PROTECTION

OF

HUMAN RESEARCH SUBJECTS

WAYNESBURG UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Reviewed by Jason M. Reiser of Pepper Hamilton LLP

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INSTITUTIONAL REVIEW BOARD
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INSTITUTIONAL REVIEW BOARD
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CHAPTER I
INTRODUCTION

A. Purpose

It is important that all individuals associated with Waynesburg University (sometimes referred to as the "University") be aware of applicable legal and ethical considerations when conducting activities and research involving the participation of humans. An awareness of the rights of individuals, their health and safety, and the confidentiality of their participation is necessary in an institution of higher learning.

The intent of this document is to bring the aforementioned awareness into the classroom and laboratory, into the office, and into the thought processes of all persons in this educational institution so that proper procedures can be followed without violating human rights or ethical principles of conduct, or exposing the participants to undue risk or liability.

Departments of Waynesburg University and all those who represent or are employed by the University must ensure that all individuals conducting research involving the participation of human subjects are in compliance with the following policies and with any other ethical considerations that may apply.

This entire document is a modified and edited version of the document kindly provided by West Virginia University, Morgantown, West Virginia, and Institutional Review Board for the Protections of Human Research Subjects Guidelines, Fall 1992.

B. Basic Definitions

"**Activities**" are defined as any planned protocol using humans: (1) as part of a classroom or laboratory exercise that may be either experimental or a part of work required for a course; (2) as part of a survey or interview or exercise occurring on or off the premises of Waynesburg University.

"**Human subject**" is defined as any living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. A human subject may be either a healthy individual or one with a medical condition or disease. The term "subject" is used interchangeably in this document for ease of reference.

"**Identifiable information**" is defined as information that is individually identifiable (for example, the identity of the subject is or may readily be ascertained by the Investigator or associated with the information).

"**Interaction**" is defined as communication or interpersonal contact between the Investigator and the human subject.

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

"**Private information**" is defined as information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

"**Protocol**" is defined as the formal design or plan of research or scholarly activity; any protocol submitted to the IRB must include the elements specified in the individual application.

"**Research**" is defined as a systematic investigation designed to develop and contribute to generalizable knowledge.

C. Institutional Review Board Membership

The Institutional Review Board, hereinafter referred to as the IRB, will act as Waynesburg University's review group for the Protection of Human Subjects for both research studies and quality improvement projects. The IRB functions under the general direction of the Provost, who is the institutional representative under mandate of the President of Waynesburg University, the Office of Human research Protections (OHRP), and the Federalwide Assurance (FWA). The IRB meets approximately once a month during the regular academic year and other times as needed.

The IRB consists of seven members including at least two members whose primary concerns are in scientific areas and at least two members whose primary concerns are in non-scientific areas. Further, at least one (1) member shall not be affiliated with Waynesburg University or an immediate family member of a person affiliated with Waynesburg University. The IRB may not consist solely of members of one profession, and every effort will be made to ensure that the IRB does not consist entirely of one gender, one culture or one academic department. At least one member will represent the perspective of research participants and may be the same person as the unaffiliated member.

The IRB may also designate two alternate members (one scientist and one non-scientist) who will attend meetings, have access to protocols, and review protocols with primary and secondary reviewers. Alternate members are also appointed by the Provost. Alternate members may vote only if a regularly appointed IRB member from their respective background (scientific/non-scientific) is unable to vote. Any alternate member will assume the duties of the regular member who he/she is replacing.

Individuals appointed to the IRB will serve three-year terms and may be appointed to two consecutive terms on the IRB. Appointments will be made by the Provost after consultation with the Professional Development Committee. Appointments will be staggered years to allow for a systematic rotation on and off of the IRB while providing continuity of understanding and experience. IRB members are required to declare all conflicts of interest including, but not limited to: financial, academic, professional and

personal in accordance with the University's respective written policies. All IRB members, including alternates, will provide evidence of completion of approved education in the protection of human subjects. National Institutes of Health (NIH) or Collaborative Institutional Training Initiative (CITI) training is recommended, other programs will be considered with proper documentation. Training must be current within five years. No compensation is paid for IRB participation.

The IRB will have an administrator appointed by the Provost. The IRB administrator will be a non-voting, ex-officio member who bears the responsibility of receiving, logging, and maintaining complete communication files for all IRB applications/protocols. The IRB administrator, in conjunction with the IRB Chair, may also assign incoming applications/protocols to IRB members for primary and secondary review. In addition, the IRB administrator will ensure accurate records of IRB Committee activities are kept and reported to the Professional Development Committee.

