EAST STROUDSBURG UNIVERSITY OF PENNSYLVANIA
INSTITUTIONAL REVIEW BOARD
FOR THE PROTECTION OF HUMAN SUBJECTS

POLICY
&
PROCEDURE MANUAL

UPDATED August 2025
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IRB Chair

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All policy statements contained herein are based on existing law. The policy is designed to be supportive of all research and provides for exemption from formal review whenever possible. If you have any questions about this policy or about making submissions for review, please contact Dr. Shala Davis at extension 3336.

2025-2026 Committee Membership

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Chin Hu, Ph.D.	**X3369**
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INSTITUTIONAL REVIEW AND APPROVAL FOR RESEARCH

All students should review and complete the contents of this manual in consultation and supervision with a faculty research advisor.

All research involving human subjects, conducted at the East Stroudsburg University of Pennsylvania, or under its sponsorship at another location, must be reviewed and approved by an Institutional Review Board (referred to as IRB). Review is also required of research carried out under the sponsorship of an institution other than the East Stroudsburg University but which is performed on the premises of East Stroudsburg University, even if the research has already been approved by the IRB at the sponsoring institution or elsewhere.

These policies result from the desire of the East Stroudsburg University of Pennsylvania to comply with federal regulations (45 CFR 46- Revised Common Rule, 2018) requiring the establishment of such a board. More fundamentally, the policy stems from the University's self-imposed commitment to safeguard privacy, the rights and welfare of human participants in all research under its sponsorship, and to serve as their protector on behalf of the community of persons of which the University is a part. Office for Human Research Protections (OHRP) was created to provide oversight for compliance with federal regulations on research involving human subjects.

The review process described in this document is based upon federal regulation. This process is not intended to be a barrier to research, but rather a facilitation of ethical research. It is intended to help the researcher reach compliance with federal regulations in addition to protecting the welfare of the human subjects. With careful consideration to the directives of the Nuremberg Code and the Belmont Report the following policies and procedures for the protection of human subjects are required.

The IRB is to provide an independent determination concerning:

1. The safeguarding of the rights and welfare of individual research participants.

2. Whether these participants are placed at risk; and, if risk is involved, whether:

    a) the risks to the participants are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept such risks;

    b) the rights and welfare of any such subject(s) are protected;

c) legally effective informed consent will be obtained by adequate and appropriate means;

d) the conduct of the activity will be reviewed at timely intervals

IRB ADMINISTRATION

Membership

Members of the IRB are appointed by the President of the University upon the recommendation of the Provost to protect the welfare of the human subjects. IRB members are appointed for a three-year term and may be reappointed when this initial term expires. There are at least 6 members of the IRB, with various backgrounds and fields of expertise. The IRB will have a minimum of one member who is a community representative with competence in special areas as a permanent member of the IRB with voting privileges. The committee is diverse in race, gender and cultural backgrounds. Procedures followed by the IRB for review and approval of research involving human subjects are described in detail in the following paragraphs and pages of this document.

The IRB meets on a monthly bases and reviews research, that involves human subjects especially a vulnerable category of subjects, such as children, prisoners, pregnant women, mentally disabled persons, etc. Consideration shall be given to the inclusion of one or more individuals who have specific knowledge about and experience in working with these subjects.

Meetings

The IRB meets each month (usually third Wednesday). Contact IRB Chair for date of meeting. All review proposal requests (**1 electronic submitted**) must be received by the IRB Chair 7 days prior to the next scheduled meeting for consideration. Application includes all corresponding documentation (consent forms, CITI certificate, site approvals, survey instruments, and interview questions etc).

Who May Submit a Proposal for Review

All researchers conducting human subject research that gathers or creates data from outside of the public domain are required to submit their proposal to the IRB. The public domain is defined to include: publicly accessible information or archives; published or broadly disseminated information; public behaviors (as legally defined) of adults; information regarding government or public officials where disclosure is required by law; comments, statements or responses to questions by public or government officials regarding their official duties. Information regarding minors, regardless of the source is specifically excluded from this definition of the public domain. While studies of information in the public domain do not require IRB approval, researchers are still expected to act in a socially responsible manner and make every effort to protect the wellbeing of individuals.

