

# IRB POLICIES AND PROCEDURES

Hanover College



Updated: 12/2018

Approved by Faculty: 1/14/19

IRB Committee, Hanover College

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## IRB POLICIES AND PROCEDURES

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### I. RESPONSIBILITIES OF THE IRB

- ❖ The Hanover College IRB is responsible for approving, requiring modifications in (to secure approval), or disapproving all research activities involving human subjects conducted by representatives of Hanover College (45 CFR 46.109).
- ❖ Definitions
  - Representatives of the College are Hanover students, faculty, or staff acting as such. If students or members of the faculty or staff engage in research in an unofficial capacity (by pursuing a personal interest without using Hanover resources), their research is not under the purview of the committee.
  - Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)).
    - In the Hanover context, the intended audience is relevant to this definition. If reports of research will be distributed only within a classroom setting (for example through a class demonstration or student project that only involves classroom members), the project is not considered research, and it does not fall under the purview of the IRB. If reports of research will be distributed outside of a class setting (for example by posting a manuscript online, presenting the report at a conference, or submitting the report for publication), then the project is considered research.
  - Human subject refers to “a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information” (45 CFR 46.102(e)).
    - “Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes” (45 CFR 46.102(e)).
    - “Interaction includes communication or interpersonal contact between investigator and subject” (45 CFR 46.102(e)).
    - “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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects” (45 CFR 46.102(e)).
- ❖ Research approved by the IRB may be disapproved by Hanover College officials, but these officials may not approve research that has not been approved by the IRB (45 CFR 46.112).

## II. MEMBERSHIP IN THE IRB

- ❖ As required by HHS regulations at 45 CFR 46.107(a) through (d), the Hanover College IRB will have at least five members:
  - One faculty representative from the Hanover College faculty with expertise in research involving humans and non-human animals;
  - One faculty representative from the Doctor of Physical Therapy Program with experience in the field of physical therapy practice;
  - One faculty member from either the Division of Arts and Letters or the Division of the Humanities, to fulfill the requirement of a having “at least one member whose primary concerns are in nonscientific areas” (45 CFR 46.107(c));
  - One student, nominated by Student Senate and approved by the Expedited Review Board;
  - One member of the local community “who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution” (45 CFR 46.107(d)).
- ❖ In addition to the above requirements, every effort will be made to staff the IRB so that:
  - It has sufficient experience, expertise, and diversity, “including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects” (45 CFR 46.107(a));
  - It is able “to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice” (45 CFR 46.107(a));
  - “Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession” (45 CFR 46.107(b)).
- ❖ Consultation
  - If the IRB reviews research that involves risks outside the range of its members' expertise, it will consult with outside sources to ensure that the rights and welfare of human subjects are protected. This consultation may range from IRB members contacting an expert for advice to inviting an expert to attend an IRB meeting. This invited expert may not vote (IRB Guidebook, chapter 1, part B).
  - Special attention to potential risks, including consultation with outside individuals with expertise in these areas, will be made when the research involves “a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons” 45 CFR 46.107(a)).

### III. PROCEDURES FOR RESEARCHERS TO APPLY FOR APPROVAL OF RESEARCH ON HUMAN SUBJECTS

- ❖ Instructions and application forms will be available to researchers at a website maintained by the Hanover College IRB.
- ❖ Research exempt from review
  - HHS regulations at 45 CFR 46.101(b) describe a small number of conditions under which research involving human subjects is exempt from the review process. These conditions are discussed below under the section titled “PROCEDURES FOR IRB REVIEW OF PROPOSED RESEARCH INVOLVING HUMAN SUBJECTS.”
  - Researchers conducting research in these areas are still obligated to complete an application form that specifies how the research qualifies as exempt and provides sufficient detail about the proposed procedures to enable a reviewer to decide whether the research meets the criteria for exemption.
    - Because of the potential for a conflict of interest, the Office for Human Research Protections (OHRP) recommends that investigators not be given the authority to make an independent determination that human subjects research is exempt (described in the FAQ available online at; <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html>)
  - Even when researchers expect that their research will qualify as exempt, they must wait to receive confirmation from the Hanover College IRB before they can begin data collection.
- ❖ New Proposals
  - HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111. Materials must include:
    - the full protocol (description of procedures and materials encountered by subjects);
    - a proposed informed consent document;
    - any relevant grant application(s);
    - the investigator's brochure (if one exists) and any recruitment materials, including advertisements intended to be seen or heard by potential subjects;
    - for HHS-supported multicenter clinical trials, a copy of the HHS-approved sample informed consent document and the complete HHS-approved protocol, if they exist;
    - For initial reviews conducted under an expedited review procedure, the specific permissible categories justifying the expedited review (see 63 FR 60364-60367 at; <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html>)