The Chair of the IRB will be appointed by the Provost and should be a person who possesses background knowledge and expertise in the rigors of academic research. The duties of the Chair of the IRB are to ensure appropriate and fair assignment of incoming IRB applications/protocols, in consultation with the IRB administrator. The Provost has the discretion to also appoint a Vice-Chair to assist with a smooth transition of Chair duties. The IRB Chair will assign both research and quality improvement protocols to IRB members for primary and secondary review, plan and preside over all IRB meetings, communicate with Principal Investigators, educate Waynesburg University faculty and staff about IRB laws and processes, and report substantive committee business and/or messages to the full faculty.

Additional duties of the IRB Chair are: be prepared to discuss, along with the primary and secondary reviewers, each research or quality improvement protocol at each IRB meeting; convene and preside over all IRB meetings, with special attention to full-board review hearings; and approve or designate approval responsibility for exempt, expedited and quality improvement reviews without full board review. The Chair of the IRB or designee may request amendments to, or additional information for, expedited reviews but may not deny expedited reviews without consultation with, and approval of, the full board.

The appointed Chair can serve a maximum of six (6) consecutive years. The Chair may subsequently serve an additional three (3) years on the IRB committee to facilitate a smooth transition of Chair duties.

The IRB may, at its discretion, invite individuals to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote. Consultants are subject to the University Conflict of Interest policies. Consultants must declare in writing that they have no conflicting interest regarding their review of the protocol. Any consultant must be informed of and understand the background, aims and methods of the research.

D. Governing Principles

Respect for individuals and their rights and welfare are the basic tenets underlying these guidelines. These IRB guidelines are based on the following general ethical principles:

1. The rights and welfare of all human subjects must be adequately protected. This principle applies to the need to safeguard the physical and psychological well-being of a human subject and to preserve the rights of privacy and self-determination.

2. Risks must be minimized using procedures which are consistent with sound research design and do not unnecessarily expose human subjects to risk. Whenever appropriate, investigators should use procedures that are generally acceptable for this activity when conducted in the scientific or academic community. In addition, risks to personnel not directly involved with the activity must be minimized and all precautions taken so those peripherally associated with the activity are not subjected to risk.

3. Risks must be reasonable in relation to anticipated benefits to subjects or to importance of the knowledge that may be gained. The IRB reviews research and activities for scientific merit with respect to the risk or benefit to human subjects, including the anticipated benefits from the knowledge that may be expected to result. Payment for participating in the research is not considered a benefit. In addition, the IRB shall not consider the possible long range effect(s) of applying the knowledge gained through the research as a benefit when making such a determination.

4. Recruitment and selection of human subjects must be equitable within the confines of the purposes and design of the research.

5. Informed consent must be obtained from each prospective participant or the participant's authorized representative in advance of research participation.

    a) The informed consent process must be documented by a written "consent form," a copy of which must be given to the human subject. Final approved consent forms must bear an official IRB approval stamp.

    b) To the fullest extent possible, the human subject's consent must be based upon an understanding of the research, the risks, possible discomfort, benefits, and alternative options, if any.

    c) The informed consent document must provide for the human subject's ability to refuse participation or to discontinue participation at any time without prejudice.

6. Provisions must be made to monitor data to ensure the safety of human subjects.

7. Adequate provisions must be made to protect the privacy of human subjects and the confidentiality of data. In addition, the IRB must be satisfied that questionnaires and protocols involving sensitive issues (which could, if they became known outside the setting, place the subject at physical or social risks) are carefully designed to avoid gathering more private information than is absolutely essential to the research.

8. Additional safeguards must be included in the protocol to protect the rights and welfare of human subjects who are likely to be vulnerable to coercion or undue influence.

E. Authority of the IRB

The IRB has the authority and responsibility to approve and monitor compliance with sound ethical principles and applicable regulations of all activities involving human subjects conducted by Waynesburg University faculty, staff, or students. In particular, the IRB has the authority to:

1. Approve or disapprove a protocol or to require revisions to a protocol/application (including the consent form) as a condition for approval;

2. Oversee the conduct of a study and require progress reports; and

3. Suspend or terminate a study, or impose restrictions or require modifications to a study as a condition for continuation.

The IRB **DOES NOT** have the authority to grant retroactive approval once human subjects have already been involved.

An Investigator whose protocol has been disapproved, modified, restricted, suspended, or terminated by the IRB may request the IRB reconsider the protocol.

F. Responsibilities of Investigators

1. Principal Investigators must be either Waynesburg University employees or doctoral-level students, operating within their proper roles of the University in conducting the study. The faculty member must be listed as the Principal Investigator with the student listed as a sub-investigator for undergraduate and master level students.

2. Individuals wishing to conduct activities or research projects that involve human subjects must submit a written protocol describing the project to the IRB administrator.

