

ELON UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB)

STANDARD OPERATING PROCEDURES FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH

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DEFINITIONS

Adverse event is an undesirable and unintended, though not necessarily unanticipated injury or physical or emotional consequence, to a human subject.

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In North Carolina the age of majority is 18 years.

HIPPA and Covered Entity: HIPAA is an acronym that stands for the Health Insurance Portability and Accountability Act, a US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers. These standards provide patients with access to their medical records and more control over how their personal health information is used and disclosed. **Covered entities** is a term that HIPAA regulations use to describe the businesses in the health care industry that are subject to HIPAA regulations. Specifically, covered entities are health plans, health care clearinghouses and health care providers who transmit any health information in electronic form in connection with the following transactions: health care claims or encounter information, health care payment and remittance advice, coordination of benefits, health care claim status, enrollment or disenrollment or eligibility information re health plans, health plan premium payments, referral certification and authorization, first report of injury, or health claims attachments.

Family member means any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data

through intervention or interaction with the individual, or (2) Identifiable private information.

Institution means any public or private entity or Agency (including Federal, State, and other agencies).

Institutional Review Board (IRB) means an Elon University committee formally designated by the University to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects. The primary purpose of such review is to protect the rights and welfare of the human subjects.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Intervention includes both physical procedures by which data are gathered (e.g., external electrodes) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Investigator means an individual who actually conducts research or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk (for human subjects other than prisoners) 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.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

Pregnancy encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. The Elon University IRB is not constituted to review research involving prisoners.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Protected Health Information (“PHI”): HIPAA defines protected health information (“PHI”) as individually identifiable health condition, health care and health care payment information, including the demographic data that is a potential identifier of the individual, maintained in the records of “covered entities” for treatment, payment and healthcare operations purposes. (See definition of “covered entity” above. Most health care providers and health plans and health care clearinghouses are covered entities) PHI does not include individually identifiable health information in personnel records or education records covered by the Family Educational Right and Privacy Act (“FERPA”).

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Serious Adverse Event (SAE) is one which is fatal or life threatening; results in significant or persistent disability; requires or prolong hospitalization; results in a congenital anomaly/birth defect; or, represents other significant hazards or potentially serious harm to research subjects or others. [See also “Adverse Event”]

Sponsor is an entity external to the university that is providing support for a university research project pursuant to terms and conditions in an agreement between the sponsor and the university.

Test article means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act. Research requiring FDA compliance is not performed at Elon University.

Unexpected or unanticipated refers to adverse events or other problems in the research, the specificity or severity of which is not consistent with the information already provided to the IRB, including the investigator's brochure, research protocol or consent form.

Unanticipated Problems (UP) may or may not include specific events experienced by individual subjects, but are developments within the research activity that suggest a potential for increased risks to subjects or others.

INTRODUCTION

Human subjects are partners and participants in research and a precious resource to the University. At Elon University, human subject research is a privilege, not a right. Consistent with that philosophy, it is the mission of the Elon University IRB to facilitate:

1. the rights and welfare of human subjects are paramount in the research process;
2. the highest standards of ethical conduct are employed in all human subjects research;
3. research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;
4. research investigators deal honestly and fairly with human subjects, informing them fully of procedures to be followed, and the risks and benefits of participating in research; and
5. research using human subjects at Elon University conforms to all applicable local, state and federal laws and regulations and the officially adopted policies of the University.

PRINCIPLES, ROLES, RESPONSIBILITIES

Ethical and Regulatory Mandates for the Elon University IRB

The Institutional Review Board (IRB) of Elon University is concerned with the ethical treatment of humans when they are involved as participants in research. The committee seeks to ensure that the principles of confidentiality, informed consent, benefit, and minimal risk are adhered to in the conduct of such research if the activities are conducted in the name of Elon University and/or using students or personnel of Elon University as participants.

The regulation of human subjects research by the U.S. Department of Health and Human Services is codified in 45 CFR 46. Because Subpart A of 45 CFR 46 has been adopted for human subjects research by many federal agencies it is known as the “Common Rule.” The Common Rule requires that every institution performing federally supported human subjects research file an assurance of protection for human subjects. This research should be guided by the ethical principles espoused in the Nuremberg Code and the Declaration of Helsinki and, additionally, should conform to the guidance documents described below:

The Belmont Report

The Belmont Report elucidates three ethical principles that should guide research:

- Respect for persons (applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations);
- Beneficence (applied by weighing risks and benefits);
- Justice (applied by the equitable selection of subjects)

This regulation, published by the Department of Health and Human Services, codifies basic human subject protection measures.

Assurance and IRB registration process

Elon University, as an institution involved in social/behavioral, educational and physical activity research, should have in place a set of principles and guidelines that govern the institution, its faculty, and staff, in the discharge of its responsibilities for protecting the rights and welfare of human subjects taking part in research conducted at, or sponsored by, the institution, regardless of the source of funding. Assurances applicable to federally supported or conducted research must, at a minimum, contain such a statement of principles, which may include an appropriate existing code, declaration, and/or statement of ethical principles as formulated by the institution. *The Belmont Report* serves as such a document for Elon University.

The *IRB Standard Operating Procedures Manual* represents the written procedures and guidelines provided for in Elon University's Assurance.

Roles in the protection of human research subjects at Elon University

The Institutional Official

The Institutional Official at Elon University is the Director of Sponsored Programs. It is the responsibility of the Institutional Official to oversee the University's compliance with federal regulations pertinent to human subjects research. The official document pledging this responsibility is called the Federalwide Assurance (FWA), approved by the Office of Human Research Protections (OHRP) at DHHS. The Institutional Official shall be responsible for all required institutional reports to sponsors and federal agencies.

Institutional Review Board (IRB)

The IRB reports to the Provost designee. The IRB is an appropriately constituted group that the University has designated to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects. The primary purpose of such review is to protect the rights and welfare of the human subjects. The University's IRB has the expertise required for the review of the University's widely varied human subjects research studies.

Principal Investigator (PI)

The principal investigator is the individual responsible for the implementation of research, and, as such, must personally conduct or supervise the research. The PI is responsible for ensuring that the research study is accurately and completely submitted for IRB review, that IRB approval is obtained prior to initiation of research or before making any changes or additions to the research; that the IRB is informed of all changes in information previously presented to the IRB; that progress reports are submitted to the IRB as required; and that all unanticipated problems or serious adverse events involving risk to human subjects are reported to the IRB. The PI is also responsible for ensuring that all members of the research team comply with the findings, determinations, and requirements of the IRB, including adequate performance of the informed consent process. The role of PI implies ultimate administrative and fiscal responsibility for the project, subject to University review and oversight.

Students may not serve as a Principal Investigator on an IRB study. A faculty or administrative staff member must serve as the PI and submit a protocol on the student's behalf. Ultimate responsibility and oversight remains with the faculty or administrative staff advisor for the research project.

Research team members

Every member of the research team is responsible for protecting human subjects in accordance with the guidelines specified above, and for complying with all IRB findings, determinations and requirements.

IRB Authority

Scope and purpose

The purpose of the Elon University IRB is to protect the rights and welfare of human research subjects. To achieve this, the IRB must

advise investigators in designing research projects in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects are indeed protected.

The IRB also informs and assists Elon University and its researchers on ethical and procedural issues related to the use of human subjects in research; facilitates compliance with relevant regulations of the United States Government; and provides a framework suitable for continued support by Government agencies, private foundations and industry for research involving human subjects at Elon University.

