

YOUNGSTOWN STATE UNIVERSITY

Institutional Review Board

for the

Protection of Human Subjects

Regulations and Procedures

Effective July 5, 2011

HUMAN SUBJECT PROTECTIONS AT YOUNGSTOWN STATE UNIVERSITY

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HUMAN SUBJECT PROTECTIONS AT YOUNGSTOWN STATE UNIVERSITY

INTRODUCTION

Youngstown State University (YSU) recognizes that the use of human subjects imposes both ethical and legal responsibilities upon the University and researchers (including student researchers) for ensuring that the rights and welfare of the human subjects are adequately protected. Therefore, the Institution, each Principal Investigator, and all study personnel must follow these regulations and procedures to ensure that such protection occurs.

The Regulations and Procedures have been developed in accord with federal regulations (45 CFR 46, 21 CFR 50, and 21 CFR 56), YSU policies, human research ethical codes, and the ethical principles embodied in The Belmont Report (respect for persons, beneficence, and justice). See Appendix for links to these documents.

This document serves as a guide for disseminating regulations and procedures about research with humans and therefore exists as a living document, subject to revisions mandated by federal, state and local regulations.

To assist investigators in complying with federal regulations related to humans as research subjects, YSU requires investigators to undergo training in the protection of human subjects. Investigators must submit a certificate of training completion before a protocol can be reviewed by the IRB. Refer to the YSU IRB webpage for instructions regarding training.

An investigator must refer all research to Youngstown State University's Institutional Review Board (IRB) whenever human subjects (including medical records, tissues, and other individually identifiable records) are involved. It is the sole responsibility of the IRB, not the project director, investigator, or any University official to determine if a research protocol meets the criteria for exemption from IRB review. YSU-related research may be undertaken only after appropriate IRB approval and may be continued only so long as that approval remains in effect (approval intervals are one year or less depending on the level of risk involved). Changes in a research study, or continuation of the study following adverse or untoward occurrences, are also subject to IRB review and approval.

These procedures are formulated to protect the University and the researcher, including the student and faculty advisor, from liability by imposing minimum standards for research and careful review of projects. Current law places the burden of liability for negligence or misconduct directly on the researcher and the institution. Failure to follow these guidelines may cause individuals to incur personal liability for negligence and harm and the University to lose federal funding, prevent individuals from receiving federal research funds, or result in a federally imposed suspension of all human research activities at YSU.

POLICIES AND PROCEDURES

I. REGULATION OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Authority of the IRB

The actions of the IRB, its chairperson, members, and administrative staff in matters of human subject protection derive authority from federal regulations, separate and distinct from Youngstown State University. It is the responsibility of the Associate Provost for Research to maintain and enforce the independent nature of the relationship between the IRB and Youngstown State University. The IRB functions independent of but in coordination with other committees within the structure of Youngstown State University. All decisions made by the Board are binding and cannot be overturned or overruled by any Institutional Official.

The Human Subjects Review Committee, now known as the Institutional Review Board, was established by the Board of Trustees to protect the rights and welfare of human research subjects and ensure YSU's compliance with federal and state regulations regarding the treatment of humans as research subjects. To this end, the Board enacted resolution YR 1999-87, which states:

“The University conducts research with integrity requiring the protection of the rights, well-being, and personal privacy of all persons utilized as participants. The University is responsible for the development of procedures that are in conformance with, but not limited to, relevant federal and state regulations. All research conducted under University auspices that involves human subjects shall fall under the purview of this policy and its procedures.” (YSU Guidebook, number 1014.01, see Appendix)

The IRB has authority to review all research involving human subjects, regardless of sponsorship, and all research is subject to these policies and procedures. The IRB will ensure that human research is designed and conducted in a manner that protects the rights and welfare of participating subjects. Specifically the IRB:

- reviews and has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction;
- has the authority to conduct continuing review to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators and auditing the conduct of the study, observing the informed consent process, and/or auditing the progress of any study under its jurisdiction as it deems necessary, to protect the rights and welfare of human subjects;
- may suspend or terminate approval of a study;
- may place restrictions on a study;
- makes the final decision about Investigator attendance at a review meeting. The Investigator may request attendance at the IRB meeting to provide additional information but final decision about attendance rests with the IRB. Research investigators may not select the primary reviewer of a submitted protocol nor be present during IRB deliberation or voting about the protocol.

The IRB's Relationships

YSU may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed by Multiple Project Assurance or Federal Wide Assurance agreements.

II. CONFLICT OF INTEREST

Definition of Conflict of Interest (COI) and Disclosure

Characteristics that promote quality research and strengthen the research process are openness and integrity. Therefore, conflicts of interest should be eliminated, or disclosed when they cannot be eliminated. A COI is defined as a close personal or professional association with the submitting Investigator(s); direct participation in the research (e.g., protocol development, principal, or co-investigator); or any significant financial interest in the sponsoring company. The Associate Provost for Research has the authority to determine when COI exists as defined by institutional policy (YSU Guidebook, 7001.01, see Appendix), and to impose and enforce disciplinary action in the event that COI is not disclosed.

The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the IRB will consider COI issues in its deliberations of applications.

All Investigators must reveal on their application to the IRB whether they or any other person responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research.

Management of Investigator Conflict of Interest (COI)

All investigators must disclose COI to the IRB as well as all financial relationships associated with the research protocol. Each potential conflict will be reviewed on an individual basis. The IRB may require that conflicts be disclosed in the informed consent, that the investigator recuse him/herself as the principal investigator, or from the study entirely.