A review and approval of research activities will be made by the IRB only for studies sponsored by members of the faculty, staff, or administration of the East Stroudsburg University of Pennsylvania. In those instances where individuals from an institution other than ESU wish to conduct research on ESU's campus, a faculty member of the East Stroudsburg University of Pennsylvania **must** sponsor the application to IRB. Faculty or staff members must sponsor the research of students. The Chief Academic Officer (Provost) must first approve the request for research to be completed prior to the IRB review process.

Federal regulations now require that every IRB member, researcher and key personnel of a research team certify knowledge of federal regulations and policies dealing with human subjects. Consequently, the IRB requires that before a protocol is reviewed, the researcher and all key personnel on the research project must complete the Collaborative Institutional Training Initiative (CITI) Course (select either the Biomedical Research or Social/Behavioral Research Modules. A hard copy of the certificate issued by CITI at the end of the course needs to be submitted to the IRB with each proposed request. This certificate expires three years from completion date. To access the CITI training program you can use the link provided on the ESU Institutional Review Board webpage and upon completion print report.

The IRB will provide an educational module for presentation in all Introduction to Research coursework offered at the University. The IRB chair will be available to present the module once yearly to the graduate programs which require a thesis, research project or dissertation.

Student Research

Students attending East Stroudsburg University of Pennsylvania (both undergraduate and graduate) are bound by the same procedures and policies. Moreover, no applications to the IRB from either an undergraduate or a graduate student will be reviewed unless sponsored by a faculty or staff member familiar with the student and the proposed activity. The faculty sponsor must be familiar with proposal protocol and accept responsibility to oversee the research. Specific guidelines for the review and approval of student research are presented in this document. All bound thesis must include a copy of the IRB approval.

Submission of Applicants

Any individual intending to conduct research involving human subjects, whether or not the research is supported by a grant, contract, or fellowship from any public or private agency, has the responsibility to file the "Research Application" in order to determine whether the activities proposed require formal IRB review. The IRB determines exemption status. If a grant or contract application is involved, this application should be sent directly to the IRB, and sufficiently in advance of the due date of the application in order to allow time for the review process, should it be deemed necessary. All research

involving more than minimal risk must be reviewed by the IRB. Applications for review are to follow the "General Procedures" described in the pages that follow.

DEFINITIONS

Activities within the scope of the IRB's responsibilities include research, development, and related activities which would normally be construed as biological, behavioral, or psychological investigations involving human subjects. For the purposes of IRB review, The East Stroudsburg University of Pennsylvania stipulates the following definitions:

I. **Research** - any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for the IRB, whether or not they are considered research in other contexts.

Excluded from this definition are activities whose sole purpose is instructional; also excluded are activities whose purpose is related to routine course or program development.

The revised Common Rule adds a provision that identifies four types of activities as not being "research" as defined in the Rule. In other words, the revised Common Rule does not apply to the following types of activities because they do not meet the regulatory definition of research:

•Certain scholarly and journalistic activities,
•Certain public health surveillance activities,
•Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and
•Certain authorized operational activities for national security purposes

[Please refer to 45 CFR 46.102(l) of the revised Common Rule for the full description of the excluded categories of activities.]

Research activity would normally include the following:

1. Persons or programs requesting extramural (federal, state or private) funds for research or training.

2. Individual faculty members (as well as members of the staff and administration) engaged in research as part of their professional role within the University or as part of their job assignment.

3. Graduate students doing research which is of the nature of a thesis and is part of a degree program.

4. Students (undergraduate and graduate) performing research as part of an independent study of the Honors Program.

5. Individuals (including students or persons from outside the University) other than faculty, staff, or administration, conducting research at East Stroudsburg University of Pennsylvania.

II. **Human Subject** - a living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, or (2) using, studying, or analyzing individuals' information or biospecimens or generating identifiable private information or identifiable biospecimens.

III. **Minimal Risk -** the probability of 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. (Investigators have the obligation to request a clarification by the IRB regarding activities or procedures which are seen by the IRB as questionable in terms of their inclusion in this description).

IV. **IRB Approval -** means that the IRB has reviewed the research and that the research may be conducted at an institution within the policies and procedures outlined in this booklet and within the constraints of other institutional and federal requirements. IRB approval must be granted **prior to** starting any research.

GENERAL PROCEDURES FOR SUBMITTING AN APPLICATION

There are specific guidelines for completing the research proposal for each of the three types of IRB protocol review.

