IRBIRB Policies, Procedures, and Review Guidelines

March 2016 (Revised October 2018, August 2019, August 2024)

This document (and associated website) provides Hampden-Sydney College's policies, procedures and review guidelines on research involving human subjects as well as the forms necessary for obtaining approval from the Institutional Review Board (IRB) serving Hampden-Sydney College.

If you are conducting a research project using human subjects, you will need to obtain approval of the IRB prior to collecting data. The purpose of this policy is to provide a single, comprehensive standard of protection for human subjects of research conducted by students, staff, faculty, or visiting researchers at Hampden-Sydney College. The intent is to assure that investigators do not unduly put at risk or harm humans who are the subjects of research, and that the subjects of such research are aware of their rights as defined in Title 45, part 46 of the Code of Federal Regulations. IRB approval must precede commencement of any work involving human subjects.

Hampden-Sydney College Policies

Hampden-Sydney College is committed to safeguarding the welfare, rights, and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of their rights and the protections available to them. These safeguards derive from the following ethical principles, which were first articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979:

Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information about the research project and the potential consequences of participation in the study.

Beneficence: The obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.

Justice: Fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

The procedures for review adhere to the regulations of the Department of Health and Human Services, 45 CFR 46, as amended and published in the Federal Register on June 18, 1991. In addition, the IRB has repeatedly consulted Protecting Human Subjects: Institutional Review Guidebook (1993) – prepared by the Office for Human Research Protections (OHRP) of the National Institutes of Health – which you can view or download via http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm. Last but not least, Hampden-Sydney

College's IRB would like to acknowledge the broad adoption of the guidelines prepared and published by Amherst College for the current policy.

The Institutional Review Board

The IRB is the body charged with reviewing, prior to its commencement, all research, whether funded or not, involving human subjects conducted under the auspices of Hampden-Sydney College by its faculty members, students, or staff, as well as research by outside investigators using Hampden-Sydney College students, personnel, or facilities.

Research is defined in the Code of Federal Regulations (CFR) as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d). Research subject to review thus includes, but is not limited to, pilot studies; class projects aimed for publication; master's theses; Ph.D. dissertations; co-supervised work; independent research; and senior theses, whether such research takes place on or off the Hampden-Sydney College campus, including work done outside of the United States.

Membership of the IRB consists of: three faculty members appointed by Dean of the Faculty for three-year staggered terms, with one person from each of the academic divisions (ideally, with one from the Department of Psychology, and one with some background in ethics); a member of the College administrator or staff appointed by the President for a three-year term; a current student appointed by the Dean of Students for one year; and a member of the community without any direct ties to the College appointed by the Dean of the Faculty for a three-year term. The chair of the committee is to be elected annually from the ranks of the Faculty on the committee. An investigator can be a member of the IRB, however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest. Where the investigator-member has a conflicting interest, he or she is present only to provide information requested by the IRB. You can view the criteria for IRB membership – as stipulated in 45 CFR 46.107 – via https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107.

Please visit the Provost and Dean of the Faculty's Committee web page to view the current membership of the IRB, via http://www.hsc.edu/faculty-and-staff/dean-of-faculty/faculty-committees.

The IRB Review Process (Overview)

Application. Faculty members, staff members, or students who are planning research projects involving human subjects are responsible for beginning the review process by submitting the IRB application. The Chair of the IRB has been designated to oversee initial reviews at the College.

Review. The Chair assigns the proposal to one of three categories: Level I: Exempt (no foreseeable risk), Level II: Expedited Review (minimal risk), and Level III: Full Board Review (more than minimal risk and protected subjects). If the Chair wishes to submit his or her own proposal to the IRB, it is sent to a faculty member of the IRB with the most seniority in service

on the Committee. Under such circumstances, the proposal will not be eligible for Expedited Review.

It is expected that most research projects may well fall into the Exempt category. Research in this category requires no further review beyond the initial review level. Those proposals the Chair decides require Expedited Review will be forwarded to one member of the IRB who then has responsibility for the review of that proposal. Proposals judged by the Chair to require Full review will be forwarded to all members of the IRB, and the IRB as a whole will perform the review. All research proposals evaluated by the Chair, by one other member, or the full IRB are done so with regard to the degree of "risk," if any, to human subjects.

If a research proposal is determined by Chair to involve minimal risk (defined in Expedited Review Part A.4), he or she will send the proposal to one other member of the IRB for Expedited Review. The proposed research must involve no more than minimal risk, and the involvement of human subjects must fall under one or more of the categories specified under Expedited Review. Full Committee Review is required when the procedures of the research present more than minimal risk to the subject and/or fall into one or more of the categories specified under Full Committee Review.

Outcomes. There are four possible outcomes to a review:

Approved: No further action is required from the investigator prior to initiating the study.

Approved if Designated Changes are Made: The investigator may initiate the study after requested changes are made, and the IRB receives these revisions and notifies the investigator that he or she may proceed.