The Investigator may not select the primary reviewer of the submitted protocol nor be present during IRB deliberation or voting about the protocol. The Investigator may request attendance at the IRB meeting to provide additional information, but final decision about attendance rests with the IRB.

Management of IRB Member or Staff Conflict of Interest (COI)

No IRB member or staff may participate in the initial or continuing review of any research project in which the member has a COI, except to provide information as requested. An IRB member found to have a COI may not be considered as part of the quorum for the project review or vote regarding the project. It is the responsibility of each voting member or alternate member of the IRB to disclose any COI in a submitted study and recuse him/herself from the review process. The IRB chairperson is the sole person to assign the primary reviewer of a protocol.

III. REVIEW OF RESEARCH PROTOCOLS WITH HUMAN SUBJECTS

General Information

The YSU IRB reviews only research involving human participants. Human Research is defined by the Federal Regulations as a systematic investigation of human subjects, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The Office of Human Research Protections defines human subject as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. NOTE: FDA's regulations define human subject as an individual and do not use the adjective "living."

Some projects are not research based on this definition and exempt from IRB review even though data is collected from human participants. The IRB chairperson makes final determination of whether a project is exempt. Program Assessment for the sole purpose of program improvement is an example of a project involving human subject data collection that does not qualify as research and is exempt from IRB review. See the section entitled Exempt Review for other categories of exemption.

The YSU IRB review process uses the definition of minimal risk as defined by Federal Policy for the Protection of Human Subjects: 45 CFR 46 (see appendix for link), to determine whether expedited or fully convened IRB review is needed. Risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. Protocols that exhibit minimal risk may be reviewed using an expedited process. See the section entitled Expedited Review for other categories of expedited research.

Approval by the IRB to conduct human research is based on the principles of justice, beneficence, and autonomy as discussed in the Belmont Report. For all non-exempt research projects, the IRB reviews each protocol and must find that the risks to subjects are minimized and reasonable in relation to anticipated benefits; that informed consent will be sought from research participants; or a waiver of consent is approved by the IRB. Fully convened IRB review is completed on all protocols determined by the IRB chairperson to need full review even if minimal risk could be perceived.

Changes in approved research, during the period for which approval has already been given, may not be initiated without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects. Investigators must submit requests for changes to the IRB in writing.

The IRB also conducts ongoing review of studies at periods appropriate to the degree of risk the research subject is exposed to due to their participation in the study, but at least annually.

Non-YSU affiliated Investigators

Non-YSU affiliated Investigators wishing to conduct research at YSU and who do not have approval from another IRB must obtain a YSU liaison (faculty or staff) before the project can be submitted to the YSU IRB for review. Non-affiliated investigators with approval from another IRB may be required to obtain a letter of support from a YSU person of authority appropriate for the project or the Dean of Graduate Studies and Research.

Exempt Research

Research activities in which the involvement of human subjects meets the criteria listed below are exempt from IRB review. The IRB chairperson or designee makes the final determination of whether a project is exempt from IRB review. If the researcher feels the proposed project meets the categories of exemption, s/he should complete the Exempt Form and Checklist and submit an electronic copy and one fully signed hard copy to The Office of Grants and Sponsored Programs. A finding of exemption from IRB review does not exempt the project from ethical conduct to seek Informed Consent from participants. An Informed Consent document or Waiver of Informed Consent request form must accompany the protocol application. After determining that a project meets exempt status, the IRB chairperson or designee will provide written notification to the researcher of exemption status.

The specific categories of exemption are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. Research on regular and special education instructional strategies;
 - b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research 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 of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, if
 - a. The human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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.

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;
 - d. Possible changes in or alternatives to those programs or procedures; or
 - e. Possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food qualitative 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Federal rules permit expedited review for research activities that meet the criteria in one or more of the below listed categories. Expedited initial and ongoing review of research may be completed by the IRB Chairperson or a designated voting member or group of voting members rather than by the entire IRB. The IRB chairperson makes the final determination of whether a project may undergo expedited review or be referred for full committee review. If the researcher feels the proposed project meets the categories of expedited review listed below, s/he should complete the Full/Expedited Review Form and Check-off Sheet and submit an electronic copy and one fully signed hard copy to the Office of Grants and Sponsored Programs. Informed consent is still a requirement even if expedited review is granted. An Informed Consent document or Request of Waiver of Informed Consent Form must accompany the protocol application. The IRB chairperson or designee will review the protocol and notify the researcher in writing of decisions about expedited status and approval of the project.

Applicability of Expedited Review

Research activities that (1) present no more than minimal risk to human subjects, and (2) 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.

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

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.

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

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened.

Categories of Expedited Research

Categories one (1) through (9) pertain to both initial and continuing IRB review.

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (1) an investigational device exemption application is not required; or (2) 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:
 - (a) 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
 - (b) 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 per 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.
 - (a) Examples: (1) hair and nail clippings in a nondisfiguring 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 subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (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 device for new indications.)

- (a) 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 HHS 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 survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.) This listing refers only to research that is not exempt.
- (8) Continuing review of research previously approved by the convened IRB as follows:
 - (a) Where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) 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.

Notification of IRB and documentation of expedited review

When the expedited review procedure is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting. If the study qualifies for expedited review, the IRB chairperson or designee will document his/her determination of risk. The minutes will include documentation of the studies that were reviewed via expedited review and any issues resolved relating to questions that IRB members had concerning the research reviewed.