These types are:

Exempt Review: No risk to the subject (requires an application).
Expedited Review: Minimal risk to the subject.
Full Review: Research for which there is a risk to the subject and the research does not fall into the Expedited Review category.

The basic premise of the human subjects review process is that all studies are subject to continuous review. However, some studies may require only an initial review and are EXEMPT from ongoing review. No study is totally exempt from review.

The University has adopted eight categories of research as exempt from the continuing Institutional Review Board for the Protection of Human Subjects (IRB) review based upon the Department of Health and Human Services (DHHS) regulations published in the Code of Federal Regulations, 45 CFR 46, amended in 2018. In order to establish an

individual research project as exempt, an investigator must complete an IRB application. Final determination as to whether a project is exempt rests with the IRB.

If a research project is certified as exempt by the IRB, the investigator need not resubmit the project for continuing IRB review as long as there are no modifications in the exempted procedures. In other words, the use of the term "exempt" refers to the requirement for continuing IRB review but not to the general requirements for informed consent and protection of subjects. Thus, even if a project is determined to be exempt, the investigator still must inform potential subjects of the proposed procedures and their rights as subjects.

In accordance with DHHS regulations for the Protection of Human Subjects (45 CFR 46, as amended), the following categories of exemption have been adopted by East Stroudsburg University of Pennsylvania. The exempt categories do not, however, apply to research involving deception of subjects (i.e., where the researcher deceives the subject with regard to the purpose of the research and/or the results of the subject's actions in the study), sensitive behavioral research, or to research involving pregnant women, prisoners, mentally disabled people, and other subject populations determined to be vulnerable.

Exempt Categories

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular or special education instructional strategies, or (b) research on the effectiveness of or comparisons among instructional techniques, curricula, or classroom management methods.

Educational research proposals are exempt **providing all of the following conditions are met:**

a. All of the research is conducted in a commonly accepted educational setting (e.g., public school).
b. The research involves normal educational practices (e.g., comparison of instructional techniques).
c. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existent at the study site.
d. The study procedures involve no increase in the level of risk or discomfort associated with normal, routine educational practices.
e. The study procedures do not involve sensitive topics (e.g., sex education).
f. Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.
g. The school or other institution grants written approval for the research to be conducted.
h. the subjects do not belong to a protected group such as prisoners, minors, etc.

Update from Common Rule 2018: the research must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.

2. Research that **only includes interactions** involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly, or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects
at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, reputation, **and educational advancement**.

NOTE: Sensitive survey research is not exempt. A sensitive survey is one that deals with sensitive or highly personal aspects of the subject's behavior, life experiences or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc.

The principal determination of sensitivity is whether or not the survey research presents a potential risk to the subject in terms of possible precipitation of a negative emotional reaction. An additional risk consideration is, of course, whether or not there is risk associated with a breach of confidentiality should one occur.

With respect to potential psychological risk associated with a survey, the presence or absence of subject identifiers is not necessarily a consideration since the risk may be primarily associated with the sensitive nature of the survey as opposed to being dependent upon confidentiality. Subject identifiers do, however, become a factor when confidentiality is an issue.

NOTE: When children under the age of 18 are involved as subjects in research using survey or interview procedures, the research is **not** exempt.

NOTE: When children under the age of 18 are involved as subjects in research using observation techniques, the research is **not** exempt.

NOTE: Observation research involving sensitive aspects of a subject's behavior is **not** exempt.

NOTE: where identifiable information (even if sensitive) is recorded, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

3.Applies to research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings. The criteria for when Exemption 3 applies to such research is the same as for Exemption 2, in summary: (1) the information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subjects; or (2) any disclosure of this information would not place the subjects at risk of certain harms, or (3) the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that , when appropriate, there are adequate privacy and confidentiality protections in the study.

Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research. Additionally, it applies only to research with adults; it is not applicable to research with children.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

In addition, when the investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health." Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).

When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for nonresearch purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; and/or (d) possible changes in methods or levels of payment for benefits or services under those programs (e) **to include research that is also supported by a federal department or agency (for example, through a grant of funding).**

6. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **A new exemption in the revised Common Rule that covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for nonresearch purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.**

8. A new exemption in the revised Common Rule that covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for nonresearch purposes or for research other than the current proposal. There are four requirements that must be satisfied to use exemption 8: broad consent must be obtained from the subjects for the secondary research use of their identifiable materials, documentation or waiver of documentation of informed consent must be obtained, an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and investigators cannot include the return of individual research results to subjects in

the study plan. Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.

