University of Lynchburg

Institutional Review Board for Human Subjects Research

Policies and Procedures Manual

The University of Lynchburg Institutional Review Board (IRB) for Human Subjects Research Policy and Procedure Manual reflects the Lynchburg IRB policies, procedures, and practices and identifies the federal and state laws, policies, regulations, and recommendations that govern the protection of human subjects research. Upon initial origination, endorsement, and approval of this Policy and Procedure Manual, the IRB Director is hereby delegated by authority of the full membership of the IRB (also referred to as 'the Board') to make minor corrections and updates to the manual as necessary. However, the manual will be reviewed at least annually for renewal and to determine if updates are required to align with federal or state guidelines.

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Additional information regarding the IRB process and human subjects protection is posted on the Lynchburg IRB website (http://www.lynchburg.edu/institutional-review-board-irb-human-subjects-research); the website has been designed to be a more accessible and user-friendly version of the policies contained in this manual.

The website and this manual are meant to be and should be consistent. Anyone noting inconsistencies or errors is encouraged to bring them to the attention of the IRB Director via email at IRB-HS@lynchburg.edu. The University of Lynchburg IRB expresses appreciation and gratitude to the University of Richmond IRB under the direction of Dr. Kirk Jonas and the Centra IRB under the direction of Dr. Fred Blanchard, for authorizing the use of language and concepts from within their IRB manuals toward the goal of developing the Lynchburg IRB manual. Some sections herewithin are the original work of these entities. Do not copy or distribute this material; any requests to copy or distribute must be sent to the Lynchburg IRB Director to allow appropriate citation and credit.

Section 1. Charter of the University of Lynchburg Institutional Review Board (IRB) for Human Subjects Research

The purpose of the Lynchburg IRB is to perform ethical review of proposals for human subjects research, and to provide leadership in the development of and education on policies and procedures for the responsible and ethical conduct of human subjects research. The primary concern of the Lynchburg IRB is the protection of the rights and welfare of human subjects involved in research conducted at or by researchers affiliated with the University of Lynchburg. The Lynchburg IRB is charged with reviewing, taking action on, and monitoring all proposed research activities conducted by the students, faculty, staff, or other agents/affiliates of the University of Lynchburg based on current federal, state, institutional or other regulations regarding research and/or investigational activities with human subjects. The Provost of the University of Lynchburg serves as the signatory official for the Lynchburg IRB. The information within this Charter is consistent with the University of Lynchburg Faculty Handbook 2.3.3, Institutional Review Board (IRB).

Registrations and Assurances

Federal Registration Organization #: IORG0006657

IRB Federal Registration #: IRB00007987

Federalwide Assurance #: FWA00020527

IRB Director

Dr. Alisha Walker Marciano

Research Integrity Officers (RIOs)

Dr. Allison Jablonski, Associate Provost and Dean of General Studies

Dr. Alisha Walker Marciano, Director, Institutional Review Board

Signatory Official

Dr. Sally Selden, Provost

Board Organization

The Board is divided into two panels, Biomedical and Health Science and Social and Behavioral Science. Board members will be placed on either the Biomedical and Health Science or Social and Behavioral Science panel based on their discipline and experience. The number of members in each panel is up to the discretion of the Board Director and may vary depending on the number of protocols typically received by each panel. One member of each panel will serve as Assistant Director. The Assistant Directors will be responsible for assisting the Director with various administrative duties deemed appropriate by the Director. In addition, the Assistant Directors will be responsible for review of any protocol in which the Board Director serves as a research team member.

Membership

The IRB (Board) consists of at least seven faculty who have current experience in scientific research. Pursuant with federal regulations: at least one of the members of the Board must be a community member who is not affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University; and at least one of the members must be someone whose primary teaching and research are in nonscientific areas (as defined by OHRP). Membership reflects federal regulations for IRB membership as further stated in 45 CFR 46.107 – IRB Membership. The President appoints an IRB Director who serves as a voting member of the Board and is responsible for Board oversight. The President and the Provost or her/his representative serve as ex-officio members of the Board.

Selection of Members

The IRB Director is responsible for making recommendations to the President for faculty and community members of the Board. The members of the Board, including the IRB Director, are appointed by the President. Interested faculty members are recommended by the Faculty Steering Committee to the IRB Director, who will in turn work with the President and the Provost to identify faculty to appoint to the IRB.

Term of Members

Members of the Board typically serve three year terms, depending on the needs of the IRB as necessary to maintain compliance with federal regulations on IRB membership. Term recommendations are made to the President by the IRB Director. Members of the Board may serve multiple terms.

List of Members

Dr. Gary Austin (term ends 6/2020)

Dr. Sara Bennett (term ends 6/2021)

Dr. Andrew Bruce (term ends 6/2020)

Dr. Sean Collins (term ends 6/2019)

Dr. Sue Curfman (term ends 6/2021)

Dr. Lee Ann Eagler (term ends 6/2021)

Dr. Sara Hallowell (term ends 6/2020)

Dr. Ei Hlaing (term ends 6/2021)

Dr. Michael Klein (term ends 6/2021)

Leslie Loucks, community member (term ends 6/2019)

Dr. Joyce Nicholas (term ends 6/2021)

Dr. Lindsay Pieper (term ends 6/2021)

Dr. Jimmy Roux (term ends 6/2019)

Meetings

Full Board Meetings: Members of the Board are expected to attend all regularly scheduled full board meetings when possible. These meetings are scheduled for once per month during the regular academic year (September – May). These meetings are held in person, and can be attended via teleconference or web conference.

Section 2. Goals of the Human Subjects Protection Program at University of Lynchburg

Oversight of the human subjects protection program is provided by the University of Lynchburg Institutional Review Board for Human Subjects Research (hereinafter, IRB). The purpose of the IRB is to perform ethical review of proposals for human subjects research, and to provide leadership in the development of and education on policies and procedures for the responsible and ethical conduct of human subjects research. The primary concern of the IRB is the protection of the rights and welfare of human subjects involved in research conducted at or by researchers affiliated with the University of Lynchburg.

Another important goal of the human subjects protection program is that the University of Lynchburg be in compliance with its Federalwide Assurance Agreement with the U.S. Office for Human Subjects Protection (OHRP). Compliance with this formal agreement entails applying the ethical principles of the 1979 Belmont Report to all human subjects research, regardless of its funding source or lack of a funding source. This agreement also stipulates that the University of Lynchburg will apply the federal policy known as "The Common Rule" as well as subparts B, C, and D of the Department of Health and Human Services (HHS) regulations at 45 CFR 46 to all federally funded research. In addition, the University of Lynchburg's IRB policies are designed to conform with §32.1-162.16-.20 of the *Code of Virginia* and other State laws related to the protection of human subjects of research. Federal regulations are generally considered a "floor" and not a "ceiling" on human subjects' protection. The University of Lynchburg expects adherence to the highest ethical and moral standards in the conduct of research and scholarly activity by all members of the University community, including faculty, staff and students.

Section 3. Determining Reviewability and Special Categories: Non-reviewable Classifications, Quality Improvement, Institutional Assessment

3.1 Definition of Human Subjects Research. In general, the IRB has jurisdiction over research involving human subjects. The federal government (45 CFR 46.102(l)) defines "research" as:

> (l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
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> > (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

If such research involves obtaining information about "a living individual" (45CFR46, 102(e)), then the activity is human subjects research. This definition follows:

(e) *Human subject* means 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.

In accordance with federal regulations, all such human subjects research must be reviewed and approved or exempted by the IRB prior to the initiation of the research.