Full IRB Review

All research proposals that do not meet the criteria for exempt or expedited review must undergo initial and ongoing review by the fully convened IRB prior to human subject recruitment. Approval by the full IRB will be given when the protocol meets criteria that are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and are specified below. In addition, other criteria that are unique to Youngstown State University's system may apply and must be met as well. It is the responsibility of the investigator to be cognizant of any local or State law(s) that affect the conduct of human subject research in his/her State and apply these rules appropriately. An example of a state law is the legal age of adulthood.

To have a protocol undergo a fully convened IRB review, researchers must submit the Full Review Application which allows the IRB to evaluate whether the researchers have met federal and institutional requirements. The protocol explanation form is designed to get information needed for the most commonly submitted projects at Youngstown State University. If a researcher has a project with an inquiry design that doesn't seem to fit the items on the form, the researcher should consult the IRB chairperson rather than leave items blank. A submitted protocol will be scheduled for IRB review when staff has determined that the information and materials submitted present an adequate description of the proposed research.

The IRB meets monthly and meeting dates are posted on the Office of Grants and Sponsored Program's website. To ensure adequate time for IRB members to evaluate the protocol, the application must be submitted 7 days prior to the IRB meeting. The researcher must complete the Full IRB review form and submit an electronic copy and one fully signed hard copy to the Office of Grants and Sponsored Programs. An Informed Consent document or Waiver of Informed Consent Request Form must accompany the protocol submission.

For a research project to be reviewed, a quorum of the IRB membership must be present, including at least one member whose primary concerns are in nonscientific areas and one community member. For the research to be approved, it must receive the approval of a majority of those members present. Staff will use a checklist to determine if the researcher has submitted all of the required information or if additional information is needed prior to the IRB meeting. The IRB will then evaluate the protocol as per policy. Required information for the protocol to be evaluated include:

- Submission of the investigator's certificate of training completion
- Title and Purpose of the study (including the expected benefits obtained by doing the study)
- Sponsor of the study
- Results of previous related research
- Subject inclusion/exclusion criteria and justification for exclusion of subjects if only of homogenous populations
- Justification for use of any special/vulnerable subject populations (e.g., the decisional impaired children)
- Study design (including as needed, a discussion of the appropriateness of research methods)
- Description of procedures to be performed

- Provisions for managing adverse events
- The circumstances surrounding consent procedures, including setting, subject autonomy concerns, language difficulties, vulnerable populations
- The procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses or translators, and document storage
- Compensation to subjects for their participation
- Any compensation for injured research subjects
- Provisions for protection of subjects' privacy
- Extra costs to third party payers because of subject's participation

Other information that the IRB may require for submission include: recruitment flyer or brochure, letter of support from facility personnel where the research takes place, photography consent forms, and the qualifications of the Principal Investigator. Researchers must have the appropriate qualifications and experience and facilities to ensure that all aspects of the project and follow-up will be conducted rigorously and with due regard for the safety and well-being of the subjects.

IRB actions following full convened IRB review

Following review of each protocol, an action will be voted upon. IRB actions may be to: approve, conditionally approve, require modification, restrict, table, or disapprove a protocol.

- (1) Conditional Approval: Conditional Approval means the protocol is approved pending the investigator submits minor revisions to the protocol; revisions to consent documents and other documentation; or clarifications. These submissions are a condition to final approval. The conditional information may be reviewed by the IRB chairperson or his/her designee rather the full IRB. Final approval will be issued providing the revisions, documentations or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.
- (2) Approval with restrictions: The IRB may vote to approve a protocol methodology but place restrictions prior to or when the study is conducted. Examples of restrictions are: require a letter of support from the facility where data collection will take place; a physician must be present during specified testing procedures; a faculty advisor must be present during data collections.

Members of the IRB vote upon the recommendations made by the primary reviewers according to the criteria for approval.

Members also will determine:

- level of risk,
- frequency of review for each protocol,
- monitoring of the investigative site, and
- whether third party assessment and follow-up will be needed.

Criteria to approve research

The decision of the IRB to approve a protocol is based on the principles of justice, beneficence, and autonomy as discussed in the Belmont Report. Specifically, the decision to approve is based on findings that:

1. Risks to subjects are minimized
 - a. By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
3. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
4. Selection of subjects is equitable
 - a. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.
5. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by appropriate local, state, and federal regulations.
6. Informed consent will be appropriately documented as required by local, state and federal regulations.
7. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
8. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
9. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.
10. Studies are reviewed at periods appropriate to the degree of risk research subjects are exposed to due to their participation in the study, but at least annually.

Emergency research

Emergency research is research that is performed when the subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of scientific evidence is necessary. Obtaining Informed Consent during emergency research is not feasible because the subject's medical condition precludes consent, there is no time to get consent from a legally authorized representative, or the prospective identity of likely subjects is not reasonable. This type of research has not historically been done by YSU related investigators, but in the event a protocol is submitted and a Waiver of Consent is requested, the IRB would follow the federal regulations governing emergency related research. Additionally, consultants would be utilized to understand risks/benefits related to the specific protocol. If the YSU IRB determined it was unable to evaluate the protocol adequately, the protocol would be referred to another IRB with expertise in this research type.

IV. SPECIAL SUBJECT POPULATIONS

Research involving prisoners as subjects

A prisoner is defined as any individual held in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and the ability to leave the institution is restricted. The term "prisoner" is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

All protocols involving prisoners as subjects must undergo full convened IRB review. In addition to the requirements of subpart A, subpart C of the HHS regulations at 45 CFR part 46 identifies additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects. In summary, the major additional considerations are:

- The exemptions that generally apply to certain types of research involving human subjects do not apply to research involving prisoners;
- In order to approve research involving prisoners, the IRB must find that the proposed research falls into one of the permissible categories of research, and make six other findings;
- When the project involves funding for the project, the institution must certify to OHRP that an IRB has reviewed the proposal and made seven required findings, and receive OHRP authorization prior to initiating any research involving prisoners;
- The IRB must include a prisoner or prisoner representative, and meet a membership requirement concerning the number of IRB members not associated with a prison involved in the research; and
- Secretarial waiver of informed consent in certain emergency research is not applicable to research involving prisoners.