3. If the requested protocol meets exempt or expedited review criteria, the IRB Chair or designated committee member(s) has(have) the authority to review, grant approval and request revisions. If denial of the protocol seems appropriate, full IRB review is required. In such cases, the IRB will review the protocol at its next regular meeting. The IRB Chair has the right to request full IRB review and discussion of any IRB/QI application/protocol.

4. If the requested protocol meets neither exempt nor expedited review criteria, the protocol will be reviewed by the full IRB at the next meeting.

5. Research projects must receive approval from the IRB **BEFORE** investigators involve human subjects in the study or begin ANY part of recruitment or data collection. Failure to comply with this requirement is a direct violation of Waynesburg University policy and may result in discipline up to and including dismissal from the University.

6. Investigators must receive approval prior to making **ANY** changes to a protocol including addition of investigators; change of venue; or revision of consent forms, assent forms or procedures.

7. Investigators must comply promptly with all IRB requests for information concerning a protocol (e.g., revisions or monitoring report). Following requests for additional information, protocols will remain pending for a maximum of 90 days at which time they will be closed or rejected.

8. Investigators must notify the IRB of any intended changes, adverse reactions, unforeseen events, termination of human subject involvement, and completion of study.

9. Investigators must maintain appropriate credentials to conduct the portion(s) of the study in which they are involved and apprise the IRB of any changes to their qualifications.

10. Investigators are requested to forward a final closure report to the IRB: (1) upon completion of all phases of the study, or (2) when the approval period has ended without investigator request of continuation. If closure report is not received by the IRB administrator, the protocol will be administratively closed in compliance with Federal Law (364 days after most recent approval).

G. Underlying Legal, Regulatory and Ethical Standards

1. Department of Health and Human Services Title 45 CFR Part 46: Protection of Human Subjects

2. Food and Drug Administration, Title 21 CFR Part 50: Protection of Human Subjects

3. Food and Drug Administration, Title 21 CFR Part 56: Institutional Review Boards

4. National Institutes of Health, Office of Human Subjects Research: The Belmont Report; Ethical Principles and Guidelines for the Protection of Human Subjects of Research

CHAPTER II
CATEGORIES AND PROCEDURES FOR REVIEW

No contact with human subjects is permitted prior to official IRB approval date. This includes advertisement to and recruitment of human subjects. No IRB member may review a protocol (both initially and on a continuing basis) if he/she has a conflict of interest.

All research or activities fall into one of the following three categories:

1. Research or activities exempt from review by the IRB, including quality improvement projects;

2. Research or activities that may be eligible for expedited review by the IRB; or

3. Research or activities that require full review by the IRB

A. Research or Activities Exempt from Review by the IRB

There are six categories of research or activities that are generally exempt from review by the IRB:

1. **Normal Educational Practices and Settings** - This category is limited to the study of normal educational practices and are conducted in commonly accepted settings such as elementary, secondary, or postsecondary settings.

2. **Anonymous Educational Tests, Surveys, Interviews, or Observations** – If the research data contain any subject identifiers and if disclosure of data to unauthorized persons could harm the subject in any way, the research is not exempt.

3. **Identifiable Subjects in Special Circumstances** – These include tests, surveys, interviews or observation of public behavior if the subjects are elected or appointed public officials or candidates for public office.

4. **Collection or Study of Existing Data** – The data must be publicly available, or the information derived from use of the data, records, or biological specimens must be recorded so that subjects cannot be identified.

5. **Public Benefit or Service Programs** – This includes research and demonstration projects that are conducted by or subject to the approval of governmental department or agency heads, such as Welfare, Medicaid, and Social Security.

6. **Taste and Food Evaluation and Consumer Acceptance Studies** – This should be limited to taste and food quality evaluation studies that do not

involve consumption by the subject of any type or volume of food that has any potential risks.

Research or activities falling into one of the above categories and for which there is minimal or no risk (defined below) to human subjects may be considered by the IRB to be exempt from IRB review. Investigators who believe that their project or study is exempt should file an "Application for Determination of Exemption" with the IRB (see form attached). These studies MUST be approved as exempt by the IRB for before any part of the research is begun.

Generally, the following types of research or activities are not eligible for exemption:

1. Studies in which subjects will be asked to sign consent forms;
2. Studies in which subjects are filmed or videotaped;
3. Studies in which the investigator attempts to influence or change a subject's behavior;
4. Studies in which subjects are asked to perform physical tasks beyond those encountered in ordinary daily life; or
5. Studies in which deception is employed

"Minimal or no risk" means that the probability and/or magnitude of physical or psychological harm does not exceed that encountered in ordinary daily life or during routine physical or psychological examinations or tests.

Although informed consent may not be technically required for exempt projects, the IRB reserves the right to require such informed consent. The basic elements of informed consent should be communicated to each human subject participating in an exempt study. This may be accomplished by means of a consent form or by a cover letter or information sheet.

