

University of Charleston

Institutional Review Board for the
Protection of Human Research Subjects

Guidelines

University of Charleston
2300 MacCorkle Avenue, SE
Charleston, WV 25304



University of Charleston Institution Review Board Historical Overview

In late 2002, a small group of faculty members at the University of Charleston began the process of gathering information regarding the ethical treatment of human subjects used for biomedical and behavioral research. The ultimate goals of this *ad hoc* committee were to establish standards for the ethical treatment of students, faculty, and staff participating in research at the University of Charleston or conducting research either at the University of Charleston or in cooperation with other institutions. Further, the faculty committee also wished to establish guidelines to ensure the protection of University of Charleston students, faculty, and staff who may participate in research conducted on campus by external institutions or agencies.

Following the initial gathering of information on the origins of human subject protection and the requirements of the Office for Human Research Protection (OHRP), the committee undertook the formation of an Institutional Review Board (IRB) to review and monitor research conducted at the University of Charleston by either internal or external researchers.

Between the original undertaking in 2002 and November 2004, the *ad hoc* committee's efforts to produce a manual of guidelines, appropriate forms, organize processing requests, and set meetings were challenged by the departure of two of the original members and lack of time and office support. During this time, however, the *ad hoc* committee did obtain resources for use in instructing students and faculty on the ethical treatment of human subjects; create a draft manual of guidelines and forms; identify interested committee members; and arrange for administrative support to receive, process, and retain request for IRB approval.

In November 2004, the University of Charleston IRB was officially recognized by the Office of Human Research Protection as IRB #1 (IRB00004547). In 2005, a schedule of training for both IRB members and faculty wishing to conduct research will be offered and the deadlines and meeting dates of the IRB will be posted.

In 2011, the former University of Charleston IRB #1 was deactivated and U of Charleston IRB #2 created. The IRB number is 00008153. The organization ID number of University of Charleston is 0003843. The Federal Wide Assurance number of University of Charleston is 00017633.

Preface

This document is a revision of the 2002 *Guidelines*. It attempts to clarify local practices and procedures which have evolved over the years. Please consult all appropriate sections of these new *Guidelines* before submitting a protocol for review.

These *Guidelines* have been approved by the Institutional Review Board for the Protection of Human Research Subjects and by the president of the University of Charleston.

If you have any questions or if you need assistance, please contact the IRB chair, Dr. Rebecca Linger at the University of Charleston.

Institutional Review Board For the Protection of Human Research Subjects Guidelines

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Chapter 1

Introduction

A. Purpose

In 1966 the Surgeon General of the United States issued a formal policy statement on protecting human subjects in research sponsored by the Public Health Service. In response to that statement, the University of Charleston formed its first Institutional Review Board (IRB) for the Protection of Human Research Subjects.

The purpose of the IRB is to protect the rights and welfare of individuals who serve as subjects of research conducted by faculty, staff, and students and to ensure institutional compliance with those ethical considerations contained in the Code of Federal Regulations (45 CFR 46). To meet those obligations, the IRB

- Maintains guiding principles and operating policies (as contained in this document) demanding the highest professional standards in dealing with human subjects and
- Reviews all research projects involving human subjects to ensure that appropriate standards are met and the research procedures do not infringe upon the safety, health, welfare, or life of those subjects.

B. Basic Definitions

1. Research

“Research” is defined in the Code of Federal Regulations as “a systematic investigation designed to develop and contribute to generalizable knowledge.” The IRB at the University of Charleston extends that definition: “Research is any project using a systematic methodology and designed to collect data from living or deceased human subjects. Even if the results are generalizable or not, published or not, it is the interaction between researcher and subject that is important.”

Examples of activities that constitute research include:

- Any study intended to result in publication or public presentation, including classroom projects.
- Any activity resulting in publication or public presentation, even though it involves only review of existing data that was collected with no intent to publish.
- Or any use of an investigational drug or device (see Chapters III and VIII)

Examples of activities that are not research include, but are not limited to:

- Evaluation of an employee.
- Course, teacher, program, or service evaluations where such evaluation is not designed to lead to generalizable knowledge.
- Market research leading to the development of a product.
- De-identified, publicly available data.
- Oral histories gathered to preserve historical information through recorded interviews with participants in past events and ways of life where the researchers do not seek to contribute to generalizable knowledge but instead aim to provide a deeper understanding of historical events.

If an activity does not involve research, or does not involve human subjects, it does not require approval or review by the IRB. *If you have any doubt as to whether an activity constitutes research please consult with the IRB staff.*

2. Board; IRB

IRB or Board refers to members of the Institutional Review Board for the Protection of Human Research Subjects acting collectively. The Board functions under the mandate of the president of the University of Charleston and is responsible for reviewing all research involving human subjects.

3. Protocol

A protocol is the formal design or plan of a research activity. Any protocol submitted to the IRB must include the elements specified in Chapter III.

4. University of Charleston; UC

The University of Charleston or UC refers to UC and its associated affiliates.

C. Governing Principles

Respect for individuals and their rights and welfare are the basic tenets underlying the IRB guidelines. Statements supporting the ethical principles and standards adopted by the Board can be found in the following major documents, which are on file in the IRB office.

The Declaration of Geneva
The Nuremberg Code
The Helsinki Declaration
The Belmont Report

The IRB guidelines are based on these general ethical principles.

1. *The rights and welfare of all subjects must be adequately protected.* This principle applies to the need for safeguarding the physical and psychological well-being of a subject and to preservation of the rights of privacy and self-determination.
2. *Risks must be minimized* by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Whenever appropriate, investigators should use procedures already being performed on the subjects for diagnosis or treatment.
3. *Risks must be reasonable* in relation to anticipated benefits to subjects or to importance of the knowledge that may be gained. The Board reviews research 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.
4. *Recruitment and selection of subjects must be equitable* within the confines of the purposes and design of the study; subjects may not be arbitrarily excluded on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status.
5. If *informed consent* is required, it must be obtained from each subject or the subject's authorized representative.
 - a. A written "consent form" or a "consent and information form" must document the informed consent process, a copy of which must be given to the subject.
 - b. To the fullest extent possible, the subject's consent must be based upon an understanding of the research, the risks, possible discomforts, benefits, and alternative procedures.
 - c. The informed consent document must provide for the subject's ability to refuse participation or to discontinue participation at any time without prejudice.

- d. The signed informed consent must be available for review by the IRB or federal regulations authorities.
6. Provisions must be made to monitor the study to ensure the safety of subjects.
7. Adequate provisions must be made to protect the *privacy* of subjects and the *confidentiality* of data. In addition, the Board must be satisfied that questionnaires and protocols involving sensitive issues (which could, if they become known outside the research, affect employment or place the subject at various physical or social risks) are carefully designed to avoid gathering more personal data than is absolutely essential to the research. Confidential data from the study is not to be posted on a website that can be accessed by anyone but the investigators.
8. Additional safeguards must be included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence or who belong to potentially *vulnerable populations* as described in Chapter VI.
9. In addition, several professional organizations and societies have formulated their own guidelines for research involving human subjects. Such guidelines can supplement but do not supersede or diminish the protections and requirements outlined in this document.

D. Authority of the Board

The Board has the authority and responsibility to approve and monitor for compliance with sound ethical principles and applicable regulations all research involving human subjects conducted by university faculty, staff, or students. In particular, the Board has the authority to:

1. Approve or disapprove a protocol or to require modifications to a protocol (including the consent form) as a condition for approval;
2. Oversee the conduct of a study and require progress reports;
3. Suspend or terminate a study, or impose restrictions or require modifications to a study as a condition for continuation.

The Board 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 (pursuant to the appeal procedures set forth in Chapter XI) request the Board to reconsider the protocol or request the Board to convene an Advisory Review Panel. No university administrator, faculty, or staff can override Board decisions.

E. Responsibilities of Investigators

1. Investigators must receive written approval from the IRB **before** they can involve human subjects in research projects. Failure to comply with the requirements is a direct violation of university policy. Penalties for noncompliance are outlined in Chapter X.
2. Investigators must receive a written “exemption approval” **before** involving human subjects in research projects that are exempt from Board review (See II.A.)

3. Investigators must receive a **written** approval prior to making any changes to a protocol (which includes adding investigators or modifying advertisements, consent forms, assent forms, or procedures.)
4. Investigators must **comply promptly** – within 90 days – with all Board requests for information concerning a protocol (e.g., progress report).
5. Investigators must **notify** the Board of any adverse reactions, unforeseen events, termination of human subjects involved, and completion of study.
6. Investigators must **keep copies** of signed consent forms as well as research records, for a period of 3 years from the date of project completion or publication; whichever, was most recent.

F. Qualifications of Investigators

1. Principal Investigators must be a UC faculty member (full time, part time or adjunct) or an administrator at UC. If the Principal Investigator no longer works at UC, the IRB should be notified immediately, and the project may be terminated.
2. All Investigators must complete the NIH IRB training available at the <http://phrp.nihtraining.com> website. A copy of the NIH completion certificate for each Investigator must be submitted with all applications and review requests. Expiration of the training is cause for termination of the project.

Chapter II

Categories and Procedures: Exempt, Expedited and Full Review

All research falls into one of the following three categories:

- Exempt from Board Review (see Section A)
- Expedited Review (see Section B)
- Full Review (see Section C)

A. Exempt Research

“Exempt research” is research that does not require expedited or quorum review by the Board, although it does require an “exemption approval.” (see A.3 below.)

1. Criteria for Exemption from Board Review

A project is exempt if all the research activities belong in one or more of the following categories:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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

- a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

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

- a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

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

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- a. The identifiable private information or identifiable biospecimens are publicly available;
- b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is for the purposes of "health care operations" or "research" for "public health activities and purposes"; or
- d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

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

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

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations as required.

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
- b. Documentation of informed consent or waiver of documentation of consent was obtained;
- c. An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent; and
- d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

2. Exempt Research Involving Children

The exemptions in categories 1), 3), 4), 5) and 6) above are applicable to research involving children.

However, the exemption at category 2) for research involving survey or interview procedures or observations of public behavior is not exempt, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

See VI.A for more information about research involving children.

3. Procedures for Exempt Research

Exemption Procedures for Investigators

If your study is eligible for exemption, you must obtain written approval from the IRB of the University of Charleston **before** beginning any research activities involving human subjects. (See Appendix B for the “Application for Exemption.”)

B. Expedited Review

“Expedited review” is the review of a protocol two board members and applies to certain types of low or minimal risk research.

“Minimal risk” means that the probability 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.

1. Research Eligible for Expedited Review

Research is eligible for expedited review if all of the research activities belong in one or more of the following categories:

- 1) Collection of hair and nail clippings (in a non-disfiguring manner), deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
- 2) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

- 3) Voice recordings made for research purposes such as investigations of speech defects.
- 4) Moderate exercise by healthy volunteers (the American College of Sports Medicine Guidelines should be followed in research of this type.)
- 5) The study of identifiable existing data, documents, records, pathological specimens or diagnostic specimens not otherwise exempt.
- 6) Research on individual or group behavior or characteristics of individuals (such as studies of perception, cognitive game theory or test development) if:
 - a) the investigator does not manipulate* the subject's behavior, and
 - b) the research will not involve stress* to the subject, and
 - c) the research will not involve deception* of the subject.
- 8) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
- 9) Recording of data from subjects who are not children using noninvasive procedures routinely employed in clinical practice.
- 10) Collection of blood samples by venipuncture, no more than two times per week, in amounts not exceeding 450 milliliters in an eight-week period, from subjects who are in **good health** are not pregnant, and are not children.

***Manipulation**

The investigator attempts to change the subject's psychological or physical functioning.

***Stress**

Situations in which the demands on individuals tax or exceed their resources, with a potential to endanger well being or health.

***Deception**

Procedures that conceal or mislead subjects about the true purpose of a study.

All research eligible for expedited review requires informed consent (see Chapter V) unless the IRB grants a waiver.

2. Expedited Review of Research Involving Children

Research involving children is eligible for expedited review if it falls into categories 1 through 7 above.

