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I. General Policies

The following policies apply to the protection of human subjects who participate in research conducted by Elizabethtown College employees or students. These policies apply to research conducted on campus and off-campus, by outside sources and research funded by Elizabethtown College.

Research should not involve any physical, emotional, or psychological harm to the subjects, and should be conducted in accordance to federal guidelines.[2] Any risks to subjects should be considered in the context of potential benefits of the study.

Researchers must protect the identity of the subjects. This involves not only confidentiality, but also protection against accidental or inferred identity. Clear procedures must protect the identity of the subjects.

Research normally should be conducted with a subject's full, prior consent. Deceptive or covert research will be acceptable only if the IRB determines that the use of deceptive techniques is justified by the study's scientific, educational or applied value, and when alternative methods not using deception are infeasible. Informed consent typically is obtained in writing.

Informed consent should provide the subject an opportunity to decline participation in the study. Specifically exempted, however, might be the case of research on student subjects that is necessary for institutional assessment. In such cases, consent should be obtained upon enrollment at Elizabethtown College.

The purpose of any proposed research should have clearly identifiable value to either the College or the wider scholarly community. Research without a clear value or scholarly merit will not be approved.

When research involves subjects in the Elizabethtown College community (faculty, students, employees), results of the research should be made available to the College community and, if desired, to the subjects.

Effective August 19, 2013, the Elizabethtown College IRB will utilize an online management system (IRBNet) to process all IRB applications.

All international research involving human subjects must be approved by the Elizabethtown College IRB, the authority responsible for human protection in the country where the study will be conducted and by the Elizabethtown College Senior IRB Administrator.

II. Research Activities and Human Subjects

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

[2] See the procedures established in Code of Federal Regulations (CFR) Title 45, Part 46 (Protection of Human Subjects).

A **human subject** is a living individual about whom an investigator is conducting research; obtains information **or biospecimens** through intervention or interaction with the individual, **and uses, studies, or analyzes the information or biospecimens**; or obtains, **uses, studies, analyzes, or generates** identifiable private information or **identifiable biospecimens**.

Specifically covered are research activities involving observation, interviews, completion of surveys, and any other overt or covert data gathering procedures. Specifically exempted are College-funded research activities conducted as part of College's courses (which will be governed by departmental policies and ethical guidelines of the relevant disciplines), as well as the types of institutional assessment, educational testing, and other activities described in 45 CFR 46.101(b). Anyone considering a research project who is unsure of whether the research is exempt from institutional review should contact the Chair of the IRB for clarification prior to initiating the project.

Elizabethtown's Institutional Review Board (IRB) must review and approve:

1. Proposed research projects involving human subjects before any work is started;
2. Ongoing research, involving a full review at least annually;
3. All changes to research projects involving human subjects before implementation.

III. Institutional Review Board

A. Composition

The Elizabethtown College Institutional Review Board (IRB) for human subject research has at least five voting members appointed by the Associate Dean of Institutional Effectiveness, Research, and Planning, over staggered, three-year terms. The Associate Dean shall appoint two of the members as chair and vice-chair for annual, renewable terms. The IRB shall not consist entirely of men, entirely of women, or entirely of members of one academic discipline. At least one member shall be a person whose primary training and research concerns are in nonscientific areas; for example, laws, ethics, civic leadership, and theology. At least one member shall be a person who is not otherwise affiliated with the College or part of the immediate family of a person who is affiliated with the College. The College IRB shall be comprised of no fewer than the following members:

1. Two faculty members
2. One College Life Professional Staff
3. One External Member
4. Others as appropriate

When research involves a category of vulnerable subjects (e.g., prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include at least one member with a primary concern for the welfare of these subjects or in such cases, the IRB may invite a qualified person familiar with such populations to comment on a proposed research project. IRB members should be sufficiently qualified through their experience, diversity of racial and cultural backgrounds, and sensitivity to community attitudes to establish respect for its advice and counsel in safeguarding human subjects.

To avoid conflicts of interest, an IRB member shall not participate in the IRB's review of any project in which the member is involved as a researcher or subject.

The IRB is responsible to the Associate Dean of Institutional Effectiveness, Research and Planning.

B. Functions

Safeguarding the rights and welfare of subjects at risk in any research is the responsibility of the College. To discharge this responsibility, no research activity supported or funded by the College involving human subjects should be undertaken until those activities have been reviewed and approved by the IRB.