Expedited Review

Department of Health and Human Services (DHHS) regulations (45 CFR 46, as amended) recognize that there are certain categories of research which involve procedures which pose no more than minimal risks to subjects and for which clear standards can be set. Accordingly, research projects which fall under one of the categories listed below will be reviewed by the Expedited Review Subcommittee, which will consist of the Institutional Review Board for the Protection of Human Subjects (IRB) Chair and/or one or more experienced IRB member/s selected by the Chair.

All members of the Expedited Review Subcommittee must agree that the protocol falls under one of the expedited categories. Any member may object to the application for expedited review or may have further questions that the investigator must answer. Similarly, each member has the option of referring the application to the IRB for full review.

If the application is approved by the Expedited Review Subcommittee, it will be reported to the IRB as a consent calendar item at the next convened meeting. The IRB is likely to approve the Expedited Review Subcommittee's action but has the option of requesting more information, requiring modification of the protocol, or disapproving the project.

Listed below are ten categories subject to expedited review. Expedited review will be given only for research protocols that fall under one of these categories. These categories, as determined by the IRB, may not apply to pregnant women, children, prisoners, mentally disabled persons, and other classes of subjects considered vulnerable.

1. Minor modifications or additions to existing approved studies;
2. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;
3. Voice recordings made for research purposes such as investigations of speech defects;
4. Moderate exercise by healthy volunteers;
5. Collection of blood samples by venipuncture, in amounts **not** exceeding 550 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant;
6. Collection (in a nondisfiguring manner) of hair, nail clippings, and deciduous teeth; and permanent teeth if patient care indicates a need for extraction;
7. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;
8. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of

physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. (These procedures include weighing, testing sensory acuity, electrocardiogram electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range, (e.g. x-rays, microwaves.);

9. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques and;
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Full Review

Every application for full formal review made to the IRB must include a description of research as outlined previously. A new application for review is required for each research project that differs significantly in terms of procedures or subject populations from a previously approved application.

The ultimate determination of whether subjects are at risk can be made only by the IRB. If, however, the investigator believes subjects will be placed at more than MINIMAL RISK (as defined previously), then the IRB must approve the consent form to be used. The IRB must approve both the form and the procedure by which consent is to be obtained. It is the policy of the IRB to require an informed consent for any study involving children (under 18 years of age) and other vulnerable populations, no matter what the condition of risk. The procedures necessary for a proper informed consent are described in this document.

Limited Review

Limited IRB review is a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria in §46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

RESEARCH DESCRIPTION

When reviewing research proposals, the IRB is primarily interested in safeguarding the rights and well-being of the human subject and in assessing the ethical implications of the proposed procedures. In this context, the IRB may examine the “research design”, but only to the extent that such design affects the rights or well-being of human subjects. In

analyzing the risk/benefit ratio of a research activity, both the stated goals and the scientific merit of the research will be considered.

Therefore, the research must be described to the IRB in a manner that allows adequate review of all these aspects of the research. The modified research application form includes the research description. One hardcopy and one electronic of this form and all supplemental materials must be submitted 7 days prior to the scheduled IRB meeting.

STUDENT RESEARCH

A student intending to do research involving human subjects as a part of an individual project (e.g., graduate or under-graduate thesis, Honors Tutorial, independent research) should discuss the project with his or her major advisor.

The student and the advisor shall together prepare a description of the project in the manner described previously in this document and shall submit **one electronic copy** of this description to the IRB together with:

a) IRB Research Application form
b) consent form
c) any additional items (survey instrument, interview questions etc)
d) copies of CITI certificate

The IRB Chair will determine if the project meets exemption criteria or requires full review.

COURSE-RELATED RESEARCH

Course-related research, beyond that specified above, does not fall under the purview of IRB policies EXCEPT WHEN **(1)** the research is not a routine procedure that is employed on a regular basis in the course, OR (2) the research involves more than minimal risk, OR **(3)** involves subjects outside the University OR **(4)** the professor or instructor is involved in research for a personal educational requirement.