IRB responsibilities and authority

All human subjects research carried out at Elon University or under its auspices must be reviewed and approved or determined exempt from further review by the IRB prior to the involvement of human subjects in research.

The Elon University IRB reviews human subjects research: (1) sponsored by the University; (2) conducted by or under the direction of any employee or agent of the University in connection with his or her institutional responsibilities; (3) conducted by or under the direction of any employee or agent of the University using any property or facility of the University; or, (4) involving the use of Elon University non-public information to identify or contact human subjects.

The IRB must conduct initial and continuing reviews of research and report the findings and actions to the investigator and the institution. These reviews include: the review of all research involving human subjects at a convened meeting of the IRB (except research classified as exempt or evaluated in expedited review); the approval of research with the concurrence of the majority of IRB members; the evaluation of proposed changes in approved research protocols; and, the determination if any project requires verification from sources other than the investigator that no material changes have occurred since previous IRB review. In addition:

- The IRB has responsibility for oversight of all human subjects research that is not exempt from IRB review;
- The IRB must protect the rights and welfare of subjects according to 45 CFR 46. (Research requiring FDA compliance is not performed at Elon University.)

- The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities;
- The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, Institutional Official, Senior Associate Provost for Faculty Affairs, and appropriate federal regulatory agency.

Agreements to provide IRB review of research conducted by unaffiliated investigators

Occasionally Elon University may be asked to provide IRB review for investigators who are affiliated neither with Elon University nor with another institution that has an IRB. Circumstances in which this arrangement might be considered would typically involve a study based at Elon University in which the unaffiliated investigator is collaborating. It will generally not be considered appropriate to extend IRB oversight to research by unaffiliated investigators in which Elon University is not otherwise engaged.

All requests for Elon University to serve as the IRB of record for an unaffiliated investigator should be referred to the Institutional Official/Director of Sponsored Programs. This referral should include an "Unaffiliated Investigator Agreement" based on the Elon University approved template together with a recommendation from the IRB Chair. In most instances this agreement will apply to a single research project; less often, to a defined group of studies involving the unaffiliated investigator. The Institutional Official/Director of Sponsored Programs, in consultation with the IRB Chair will determine whether the University will agree to extend IRB oversight to the unaffiliated investigator. If the decision is that Elon University will provide IRB oversight for the unaffiliated investigator, the Institutional Official/Director of Sponsored Programs will be responsible for executing the "Unaffiliated Investigator Agreement" documenting this arrangement. Copies of this documentation will be returned to the unaffiliated investigator and kept on file in the Office of Sponsored Programs.

Agreements for deferral of IRB review from one FWA institution to another

On some occasions when two FWA institutions are engaged in the same research study, it is appropriate for one institution to provide IRB review and continuing oversight of that research. Circumstances

in which this arrangement might be considered would typically involve studies primarily based at one institution, with somewhat peripheral involvement by investigators at the other. In effect, this constitutes a deferral of the right of review by the institution with lesser involvement, which retains responsibility for ensuring compliance with all IRB requirements.

An “IRB Authorization Agreement” is the form of agreement executed between the institutions to document this delegation of IRB oversight. Elon University may be either the institution deferring to another institution or the institution to which the IRB review is delegated. All requests for such delegations should be referred to the Institutional Official/Director of Sponsored Programs. The Institutional Official/Director of Sponsored Programs, in consultation with the IRB Chair will determine whether the University will agree to the deferral. If the decision is to agree to the IRB delegation, the Institutional Official/Director of Sponsored Programs will be responsible for executing the Authorization Agreement form. Copies of this agreement will be filed with the IRB accepting responsibility for ongoing oversight and the IRB deferring.

IRB ORGANIZATION AND ADMINISTRATION

IRB Membership

Membership

- (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- (b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the

institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals **may not** vote with the IRB

IRB Membership from Faculty Handbook

- Director of Sponsored Programs, without vote
- Five members of the teaching faculty appointed by the Provost designee. ; one from Elon College and one from each of the schools of the University. Appointments to the Institutional Review Board occur in a four-year cycle. In the first year of the cycle, one member will be appointed from Elon College. In the second year of the cycle, one member will be appointed from the Martha and Spencer Love School of Business and one from the School of Communications. In the third year of the cycle, one member will be appointed from the Dr. Jo Watts Williams School of Education. In the final year of the cycle, one member will be appointed from the School of Health Sciences.
- Three members of the teaching faculty appointed by the Provost designee. ; one from the biomedical sciences (Biology, Exercise Science, School of Health Sciences), one from the Department of Psychology, and one from Elon College, the College of Arts and Sciences
- An additional member of the committee will be named by the Provost designee. from the non-institutional population.
- Invited non-members, without vote. If the committee reviews projects involving a category of vulnerable participants or involving issues requiring competence in special areas, it may invite one or more non-members to provide special expertise.
- The committee must always include at least two scientists and two non-scientists. (Any faculty who has had substantive training or experience in a scientific discipline or in a scientific method should be considered a scientist.)

- Committee members who have a conflict of interest regarding a specific project may not participate in the review of such a project.

Appointment of the chair and vice-chair

The Provost designee appoints the chair from among the full-time teaching faculty members of the committee. The vice-chair is selected from and by the sitting members of the IRB, and elected to one-year terms by the remaining members of the IRB via simple majority vote. There are no term limits.

Alternate members

HHS regulations at 45 CFR part 46 do not address the designation of alternate IRB/IEC members. However, for many years, the Office for Human Research Protections (OHRP) has permitted organizations submitting IRB registrations to OHRP to identify alternate members for primary members. When reviewing rosters that include alternate members OHRP assumes that, in general, with respect to the capacity in which the primary IRB member was intended to serve, each alternate IRB member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. The minutes of an IRB meeting should document the attendance of all primary and alternate IRB members who attended any part of the IRB meeting. If both a primary IRB member and his or her alternate(s) attend the same IRB meeting, OHRP assumes that the primary member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member. OHRP recommends that the reason for the substitution of the alternate IRB member also be documented in the minutes.

Non-voting members

The IRB Chair may, at his/her discretion, recruit non-voting members from among the academic or administrative staff of Elon University,

whose presence at the meetings of the IRB would aid the IRB in conducting its duties. Non-voting members are appointed to the IRB according to the same procedures that apply to voting members. These members may take part in all meetings of the IRB, participate in the discussions, and make recommendations, but they may not vote on the decisions. Non-voting members are not included in determining or establishing a quorum at the meetings. IRB meeting minutes reflect the presence of non-voting members.

Member conflict of interest

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Examples of such conflicts of interest could include: a member of the IRB who serves as an investigator on research under consideration by that IRB; or a member who holds a significant financial interest in a sponsor or product under study.

IRB Record Requirements

IRB Documentation

The IRB shall prepare and maintain adequate documentation of IRB activities listed below. Some of this documentation may be subject to public perusal under the North Carolina Open Records Act; however, the Institutional Official/Director of Sponsored Programs should be consulted prior to responding to any request for public access to IRB records.

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by investigators, reports of injuries to subjects, and statements of significant new findings provided to human subjects.
- Records of continuing review activities including any activity occurring after initial approval. These may include modifications, renewals, adverse and unanticipated event reports, and descriptions of amendments.
- Copies of all correspondence, including substantive email, between the IRB and the investigators.
- A roster of IRB members identified by name, department/school, and academic rank.
- Copies of the minutes of all convened IRB meetings.