Quality Improvement Projects: Although federal law does not require ethical oversight of Quality Improvement Projects, Waynesburg University has entrusted ethical oversight of Quality Improvement Projects to the IRB to ensure protection of subjects, employees, and protected health information. See Appendix A: HIPAA Policy.

B. Research or Activities Eligible for Expedited Review

Research or activities that (1) present minimal or no risk to human subjects and (2) involve procedures set forth in the lists published in the Federal Register pursuant to 45 CFR 46.110 and 21 CFR 5.110, may be reviewed by the IRB through an expedited review procedure. Investigators seeking expedited review should complete and file an "Application for Full or Expedited Review," and indicate on that form why they believe the project qualifies for expedited review. The signed consent of human subjects is required for all projects for which expedited review is sought.

Expedited reviews can be approved by the IRB chair or designee (experienced reviewer) without going to committee. Full IRB review is required if the reviewer has concerns about the protocol.

C. Research or Activities That Require Full Review by the IRB

Protocols for research or activities involving human subjects who do not fall under categories A and B above require full IRB review as set forth in Chapter VIII.

Protocols involving participants under the age of 18 years or protocols involving deception of human participants always require full IRB review.

CHAPTER III
PROTOCOL ELEMENTS

The required elements are included on each electronic application; applicants will find descriptors of elements on each application. This chapter includes additional details for specified elements.

A. Investigators

The Principal Investigator and all sub-investigators must be identified in the protocol.

B. Vulnerable Subjects

Vulnerable subjects include human fetuses, neonates, prisoners, parolees, incarcerated subjects, children, persons with physical handicaps, persons with mental disabilities, economically disadvantaged, educationally disadvantaged, cultural minorities, the very sick, and any institutionalized individual. The inclusion of human subjects from any of these populations may raise added concerns about research risks and the informed consent process because such subjects may be vulnerable to injury, coercion, or undue influence. Should an Investigator wish to change the protocol at a later date to include any of these populations, the Investigator must submit an amendment and receive approval from the IRB prior to continuing the study with such subjects.

The following populations are considered vulnerable under some circumstances:

1. Women - if the study includes risk to pregnant or potentially pregnant women

2. Associates of the Investigator(s) - if any Investigators have influence over evaluation, employment standing, or selection for team participation

3. English as a Second Language or illiterate human subjects - unless study materials are presented in their native language or appropriately interpreted

C. Items of Special Concern

The items listed below raise special concerns about safety, privacy, confidentiality, or other regulatory matters. PLEASE NOTE: If any of the following are involved, full IRB review may be required.

1. Sensitive topics include: sexual orientation, sexually-transmitted diseases, incest, rape or date rape, sexual harassment, molestation, race relations, use of licit or illicit drugs, eating disorders, abortion, contraception or pregnancy, the subjects' own mental health (suicide, depression, and compulsive behaviors), religion, illegal conduct, stressful experiences;

2. Use of existing data collected from medical records;

3. Generation of data to be stored in data banks, archives, medical records;

4. Filming, videotaping, or voice recording of subjects; or

5. Deception of human subjects

D. Signatures

The IRB will not review protocols without **ALL** appropriate signatures. By signing, department chairs/program directors acknowledge approval of the study on the basis of scientific merit and compliance with applicable professional standards; dean and/or other administrators signify their approval of the use of resources and faculty and student effort on the study.

E. Abstract

The abstract is a brief summary of the purpose and procedures written in language that can be understood by the non-specialist. Language should not exceed 8th grade reading level. The IRB may request investigators to submit grade reading level assessment from Microsoft Word or comparable word processing program for consent/assent forms and advertisements.

F. Intervention

Describe and explain any intervention that may be legally required or ethically appropriate. Intervention may be necessary in response to adverse reactions during or following experimental procedures used or in response to a physical or psychological reaction (e.g., abnormally elevated heart rate or blood pressure; allergic reactions; extreme fear, anger or anxiety). Intervention may not require action by the investigator beyond an appropriate referral.

G. Confidentiality

Explain how and to what extent confidentiality will be maintained for records that identify a subject. Describe how audiotapes, videotapes, and/or electronic data files will be stored and secured during the study. Include how they will be disposed of at the end of the study.

H. Attachments

Attachments to the protocol include advertisements, scripted communication or telephone texts to be used in recruiting subjects, a copy of surveys or other test instruments that will be used, and permission to use (if the survey is not owned by the Principal Investigator). Written permission for Investigators to use facilities or resources other than Waynesburg University will be required.