3.2 Determining Reviewability of an Activity. A research determination protocol form is available for submission to those completing quality improvement or general assessment projects. Many investigators know that their research activity necessitates review by the IRB. Sometimes, there are elements of a proposed activity that lead the investigator to question whether the activity necessitates review by the IRB. A person engaging in an activity that she or he believes is not reviewable research can receive a written determination on the matter from the IRB Director by submitting a research determination protocol.

3.3 Special Categories and Reviewability

3.3 (a) Non-reviewable designation. If the IRB Director determines that an activity/project does not meet the criteria for human subject research and therefore does not require IRB oversight, then a letter of determination will be provided by the IRB Director. This will mean that an activity has been classified as "non-reviewable" status.

3.3 (b) Quality Improvement. Quality improvement activities (frequently referred to as QI) represent a wide variety of activities, and what constitutes a QI activity often varies among disciplines and professions. Some of these activities might fall under the non-reviewable status. If the individual feels that the activity does not meet the parameters for human subject research, he or she should submit a research determination proposal for review.

3.3 (c) Institutional Assessment. Institutional assessment activities represent a wide variety of activities, and what constitutes an assessment activity might vary depending on the level of analysis or unit of measurement. Some of these activities might fall under the non-reviewable status. If the individual feels that the activity does not meet the parameters for human subject research, he or she should submit a research determination proposal for review.

3.3 (d) What is <u>Not</u> Human Subjects Research? While a determination as to whether an activity is human subjects research should typically be referred to the IRB, there are numerous areas of research that are clearly not human subject research and do not need to be submitted to the IRB for review. Among the areas that are not human subjects research are the following:

- Research that does not "involve obtaining information about living individuals." *See 45 CFR 46.102(d)*. Most research in the physical sciences and history is not considered human subject research. Note that biographies and oral histories conducted solely to create a record of specific historical events are not subject to IRB review; however, other biographies and oral histories conducted for other intents may be subject to IRB review.
- Research that involves non-human animals is not subject to IRB review despite the use of humans to handle the animals, unless the research activity involves collection of data from those human handlers. Note that animal research is subject to review by the Institutional Animal Care and Use Committee (IACUC).
- Research that involves only data and information from a publicly available data source such as the United States Census or General Social Survey.
- Service learning and professional development activities would only be subject to IRB review if there was a research or evaluation component.
- Most oral history and journalism projects are not considered "human subjects research" by the federal and state regulations, and as such also by the Lynchburg IRB.

Section 4. Types of IRB Review and Review Procedures.

All human subjects research conducted by students, staff, faculty, and those otherwise affiliated with the University of Lynchburg must be reviewed by the IRB and approval must be obtained before the research may begin.

Non-federally funded human subjects research falls into one of two categories:

Minimal risk review- Inherently minimal risk or risk that has been sufficiently minimized; less than minimal or no foreseeable risk or discomfort that is no more than what someone would experience in their daily lives if they were not participating in the study

Full board review- Research with more than minimal foreseeable risk or discomfort; may or may not involve vulnerable populations); research involving minors (individuals under age 18).

Federally funded research falls into one of three categories:

Exempt from continued oversight- Exempt review status – less than minimal or no foreseeable risk or discomfort that is no more than what someone would experience in their daily lives if they were not participating in the study; no involvement of vulnerable populations and no collection of potentially personally identifiable information (categories 1-6 in section 4.2).

Expedited review- Expedited review status – no more than minimal foreseeable risk or discomfort; may involve a vulnerable population but not one federally protected/requiring full board review (categories 7-13 in section 4.2).

Full formal review- Full board review status – more than minimal foreseeable risk or discomfort; may or may not involve vulnerable populations).

4.1 The Research Team. The Principal Investigator (PI) is the lead researcher for the study. Faculty Research Sponsors advising student research share in the responsibility for making certain that student research complies with policies and procedures. Undergraduate students are not permitted to serve as the PI of a research study and must be listed under the research team as a student researcher. Graduate students may serve as Co-PIs (not as a sole PI) with a Lynchburg faculty or staff member, or as members of a research team. In instances where the researcher is a Lynchburg employee and a student (graduate or undergraduate), the purpose of the research is used to determine the researcher's primary role. All researchers who will have access to the data that are being collected, including student researchers, must be listed on the appropriate form(s) and complete the appropriate ethical research training required for research team members prior to the initiation of the study. Only Lynchburg faculty/staff serving as PIs may submit completed IRB forms for review.

4.2 Minimal Risk Research Status. "Minimal risk," according to 45 CFR 46.102(j), 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." There are many factors that may increase risk level beyond the "minimal risk" threshold requiring a full board review. Proposals that address illegal behavior by subjects (such as underage drinking or drug use) are more than minimal risk because they may expose subjects to criminal liability. Other examples of factors that could increase the risk level beyond minimal risk include threats to reputation, financial standing, or employability. Stating that a data collection instrument is anonymous or confidential does not negate or counterbalance the potential for risk or discomfort. In many instances, knowing that one's identity is protected is not sufficient to completely minimize risk. Questions or other study dynamics to which subjects are exposed that elicit responses to life events that are so upsetting that they may cause significant distress might also increase level of risk.

Thirteen research categories that may apply to minimal risk research are provided below. These are based on federal guidelines and are described as explained by OHRP special guidance.

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

CATEGORY 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

CATEGORY 3: (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

CATEGORY 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a,

and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

CATEGORY 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

CATEGORY 6: Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) 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.

CATEGORY 7: Clinical studies of drugs and medical devices only when condition (a) or (b) is met. 1. (a) 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.) (b) 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.

CATEGORY 8: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant 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(b) from other adults and children [2], 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.

CATEGORY 9: Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring 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.

CATEGORY 10: 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.) Examples: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

CATEGORY 11: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

CATEGORY 12: Collection of data from voice, video, digital, or image recordings made for research purposes.

CATEGORY 13: 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 in situations when the behavioral interventions may be considered of lengthy duration, may cause potential harm/pain, may be physically invasive, may have a significant adverse lasting impact on the participants, and/or may cause participants to feel offended or embarrassed. Also, research that includes deception and does not make participants aware of deception in the informed consent.

4.3 Full Board Research Status. Studies that do not meet the criteria for minimal risk must be reviewed by the full Board at a convened meeting. If in doubt about whether the study poses more than minimal risk, the Director will most often bring a proposal to the full Board for its review. Factors taken into consideration in making such a decision will include the level of risk to subjects, the nature of the proposal, and the subject population. For example, a study that might otherwise be minimal risk would likely be taken to the full Board if it involved vulnerable populations as subjects, such as the following: pregnant women, human fetuses, and neonates; prisoners; children (anyone under the age of 18 years); cognitively impaired persons; students and employees; minorities; economically and/or educationally disadvantaged; AIDS/HIV+ subjects; terminally ill subjects. Per University of Lynchburg policy, all research involving minors (individuals under age 18) requires full board review.

4.4 Waiver of documentation of consent. The IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(d), provided that the IRB finds and documents that all of the following four conditions are met:

a. the research involves no more than minimal risk to the subjects;

b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. the research could not practicably be carried out without the waiver or alteration; **and**

d. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Section 5. Training Requirements for Investigators

In order to maintain an institutional standard for our commitment to research integrity and the responsible conduct of research and in congruence with OHRP guidance, investigators involved in human subjects research at the University of Lynchburg are required to present certification to the IRB that they have completed training in human subjects' protection. The following is the Ethical Research Practices Policy, which directly addresses the training requirements for investigators.