In cases outlined above, complete the application form, description of the research and submit to the IRB. The IRB discourages the use of one's own students as participants in research project(s).

INFORMED CONSENT

The basic goal of informed consent is to fully inform the potential subject on the nature of the research and minimize coercion (or the perceived potential for coercion) to force subject participation. Informed consent cannot include language which attempts to waive legal rights of subjects or releases investigator, sponsor, or institution from liability

or negligence. **One of the new standards is that the consent form, and the consent process, should provide subjects with the information needed to make an informed decision about whether to participate. One change is introducing the requirement that informed consent must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision about whether to participate. Using this standard, informed consent remains focused on what information a reasonable person would want to have to make an informed choice about participation.**

An additional change is that the information needs to be presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate.

Informed consent is a process. A written consent documents this process, but cannot serve as a substitute for it. No subject may be involved in research without the legally effective informed consent of the subject or the subject's legally authorized representative. This consent shall be sought under circumstances that provide sufficient opportunities for the subject to freely consider whether or not to participate. If the subject is a minor, written parental consent or legal guardian consent is required, and the investigator must obtain the assent of the child unless the child is incapable of giving assent.

The information given to the subject, or the subject's legally authorized representative, must be in simple, easily understood language. If the subject population is non English-speaking, the informed consent must be presented in whatever language is appropriate to that population. If the person uses an alternative form of communication (e.g. Sign Language), the informed consent process must be designed to enable effective communication in the appropriate mode. (If a potential subject is illiterate, the investigator will be required to use a competent witness to verify voluntary informed consent.)

Written documentation of the consent process (e.g., a cover letter or cover sheet) is always required unless specifically waived by the IRB. The consent document should be signed by the subject or the subject's legally authorized representative unless this requirement is waived by the IRB.

In some types of projects, it may be important for information pertaining to consent to be provided verbally. In such an instance, a written summary (script) of what the potential subject will be told must be provided to the IRB for review and approval. Investigators should explain the rationale for not obtaining written informed consent in order that the IRB may approve such an exception.

No informed consent, whether oral or written, may waive or limit in appearance or in fact, the subject's legal rights, including any release of the institution or its agents from liability or negligence.

INFORMED CONSENT REQUIREMENTS:

The following information must be part of all written consent documents:

1. A new requirement **key information** about the study must be provided at the beginning. This will likely include information about the purpose, the risks, the

benefits, and alternatives, and it will explain to the person how to think about these pieces of information in terms of making a decision. It should be presented in a concise and focused manner.

2. Identification of the investigator, faculty sponsor (if relevant), as well as the name of any other sponsoring or funding source supporting the research. East Stroudsburg University of Pennsylvania should be identified as the responsible institution or as one of the responsible institutions. The ESU IRB Chair contact information should be included on consent form.

3. The following statement will be included in ALL written informed consents (including cover letters). It is suggested that this statement be inserted at the bottom margin of the form, letter or portion of the form that is to be retained by the subject. THIS PROJECT HAS BEEN APPROVED BY THE EAST STROUDSBURG UNIVERSITY OF PENNSYLVANIA INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS.

4. A description of any reasonable foreseeable risks or discomforts to the subject (including likely results if an experimental treatment should prove ineffective). If the risk potential is currently unknown or not measurable, statement to that effect is required.

5. A statement regarding the availability of compensation, medical treatment, or other services if injury occurs will be required for research which involves more than minimal risk. If compensation or medical treatment will be provided, information about how it may be obtained or where further information may be secured will be required.

6. A statement of any new information developed during the course of the research which may relate to the subject's willingness to continued participation will be provided. Related to this, an offer to answer any questions the subject (or the subject's representative) might have regarding the subject's rights shall be included. This statement should include the name, address and/or telephone number of the principal investigator as the contact point if questions or problems should occur.

7. A statement describing the method by which confidentiality of records identifying the subject will be maintained.

8. A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. The statement should include a description of the consequences, if any, that accompany such a decision to withdraw and should explicitly state methods of withdrawal.

9. A statement about whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future.

10. A copy of the informed consent shall be provided to the subject or the subject's legally authorized representative.

11. Federal law mandates that copies of all consent forms be retained for a minimum of three years after completion of the research. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of

these records. If the investigator leaves the institution within this three year period, all records must be forwarded to the Institutional Review Board Chair.