Definition of minimum risk for prisoner populations

The definition of minimal risk used by the IRB to evaluate the risk to the subject is different for prisoners and defined as the probability and magnitude of physical or psychological harm that is normally

encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Special composition of IRB for prisoner research review

When the IRB reviews a protocol involving prisoners as subjects the composition of the IRB must satisfy the following requirements of HHS regulations:

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB;
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

Subject becomes a prisoner during the study

When a previously enrolled research subject becomes a prisoner and the research protocol was NOT reviewed and approved by the institutional review board (IRB) in accordance with the requirements for prisoner review, the principal investigator should promptly notify the IRB of this event. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerate prisoner must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol. In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.

Categories of prisoner related research

Research involving prisoners is permissible only if the research involves one or more of four permissible categories listed below, or the research meets the criteria that applies to certain epidemiological research.

Research in the first two categories is permissible only if the research involves one or more of four permissible categories listed below, or the research meets the criteria that applies to certain epidemiological research.

Research in the first two categories is permissible only if the study presents no more than minimal risk, and no more than inconvenience to the subjects.

- (1) The study of the possible causes, effects, and processes of incarceration, and of criminal behavior;
- (2) The study of prisons as institutional structures or of prisoners as incarcerated persons;

If funded or supported by the Department of Health and Human Services (DHHS), research in categories three and four may proceed only after the DHHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research.

- (3) Research on conditions particularly affecting prisoners as a class; the regulations list as examples vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere, and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults;
- (4) Research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research. OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.

Epidemiology studies in prisoner population

There is a HHS secretarial waiver for certain epidemiological research conducted or supported by HHS that functions as a fifth category of permissible research. The criteria for this category are that the research must have as its sole purpose:

- to describe the prevalence or incidence of a disease by identifying all cases, or
- to study potential risk factor associations for a disease.

The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

Along with the requirements of subpart A (research involving prisoners), an IRB must make the following *seven additional findings* required by the regulations in order to review and approve research involving prisoners:

- (1) The research under review represents one of the categories of research permissible;
- (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired;
- (3) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- (4) Procedures of the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides the IRB with written justification for following some other procedures, control subjects

must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;

- (5) The information is presented in language that is understandable to the subject population;
- (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole;
- (7) Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Research involving children as research subjects

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child. When reviewing research with children as subjects, in addition to ensuring adherence to the general regulatory requirements of 45 CFR 46, subpart A, the IRB also considers the potential benefits, risks, and discomforts of the research to children and assess the justification for their inclusion in the research. In assessing the risks and potential benefits, the IRB considers the circumstances of the children to be enrolled in the study—for example, their health status, age, and ability to understand what is involved in the research—as well as potential benefits to subjects, other children with the same disease or condition, or society as a whole.

For any protocol involving children, the IRB must determine which of the four categories of research apply to a particular study, if any. OHRP recommends that the IRB document the rationale for this choice. The HHS regulations at 45 CFR part 46, subpart D permit IRBs to approve three categories of research involving children as subjects. A fourth category of research requires a special level of HHS review beyond that provided by the IRB.

Categories of children related research subjects

- (1) Research not involving greater than minimal risk to the children. To approve this category of research, the IRB must make the following determinations:
 - (a) The research presents no greater than minimal risk to the children; and
 - (b) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations.
- (2) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research. To approve research in this category, the IRB must make the following determinations:
 - (a) The risk is justified by the anticipated benefits to the subjects;
 - (b) The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and
 - (c) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations.

- (3) Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. In order to approve the research in this category, the IRB must make the following determinations:
- (a) The risk of the research represents a minor increase over minimal risk;
 - (b) The intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
 - (c) The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; and
 - (d) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations.
- (4) Research that the IRB believes does not meet the conditions of Categories 1-3, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. This category of research may proceed only if the Secretary, HHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines, and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of one of the first three categories or (2) the following:
- The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - The research will be conducted in accordance with sound ethical principles; **and**
 - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

Research involving pregnant women, human fetuses and neonates

Special regulations apply to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates. This type of research has not historically been done by YSU related investigators, but in the event a protocol is submitted, the IRB would follow the federal regulations governing research where pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates are used in the research. Additionally, consultants would be utilized to understand the risks/benefits related to the specific protocol. If the YSU IRB determined it was unable to evaluate the protocol adequately, the protocol would be referred to another IRB with expertise in this research type.

V. STUDENTS AS INVESTIGATORS OR SUBJECTS

Student-conducted research

As stipulated in a Statement of Authority and Purpose, all activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree

must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include:

- All master's theses and doctoral dissertations that involve human subjects;
- All projects that involve human subjects and for which findings may be published or otherwise disseminated.

All students applying for IRB review must obtain the signature of their faculty advisor on the IRB Face Sheet and the Signature Page of the Study Summary Form. Student projects will be reviewed to determine if any procedures require the faculty advisor as PI to be present during implementation.