1. Provide a copy of each survey or other test instrument. Include communication of "permission to use" if proprietary.

2. Provide other appropriate attachments.

CHAPTER IV
CHANGING A PROTOCOL

If changes to a protocol become necessary, Investigators must obtain IRB approval prior to instituting such changes. When changes to a protocol are submitted for approval, the entire amended protocol and consent form(s) are subject to review for compliance with current IRB standards. Minor changes may be approved by the IRB Chair. Major changes may require full IRB review.

A. Definitions

"Major" changes are those which directly affect the level of risk to the subjects. Examples include the addition of new, vulnerable populations as subjects, any change in strategies or interventions, or study site location.

"Minor" changes are those which do not affect the level of risk to subjects. Examples include changing the project duration, increasing or decreasing the sample size, changing co-investigators, or substituting comparable questionnaires or test instruments. Minor changes may be approved by the IRB Chair or designee but are also eligible for full IRB review if requested by the Principal Investigator, IRB Chair, or designee.

If you have any doubt as to whether proposed changes qualify as major or minor, contact a member of the IRB.

B. Emergency Changes

If changes to a protocol become necessary to avoid an **IMMEDIATE HAZARD** to subjects, you may make those changes without prior IRB approval but must attempt to obtain authorization from the IRB Chair. Whether or not you receive such authorization, you must notify the IRB within five (5) days of making an emergency change and must submit a written request to amend the protocol within ten (10) days. The IRB will review the request to amend the protocol and also determine whether any change made without prior approval was justified.

C. Adverse Event

An adverse event is an unanticipated (and possibly related) event that places subjects at a greater risk of harm that was previously unknown. Any suspected adverse events must be reported to the IRB using the Adverse Event Reporting form. The research/project should be halted, and the Principal Investigator should seek consultation with the IRB.

CHAPTER V
INFORMED CONSENT

A. Consent

General Rule: Written informed consent is required except when the research involves minimal or no risk to the subjects.

Informed consent is a person's documented, voluntary agreement that is based upon adequate knowledge, provided at a grade reading level appropriate to the majority of intended subjects, and comprehension of relevant information to participate in research activities.

Obtaining informed consent from a subject is a two-step process: (1) giving the subject sufficient information at the subject's level of comprehension to enable an "informed" decision about participation, and (2) obtaining his/her consent (if he/she chooses to participate) in a manner that documents the information that was given and that the subject's consent was obtained prior to the collection of any data.

Legally, minors (individuals less than 18 years old) cannot give consent on their own behalf. The consent of their parents or a legal guardian is required.

The IRB shall determine, in accordance with and to the extent that consent is required, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 (minimal risk) or 45 CFR 46.405 (greater than minimal risk, potential for direct benefit). Where research is covered by 45 CFR 46.406 and 45 CFR 46.407 (greater than minimal risk, no prospect of direct benefit) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Permission is required to be obtained from both parents or guardians, if reasonably available and competent to consent, even when the research potentially offers direct benefit, when:

- The research presents significant increases in magnitude or probability of risk, above the alternative approaches; or
- The research procedure is so novel that the risks are unknown; or

- The research presents potential risks that could be life threatening or severely debilitating, or that have the potential to cause major irreversible morbidity (e.g., blindness, hearing loss, paralysis, stroke).

A parent is "reasonably available" if the parent's role in the care and/or decision-making of the child, even on a limited basis, is such that his or her involvement and availability may be readily ascertained from University records; or the parent's whereabouts are known at the time the child is approached for research purposes.

If, in situations in which the above referenced criteria are met, the investigator is unable to make contact with the parent, the investigator is to document the attempts made, including the date of the attempt and the method of attempted contact (e.g., phone, fax, email). After multiple attempts at contact parents have been made (usually three at a minimum), it may be reasonable to conclude that the parent/guardian is not reasonably available.

Researchers wishing to utilize surrogate consent when the research involves incapacitated subjects (i.e., those unable to provide consent themselves) will be asked to provide additional information regarding this population in addition to completing the electronic submission form in full. In each case, a "Legally Authorized Representative" must provide consent for the incapacitated subject. A Legally Authorized Representative is defined as *"an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research" (45 CFR 46.102(c); 21 CFR 50.3(l))*. The Legally Authorized Representative is considered to be providing consent by substituted judgment, which means that *"the decision is based on what the ward would have preferred or decided if competent".*

The following individuals may be considered legally authorized representatives of the subject and capable of providing surrogate consent (or surrogate HIPAA Authorization):

- A court-appointed guardian authorized to consent to the subject's participation in the protocol in a current court order issued within the subject's jurisdiction.
- A health care agent appointed by the subject in a power of attorney.
- A "health care representative" when the subject cannot speak for themselves and where there has been no guardian appointed by the court or health care power of attorney designated by the patient. (PA Act 169). Any member of the following classes, in descending order of priority, who is reasonably available may act as the subject's health care representative:
    - The spouse (unless an action for divorce is pending) and adult child or children of another relationship;
    - Adult children (18 years of age or older);
    - A parent;

- An adult sibling;
- An adult grandchild; and
- An adult who has knowledge of the patient's preferences and values, including but not limited to religious and moral beliefs, to assess how the patient would make decisions.