> **Ethical Research Practices Policy**
>
> All faculty, staff, and students seeking approval from the IRB (Human Subjects Research) for research protocols must pass a research ethics training course on protection of human research participants offered by the National Institute of Health (NIH). Successful completion of this training is required to ensure that all members of the Lynchburg community who plan to conduct research are familiar with ethical research practices. Confirmation of certification is required prior to the IRB providing final approval for all research proposals. An ethics certificate for EACH research team member must be included in the protocol proposal. Instructions for completing the NIH training can be found on the IRB website.

Completion of the NIH training is currently the only avenue through which faculty, staff, and students may meet this training requirement. Training requirement is not waived for other certifications, training, coursework, or life experience. Community affiliates and non-Lynchburg affiliated research team members will need to provide proof of some ethical research training (NIH, CITI, etc.) at the discretion of the IRB Director.

Section 6. Organization and Responsibilities of the IRB at the University of Lynchburg

The *Provost of the University of Lynchburg* is the signatory official for the Federalwide Assurance agreement with the U.S. Office for Human Research Protections. The President of the University appoints an IRB administrator (the IRB Director) and members of the IRB. Appointments are typically based on recommendations made by the IRB Director in consultation with the Board, the Provost, the Assistant Provost, and Faculty Steering. The *IRB Director* is responsible for the day to day operation and administration of the IRB, for the review of research determinations and modifications, and assists with reviews of minimal risk proposals. The *Institutional Review Board* assists with review of minimal risk proposals and convenes for full board proposals. *Investigators* (whether faculty members, staff members, or students) are ultimately responsible for the protection of subjects and for ensuring that the participation of subjects in research is voluntary and based on informed consent. Responsibilities for various participants in the process for protecting human subjects of research are described below.

6.1 Responsibilities of Investigators. Ultimately, the protection of human subjects is the responsibility of researchers or investigators conducting the research. Investigators must make sure that they possess the knowledge and competence to carry out their research. They must exercise judgment with regards to unanticipated events which may adversely affect subjects. They must take action to terminate research if subjects are harmed and to report any such events as soon as possible (maximum: within three working days of the discovery of the occurrence) to the IRB. Investigators must abide by international, federal, state and University policies involving the conduct of research with human subjects. Investigators are encouraged to consult the University of Lynchburg IRB Website at http://www.lynchburg.edu/academics/institutional-review-board/ and the "OHRP Investigator Responsibility Frequently Asked Questions" at http://answers.hhs.gov/ohrp/categories/1567. It is important to note that undergraduate students are not permitted to be principal investigators (PI) at the University of Lynchburg. Therefore, faculty/staff advisors who are principal investigators are ultimately responsible for the protection of the human subjects of their research. (Note: The terms researcher and investigator are used interchangeably in this IRB Policy and Procedure Manual). Graduate students may serve as co-PIs with faculty/staff advisors.

6.2 Responsibilities of the Provost as Signatory Official. The Provost of the University of Lynchburg reviews and signs the Federalwide Assurance (FWA) document, which is the University's formal agreement with the U.S. government regarding research with human subjects. This agreement allows the institution to receive federal funds in support of research activities. The University's FWA document states that the University of Lynchburg will be guided by the ethical principles of the Belmont Report.

Federally funded research at the University adheres to "the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46" and the ethics of non-federally funded research are guided by these principles.

6.3 Responsibilities of the Institutional Review Board (IRB) for the Protection of Human Subjects of Research. Members of the Institutional Review Board (IRB) are appointed by the University of Lynchburg President for terms of 3 years. Membership of the IRB must conform to the provisions of Section 46.107 and consist of at least five members, including at least one non-affiliated (or community) member. The University of Lynchburg IRB consists of at least 7 members and up to 12 members in order to cover the broad range of research subjects studied in the various schools of the University. A current list of Board members can be found on page 3.

Members of the IRB are responsible for reviewing and acting on all research proposals submitted to the IRB. Members are required to attend scheduled and called meetings of the IRB and to prepare themselves for such meetings by reviewing proposals and other materials referred to them in advance of the meeting. Members are responsible for completing training on human subjects' protection and for determining training requirements for other University researchers. IRB members are responsible for recusing themselves on votes where they have a conflict of interest and such recusal shall be noted in meeting minutes. Basic regulatory responsibilities of Institutional Review Boards are outlined in the sections detailed below (principally in Sections 46.108 and 46.109 of 45 CFR 46.)

The Institutional Review Board serves as an advocate for the human subjects of research, ensuring that researchers adhere to the Belmont Report's principles of respect for persons, beneficence, and justice. Institutional Review Boards derive their authority from federal law and regulations (See 45 CFR 46.109). Responsibilities of Institutional Review Boards include, but may not be limited to, the functions and operations detailed in the following sections of 45 CFR 46:

- 46.108 – IRB Functions and Operations
- 46.109 – IRB Review of Research
- 46.110 – IRB Expedited Review Procedures
- 46.111 – Criteria for IRB Approval of Research
- 46.112 – Review by Institution
- 46. 113 – Suspension or Termination of IRB Approval of Research
- 46.114 – Cooperative Research

The University of Lynchburg IRB may invite non-IRB members to participate in the review process when it deems that their expertise is needed. Meeting practices of the IRB are more fully described in Section 8 of this guide, "Meetings of the IRB."

6.4 Responsibilities of the IRB Director. The IRB Director is appointed by the President of the University of Lynchburg. The responsibilities of the IRB Director are designated by the signatory official, the IRB, and this IRB Policy & Procedures Manual. In addition, the Director directly reports to the Provost of the University of Lynchburg and may receive assignments from the Associate Provost.

Currently, the Director has been delegated the following duties and responsibilities:

a. Serve as the University of Lynchburg liaison to the U.S. Office for Human Research Protections (OHRP), including:

1) Preparation of the University's Federalwide Assurance Agreement (FWA) with the OHRP for the University Provost's periodic review and signature.
2) Ensuring that the FWA is always up to date.
3) Preparing the IRB's organizational registration forms for OHRP and ensuring that the University's registration is up to date.
4) Preparation of necessary materials to be submitted to OHRP through the OHRP Electronic Submission System, such as information on the IRB's administration, Board membership, and other information.
5) Submission of reports as required or necessary (reports of noncompliance, adverse events, etc.)
6) Communication with OHRP staff on questions or matters of interest to the IRB.
7) Staying up to date on OHRP policies and procedures and communicating relevant information to the Board and the University research community.

b. Serve as a voting member of the IRB.

c. Direct meetings of the convened Institutional Review Board.

d. Provide or coordinate administrative support for IRB meetings.

e. Prepare and maintain minutes of IRB meetings and other records as required by 45 CFR 46.115 IRB Records. Submit these minutes to members of the IRB for their review and correction, if necessary. Maintain electronic versions of minutes. (See Section 8 "Meetings of the IRB" and Section 9 "Records of the IRB" for more detail on minutes and meetings.)

f. Prepare notices of IRB meeting actions and communicate these notices of action to researchers via email.

g. Receive proposals and perform reviews or designate reviews to IRB members.

h. Review research determination queries on whether or not IRB review is necessary. In most cases the Director will independently determine whether an activity is or is not reviewable research and will inform the researcher of such a determination.

i. Develop and maintain a system of educating and training University researchers on the protection of human subjects of research.

j. Serve as a resource for the University of Lynchburg research community on the protection of human subjects. Make presentations to University groups as requested.

k. Report the findings and actions of the IRB to the Provost and the President as appropriate. The Director will normally make a verbal report to the Provost monthly and will provide a yearly annual written report. Other reports may be generated on an as needed basis. Any reports of noncompliance, adverse events, or other matters of importance will be made to the Associate Provost and the President of the University in writing.

l. Other duties as assigned by the President, the Provost, or the Board.