The review and approval process considers the proposed methods for collecting data, obtaining prior informed consent (unless waived under conditions described below), and protecting the confidentiality of subjects. Since the "risks" to subjects are affected by these procedures, it is the responsibility of the principal investigator (PI) to be fully familiar with the Code of Federal Regulations (45 CFR 46) which governs the protection of human subjects and which forms the basis of College policy. The PI must demonstrate that appropriate safeguards will be followed for human subjects in order to receive IRB approval.

To further ensure that researchers are fully aware of the precautions necessary to protect human subjects in any research study, effective January 1, 2019, the Elizabethtown College IRB requires Human Protection Certification from the Collaborative Institutional Training Initiative (CITI). This online tutorial training is required of all students, staff, and professors on the roster of a research project application. A current certificate of completion is required to be on file or submitted with the IRB application. CITI program and Elizabethtown College entered into an agreement on Jan. 1, 2019. Elizabethtown College paid the required fee for students, staff and professors. Certification will be considered current if completed within the past 4 years of the application submission date. The following link is the approved training site:

https://about.citiprogram.org/en/homepage

C. Operations

Section 46.108 (b) of the Department of Health and Human Services' Protection of Human Services Regulation (45 CFR 46) requires face-to-face convened IRB member meetings to review, discuss, and vote on category III applications. Category III Applications are primarily projects involving participants noted as vulnerable, including all children. In accordance with this regulation, the IRB conducts all full reviews on the 2nd Thursday of each month. To schedule these reviews, **all full Category III IRB applications must be submitted the first day of the month in which review is requested. If this deadline is not met, the application will be reviewed the following month.**

Overview of Reviews and Levels of Risks

Type of Review	Level of Risk	Application Form
Exempt*	None	Preliminary
Expedited*	No Apparent	Complete
Full**	Minimal***	Complete

* Does not require IRB meeting
** requires IRB meeting

*** The federal rules define **minimal risk** as a risk of harm to the subject from participation in the research that is no greater than the risk encountered in normal day-to-day activities or during routine physical or psychological examinations.

IV. TYPES OF REVIEW (Exempt, Expedited, Full)

A. Exempt

Six categories of research [federal rules, 45 CFR 46.101(b)(1-6)], are eligible for exemption (see below). Although these six categories involve research with human subjects, the research does not expose participating subjects to psychological, social, or physical risks. The investigator/researcher should submit the project to the IRB Administrator with enough information to determine the exempt status of the project. If a project is judged exempt from review, it will not require continuing review.

In order to receive an exemption from review by the IRB, the research project must **involve no more than minimal risk to subjects, no ethical concerns, and ONLY procedures listed in one or more of the following categories of research** (Six types of Exempt Research).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, so long as the research is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

- Research on regular and special education instructional strategies
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

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

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, either directly or through identifiers linked to the subjects;
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

Note: The exemption under category 2 does not apply to research involving survey or interview procedures or observations of public behavior when individuals under the age of 18 are subjects of the activity except for research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.

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

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, either directly or through identifiers linked to the subjects;
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

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

4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- The information, which may include information about biospecimens, is recorded by the investigator in such a way that the identity of the human subjects cannot readily be ascertained, either directly or through identifiers linked to the subjects, and the investigator does not contact the subjects, and the investigator will not re-identify the subjects;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, for the purposes of health care operations or research, or for public health activities and purposes as defined in HIPAA; or
- The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, provided that the original collection was subject to specific federal privacy protections and continues to be protected.

Note: The exemption under category 4 does not apply to research involving identifiable health information regulated by HIPAA when that information is sent to or received from external collaborators who are not a part of covered entities under the Privacy Rule.

5. Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine:

- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if:

- Wholesome foods without additives are consumed; or
- A food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, approved by the Food and Drug Administration, the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

B. Expedited Review

Federal rules allow for expedited review of some research if it involves no more than minimal risk and it falls within one of the categories defined in the federal rules (45 CFR 46.110) and OHRP guidance documents.