1. Format and Style of the "Consent Form"

   The consent form must adhere to the following requirements:

   a) Print on departmental letterhead of the Principal Investigator. If scholarly project is to be conducted at a healthcare facility, this document may be printed on letterhead bearing that facility's identity.

   b) Include introduction, purpose, description of study, risks/discomforts, benefits, contact information for Principal Investigator and IRB Chair, confidentiality, and voluntary participation. For multi-page consent forms, each page must include page numbers, total number of pages, and initials of both subject and Principal Investigator. For amended consent forms, each page should also include version number and date amended.

   c) Distribute as legible copies.

   d) Use understandable language throughout at a reading level not to exceed 8th grade for consent by lay public or 4th grade for assent. Grade reading level of consents intended for professional subjects should be at a reading level commensurate with the intended subjects expected level of education. If reading is not an inclusion criterion, PI must address modified consent procedure in protocol.

2. Elements of the "Consent Form"

   The consent form must contain all applicable items listed below (items a-l). The IRB may waive any of these requirements upon the written request of the investigator. Written request must include explanation of why the provision is unnecessary or inappropriate. The IRB does not permit language by which the subject or his or her representative waives any of the subject's legal rights or releases the investigator, the sponsor, the institution or its agents from liability for negligence.

   a) The words "Consent Form" at the top of the page

   b) The complete title of the study must be provided

c) “Introduction”

(1) Include the following statement or its equivalent: “I have been asked to participate in this research study.”

(2) Inform participants if the research is being done to fulfill requirements for a classroom assignment or academic degree.

(3) Identify any external sponsor or funding agency.

d) “Purpose”

Explain why the study is being conducted.

e) “Description” or “My Involvement”

(1) Describe the procedures to be followed, specifically identifying any experimental procedures.

(2) Include a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the human subject.

(3) State the expected duration of the subject’s participation.

(4) Describe location of where research will take place.

(5) State the approximate number of subjects in the study, as appropriate.

(6) Explain the randomization process and the likelihood of the subjects being assigned to an alternative.

(7) Explain any special circumstances under which you would terminate the subject’s participation.

(8) If questionnaires or interviews are involved, inform subjects that they can see them before they sign the consent form and that they do not have to answer all of the questions.

(9) Subjects must be informed that appropriate care will be available, or an appropriate referral will be made, if a particular problem is discovered, and if they have an adverse physical or psychological reaction to the study.

(10) Explain whether any compensation is being provided to subjects for participation in the study.

f) Additional elements of informed consent: When appropriate, one or more of the following elements of information shall also be provided to each human subject:

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

(2) Anticipated circumstances under which the human 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 human subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of human subjects involved in the study.

g) "Risks" or "Risks and Discomforts"

Describe any reasonably foreseeable risks or discomforts to the subject.

h) "Benefits"

Describe any anticipated benefits to the subject or to others (such as generalizable knowledge).

i) "Contact Persons"

(1) In studies involving more than minimal risk, application/protocols will state the name of the person(s) who should be contacted in the event of a research-related injury.

(2) Provide the name(s) and telephone number(s) of the Principal Investigator(s). If available, you may also include e-mail contact information for the Principal Investigator.

(3) Inform subjects that, if they have questions concerning their rights as subjects of research, they may contact the IRB Chair.

The consent form should include telephone contact information of the current IRB Chair.

j) "Confidentiality"

(1) The following statement is mandatory (If anonymous data, this statement is not required):

"I understand that any information about me obtained as a result of my participation in this research will be kept confidential."

(2) Explain any foreseeable circumstances under which the investigator might be required to give information about the subjects to third parties.

k) "Voluntary Participation"

(1) State that participation is voluntary.

(2) State that refusal to participate or withdrawal from the study involves no penalty or loss of benefits to which the subject is entitled, that grades and class standing will not be affected (for students or trainees), that status on an athletic team or curricular participation will not be affected, and that job standing will not be affected (for employees or associates). If students are to receive class credit, other opportunities (requiring comparable amounts of student effort) must be available to earn comparable credit, and the consent form must so indicate.

(3) State that the subject's questions about the research have been answered.

(4) Include a statement informing subjects they will receive a copy of the signed consent form.

l) Include lines for the following signatures and dates for each:

(1) The subject or the subject's authorized representative

(2) The Principal Investigator

B. Assent

For minors from 7 to 17 years old, the assent or affirmative agreement of the minor to participate in the study must be obtained and documented. Assent documents should be grade-level appropriate; however, they should not exceed the 4th grade reading level.