Research involving any of the procedures listed in 8 and 9 above are not eligible for expedited review if the subjects are children. See VI A for more information about research involving children.

If you request expedited review of research involving children, you must provide for obtaining consent (permission) of each child's parent(s) or legal guardian(s) and assent of the child. (See Chapter V.)

3. Procedures Required for Expedited Review

The protocol submission to the IRB is described in Chapter III and is the same for both expedited and full review.

The IRB staff screens all protocols for compliance with the required format, necessary signatures and inclusion of consent form. The staff then sends the protocol to the reviewers.

Protocols may be submitted at any time for the type of review. The IRB staff will notify you in writing of the decision in approximately 4 weeks. You **must** have an official approval letter from the IRB **before** enrolling subjects in the study. All consent forms, letters, and other documents to be used with subjects must list the IRB project number that is given upon approval. The initial approval is valid for one year, and if not reapproved by the anniversary date, the protocol will be closed. Each re-approval is valid for one year only. Note that approval of an addendum does *not* constitute re-approval of an entire protocol.

4. Results of Expedited Review

Reviewer(s) may:

- Approve the protocol,
- Require changes for approval under expedited review (changes must be made within 90 calendar days),
- Refer the protocol for quorum review.

C. Research Requiring Full Review

Full review consists of the review of a protocol by a quorum of board members attending an IRB meeting.

1. Criteria for Full Review

Full review is necessary for research involving risk of physical or psychological harm greater than that encountered in daily life or during routine examinations or tests. Research involving deception also requires quorum review.

2. Procedures Required for Full Review

To have a protocol placed on the agenda for the quarterly board meeting you must submit the required forms to the IRB at least two weeks before a scheduled IRB meeting.

Before a protocol can be placed on the agenda, the IRB staff will screen it for compliance with the required format, necessary signatures and inclusion of consent and assent forms. For information on preparing a protocol, see Chapter II.

3. Results of Full Review

At its quarterly meeting the Board may:

- Approve the protocol as submitted
- Require modifications Request additional information
- Invite investigator(s) to attend the meeting to address concerns.
- Disapprove the protocol.
- You **must** have an official, approval letter from the IRB before enrolling subjects in the study. All consent forms, letters, and other documents to be used with subjects must contain the IRB number given upon approval. The initial approval is valid for one year, and if not re-approved by the anniversary date, the protocol will be closed. Each re-approval is valid for one year only. If the Board disapproves a protocol, any re-submittal must be accompanied by a new "Protocol Statement," including all appropriate signatures.

You may invoke the appeal procedures outlined in Chapter XI if your protocol is not approved.

Chapter III

Preparing a Protocol for Expedited or Full Review

An IRB Protocol for both expedited and quorum review consists of the following elements:

- A. Appropriate forms, fully completed
- B. Narrative Description of Study
- C. Consent form(s)
- D. Letter of permission of host site/organization (if study is to be done offsite).
- E. Other relevant information the researcher may wish to include.

All submissions must be legible and submitted electronically as well as in hard copy. The forms must be signed by the appropriate officials. The IRB staff may return protocols if any materials are not sufficiently legible or if any sections are incomplete or filled out improperly

The Board also reserves the right to ask for more detailed information about the study prior to approval.

Chapter IV

Changing a Protocol

Investigators must obtain Board approval prior to instituting any changes to a protocol. See Section C below for procedures involving emergency changes without Board approval.

When changes to a protocol are submitted for approval, the entire amended protocol and consent form are subject to review for compliance with current IRB standards.

A. Definitions

“Major” changes are those which directly affect the level of risk to the subjects. Examples include the addition of new and vulnerable populations as subject, increasing the sample size in vulnerable populations, or any change in strategies or interventions, drug dosage, period of administration of drugs, or age of subjects. Major changes must undergo quorum review.

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

B. Submissions Required

1. You must submit the “Protocol Amendment Form: to revise a protocol. If needed, use additional sheets to describe in detail the nature of the requested changes, the reasons for making each change and any possible effect the changes may have on subjects.
2. For changes involving a different principal investigator or a new co-investigator, attach the new investigator’s name, signature, title and qualifications. Do not submit entire vitae.
3. For changes to the consent form, submit a new consent form with brackets around any modifications. Also submit a clean copy of the new consent form.
4. For modifications to any other attachment(s), submit the document(s) with brackets around any modifications.

C. Emergency Changes

If changes to an IRB-approved protocol become necessary to avoid an immediate hazard to subjects, you may make those changes without prior Board approval, but – you must attempt to obtain authorization from the IRB chair. You must

- Notify the IRB within five (5) days of making an emergency change and
- Submit, within ten (10) days, a written request to amend the protocol.

The Board will review the request to amend the protocol and also determine whether any change made without prior approval was justified.

Chapter V

Consent and Assent

A. Consent

General Rule: Written informed consent is required, and you must use copies of the most recent stamped, approved consent form to enroll subjects in a study.

Informed consent is a person's documented, voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic therapeutic or preventive procedure.

Investigators must obtain informed consent from each subject or from the subject's authorized representative for any nonexempt research. Subjects document their consent by signing the most recent copy of the consent form that has a signed and dated approval.

In exceptional cases, detailed in Section B, you may obtain the Board's permission to depart from usual procedure. Alternative procedures include:

- Oral narrative coupled with a short-form consent document (see Section B.1 below).
- Oral consent for impaired or illiterate subjects (see Section B.2 below),
- Waiver of consent form to preserve anonymity (see B.3 below),
- Other waivers or alternations of the consent process (see Section B.4 below).

The Board must approve all consent forms. Once the Board has approved a consent form, you must use that form; the Board must approve any proposed changes. (See Chapter IV.)

1. Format and Style

The consent form must adhere to the following requirements. (See sample forms in Appendix C.)

- a. Use departmental letterhead of the principal investigator if possible.
- b. Produce word-processed, legible size copies. Larger-than-normal type size may be necessary for some populations – such as children, the elderly, or the visually impaired.
- c. Number all pages. Each consent / assent form should have its own, distinct pagination; each page should have a header, a page number and a line for the subject to initial signifying that the page has been read. The form should be in 12-point proportional type or larger or in 10-character-per-inch monospace type such as Courier.
- d. Divide the consent form into sections and use descriptive headings (e.g., "Purpose", "Risks and Discomforts", "Confidentiality"), all of which should be in boldface type. Section titles may appear on a separate line or be underlined at the beginning of a paragraph.
- e. Use the first person, as though the subject were explaining the study to someone else (e.g., "I understand the..." or Dr. X will do... to me"). You may speak to the subjects in the second person only in a separate cover letter, cover page or narrative. A consent form to be signed by a parent, a guardian or authorized representative should be written in the first person, but refer to the subject in the third person (e.g. "I understand that my child will... or Dr. X will do... to my child".)

- f. Use lay language throughout. Explain the nature of the project, the nature of the subject participation, and the nature of the risks and benefits involved in language clearly understandable to the anticipated subjects.
- g. The Board does not allow separate signature pages; at least some portion of the text must be on the signature page.
- h. The Board will not accept consent or assent forms with excessive blank spaces in the text.

2. Contents and Structures

The consent form must contain all applicable items listed below (items a - o). (See sample consent forms in Appendix C).

The Board may waive any of these requirements upon the written request of the investigator. Explain why the provision is unnecessary or inappropriate. (See Section B below.)

The Board 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 and Information Form" must be at the top of the page. Following pages should have consecutive page numbers, an abbreviated title at the top and an initial line at the bottom (see 1.c. above)
- b. Give the complete title of the study. If the title on the consent or assent form differs from the title of the protocol, explain why in the discussion section.
- c. "Introduction"
 - 1) Include the following statement or equivalent: "I have been asked to participate in this research study."
 - 2) Indicate who explained the study to the participant, who is conducting the study, and where the study will be held.
 - 3) Inform participants if the research is being done to fulfill requirements for a doctoral dissertation, master's thesis or classroom assignment.
 - 4) Identify any external support.

d. "Purposes"

Explain why the study is being conducted. If applicable, state that the investigational drug or device being used in the study has not yet received approval from the Food and Drug Administration.

e. "Procedures"

- 1) Describe the procedures to be followed, specifically identifying any experimental procedures.
- 2) State the expected duration of the subject's participation.
- 3) State the approximate number of subjects in the study and state the anticipated number of subjects in the study at UC.
- 4) Explain the randomization process in lay language and the likelihood of the subject's being assigned to an alternative group.
- 5) Explain any special circumstances under which you would terminate the subject's participation.
- 6) If Questionnaires or interview are involved, inform subjects of the time involved, the nature of the questionnaire or interview, that they can see questions before they sign the consent form, and that they do not have to answer all of the questions. If parental or guardian consent is required, state that the parent(s) or guardian(s) may review the questionnaire or interview questions before signing the consent and that the child or ward does not have to answer all the questions.

- 7) If you will be audio taping or videotaping, the consent form must inform subjects of that procedure and also inform them of the methods of storing and disposing of tapes.
 - 8) Subjects *must* be informed that appropriate care will be available or an appropriate referral will be made if a particular problem or disease is discovered or if they have an adverse physical or psychological reaction to the study.
- f. “Benefits”
- 1) Describe any anticipated benefits to the subject or to others (such as generalizable knowledge).
 - 2) Describe any monetary rewards or payments for participating, include an explanations of the extent to which payment will be made if the subject withdraws or is removed from the study prior to its completion, including any proration or bonus for completing the study.
 - 3) If students are to receive class credit, the consent form must state that other opportunities are available to earn the same credit, For example:
“I understand that I will earn extra credit for participating in this study. I also understand that other options are available for earning the same extra credit.”
- g. “Risks” or “Risks and Discomforts”
- 1) Describe any reasonably foreseeable risks or discomforts to the subject.
 - 2) For studies involving radiation, state the nature of the radiation and the risks involved.
 - 3) For studies involving more than minimal risk, explain that the treatment or procedure may involve risk that are currently unforeseeable.
 - 4) The following statement is necessary for studies that may include female subjects if there could be a risk to an unborn child:
“This study may involve risks to the unborn child. For this reason, I understand that if I am a female of child-bearing potential. I will not be allowed to participate in this study until I have had a pregnancy test and the test has indicated that I am not pregnant. I understand that I must use a medically approved method of birth control while I am participating in the study.”
Some investigational drug studies may require that males use appropriate contraceptive methods.
- h. “Financial Considerations”
- 1) Explain any costs associated with participation. For studies involving clinical treatment, explain any expenses that would not ordinarily be incurred with standard treatment for the subject’s condition. Also explain that the subject or the insurance carrier may be billed.
 - 2) State if the drug will be given free of charge.
 - 3) State whether subject must pay for the drug if it becomes commercially available during the study period.
- i. “Voluntary Compensation”
- For studies involving more than minimal risk, state if any money will be paid voluntarily as compensation for injury that occurs as a consequence of the research. For example
“If I am injured as a result of this research, treatment will be available. Compensation for my injuries will not voluntarily be provided by the investigator, sponsor, University of Charleston, or other associated affiliates.”
- j. “Alternatives”
- You *must* disclose alternative procedures or courses of treatment and their consequences and risks, including nonparticipation in the study and no treatment whatsoever.
- k. “Plasma/Tissue Banking”
- If tissue banking for future studies (not the study in which the subject is enrolled) is involved, the following language (as appropriate) is needed:

“I understand that the study will also involve a system for storing blood fluid (plasma) or tissue to use in future research. None of the studies would be of benefit to me, but could help researchers learn about other ways to prevent cancer. For this purpose, and extra _____ will be drawn for future research purposes.

“As part of the ongoing scientific and biotechnological activities of the ____ and its agents, these blood samples or tissue specimens will be preserved and used for research and development purposes. As a result of these activities, an economic benefit may be derived directly or indirectly by the ____, individual researchers, and others engaged in these activities. By signing this consent form I authorize the preservation and use of these specimens.”