Meeting minutes

IRB Meeting Minutes should be in sufficient detail to show the following:

Attendance at the meetings:

- date and time meeting starts and ends
- names of members present
- names of members absent
- names of investigators present

Actions taken by the IRB, including the basis for requiring changes in or disapproving research

Approval period

A written summary of controverted issues and their resolution

IRB findings and determinations

The following are required findings and determinations, and must be noted in the minutes with reference to the appropriate federal regulations:

Determination of the level of risk for human subjects in the research study (no citation required).

Justification for waiver or alteration of informed consent; [45 CFR 46.116(c) and (d)]

Justification for the waiver of the requirement for written documentation of consent; [45 CFR 46.117]

Justification for approval of research involving pregnant women, human fetuses and human in vitro fertilization; [45 CFR 46.204]

Justification for approval of research involving prisoners; [45 CFR 46.306]

Justification for approval of research involving children; [45 CFR 46.404-407] and

Special protections warranted in specific research projects for groups of subjects who 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.

IRB RESEARCH EVALUATIONS, PROCEDURES, CRITERIA AND ACTIONS

Determination if a project constitutes human subjects research subject to Elon University IRB review

The IRB has been charged with the responsibility for reviewing and monitoring human subjects research conducted under the aegis of Elon University. Therefore, the first question with respect to IRB review of a project is a determination of whether the project fits the definition of human subjects research. In light of the mission to protect human subjects, the IRB should err on the side of conducting an IRB review when the determination is not clear. The definitions of “research” and “human subjects” for this purpose are derived from federal research regulations. The criteria for “under the aegis of Elon University” have been determined by the campus and may extend beyond what is required by federal regulations.

Is it research?

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program that is considered research for other purposes.” (45 CFR 46.102(d)) As described in the Belmont Report, “...the term 'research' designates an activity designed to test an hypothesis [and] permit conclusions to be drawn... ” Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

Thus, a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge. Research can encompass a wide variety of activities, including: experiments, observational studies, surveys, tests, and recordings.

“Research” generally does **not** include such operational activities as: defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring in public health); studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, or marketing studies. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is clear advance intent to contribute to generalizable knowledge with a scientific protocol. Intent to publish is one possible indication of contributing to generalizable knowledge.

Does it involve human subjects?

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)) Identifiable private information “includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).” (45 CFR 46.102(f)) Although there is no definition of “identifiable” information in the Common Rule, “identifiable” means that the information contains one or more data elements that can be combined with other reasonably available information to identify an individual.

Intervention includes physical procedures, manipulations of the subject or manipulations of the subject's environment for research purposes. Interaction includes communication between the investigator and the subject. This includes face-to-face, mail and phone interaction as well as any other mode of communication. Private information includes observation of behavior when an individual can reasonably expect that no observation is taking place, or information for specific purposes (such as a health care record) that individuals can reasonably expect will not be made public. Thus, approaches involving only existing records or human specimens or observations may still constitute human subjects research requiring IRB approval. The IRB will make this determination. Simple observational studies of public behavior (including television and internet chat rooms) do not involve human subjects as defined, because there is no intervention or interaction and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individual identity is not identifiable. Examples include programmatic data such as service statistics, school attendance data, crime statistics, or election returns. Studies based on data that are individually identifiable data but also are publicly available may not constitute human subjects research [45 CFR 46.101(b)(4)]; however, the term “publicly available” is intended to refer to record sets that are truly readily available to the broad public, such as death certificates.

Is it conducted under the aegis of Elon University?

In the interests of protecting human subjects participating in research that is either under university aegis or would appear to be under university control, human subjects research that meets any of the following criteria will be subject to Elon University IRB review and monitoring:

- The research is sponsored by Elon University.

- The research is conducted or directed by any employee or trainee of the university in connection with his or her Elon University responsibilities.
- The research involves access to any property or facility of Elon University other than access to open spaces on the University campus that are readily available to the public at large.
- The research involves the use of non-public information in the custody of Elon University to identify or contact human research subjects or prospective subjects.

INSTRUCTIONS TO INVESTIGATORS

To facilitate appropriate and ethical research practices, all faculty and staff involved in human subjects research must complete the Collaborative Institutional Training Initiative (CITI) modules located at www.citigroup.org. Once all modules have been completed, a certificate of completion should be downloaded and then uploaded into IRB MENTOR.

All IRB proposals are submitted electronically using IRB MENTOR located at <https://www.axiommentor.com> or www.elon.edu/irb.

Body of proposal

A proposal as outlined in IRB MENTOR located at www.elon.edu/irb under Application Materials should be submitted to the IRB and shall contain the following elements:

Statement of the research problem

Description of the study population, sampling methodology, and specific criteria for selection of the participants

Detailed description of the research design

Your assessment of the risk and risk management (how risk is to be minimized)

Potential benefits to human participants (even if there is/are none)

Informed consent procedure

How investigator intends to obtain informed consent

Copy of consent form if written

Describe procedures for insuring the confidentiality of data and anonymity of participants

Length of time that records will be kept, where kept, by whom the records will be kept, and time and methods of destroying the data (can be included in confidentiality section)

Feedback sheet or explanation of procedures for participant feedback (how will you provide individual and/or study results back to the subjects)

Other documentation that the researcher feels would help the IRB better evaluate the proposal.

Statement of compliance. The following statement of compliance must appear on all proposals submitted for review:

To the best of my knowledge, the plan of conduct for this research conforms to the policies and procedures for the use of human participants at Elon University.

Note: Students cannot serve as the primary Principle Investigator

Informed Consent

A copy of the letter/script that will be used to inform participants of the nature of the research and the informed consent template the subjects will sign must be attached to the application. Informed consent shall be obtained from all persons participating as subjects in a research study. Most of the time, this will be obtained through the use of a written consent form. The form should be titled "Consent Form" NOT "Informed Consent". The form is a means of achieving informed consent. (One is the action of obtaining the other.)

Procedures: informed consent shall be obtained through any of the following methods.

1. Written consent document embodying the elements of informed consent.
2. 'Short form' written document which states that the elements of informed consent have been presented orally to the participant.
(Note: Participants have to sign the forms used in #1 and 2 above.)
3. An alternative informed consent procedure provided that the proposal adequately documents a compelling reason for such deviation. For example, certain investigations of large numbers of people engaging in naturally occurring, public behavior might preclude obtaining prior informed consent from all persons present. Alternative informed consent procedures including waivers of informed consent are specified in 45 CFR 46.116.

To understand what constitutes Informed Consent, see **Informed Consent** on page 25.

Determination of type of review

Levels of IRB review: exempted, expedited, full

Determination of review type

In order to determine the type of review necessary, the chair or his/her designee screens the entire application and makes determinations as to whether the project constitutes human subjects research and, if so, the type of review required. All applications are assigned to be reviewed at a convened meeting unless (1) they meet the criteria for expedited review or, (2) they meet the criteria for exemption, as explained below.

◆Exempted

Reviewed by IRB Chair and/or chair designee.

Possible outcomes

Exemption certified

Certified contingent upon specific modification/clarification

Referred for expedited or full IRB review

◆Expedited

Reviewed by IRB Chair (or chair designee) and at least one other members

Possible outcomes

Approved

Approved contingent upon specific modification/clarification

Referred for full IRB review

◆Full

Reviewed by full IRB

Possible outcomes

Unconditional approval (2/3 majority)

Conditional approval (2/3 majority)

Rejection (less than 2/3 majority approval based on noncompliance with policies or guidelines)

Tabled (requires significant amount of additional information)

Review by Convened IRB

Scheduling of meetings

The IRB sets its own meeting schedule, but, at a minimum, the IRB will meet at least quarterly.