An expedited review is conducted by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

Research That Qualifies for Expedited Review

(A) Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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

    1. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product are not eligible for expedited review).
    2. Research on medical devices for which an investigational device exemption application (21 CFR 812) is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    1. Samples from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

2. Samples from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

1. Hair and nail clippings in a non-disfiguring manner
2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
3. Permanent teeth if routine patient care indicates a need for extraction
4. Excreta and external secretions (including sweat)
5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
6. Placenta removed at delivery
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
8. Supra- and sub-gingival dental plaque and calculus provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
10. Sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
2. Weighing or testing sensory acuity
3. Magnetic resonance imaging
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, such as medical treatment or diagnosis. Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing surveys, interviews, oral history, focus groups, program evaluations, human factors evaluations, or quality assurance methodologies. Note: Some research in this

category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB as follows:

1. Where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for the long-term follow-up of subjects; or
2. Where no subjects have been enrolled and no additional risks have been identified; or
3. Where the remaining research activities are limited to data analysis.

9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

C. Full Review

Any research not covered under the exempt or expedited review categories is referred to the IRB for full committee review. The researcher may be invited to attend the review. The research may be either approved, approved pending modifications which must be verified by an IRB member (with revisions documented in IRB files), or not approved. Researchers will be notified in writing about the IRB's decision.

V. Application Procedures

The PI and/or Department Chair (in the case of students) shall make a determination as to whether or not research will involve human subjects. When it is not clear whether the research will involve human subjects as defined in 45 CFR 46.102, the investigator should consult IRB. If human subjects are involved, the PI shall make a tentative determination of whether the research project is exempt from IRB review under the provisions of 45 CFR 46.101.

All applications shall be submitted to the IRB utilizing IRBNet. The IRB Chair will determine if a project is exempt.

A. Expedited/Full Review

If it is clear that the proposed research activity involves potential risk to human subjects and is not otherwise exempt from IRB review, the PI shall submit an application via IRBNet containing:

1. Title of project.
2. Name of principal investigator/association with the College/address/telephone/faculty sponsor and/or Department Chair.
3. Other project participants (individuals or institutions/agencies).
4. Subjects of the study (describe how they will be obtained).
5. A summary of the research methods and procedures.
6. A discussion of how subjects will be debriefed, if needed.
7. A discussion of any and all risks and the procedures to minimize them.
8. Benefits to participants and non-participants.
9. The nature of the subjects' participation and an assurance letter signed by the principal investigator certifying that:

    a. The risks and welfare of the subjects will be adequately protected.

b. Any risks or discomfort to subjects have been clearly identified and are outweighed by potential benefits to the subject or by the importance of the knowledge to be gained.
c. Informed consent of subjects will be obtained by appropriate methods.
d. Any changes which may alter the investigational situation will be reported to the IRB.
e. The storage or disposal of the human subjects' data obtained in the study will follow proper guidelines of confidentiality

10. Informed Consent Procedures Should Describe:

a. The information that will be given to human subjects in the project.
b. Risks and benefits to subjects in the project.
c. The procedures to prevent any violation of the subjects' right to privacy.
d. The provisions for the subject to respond to the information.
e. The procedures for the subjects to consent to participate.
f. The means for subjects to contact the principal investigators.

11. Waiver of Informed Consent. If applicable, a Principal Investigator (PI) may request a waiver or alteration of the requirement to obtain informed consent from subjects prior to the research. This request must be supported by evidence that allows the IRB to conclude that:

a. The study will present no more than minimal risk to subjects.
b. Waiver of full informed consent will not adversely affect the welfare of subjects.
c. The subject cannot practicably be carried out without the waiver; and
d. When appropriate, subjects will be given pertinent additional information after they have participated in the study.

Completed proposals will be submitted and administered utilizing IRBNet. The PI will be notified of the application status via email and IRBNet.

If the application is determined to require full review, the IRB Chair will assign one principal reviewer to each proposal. The review process typically takes between **two weeks and four weeks.** Each member of the IRB will receive a proposal abstract and all associated materials for review. The PI may be asked to submit additional materials.

At the IRB meeting for a full review, the principal reviewer will present the proposal to the Board with his or her recommendations. Following a discussion of the proposal, the Board will determine the disposition of the proposal. This decision will typically be made within thirty days of the submission and the PI will be informed of the decision via email and IRBNet.

If the decision is negative, the notification will include a written explanation including reference to principles which the proposed research violates. A revised proposal may be submitted for re-examination. Materials and IRB decisions will be documented and stored in the institutional IRB files.