C. Signatures

Investigators must obtain legally valid informed consent/assent from each human subject or from the human subject's authorized representative prior to beginning any research activities. Human subjects document their consent by signing a written consent/assent form. The IRB must approve all consent/assent forms.

CHAPTER VI
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

The Privacy Rule, at 45 CFR parts 160 and 164, establishes a category of health information, defined as Protected Health Information (PHI). Protected Health Information includes:

Names Telephone numbers Email addresses Social Security numbers Medical records numbers Fax numbers Health plan beneficiary numbers Account numbers Certificate/license numbers Vehicle ID & serial numbers, license plate numbers Device identifiers & serial numbers Web URL's IP addresses Biometric ID's, including finger and voice prints	Full face photographic images & comparable images All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, & their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the current publicly available data from the Census Bureau, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and [t]he initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older Any other unique identifying number, characteristic, or code, except as permitted in section immediately above

If any Investigator or other member of a research project team will have access to any PHI element, you must either obtain informed consent from subject or apply for Waiver of Authorization.

CHAPTER VII
MONITORING RESEARCH

A. Authority of the IRB

The IRB has the authority and responsibility to monitor all research involving human subjects, in consultation with the Provost.

The IRB can legally approve research projects for a maximum of 364 days after approval. Interim monitoring reports may be required.

The IRB will monitor current protocols at its regular meetings. Upon reviewing a Monitoring Report for a project, the IRB will take one of the following actions with respect to that project:

1. Approve the project for renewal;
2. Approve the project conditionally for renewal;
3. Require additional information prior to approval of the project for renewal; or
4. Suspend or terminate the research.

B. Scholarly Misconduct or Non-compliance with the Review Process

Scholarly misconduct or non-compliance with the review process may result in suspension or termination of the project or more serious discipline as approved by the Provost.

The U.S. National Science Foundation defines three types of research misconduct: fabrication, falsification, and plagiarism.

1. *Fabrication* is making up results and recording or reporting them. A more minor form of fabrication is where references are included to give arguments the appearance of widespread acceptance, but are actually fake, and/or do not support the argument.
2. *Falsification* is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record.
3. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

C. Reporting by Investigators

1. Injuries/Unanticipated Events

   The Principal Investigator must report in writing all study related injuries (physical or psychological), adverse reactions, complaints, unanticipated problems, or breaches of confidentiality to the IRB within 72 hours of the occurrence. The IRB will review the report and determine whether any change to the protocol or the consent form including possible suspension or termination of the study is indicated.

2. Periodic Review—Amendment, Renewal and Monitoring Reports

   An Amendment, Renewal and Monitoring form is required if a Principal Investigator wishes to renew or amend an approved project.

   a) Amendment: Investigators must seek approval of the IRB prior to making any changes to an approved protocol. No changes may be made to an approved protocol without acceptance of this form.

   b) Renewal: Research that is not complete within the 364 day initial approval period must be renewed prior to the expiration date. If renewal is not sought by the investigator prior to the expiration date, the existing protocol will be administratively closed by the IRB committee/Chair. If further scholarship on this same topic is to be continued, the Principal Investigator will be required to submit a new protocol before continuing this research.

   c) Monitoring: The IRB has the authority to require Principal Investigators to submit monitoring reports at any time.

3. Closure Reports

   The Principal Investigator must submit a written report to the IRB when the study is completed. This report will generally outline the number of subjects participating in the study, their experiences, a summary of the results, and observed risks and benefits.

4. Comprehensive Review

   In addition to standard monitoring, the IRB may undertake a comprehensive review of any approved project, at any time, including on-site inspection of all records pertaining to the research.

CHAPTER VIII
IRB REVIEW PROCEDURES

A. Submission Procedures and Dates

Protocols requiring full or expedited review must appear on the agenda of the regular IRB meeting. Such protocols will only be reviewed at convened meetings of the IRB at which a quorum of greater than half of the voting IRB members are present. A simple majority of the members present must approve each proposed protocol. The IRB requires an original of each protocol by the 15th of the month preceding the meeting at which the protocol is to be discussed. Protocols submitted too late may be placed on the current month's agenda or may be held for the next meeting, depending on the current workload of the assigned reviews. Any protocol receiving approval via exempt review will appear in the minutes of the meeting immediately succeeding the approval.