- HIPAA Authorization Regulation (45 CFR 164.508). Researchers should obtain written authorization from subjects before using or collecting protected health information;
  - Documentation of training in research ethics and compliance training appropriate for the field of study.
- ❖ Continuing research
- Continuing review of research must be substantive and meaningful. The IRB must ensure that the criteria set forth by HHS regulations at 45 CFR 46.111 are satisfied at the time of continuing review. The procedures for continuing review by the convened Hanover College IRB will include a primary reviewer system. Materials must include:
    - the full protocol (description of the procedures and materials encountered by subjects), including any modifications previously approved by the IRB;
    - the number of subjects accrued;
    - a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure);
    - a summary of any withdrawal of subjects from the research since the last IRB review;
    - a summary of any complaints about the research since the last IRB review;
    - a summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last IRB review;
    - any relevant multi-center trial reports;
    - any other relevant information, especially information about risks associated with the research; and
    - a copy of the current informed consent document and any newly proposed consent document;
    - If the initial review was conducted under an expedited review procedure, continuing review requires:
      - the specific permissible categories justifying the expedited review (see 63 FR 60364-60367 at; <http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm>), and
      - documentation of the review and action taken by the IRB chairperson or designated reviewer and any findings required under the HHS regulations.
- ❖ Proposed changes to approved research
- If the initial proposal qualified for expedited review and the proposed changes still qualify the research for expedited review, the changes may be evaluated using the expedited review procedure.
  - Even if the initial proposal qualified for full review, proposed changes may be reviewed using the expedited procedure if the changes are minor and are proposed for the period for which approval is authorized (45 CFR 46.110(b)(2)).
  - Note that these changes cannot be implemented until approval is received except when the changes are necessary to eliminate apparent hazards to the subjects.

#### IV. PROCEDURES FOR IRB REVIEW OF PROPOSED RESEARCH INVOLVING HUMAN SUBJECTS

- ❖ Conflicts of interest
  - HHS regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the IRB’s initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. Except when requested by the IRB to be present to provide information, IRB members will absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such will be noted in the IRB meeting minutes.
- ❖ Receipt of application materials and classification as exempt, expedited, or full
  - All applications for approval of research involving human subjects will be initially reviewed by the Chair of the IRB or by a member of the IRB designated by the Chair (hereafter called the Reviewer), who will decide whether the research qualifies as exempt from review or if it requires expedited or full review.
- ❖ Criteria for review
  - HHS regulations at 45 CFR 46.111 detail the criteria to be used in the evaluation of proposals for research involving human subjects. The following guidelines are based on those criteria.
  - Minimizing risk. “Risks to human subjects are minimized:” (45 CFR 46.111(a)(1))
    - “By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and” (45 CFR 46.111(a)(1)(i));
    - “whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes” (45 CFR 46.111(a)(1)(ii)).
  - Balancing risks and benefits. “Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.” (45 CFR 46.111(a)(2)). If the research involves some risk to subjects, then these risks must be justified by the potential benefits, either to the subjects themselves through the discovery of more effective treatments or to the contributions of the research to new knowledge.
    - “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 subjects would receive even if not participating in the research).” (45 CFR 46.111(a)(2)). “For example, if the research is designed to measure the behavioral results of physical interventions performed for therapeutic reasons (e.g., effects on memory of brain surgery performed for the relief of epilepsy), then only the risks presented by the memory tests should be considered when the IRB performs its risk/benefit analysis. It is possible for the risks of the research to be minimal even when the therapeutic procedure presents more than minimal risk” (IRB Guidebook, chapter 3, part A).
    - “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.” (45 CFR 46.111(a)(2), emphasis added). Chapter 5 in the Institutional Review Board Guidebook discusses this issue: “Some behavioral research involves human subjects in studies of heredity and human behavior, genetics, race and IQ, psychobiology, or sociobiology. Vigorous ethical debates about these studies arise out of the fear that scientific data may be used to justify social stratification and prejudice, or that certain groups will appear to be genetically inferior. The possible use - or misuse - of research findings, however, should not be a matter for IRB review, despite the importance of this question.”
- Equitable selection of subjects. “In making an assessment regarding the equitable selection of subjects, 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, mentally disabled persons, or economically or educationally disadvantaged persons.” (45 CFR 46.111(a)(3).
    - In other words, research should not unnecessarily exclude a group of people (e.g., women, members of minority groups) for the reason that doing so would potentially exclude that group from the applicability of the findings.
    - The equitable selection of subjects is a central tenet of the Belmont Report, a statement of principles that Hanover College has adopted as its guidelines for the protection of human subjects of research.
  - Obtaining informed consent. “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 §46.116.” (45 CFR 46.111(a)(4)). Freely given consent to participate in research is the cornerstone of ethical research involving human subjects. The requirements from 45 CFR 46.116 are detailed below:
    - “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence” (45 CFR 46.116);
    - “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative” (45 CFR 46.116);
    - “No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence” (45 CFR 46.116);
    - Basic elements of informed consent. Except as provided in paragraph (g) of this section (conditions for waiving some or all of the elements of informed consent), 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” (45 CFR 46.116(a)(1));