VI. Policy for Student Researchers

Research Projects

In accordance with federal regulations and Elizabethtown polices, all research involving human subjects must be reviewed and either classified as exempt from (IRB) review or approved by the IRB prior to any research intervention with a participant.

All Elizabethtown students engaged in any kind of research project (including independent study, research credits, senior thesis, special projects, etc.) involving human subjects must obtain IRB approval before beginning research. A student who submits a request for review (exempt, expedited or full review) must list a faculty member or instructor as an advisor. Approval may also be granted as part of a previously approved project by agreement of the principal researcher.

Department Guidelines

Academic departments may establish procedures for determining exempt projects or conducting expedited reviews if the reviews involve two faculty members other than the advisor to the project. Departmental procedures must be written and approved by the IRB.

Course Assignment versus Disseminated Research

Student projects conducted within an academic course that involve Human Subjects may be categorized as either a Course Assignment or Disseminated Research. Disseminated Research involves the formal presentation (e.g. poster, oral or written, seminar) of information to any audience beyond the course. Disseminated research must be reviewed by the College's IRB. Course Assignments involve data collection and interpretation for educational purposes that are contained wholly within the course environment.

Course Assignments must be planned and carried out with due consideration of Elizabethtown's ethical and legal responsibility to protect human subjects, especially when subjects are exposed to more than a minimal risk. "Minimal risk" is defined as risks anticipated in the proposed activity that are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

All projects involving special populations as subjects (e.g., prisoners, individuals with physical or mental disabilities, economically or educationally disadvantaged, institutionalized individuals, fetuses) require additional safeguards.

Suitable precautions must be taken to ensure the confidentiality of the results of any procedure pertaining to a particular person who is a participant in the activity.

Faculty/Instructor Responsibilities for Human Subjects Protection

- When a faculty member/instructor authorizes (via electronic signature on IRBNet) a student project, the faculty member/instructor is assuming the role and responsibility of Co-Principal Investigator for the project and should review the proposed project accordingly.

- The faculty member/instructor is responsible to discuss research ethics with students in the context of assignments that involve human subjects.

- The faculty member/instructor should determine, prior to assigning a project, whether the project is a Course Assignment or Disseminated Research. Disseminated Research must be reviewed by the IRB. If a student research project is originally conducted as a Course Assignment, but develops into Disseminated Research, IRB approval must be obtained immediately.

- The faculty member/instructor should assure that all students planning to conduct research involving human subjects submit an application to the IRB in a timely manner. The IRB may request additional information or require changes before projects can be approved.

- If the faculty member/instructor is planning to use data from class assignments for disseminated research, IRB approval must be obtained.

- The faculty member/instructor should monitor student projects from beginning to end for impact on human subjects. Special attention should be paid to maintaining confidentiality, minimal levels of risk for participants, assuring freedom to withdraw without penalty, and providing informed consent to participants.

- **The faculty member/instructor should report unexpected adverse effects or complaints involving human subjects to the IRB.**

VII. Changes in Protocols and Adverse Reactions

The researcher is responsible for ensuring that any changes to the protocol are submitted to the IRB for review **before** the changes are incorporated into the research. Researchers should note that only those procedures specifically approved by the IRB may be initiated.

New information which would affect the potential risk to subjects must be brought to the IRB's attention in a timely way. Adverse reactions by subjects to research interventions should be reported to the IRB immediately.

VIII. Continuing Review of Ongoing Research

The Federal rules mandate that ongoing full-review research must be reviewed by the IRB at least once a year (exempt and expedited research do not need further review). Most protocols are approved for one year, although the review interval may be less if the IRB determines that it is necessary, for whatever reason, to review the protocol on a shorter review cycle.

It is the responsibility of the researcher to see that ongoing research is submitted for review before the approval lapses. If IRB approval lapses, the researcher must suspend any ongoing research interventions with subjects and must not recruit any additional subjects.

For expedited and exempt research, we ask that the researcher indicates whether the research is continuing on a yearly basis.