“Some research may require no identification of blood or tissue, so there would be no risk to me. This file will be kept to allow identification of samples. If further projects are planned that require use of identifiable samples. I will be contacted and my consent would be necessary to do such research. If I do not want to be contacted for further studies, I can check a box at the end of this form.”

l. “Contact Person”

- 1) In studies involving more than minimal risk, state whom to contact in the event of a research-related injury.
- 2) Provide the name(s) and telephone number(s) of the principal investigator(s) for questions about the research.
- 3) Inform subjects that if they have questions concerning their rights as subjects of research, they may contact the executive secretary of the Institutional Review Board at 555-5555.

m. “Confidentiality”

- 1) The following statement is mandatory:
“I understand that any information about me obtained as a result of my participation in this research will be kept as confidential as legally possible.”
- 2) State that research records will, as appropriate, become part of a participant’s hospital or medical records.
- 3) For all drug and device studies, the following statement is mandatory:
“I understand that my research records and test results, just like hospital records, may be obtained through legal processes such as a subpoena or a court order or may be inspected by the sponsor or federal regulatory authorities, including the Food and Drug Administration, without my additional consent.”
- 4) Explain how confidentiality will be maintained.
- 5) Explain any foreseeable circumstances under which the investigator might be required to give information about the subjects to third parties (e.g., mandatory reporting of infectious diseases, mandatory reporting of information concerning child abuse.)
- 6) If there is a possibility of publishing the results of the research, include the following:
“In any publication that results from this research, neither my name nor any information from which I might be identified will be published without my consent.”
- 7) State where audio and videotapes will be kept, how their confidentiality will be maintained and when they will be destroyed.

n. “Voluntary Participation”

- 1) State that participation is voluntary.
- 2) State that refusal to participate or withdrawal from the study involves no penalty to the subject, that grades and class standing will not be affected (for students or trainees) that status on the team will not be affected (for athletes), or that job standing will not be affected (for employees or subordinates).
- 3) State that the subject’s questions about the research have been answered.

- 4) For studies involving more than minimal risk, the following statement (or its equivalent) is mandatory:
“In the event new information becomes available that may affect my willingness to participate in the study, this information will be given to me so that I can make an informed decision whether or not to continue my participation.”
 - 5) Include a statement telling subjects they will receive a copy of the signed consent form.
- o. Include lines for the following signatures and dates for each:
 - 1) the subject or the subject’s authorized representative,
 - 2) the investigator or the investigator’s representative,
 - 3) the person obtaining the consent (if different from the investigator),
 - 4) the attending physician (if applicable and if different from the investigator),
 - 5) a witness to the subject’s signature if the form is to be read to the subject or signed by the subject’s authorized representative, attesting that coercion was not used. (See C.1 and C.2.)

B. Waiver or Alteration of the Consent Process

1. Oral Narrative with Short-Form Consent

In rare instances, such as studies of subjects in emergency situation, the Board may approve the use of a oral narrative coupled with a short-form consent.

Procedure

- a. The investigator must provide a narrative that contains all the information and elements of the standard consent form; this narrative may be read to the subject verbatim or may be paraphrased. (The narrative may be in the first or second person).
- b. The subject (or the subject’s authorized representative) signs only a short-form consent which states that the subject willingly agrees to participate in the research described in the narrative.
- c. A witness must be present when the narrative is read to the subject. The witness signs the narrative and the short-form consent to verify that the oral and written information were the same.
- d. The investigator signs the narrative and the short-form consent.
- e. The investigator gives the subject signed copies of the narrative and the short-form consent

If you wish to use this procedure, the Board requires three items:

- Justification in section of the protocol,
- The narrative that will be read to the subjects,
- The short-form consent.

2. Oral Consent and Waiver of Signed consent Form for Impaired or Illiterate Subjects

In rare instances, such as with impaired (e.g., blind or dyslexic) or illiterate subjects who are fully capable of consenting but are not capable of reading or signing a consent form, the Board may approve the use of a oral consent. In such cases, the investigator reads the consent form to the subject in the presence of a witness, and the witness signs a form to verify the subject’s oral consent.

Procedure

- a. The consent form must be read to the person verbatim.

- b. After the narrative is read, the subject indicates consent orally.
- c. A witness must be present when the consent form is read to the subject. The witness signs the consent form and a “Verification of Oral Consent” form to verify that the consent form was presented exactly as written and that the subject consented.
- d. The investigator signs the narrative and verification form.
- e. The investigator gives the subject a signed copy of the narrative and the verification form.

If you wish to use the oral consent process, the Board requires three items:

- Justification in Section C of the protocol,
- The consent form that will be read to the subjects,
- The verification of oral consent form that will be signed by the witness and the investigator.

3. Waiver of Signed Consent Form to Preserve Subject Anonymity

In some instances – especially in research involving the use of educational tests questionnaires, surveys, interviews, or observations – the principal risk to the subject would be a breach of confidentiality. When data are recorded so that subjects can not be identified, the only record linking the subject and the research would be the consent document. In such cases, the Board may waive the requirement of signed consent if it finds the risks resulting from a breach of confidentiality warrant such action. In these cases, after the subject has read a narrative that contains all elements of the standard consent form, he or she may provide explicit oral consent or implicit consent by means of voluntarily participating in the research.

Procedure

- a. All subjects must receive an information sheet, signed by the investigator and containing all elements of the standard consent form.
- b. The information sheet may be in the form of a narrative or cover letter and may be in the first or second person.
- c. Subjects must have an opportunity to read it before deciding whether to participate.

If you wish to obtain a waiver of signed consent, the Board requires the following:

- Justification in Section C of the protocol and explanation of why it is appropriate
- A copy of the information sheet that will be read by the subjects.

4. Other Waivers or Alterations

The Board may approve substantial alterations to or waive any element of written informed consent only if all of the following conditions apply:

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

These conditions apply, for example, to any research that would involve participants in research without their prior informed consent or to any research that would involve deception of subjects through incomplete or misleading information in the consent process.

Protocols in which the investigator seeks a waiver or alteration of the consent process under this provision may be eligible for expedited review by two board members.

C. Assent

Assent is agreement by an individual who is unable to give legally valid consent to participate in research.

General Rule: Written informed assent is required.

When potential research subjects are not competent to give legally valid informed consent, respect for personal autonomy mandates that the investigator obtain their voluntary assent to participate in addition to obtaining the informed consent of a parent, guardian or other authorized representative addition to obtaining the informed consent of the parent, guardian or other authorized representative.

Assent is generally required whenever:

- Subjects are children between ages of 7 and 18 (see VI.A.3) or
- Intellectually or emotionally impaired subjects are not legally competent to give their informed consent (see VI.B.3 and VI.C.3).

Subjects manifest their “assent” to participate by signing an assent form which, like the consent form, explains the nature of the research project, the nature of the subjects’ participation, and the nature of the risks and benefits involved.

The Board must approve all assent forms. Once the Board has approved an assent form, you must use that form; the Board must approve any proposed changes. (See Chapter IV)

Format, Style, and Content

The format, style and content of the assent form are essentially the same as for a consent form, except:

- a. The language should be appropriate for the age and capacity of the subjects.
- b. Certain provisions may be omitted if they would be confusing or would not be meaningful to the subjects.

The following items ordinarily are included in an assent form (see Section A.2 for specifics):

- a. The words “Assent Form” at the top of the page
- b. The title of the study
- c. The statement “have been asked to be in this research study.”
- d. “Purpose”
- e. “Benefits”
- f. “Risks” or “Risks and Discomforts”
- g. “Confidentiality” [omitting b) and c)]
- h. “Voluntary Participation” [omitting d)]

Sample forms 3 and 4 in Appendix C are examples, respectively, of a parental consent form and an assent form suitable for young children or those who are unable to give legally valid informed consent.

D. Waiver or Alteration of the Assent Process

When an intervention or procedure involved in the research may directly benefit the subject and is available only through participation in the research, the consent of the subject's parent(s) or guardian(s) is sufficient, and the subject's assent is not required. (See VI.A.4.b) You should nevertheless solicit the assent of the subject, in such cases you may use a short-form assent document. You may give the subject a signed copy of the consent form or narrative and a signed copy of the short-form assent document.

If you wish to use a short-form assent, the Board requires three items:

- Justification in Section C of the protocol and explanation of why it is appropriate,
- The narrative that will be read to the subject, if different from the consent form to be signed by the subject's parent(s), guardian(s), or legally authorized representative,
- The short-form assent.

For additional information, contact the Chair of the UC-IRB, Rebecca Linger at rebeccalinger@ucwv.edu.

Chapter VI

Special Populations as Subjects of Research

Whenever subjects in a study may be vulnerable to injury, coercion, or undue influence, the study must include additional safeguards to protect their rights and welfare.

Special populations requiring additional safeguards are:

- Children (Section A)
- Person who are intellectually or emotionally impaired (Section B)
- The elderly (Section C)
- Pregnant women and fetuses (Section D)
- Prisoners (Section E)
- Persons who are illiterate or whose primary language is not English (Section F)
- Students or trainees (Section G)
- Employees of institutions associated with the study (Section H)

A. Children

1. Definitions

A “child” is anyone who has not reached the legal age for consent when the research will be conducted. In West Virginia, the age of consent is 18 years, unless the child is an “emancipated minor” – a child over the age of 16 who is married or who has been declared emancipated by court order.

“Assent” is the agreement, by a child or any individual who is unable to give legally valid informed consent, to participate in research. Mere failure to object is not assent. (See V.C. for complete information.)

2. Criteria for Approval

The Board will approve research involving children only if it falls within one of the following categories:

- a. The research involves no more than minimal risk
(Requires the consent of one parent or guardian)
- b. The research involves more than minimal risk, but presents the prospect of direct benefit to individual subjects, which is sufficient to justify the risk.
(Requires the consent of one parent or guardian.)
- c. The research involves more than minimal risk and presents no direct benefit to subjects but is likely to yield important generalizable knowledge.
(Requires the consent of both parents – see below under 3.)
- d. The research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
(Requires the consent of both parents – see below under 3.)

See II.B and II.C for information on exempt and expedited research involving children.

3. Consent and Assent

All research that involves children as subjects requires the signed informed consent of one of child's legal parent(s) or guardian(s). If the consent of both parents is required (see 2.c and 2.d above), one parent can consent if the other 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.

All children must provide their written assent unless they are under age 7, or incapable of understanding, or the intervention or procedure involved may directly benefit them and is available only through participation in the research. You should attempt to obtain written assent even though it is not a re-requisite for participation; you may use a short-form assent document.

The Board has authority to waive the assent requirement.

B. Persons Who Are Intellectually or Emotionally Impaired

1. Definition

An "intellectually or emotionally impaired" person is one who cognitive or emotional functions are affected or whose capacity for judgment and reasoning is significantly diminished either by a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), a developmental disorder (e.g., mental retardation), or a neurological disorder. These individuals may be vulnerable to coercion or may not be able to give legally valid informed consent.

2. Criteria for Approval

The Board will approve research that targets intellectually or emotionally impaired persons only if it fall within one of the following categories:

- a. The research involves no more than minimal risk.
- b. The research involves more than minimal risk but presents the prospect of direct benefit to individual subjects, which benefit is sufficient to justify the risk.
- c. The research involves more than minimal risk and presents no direct benefit to subjects but is likely to yield generalizable knowledge about the subject's condition.
- d. The research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of intellectually or emotionally impaired persons.

3. Consent and Assent

If an impaired subject is capable of giving legally valid informed consent, you must obtain his or her consent according to the requirements in Chapter V. The contents and language of the consent form should be appropriate to the nature and extent of the subject's impairment.

If an impaired subject has a legal guardian, you must obtain informed consent from the guardian and assent from the subject in accordance with the procedures and criteria applicable to research involving children.

C. Elderly Subjects

1. Definition

"Elderly" subjects are those over the age of 65. Advancing age may entail a decline of some physical capabilities, making some elderly individuals more vulnerable to the risks posed by a research protocol. A

decline of some mental capabilities may, in addition, make some elderly individuals vulnerable to coercion or incapable of giving legally valid informed consent.