- “A description of any reasonably foreseeable risks or discomforts to the subject” (45 CFR 46.116(a)(2));
- “A description of any benefits to the subject or to others which may reasonably be expected from the research” (45 CFR 46.116(a)(3));
- “A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject” (45 CFR 46.116(a)(4));
- “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained” (45 CFR 46.116(a)(5));
- “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” (45 CFR 46.116(a)(6));
- “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” (45 CFR 46.116(a)(7));
- “A statement that participation is voluntary, refusal to participate will not involve 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.” (45 CFR 46.116(a)(8)).
- Additional elements of informed consent. Based on the nature of the research, the IRB may decide that one or more of the following elements of information shall also be provided to each subject:
  - “A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable” (45 CFR 46.116(b)(1));
  - “Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent” (45 CFR 46.116(b)(2));
  - “Any additional costs to the subject that may result from participation in the research” (45 CFR 46.116(b)(3));
  - “The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject” (45 CFR 46.116(b)(4));
  - “A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and” (45 CFR 46.116(b)(5));
  - “The approximate number of subjects involved in the study” (45 CFR 46.116(b)(6)).
- For subjects under the age of 18, a consent form from the parent will be required. For those subjects ages 7-17, both an assent form and consent form from the parent will be required.

- The IRB may also decide that additional information beyond the basic elements and additional elements be given to subjects during the informed consent process, when in the IRB's judgment the additional information would meaningfully add to the protection of the rights and welfare of the subjects (45 CFR 46.109(b)).
- There are conditions under which a consent procedure may not include, or may alter, some or all of the elements of informed consent. These conditions are:
  - Public benefit or service programs. "The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration" of informed consent (45 CFR 46.116(c));
  - Minimal-risk designs where full consent is not possible. "The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation" (45 CFR 46.116(c)).
- Documenting informed consent. "Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117." (45 CFR 46.111(a)(5)). The requirements from 45 CFR 46.117 are detailed below:
  - Except as provided in paragraph (c) of this section, informed consent shall be documented "by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form."
  - Except as provided in paragraph (c) of this section, the consent form may be either of the following:
    - "A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed, or" (45 CFR 46.117(b)(1));
    - "A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the

summary shall be given to the subject or the representative, in addition to a copy of the short form” (45 CFR 46.117(b)(2));