Students as subjects

An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary, and based upon full and accurate information. The relationship of teacher and student is inherently of unequal power. No matter how well intentioned the teacher is, students may feel compelled to participate, believing that failure to do so will negatively affect his/her grades and the attitude of the teacher (and perhaps other students) toward them. The student research subjects must be fully informed and be true volunteers. The recruitment process, informed consent procedures, and data gathering procedures must be crafted such that no coercion (or perceived coercion) is placed upon the students. The teacher investigator may be asked to include in the consent forms, the name and contact information of a neutral third party to contact should a student feel coerced at any time during the process.

Additionally, if extra credit is offered for participation in the research, an alternate opportunity for extra credit must be made available for students who choose not to participate. The amount of credit offered should be equal for each student and representative of the effort required for the research project and alternate activity.

VI. MODIFICATIONS TO APPROVED RESEARCH

Once a protocol is approved, deviations from the approved protocol must not occur without permission of the IRB except where necessary to eliminate apparent immediate hazards to human subjects.

Modifications to protocol methodology: The investigator must submit the proposed changes in writing via an electronic copy and one hard copy to the Office of Grants & Sponsored Programs. The IRB chairperson will determine if the requested revision meets the criteria for minimal risk. If the change represents more than a minimal risk to subjects, it must be reviewed and approved by the fully convened IRB. Minor changes involving no more than minimal risk to the subject will be reviewed by the expedited review process as long as it is being reviewed during the period for which approval is authorized.

Revisions to informed consent documents: Minor changes to informed consent documents that do not affect the rights and welfare of study subjects, or do not involve increased risk or significant changes in study procedures may be reviewed and approved by the chairperson/designee.

Revisions to Advertisements: The IRB chairperson, or his/her designee may approve new or revised recruitment advertisements or scripts.

Translations: Translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner. There are two options available to obtain approval of translated consent forms:

Option #1: The IRB-approved consent form is translated by the Sponsor or site and submitted to the IRB. The IRB will have a member or consultant fluent in the language of the consent review the translated document for accuracy. It must match the English version.

Option #2: the investigator (or sponsor) may submit the IRB-approved version of the consent to an IRB-approved, certified translator.

VII. CONTINUING REVIEW

It may be only after research has begun that real risks can be evaluated. Therefore, the IRB conducts ongoing review of approved studies at periods appropriate to the degree of risk the human subject is exposed to during their participation in the study, but at least annually. The date that a continuing review must be conducted by is specified in the initial IRB approval document provided to the investigators. The research study must be reviewed on or before the specified date even though the research activity was not begun immediately following IRB approval. There is no grace period extending the conduct of the research beyond the IRB specified review date. If continuing review by the IRB is not completed prior to the review date, the Investigator must suspend the study and study enrollment until reports are reviewed and approved.

To undergo continuing review and obtain approval to renew the study, investigators or their designees and/or sponsors are required to provide a report to the IRB. An IRB Continuing Review Report/Renewal Request Form is available to the Investigator for this purpose. Investigators complete and submit this form electronically and hard copy to the Office of Grants and Sponsored Programs. Submission must be in time for an IRB meeting scheduled prior to the specified review date.

During the continuous review, the IRB will re-determine risk and benefits by reviewing unanticipated risks/problems, adverse event reports, protocol revisions, subject complaints, findings related to the study, reports generated from a Data and Safety Monitoring Board (DSMB), current literature, and other sources, to ascertain the status of the study and assess whether or not the risk/benefit balance is still acceptable. As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. The IRB will determine whether or not new information needs to be conveyed to subjects, or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy. The IRB will also determine the next continual review date based on the new risk/benefit assessment. A protocol that was originally reviewed using the expedited review procedure may receive its continuing review on an expedited basis. Additionally, a protocol that had no accrual during the previous approved period, or which has not been awarded funding, or which remains open only to data analysis may be reviewed using an expedited review process.

In addition to the continuous review that must occur by the IRB determined date, the investigator must also submit reports or continuous review in the event of:

- Unforeseen deviations from the approved protocol occur
- Unanticipated problems are identified
- An adverse event related to the study occurs
- A study is completed

Unanticipated Problems

All unanticipated problems must be reported by the investigator promptly to the IRB. An Unanticipated problem is defined as any unforeseen event or events that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research. Examples of an unanticipated problem include, but are not limited to: difficulty recruiting subjects; higher than expected adverse events; higher than expected subject drop out rate; higher than expected protocol deviation rate; loss of multiple staff members; injury to a staff member while conducting study-related procedures; or subject difficulty understanding the informed consent.

Adverse Event Reporting

Subject safety is of the greatest importance for both the individual subject and the goals of the clinical study. The IRB must be informed promptly of any serious, unexpected, or alarming adverse events that occur during the approval period. An IRB form for reporting adverse outcomes is available on the IRB Website, but reports of the serious adverse events will be accepted in any format. It is the investigator's responsibility to keep the IRB informed of findings that could affect the risk/benefit ratio of the research.

Adverse Event Reports will be reviewed by the IRB chairperson or designee as soon as possible. If the Chairperson determines that action may be needed to protect the safety of research subjects due to the nature or frequency of reported adverse events, he/she may take such action and/or the full IRB or designated subcommittee will review the adverse events and study in question to determine action, if any, by the IRB. The Investigator is responsible for the accurate documentation, investigation, and follow-up of all possible study related adverse events. Investigators are also responsible to work in conjunction with the IRB to inform government and other sponsors of any unanticipated or serious adverse events, as appropriate.

Completion Report

The completion or termination of the study is a change in activity and must be reported to the IRB. Although subjects will no longer be "at risk" under the study, a final report/notice to the IRB allows it to close its files as well as provide information that may be used by the IRB in the evaluation and approval or related studies.