IX. IRB Liability

1. Employees of the College are covered by the College's liability insurance while performing activities related to their job.
2. Students of the College are covered by the College's liability insurance while performing activities related to their education.
3. Individuals performing service to the College who are not employees or students of the College are covered by the College's liability insurance. However, licensed professionals who are not students or employees of the College are only covered for activities **outside** of their profession.
4. The College does not carry professional liability insurance. The exception to this rule is with the Social Work, Music Therapy and Occupational Therapy academic departments.
5. The College provides limited professional liability insurance for students participating in Social Work, Music Therapy, and Occupational Therapy ($1M/$3M coverage)
6. To be covered by the College's liability insurance when conducting research:
    a. The research must be a College activity.
    b. If the researchers are performing a medical procedure or medical intervention at another facility, the researchers must ensure that they are covered by that facility's liability insurance. The exception to this rule is with researchers participating in the Social Work, Music Therapy, and Occupational Therapy academic departments ($1M/$3M coverage).
    c. Researchers are **not** covered by the College's liability insurance when performing medical procedures or medical interventions at Elizabethtown College. The exception to this rule is with researchers participating in the Social Work, Music Therapy, and Occupational Therapy academic departments ($1M/$3M coverage).
    d. If the research involves a medical procedure or medical intervention, the researcher must be accompanied by a licensed professional who is responsible for the researcher's actions.

X. External Human Subject Research Study Policy

Elizabethtown College does not accept applications from external researchers without an Elizabethtown College sponsor. This sponsor must be a faculty or staff member, not a student. For the IRB to consider Elizabethtown College human subject* participation in a study whose primary investigator is outside of the Elizabethtown College community, the following steps must be followed:

- Recruit an Elizabethtown College sponsor. This sponsor must be a faculty or staff member, not a student.
- Submit an Elizabethtown College IRB application. The application will need to include the following attachments:
    - A copy of the external institution's IRB application**
    - A copy of the external institution's current IRB approval letter
    - Copies of the survey, recruitment letters, informed consent forms and the study protocol.
- The application must be signed by the Elizabethtown College sponsor and the Department Chair or Supervisor, and then submitted to the IRB.
- The Elizabethtown College sponsor must provide a statement identifying the benefit(s) to the College.

If you submit an IRB application, your study will be reviewed and considered. If you can't provide this information, Elizabethtown College will not be able to participate.

* 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.

** If the outside institution does not have an IRB, documentation of site consent is required.

Appendix A: DEFINITIONS

Federal regulations define *research* and *human subjects* as follows:

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

> Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected

Human subject is a living individual about whom an investigator is conducting research; obtains information **or biospecimens** through intervention or interaction with the individual, **and uses, studies, or analyzes the information or biospecimens**; or obtains, **uses, studies, analyzes, or generates** identifiable private information or **identifiable biospecimens**.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

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

Appendix B: ETHICAL ISSUES:

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human of Research, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provides the philosophical underpinnings for current federal laws that govern research involving human subjects.

Several basic ethical principles relevant to the ethics of research are described in The Belmont Report:

1. **Respect for persons** – This principle requires that researchers recognize that each individual's judgments and choices about participating in the research must be respected. For those not capable of deciding for themselves or classified by the government as vulnerable subjects (e.g., children, prisoners, pregnant women, fetuses), special protection must be made.

   Research subjects or their legal representative usually must sign an informed consent form detailing the research to be done, the potential risks and benefits, and anything else that might influence their decision to participate. The IRB reviews the project to ensure that participation of subject is voluntary, and that the information provided to gain consent is adequate and appropriate. See pages 6-8 for more detail.

2. **Informed Consent** – Voluntary agreement to participate. See Appendix C for full description.

3. **Beneficence** – This principle embodies three concepts: 1) do not harm; 2) maximize possible benefits; and 3) minimize possible harms. All research should be designed to minimize risk and maximize benefit to the participant and to society. The IRB will review the project to determine if risks are outweighed by potential benefits.

4. **Justice** – This principle considers whether the benefits and burdens of participating in the research are fairly distributed among all populations to ensure justice. Researchers must be careful not to select already burdened or vulnerable groups who might be more easily coerced to participate. This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." The goal is to distribute burdens and benefits in just ways. The IRB reviews the project to ensure that subjects are selected fairly.

Appendix C: INFORMED CONSENT:

General Requirements

Informed consent is the process of communicating to prospective research subjects all that they need to know about participating in a research project, and then obtaining and documenting their agreement to participate. The procedures used in obtaining informed consent should be designed to educate prospective subjects in terms they can understand. Therefore, a consent form must be written in lay language. Informed consent should be obtained for all studies where human subjects are being recruited for the study, including exempt studies. Exceptions are available in cases where obtaining consent would be intrusive on the rights of the participants, such as in observational studies (see waiver of consent below).