2. Criteria for Approval

The Board will approve research that targets elderly persons only if it falls within one of the following categories:

- a. The research involves no more than minimal risk.
- b. The research involves more than minimal risk, but presents the prospect of direct benefit to individual subjects, which is sufficient to justify the risk.
- c. The research involves more than minimal risk and presents no direct benefit to subjects but is likely to yield generalizable knowledge about the subject's disorder or condition.
- d. The research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the older person.

3. Consent and Assent

If the subject has a legal guardian, you must obtain informed consent from the guardian and assent from the subject in accordance with the procedures and criteria applicable to research involving children.

D. Pregnant Women and Fetuses

1. Definitions

"Pregnancy" encompasses the period of time from the confirmation of implantation until the expulsion or extraction of the fetus.

A "fetus" is the product of conception from the time of implantation until birth by expulsion or extraction and until it is determined to be viable.

"Viable" refers to the ability of the fetus, after either spontaneous or induced delivery to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

"Nonviable fetus" means a fetus ex utero which (outside the body) which, although living, is not viable.

"Dead fetus" means a fetus ex utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movements of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

"in vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

2. Criteria for Approval

The IRB will approve research involving pregnant women and fetuses only if all of the following conditions are met:

- a. Appropriate studies on animals and nonpregnant subjects have been completed.
- b. The risk to the fetus is minimal, except where the purpose of the activity is to meet the health needs of the mother or the fetus.

- c. The risk to the fetus is the least possible risk for achieving the objectives of the research.
- d. Investigators involved in the study will have no role in any decision regarding (i) the timing method or procedure used to terminate the pregnancy, or (ii) the viability of the fetus.
- e. When termination of a pregnancy is involved, no changes from standard procedures, which may cause more than minimal risk to the fetus or to the pregnant woman may be introduced solely for purposes of the research.
- f. No monetary or other inducements may be offered to terminate a pregnancy for purposes of the research.

3. Special Considerations

- a. The fetus in utero - The fetus in utero may be involved as a research subject only if the purpose of the research is to meet the health needs of the particular fetus, and the fetus will be placed at the minimum risk necessary to meet such ends or the risk to the fetus is minimal and the purpose of the research is to obtain important biomedical knowledge which cannot be obtained by other means.
- b. The fetus ex utero - Until it has been ascertained whether or not a fetus is viable, a fetus ex utero may be involved as research subject only if there will be no added risk to the fetus and the purpose of the study is to develop important biomedical knowledge which cannot be obtained by other means, or the purpose of the research is to enhance the possibility of survival of the fetus to the point of viability.
- c. The nonviable fetus - A nonviable fetus may be involved as a research subject only if vital functions will not be artificially maintained solely for purposes of the research, experimental procedures which would of themselves terminate heartbeat or respiration are not used, and the purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means.

4. Content for Research Involving Pregnant Women or Fetuses

The mother of the fetus must be legally competent and have given her informed consent for any research involving her or the fetus. The mother's consent alone is sufficient if the purpose of the activity is to meet the health needs of the mother, the father's identity or whereabouts cannot be reasonably determined, the father is not reasonably available, or the pregnancy resulted from rape. In all other circumstances, informed consent must also be obtained from the father of the fetus.

E. Prisoners

1. Definition

A "prisoner" is an individual involuntarily confined in a penal institution; including persons (1) sentenced under a criminal or civil statute, (2) detained pending arraignment trial or sentencing, and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing alternative to criminal prosecution or incarceration in a penal institution.

2. Criteria for Approval

The Board will approve research targeting prisoners only if:

- a. The research is (1) a study of possible causes, effects, and processes of incarceration and of criminal behavior; (2) a study of prisons as institutional structures or of prisoners as incarcerated person; (3) a study of conditions particularly affecting prisoners as a class, or (4) as study of

practices (both innovative and accepted) having the intent and reasonable probability of improving the health and wellbeing of the subjects.

- b. Any possible advantages to the prisoner resulting from participation in the research must not be of such a magnitude that they impair the prisoner's ability to weigh the risks of the research against the values of such advantages in the prison environment.
- c. The risks involved in the research must be commensurate with risks that would be accepted by non-prisoner volunteers.
- d. Procedures for the selection of subjects within the prison must be fair to all prisoners.
- e. Adequate assurance exists that participation in the research will have no effect on the subject's parole, and the investigator must clearly inform each prisoner of this fact in advance.

F. Subjects Who Are Illiterate or Whose Primary Language Is Not English

1. Illiterate Subjects

If the research targets subjects who are illiterate, the protocol should use an oral consent process. (See V.B.2.)

2. Subjects Whose Primary Language Is Not English

If the research targets subjects whose primary language is not English, your protocol must include a consent form written in the subjects' primary language and a certification that the translation is accurate.

G. Students or Trainees

1. Students in General

The fact that a person is a student can affect that person's ability to make a voluntary and noncoerced decisions about participating as a subject of research.

If prospective subjects are students at UC or any institution associated with the study, the consent form must state that class standing or grades or status on an athletic team will not be affected by refusal to participate or by withdrawal from the study.

If students are to receive class credit, the consent form must indicate this. Other opportunities must be available to earn equivalent credit for students not participating in the study..

2. Students or Trainees of an Investigator

Except in special circumstances, the Board will approve a protocol involving the investigator's current students or trainees as subjects only if the study is designed to assure anonymity, including whether or not any particular individual elected to participate. (One method of assuring anonymity is for all contact with subjects to be made by persons other than the investigator.)

H. Employees or Subordinates

1. Employees of Institutions Associated with the Study

If prospective subjects are employees of UC or any institution associated with the study, the consent form must state that job standing will not be affected by refusal to participate or by withdrawal from the study.

2. Employees or Subordinates of an Investigator

Except in special circumstances, the Board will approve a protocol involving the investigator's current employees or subordinates as subjects only if the study is designed to assure anonymity, including whether or not any particular individual elected to participate (One method of assuring anonymity is for all contact with human subjects to be made by persons other than the investigator).

Chapter VII

Recruitment and Selection of Subjects

A. Equitable Selection of Subjects: Nondiscrimination

1. General Guidelines

Recruitment and selection of subjects must be equitable within the confines of the study. You should include subjects on the basis of gender and race and may not arbitrarily exclude subjects on the basis of national origin, religion, creed, education, or socioeconomic status. (See I.C.4)

2. Economically Disadvantaged Subjects

a. *Added Costs*

The Board will be concerned if added costs are so great as to preclude participation by the economically disadvantaged.

b. *Financial Remuneration, Reward or Reimbursement*

Financial remuneration, reward, reimbursement for expenses, or other inducement for participation should not be so great as to be coercive to potential subjects.

B. Advertisements

Advertisements used to recruit subjects must be approved in advance by the Board.

Recruiting advertisements should be limited to:

1. The name of the investigator and UC affiliation
2. The purpose of the research and, in summary form, the eligibility criteria for subjects
3. The location of the research
4. If appropriate, a brief description of the procedures
5. A description of the potential benefits
6. The person to contact for further information

For drug or device studies, no claims may be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation or that the drug or device is in any way equivalent or superior to any other drug or device.

C. Recruiting Patients or Clients

Physicians, psychologists, counselors, lawyers and others who have confidential relationships with patients or clients may not release their names without their express consent. You *may not* contact subjects without this consent.

Chapter VIII

Compassionate Use of an Investigational Drug or Biologic

A. Definitions

“Compassionate use” is the use of an investigational drug or biologic on a human subject in a life threatening situation for which no standard acceptable treatment is available and in which there is not sufficient time to obtain prior IRB approval. You must report any such use to the IRB within five (5) working days.

B. Procedure for Compassionate Use

If determined that the use of an investigational drug or biologic holds the greatest promise of improving the condition of a single patient, you must proceed as follows:

1. Use the investigational drug or biologic only in accordance with a protocol currently in effect with the FDA.
2. Use the investigational drug or biologic only in patients under your direct supervision or under the supervision of physicians who are directly responsible to you.
3. Obtain informed consent from the patient or the patient’s authorized representative. (See Appendix C for a copy of the “consent for Compassionate Use”. The forms should be available in emergency rooms, in-patient pharmacies and clinical department offices.)
4. Notify the IRB – in writing and within five (5) working days – that you have used the investigational drug or biologic. (See Appendix C for the “Notification of the Compassionate Use of an Investigational Drug or Biologic” form.)

C. Notifying the IRB of Compassionate Use

The notification that an investigational drug or biologic has been used on a compassionate use basis should be written in non-technical language and it must include the information indicated below. Use the “Notification of the Compassionate Use of an Investigational Drug or Biologic” form. (See Appendix C for a sample).

1. A description that an investigational drug or biologic, including (where applicable) its commercial name and the full scientific or chemical name.
2. The name of the company manufacturing the investigational drug or biologic.
3. The drug IND number or device IDE number.
4. The date and time the investigational drug or biologic was first used.
5. The name of the organization that dispensed the investigational drug or biologic to the investigator (e.g., the manufacturer.)
6. A detailed explanation of the reason the investigational drug or biologic was used instead of an approved drug or standard treatment.

7. The potential risks or side effects associated with the use of the investigational drug or biologic.
8. The outcome of the use of the investigational drug or biologic in the patient. (If this is incomplete at the time of notification, submit supplemental information later.)

Attachments to the notification must include the protocol in effect with the FDA and a fully signed copy of the “Consent for Compassionate Use” form.

The physician using the investigational drug or biologic must sign the notification and submit it with the appropriate attachments to the IRB executive secretary.

D. Limitations on Compassionate Use

1. Single Use

The foregoing procedure applies *only* to the compassionate use of an investigational drug or biologic in a single patient. If you plan to continue using the investigational drug or biologic, you must submit a complete protocol for review and approval. For purposes of the “single use” limitation, the investigator’s entire department is considered collectively.

2. Exception to the Single Use Limitation

If an investigator or any member of the investigator’s department determines that a second compassionate use of a particular investigational drug or biologic is necessary and there is not sufficient time for submission and approval of a protocol, the investigator may use the investigational drug or biologic by following the above procedures for use and notification and then must submit a *complete protocol* within *30 days* of the second use of the investigational drug or biologic.

Chapter IX

Continuing Review Process

A. Authority of the Board

The Board has the authority and responsibility to monitor all research involving human subjects and may choose to observe the consent process.

B. Reporting by Investigators

You must notify the Board immediately if you become aware of any injuries or deaths or if you learn of any unforeseen risks or adverse reactions. You must also notify the Board when a project terminates or no longer requires the use of human subjects.

According to the Code of Federal Regulations, Section 312.32 the FDA and the IRB must be notified in the event of any serious or unexpected adverse experience associated with the use of an investigational drug. A serious adverse experience is considered any event that is fatal or life threatening, is permanently disabling, requires in-patient hospitalization, or is a congenital anomaly, cancer, or overdose. An unexpected adverse experience is an event that is not identified in nature, severity or frequency in the current investigator brochure.

C. Continuing Reviews

When the Board approves a protocol, it determines how frequently it will review the research and what specific information it will request beyond that on the standard review form.

The Board reviews a list of current protocols at its monthly meeting and can

- Approve for renewal
- Approve conditionally for renewal
- Require additional information prior to approval for renewal
- Suspend or terminate the research

1. Annual Review

All protocols must be re-approved by the anniversary date of the first approval, i.e., the protocol must be reviewed and any requested revisions must be approved before that date. If this has not occurred, the protocol will be suspended, and no subjects may be enrolled until re-approval has been granted. All protocols that initially underwent quorum review will undergo quorum for re-approval. All protocols that initially underwent expedited review will undergo expedited review for re-approval. Protocol review forms will be sent to investigators two months before the renewal date to allow sufficient time for the renewal process.

No consent form may be used with a date beyond that of the one-year anniversary of the previous review.

2. Noncompliance with the Review Process

Noncompliance with the review process may result in suspension or termination of the project. (see Chapter X.)

D. Comprehensive Review

In addition to the standard annual review, the Board may undertake a comprehensive review of any approved projects, including on-site inspection of all records pertaining to the research.