Informed consent must be obtained by the investigator from each of the participants; or, in the case of those not able to give consent (e.g., children, mentally disabled), parental permission form must be obtained from their guardians or legal representatives. A copy of the consent form should be given to the person signing the form. The IRB must approve all consent documents and copies of such are to be kept on file by the IRB.

Broad consent is a new type of informed consent provided under the revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for nonresearch purposes, such as materials that are left over from routine clinical diagnosis or treatments. Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.

Not all the required elements for standard informed consent are included in broad consent. Under the revised Common Rule, broad consent includes some of the basic elements of informed consent that are required in the standard informed consent (and outlined in 45 CFR 46.116(b) of the revised Common Rule). These include disclosing: reasonably foreseeable risks; reasonably expected benefits to subjects or others; confidentiality safeguards; and that participation is voluntary and may be discontinued without penalty.

There are also additional elements of informed consent (outlined in 45 CFR 46.116(c) of the revised Common Rule) that are included in the broad consent. These are: when appropriate, a statement about commercial profit and whether subjects will or will not share in it; as well as, when appropriate, whether research might include whole genome sequencing. The basic and additional elements of informed consent that are required in broad consent are outlined in 45 CFR 46.116(d)(1) of the revised Common Rule.

Broad consent is also required to comply with most of the general elements of informed consent outlined 45 CFR 46.116(a). These include: obtaining informed consent before involving a human subject in a research activity; only seeking informed consent under circumstances that provide the prospective subject sufficient opportunity to discuss and consider whether or not to participate; providing information to potential subjects in a way that is understandable to the subject; providing prospective subjects with all of the information that a reasonable person would want to have in order to make an informed decision about participation; and not including certain types of exculpatory language in informed consent.

In addition to the elements described above, there are elements unique to broad consent found in 45 CFR 46.116(d)(2)-(7). For example, there needs to be a general description of the types of research that may be done, with sufficient information that a reasonable person would expect the broad consent would permit the types of research conducted. There also needs to be a description of the identifiable private information or identifiable biospecimens that might be used, whether they might be shared, and which types of institutions or researchers may use the information or biospecimens for research. There needs to be a description of the period of time the materials may be stored, maintained, or used. Information needs to be provided on who to contact about subject rights, storage and use of materials, and research-related harm. As applicable, broad consent also needs to include a statement that subjects will not be informed about specific studies and that they might have chosen not to consent to some of these studies. As applicable, broad consent needs to include a statement that clinically relevant research results might not be disclosed to the subject. Finally, broad consent needs to include an explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research related harm.

Consent Form Guidelines

In clear and non-technical language, subjects must be informed of:

1. The fact that the study is research.
2. The purposes of the research.
3. The expected duration of the subject's participation.
4. The procedures to be followed.
5. Any reasonably foreseeable risks or discomforts.
6. The benefits to the subject or to others which may reasonably be expected from the research.
7. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
8. The extent, if any, to which confidentiality of data and privacy of subjects will be maintained to the extent possible in the law.
9. For research involving more than minimal risk, whether any compensation and whether any medical treatments are available if injury occurs.

10. Whom to contact for answers to pertinent questions about the research, subjects' rights, and research-related injury to the subject. This should include the researcher and IRB chair.

11. The fact that participation is voluntary and that the subject may withdraw his or her consent at any time without penalty or loss of benefits.

There may be cases in which the use of these procedures for obtaining informed consent may be considered inappropriate by the investigator because they would adversely affect the experimental design or procurement of valid results. Accordingly, modifications to the above informed consent procedures can be recommended to the IRB. However, **all modifications must be approved by the IRB prior to implementation of the proposed research.** This approval must be recorded in the Committee's minutes.

No such modification will be approved unless and until the IRB determines:

1. That the risk to any human subject is, in fact, minimal, justifying a less full disclosure in the informed consent procedures than would normally be required; or,

2. That the use of either consent procedure would, in fact, invalidate objectives of considerable immediate consequence, and that the use of any reasonable alternative means for attaining these objectives would be less advantageous to the subject.

REVIEW AND APPROVAL

Specific review and approval procedures of the IRB are as follows:

1. The committee meets formally monthly. For a research proposal to be reviewed at a scheduled meeting, it must be received in the IRB Chair's office 7 days prior to the meeting.