A study can be closed and a completion report submitted when individually identifiable follow-up data are no longer being collected on subjects enrolled in a protocol and analysis that could indicate new information is complete. Completion reports should be submitted within 30 days after completion or termination of the study. Completion reports may be submitted in any format that provides adequate

information about the status of the study, such as computer printouts, telephone reports, letters, etc. The IRB Chairperson will review all reports of study completion and, if needed, request further information from the investigator to clarify any questions that may arise.

A listing of closed studies will be kept in the IRB records and are made available to the IRB members upon request.

VII. INFORMED CONSENT

The Investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative to participate in research, unless

- the research is exempt;
- the IRB finds and documents that informed consent can be waived

Legally effective informed consent means any investigator should seek consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether to participate and that minimizes the possibility of coercion or undue influence. The information provided should be in language that is understandable to the subject or the representative.

The Informed Consent process involves three key features:

- (1) disclosing to potential research subjects information needed to make an informed decision;
- (2) facilitating the understanding of what has been disclosed; and
- (3) promoting the voluntariness of the decision about whether or not to participate in the research.

Informed Consent must be legally effective and obtained prior to beginning data collection

The informed consent process is an ongoing exchange of information between the Investigator and the subject and could include, for example, use of question and answer sessions, community meetings, and videotape presentations. In all circumstances, however, individuals should be provided with an opportunity to have their questions and concerns addressed on an individual basis.

The consent process and its documentation should be revised when deficiencies in its accuracy or completeness are noted, when new information about reasonably foreseeable risks and potential benefits becomes available, or when other additional information becomes known that will improve the consent process. Such revisions must be reviewed and approved by an IRB prior to the revised consent being utilized except when necessary to eliminate apparent immediate hazards to subjects.

Informed Consent Criteria

To obtain informed consent, the following information must be conveyed to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

If appropriate, the Institutional Review Board (IRB) may determine that subjects must be provided with one or more of the following additional elements of information during the informed consent process:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

Documentation of Informed Consent

Informed Consent is documented using a written document that provides key information regarding the research. The Informed Consent Form is intended, in part, to provide information for the potential subject's current and future reference and to document the interaction between the subject and the investigator.

Waiver of Informed Consent

The IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that all of the following four criteria are met:

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

Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subjects wants documentation linking the subject with the research and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, ask shoppers in a mall about ambient lighting or temperature).

Child Assent

In addition to parent/guardian informed consent (or waiver of informed consent), child assent is required, except in the following three circumstances:

- (1) The capability of some or all of the children is so limited that they cannot reasonably be consulted;
- (2) The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
- (3) The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults.

Documentation of child assent

Based on such considerations as the child's age, maturity, and degree of literacy, the IRB will decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where an informed consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent. If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.

IX. COMPLIANCE

Researchers are responsible for complying with all IRB decisions, conditions, and requirements including continuing review submissions and notification of completion of the project. The IRB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

The IRB is responsible to ensure that only approved procedures are implemented during the study. The chairperson or a designee can be assigned to pursue information via all of the following methods or those determined by the IRB to be needed to gain a full review of the project: site visits or third party verification, review of serious and unexpected adverse events, amendments, review of significant new findings, reports from employees, staff and faculty, and/or noncompliance reports.

Projects that need third party verification from sources other than the Investigator that no changes have occurred since previous IRB review is determined, will have such assessment performed as necessary. The criteria used to determine whether third-party verification is required may include:

- Investigators that conduct studies that involve a potential high risk to subjects;
- Studies that involve vulnerable populations;
- Investigators that conduct studies that involve large numbers of subjects; and
- Investigators selected at the discretion of the IRB.

During the course of a study, the IRB may review reports from any and all pertinent sources to ascertain the status of the study and assess whether or not the risk/benefit balance is still acceptable. The IRB will determine whether or not new information needs to be conveyed to subjects, or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy. It is the responsibility of the IRB staff and members to act on information or reports received from any source that indicate a study being conducted at any facility under the jurisdiction of the IRB could adversely affect the rights and welfare of research subjects. These sources may include but are not limited to: IRB members, Investigators, subjects, institutional personnel, the media, anonymous sources, or the public. All credible reports of inappropriate involvement of human subjects in research must be referred to the IRB and investigated by the Associate Provost for Research. The results of the investigation will be reported to the appropriate YSU official(s). Regulatory authorities or sponsors may also be notified. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects. All such suspension and/or terminations will be reported to the OHRP and FDA as appropriate.

X. IRB OPERATIONS

Operations of the IRB are governed by Federal regulations that define IRB membership, communication and record keeping requirements and resource support.

IRB Membership

The YSU IRB, in compliance with Federal Guidelines shall consist of at least five regular, voting members. The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Qualified persons from multiple professions and of both sexes must be considered for membership. IRB membership shall not consist entirely of men or of women. There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall

be one member, knowledgeable about the local community, who has no affiliation with this institution, either self or family member.

Appointment of IRB members

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of the research. The IRB is appointed as an Institutional Committee. As such, IRB members serve Youngstown State University as a whole, rather than a particular department. Therefore, members must not allow their own interest or that of their department to supercede their duty to protect the rights and welfare of research subjects.

Term of Duty

Members, including the Chairperson, will serve on the IRB for a term of three years. Members are selected and appointed by the Research Compliance Officer to fulfill the Federal requirements of IRB membership. Reappointment for additional terms may occur, by mutual agreement.

Specific Duties

Nonaffiliated member(s): Nonaffiliated members are expected to attend IRB meetings and provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

Non-Scientific Members: are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects. They may be assigned as a primary Reviewer for assigned studies at IRB meetings.