Annual reviews are required for all protocols which are closed to accrual but for which participants are subject to follow-up. At this time, the investigator must inform the IRB of any new information, either in the literature or received from the sponsor, which may be of interest to subjects who participated in the study. Any new information that you have given to the subjects or that you propose to give them must accompany the review form.

E. Project Closure Notification

Once you have completed your project, you must formally close it. You will need to complete a “Closure Report” and have it signed by the Primary Investigator, then attach a copy of your summary before forwarding to the IRB. If your project requires work beyond the expiration of approval, you will need to complete a “Renewal Application / Progress Report.”

Chapter X

Noncompliance

Whenever questions arise concerning possible noncompliance with IRB guidelines and the applicable regulations, the chair and the Board have the authority to investigate and take appropriate action to ensure compliance or to terminate the research.

A. Action by the Chair

1. Authority

The chair has discretion to temporarily suspend research if there exists

- Substantial evidence of noncompliance;
- Reasonable suspicion of noncompliance, which may be associated with more than minimal risk to human subjects; or
- Information suggesting that the research involves substantially greater risk than was anticipated at the time of initial IRB approval.

2. Procedures

If the chair does suspend research, he or she will:

- Provide written notice to the investigator(s) and the Board members of the suspension and the reason for it.
- Provide the investigator(s) with a copy of this section of the guidelines.
- Offer the investigator(s) an opportunity to meet with the chair;
- Place the matter on the agenda for the next IRB meeting, at which time the Board may confirm or rescind the suspension, convert the suspension to a termination, or take any other action consistent with its authority and obligations.
- If the research is time sensitive, the Chair may call an emergency Board meeting to address the research in question. The investigator(s) will be provided notice of the time and location of the meeting. The only action the Board may conduct at such meeting will be to confirm or rescind the suspension. Other actions may be taken at the next regularly scheduled IRB meeting.

B. Action by the Board

1. Authority

If the Board finds research has been conducted in violation of IRB guidelines or other applicable regulations, it may:

- Disallow the publication of data collected during periods of noncompliance,
- Require destruction of data collected during periods of noncompliance,
- Impose restrictions as a condition for continuation of the research,
- Suspend or terminate the research,
- Take other action as appropriate.

2. Procedures

- Questions or concerns regarding noncompliance with IRB guidelines should be directed to the IRB Chair, who will report preliminary findings to the Board.

- The Board shall initiate an investigation concerning the preliminary findings.
- The Board may suspend research during the investigation.
- The Board will notify the investigator(s) of the nature of the concerns that have been raised and the time, date, and place of the meeting to discuss them. The investigator will have an opportunity to attend and explain. It is the duty and responsibility of the principal investigator to cooperate with the IRB and to provide any documentation the Board may request.

3. Board Decision

Within seven calendar days of its decision to uphold a suspension the Board will provide written notice to the investigator(s) and to the department chair(s), dean(s), vice-president(s), office of the provost, and office of the general counsel. In accordance with UC's agreement of assurance with HHS, the Board will submit an initial report of any serious or continuing noncompliance with IRB requirements to the Office for Protection from Research Risks (OPRR), the Food and Drug Administration (FDA) and other agencies (as appropriate). This report will include a statement of the Board's decision and other appropriate information, copies of this report will be sent to all appropriate parties.

See Chapter XI for appeal procedures available to the investigator(s). Should the investigator(s) choose not to appeal, the decision of the Board will stand and the IRB will so notify all appropriate parties. The notification will include a statement of the reasons for the Board's decision and a description of any action taken by the Board.

Chapter XI

Appeal Procedures

If an investigator disagrees with any Board decision or action, he or she may request reconsideration of the decision or action. This request must be made to the IRB Chair, in writing, within seven calendar days of the investigator(s) receipt of the Board's decision.

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

- The investigator chooses not to appeal
- The investigator fails to appeal within seven calendar days of the decision.
- The investigator or a representative fails to appear before the Board when requested to do so.
- 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.

A. Investigator Appears Before the Board

An investigator may ask to appear before the Board to request that the Board reconsider a decision. Within seven calendar days of meeting with the investigator, the Board will notify the investigator of its decision to affirm, modify, or reverse its original decision. If the investigator is still dissatisfied, he or she may request (in writing to the executive secretary) formation of an advisory review panel. Any such request must be made within seven calendar days of receipt of the Board's decision.

B. Advisory Review Panel

If the investigator remains dissatisfied with the Board's decision, he/she may request the formation of an Advisory Review Panel. Such request must be received within seven days of the investigator's receipt of the Board's decision. The Advisory Review Panel will be formed within 15 days of the investigator's request.

The advisory review panel will be formed within 15 calendar days of the investigator's request for its information.

1. Composition

An advisory review panel shall consist of three persons:

- One member chosen by the IRB chair. This person may not be a current member of the Board or the IRB staff.
- One member chosen by the principal investigator. This person may not be a member of the investigator's department and may not have had any direct involvement in the activities in question.
- One member chosen by the office of the provost; this person will serve as chair, may not be a current member of the Board or the IRB staff, may not be a member of the investigator's department, and may not have had any direct involvement in the activities in question.

2. Procedure

Within seven days of its formation, the Advisory Review Panel will meet to consider evidence. At this meeting, a representative of the IRB will present the ARP with a summary of its actions and the reasons for those actions. The investigator is entitled to attend during the presentation of the IRB summary and will then have an opportunity to present evidence on his/her behalf. At this or subsequent meetings, the ARP may ask questions of the IRB representative, the investigator, or others having relevant knowledge. The investigator has the right to be present at any meetings during which the ARP is asking such questions.

The ARP may also request information from the investigator or others during its investigation. If the investigator fails to provide the requested information, the appeal will be administratively withdrawn and the IRB's original decision will be final.

Within 30 days of its formation, the panel will complete its investigation and transmit a report of its findings and recommendations to the IRB Chair. This report should contain a summary of the evidence considered by the ARP, the findings and recommendations of the ARP, and the reasons for its recommendations.

It is recognized that the ARP acts in an advisory capacity only and that its work must be completed expeditiously. Therefore, formal rules of evidence and procedure shall not apply to the ARP's activities.

3. Board Consideration of ARP Report

The IRB will consider the ARP report within 15 days of receipt of the report. The Chair of the ARP will present the IRB with a summary of the report. The investigator is entitled to be present at this meeting. The IRB may ask questions of either the Chair of the ARP or the investigator. Questions should be limited to clarifying evidence already collected rather than directed at gathering new evidence. After asking questions of the Chair of the ARP and the investigator, the IRB will then enter executive session to discuss all the evidence presented. No persons other than IRB members and the IRB secretary may be present during these discussions. Upon the conclusion of these discussions, the IRB will vote to affirm, rescind, or modify its original decision via a simple majority of those IRB members present. If the investigator chooses to wait outside the room while the IRB deliberates and votes, the IRB will provide the investigator with an oral summary of its decision once the decision is reached. Within seven days of its decision, the Board will provide written notice of its decision to the appropriate investigator(s) and to their department chair(s), dean(s), vice-president(s), the office of the provost, the university's general counsel, and members of the ARP. The Board will also notify, as appropriate, OPRR, the FDA and other agencies.

Appendix A

Advisory Review Panel

1. Composition of Panel

An advisory review panel shall consist of three persons, selected as follows within 15 calendar days of the investigator's request.

- a) One member chosen by the IRB chair; this person may not be a current member of the Board or the IRB staff.
- b) One member chosen by the principal investigator; this person may not be a member of the investigator's department and may not have had any direct involvement in the activities in question.
- c) One member chosen by the office of the provost; this person will serve as chair, may not be a current member of the Board or the IRB staff, and not be a member of the investigator's department, and may not have had any direct involvement in the activities in question.

2. Meeting and Report

Members of the advisory review panel will convene and use the following procedures:

- a) A member of the Board or the IRB staff will summarize the relevant facts and explain the reasons for the Board's decision. The investigator may be present during this report. The panel may involve the office of the university's general counsel.
- b) The investigator may make a statement and present additional information.
- c) The investigator and the IRB representative may call additional individuals to address the panel on the issue.
- d) Members of the panel may ask questions of the investigator, the IRB representative, or other persons addressing them.
- e) The panel will then meet in executive session to reach its decision.

Formal rules of evidence will not apply at an advisory review panel meeting.

The advisory review panel will complete its investigation and transmit, within 30 days of its formation, a written report of its findings and recommendations to the IRB chair.

3. Board Reconsideration Based on Report of the Panel

The Board will consider the report at a regular or special meeting held within 30 days of its formation, a written report of its findings and recommendation to the IRB chair.

The investigator and the members of the advisory panel may not be present at this meeting, which will proceed essentially as follows:

- a) The IRB chair will summarize the relevant facts, the decision of the Board that is under review and the findings and recommendations of the advisory review panel.
- b) The chair of the advisory review panel may supplement the panel's written report with an oral presentation.
- c) The investigator may make a statement to the Board
- d) Board members may ask questions of the members of the advisory review panel or of the investigator.
- e) The Board will meet in executive session and, by a simple majority vote of members present, may affirm, modify, or reverse its original decision. The Board is under no obligation to accept the panel's findings or recommendations.

The Board will provide written notice, within seven calendar days, of its decision to the appropriate investigator(s) and to their department chair(s), dean(s), vice-president(s), the office of the provost, the

university's general counsel, and members of the advisory review panel. The Board will also notify, as appropriate, OPRR, the FDA and other agencies.

Appendix B

IRB Forms

**Application No.**

This Number is assigned by the IRB upon approval.

UC IRB - APPLICATION FOR EXEMPT REVIEW**TO: IRB CHAIR, UNIVERSITY OF CHARLESTON**

Date: _____

Primary Investigator: (Must Be A Faculty Member or Administrator) _____

Email: _____

Other Investigators: _____

Email: _____

Email: _____

Degree / _____

Program: _____

Department: _____

Project Title: _____

Funding Agency: _____

TYPE OF EXEMPTION

Check the type of exemption you are claiming:

A. Exemptions:

Research in which the only involvement of human participants is in one of the following categories is exempt from full review by the IRB, provided that the researcher submits and obtains Committee approval of an Application for Exemption from IRB Review. No research is exempt if any of the targeted populations for this research consists of persons who are:

- legally incompetent;
- significantly mentally ill or impaired; or
- vulnerable to extraordinary institutional coercion, such as prisoners, residents of 24-hour skilled nursing facilities, or anyone who is involuntarily confined.

B. Categories:

- ☐ **1. Educational Practices:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
- ☐ **2. Educational Tests, Surveys, Interviews, Observation of Public Behavior:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempt, if:
1. the information obtained is not identifiable;
 2. the information, if disclosed outside the research, could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
 3. the information in the researcher's private data (including field notes) as well as in any published material, information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: This exemption does not apply if the participants are minor children. "Minor children" are persons who have not attained the legal age for consent under the applicable jurisdiction in which the research will be conducted. In the United States, this age is 18 years.

- ☐ **3. Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects:** Benign behavioral interventions are defined as "brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing"

Note: Research using deception is not eligible for exemption in this category unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research.

- ☐ **4. Secondary Research for Which Consent is Not Required:** This category covers secondary research uses of identifiable private information or identifiable biospecimens. Informed consent is not required if at least one of the criteria listed below is met:

1. Use of publicly available identifiable private information or identifiable biospecimens.

2. Information recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.
3. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA.
4. Analysis of data on behalf of a federal agency or department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

- ☐ **5. Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency:** This category covers research and demonstration projects that will serve as a public benefit and service and must meet the following criteria:
1. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
 2. The research or demonstration project must be conducted pursuant to specific federal statutory authority.
 3. There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
 4. The project must not involve significant physical invasions or intrusions upon the privacy of participants
- ☐ **6. Taste and food quality evaluation and consumer acceptance studies:** Research in this category must meet the following criteria:
1. Wholesome foods without additives are consumed, or
 2. Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- ☐ **7. Storage or maintenance for secondary research for which broad consent is required:** This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis. The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if broad consent is obtained.
- ☐ **8. Secondary Research for Which Broad Consent is Required:** This category allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and that the use is within the scope of the broad consent. Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

NOTE: all procedures for all participants in a project must be exempt in order for the project to be exempt from Committee review.