2. Upon receipt of the necessary copies of the research protocol (or electronic PDF), the **Chairperson** of the IRB checks to ensure that the properly completed accompanying forms are present and that the necessary description of the research is provided. Copies are then distributed to members of the IRB.

3. Upon request to the IRB, the investigator may be asked to provide additional information or to appear in person before the committee to present a full explanation of risks and protection for the human subjects. **Any investigator may ask to appear before the committee to describe the proposed research.**

4. In cases where it is deemed necessary by the committee, consultants to the IRB may be asked to comment on a proposed research activity.

5. A necessary quorum for the IRB to consider a proposal is a majority of the total membership. In addition, a non-scientist must be present for a quorum according to federal guidelines. No IRB may have a member participate in the board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

6. The IRB will decide by a quorum of the members present or by a majority of members reviewing the proposal:

a) to approve the proposal
b) to approve the proposal with restrictions or conditions
c) to table the proposal, pending modification in the application or receipt of additional information from the investigator or consultants to the IRB
d) to deny the proposal.

NOTE: Approval is for 12 months, renewal is required after time frame expires.

7. Minutes will be taken at all IRB meetings. Records (research proposals and all correspondence) will be retained by the IRB for a period of three years.

8. The IRB Chairperson will inform the principal investigator in writing of the decision of the Committee of the following:

a) If changes are recommended by the board, the IRB Chairperson or designated member will communicate these in writing to the investigator.

b) The IRB Chairperson or designated member will be responsible for review and approval of the investigator's submitted modifications.

c) If the investigator deems it necessary to make further modifications, these can be submitted to the Chairperson or designated IRB members for review and approval.

d) <u>If there are changes in the study which the Chairperson or designated committee member feels may change the level of risk to human subjects</u>, <u>the investigator will be requested in writing to submit the proposal to the</u> <u>full committee for further review</u>. If the modifications change the protocol significantly from the original proposal a new review is necessary.

The IRB shall have the authority, in conjunction with the Provost's office, to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects. A list of the reasons for any suspension or termination will be

provided to the investigator, all appropriate department heads and the Dean of Graduate College.

RESPONSIBILITIES OF INVESTIGATORS (Including Reporting Adverse Events)

1. Familiarize themselves with federal guidelines (Belmont Report and HHS 45 CFR 46- Common Rule Revised-2018) to discuss with members of the IRB any questions regarding proposed research activities. Federal regulations now require that every IRB member, researcher, and key personnel of a research team certify knowledge of federal regulations and policies dealing with human subjects. Consequently, the IRB requires that before a protocol is reviewed, the researcher and all key personnel on the research project must complete and provide certificate from the CITI training module Basic Refresher. The CITI modules can be accessed from the ESU IRB webpage.

2. To obtain permission to do research:

   a) Submit either an adequately prepared Human Subjects Research Application and identify which category for review is applicable (Exempt, Expedited, Full Review). However, the IRB will make the final decision on review status.

   b) Submit all supplemental forms to the IRB for review. Be sure to include the consent materials, and other supporting documents.

3. **Immediately notify the IRB and the departmental chairperson of any injury-physical, psychological or social-suffered by a subject because of his or her participation in a research activity. Based on the incident further action to report to OHRP or funding agencies will be conducted by IRB Chairperson in consultation with senior administration at university.**

4. Request a continuing review if the research is judged by the IRB to involve more than MINIMAL RISK and extends beyond twelve months.

5. Make provisions to keep records, documents, and informed consent forms normally for at least three years following the completion of the project or activity, or for a longer period if requested by IRB.

6. Take proper measures to protect confidentiality and security of all information obtained from the subjects (data storage).

7. **To submit a final report to the IRB at the completion of the research project**. This final report shall provide the termination date of the study and the number and breakdown of subjects (gender, ethnicity, age). No new research reviews will be conducted by the IRB if a final report is missing from a previous project.

Procedures for Renewal

Under the revised Common Rule, continuing review is not required for:
•Research that is eligible for expedited review,
•Exempt research conditioned on limited IRB review,
•Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,
•Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

All research approvals are for up to 12 months. If additional time or subjects are needed for study completion a renewal is required. Resubmit Research Application Form outlining the necessity to continue the research methodology. No significant methodological changes can be approved under a renewal. Provide the IRB with a copy of your original research approval letter and supporting documents for review.