Scientific members: are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects. They may be assigned as a Primary Reviewer for assigned studies at IRB meetings.

Chairperson: In addition to the above responsibilities, chair meetings of the IRB. The IRB Chairperson may exercise all of the authorities of the IRB except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the full IRB. Chairpersons perform or delegate to an appropriate voting IRB member expedited review when appropriate. The Chairperson is empowered, pending IRB review, to suspend the conduct of a study if he/she determines that participants are placed at an unacceptable risk or an Investigator is not following the IRB's requirements. The Chairperson may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Documentation of such must be in writing and maintained by the IRB record keeping personnel.

Representatives of special groups of subjects: When certain types of research are reviewed (e.g. vulnerable populations), members or consultants who are knowledgeable about the concerns of the specific group may be required. For example, if an IRB reviews research involving prisoners, a member

who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group must be included on the IRB.

IRB Subcommittees: The IRB may use subcommittees to manage a specific task of the IRB or make specific types of decisions related to IRB function. Examples are serious adverse event reports, policies/procedures, compliance audit, revision request, etc.

Termination of IRB Members: Members of the committee may be removed for demonstrated inability to carry out IRB responsibilities such as habitual missing of meetings, not providing assigned input on protocols, etc. The IRB committee makes a recommendation of removal to the Associate Provost for Research who will make the final removal decision. This officer will provide written notification of removal from the IRB to the individual.

Training of Institutional Review Board members: The IRB committee members must effectively conduct review of human subject research and protect the rights and welfare of human subjects. All IRB members and staff will be apprised of Youngstown State University's organizational structure with emphasis on the independent nature of the relationship between the IRB and Youngstown State University. The IRB manager establishes the educational and training requirements for IRB members and staff who review research involving human subjects at this institution and who perform related administrative duties. Training will ensure expertise needed for chair person responsibilities and the protection of vulnerable populations of subjects. Training and continuing education of IRB members and staff will be documented and added to the records of the IRB.

IRB staff will provide new IRB members with orientation of the mechanics of serving on the Committee. The IRB library, which provides basic reference material will be available for ongoing training germane to the responsibilities of membership.

Compensation of IRB members: Participation by Youngstown State university faculty, staff, or students is considered a component of their job responsibilities. Regular members who are not affiliated with Youngstown State University shall receive reimbursement for parking and other miscellaneous expenses.

Liability coverage for IRB members: IRB members have liability insurance coverage as part of their IRB membership in their capacity as agents of the Youngstown State University.

Use of consultants to the IRB: The Chairperson may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the Board. These individuals may not vote with the regular and alternate members of the IRB and their presence or absence will not be used in establishing a quorum for a Board meeting. Consultants will be used at the Chairperson's discretion. The consultant will be notified of privacy laws of confidentiality.

Resources

Secretarial/administrative support staff: Youngstown State University provides the IRB with sufficient secretarial/administrative staff to support IRB reviews and record keeping duties. Duties of the

secretarial/administrative staff include, but are not limited to, receipt and dissemination of protocols to IRB members, pre-IRB meeting organization, recording meeting minutes and maintaining records.

Other Resources (e.g., meeting area, filing space, reproduction equipment, computers): Youngstown State University provides the IRB with sufficient meeting space and staff to support IRB reviews and record keeping duties. Records are housed in the Office of Grants and Sponsored Programs.

IRB Meetings

Scheduling of meetings

The IRB will meet monthly (or at some other frequency according to need) as determined by the IRB to review those protocols requiring full committee review. The IRB will review proposed research at convened meetings at which a quorum is present. A quorum is defined as one half of the number of regular members plus one. A quorum consists of regular and/or their alternate members and includes: at least one member whose primary concerns are in scientific areas and one member whose primary concerns are in nonscientific areas. An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above. When FDA-regulated research is reviewed, there shall be one member who is a physician. A special consultant(s) will not be used to establish a quorum. If a member abstains from voting, the member may be used to establish a quorum. If a member recuses him/herself from deliberations and voting, the member may not be used to establish quorum for the duration of review of the item from which the member is recused. A member experiencing a conflict of interest must recuse him/herself.

Primary reviewers

Prior to the meeting, an IRB staff member may designate a primary reviewer using a rotating assignment for each research proposal. Secondary Reviewers may also be assigned. The Primary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. He or she leads the IRB discussion of the study. The Primary Reviewers may be required to review additional material requested by the IRB for the purpose of study approval. The Secondary Reviewer, if assigned, adds to the discussion as necessary.

Meeting materials sent prior to IRB meetings

All IRB members will be sent a meeting agenda and sufficient study documentation in advance of the meeting to allow time for adequate protocol review. These include as appropriate:

- Full Investigator's or Sponsor's protocol
- A completed IRB Face Sheet, Study Summary Form with a signature page and conflict of interest statement
- Proposed Informed Consent document(s)
- Copies of surveys, questionnaires, or videotapes
- Copies of letters of assurance or cooperation with research sites
- Investigator Brochure (if one exists)

- Advertising intended to be seen or heard by potential subjects, including email solicitations and physician letters
- Protocol Review Worksheet: Protocol Review Worksheet and Informed Consent Checklist

Federally Funded Projects

The primary reviewers will review the grant application, if any, to ensure that the research described in the IRB proposal is consistent with the grant application. The grant application does not need to be reviewed by every IRB member. A copy of the grant application or proposal should be retained by the IRB office and made available to any IRB member who may wish to review it. The IRB may require the Investigator(s) to: (1) summarize, and cross reference to the application, specific information contained in the grant application; (2) identify any IRB approved protocols that describe the proposed research; and (3) either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies. The Investigator must also submit any forms required for other regulatory agencies such as NIH, DOE, DHHS.