INSTRUCTIONS TO INVESTIGATORS

This application must be completed in its entirety with all required attachments to be considered for review. Please check to ensure that you have all of the following attached before submitting:

- ☐ List a UC Faculty Member or Administrator as the Primary Investigator.
- ☐ List Students, Non-UC Faculty/Administrators, and additional investigators as Other Investigators.
- ☐ List the Department your program falls under if academic, listed your actual department if employment or grant related.
- ☐ List the Degree and Program you are conducting this research for, if applicable.
- ☐ List the Title of Your Project.
- ☐ List any Funding Agency, if applicable.
- ☐ Check the Type of Exemption that you are claiming.
- ☐ Attach a **short (maximum of two pages) research proposal summary** that describes your project, clearly shows how the participants and procedures in your project fit the requirements for exemption in the category you have selected, describes how you will be protecting the privacy of the participants, how you will be maintaining the confidentiality of data collected, and where the research will be performed. If you are surveying your subjects, **please include your survey instrument.**
- ☐ Attach a current NIH or CITI Certificate for each Investigator on this project (Primary Investigator and Other Investigator). All Investigators are required to have NIH or CITI Training within three years.
- ☐ Consent Form that you plan to use with your participants, if applicable.

- ☐ Organization Permission Letter to conduct research on non-UC premises. Letter must be on the organization's letterhead and signed by an officer of the organization. If the organization is an educational facility, it must be signed by a President, Vice President, Provost, Principal, or Vice Principal.
- ☐ Attach a copy of your survey, questionnaire, or interview questions as you plan to deliver them to the participants.
- ☐ Attach a copy of any other method of data collection, if not from survey, questionnaire, or interview.
- ☐ Attach a copy of the Consent to Audio Tape / Video Tape, if applicable.
- ☐ Attach any other pertinent documentation. Please specify: _____
- ☐ Have ALL Required Persons signed this application? *(Your application will not be reviewed, if it is not signed and submitted with ALL required documentation. Acceptable forms of signature: Scanned, Faxed, or Adobe Digital Signature. Typed names are not considered signatures.)*
 - 1) Principal Investigator (Faculty Member or Administrator)
 - 2) Other Investigator (Student doing project)
 - 3) School or Division Chair (Can not be one of the Investigators)

If you have questions, please direct them to the Chair of University of Charleston's Institutional Review Board.
Rebecca Linger, IRB Chair, 304-357-4998,
UC-Charleston, Pharmacy Room 304G, rebeccalinger@ucwv.edu or irb@ucwv.edu

Please submit your completed application to:

Electronic Copy:
irb@ucwv.edu

Printed Copy: UC – Campus Mail
John Adkins, IRB Coordinator -- Library

Certification of Application

I certify that all research conducted pursuant to this application will be conducted in compliance with all applicable University of Charleston policies and Federal and State regulations. Student projects must be supervised by a full-time University of Charleston faculty member. In addition, only the faculty advisor may be the Principal Investigator. Although non-University of Charleston investigators may be involved in a project in any capacity, all projects must be sponsored by a full-time University of Charleston member who is ultimately responsible for the safe conduct of the study.

Signature of Principal Investigator
(Faculty Member or Administrator)

Principal Investigator's Email Address and Phone

Signature of Other / Student Investigator
(Only one required)

Other / Student Investigator's Email Address

Signature of Principal Investigator's Supervisor
(Not an Investigator on this project)

Supervisor's Email Address

Do Not Write Below – For IRB Use Only

Reviewer's Comments:

- ☐ The project is exempt from Committee review.
- ☐ The project must be reviewed. Please complete **The IRB Application for Expedited or Full Review**.

Signature of Reviewer

Date

Print Name of Reviewer

Short-Form Consent

You are invited to participate in a research study conducted by *Name of Investigator*, from the University of Charleston *Departmental Affiliation*. I hope to learn *state what the study is designed to discover or establish*. You were selected as a possible participant in this study because *state why subject was selected*.

If you decide to participate, *describe procedures, including their purpose, how long they will take, their location and frequency. If activities are to be audio or videotaped, indicate this.*

Deescribe risks, discomforts, inconveniences, and how these will be managed. Describe any alternative procedure or courses of treatment, if applicable. Indicate costs of participating, if any. Describe benefits to subjects and humanity expected from the research. However, I cannot guarantee that you personally will receive any benefits from this research. *If subject will receive compensation, describe amount and when payment is scheduled.*

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Subject identities will be kept confidential by *describe coding procedures and plans to safeguard data. If information will be released to any other, for any reason, state the personal agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.*

Your participation is voluntary. Your decision whether or not to participate will not affect your relationship with *name of agency, school, etc., where subject was recruited*. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty.

If you have any questions, please feel free to contact *list your name, phone number, and address. If student, also provide advisors name, phone, address, and identify him/her as your advisor*. If you have questions regarding your rights as a research subject, contact Dr. Rebecca Linger, Chair University of Charleston, Institutional Review Board [phone: 304-357-4998, email: rebeccalinger@ucwv.edu]. You will be given a copy of this form to keep.

Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation without penalty, that you will receive a copy of this form, and that you are not waiving any legal claims.

Signature: _____

Print Name: _____

Date: _____

This form is adapted from similar forms from Shenandoah University.



Application No. _____

Application No. _____

This Number is assigned by the IRB upon approval.

**UC IRB - APPLICATION FOR EXPEDITED OR FULL REVIEW
FOR USE OF HUMAN PARTICIPANTS IN RESEARCH**

TO: IRB CHAIR, UNIVERSITY OF CHARLESTON

Date: _____

Primary Investigator: Must Be a Faculty Member

Email: _____

Other Investigators: _____

Email: _____

Email: _____

Degree /
Program: _____

Department: _____

Project Title: _____

Funding Agency: _____

Check the most appropriate answer for each question. Do not leave any questions unanswered.

- | | | | |
|---|------------------------------------|-------------------------------|------------------------------|
| 1. The investigator(s) request the following type of review: | <input type="checkbox"/> EXPEDITED | <input type="checkbox"/> FULL | |
| 2. Will human participants be participating in: | | | |
| a. biomedical procedures | <input type="checkbox"/> YES | <input type="checkbox"/> NO | |
| b. procedures to elicit information (personality tests, questionnaires, inventories, surveys, feelings, or other aspects of the behavior of participants?) | <input type="checkbox"/> YES | <input type="checkbox"/> NO | |
| c. procedures specifically designed to directly modify the knowledge, thinking, attitudes, feelings, or other aspects of the behavior of participants? | <input type="checkbox"/> YES | <input type="checkbox"/> NO | |
| 3. If biomedical procedures are involved: | | | |
| a. are provisions for emergency medical care necessary?
(If yes, give details on the Informational Survey #8 & 9) | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> N/A |
| b. has a qualified MD participated in the planning of the project? | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> N/A |
| c. will this study involve drugs or chemical agents (dosages), ionizing radiation, non-ionizing radiation (microwaves, lasers), or high intensity sound? | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> N/A |
| 4. Does this study involve giving false or misleading information to participants or withholding information from them such that their "informed consent" is in question? (If yes, give details on the Informational Survey; deception method on #5 and debriefing method on #11) | <input type="checkbox"/> YES | <input type="checkbox"/> NO | |
| 5. Are procedures to be used new or innovative (not established and accepted)?
(If yes, give details on the Informational Survey # 8&9.) | <input type="checkbox"/> YES | <input type="checkbox"/> NO | |
| 6. Will the procedures: | | | |
| a. cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, or threat to the dignity of participants, or be otherwise potentially harmful to participants? | <input type="checkbox"/> YES | <input type="checkbox"/> NO | |

b. if answer to 6a is yes, have specific provisions been made to correct any harmful or adverse conditions that may arise? (Give details on the Informational Survey #10)	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
7. Can the potential benefits to participants from the conduct of this study be considered to outweigh the risks to participants? (If yes, explain on the Informational Survey)	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
8. Can the potential benefits to society from the conduct of this study be considered to outweigh the risks to participants? (If yes, explain on the Informational Survey)	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO	
9. Will participants come in direct contact with any type of electrically powered equipment? (If yes, detail on the Informational Survey #6, the name and qualifications of the individual who will check for electrical safety and attach a signed letter from that person which indicates his/her level of involvement with the project.)	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
10. Is the project specifically designed to involve participants who are:			
a. minors (less than 18 years of age)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
b. pregnant women?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
c. prisoners?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
d. developmentally intellectually disabled?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
e. mentally disabled (brain-injured, psychiatric patients, etc.)	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
f. physically disabled	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
g. institutionalized?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
11. Will participants receive any payment for participating (money, course credit, etc.)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
12. Are procedures for maintaining confidentiality of all participants' data fully described?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
13. Will survey software be used?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
If yes, please list the company or educational facility.			
Is it secured with a single user logon and password?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
14. Do procedures include obtaining parental/guardian consent and/or institutional authorization for access to participants if minor, mentally disabled or institutionalized participants?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
15. Are procedures for obtaining informed consent fully described?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
16. Will a copy of the informed consent document and explanation of the study be provided to each participant?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
17. Have copies of informed consent documentation been submitted along with the protocol (ie: signature document with explanation of study, transmittal letter, debriefing statement or other)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
18. Will any non-University of Charleston site(s) be included in data collection?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
19. If an educational facility, please list the grade of any students involved	Click here to enter text.		
20. Fill in the estimates below:	Click here to enter text.		
Average amount of time required for participation (in hours).	Click here to enter text.		
If questionnaires or tests are involved, the total number of items.	Click here to enter text.		
Number of volunteers (participants) to be involved in this study.	Click here to enter text.		
21. Beginning date (pending approval)	Click here to enter text.		
22. Ending date of involvement.	Click here to enter text.		

INSTRUCTIONS TO INVESTIGATORS

This application must be completed in its entirety with all required attachments to be considered for review. Please check to ensure that you have all of the following attached before submitting:

- ☐ List a UC Faculty Member as the Primary Investigator.
- ☐ List Students, Non-UC Faculty/Administrators, and additional investigators as Other Investigators.
- ☐ List the Department your program falls under if academic, list your actual department if employment or grant related.
- ☐ List the Degree and Program you are conducting this research for, if applicable.
- ☐ List the Title of Your Project.
- ☐ List any Funding Agency, if applicable.
- ☐ Attach a **short (maximum of two pages) research proposal summary** that fully describes your project, clearly shows how the participants and procedures in your project fit requirements for the expedited category (if selected), describes how you will be protecting the privacy of the participants; how you will be maintaining the confidentiality of data collected; and where the research will be performed. If you are surveying your subjects, **please include the survey instrument**.
- ☐ Attach a current Human Research Subjects Training Certificate for each Investigator on this project (Primary Investigator and Other Investigator). All Investigators are required to complete this training within 3 years of this proposal submission.
- ☐ Consent Form that you plan to use with your participants, if applicable.
- ☐ Organization Permission Letter to conduct research on non-UC premises. Letter must be on the organization's letterhead and signed by an officer of the organization. If the organization is an educational facility, it must be signed by a President, Vice President, Provost, Principal, or Vice Principal.
- ☐ Attach a copy of your survey, questionnaire, or interview questions as you plan to deliver them to the participants.
- ☐ Attach a copy of any other method of data collection, if not from survey, questionnaire, or interview.
- ☐ Attach a copy of the Consent to Audio Tape / Video Tape, if applicable.
- ☐ Attach any other pertinent documentation. Please specify: _____
- ☐ Have ALL Required Persons Signed this application?

(Your application will not be reviewed, if it is not signed and submitted with ALL required documentation. Acceptable forms of signature: Scanned, Faxed, or Adobe Digital Signature. Typed names are not considered signatures.)