Revise and Resubmit: More extensive changes are required before the study may begin. Additional information must be submitted to the IRB prior to approval.

Denied: The proposed research, because of the level of risk involved, cannot be initiated.

Expiration and Renewal. Research approved by the IRB that is continuing must be re-reviewed on an annual basis by the IRB. The Chair will determine whether a Full or Expedited Review is required for re-review.

Categories of Review

All research, including that which the investigator believes falls into the Exempt category, must be submitted to the Chair for confirmation of the relevant review category. The criteria used to determine the categories of review are described below.

Please note that according to the Office for Human Research Protections (OHRP) of the National Institutes of Health, oral history projects are excluded from IRB review. However, the treatment of participants in oral history projects must conform to the standards of the Oral History Association and/or other professional organizations in the field.

Exempt

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B; or if they are currently enrolled as full-time college students). Category B 2 studies that include minors should be submitted for expedited review.

5. The research does not involve deception.

6. The procedures of this research are generally free of foreseeable risk to the subject.

7. The research does not require a waiver from informed consent procedures.

Part B (at least one item should apply)

1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is Exempt, whether or not data collection is anonymous.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those

programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of this research present no more than minimal risk to the subject. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Part B (at least one item should apply)

1. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or-videotapes, names will be recorded, even if they are not directly associated with the data).

2. Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.); b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, Doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

3. Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

4. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows:

a) Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;

b) Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or videotapes, names will be recorded, even if they are not directly associated with the data).

6. Research that involves deception. Deception must be scientifically justified and de-briefing procedures must be outlined in detail.

7. Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.

8. Research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; (d) where no subjects have been enrolled and no additional risks have been identified.

Full Committee Review

If ANY of these apply:

1. The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.

2. The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of the research involve more than minimal risk to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

5. Any research which does not fall into any of the categories explicitly identified as qualifying for Exempt or Expedited status.

6. Any research being proposed by investigators outside Hampden-Sydney College.

Components of Informed Consent

Subjects must have sufficient information to make an informed decision to participate in the research study. If subjects cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under eighteen) or when they are mentally incapacitated, legal representatives are required. Consent requests should be either clearly written or orally conveyed in a manner understandable to subjects, using language that is non-technical. Scientific, technical, or medical terms should be plainly defined.

Assent

Children (those under 18, with the exception of anyone who is enrolled full-time as a college student) should be given an explanation—at a level appropriate to the child's age, maturity, experience, and condition—of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should be asked if they wish to participate in the research or not. Mere failure to object on the part of the child should not, in the absence of affirmative agreement, be construed as assent. In the proposal, the investigator should indicate: 1) how assent will be obtained (what the investigator will say to the child and whether or not the child's parent(s) or guardian(s) will be present); 2) how assent will be documented. The child may either sign a very brief assent form or verbally indicate a willingness to participate.

Circumstances in Which a Written Consent Form May Not Be Required

In all research involving human beings, respondents must be made aware of the nature and purpose of the research, of the voluntary character of their participation, of the benefits and risks—if any—they may incur as a result of participation, and of the ways in which their privacy will be protected. The method by which informed consent is obtained, however, differs according to the type of research in question. In many cases, the use of informed consent forms, signed by respondents, is the best means of obtaining consent. This is particularly true in biomedical or clinical research, or in social scientific research that utilizes similar formats.

However, this method may be impossible to utilize in some types of social-scientific and humanistic investigations, especially in research of the "participant-observation" type involving the researcher's immersion in the everyday life of a community. In research of this sort, knowledge is typically gained through the give and take of ordinary conversation, often casual and in unstructured situations, and by observing activities and interactions in their living context. In such cases, the IRB may authorize oral informed consent—by which is meant consent obtained orally without the use of written forms—under the following conditions: 1) that the research involves no more than minimal risk to respondents, 2) that the substitution of an oral format will not harm respondents, 3) that the research could not be carried out without the substitution, and that 4) where appropriate, respondents will be provided additional information after their participation. Oral consent will also be allowed in research requiring the use of telephone interviews, provided that the aforementioned conditions obtain. In addition, oral consent will be authorized in cases in which a breach of confidentiality might be dangerous to respondents and the consent form is the only the only link between the respondent and the research. However, whether consent documents are used or not, researchers have an obligation to ensure that respondents understand the purpose and nature of the research.

Some research requires the use of mailed or emailed questionnaires. In such cases, a mailed or emailed response will itself be regarded as evidence of informed consent, provided that the questionnaire clearly explains the purpose and nature of the research.