Section 7. The University of Lynchburg Specific Policies

University of Lynchburg affirms that, in the pursuit of knowledge, individual rights must be preserved and human rights protected. The following policies and procedures are designed to comply with the federal and state laws protecting human subjects involved in research. Federal and state regulations are to be seen as a "floor" and not a "ceiling" for the protection of human subjects in research.

All systematic biomedical, health science, behavioral, or social science research involving human subjects which is associated with this University must comply with the policies and procedures set forth below and must be properly reviewed and approved by the Institutional Review Board (IRB) before the research begins. These policies apply not only to research done in academic departments, but to all systematic biomedical, health sciences, behavioral, and social science research executed by any individual, office, or department at the University of Lynchburg. Individuals from outside the Lynchburg community who wish to involve or engage members of the Lynchburg community, or the institution as an entity, in their research activity must also comply with the policies and procedures for review outlined by the Lynchburg IRB. Please contact the IRB Director with any questions: IRB-HS@lynchburg.edu.

7.1 Ethical Research Practices Policy. All faculty, staff, and students seeking approval from the LC IRB (Human Subjects Research) for research proposals must pass a basic training course on research ethics offered by the National Institute of Health (NIH). Successful completion of this training is required to ensure that all members of the University of Lynchburg community who plan to conduct research are familiar with ethical research practices. The IRB will only review proposals submitted by those who have passed the training as evidenced by the receipt of a training certificate on file with NIH and accessible by the IRB Director. An ethics certificate for EACH research team member must be included in the protocol proposal.

7.2 Internal Assessment and Evaluation Research Policy. (This policy is consistent with the guidance provided by the OHRP in their resource "Quality Improvement Activities FAQ" found online at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html.) Research activities conducted solely for academic assessment data purposes, including quality improvement activities, and intended only for internal dissemination (within University of Lynchburg

and potentially with accrediting bodies) are not subject to oversight by the IRB. This includes items such as student opinion surveys ("course evaluations"); focus groups/interviews/surveys for development of courses, programs, and service; and other assessment research tasks that are focused solely on improving and refining the delivery of curricular and extra-curricular services and are only intended for internal audiences. Plans for the external dissemination of academic assessment data shall necessitate that IRB approval take place.

The IRB suggests that researchers conducting institutional assessment research ask the following question prior to collecting data: "If I/we learn something very interesting or extremely helpful, would I/we wish to disseminate externally to non-Lynchburg audiences?" If the answer is "yes," then your research study does need to go through the IRB approval process.

This policy applies only to academic assessment research conducted by individuals on the department, school, or university level. Individual faculty researchers and student researchers who wish to conduct research on these sorts of topics but who are not officially doing so at the behest of an academic or administrative unit must go through the IRB for approval.

If data have already been collected and a researcher, academic or administrative unit wishes to re-analyze the data for the purpose of dissemination to external audiences, then the research study proposal does need to go through the IRB approval process and would be treated as secondary data analysis.

7.3 Protection of Human Subjects Policies.

Protection against harm:

Researchers are responsible for identifying, justifying, and minimizing the risks of real or potential harm accruing to human subjects involved in their proposed research; such risks include physical, psychological, and social harm.

Physical harm may range from unnecessary discomfort or inconvenience to physical pain or disfigurement. Psychological harm includes emotional distress, loss of self-esteem, and impairment of the subject's ability to judge behaviors or make decisions. Social harm includes damage to reputation and social or legal standing.

Protection against coercion & deceit:

Researchers must respect a subject's right to autonomy and guard against unnecessary deception. Therefore, researchers are required to obtain in writing the informed consent of their subjects, except as otherwise approved in advance by the IRB.

In obtaining "informed consent" researchers must meet the following conditions: (l) before agreeing to participate in the study, prospective subjects must be given the most detailed and accurate description of the study as the research design will allow; (2) consent and subsequent participation cannot be coerced and prospective subjects must be provided with written and oral reassurance that they are free to refuse

to participate or to withdraw from the study at any time; (3) if parties other than the researchers identified with the study are to have access to the individual contributions of the participants, prospective subjects must be provided with a written statement identifying these parties; (4) under no circumstances may prospective subjects be misled or uninformed as to any risks associated with the study; (5) when the design of the study necessitates concealment or deception on other matters, researchers are ultimately required to reveal to participants the reasons for the actions; and (6) any other items required by law.

The IRB is legally required to determine whether the proposed "informed consent" contains the necessary types of information. Ideally, prospective subjects should understand all features of the research that reasonably might be expected to influence willingness to participate. Furthermore, at the conclusion of the study researchers should freely provide to participants upon request information explaining the purposes of the study, the genuine nature of the design, and the results. This access to information should be clearly stated in writing on the consent form which participants sign.

If a prospective subject is less than 18 years of age, then the prior informed consent of a parent or legal guardian is required and the conditions prescribed herein pertain also to the parent or guardian.

Protection against violations of privacy & personal integrity:

Researchers must respect the privacy and human dignity of subjects. Research participants possess the right to decide how much of themselves to share with others.

When possible, subjects should participate anonymously. If the research design precludes the anonymity of research participants, then information that may lead to identification of the individual subjects or to their contributions to the study must be treated with strict confidentiality. Once obtained, personal data about subjects may not be revealed to any third parties or the public in such a way as to make possible the identification of individual participants.

A statement explaining the anonymity or confidentiality of information associated with the individual participants and their contributions to the research must be presented in writing to proposed subjects prior to their participation.

Researchers should make every effort to preserve the personal integrity and dignity of human subjects, including refraining from research which could conceivably humiliate or belittle participants.

7.4 Research Modification Policy. Any change to an approved research project, including research plan, consent/assent process and form, co-investigators, other research personnel, and/or methods of subject recruitment, requires submission of a Research Modification Form along with all supporting documents as outlined on the form. The form is found on the main IRB webpage under Forms and Templates. Modifications to research projects may not be initiated until IRB approval has been obtained.

7.5 Research Closure Policy. All research that has been approved by the IRB must be closed within 30 days of the end of data collection. The IRB considers a study to be completed once the Principal Investigator (PI) determines that there will be no further contact with human subjects – for many studies,

this means that the study is completed once data are collected. The Research Closure Form is used for study closure and must be submitted to the IRB Director following the instructions provided on the form.

If a closure form has not been submitted one year after the approval date, the PI will be contacted by the IRB to determine whether the study should be closed or is ongoing. If the study is ongoing, the PI will be asked to complete a brief form/checklist to update IRB records regarding the status of the study. If the data collection is completed, the PI will be asked to complete the closure form. PIs of ongoing studies will be contacted annually regarding the status and to ensure a closure is submitted at the end of study completion.

7.6 Research Integrity & Misconduct Policy. Researchers are responsible for ensuring that the research activities associated with their studies are conducted in a way that is consistent with the procedures approved by the IRB and in compliance with the stated human subjects research protection policies.

Research misconduct falls into three major categories:

1. An action or inaction on the part of the lead researcher (Principal Investigator) or a member of the research team which is a deviation from the accepted research procedures approved by the IRB.
2. Fabrication, falsification, or other misrepresentation of data; plagiarism in the course of the research process (including proposal and dissemination processes); and violations of human subjects protection policies.
3. Conducting research under the auspices of and/or in affiliation with the University of Lynchburg without gaining approval for the research project from the IRB committee.

This is not an exhaustive list of potential infractions of the policy on research integrity and misconduct. Misconduct is taken seriously and is reported to the Associate Provost for investigation. Being guilty of misconduct may lead to revoking an individual's ability to conduct research at the University of Lynchburg.