Voting Process

To transact the business of voting, a quorum of the IRB membership is required. The quorum must include the appropriate members when participants to be recruited for a project involve protected populations. When FDA regulated research is reviewed, at least one physician member must be included in the quorum. A simple majority vote of the quorum is needed to approve or disapprove a study. Each regular member (affiliated or non-affiliated) of the IRB has full voting rights as long as he/she has been able to fully review and evaluate the protocol. If an IRB staff member is serving on the IRB as a voting member that staff member will not be responsible for any administrative functions during that meeting. Specifically, he or she will not take minutes.

Proxy votes (written or telephone):

Convened meeting using speaker phone:

Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone call may vote, provided they have had an opportunity to review all the material the other members have reviewed.

Meetings conducted via telephone conference calls:

On occasion, meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place—“telephone polling” (where members are contacted individually) will not be accepted as a conference call. Members not present at the convened meeting, nor participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

IRB Communications

Investigator notifications

Initial submission: The investigator will be notified in writing of the IRB's actions as soon as possible after the meeting. If approval is pending upon receipt and review of requested materials or responses from the Investigator, the IRB must receive the response within 30 days of the date of notification; however, this period may be extended if the Investigator/sponsor communicates a need for an extension.

Notification of final approval: Investigators will be notified in writing of the final approval. The IRB-approved consent form of full and expedited projects will be dated with the approval date and submitted to the Investigator with the final approval letter.

Renewals and revisions: Investigators will be notified in writing as soon as possible as to action taken by the IRB after any revisions to initial review or future revisions and continuing reviews.

Institution notification

IRB protocols and meeting minutes are maintained in the Office of Grants and Sponsored Programs. The Research Compliance Officer has access to the records as needed.

Subject and interested parties notification

Contact information of the IRB Administrator and Primary Investigator is required on all Informed Consent documents so that these parties can obtain more information or report concerns, if necessary.

IRB Records

Written records related to the process of protecting human subjects serve as a reference to investigators and the IRB and enable compliance with Federal Regulations. Documentation of IRB Proceedings is necessary to demonstrate compliance. Adequate documentation of the IRB activities will be prepared, maintained, and retained in a secure location in the Office of Grants and Sponsored Programs. Records must be accessible for inspection by YSU auditors, regulatory agencies and authorized representatives of the study Sponsor or funding department at reasonable times and in a reasonable manner.

Confidentiality of records

All material received by the IRB will be considered confidential and will be distributed only to IRB participants (investigators, regular members, alternate members, and special consultants) for the purpose of review. All application materials will be stored in an IRB study file with access limited to IRB members and staff. Consultants and visitors will be expected to sign Confidentiality Agreements.

IRB Administration Documents

Roster of IRB members: The roster will include regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations; and any employment or other relationship between each member and IRB and/or Youngstown State University (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid

or unpaid consultant). The roster shall indicate the regular member for whom the alternate may substitute. Obsolete membership rosters will be archived according to YSU policy.

Prisoner representative: For review of protocols using prisoners as subjects, there must be a prisoner representative on the roster who contributes to the quorum for that IRB review meeting. The IRB roster must specifically identify the voting member who is the prisoner representative. The roster may stipulate that the prisoner representative will only count towards quorum when he or she is in attendance and reviewing studies covered by subpart C of the Federal Guidelines.

IRB meeting minutes

Minutes of IRB meetings must record the proceedings of the IRB meeting in sufficient detail to enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions. The IRB record keeper will take minutes of each meeting using an IRB Agenda/Minutes Template. Minutes will include in sufficient detail:

- Meeting attendance, including status of each attendee (regular member, consultant, etc.), and conflicts of interest, if any;
- Determination that a quorum to conduct business has been established or not
- Actions taken by the IRB on each agenda item requiring full IRB action, including the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- Voting results, including number for, against and members who recused themselves and reasons for recusal;
- Approval of IRB minutes: Draft minutes will be distributed to members at the next IRB meeting for review and approval;

Corrections requested by the IRB will be made by the IRB Record Keeper and the minutes will be printed in final form and made available to members at the following meeting.

Budget and accounting records

The YSU IRB has no independent budget separate from the Office of Grants and Sponsored Programs. Funds for chairperson compensation and IRB staff and member training and reimbursement are provided from the OGSP budget as needed. Material, other supply, and copying costs also come from this budget.

Document retention

The IRB record files must maintain a complete history of each protocol submission. The IRB Office must retain all records regarding an application (regardless of disposition) for at least three (3) years (3 years required for FDA studies). For all applications that are approved and the research initiated, the IRB office must retain all records regarding that research for at least three (3) years after completion of the research.

Retained documents include but are not limited to:

- Initial Protocol application material, approved consent documents, continuing review reports, protocol amendment reports, adverse event reports, site visit reports, reported deviations from the protocol, and completion of study report;
- Copies of grant applications/research proposals that have been submitted to the IRB for review will be maintained with the protocol file;
- Agendas and minutes of all IRB meetings;
- Copies of all correspondence between the IRB and the Investigators;
- Statements of significant new findings provided to subjects;
- Reports of any complaints received from subjects.

Destruction of copies

All material received by the IRB which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the meeting and destroyed by a method deemed appropriate by the Associate Provost for Research.

Archiving and destruction

After three (3) years, all documents and materials germane to IRB determinations will be archived according to YSU policy. Archiving policies of YSU will determine when such archived records may be destroyed.