- 1) Principal Investigator (Faculty Member or Administrator)
- 2) Other Investigator (Student doing project)
- 3) School or Division Chair (Cannot be one of the Investigators)

All applications must be completed in its entirety and contain all required signatures and documents or they will not be processed but will be returned to the Principal Investigator. Please submit your completed application using one of the following methods:

- 1) Electronically to irb@ucwv.edu (Save the entire application packet as one single PDF file and send as an attachment. Please no links)
- 2) Paper application to Institutional Review Board, UC-Charleston, Box 9 (Do not send to individual IRB members.)

If you have questions or need to report problems with your project, please direct them to the Chair of UC-IRB:

Rebecca Linger, IRB Chair304-357-4998

UC-Charleston, Pharmacy Room 304Grebeccalinger@ucwv.edu or irb@ucwv.edu

UC IRB Information Survey

APPLICATION FOR EXPEDITED OR FULL REVIEW REGARDING USE OF HUMAN PARTICIPANTS IN RESEARCH

Respond to each of the following items or questions. Provide enough detail so the reviewers will be able to judge how well your study protects human participants. Your responses must be preceded by the exact question and typed in the original order. Normally, your response will not exceed five pages.

1. Provide a brief description of the proposed study (purpose, problem to be investigated).

[Click here to enter text.](#)

2. What are your qualifications for conducting the study? (What is your experience with the procedures and instrumentation to be used in this study? If a student, what is your status and which faculty member will supervise your research and what are his/her qualifications?)

[Click here to enter text.](#)

3. What are the requirements for and characteristics of the participant population? (What gender, age range, health or medical status, prisoners, institutionalized, adults, mentally disabled, etc.?)

[Click here to enter text.](#)

4. How will participants be sampled, recruited or otherwise enlist as participants in the study?

[Click here to enter text.](#)

5. Describe in detail the methodology of your study (how will the study be conducted from start to finish as far as human participants are concerned? Be specific about the methods, instrumentation, types of data collected, any incentives or compensation, etc.)

[Click here to enter text.](#)

6. Describe the personnel, materials/equipment, or other resource requirements for your study. (Identify all personnel involved in the study, their role, their qualifications and their access to the data.)

[Click here to enter text.](#)

7. How will you obtain the informed consent of the participants? (How, where, and when will the study be explained to participants? How will participants indicate their consent?)

[Click here to enter text.](#)

8. What are the potential risks to the participants and what is the likelihood and seriousness of these risks? Risks could be physical, psychological, social, legal, etc. and may result from your experimental procedures, medical treatment, or your methods of obtaining, handling, or reporting data, and compensation. (Studies with greater than minimal risk will require annual review by the IRB.)

[Click here to enter text.](#)

9. As applicable, for each risk identified in #8, describe other methods that were considered that would reduce or eliminate these risks, and explain why they will not be used.

[Click here to enter text.](#)

10. What are the potential benefits to the individual participants and/or society as a result of the proposed research?

[Click here to enter text.](#)

11. As applicable, describe how you will minimize or protect against potential risks to participants throughout the study. (Describe emergency procedures, confidentiality safeguards, deception involved and the debriefing procedures, security measures for storing and accessing data, etc.)

[Click here to enter text.](#)

12. As applicable, provide the names and addresses of experts in your field (not including the investigator) with whom the committee members could communicate to discuss the potential risks of your procedures.

[Click here to enter text.](#)

13. If appropriate, provide references to any published materials that would help the committee make a judgement regarding your procedures for safeguarding the rights and safety of your participants.

[Click here to enter text.](#)

EXPLANATORY NOTE: If any of the items listed above is not applicable to your study, type N/A after the question instead of leaving the question blank.

**UC Institutional Review Board
Informed Consent
Type Title of Project Here**

Introduction	NAME OF PRINCIPAL INVESTIGATOR AND OTHER INVESTIGATORS, in the NAME OF DEPARTMENT Department at the University of Charleston, is conducting a research study to examine PROJECT PURPOSE. By signing below, you have volunteered to take part in the study because you EXPLAIN SUBJECT CRITERIA.
Procedures	BRIEFLY EXPLAIN PROCEDURES IN LAY TERMS.
New Findings	If new information is found during the course of this study, your consent to continue to participate in this study will be re-obtained. If you are interested in the results of this study, you can request the results at the completion of the study. EXPLAIN WHAT RESULTS WILL BE AVAILABLE. FULL STUDY, INDIVIDUAL, ETC.
Risks	Participation in this study will not include any risks beyond EXPLAIN RISKS..
Care if Harmed	If you are injured as a direct result of participation in this study, you must immediately contact the Primary Investigator PRIMARY INVESTIGATOR and the Chair of the UC-IRB, Dr. Rebecca Linger (304) 357-4998. FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK, INCLUDE 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.
Benefits	There may or may not be any direct benefit to participants from these procedures. EXPLAIN ANY BENEFITS TO THE PARTICIPANTS
Explanation & Offer to Answer Questions	PRINCIPAL INVESTIGATOR has explained the study to you and answered your questions. If you have other questions or research-related problems, you may reach PRINCIPAL INVESTIGATOR at PHONE NUMBER . If you have questions about your rights as a research participant, please contact Dr. Rebecca Linger, Chair, Institutional Review Board at (304) 357-4998.
Right to Withdraw Without Consequences	Participation in this research is entirely voluntary. You may refuse to participate or withdraw at any time without consequence or loss of benefits. Whether or not you participate and/or withdraw in this study will in no way affect your relationship to the University of Charleston. You may be withdrawn from this study without your consent by the investigator. DESCRIBE ANY MISUSE IF APPLICABLE.
Confidentiality	Research records will be kept confidential to be consistent with federal and state regulations. Only the investigators will have access to the data and it will be kept in a locked file cabinet in a secure room. Videotape records (if used) will be kept for five years and then destroyed. The results of the study may be presented at professional meetings and published in professional journals but you will be asked permission before your image may be used in these settings.
IRB Approval Statement	The Institutional Review Board for the Protection of Human Participants at the University of Charleston has reviewed and approved this research project.
Copy of Consent	You have been given two copies of this Informed Consent. Please sign both copies and retain one copy for your files.
Investigator Statement	I certify that the research study has been explained to the above individual, by my research staff and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.

Signature of PI &
Student Investigator

Signature of Primary Investigator

Signature of Student Investigator

I agree to participate in this study

Signature of Participant

Date

Certification of Application

I certify that all research conducted pursuant to this application will be conducted in compliance with all applicable University of Charleston policies and the institutional assurance with the U.S. Department of Health and Human Services regarding the use of human participants. University review and approval is requested. Major additions to or changes in procedures involving human participants that occur after review of the application will be brought to the attention of the review committee by the investigator. In addition, the committee will be notified of any unanticipated events that do or could affect the safety and wellbeing of participants. Student projects must be supervised by a full-time University of Charleston faculty member. In addition, only the faculty advisor may be the Principal Investigator. Although non-University of Charleston investigators may be involved in a project in any capacity, all projects must be sponsored by a full-time University of Charleston member who is ultimately responsible for the safe conduct of the study.

I agree to abide by all policies as set forth by the UC-IRB regarding human subjects in research and to file all reports as required and in a timely manner. I understand that I am the responsible party in this application and it is my duty to oversee this project and all reporting. I understand that I must maintain all records on file for a period of three years from the latter date of completion or publication.

[Click here to enter text.](#)

[Click here to enter text.](#)

Name: Principal Investigator
(UC Faculty Member)

Email Address

Phone

Signature

I agree to abide by all policies as set forth by the UC-IRB regarding human subjects in research and to report any issues promptly to the Principal Investigator and the IRB.

[Click here to enter text.](#)

[Click here to enter text.](#)

Name: Other Investigator

Email Address

Phone

Signature

I have read and approve of this application. I understand that, in the event the Principal Investigator is no longer with the University, the records and reporting will fall to me as the School/Department Chair.

[Click here to enter text.](#)

[Click here to enter text.](#)

Name: Primary Investigator's
Supervisor
(May NOT be an investigator
on this project)

Email Address

Phone

Signature



Sponsored Research at the University of Charleston

Instructions: This form is to be used when another institution is requesting that University of Charleston faculty, staff and/or students participate in its study. The University of Charleston will submit the approved protocol from the requesting institution, along with this form, to the Institutional Review Board (IRB) Chair for UC approval. If you have questions, please direct them to the chair of the University of Charleston's IRB.

Submit completed forms to: 1) irb@ucwv.edu and 2) signed paper copy to IRB Mailbox 9, UC-Charleston. If you have concerns, please contact Dr. Rebecca Linger, Chair, UC-IRB, at (304) 357-4998 or in person at PHAR-304G.

Primary Contact: [Click here to enter text.](#)
(must be a UC faculty or administrator)

Proposal #: _____
(Leave blank. You will receive this number when the project is approved)

University of Charleston Information

Sponsor's Name: [Click here to enter text.](#)

Department: [Click here to enter text.](#)

Requesting Institution Information

Primary Research Institution: [Click here to enter text.](#)

Primary Researchers: [Click here to enter text.](#)

Faculty Advisor: [Click here to enter text.](#)

Title of Research: [Click here to enter text.](#)

FWA # of Institution: [Click here to enter text.](#)

Signature of UC Sponsor

Date

DO NOT WRITE BELOW – FOR IRB USE ONLY

I approve of the project as written

Signature of UC-IRB Reviewing Member

Date



**Institutional Review Board
for the Protection of Human Participants in Research (IRB)
Application for Annual Renewal/Progress Report**

Regulations require an annual review of approved projects with greater than minimal risk to subjects.

Date: _____

Protocol #: _____

Investigator(s): _____

Title of Project: _____

1. Is this research still being conducted?

☐ No, ***STOP here and complete a Closure Report.***

☐ Yes, Continue with this form:

2. Provide the number of subjects in the study on the following table:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

3. Have any of the following situations occurred during this project?

a. Adverse events or unanticipated risks to subjects or others? ☐ Yes ☐ No

b. Withdrawal of subjects from the research? ☐ Yes ☐ No

c. Complaints about the research? ☐ Yes ☐ No

d. Changes made to your study? ☐ Yes ☐ No

e. Have these changes been approved? ☐ Yes ☐ No

If answer is "Yes" to any of the above questions, please attach explanatory material.

4. Has there been any recent literature, findings, or other information about risks associated with your type of research project? ☐ Yes ☐ No

If answer is "Yes," please attach a summary of relevant information.

5. Enrollment Status:

a. Subject Enrollment is: ☐ Open ☐ Closed ☐ Has not been started

b. Data Collection: ☐ Ongoing ☐ Completed/Analysis Only

Researcher's Signature: _____ Date: _____

Please return this form to:

Electronically to:

irb@ucwv.edu

Campus Mail to:

IRB, Box 9, UC-Charleston

--- For IRB Use Only ---

APPROVAL:

Reapproved for the _____ to _____
period: _____

Print or Type Name

Signature

Chair/Administrator, IRB



UNIVERSITY OF CHARLESTON

INSTITUTIONAL REVIEW BOARD FOR HUMAN
PARTICIPANTS IN RESEARCH

Project Closure Form

To: Chair, UC-IRB

Protocol #: [Click here to enter text.](#)

Date: [Click here to enter text.](#)

Primary Investigator: [Click here to enter text.](#)

Other Investigators: [Click here to enter text.](#)

School/Division: [Click here to enter text.](#)

Project Title: [Click here to enter text.](#)

Funding Agency: [Click here to enter text.](#)

Date Project Closed: [Click here to enter text.](#)

Reason for Closure: [Click here to enter text.](#)

Total Subjects in the Study: [Click here to enter text.](#)

Signature of Principal Investigator

[Click here to enter text.](#)

Date

Please attach a summary of project findings to this form.

Submit application to:

Electronically: irb@ucwv.edu (single PDF)

Intercampus mail: UC-IRB, Box 9 (signed paper copy)

Direct problems or issues to:

Dr. Rebecca Linger, Chair, UC-IRB, PHAR 304G

rebeccalinger@ucwv.edu



Institutional Review Board Adverse Event Report

Federal guidelines require timely reporting (within 10 days) of unanticipated, life-threatening or fatal events (OFR 46.108).