7.7 Student Research Policy. Student research projects involving human subjects must comply with the policies and procedures prescribed in the IRB policies and must be properly reviewed. Faculty research sponsors guiding such research share with their students the responsibility of compliance. Faculty research sponsors must serve as the Principal Investigator (PI) for a student's research study if the student is classified as an undergraduate student; faculty research sponsor may serve as Co-Principal Investigator (Co-PI) along with a graduate student, or may choose to serve as the only PI. Faculty research sponsors are responsible for ensuring that the student research follows all policies and procedures prescribed in the IRB policies. Students are not permitted to submit materials directly to the IRB on behalf of the research team. Only Lynchburg faculty/staff serving as PIs may submit completed IRB forms for review.

7.8 Policy on Classroom Research Projects. It is common for instructors, especially those teaching courses in research methods, to design class assignments that utilize questionnaires, interviews, and other interactions with human subjects. Novel and imaginative classroom exercises help students learn and are, therefore, integral to high quality teaching. All teaching assignments, however, must respect the rights and welfare of all individuals involved. The IRB distinguishes between *student research projects*, which require IRB approval, and *class assignments*, which often do not. Student research projects require review and approval by the IRB, whereas class assignments, in general, do not. Class assignments do, however, require a waiver of IRB review application, which may be found on the IRB webpage under Forms and Templates. There are two categories of class assignments that require IRB oversight—those that lead to dissemination of data or findings outside of class and those that involve more than minimal risk to human subjects.

Faculty members may design assignments that engage students in interaction with individuals or data about individuals to teach research methods or to help students understand concepts covered in their courses. Such required class assignments often involve University of Lynchburg students beyond those on the class roster as well as other participants. These assignments are not intended to create new generalizable knowledge or lead to scholarly publication. Therefore, class assignments, as a general rule, are not systematic data collection efforts intended to develop or contribute to generalizable knowledge and, thus, do not meet the federal regulatory definition of "research." Such assignments do not fall under the jurisdiction of the IRB and do not require IRB application, approval, or oversight but do require a class project waiver form. There are two exceptions in class assignments that require IRB review:

Exception 1: When class assignments are intended to contribute to generalizable knowledge (e.g., publish findings, presentations at research conferences inside or outside of the University of Lynchburg, etc.), the assignments are, indeed, "research" and fall under the jurisdiction of the IRB. Instructors and students wishing to use such assignments for presentation outside of class must apply to the IRB for review and approval of these assignments before they begin.

Exception 2: When class assignments extend to human subjects beyond queries of University of Lynchburg students to minors or other vulnerable populations, or involve more than minimal risk to participants, such assignments fall under the jurisdiction of the IRB. Class assignments that involve more than minimal risk are assignments that ask students to survey, interview, or interact with the following populations:

- Minors (i.e., persons under the age of 18);
- Vulnerable individuals (e.g. those whose capacity to freely give consent may be compromised because of socio-economic, educational, or linguistic disadvantage; cognitive impairment; advanced age; or terminal illness);
- Individuals involved in potentially stigmatizing behaviors which, when anonymity cannot be sustained, place participants at more than minimal risk physically, socially, or economically or for civil or criminal liability;

- Other individuals who, by the nature of the class assignment, are placed at more than minimal risk (e.g. research on sensitive topics such as rape, abuse, criminal behavior, etc.).

In such cases, the class assignment requires IRB review and approval.

It is the instructor's responsibility to ensure that her/his students understand the importance of protecting human subjects. Although many class assignments are designed as instructive measures and are not the type of activities typically reviewed by the IRB, there are instances when the nature of these projects is such that participants could be put at risk of harm, and IRB approval is required. For example, if a student proposes to ask peers about their safe-sex habits, names and responses could circulate, and the questions themselves could create emotional distress since they pertain to potentially stigmatizing behavior. Research on topics such as these would require IRB review. In all cases, instructors are responsible for minimizing risks to participants in class assignments. The IRB strongly encourages instructors to ensure that their students are educated about risks and how to minimize them. If a faculty member is unsure as to whether a planned project requires IRB review, the faculty member or student may submit a research determination form to be reviewed by the IRB so that a determination can be made as to whether the project requires IRB review and oversight.

*If an instructor is unsure as to whether the design or topic for a particular study qualifies for a class project waiver, please contact the IRB Director for guidance.

Note: Content in section 7.8, is largely taken, with permission, from the Sacred Heart University IRB.

7.9 Policy on Consultations and Assistance from Members of the Board. The Lynchburg IRB is charged with protecting the rights and welfare of human subjects involved in research conducted at the University of Lynchburg and/or by investigators affiliated with the University of Lynchburg. With the exception of the Director, members of the Board do not provide direct consultation or assistance to investigators unless the Director requests a special consultation. A special consultation might be desired if the consultation topics are discipline specific and in alignment with the area of expertise of a member of the Board.

In connection with the review of a research study proposal and consultation with the Director, suggestions may be made in relation to ways to minimize risk/discomfort to participants in such a way that might impact the research study methodology; this is in no way meant to indicate an endorsement for a specific methodological plan, authorization for specific data collection instruments or procedures, or validation of a procedure. Instead, these suggestions should only be viewed as examples as a part of an overall conversation on the nature and practice of human subjects protection.

If a member of the Board wishes to assist with the development of a research study, then that member of the Board shall be listed on the appropriate proposal forms and materials as a member of the research study team. If the member of the Board is not directly involved beyond the study development stage, then the role of the individual shall be listed as such (e.g., methodological consultant, human subjects

protection consultant, statistical procedures consultant, dissertation proposal consultant). In these instances, the involvement of the individual is that of a research study team member and not as an official representative of the IRB. The individual would abstain from participation in approval proceedings.

7.10 Hold Harmless Policy Pertaining to Evaluations of IRB Members' Academic and Service Performance. A member of the Board shall not incur benefits, reimbursement, subsidies, harms, detriments, or any other gains or losses based on the actions and determinations of the IRB. Concomitant with their service to the IRB, members of the Board, including the Director, are colleagues within departments, programs, schools, and other University entities. The actions and determinations related to one's service shall not be utilized as an indicator of performance evaluation, contract continuation or termination, and/or determinations related to promotion and tenure. It is not appropriate or authorized for a principal investigator, research team member, or other individual holding interest in or relationship to the research team to request that a member of the Board assist with developing a study proposal (in whole or in part), review proposal materials prior to submission or otherwise outside of standard procedure, and/or request special treatment or considerations for the proposal unless that individual has agreed to become a member of the research team thereby separating one's involvement from that of his or her position as a member of the Board and thus becoming a part of his or her scholarship activities.

7.11 Policy on Disclosure of Conflict of Interest. The University of Lynchburg IRB members should make known to the Board any potential conflicts of interest that result from financial interests, such as outside income from funders of research. A member desiring clarification of whether or not a conflict of interest exists should disclose and resolve the issue with the IRB Director. Such disclosure shall take the form of at least one written query to the IRB Director. IRB members will recuse themselves from voting on proposals in which they have a conflict of interest. A conflict of interest will not be considered to exist when an IRB member teaches or has experience or expertise in a given area. A research proposal for which an IRB member is the principal investigator, research team member, or faculty advisor will be considered a conflict of interest and the member will not vote on the action and will not count as part of the quorum on the action. Members who recuse themselves from voting on an IRB matter will not be required to absent themselves from the meeting room unless the issue of the member's presence is raised (either before or during the meeting). The IRB may amend or adapt this policy at a sitting meeting when common sense indicates that a conflict of interest does or does not exist. Such action will be documented in the minutes of that IRB meeting.