Scheduled meetings may be canceled by the chair due to a) insufficient number of applications requiring review at a convened meeting, b) inability to secure a quorum for attendance, or c) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate.

The Chair will notify members of meetings.

Open meetings

The meetings of the Elon University IRBs are not subject to North Carolina “Open Meeting” laws because the Elon University IRB does not constitute a “public body” within the meaning of the Open Meeting laws.

Recusal of members with a conflict of interest

When an IRB member has a conflict of interest that requires him/her to recuse himself/herself from discussion of and voting on a particular protocol, that member should leave the meeting room for the duration of the discussion and vote, except as requested to address questions raised by other members. If the member’s recusal causes a loss of quorum, the vote should be postponed to another meeting. For this reason, IRB members should notify the chair prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure adequate members in attendance.

Attendance by investigators

Investigators may be invited to attend the portion of the IRB meeting at which their protocol is discussed. The investigator may answer questions raised by the IRB. The investigator should not be present for the final deliberation and vote on his or her protocol.

IRB Actions following review by the convened IRB

Approval of research

In the case of an approval with no changes, the research may proceed once the PI receives electronic documentation of IRB approval. Unless otherwise specified, the approval period for research approved without changes is one year from the date at which approval was granted.

Stipulated minor changes or clarifications required prior to approval

The IRB may determine that a study may be approved with stipulated minor changes or clarifications. Minor changes are those changes that do not involve potential for increased risk or decreased benefit to the human subjects. Some examples of minor changes are: changes in contact information or identity of non-key research personnel,

changes in the study title, and changes in the consent form that reflect the minor changes listed earlier.

For minor changes, the IRB Chair or a voting IRB member(s) designated by the Chair must ensure that the PI makes the appropriate changes to the research protocol. The research may proceed after the required changes are verified and the designated reviewer approves the protocol.

Unless otherwise specified, the approval period for research for which minor changes were stipulated is one year from the date at which protocol approval was granted.

Deferral

The term “deferral” is used to describe the situation in which an IRB determines that substantive changes must be made before approval may be granted. The PI’s response, including any amended materials, must be reviewed by the IRB and approved before the research may proceed.

Subject to IRB discretion, a proposal may be withdrawn if the PI does not respond to a deferral within a reasonable amount of time. If the investigator wishes to conduct a study that has been withdrawn, he/she must submit a new application, incorporating comments from the prior IRB review.

Disapproval

If the IRB determines that the research cannot be conducted at Elon University or by employees or agents of the University or otherwise under the auspices of the University, the project, as proposed, is disapproved and may not go forward.

Disapproval usually indicates that a proposal requires major changes not likely to be feasible without a complete reassessment of the protocol by the investigator and/or sponsor.

Suspension and termination of research study by IRB

The IRB Chair or the convened IRB may suspend a study at any time if it is determined that the study requires further review or evaluation. This determination may be made due to an adverse event, noncompliance or other danger to human subjects. Once a study has been suspended, the convened IRB should review the study and either require changes to the protocol, allow the study to restart, or terminate the study.

Though the IRB Chair may suspend the study, only the convened IRB can make the decision to terminate a study.

When a study is suspended or terminated, the IRB must notify the Institutional Official/ Director of Sponsored Programs. The Institutional Official/Director of Sponsored Programs, in consultation with the Senior Associate Provost for Faculty Affairs or appointee, is responsible for all required reports to federal agencies.

Notification of IRB actions

The IRB sends notification of actions taken to the PI. If revisions to new and continuing human subjects applications are required, correspondence is sent to the investigator detailing requests for revisions, clarification, or additional information as well as information regarding continuing review.

Appeal of IRB decisions

Investigators may appeal IRB requirements for specific changes in the protocol and/or consent document(s). The investigator may make such an appeal in writing to the IRB. At the IRB's discretion, the PI may be invited to the IRB meeting at which his or her appeal will be considered.

If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person and/or in writing. An appeal of a disapproved research project must be reviewed at a convened meeting.

Other university officials may, in certain cases, decide that a research study may not be conducted despite IRB approval. One example could be a circumstance in which a certain project or area of research is deemed to be inappropriate or under funded. In the case of a decision by the IRB to disapprove, suspend, or terminate a project, only the Senior Associate Provost for Faculty Affairs may request that the IRB reevaluate a project because of procedural questions related to the IRB review. However, the IRB decision to disapprove, suspend, or terminate a project may not be reversed by the any officer or agency of Elon University, state government or federal government.

Modifications to previously approved projects

A modification is a change in an approved research protocol. IRB review and approval is required before investigators can modify research protocols,

except when necessary to eliminate apparent immediate hazards to the subjects. Any proposed change to a previously approved project must be submitted as an amendment to that project and may be reviewed by the expedited review procedure or by the convened IRB, depending on the chair's assessment of associated risk. Any modification involving increase in risk must be reviewed by the convened IRB.

Continuing Review for Renewal

Continuing review

The IRB shall conduct a continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. The IRB shall have authority to observe or have a third party observe the consent process and the research. IRB continuing review responsibilities include reviewing reports of any unanticipated problems that involve risk to research subjects or others. This information may be gathered through investigator or sponsor reports, by third party observations, or by IRB inquiries.

Reminders

When a research project is due for continuing review, an electronic reminder is sent for the IRB to the PI via IRB MENTOR approximately 14 days before the date of continuing review. If an application for renewal is not received from the PI by the expiration date, then IRB MENTOR will send an expiration notice to the PI. Copies of all reminders and expiration notices are kept on file.

Lapsed studies

A lapsed study is one for which the approval period has expired prior to the renewal of approval by the IRB. If the PI fails to submit the materials for continuing review within one month following the expiration date, then the lapsed study will be classified as inactive.

Once a study has lapsed:

- All study-related measures must immediately cease except those necessary for welfare of the human subjects;
- If the PI desires to continue a study that has lapsed for more than one month, then the PI must submit a new application for re-review by the IRB, and must wait for IRB approval before resuming research under the protocol.

Study Closure or Completion

Research studies can be deemed completed for a number of reasons, each requiring a different degree of IRB involvement. In some cases, the IRB must perform in a supervisory or disciplinary fashion and require that a study be ended. More often, however, the investigator or sponsor will close the study and the IRBs role will be more passive, receiving and archiving study completion documents via MENTOR.

Voluntary completion by investigators

By submitting a notice of completion, the researcher confirms that the study is finished and that researchers have no further interaction with subjects or their data. Once the IRB receives and accepts the study completion form, the researcher is no longer required to submit for continuing review for renewal. If the investigator wishes to enroll new subjects for the study, or otherwise engage human subjects in research, he/she must reactivate the protocol with the IRB. Therefore, an investigator should only close a study when he/she is no longer enrolling new subjects, using research interventions on existing subjects, collecting data (including follow-up data), or performing any other tasks that were identified as part of the approved study. A study will not invariably be considered completed when it is closed to accrual, as research-related procedures may still be continuing. *In special circumstances*, the IRB, in consultation with the PI, may consider closing a study when active data analysis and publication pursuant to the approved study has ceased, even if the investigator retains records that may identify individual subjects. In this circumstance, the researcher must have adequate protections in place to protect confidentiality and IRB approval. This is especially pertinent in biomedical research as new information may become available after the study is closed and subjects would need to be contacted. Additional research projects using data acquired in the approved study may constitute new human subjects research studies subject to separate IRB review.