The process of obtaining informed consent, and the documentation of informed consent, must comply with the requirements of the Common Rule (45 CFR 46.116 and 46.117). It should include the following eight elements of consent. In some cases, additional elements may be necessary as required by 45 CFR 46.116(b).

Eight Elements of Consent

1. A statement that the study involves research; an explanation of the purpose of the research and expected duration of the subject's participation; a description of procedures to be followed and identification of any procedures that are experimental

2. Description of risk or discomforts to the subject

3. Description of benefit to subject or others

4. Disclosure of alternative procedures, as appropriate

5. Description of the extent to which confidentiality will be maintained

6. For research that involves more than minimal risk, an explanation as to whether compensation and medical treatments are available if injury occurs

7. Explanation of whom to contact if questions arise about the research, the subject's rights, or whom to contact if research-related injury occurs

8. A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue participation at any time

Note: If the research study involves collections of images or audio recordings of subjects, the consent form must clearly state that fact. In addition, there must be a statement of how the material will be used, who will see the images or hear the recordings, and in what setting (e.g., research lab, classroom, professional meeting, public broadcast, etc.). If the investigator wants permission to share the materials with anyone other than the research staff or if the material contains sensitive information, the subject should be given the opportunity to view or hear the materials after they are collected and be told how long they will be kept. The investigator must obtain specific permission from the subjects to use this material.

Additional informed consent elements that are required if they apply to the study and are important for subjects to know:

- Unforeseen risks statement (if applicable).
- Reasons for involuntary termination of participation (if applicable).
- Additional costs to participate (if any).
- Consequences for withdrawal (adverse health/welfare effects, if any).
- New findings statement (to be provided if relevant).
- Number of subjects (if it may have an impact on the decision to participate).
- Payments (incentives and/or expense reimbursements if any).

Documentation of Informed Consent

Informed consent is documented using a written consent form that is approved by the IRB and signed by the subject or his/her legally authorized representative. A copy is given to the person signing the form. The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent described above; or
2. A short form written consent document stating that the elements of informed consent described above have been presented orally to the subject or his/her representative.

In addition, when the short form and oral presentation method is used:

1. The IRB must approve a written summary of what is to be said to the subject or to the person representing the subject.
2. The short form must state that "the elements of informed consent required by the Code of Federal Regulations, Title 45, Part 46.116 have been presented orally to the subject or the subject's legally authorized representative."
3. There shall be a witness to the oral presentation and the witness shall sign both the short form and a copy of the written summary.
4. The person obtaining consent shall sign a copy of the summary.
5. A copy of the written summary shall be given to the subject or the person authorized to consent for the subject, in addition to a copy of the short form.

Waiver of Elements of Informed Consent

The IRB may approve a waiver of some or all of the consent requirements provided that:

- The research involves no more than minimal risk to subjects;
- The waiver will not adversely affect the rights and welfare of subjects;
- The research could not practically be carried out without the waiver; and
- Whenever appropriate, the subjects will be debriefed after participating in the study**.**

Waiver of Signed Informed Consent

The IRB may approve a waiver of signed informed consent provided:

- The research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context;
- The waiver will not adversely affect the rights and welfare of subjects;
- The principle risks are those associated with a breach of confidentiality, where the consent documentation is the only record linking the subject with the research.

In the case of mailed questionnaires, the researcher must provide a written explanation of the study and inform subjects of their rights. The information can be provided in a cover letter that the subject can retain. In the case of telephone surveys, the investigator must provide a verbal explanation of the study and inform subjects of their rights. For online studies, participants must be informed of their rights before taking part in the study. These explanations must be submitted to the IRB for approval.

Appendix D: SPECIAL POPULATIONS:

Research involving special populations require additional protections that must be described in the research proposals. Because these reviews are often more complicated, the investigator should allow extra time for review of projects involving special populations.

Children – 45 CFR Part 46, Subpart D

Children (anyone under 18 years of age) can participate as subjects of research only if there is no greater than minimal risk to the children and the IRB finds adequate provisions are made for soliciting the assent of the children and the consent of the parents or guardians of the children (see 45 CFR 46.408). The consent form should always indicate, regardless of the age of the child, that either the parent or the child may withdraw the child from participation in the research at any time. The assent form should be written in language appropriate to the age level of the children involved. Investigators should review Subpart D of the federal rules (45 CFR 46) to ensure that the proposed research follows federal rules for research involving children.