7.12 Compensation for Research Participation. At times researchers choose to compensate research participants for completing a study. Any form of compensation must be clearly stated in the informed consent form and in the research proposal form that is submitted for IRB review. In addition, the business office at the University of Lynchburg will need to access personally identifiable information for each participant earning compensation in accordance with federal tax law. If money is being provided, a W-9 form will need to be completed by each participant receiving funds (name, address, social security number or tax ID number) for those not affiliated with the University of Lynchburg. A pay authorization

form from Human Resources will need to be completed for all participants receiving compensation who are members of the faculty, staff, or student body at the University of Lynchburg. If participants are being compensated with gift cards, please contact the Business Office at 434-544-8213 to obtain the required form to track distribution. A signature acknowledging receipt of the gift card must be obtained from each participant on the distribution tracking form or an email must be obtained and saved verifying receipt of each gift card. A copy of the consent form and the IRB approval letter must be provided to the University of Lynchburg Business Office for all compensation requests (cash or gift cards). After compensation is provided, all materials need to be provided to the Business Office for verification.

Researchers are required to inform participants in the informed consent form that their personal identifiable information, and what specific information, will be viewed by the University of Lynchburg Business Office in order to process payment. It must be clearly stated in the confidentiality section of the informed consent form who will have access to compensation documents. If participants do not want their personally identifiable information to be viewed by business office personnel, they can waive their right to receive compensation for research participation. Research participants may participate but cannot be compensated if they do not want to complete a W-9 form or sign for acceptance of a gift card.

Ethical practices when providing research participation compensation are vital. Compensation should not be unduly influential, but be used to balance the time, effort, or other specific reason based on the engagement of the participants in the research study. Gift cards that are provided to participants cannot be reused or have any additional funds added to them. Data obtained from the research study should never be shared with business office personnel, only the required documentation to allow them to track receipt of compensation. Research team members should not keep any copies of W-9 forms past the time period required to process payment. After payment is processed, research team members must shred and/or delete any copies of W-9 forms. The Human Resources and Business Office administration will maintain the confidentiality of personal information by allowing only essential staff to view completed W-9 forms.

Section 8. Meetings of the IRB.

The University of Lynchburg IRB will hold regularly scheduled meetings for the purposes of reviewing and acting on proposals, setting policies, conducting oversight, and fulfilling its other responsibilities. This section describes meeting policies and procedures.

8.1 Announcement of meetings. Meetings will occur at a time set prior to each academic semester based on the availability of the Board during the academic year. Meeting dates will be set by the Director with the agreement of the Board. Additional meetings will be scheduled as necessary.

8.2 IRB quorum. A quorum for the Board is a simple majority. Quorum will depend on the size of the Board. If the number of appointed members changes, quorum requirements may change with it. Quorum is required when voting on approval for a Full Board Review.

8.3 Discussion of proposals. Each member will have carefully read each proposal brought before the Board. The committee, in its deliberation, will apply the criteria set forth in 45 CFR 46.111, as follows:

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) 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.

(2) 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. 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). 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.

(3) 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 the following: pregnant women, human fetuses, and neonates; prisoners; children (anyone under the age of 18 years); cognitively impaired persons; students and employees; minorities; economically and/or educationally disadvantaged; AIDS/HIV+ subjects; terminally ill subjects.

(4) Informed consent will be sought from each prospective subject or the prospective subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) 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.

8.4 IRB voting. A majority vote *of participating members* decides the action, provided that a quorum is present. For example, if six members are present at the meeting and that is sufficient for quorum, a vote of 4-2 would be adequate to take action. The names of members and their votes will be recorded as part of the minutes. Actions available to the IRB are enumerated in 45 CFR 46.109. These actions include:

8.4a. Approving the proposal as submitted.

8.4b. Approving the proposal with conditions for modification. A conditional approval does not need to be resubmitted to the entire Board. The Director or a subcommittee can review the modifications and approve the modified proposal, unless the Board directs that the proposal be resubmitted for review by the convened Board.

8.4c. Disapproving a proposal. The Director or an IRB subcommittee cannot disapprove a proposal. Only the convened Board can disapprove a proposal. Disapproval will take place by a recorded vote of the Board. A resubmitted proposal that was previously disapproved by the Board must be returned to the Board for review, unless the extent of revisions in the resubmission is modified so that it poses no more than minimal risk and no longer requires full board review.

8.4d. Not acting on a proposal. Reasons for not acting on a proposal may include the absence of necessary information on which to base a decision, the need for more time to review the proposal, lack of Board consensus on a course of action, determination that project does not meet the conditions of human subjects' research, or other reasons as determined by the IRB. When no action is taken, the Director will notify the researcher that no action has been taken and provide other such information as directed by the Board.

8.4e. Appointing subcommittees. In some cases the IRB may take an action at a convened meeting and empower a subcommittee to finalize the notice of action to the researcher. When such an action is taken, the date of IRB action will be the meeting date of the convened IRB. The minutes of the IRB will reflect the named members of the subcommittee and the language provided by the subcommittee in its written notice of action to the principal investigator. The Chair of the subcommittee will be appointed by the IRB Director or will be elected by the subcommittee members.

8.4f. Other action as appropriate to the proposal or situation.

8.5 IRB minutes. Minutes will be recorded and maintained by the IRB Director in accordance with 45 CFR 46.115(a) (2). The Director, Assistant Director, or Board member will generally prepare notes during the meeting that reflect the position(s) of the IRB. The meeting minutes will reflect IRB notices of action as well as the discussion and votes of the convened Board. The Director will maintain

electronic copies of these records on the password protected University of Lynchburg IRB Google Drive folder and will be kept for a minimum of 3 years. The Director will make the minutes available to other members of the IRB on the IRB Google Drive folder. Members should not forward these minutes to non-IRB members or make them otherwise available for review by non-Board members.

8.6 IRB confidentiality. The discussions of the IRB are considered confidential. The minutes of the IRB will also be considered confidential, although they are subject to review by OHRP or other appropriate federal entities (e.g. NIH). The minutes will generally not include the identities of persons making arguments for or against a proposal. The principle of IRB confidentiality will not, however, be a basis for obscuring IRB decisions. The IRB will attempt to communicate clearly to researchers the basis for its decisions. Reports to researchers will not be considered a breach of IRB confidentiality. The Director may exercise discretion in making IRB minutes available to researchers or other University personnel. The IRB Director may report on any Board matters, including confidential discussions, to the Lynchburg College Vice President and Dean for Academic Affairs or the Lynchburg College President. When such reports are made, the Director will inform the IRB at its next convened meeting or by other means as he or she deems appropriate.

8.7 Attendance of others at IRB meetings. Researchers or other persons may be invited to attend a meeting of the IRB for the purposes of answering questions or providing information to the IRB. Non-Board members will be asked to leave when the Board discusses and votes on a proposal.

8.8 IRB Meetings Convened by Telephone Conference Call. There may be rare occasions when the IRB may choose to meet by telephoned conference call or video conferencing. This Lynchburg policy will comply with the HHS Guidance Letter of March 28, 2000. The HHS policy letter states that "Wherever possible, OPRR strongly recommends that such meetings take place with all participating IRB members physically present. However, OPRR recognizes that circumstances sometimes warrant conducting IRB meetings via telephone conference call."

The University of Lynchburg IRB's policy is that such meetings conducted via conference call or video conferencing may consist of some or all IRB members. The intent of the IRB is that this policy be used rarely and principally between regular convened meetings of the IRB. This policy should not be interpreted by IRB members as a vehicle for participating in regular convened meetings for which a quorum is physically present.