- Implied Consent: Federal regulations at 45 CFR 46.116(d) permit an IRB to approve a consent procedure that eliminates or alters the required elements of informed consent, or to waive the requirement to obtain informed consent altogether. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The IRB may waive the requirement of informed consent if it finds either:
  - “That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or” (45 CFR 46.117(c)(1));
  - That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context” (45 CFR 46.117(c)(2));
  - An implied consent template has been developed and approved by the IRB. This template should be used in place of the informed consent if the researcher feels that their project meets the above description of minimal risk.
- Monitoring for safety. “When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects” (45 CFR 46.111(a)(6)).
- Privacy and confidentiality. “When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” (45 CR 46.111(a)(7)).
- Vulnerable populations. “When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects” (45 CFR 46.111(b)).
- ❖ Additional considerations for review
  - Qualifications of the principal investigator. “The investigator's professional development should be taken into account and related to the degree of protocol complexity and risk to human subjects. IRBs may require less experienced research investigators to be sponsored by seasoned researchers. Proposals that require skills beyond those held by the principal investigator should be modified to meet the investigator's skills, have additional qualified personnel added, or be disapproved.” (IRB Guidebook, chapter 1, part C).
  - FDA Regulations. Additional regulations apply to research involving products regulated by the FDA, including research and marketing permits for drugs, biological products, or medical devices for human use, food and color additives, or electronic products. Federal funds do not need to be involved. The relevant regulations are 21 CFR 50 and 56. For the most part, FDA regulations conform to the Department of Health and Human Services’ regulations at 45 CFR 46. The two differences likely to be relevant to research reviewed by the Hanover College IRB are that:

- FDA regulations do not permit modifications or waivers of the informed consent requirements (except for emergency use of test articles, a procedure very unlikely to be used by investigators at Hanover College);
  - Special regulations apply to investigational new drugs (INDs). A description of Treatment INDs and the requirements for receiving approval for treatment use is contained in the FDA's Clinical Investigator Information Sheet titled "Treatment Use of Investigational Drugs" (May 1989).
- ❖ Target deadlines for review
- The IRB will strive to minimize delays to researchers while at the same time fulfilling its obligation to protect the rights and welfare of human research subjects.
  - The target interval between the time that researchers submit applications for review and the time researchers are informed about the decision of the IRB depends upon the level of review required, as follows:
    - For research that is exempt from review or that qualifies for expedited review, a maximum of one week;
    - For research that requires full review, a maximum of two weeks.
- ❖ Research exempt from review
- HHS regulations at 45 CFR 46.101(b) describe six categories of research involving human subjects that are exempt from the review process. These categories are:
    - Educational settings. "Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;"
    - Confidential and minimal-risk or anonymous tests, surveys, interviews, or naturalistic observations. "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless;
      - information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
      - any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."
    - Public officials and statutory confidentiality. "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) of this section, if:
      - the human subjects are elected or appointed public officials or candidates for public office; or
      - federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter."

- Archival research. “Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.” Retrospective case reports are an example of the use of patient records as a method to present research findings.
- Program evaluation of public benefit or service programs. “Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - public benefit or service programs;
  - procedures for obtaining benefits or services under those programs;
  - possible changes in or alternatives to those programs or procedures; or
  - possible changes in methods or levels of payment for benefits or services under those programs.”
- Taste testing. “Taste and food quality evaluation and consumer acceptance studies:
  - if wholesome foods without additives are consumed or;
  - if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.”
- If the Chair or Reviewer decide that the proposed research meets the criteria for exemption from review, the research is recorded as an ongoing research protocol in the records maintained by the IRB and the researcher is informed that he or she may begin data collection.
- If the Chair or Reviewer decide that the proposed research does not meet the criteria for exemption from review, the Chair or Reviewer classifies the research as qualifying for either Expedited or Full review, notifies the researcher of this classification, and submits the application for either Expedited or Full review.
- ❖ Expedited Review
  - HHS regulations at 45 CFR 46.110 describe a list of categories of minimal-risk research that qualifies for expedited review. In addition, minor changes in approved research may also qualify for expedited review. (45 CFR 46.110).
    - “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (45 CFR 46.102(i)). “For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.” (IRB Guidebook, chapter 3, part A)
    - Expedited review “may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be

- damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal." (63 FR 60364-60367, November 9, 1998)
- Expedited review may not be used for classified research involving human subjects.
  - Categories of research acceptable for expedited review. (Unless otherwise specified, the following quoted material is from 63 FR 60364-60367, November 9, 1998)
    - Clinical studies of drugs and medical devices only when the following two conditions are met.
      - "Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review)."
      - "Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling."
    - "Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:"
      - "from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or"
      - "from other adults and children (persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. 45 CFR 46.402(a)), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week."
    - "Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization."