Assent means a child's affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 12 years and older, written assent is required. For children under 12, verbal assent may be obtained. The researcher must inform the IRB about the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding where assent must be obtained and how it will be documented.

Note: The exemption from review for survey and interview procedures or observations of behavior does not apply to research with children as subjects, except for research involving observation of public behavior when the investigator does not participate in the activities being observed. This type of research must be reviewed by the full IRB (e.g., it does not qualify for either exempt or expedited review).

Prisoners – 45 CFR Part 46, Subpart C

A prisoner is defined by federal rule as any individual involuntarily confined or detained in an institution. This definition includes individuals detained in other facilities by statutes or procedures which provide alternatives to criminal prosecution or incarceration in a penal institution as well as individuals being held prior to arraignment, trial, or sentencing. Additional time is required to schedule an IRB meeting when prisoner research is involved. Projects involving prisoners must be reviewed in full by the IRB; they cannot receive an expedited review.

Institutionalized People

Institutionalized individuals require special consideration. Written permission for the conduct of the research at the institution must be obtained from the appropriate officials at that institution. In addition, if the subjects are not capable of giving consent for themselves, it must be obtained from their legal guardians. If subjects are capable of giving consent, the consent form should be written in language appropriate to the subjects.

Other Vulnerable Populations – 45 CRF Part 46, Subpart B

Investigators conducting research on human fetuses and neonates should Subpart B of the federal rules (45 CFR 46), which includes additional protections required.

Appendix E: OTHER ISSUES

INTERNATIONAL RESEARCH

Field research done outside of the United States, especially in non-western societies or places where the subjects do not speak English, may pose problems in obtaining documentation of informed consent.

In these situations, it is sometimes impossible, for a variety of reasons, to obtain written consent. If that is the case, the investigator must provide the IRB with a statement of the reasons why it should waive written consent, and also provide an acceptable alternative method of obtaining oral consent, which is appropriate to both the subjects and their culture.

USE OF DECEPTION IN RESEARCH

The use of deception in research raises special problems that the IRB will review closely. One consideration is whether the deception is necessary. A researcher proposing to use deception should justify its use. Present federal rules prohibit deceptive techniques that place subjects at more than minimal risk.

A second consideration is debriefing. The IRB expects researchers to debrief subjects who have been deceived during research activities. The debriefing should include a detailed description of the ways in which deception was used. The researcher is responsible to ensure that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to the IRB as a part of submitted protocols.

Appendix F: FEDERAL REQUIREMENTS AND GUIDELINES:

The Department of Health and Human Services (DHHS) policy as expressed in Title 45, Part 46 of the Code of Federal Regulations, also known as 45 CFR Part 46, is the heart of the federal policy on protecting human subjects in research. In 1991, many federal agencies accepted Subpart A, the general provisions of 45 CFR Part 46, as the federal Common Rule. Each "Common Rule agency" publishes an identical version of this Federal Policy for the Protection of Human Subjects in its own section of the Code of Federal Regulations. The DHHS Office for Human Research Protections (OHRP) exercises an important leadership role among Common Rule agencies.

The Federal Policy applies to all research sponsored by the Common Rule agencies. In addition, the Food and Drug Administration (FDA) has the authority to regulate a wide variety of research activity, including all research that involves biological products, drugs, and medical devices, regardless of who sponsors the research. The FDA's core policies are published as Title 21, Parts 50 and 56 of the Code of Federal Regulations. Subject-specific FDA regulations apply to research that involves:

- new pharmaceuticals (21 CFR Part 312)
- biological products (21 CFR Part 600)
- medical devices (21 CFR Part 812)

Some federal agencies impose requirements above and beyond those in the Common Rule. For example, DHHS policy includes additional protections for fetuses, pregnant women, human in vitro fertilization (Subpart B, 45 CFR Part 46), prisoners (Subpart C), and children (Subpart D). Agency-specific requirements apply to research sponsored by that agency.

In addition to the federal Common Rule and the FDA regulations, the OHRP Guidance Documents are the third key source of information about legal requirements.