Section 9. Records of the IRB.

The IRB Director maintains electronic copies of all materials. Records must be retained at least three years from the date of project completion, as required by 45CFR46.115 (b). The University of Lynchburg IRB will comply with the records required that are detailed there.

9.1 Electronic Records. An electronic copy of all project files is maintained by IRB reference number and lead Principal Investigator last name. The IRB moved to an electronic submission and documentation system in August of 2015. Records prior to August 2015 are mainly in hard copy, with some electronic files. All notices of action are sent to researchers via email. Subfolders, whose titles are generally self-explanatory, are also included in the IRB Google Drive folder.

Electronic copies of IRB meeting records are maintained for each meeting. Meeting records include an agenda, materials and proposals sent to members prior to the meeting and given to members at the meeting, meeting minutes, recorded votes on any matters, and a copy of all of the actions (e.g. proposals) brought before the IRB. The IRB minutes on individual proposals will generally serve as the conditions of approval or other notes on each proposal.

Section 10. Overview – Commonwealth of Virginia Regulations and Recommendations

The Commonwealth of Virginia has a human subject research law which provides definitions of human subject research, consent, and other terms. The most important section of relevant Code of Virginia provision is Section 32.1-162.20, which essentially states that federal statutes are applicable to human subject research in Virginia. Consequently, Virginia statute largely mirrors 45 CRF 46 and refers to the Code of Federal Regulations (CFR) in several sections. For example, Virginia law in Section 32.1-162.17 (Exemptions) of the *Code of Virginia* is – for the most part – taken word for word from the exemption section of 45 CFR 46.

Virginia statutes do, however, offer clarification on some points where there is ambiguity in the federal regulations. While federal statutes take precedence over state statutes, Virginia laws on human subject protection appear to have been written largely to provide guidance where federal statutes are silent. For example, in paragraph 5 of 32.1-162.16 (Definitions), the state statute provides an operational definition of "legally authorized representative." In addition, State law provides the definition of a "child" where research is involved. Section 1-207 of the Code of Virginia states that a "child," "juvenile," "minor," or "infant" … "means a person less than 18 years of age." Because federal regulations leave the definition of "children" to the states, any research at the University of Lynchburg must recognize that for research (and other purposes) someone under 18 is a child under the law. This is very important for researchers who use students at the University of Lynchburg as subjects. In any research subjects must be 18 years of age or older. If a subject is younger than 18 years of age, the subject cannot provide informed consent. In such cases, parental/guardian consent must be obtained, along with the assent of the subject. Even if a researcher is conducting minimal risk research, he or she must be careful to ascertain that the subjects are 18 or older. It is not uncommon for 17 year olds to attend the University of Lynchburg. For research purposes, the 17 year old is a child and the provisions of 45 CFR 46, Subpart D: Children must be adhered to. Even a legally "emancipated" minor does not have the specific statutory authority under Section 16.1-334 of the *Code of Virginia* to provide informed consent and should not be used as a research subject. A researcher should consult with the IRB Director or the University legal counsel if a student makes a claim to be an emancipated minor.

Researchers at the University of Lynchburg should be aware that state statutes establish "Human Research Review Committees" (HRRC's) in State institutions. The HRRC is comparable to an IRB and in most agencies the HRRC is the IRB for the State institution. The *Code of Virginia* requires that "every person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee…" This language does not contradict the University of Lynchburg's policy. Indeed, it provides another source of authority for the actions of the IRB.

Basic provisions of the *Code of Virginia* related to the protection of human subjects of research include the following:

§ 32.1-162.16. Definitions.

§ 32.1-162.17. Exemptions.

§ 32.1-162.18. Informed consent.

§ 32.1-162.19. Human research review committees.

§ 32.1-162.20. Applicability of federal policies.

Persons with questions on Virginia law should consult with the IRB Director or the University of Lynchburg legal counsel.

Section 11. Research Involving Multiple Institutions, Organizations, and/or IRBs

Once an activity is determined to involve non-exempt human subjects research, IRB oversight is required. Researchers often collaborate with colleagues at institutions outside of the University. Determining how to obtain IRB approval depends on if researchers from an *institution* involved in some aspect of the research are *engaged* in that human subjects research. *An Institution*, as defined by 45 CFR 46.102(b), is any public or private entity or agency (including federal, state, and other agencies). An institution's *employees or agents* refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

11.1 Interpretation of Engagement of Institutions in Human Subjects Research.

Based on the HHS website (http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html), an institution is generally considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. The determination of engagement depends on the specific facts of a research study and may be

complex. In applying this guidance, it is important to note that at least one institution must be determined to be engaged in any non-exempt human subjects research project that is conducted or supported by HHS (45 CFR 46.101(a)).

Examples of engagement and examples where no engagement occurs are listed on the HHS website to provide additional guidance to researchers.

11.2 IRB Review Considerations for Cooperative Research. OHRP notes that multiple institutions may be engaged in the same non-exempt human subjects research project. For such cooperative research projects, institutions may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements to avoid duplication of effort, in accordance with HHS regulations at 45 CFR 46.114.

When an institution is engaged in only part of a cooperative research project, the institution must ensure that the IRB(s) designated under its FWA reviews and approves the part(s) of the research in which the institution is engaged. When an institution is engaged in only part of a cooperative research project, the reviewing IRB may decide to review the entire research study, even if information about the entire study is not necessary to approve the institution's part of the research under 45 CFR 46.111.

Note: Content in section 11 was obtained from the HHS webpage: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.

Section 12. Examples of Possible IRB Situations, Actions, and Determinations

Examples are provided below to guide the IRB or institutional officials involved in such decisions. These examples do not limit the action of the IRB or institution in any way, but provide a guideline for how situations may be handled by the University.

1. *A researcher studying underage drinking receives three surveys with identifying information. Rather than removing the identifiers from the records, the researcher places these records into what he designates as a "special action" file for longitudinal analysis. Later, a student complains to the IRB that she has been selected for follow-up review regarding her underage drinking. The student complains that the consent form promised confidentiality and wants to know what has been done with information that she reported on related behaviors while under the influence of alcohol.* ***What action should be taken?*** The IRB should inform the Provost and Vice Provost of a possible research misconduct. The Provost and Vice Provost will determine the next steps including a potential investigation into the allegations. A preliminary report of noncompliance is made to OHRP depending on the outcome of the investigation.

2. *A person affiliated with the University of Lynchburg is providing free legal services to minors incarcerated by the Virginia Department of Juvenile Justice. The person sees interesting trends*

in the backgrounds of these juveniles and begins to collect family history background and other data on the incarcerated juveniles. The person requests help from a colleague in the Department of Computer Science to run a regression analysis testing the relationship between severity of abuse in the home and the severity of crime for which the juvenile is convicted. The colleague in Computer Science asks for a copy of the proposal that was approved by the IRB. "What IRB?" is the response. The Computer Science colleague reluctantly reports this noncompliance to the IRB Director. What action might be taken? While the person collected the information in ignorance but "in good faith," human subjects' protections have been ignored in multiple ways. The IRB should inform the Provost and Vice Provost of a possible research misconduct. The Provost and Vice Provost will determine the next steps including a potential investigation into the allegations. A preliminary report of noncompliance is made to OHRP and the IRB of the Department of Juvenile Justice depending on the outcome of the investigation.