Termination of a study by the IRB

In cases of Serious Adverse Events (SAEs) or Unanticipated Problems (UPs), cases of researcher noncompliance, or in cases of protocol violations, the IRB may decide to suspend a study to ensure subject safety. Upon investigation of the problem prompting suspension of the study, the convened IRB may decide that a study should be terminated. Following the vote of the IRB to terminate a study and the evaluation of any appeals made by the PI, the study will be classified as closed. Though the chair may suspend a study, pending IRB review, only the convened IRB may vote to terminate a study.

Expiration of approval period

Once the approval period for a given study has expired prior to the renewal of approval by the IRB, it is considered a lapsed study and all research-related procedures must halt, except where doing so would jeopardize the welfare of the human subjects. If the PI fails to submit the materials for continuing review within one month following the expiration date, then the lapsed study will be classified as inactive. If the PI submits the materials for continuing review within one month following the expiration date, the IRB will conduct continuing review and reactivate the protocol. This reactivation establishes a new approval period that is not retroactive to the prior date of expiration. If the PI desires to continue a study that has lapsed for more than one month, then the PI must submit a new application for re-review by the IRB, and must wait for IRB approval before resuming research under the protocol.

Note: If you are writing a paper or manuscript using data collected from the study and *no identifiers* are attached to the data an updated IRB approval is not required.

Adverse Events and Unanticipated Problems in research

Adverse events and unanticipated problems occurring at sites for which the Elon University IRB has direct oversight responsibility.

The PI is required to report via IRB Mentor and provide a written report to the IRB chair, which should contain enough information for the IRB to judge whether or not the event raises new questions about risks to participants or the research design. This report is reviewed by one or more experienced IRB members and a decision made as to whether or not the report should be presented and discussed at a convened meeting. The results of the review at the convened meeting should be forwarded to the Institutional Official who will also notify the Senior Associate Provost for Faculty Affairs.

Noncompliance of researchers

The IRB Chair reviews allegations of noncompliance. The chair makes a determination as to whether the alleged practices appear to (1) cause injury or any other unanticipated problems involving risks to subjects or others, or (2) constitute serious or continuing noncompliance with IRB determinations or federal regulations. In such cases, the chair shall suspend the study procedures pending a timely investigation and institutional review, and shall immediately notify the Institutional Official, Senior Associate Provost for Faculty Affairs, relevant dean, and department chair or director.

Investigations by the IRB focus on the protection of study subjects. In cases that involve allegations of scientific misconduct, the chair shall contact the Institutional Official for further action. Inquiries or investigations into scientific misconduct do not preclude IRB review and actions.

Information regarding noncompliance in human subjects studies may come to the attention of the IRB through several pathways. These include information contained in new applications, continuing reviews, adverse event reports, and reports from collaborators, employees, or subjects. When made aware of a potential problem, the IRB compiles file information and presents concerns to the Institutional Official and the Senior Associate Provost for Faculty Affairs.

IRB Evaluation Criteria

Risk

“Minimal risk” (for human subjects other than prisoners) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]

Risk should be considered in terms of both severity and probability, and should not be understood to include only physical risk, though such risks are important to consider. In reviewing a study, the IRB should also evaluate emotional and psychological risks, potential insurability risks, as well as risks to professional or community standing. For example, in conducting a drug use survey, respondents could face severe penalties in the workplace or in their community if confidentiality were breached even though the survey does not present a physical or psychological risk.

Risks to subjects must be minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by relying on procedures already being performed on the subjects for diagnostic or treatment purposes.

Risks to subjects must be 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 or procedures 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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

The IRB should be guided by the principles of The Belmont Report in assessing risks to research subjects.

Benefit, including assessment of scientific/scholarly merit

According to federal regulations, risks to subjects should be minimized by using procedures which are consistent with sound research design, and which do not, unnecessarily, expose subjects to risk, see 45 CFR 46.111(a). In accordance with these regulations, the IRB should consider whether or not (a) the study is designed so that the risks to subjects are minimized and (b) the potential benefits of the research justify the potential risks. It is these two directives that establish the obligation of the IRB to evaluate the study design and overall scientific/scholarly quality of each study.

Such an evaluation entails a peer-review of the research proposal and its likelihood of producing results that are both unique and significant in a given field of study. In the absence of significant risk, any concerns raised during the scientific and scholarly review of the proposed research will be conveyed to the investigator and documented. However, if revising the study design will meaningfully decrease the risk to subjects, the proposal should be revised and resubmitted for IRB approval.

Selection of subjects

In accordance with Belmont principles, both the burdens and benefits of research should be distributed equitably. Selection of subjects is one important means of ensuring this equity. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Review and documentation of informed consent

Unless specifically waived by the IRB, informed consent must be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

Safety monitoring

When appropriate, the research plan should make adequate provision for monitoring the data collected to ensure the safety of subjects.

Privacy of subjects and confidentiality of data

There should be adequate administrative, procedural and technical provisions to protect the privacy of subjects and to maintain the confidentiality of data. The assessment of adequacy should include consideration of the sensitivity of the data. Although there are some specific state and federal regulations governing privacy of some specific types of records (e.g. federal HIPAA, FERPA, state health care records privacy laws), privacy and confidentiality protections for human subjects do not derive merely from governmental regulation. They are also integral to the ethical principle of “respect for persons” as enunciated in The Belmont Report.

HIPAA

If human subjects research creates or uses individually identifiable health information that is “Protected Health Information” as defined by the Health Insurance Portability and Accountability Act (“HIPAA”), the research use of that protected health information may require additional IRB review and documentation.

FERPA

The Family Educational Rights and Privacy Act (FERPA) protects information in student education records. The term “education records” includes all information about a student that is recorded and retained by an educational institution, although the federal regulations do contain a number of exceptions. FERPA provides that information from a student’s education records may not be released to others without the student’s or parent’s prior written consent. If the student is over 18 or enrolled in college, the student must give the consent. If the student is under 18 and not enrolled in college, the consent must come from his or her parent. FERPA only applies to educational records and not to the process of informed consent related to the research itself.

In the research context, information from educational records may be released, without the student's or parent's consent, to organizations conducting studies for, or on behalf of, educational agencies or institutions, but only if the study is (1) for developing, validating, or administering [academic] predictive tests, (2) to administer student aid programs, or (3) to improve instruction. In order to qualify for this exception, the study must be conducted in such a way that parents and students may not be personally identified by anyone other than those working on the study and the information must be destroyed when it is no longer needed for the study's purposes.

Questions about FERPA and permissible uses of education records should be directed to the Registrar's Office.

Limits on Confidentiality: Reporting Requirements

A principal investigator or other researcher may encounter in a research participant a dependency, abuse or neglect situation or a specific disease condition that is required to be reported to a state or local official. Such reporting requirements should be disclosed to subjects in the informed consent process. Generally, these reporting requirements are related to whether the participant is within a protected category—based on age or mental or physical condition—or if the condition may threaten the public health.

All subpoenas for research data should be referred immediately to the Institutional Official who in turn will refer to the VP for Business, Finance, and Technology for assistance. In the event of such a subpoena, the University may confer with the state Attorney General's office about contesting the subpoena, but cannot guarantee that the subpoena will be contested successfully or at all.

The Shelby Amendment

The Shelby Amendment (Public Law 105-277 signed October 21, 1998) provides that if federally supported research results are used by the federal government in developing "an agency action that has the force and effect of law" then the federal agency may be required to obtain the research data and make it available if requested under the Freedom of Information Act (FOIA, 5 U.S.C. 552(a)(4)(A)). The extent and format of research data that must be shared is not specified in the Shelby Amendment. In some instances it has been narrowly interpreted to be limited to published data specifically cited in the promulgation of federal regulations. Seek assistance from the Institutional Official regarding any request for research data under the Shelby Amendment.

