter of appeal presenting the researcher's arguments for approval, 2) any other pertinent information in support of the appeal. The letter should be directed to the Chair of the Board. Applications submitted for appeal are considered by the full board at the next scheduled meeting date. The final decision of the HSIRB is delivered in writing to the investigator. If the proposal is not approved, the research cannot be conducted.

For projects covered by the FWA, Castleton keeps records of all applications for approval of human subjects research, including any research documents (informed consent forms, questionnaires, interview scripts, stress protocols, behavioral manipulation protocols, drug protocols, non-FDA device protocols, debriefing forms, etc.) and documentation of the researcher's research ethics training. For all other projects, Castleton retains the documentation submitted to the HSIRB and the letter of approval for a year from the date of the letter of approval or one year from the proposed end date of the project, whichever is later.

The application form (Request for Review Form) is signed electronically by the researcher and (if the researcher is a student) "co-signed" by a signature or attaching an email from the faculty

sponsor. The Administrative section of the application identifies the Institutional Review Board members who have performed the review, the Chair or Administrators notes, and all email correspondence between the applicant and the HSIRB. The approval letter is also attached. The aforementioned documentation constitutes the full records of any project approved by the HSIRB. Records of projects covered by the FWA are kept for three years after the conclusion of the research.

The researcher is responsible for keeping all data and documentation gathered during the research, including all signed informed consent forms and any publications resulting from the research. In the case of student research, the student's advisor will arrange for this documentation to be stored. For federally funded projects, all records must be kept for three years after the conclusion of the research.

Human Participant Training

All individuals submitting for project approval for a research project must have a valid training certificate, approved by the HSIRB.

VIII. Non-Compliance

All researchers conducting human subjects research are expected to comply with the provisions of the HSIRB-approved study as well as all related federal regulations, Castleton policies, and state and local laws. Examples of noncompliance include, but are not limited to:

- Failure to obtain HSIRB approval prior to conducting human subjects research
- Continuation of research activities (i.e. enrolling new subjects, collecting data) after a study has expired
- Failure to obtain informed consent of research subjects
- Failure to follow research procedures as outlined in the protocol that was reviewed/approved by the HSIRB
- Implementation of changes in research procedures prior to HSIRB approval

If a researcher becomes aware of any noncompliance with respect to a specific study, a report must be made to the HSIRB via the HSIRB Administrator or Chair. All allegations of noncompliance will be investigated by the HSIRB, which will determine if the noncompliance is serious or continuing. During the investigation, a fact finding will be conducted, and if appropriate, a subcommittee will be appointed to further evaluate the noncompliance. The HSIRB Chair, or if deemed necessary, the fully convened HSIRB will review the investigation findings and determine whether the noncompliance is serious or continuing and any necessary corrective actions. If serious or continuing noncompliance is found and the study is federally funded, a letter will be sent to the Office for Human Research Protections

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IX. Oversight and Authority

The Castleton HSIRB, as informed by the guidelines and regulations of various government agencies, is the author of these policies and shall change these policies only by consensus at official meetings of that body.