3. *A department wants to assess how much time its students spend studying for the courses it teaches. The department wants to use the study to makes its course offerings more consistent. One of the questions asks if excessive homework has ever made the student contemplate suicide. The researcher performing the study wants to present a paper on his or her research.* ***Is this reviewable research?*** Looking only at the first two sentences, the research might be appear to be non-reviewable research, as it is an assessment of the department's local practices. However, the question on suicide would make the study reviewable. The fact that a member of the department wants to present a paper on the study also elevates the activity from an internal assessment of the department to a research activity. The IRB would require that the researcher(s) submit a full proposal to the IRB before it made a determination.

4. *An IRB-approved study of more than minimal risk involves a faculty principal investigator and student co-investigators. The faculty principal investigator leaves the University of Lynchburg. The student co-investigators want to know if they can continue work on the project. What should take place?* If no alternate faculty PI can be found, the IRB approval is terminated and the study is terminated. The reason being that a student co-investigator cannot assume the role of principal investigator. This termination should be explained by the IRB Director in a brief report to the IRB and included in the minutes of the next meeting. No report to institutional officials or OHRP is required.

5. *A minimal risk survey of the freshman class experience is proposed as a means of improving services to new University of Lynchburg students. Is this survey exempt from IRB review and how would the exemption be handled?* The Director would ask that the proponents provide the purpose of the study, the project team members, where the study will take place, the objectives of the study, and the data that is to be collected among other items. Given that the survey is for the purpose of internal assessment and not research, the Board would likely determine that the

project does not require IRB oversight. The Board would provide a determination letter if there is a request by the project leader.

6. *Do persons conducting assessments that are determined to be non-reviewable have to complete the training required by the IRB?* No. The training requirement is for persons conducting reviewable human subjects research. Activities such as a program assessment are not considered research as defined by the federal government or the University of Lynchburg. Note that the determination that a study is non-reviewable must be made by the IRB, not the individual conducting the research.

7. *A student is assisting a professor with an IRB-approved human subjects research project. Does the student have to complete the ethics training required by the IRB?* Yes. Students assisting in human subject research must take required training. In addition, students must be listed on the proposal form as research team members.

8. *A teacher in a public school is seeking a Master's degree at the University of Lynchburg. As part of a research course, the teacher wants to use the students in his classroom as a convenience sample to see on which of two standardized tests the students score better. The teacher has administered the tests to his classes before to help prepare them for taking the Standards of Learning tests. Does the teacher need to submit the research proposal to the IRB and will the study require the consent of the students' parents and the students' assent? After all, the teacher has already used these tests in the classroom without having to receive any permission.* Yes. Intent is everything in this example. When the teacher was using the test instruments before, he was giving practice tests intended solely to help the students. Now, the teacher wants the students to help him. Many students suffer test anxiety, so there is some risk involved. Parents may be confused as to why their children are being tested. While the activity (a graduate school class exercise) may not meet the federal standard of research, the University of Lynchburg IRB has determined that <u>any</u> research involving children must be reviewed by the IRB. However, a teacher who writes a paper on his or her normal classroom activities (without using data on students) is not conducting research and such an activity would not be reviewable.

9. *A student proposal involves interviewing classmates about their social activities, including whether or not they use illegal drugs. What should take place?* The IRB should evaluate the proposal and likely would direct that the question on illegal drug use be removed. The reason being, the interviews potentially involve self-reports of illegal activity.

10. *When to consult the IRB?* Please contact the IRB with any questions at any time.

Section 13. Frequently Asked Questions

- **How long does the approval process take? How long before I expect to start collecting data do I need to have my proposal into the IRB?**
    - The timeline for IRB approval depends on how well the proposal is written. The overall timeline will depend on how many revisions are requested. It is best to plan one month at a minimum for IRB approval to be granted. We typically respond to exempt protocol submissions within 5 days and expedited protocols within 10 days during the fall and spring semesters. Communication regarding full Board proposals is provided within 1 week of the full Board meeting. Revisions are typically reviewed within 5 days of submission. Response times may be longer during times of high volume, over holidays, or during the summer or semester break.
- **Are students able to submit protocols or any additional documentation to the IRB?**
    - No. Students cannot submit their own protocols -- they must be submitted by their faculty/staff research mentor.
- **What are some common mistakes to avoid?**
    - Have NIH training completed/updated (must be no longer than 3 years since last training/update) for all research team members and submit the certificates for all team members with the research protocol.
    - Be sure to read the protocol form carefully.
        - Answer all questions completely.
        - Check all appropriate boxes.
        - Include all supplemental information at the end of the protocol.
- **I teach a course in which my students engage in instruction-related research involving human subjects. Do all of these projects need IRB approval?**
    - It depends on whether the goal is educational and not the dissemination of generalizable research. If the research is solely for the purpose of a class project (ie data will not be published nor will it be presented outside of the classroom) and the topic is benign (ie is not a topic that could potentially cause harm, such as rape, abuse, criminal behavior, etc.), then the projects do not need to be approved by the IRB. Instructors do, however, need to have students complete a Class Project Waiver of IRB form. This must be reviewed and approved prior to students engaging in any human subjects research-related activities.
- **Do I need to complete a training program/class to conduct human subjects research?**
    - Yes. All faculty, staff, and students who are part of a research team seeking approval from the Lynchburg IRB (Human Subjects Research) for research proposals must pass a basic training course on research ethics offered by the National Institute of Health (NIH). The IRB will only review proposals submitted by those who have passed the training as evidenced by the receipt of a training certificate on file with NIH. Training certificates are good for 3 years after which individuals must become recertified.

- **I will be collaborating with colleagues at other institutions; do I need to submit to the University of Lynchburg IRB?**
    - If you (or your collaborators) have received IRB approval at another institution, the IRB at the other institution may agree to be the IRB of record. If that is the case, Lynchburg's IRB will need a copy of the approved proposal and the approval letter. Modifications to the approved documents may be required in order gain approval from the Lynchburg IRB. You and the collaborating institution will need to complete an IRB Authorization Agreement. If the University of Lynchburg will be the institution with the IRB of record, you would submit the proposal to Lynchburg's IRB.
- **What is Assent and when is it needed?**
    - Assent is a type of consent required for subjects under the age of 18. If working with any subjects under the age of 18, the Assent Form as well as the Parental Informed Consent Form must be completed (these may be found on the IRB website). The template can be adjusted depending on the population. For example, the way the information is provided to a 14-year-old would be very different than the way the information is provided to a 4-year-old.
- **Can I use online data storage sites (e.g., Dropbox), and if so, what do I need to do to protect the security of my data?**
    - Yes, but the storage site must be password protected. We also require the computer login to be password protected.
- **How is the consent process handled for Internet-Based research?**
    - For Internet-Based research such as surveys, participants must still be presented with the consent information. Internet-based surveys can include the consent form with "I agree" or "I do not agree" buttons at the bottom of the webpage (or something similar) for participants to click their choice of whether or not they consent to participate prior to completing the remainder of the study.
- **When should a modification (amendment) to an approved research study be submitted?**
    - Any change to an approved research project, including research plan, consent process and form, investigators, other research personnel, and/or methods of subject recruitment, requires submission of a Research Modification Form. Modifications to research projects may not be initiated until IRB approval has been obtained.
- **What do I do when my study is complete**?
    - When your study is completed, please fill out the Research Study Closure Form. This form must be shared to the IRB director. Once a study is closed, it cannot be reopened.
- **What if a participant has an adverse reaction from participating in my study?**
    - Please contact the proposed individual/office mentioned in the informed consent under the Risks/Benefits immediately.
    - Please also contact the IRB immediately at irb-hs@lynchburg.edu.

Note: Content in sections 2, 3, 4, 6, 8, and 11 is largely taken, with permission, from the University of Richmond IRB guide and is credited to Dr. Kirk Jonas and the University of Richmond Institutional Review Board.