Recruitment and payment

The IRB must consider the appropriateness of the methods for identifying, recruiting and compensating subjects and potential research subjects. Compensation for subjects should be reasonable and not deemed as exploitative in nature.

Compensation for injury

Elon University will negotiate liability coverage with the sponsor of the research study on a case-by-case basis. The University itself does not provide such coverage. The IRB shall require that subjects are provided with accurate information about the availability of compensation and/or treatment for injury that is a result of participation in the research study.

Informed Consent

Informed consent is a process rather than merely a document. Any individual invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. The informed consent process should be designed to provide potential subjects with readily understandable information in an amount and timing appropriate to the level of risk in participating.

The subject's consent must follow and not precede receipt of this information unless the IRB approves a waiver or alteration of informed consent (as in some behavioral research that would be compromised by full disclosure in advance). Consent must be obtained from each subject who is legally, mentally, and physically able to provide it unless waived by the IRB. Consent should be in writing unless the IRB finds that written documentation of informed consent may be waived. Consent forms and other informational documents should be written in simple language so as to be easily understood by persons with no technical background in the field.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The standard expectation is that all subjects will sign a document containing all the elements of informed consent, as specified in the federal regulations and noted below. Some or all of the elements of

consent, including signatures, may be waived under certain circumstances.

Elements of Informed Consent, outlined at 45 CFR 46.116(b).

Unless the IRB approves exceptions, the following information must be provided to the subject when seeking informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may be reasonably expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained.
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - A statement that identifies might be removed from the identifiable private information or

identifiable biospecimens could be sued for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

-A statement that the subject's information or bio specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of Informed Consent

For some studies, one or more of the following elements or information may be appropriate and required by the IRB:

-A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

-Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

-Any additional costs to the subject that may result from participation in the research;

-The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (particularly when potentially therapeutic experimental interventions are being administered and unscheduled cessation of the intervention may pose health risks to subjects);

-A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

-The approximate number of subjects involved in the study.

Exceptions to informed consent requirements

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

Public benefit of service programs; (45 CFR 46.116(c)(1)(i))
 procedures for obtaining benefits or services under those programs; (45 CFR 46.116(c)(1)(ii))
 possible changes in or alternatives to those programs or procedures; or (45 CFR 46.116(c)(1)(iii))
 possible changes in methods or levels of payment for benefits or services under those programs; and (45 CFR 46.116(c)(1)(iv))
 The research could not practicably be carried out without the waiver or alteration. (45 CFR 46.116(c)(2))

Other exceptions to informed consent requirements 45 CFR 46.116(d)

An IRB may approve a consent procedure, that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Assent by children

Except under specific circumstances, assent to participate in a study must be obtained from minors (i.e., in North Carolina, subjects aged 17 and under) who are capable of providing assent. The IRB shall determine that adequate provisions are made for soliciting the assent of the children (this includes providing age specific language to the prospective subjects), when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child individually, as the IRB deems appropriate. If the IRB determines that the capability of

some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children (such as in a study with therapeutic potential), and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116.

Parental permission

Unless otherwise provided by state law, or unless this requirement is waived by the IRB pursuant to 45 CFR 46.408(c), the permission of the parent or legal guardian is required in order for minors to participate in research.

Where research is covered by 45 CFR 46.406 and 46.407, permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Per 45 CFR 46.408(c), in addition to the normal waiver requirements, the IRB may waive the parental permission requirement if it determines that a research protocol designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. This waiver might apply to studies involving neglected or abused children, or older adolescents presenting in medical situations wherein a parental consent requirement might deter the child from seeking needed care (e.g., seeking care at an STD clinic). If parental permission is waived, the IRB must be sure that an appropriate mechanism for protecting the children is substituted. The choice of an appropriate mechanism would depend on the nature and purpose of activities in the protocol, the risk and benefit to the subject, and their age, maturity, status, and condition.

Surrogate consent for subjects who are decisionally impaired

There is an important distinction between the legal meaning of the term “incompetent” and our broader use of the term “decisionally impaired.”

- “Incompetence” is a finding of a court of law that results in the appointment of a legally authorized representative for the individual judged incompetent by the court.
- Decisionally impaired persons are those who have a diminished capacity for autonomous decision making due to a psychiatric, organic, developmental or other disorder that affects cognitive or emotional functions. Some adult individuals who appear to be decisionally impaired may not have been declared legally incompetent. For these individuals, there may not be a representative authorized under North Carolina state law to consent to the individual’s participation in research unless the individual had previously, while of sound mind, executed a power of attorney broad enough to include consent for the individual’s research participation.
- Seek the guidance of University counsel if there are questions about legal authorization for surrogate consent in specific situations.

Obtaining consent from non-English speaking subjects

Researchers should take great care when they obtain informed consent from individuals who do not speak English or whose understanding of the language is limited. Researchers should be fluent in the subject’s language or an interpreter should be available during the consent process and throughout the subject’s participation as needed. Consent forms should be prepared in the language understandable to potential subjects.

Special Topics: Research design and context

Some of the research types described below may be eligible for exemption, but the IRB should be cognizant of the challenges and issues inherent in these types of research and should remember that all human subject protection guidelines apply to such research. Therefore, the IRB must be diligent in performing its duties even in evaluating these protocols.

Research in educational settings

Research conducted in established or commonly accepted educational settings that involve normal educational practices as well as research involving the use of educational tests, survey procedures, interview procedures, or the observation of public behavior is eligible for exemption from the Common Rule. However, such research sometimes raises special concerns to which the IRB must be especially attentive. One example of such a concern is the “two-hat” problem in which a researcher

is also an instructor with potential coercive power or undue influence over students who are also potential research subjects. (See “Strategies for decreasing potential for coercion of students” below.) Students may feel pressured to participate in such projects because they are worried about the impact of not participating on their grade, wish to help out an instructor who they like, and so forth. Such a situation does not automatically disqualify a project from exemption, but the IRB should be cognizant of the problems such an arrangement might create. Furthermore, even if the research is exempt, the investigator has an ethical obligation to ensure that students’ rights and welfare are respected.

Research in Local Educational Agencies

If you are conducting human subject’s research in a local school system e.g. Alamance Burlington, Guilford, Orange and so forth, review of the systems policies governing human subject’s research should be investigated and followed. Documentation providing the necessary approval should be uploaded with your IRB application at time of submission.

Strategies for decreasing potential for coercion of students

- Use subjects not currently enrolled in your class.
- Have someone, unaffiliated with the class or the data analyses, collect the data so that whether or not a student participated will be unknown to the instructor.
- Make it clear to students that data will not be analyzed until after the semester is completed and grades have been submitted.
- Offer an alternative assignment for those students who do not wish to participate in the study (this is required if students receive either class credit or extra credit for their participation).
- Contact Chair of IRB to discuss alternate approaches or models that colleagues are currently using in their classes.

In keeping with University policy, the instructor serves as the PI on every student project, with the full administrative and fiscal responsibility that normally accompanies that status.

Pilot studies

Pilot studies may represent complex research even though they may be conducted as preludes to more expansive studies. Therefore, pilot studies must be reviewed by the IRB.