- “Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).”
- “Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)]. This listing refers only to research that is not exempt).”
- “Collection of data from voice, video, digital, or image recordings made for research purposes.”
- “Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt).”
- Continuing review of research previously approved by the convened IRB as follows:
  - The initial review qualified for expedited review – see link: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html>
  - “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
  - where no subjects have been enrolled and no additional risks have been identified; or
  - where the remaining research activities are limited to data analysis.”
- HHS regulations at 45 CFR 46.110(b) specify that “Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).”
- Expedited review is conducted by a subcommittee of the IRB called the Expedited Review Board (ERB). The ERB is a standing committee that consists of three members: one representative from the Hanover College faculty with expertise in research involving humans and non-human animals, one representative from the Doctor of Physical Therapy Program with experience in the field of physical therapy practice and one faculty member

from either the Division of Arts and Letters or the Division of the Humanities, to fulfill the requirement of a having “at least one member whose primary concerns are in nonscientific areas” (45 CFR 46.107(c)).

- Research that qualifies as suitable for expedited review is distributed to one of the three members of the ERB. This member reviews the application and makes a decision to either 1) approve the application, 2) return the application to the researcher for revision and resubmission (along with detailed guidance on how the application should be modified to secure approval), or 3) forward the application to the full IRB because he or she believes the research is either unsuitable for expedited review or because he or she believes the research should not be approved. If the application is forwarded to the full IRB, the researcher is informed of this decision as well as the reasons behind it.
  - Although only one member of the IRB reviews research qualifying for expedited review, the proposal as well as the reviewer’s decision and rationale are available to all members of the IRB as well as the institutional official responsible for overseeing the IRB, in this case the Dean of Faculty and Vice President for Academic Affairs.
- ❖ Full Review
- “Primary reviewer” system.
    - For initial review, continuing review, review of protocol changes, and review of reports of unanticipated problems or of serious or continuing noncompliance, the Hanover College IRB will use a primary reviewer system.
    - The chair of the IRB will appoint one member of the IRB (the primary reviewer) to do an in-depth review of all pertinent documentation. All other IRB members will receive and review a protocol summary (of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111), the proposed informed consent document, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. In addition, the complete documentation will be available to all members for review.
    - The primary reviewer will be responsible for giving a brief presentation outlining the proposed research and the concerns that led to its qualification for full review. The primary reviewer must be present throughout the discussion and will participate in the vote to determine whether the proposed research is approved.
  - Quorum and majority decision rule.
    - In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(1) for the categories of research listed in the Federal Register of November 9, 1998 (see 63 FR 60364-60367 at <http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm>).
    - Approval of research is by a majority vote of this quorum.
    - Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist



- member), the IRB may not take further actions or votes unless the quorum can be restored.
- The timing of document distribution prior to IRB meetings.
    - The primary reviewer will receive the full documentation at least one week prior to the scheduled meeting of the IRB.
    - The other members of the IRB will receive a protocol summary of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111, the proposed informed consent document, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. In addition, the complete documentation will be available to all members for review. These materials will be distributed to the other members of the IRB at least one week prior to the scheduled meeting of the IRB.
  - The range of possible actions taken by the IRB for protocols undergoing initial or continuing review and protocol changes undergoing review.
    - For initial or continuing review or for changes undergoing review, the IRB can decide to 1) approve the proposal, 2) request that changes be made to the proposal and that it be resubmitted, or 3) reject the proposal.
    - No “Contingent Approval” of Research. When the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent process/documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review of responsive material. If the proposed changes are minor, the review may be conducted by a single member of the IRB appointed by the chair, who has the authority to approve the proposal if the changes are met.
  - Reporting decisions
    - To investigators:
      - If the IRB approves a proposal, it will notify investigators by email;
      - If the IRB decides to reject a proposal, it will email investigators of their decision with a detailed description of the reasons for its decision and give the investigator an opportunity to respond in person or in writing;
      - If the IRB decides that modifications are necessary before a proposal can be approved, it will email investigators with a detailed description of the changes necessary to secure approval and the reasons for these changes. Investigators may respond in writing by emailing the chair of the IRB. They may respond in person by meeting with the primary reviewer or, if they wish, with the full IRB at their next meeting. If in its initial review of the proposal, the IRB decides that the proposal would be approved if minor changes were made, the review of the resubmitted proposal may be made by a single member of the IRB designated by the chair of the IRB. This reviewer has the authority to approve the proposal or request additional modifications.
    - To the institution:

- The Vice President for Academic Affairs and Dean of Faculty (a single position at Hanover College) is responsible for overseeing the activities of the Hanover College IRB. This official will have access to all IRB proposals and decisions and will be informed by email about each IRB decision.
- ❖ Determining which projects require review more often than annually
  - Approval for all research reviewed by the IRB expires after a maximum of one year after the date on which the proposal is approved. In its consideration of whether a protocol requires review more frequently than once per year, the IRB will consider the following criteria:
    - the degree to which the study involves more than minimal risk to subjects;
    - the use of objectionable materials that subjects might find offensive, threatening, or degrading;
    - the collection of information that may make subjects uncomfortable, such as disease, disability, or criminal activity;
    - the use of deception;
    - the collection of private information;
    - the use of vulnerable populations (children under age 18, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).
- ❖ Determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review
  - The IRB may determine that the continuing review of a project must involve verification from sources other than the investigators that no material changes have occurred since previous IRB review. In considering whether to require this external verification, the IRB will consider the following criteria:
    - Unusually high risks to subjects;
    - A prior instance of the investigator failing to comply with HHS regulations or the requirements or determinations of the IRB;
    - A concern about possible material changes occurring without IRB approval.
  - To reduce the risk that investigators implement protocol changes without prior IRB approval (except when necessary to eliminate apparent hazards to subjects), investigators will be presented with a statement indicating the necessity of obtaining approval for protocol changes prior to their implementation. This statement will include the warning that failure to obtain approval may result in formal disciplinary proceedings for academic misconduct. The statement will appear in two places: 1) Immediately above the space for researchers' names on the application for approval of human subjects research; and 2) On the approval letters issued to researchers by the IRB.

## V. HIPAA AUTHORIZATION REGULATIONS

- ❖ According to HIPAA requirements outlined in 45 CFR 164.508 (.pdf), researchers should obtain written authorization from subjects before using or collecting protected health information. Authorization should be obtained in writing from prospective subjects. Under

HIPAA, the following core elements and statements must be included in the authorization document:

- A description that identifies the individually identifiable protected health information (PHI) to be used/disclosed in a specific and meaningful fashion (e.g., list the types of data to be collected from the medical records);
- The name of the person(s) or class of persons to whom the covered entity may make the requested use or disclosure (e.g., research must list all of the entities that might have access to the study's PHI such as research related personnel in the department of \_\_\_\_\_, Hanover IRB, XYZ Hospital, Food and Drug Administration, DHHS, Biosafety Committees, Data Safety and Monitoring Board or any others given authority by law);
- A description for each purpose of the requested use or disclosure (e.g., list purpose of research, list reason(s) why the PHI will be collected);
- An expiration date or an expiration event that relates to the use or disclosure (e.g., length of time researchers plan to maintain the data). The statement "end of research study," "none," or similar language is sufficient;
- A description of how the individual may revoke the authorization and the exceptions to the revocation; or a copy of the Privacy Notice which explains how to revoke the authorization and the exceptions to the revocation (e.g., HIPAA gives subjects the legal right to revoke authorization. The subjects must be told how they can withdraw. Any request for revocation must be in writing. Also, the subjects should be told that if they do revoke, that they can no longer participate in the research and that researchers may use the PHI already obtained to maintain the integrity of the data.);
- A statement that a subject's treatment, payment or enrollment in any health plan or their eligibility for benefits will not be effected if they refuse to sign the authorization;
- A statement that the subject may not participate in a research study if they refuse to sign the authorization;
- An explanation that information disclosed pursuant to the authorization may no longer be protected when re-disclosed by the recipient (e.g., if the researchers disclose the information collected to a third party then the HIPAA protections may no longer be in place).