Submitting a Request for Approval for Human Subjects Research

Submit your IRB application online using the online form provided on Hampden-Sydney's website. Your application must include:

- Description of Project and Procedures
- Consent Form and/or assent script
- Human Research Protection Training Certificate
- All measures, questionnaires, and/or interview questions
- Debriefing letter/script (if deception is used)
- Wording or advertisements for recruitment on social media, email, or paper flyers (if applicable)

College Records

The College keeps records of all original human subjects research, including request forms, IRB decisions, and copies of any research documents (informed consent forms, questionnaires, interview scripts, stress protocols, behavioral manipulation protocols, drug protocols, non-FDA device protocols, debriefing forms, etc.). The Description of Project and Procedures Form is signed by the researcher and co-signed by a faculty sponsor if the PI is a student. The aforementioned documentation constitutes the full College records of any project approved by the committee. These records and files will be transferred to the Office of the Provost and Dean of the Faculty annually, and stored in an appropriate location for a period of five years.

Review Outcomes

For proposals reviewed by the IRB, a letter will be sent to the investigator by the IRB chair, indicating one of four possible outcomes:

1.Approved: A protocol that has been approved by the IRB requires no further action from the investigator prior to initiating the study. If the study should extend beyond twelve months, the investigator should send a letter to the IRB chair, informing her/him of the current status of the project, any changes in the protocol, and whether any adverse events have occurred.

2.Approved if Designated Changes Are Made: A protocol that has been approved by the IRB on the condition that designated changes are made by the investigator and given to the IRB prior to initiating the study. If the study should extend beyond twelve months, the investigator should send a letter to the IRB chair, informing her/him of the current status of the project, any changes in the protocol, and whether any adverse events have occurred.

3.Revise and Resubmit: A protocol that has been deferred by the IRB usually requires that additional information be submitted to the IRB prior to approval. A revised application should be submitted to the IRB clarifying the issues involved or providing the requested documentation. The IRB will review the revised application at its next meeting.

4.Denial: A protocol that has been denied approval by the IRB cannot be initiated by the investigator. The reasons for the denial are provided in writing. The investigator will be given the opportunity to respond either in writing or in person at the next meeting of the IRB.

Appeals

In the event that 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; and 2) any other pertinent information in support of the appeal. The letter should be directed to the Chair of the Institutional Review Board and mailed with enclosures to the Office of the Provost and Dean of the Faculty, Atkinson Hall, Hampden-Sydney College. Applications submitted for appeal will be considered by the full IRB at the next scheduled meeting date. The final decision of the IRB will be stated in writing to the investigator. If the proposal is not approved, the research cannot be conducted.

Progress and Incident Reporting

Approval of a human subject research proposal is good for one year, unless the project has acceptable but potential risk in which case approval is given for a six-month period. If the project continues beyond the approval period, principal investigators are required to resubmit documents for review prior to the expiration date of the initial approval. These documents should include a status report of the project to date including:

- The number of subjects accrued.

- 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;
- Summary of any relevant amendments or modifications to the research since the last review;
- Other relevant information, especially information about risks associated with the research; and
- Copy of the current informed consent document and any newly proposed consent document.

In the initial approval letter, principal investigators are asked to promptly report any unanticipated problems or adverse effects of the research to the Institutional Review Board.

The IRB must be notified if adverse events occur and what actions the investigator has taken to respond.

Data collection involving human subjects that extends beyond one year must be re-reviewed, and re-approval granted, by the Chair if the status of the research is exempt, or by the IRB if the status of the research is Expedited or requires Full IRB review.

Changes in the procedures of collecting data from human subjects must be re-reviewed and approved by the Chair and/or the IRB.

Outside Investigators Wishing to Use Hampden-Sydney College Students as Subjects

Outside investigators who wish to use Hampden-Sydney College students as subjects must send a formal request and a proposal to the Dean of the Faculty. The Dean will consult with the relevant department(s). If the request is approved by the Dean and the department, the investigator should download the Request for Approval of Human Subjects Research forms, fill them out, sign them, and email a PDF of the forms to the Chair of the Institutional Review Board. The materials will be forwarded to the IRB for a Full Review.

Research Conducted at Off-Campus Sites with Their Own Human Subjects Committees

If some portion of the research is conducted at another institution, that institution must also review and approve the research protocol. The Hampden-Sydney College IRB will normally request some evidence of review and agreement from the host institution. If the host institution does not have an Institutional Review Board, a letter on institutional letterhead signed by an official of the host institution agreeing to permit access to the study population will be required.

Training

Hampden-Sydney requires all IRB members, designated reviewers, and principal investigators (faculty members and students) to complete human subjects ethics training. It is also important for investigators who receive external funding to always check the awarding agency’s training requirements.

A copy of the certifications of completion from the following online training program must be submitted to the IRB. Individuals complete an online program upload certifications of completion. The training is free of charge when only the certificate of completion is requested. The training program can be accessed online at this URL: Ethics Certificate Human Research Protection Training (Lessons 1-5): https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html

In addition, members of the IRB must become familiar with sections of the APA Code of Ethics that pertain to the conduct of research using human participants. Those sections can be accessed online at these URLs: http://www.apa.org/ethics/code/index.aspx?item=11, and http://www.apa.org/ethics/code/index.aspx.