Oral histories as a type of humanities or social science research

The goals of oral historians, represented by standard practice in the discipline, may at times seem to be at variance with the principles underlying the protection of human subjects. Oral historians generally wish to create documents that allow individuals to be identified with their actions and accomplishments. They may wish to archive individually identifiable records indefinitely and make those identifiable records available to other historians in the future. As a result, the IRB should approach protocols involving oral history with special attention to four distinct issues.

- **Description of the protocol.** As in most qualitative research, the historian may have only a general outline of the topics to be covered in a wide-ranging interview, and the list of questions to be asked may grow or shrink as circumstances dictate. The historian may not know, in advance of an interview, the level of knowledge the subject possesses about the events of interest. The IRB should focus primarily on the purposes of the interview, the more general types of information likely to be elicited, the risks to subjects who may disclose certain types of information, and the roles played by the various respondents in the events being studied.
- **Consent.** A substantial number of oral history protocols may request a waiver of written documentation of informed consent. This is especially true in cases where the events described were, or are, controversial, involve illegal behavior, or involve events that may portray powerful or influential members of a society in a negative light.
- **Use of pseudonyms by respondents to identify themselves or other actors.** Oral historians generally do not wish to have subjects use pseudonyms, or to have them use pseudonyms to describe other actors in the events being described, but may agree to such devices under circumstances that would otherwise place individuals at risk or where the protection of identities is necessary in order to obtain the data. Related to this issue is the level of quotation allowed in research reports. Protection of subjects may suggest allowing full attribution to the named source, attribution only to a

pseudonym or anonymous source, or quotation only by “role” in the events portrayed.

- **Disposition of audio or videotapes.** There are generally four options for the disposition of oral history tapes: permanently archived (in a library or similar collection); retained indefinitely by the scholar; returned to the respondent; or destroyed by a date fixed in advance.

Qualitative research

Qualitative studies, which may involve such methods as participant observation, case studies, unstructured interviews, focus groups and various other descriptive techniques, raise special issues for the IRB. Qualitative research investigators usually have a well-articulated plan for their research, often have one or more reasonably specific hypotheses to be tested, and can describe in general terms the techniques they intend to employ. However, they may undertake research projects with the full expectation that techniques will be developed in the course of research, used on the basis of opportunity, and modified as events and experiences suggest are necessary for the success of the project. As a result, qualitative research investigators may present a research protocol that doesn't fit the usual model contemplated by federal human subject regulations for research, if those regulations are narrowly interpreted.

Reviewing qualitative research projects requires flexibility on the part of the IRB and is facilitated by a willingness to waive some of the elements of informed consent and approve methods of consent that are culturally appropriate. If the study protocol approved by the IRB is intended to encompass development of one or more research instruments, it may also be necessary to give relatively wide professional latitude to scientists in the application of approved methods so that an investigator does not need to come back to the IRB repeatedly for approval of changes that would be considered normal and routine under the circumstances. However, the IRB should make clear to the investigator that significant changes, including all changes that could increase risk for the human subjects (for example, the addition of a new topic in a survey), must be approved in advance by the IRB. Finally, the IRB may need to consider an informed consent process that is multi-layered and takes place over time as the research develops and the investigator is better able to articulate both areas of further interest and the methods being employed for studying them. Whatever flexibility the IRB decides is appropriate in the

specific research context, that determination must include adequate protection for the welfare and rights of the human subjects in that specific context.

Survey research

The IRB should pay particular attention to the following issues in survey research:

- Possibilities of undue influence in administration of the survey;
- Possibility of deductive disclosure based on demographic information garnered from subjects (subject confidentiality and privacy must be protected);
- The setting of the survey and the issues raised by such a setting;
- The mode of obtaining consent, especially when implied consent is to be used. Surveys may often involve a waiver of written consent and attention should be paid to the oral presentation of required elements of consent (e.g., review of phone script for telephone surveys).

Research using existing data and materials

Each separate human subjects research study requires IRB review and approval of the specific proposed study, regardless of whether the data set or research materials have been previously compiled.

Research involving the use of data meeting **any one** of the conditions below is not considered human subjects research and does not need to be reviewed by the IRB:

- Data on decedents;
- Data that have been stripped of all identifiers that could link that data to living persons
- Data with extant identifiers that Elon University, its employees, research collaborators, and agents are contractually forbidden from accessing.

Under federal regulations, research utilizing only the types of data described above is not considered human subjects research and need not be reviewed by the IRB. Nevertheless, in certain cases, the IRB may be called upon to review projects utilizing such data.

Research involving the use of data meeting one of the conditions below is eligible for IRB exemption from continuing review:

- if these sources are publicly available; (45 CFR 46.101(b)(4))
- if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (45 CFR 46.101(b)(4))

When existing data sets contain identifiable private information about living individuals and these sets are not publicly available, IRB review and approval is required before research can proceed. The IRB must determine whether the information can be used without obtaining additional informed consent. As such, the IRB should first examine the conditions of informed consent under which the data were originally obtained. It may be that the proposed research is permissible under the conditions under which the data were obtained, including contracts, informed consent or a HIPAA authorization.

If this is not the case, the IRB should consider whether it is appropriate to waive the informed consent requirements in accordance with 45 CFR 46.116(d). In many cases, a waiver of consent will be appropriate. In other cases, the IRB may determine that the research can only proceed if the investigator obtains data with codes and identifiers removed in such a way as to preclude the investigator or the source maintaining the data set from establishing subjects' identities. If the proposed data set includes protected health information (PHI) the IRB must determine whether the original HIPAA authorization will cover the use of the data, or whether the IRB can waive authorization.

Prospective studies using materials (data, documents, records, or specimens) that will be collected for some purpose unrelated to the research do not qualify for exemption. The IRB may use expedited procedures to review research that proposes to use materials (data, documents, records, or specimens) that will be collected in the future for non-research purposes.

The IRB review should include review of the terms and conditions under which the data or materials were originally obtained and released to the investigator. The purpose of this review is to make sure that the proposed new use is not

incongruent with original purpose and permissions or approvals.

Review involving data from voice, video, digital or image recordings

If researchers wish to utilize data from voice, video, digital or image recordings, they must take a variety of special precautions. First, the researcher must obtain appropriate permissions from subjects who will not have their anonymity protected due to the very nature of the data being collected. The information or fact sheet and/or informed consent document must explain the intended use of the voice, video or image data, the provisions being taken for the storage the data, as well as the means and timeline planned for the destruction of this data. Because of these unique constraints, researchers must take great care in authoring protocols in which the use of voice, video and image data are planned.

Certain studies involve the collection of voice, video and image data for the purpose of creating an archive or registry that will preserve the data indefinitely. In such cases, researchers will not make provisions for the destruction of data, and they should take care to inform participants of the archival nature of the data gathering performed in such a study.

Photo Voice

Some researchers use a method of qualitative data collection in which participants take photographs of some aspect(s) of their lives, environment, community, etc. The photographs are then used as a basis for group discussions and to elicit important qualitative information about the photographers' attitudes, beliefs, etc. The degree of risk to subjects in such research depends, in part, on what is photographed. For example, this process may pose the risk of self-incrimination to subjects who photograph themselves taking part in certain activities.

From the perspective of the IRB, the "human subjects" in the research are the research participants who are taking the photographs and then presenting their interpretations in group or other data gathering sessions. If the photographers are minors, then written parental consent for their participation in the research is required, along with assent of the minor participant.