## VI. RECORDS PREPARED AND/OR MAINTAINED BY THE IRB

- ❖ The Hanover College IRB will be responsible for preparing and maintaining adequate documentation of IRB activities, including the following:
  - “Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects” (45 CFR 46.115(a)(1));
  - “Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution” (45 CFR 46.115(a)(2));

- “Records of continuing review activities” (45 CFR 46.115(a)(3));
- “Copies of all correspondence between the IRB and the investigators” (45 CFR 46.115(a)(4)).
- “A list of IRB members in the same detail as described in §46.103(b)(3).” (45 CFR 46.115(a)(5)). “Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office” (45 CFR 46.103(b)(3)). The necessary elements of the list of IRB members, from 45 CFR 46.103(b)(3), is described below:
  - Name;
  - Earned degrees;
  - Representative capacity;
  - “Indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB deliberations;”
  - “Any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;”
- “Written procedures for the IRB in the same detail as described in §46.103(b)(4)”, §46.103(b)(5), and (45 CFR 46.115(a)(6));
- “Statements of significant new findings provided to subjects, as required by §46.116(b)(5)” (45 CFR 46.115(a)(7)).
- ❖ “The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner” (45 CFR 46.115(b)).

## **VII. AUTHORIZED INSTITUTIONAL OFFICIAL**

- ❖ The Dean of Faculty and Vice President for Academic Affairs, a single office at Hanover College, has responsibility for oversight of IRB functions. This person has the additional responsibility of selecting the chair of the IRB.

## **VIII. REPORTING PROBLEMS TO THE IRB, INSTITUTIONAL OFFICIALS, DEPARTMENT/AGENCY HEADS, AND OHRP**

- ❖ Types of problems for which this policy applies:
  - Unanticipated problems involving risks to subjects or others;
  - Serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB;
  - Suspension or termination of IRB approval.

- ❖ Responsibilities for reporting risks to subjects and others
  - Enabling subjects to report problems. All informed consent and debriefing forms must include information enabling subjects to contact both the investigator and the chair of the IRB. In the case when the chair of the IRB is the investigator, the contact information will include contact information for another member of the IRB. Thus, the IRB will be the primary recipient of reports of problems from subjects.
  - Enabling investigators to report problems. On the application form for approval of research involving human subjects, researchers are reminded of their obligation to immediately inform the IRB of any risks to subjects.
  - Reporting to the institution and to OHRP. The IRB is responsible for sharing all reports of problems involving risks to subjects or others with both the Vice President for Academic Affairs and Dean of Faculty (a single position at Hanover College) and with OHRP within one week after receiving the initial report of problems.
- ❖ Responsibilities for reporting serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB and reporting suspension or termination of IRB approval
  - The IRB is responsible for investigating any reports of noncompliance. The IRB must meet within 1 week of receiving such a report to decide the accuracy of such claims, with its usual requirements of a quorum including one non-scientist member and a majority vote deciding the issue. Any members of the IRB with a conflict of interest in the case must recuse themselves from discussion and voting.
  - If the IRB decides that serious or continuing noncompliance has occurred, it will vote to suspend or terminate approval. In the event that approval is suspended or terminated, the chair of the IRB will contact the investigator, the Vice President for Academic Affairs and Dean of Faculty, and OHRP within one week with a detailed explanation of the decision and its rationale.

## IX. PENALTIES FOR NON-COMPLIANCE

- ❖ When unapproved research is discovered, the IRB will act promptly to:
  - halt the research;
  - assure remedial action regarding any breach of regulatory or institutional human subject protection requirements; and
  - address the question of the investigator's fitness to conduct human subject research.
- ❖ Conducting research on human subjects without obtaining approval from the IRB, disregarding the outcome of the review process, or disregarding the rules described in this document will be considered a violation of ethics (and an act of academic dishonesty), and possible violations will be adjudicated by the Dean of Academic Affairs (in the case of faculty researchers and DPT student researchers) or the Student Academic Assistance Committee (in the case of undergraduate student researchers). It is the responsibility of the researcher to ensure that all research assistants understand and follow procedures approved by the review process.

## X. REFERENCES

- ❖ 45 CFR 46, the Code of Federal Regulations Title 45 (Public Welfare, Department of Health and Human Services), Part 46 (Protection of Human Subjects), available online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- ❖ The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research, adopted April 18, 1979 by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and available online at <http://ohsr.od.nih.gov/guidelines/belmont.html>
- ❖ Institutional Review Board (IRB) Guidebook, published by the Office for Human Research Protections (OHRP) and available online at [http://www.hhs.gov/ohrp/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/irb/irb_guidebook.htm)