B. Criteria for IRB Review

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

1. Risks to subjects are minimized;

2. Risks to subjects are reasonable in relation to anticipated benefits;

3. Selection of subjects is equitable;

4. Informed consent will be secured to the extent required by law;

5. Informed consent will be appropriately documented;

6. Adequate provisions are made for monitoring data to ensure safety of subjects;

7. Adequate provisions are made to protect the privacy of subject and maintain confidentiality; and

8. Adequate provisions are made to protect subjects who are vulnerable to coercion or undue influence

C. Action by IRB

After reviewing a project, the IRB will take one of the following actions with respect to the project:

1. Approval: The protocol and consent forms are satisfactory, and therefore the Investigator may begin research immediately. Once a protocol is approved, no amendments or addenda may be made without a subsequent review and approval.

2. Conditional Approval: The project is not satisfactory as submitted; the Investigator must make minor modifications or revisions to the protocol

and/or consent forms as directed by the IRB. These modifications are then reviewed by the IRB Chair (acting on behalf of the IRB) who may then recommend approval by expedited review.

3. Deferral: The IRB has insufficient information to reach a definitive conclusion or requires major changes to the protocol and/or consent forms; the Investigator will be asked to revise the applicable documents for full IRB review at a later meeting.

4. Disapproval: The protocol places human subjects at unacceptable risk relative to benefits, and/or the research project as designed and described is not suitable for involvement of human subject participants.

Whenever possible and desirable, the Investigator or his/her designee will be present (or available for a conference call) at the portion of the meeting in which his/her proposal is under consideration in order to clarify relevant portions of the protocol and project. All decisions of the IRB with regard to a protocol shall be communicated in writing to the Principal Investigator. The Principal Investigator shall be responsible for notifying the sponsor of the IRB's decision.

D. Minutes

The IRB will keep minutes of its proceedings; these will be in sufficient detail to show attendance at meetings, actions taken, the vote on those actions, the basis for requiring changes in or disapproving a project, and a written summary of the discussion of controverted issues and their resolution. The minutes from each meeting will include Waynesburg University FWA number, the composition of those in attendance (scientists/non-scientists) and a conflict of interest query. Per 45 C.F.R. 46.115, minutes are retained for a minimum of three years.

E. Conflict of Interest

At the beginning of each academic year, IRB members and alternates will review and sign a conflict of interest policy. IRB members are required to declare any and all actual and/or potential conflicts of interest (1) when accepting a protocol review assignment and (2) before discussing/voting on any protocol. Moreover, if the IRB perceives an actual and/or potential conflict of interest in any category, the IRB Chair may request that the conflicted member recuse himself/herself from the corresponding protocol discussion and/or vote. Actual and/or potential conflicts of interest are defined as financial, academic, professional, or personal and are more fully set forth in the University's written policies.

IRB members serving as Principal Investigators will must submit make a Declaration of Conflict with each protocol. The IRB committee has the authority to request Declarations of Conflict for all sub-investigators. All actual PI conflicts of interest must be disclosed on the consent form.

F. Confidentiality

During the process of initial, continuing review, or amendment of a protocol, material provided to the IRB shall be considered privileged information and the IRB shall assure the confidentiality of the data contained therein.

CHAPTER IX
APPEAL PROCEDURES

If a Principal Investigator disagrees with any IRB decision or action, he or she may request reconsideration by the IRB. This request must be made to the Chair of the IRB in writing, within seven calendar days of the Principal Investigator's receipt of the IRB's notification or within the ten days of the mailing date of a mail-delivered notification. The entire appeal process must be completed within 120 calendar days of receipt of the IRB notification to suspend or terminate a study.

A Principal Investigator may ask to appear before the IRB to request that the IRB reconsider a decision; this appearance must be at the next regularly scheduled IRB meeting (unless the IRB grants an exception). The IRB may affirm, modify or reverse its original decision. Within seven calendar days, the IRB will notify the Principal Investigator of its decision. The decision of the IRB is final. The IRB will provide written notice (within seven calendar days) of its decision to the appropriate Investigator(s), their department chair(s)/program director(s), and the Provost.

The decision of the IRB becomes final under any of the following circumstances:

1. The Investigator chooses not to appeal;

2. The Investigator fails to notify the Chair of the IRB within seven calendar days of receipt of the IRB's notification, of a decision to appeal;

3. The Investigator fails to make documents concerning the study available to the advisory review panel within seven calendar days of being requested to do so; or

4. The Investigator or representative fails to appear before the IRB at its next regularly scheduled meeting.

REFERENCES

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APPENDIX

IRB APPLICATIONS, FORMS AND TEMPLATES

Applications:

Exemption Form

Full or Expedited Review Form

Quality Improvement

Forms:

Adverse Events Report

Amendment and Renewal Request & Monitoring Report Form

Closure Report

Conflict of Interest Policy

HIPAA Waiver

Protocol Submission Checklist

Templates:

Sample Assent Template

Sample Consent Template