Although the individuals whose photos are taken are not the subjects of the research, there may be legal requirements for obtaining permission for using their photographs. If the photographers take photos of other people, then permission to use the photo should be obtained. If the person being photographed is a minor, then permission to take the photo must be obtained from the child's parent or guardian. Those being photographed must be informed about how their photo will be used, and whether they will have the opportunity to view the photo before making a final decision about its use. If the photographs will be publicly displayed, such as at a professional meeting or community gathering, or used in manuals or brochures or other publications, then written consent to take and display the photograph publicly is required. Researchers must have a method to link pictures with the signed permission forms.

Research involving deception or withholding of information

Some research designs may require the withholding of information from human subjects. Research involving deception or withholding of information must be reviewed by the IRB with common sense and sensitivity. The withholding of information by researchers is different from the practice of deception, in which researchers provide false or misleading information to subjects. Studies involving deception need to be carefully reviewed by the IRB to ensure that the deception is justified through an examination of the risks and benefits of that deception. Furthermore, the IRB should ensure that, when appropriate, the subjects will be debriefed. Before approving a study that involves deception, the IRB should determine that the subject population is suitable and that the deceit involved in the study would not alter a subject's assessment of risk to himself/herself if he/she was aware of the deception at the time he/she agreed to participate. Deception can only be permitted where the IRB documents that a waiver of the informed consent requirements is justified according to 45 CFR 46.116(d). The IRB must document that the following criteria have been satisfied:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Internet research

The vast amount of social and behavioral information potentially available on the Internet has made it an important tool for researchers wishing to study the dynamics of human interactions and their consequences in this virtual medium. Researchers can potentially collect data from widely dispersed populations at relatively low cost and in less time than similar efforts in the physical world. However, the problem of subject identification and verification can severely limit this potential. For example, researchers could unknowingly involve protected populations or decisionally impaired subjects in the research study. There are also online data integrity issues.

Internet research protocols may involve research on the topic of the internet, research collecting data over the internet, observations of human behaviors on the internet, or some combination of these aspects. In evaluating studies utilizing the internet as a research tool, the IRB should ensure that investigators have a plan for:

- Obtaining and verifying informed consent if required; and,
- Maintaining the promised degree of privacy of subjects and confidentiality of information through the use of appropriate security measures.
- Appropriate online data collection method and data validation checks

Self-experimentation

Generally, researchers should not enroll themselves as subjects in a study that they are supervising. Such a practice presents obvious conflict of interest issues and a variety of other ethical and practical issues.

Special Topics: International Research

IRB review of research studies that involve human subjects in other countries must include appropriate expertise for evaluation of the study in the context of the specific international setting(s) and study population(s).

In addition to the usual requirements for human subjects research, some issues particularly vital for IRB review for protection of human subjects in international populations are noted below. The questions listed below should

not be understood as either prescriptive or exhaustive, but as guidance in assessing international research protocols.

Human Subjects protection administration issues

- Training in ethical conduct of research is strongly encouraged and should be documented (e.g., some large field studies have hundreds of field workers conducting interviews in 8 provinces of China, all speaking different languages).
- The PI will provide documentation that a reasonable effort was made to determine and understand regulations in the country where data collection is taking place.
- The IRB will determine whether a local IRB or other local analogous review body exists to provide local context and guidance.
- The IRB will determine whether an FWA is required for the local performance site.
- The IRB will determine whether data privacy protections are practicable in the specific research setting.
- According to the NIH, when research takes place in a country with human subject protection laws similar to those of the United States, researchers should conform to local law. Where local human subjects protections are less stringent, researchers should conform to United States law.

Risk

- The IRB must determine whether the study design anticipates and minimizes the political, social, economic and legal risks that are particular to prospective human subjects or their communities in the particular country and subculture.
- The IRB must determine whether the risks of adverse events are likely to be different in this population than in the same research performed elsewhere.
- The IRB must determine whether adequate care is readily available for injuries sustained in the course of research.

Justice/Benefit

- The IRB must determine whether the study is responsive to the needs of subject population and whether the benefits of the study will be available to this human subject population. In other words, researchers may not utilize a human subject population merely for their own convenience and without the

prospect of benefit to that population. Consideration should be given to producing benefits for the population that will continue after the termination of the study.

Understanding the protocol and consent process

- **Group consent and individual consent:** In some cultures, group consent by the family and/or the community may be an important adjunct or precursor to individual informed consent. It is important to keep in mind that although group consent may be appropriate and necessary, it is not a substitute for individual informed consent. The informed consent process should be designed to minimize the potential for coercion of the individual by the group.
- The IRB must determine how a minor is defined within the study and whether local laws defining who is an adult differ from United States laws. The IRB must also specify how researchers are to document “legal age” for giving consent (e.g., this comes up often with research on adolescents and reproductive health issues).
- In addition to the obvious necessity of conducting the informed consent process in the local language, the IRB review should address whether there are special dialects that need to be included. Translation of the informed consent documents should be performed by a qualified translator. Interpretation of the informed consent dialogue should not be performed by a family member or other individual who has a personal relationship with the participant.
- Literacy levels and diverse cultural experience may affect individuals in their ability to understand new concepts such as randomization, experiment versus treatment, use of placebos, etc. Thus, the IRB should judge whether the language and concept level is appropriate. In some cases, supplementary materials may be needed: diagrams, pictures, tools to communicate the concept of “chance,” etc.
- In cases where subjects do not read and write, or when signing documents may be a violation of local norms or customs, researchers must consider alternate methods of documenting consent. Thumbprints, marking an “x,” or an interviewer signing a statement attesting that oral consent was given by the subject are all possible modes of documenting consent in such cases.
- The question of compensation to the participant should also receive culturally-specific review. The investigator should provide clear evidence that the incentive is not excessive in the local context (e.g., providing food in famine-stricken populations). Some comparison metric is needed when

incentives are described (e.g., \$3 may seem small, but could be more than a day's wage: thus, an investigator should describe the incentive relative to a day's wage or cost of a meal, etc.).

Special Topics: Research Subject Groups

The Common Rule requires IRBs to give special consideration to protecting the welfare of vulnerable subjects (pregnant women, children, prisoners, decisionally impaired individuals). At the same time, there are also requirements that members of specific populations be permitted or encouraged to become human research subjects to ensure that specific populations are adequately represented in research and have access to potential benefits of such research. The IRB is required to ensure that it has adequate board representation or the input of appropriate external consultants to consider specific kinds of research involving these vulnerable populations in a satisfactory manner. The Elon University IRB is not constituted to review research involving prisoners.

Elements to consider in research involving vulnerable subjects

- The methods of recruitment, selection and the inclusion/exclusion criteria should be considered by the IRB, as should informed consent, the confidentiality of data, and the willingness of the subjects to volunteer.
- Group characteristics such as economic, social, physical and environmental conditions should be considered to ensure that the research includes appropriate safeguards for the protection of vulnerable subjects.
- Applicable state or local laws that bear on the decision-making abilities of potentially vulnerable populations.
- Research studies involving potentially vulnerable subject groups should have adequate procedures in place for assessing and ensuring subjects' capacity, understanding and informed consent or assent. In some cases, researchers should be expected to enhance understanding for potentially vulnerable subjects.
- Whether or not additional safeguards are necessary to protect vulnerable subjects. Such safeguards could include IRB monitoring of the consent process or the creation of a waiting period between contact and enrollment to allow for family questions.

Special Topics: Investigators from other Institutions

Occasionally an investigator from another institution will request to conduct a study on Elon's campus. The following is required to conduct a human subject's study for non-Elon employees:

- A copy of the approved IRB protocol must be provided and
- Investigators must have an Elon collaborator on campus to facilitate the process.