Date: _____ Principal Investigator: _____
IRB Number of Subjects: _____
Project#: _____
Project _____
Title: _____
Site of _____
Event: _____
Date of _____
Adverse _____
Event _____
Describe _____
Adverse _____
Event: _____

Relationship to study drug, in investigator's opinion: (check one)

☐ Drug-Related ☐ Not Drug-Related ☐ Possibly Drug-Related

Have similar adverse events been reported previously? ☐ Yes ☐ No

If yes, give a brief description of events and numbers:

Are you requesting a consent form change as a result of this event? ☐ Yes ☐ No

If yes, please include two copies of the new proposed consent. One copy should have changes bracketed and the other should be a clean copy for the IRB stamp.

If you feel a change in the consent form is inappropriate, please justify:

Should currently enrolled subjects be informed of this event? ☐ Yes ☐ No

Submit a description on how you will inform subjects (i.e., letter, telephone, office visit) If this has already been done, please explain.

Complete "Adverse Events in Study Subjects on reverse side.

Principal Investigator

Signature & Date: _____

Adverse Events in Study Subjects

[illegible]



Institutional Review Board Protocol Amendment Form

This form must be completed and submitted to the IRB for review before any changes can be made in the project that differ from what was presented and approved by the IRB.

Date: [Click here to enter text.](#)

Principal Investigator: [Click here to enter text.](#)

IRB Project #: [Click here to enter text.](#)

Number of Subjects: [Click here to enter text.](#)

Project Title: [Click here to enter text.](#)

Describe changes to protocol: Explain in detail your reasons for requesting these changes and which part(s) of the approved protocol will be amended. If adding a new site, attach the appropriate letter(s). If adding new investigators, the principal investigator and all new co-investigators must sign this form. Attach a copy of the revised drug protocol (when appropriate) with revised sections bracketed.

Describe changes to the consent form: Explain which section(s) of the consent are being changed. Attach a copy of the latest approved consent, a revised and bracketed copy showing changes, and a new clean copy for approval and stamping.

By signing below, I acknowledge that the changes have not been made and will not be made until this form has been reviewed and the proposed changes herein have been approved by the IRB.

Principal Investigator: _____

Signature

Date

New/Other Investigator: _____

Signature

Date

New/Other Investigator: _____

Signature

Date

New/Other Investigator: _____

Signature

Date

Appendix C

Sample Consent and Assent Forms

The following sample forms provide examples of format and language, which the Board has previously approved or has developed to help investigators. You must adapt these examples to the particular procedures and subjects in each study; do **not** copy them mechanically.

Sample Consent Materials for Minimal Risk Research
(Source: [hhs.gov/OHRP](https://www.hhs.gov/OHRP))

The model documents below were written to provide examples of informed consent forms that would be appropriate in the context of minimal risk research and reflect the goal of reducing the length and complexity of the consent forms used for non-exempt minimal risk research activities. All of the models comply with 45 CFR 46.116 and none would require a waiver of some or all elements of informed consent. All are acceptable and may be considered appropriate depending on the circumstances, and other approaches would be appropriate for each of the cases as well.

These examples were developed to embody previous SACHRP recommendations regarding informed consent, including “Guidance on Applying the Regulatory Requirements for Research Consent Forms: What Should and Should Not be Included?” and “Recommended Guidance on Minimal Risk Research and Informed Consent”. They demonstrate how informed consent materials for minimal risk research can be developed in a manner that is succinct while maintaining regulatory compliance. The models are intentionally provided in different formats (e.g., layout, fonts) to demonstrate the acceptability of multiple approaches to presenting information to prospective subjects.

Each model is preceded by a brief description of the research scenario and a list of key features regarding the contents of the consent document and requirements for documentation of consent. Several of the models do not include documentation of informed consent and rely on an oral process. When oral consent will be used, consideration should be given to the training of research staff on implementing an effective informed consent process.

Example 1 - Information Sheet on Participation in Research to obtain consent orally

Scenario:

This example is provided to illustrate an approach to consent where the process relies entirely on the verbal communication between researcher and potential subject.

Key Features:

- minimal risk research
- Adult subjects
- No vulnerable populations

Analysis:

There are certain circumstances where the situation warrants a written document describing participation but does not warrant a written informed consent document with the specifics of the study.

The specifics of the study would be summarized in a “Points to Consider document” (the consent script) that has been IRB approved and is used by the investigator as the basis of the oral consent conversation and process.

There is no written informed consent document; rather, there is an oral process. All prospective subjects may be given this Information Sheet, depending on circumstances of the research.

The IRB would need to consider information contained in the protocol and other materials submitted for review.

To proceed under this approach, the IRB would need to grant a waiver of documentation of consent, which it could do under 45 CFR 46.117(c)(2) as 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.

Information Sheet on Participation in Research

You are being asked to be a participant in a research study. The researcher is going to discuss with you:

1. The nature and purpose of the research;
2. That your participation is voluntary;
3. The research procedures;
4. Any reasonably foreseeable discomforts or risks*;
5. Any benefits to you from your participation*;
6. Alternatives to participation*;
7. The extent to which privacy and confidentiality will be maintained;
8. Any questions you may have; and,
9. That you can change your mind about participating at any time without penalty.

*Note: These items may be omitted if they do not apply and a waiver of element by the IRB is not required. Many minimal risk research studies will not have reasonably foreseeable risks or discomforts and will not provide benefits to subjects.

Example 2 – Simplified Consent Document with No Documentation of Consent

Scenario: A minimal risk research study involving completion of a questionnaire and four computer-based tasks.

Key Features:

- minimal risk
- adult population
- questions are not considered sensitive

Analysis:

Selected elements of consent are not included in accordance with previously approved SACHRP recommendations. Omission of these elements does not require a waiver from the IRB. Omitted elements include the following:

- alternatives to participation
- benefits
- research related injury

To proceed under this approach, the IRB would need to grant a waiver of documentation of consent, which it could do under 45 CFR 46.117(c)(2) as 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.

The complete regulatory language regarding “penalty or loss of benefits to which the subject is otherwise entitled” (45 CFR 46.116(a)(8)) is not used in an effort to simplify consent and eliminate confusion. There is a presumption that “penalty” can be interpreted to include loss of benefits.

CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Behavioral Learning Testing in Healthy Volunteers (The BLT Study)

Principal Investigator: _____

Introduction and Purpose

We would like you to consider taking part in research involving four computer tasks that help us understand how people learn. Eventually we hope to use similar tasks in research on how the brain works. You do not have to participate, and you can stop at any time without penalty.

Procedures

As part of this research, you will first be asked questions about your mood and anxiety level. This will take about 30 minutes.

The four computer tasks will require you to interact with videogame-like screens and react to pictures, faces and sounds. Some of these things are intended to be annoying (like a car alarm) or bothersome (like a scary face).

You may take part in some or all four tasks. Completing all four tasks will take about three hours. You will be paid \$15 to \$75 depending on the number of tasks you attempt.

Confidentiality

All information we collect about you will be kept confidential to the extent possible. The information may be shared with

Questions

If you have questions about this study or need to report any problems please call 800-867-5309 and ask to speak to someone about the BLT study.

If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University Office of Research Integrity at 1-866-777-9311. You may discuss your rights as a research participant with a representative of our Institutional Review Board (IRB).

Example 3 – Simplified Consent Document with Documentation of Consent

Scenario: A research study that involves a review of medical records and the completion of a questionnaire on use of complementary medicine. The objective of the research is to see whether there is a link between hypertension as disclosed in the medical records and the use of complementary medicine techniques.

Key Features:

- minimal risk
- adults
- identifiers will not be retained

Analysis:

Selected elements of consent are not included in accordance with previously approved SACHRP recommendations. Omission of these elements does not require a waiver from the IRB. Omitted elements include the following:

- benefits
- research related injury
- alternatives to participation

The complete regulatory language regarding “penalty or loss of benefits to which the subject is otherwise entitled” (45 CFR 46.116(a)(8)) is not used in an effort to simplify consent and eliminate confusion. There is a presumption that “penalty” can be interpreted to include loss of benefits.

In this example there is documentation of informed consent. Documentation is included because the research will require access to medical records, and documentation of consent may expedite that access. Individual IRBs may choose to waive documentation based on local practices.

HIPAA requirements will need to be addressed through either a separate HIPAA authorization or through the use of a combined form incorporating elements required by HIPAA into the research consent document.

CONSENT TO PARTICIPATE IN RESEARCH

Study title: Complementary Medicine and High Blood Pressure

You are being invited to be in this research study because you have high blood pressure. Please feel free to ask questions at any time. Your participation is voluntary and you can stop at any time without penalty.

We are doing this research study to learn more about the use of complementary medicine and its effect on high blood pressure control. Examples of complementary medicine include yoga, acupuncture, chiropractic care and herbal medicines.

If you agree to participate in this study:

- We will collect information from your medical records. We will only collect information about your blood pressure including the medications you take, and, information about you including age, sex, race and ethnicity.
- We will ask you to fill out a questionnaire about your use of complementary medicine. It will take about 15 minutes to answer the questions. You do not have to answer any questions that you do not wish to answer.

We will only keep information that could identify you long enough to match your responses with your medical records. We do not plan to share this information with anyone who is not connected to this research study.

We will take steps to protect your confidentiality, but there is a small risk that your information could be accidentally disclosed to people not connected to the research.

If you have any questions about the study, you can reach the investigator at the following number: xxx-xxx-xxxx

If you have any questions about your participation in this research, you can call the Institutional Review Board (IRB) at xxx-xxx-xxxx. The IRB is a committee that has reviewed and approved this research study.

If you agree to participate in this research study, please sign below:

Participants Printed Name

Participants Signature

Example 4 – Simplified Consent Document Utilizing Two Columns of Text

Scenario: A research study involving the collections of basic demographic information and recent health history, as well as a single blood draw.

Key Features:

- minimal risk
- healthy adults
- no identifiable information will be collected
- no genetic testing will be done
- the research will not lead to the creation of any sensitive information
- any remaining samples will be destroyed at the end of the study

Analysis:

This example presents the information in column style rather than traditional consent document formatting. There are no regulatory requirements for style and design. Alternative formatting may allow investigators to present information in pamphlet style or other alternative formats.

Selected elements of consent are not included in accordance with previously approved SACHRP recommendations. Omitted elements include the following:

- alternatives to participation
- benefits to subjects or others
- research related injury

To proceed under this approach, the IRB would need to grant a waiver of documentation of consent, which it could do under 45 CFR 46.117(c)(2) as 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.

In this example, the common discomforts associated with blood draw have not been described as risks.

There is an assumption that the associated discomforts are well known to prospective participants and therefore an explicit discussion is not necessary. Consistent with [previous SACHRP recommendations](#), risks or burdens that are immaterial or obvious to potential participants need not be explicitly addressed in the consent form or dialogue. Some IRBs may decide to include this risk language due to factors including the subject population involved and local practices.

The complete regulatory language regarding “penalty or loss of benefits to which the subject is otherwise entitled” (45 CFR 46.116(a)(8)) is not used in an effort to simplify consent and eliminate confusion. There is a presumption that “penalty” can be interpreted to include loss of benefits.

CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Immune System Blood Draw Study

Principal Investigator:

Introduction

You are being asked to be in this research study because you are an adult with no known illnesses. Your participation in this study is voluntary. Please ask any questions you may have about participating in this study.

Purpose

We are doing this study to learn more about how the body fights infection.

Procedures

If you agree to participate in the study we will ask you some questions about yourself and your health history. We will also use a needle to take about 2 teaspoons of blood. It will take about an hour to complete the study.

We do not plan to tell you what we find when we analyze your blood. When we finish our tests we will destroy any leftover blood.

Benefits

You will not benefit from participation in this study.

Withdrawal

You can withdraw from this study at any time without penalty.

Confidentiality

Your identifiable information will not be included on the blood sample. If study results are published you will not be identified.

Questions

If you have any questions about this study please call 800-867-5309 and ask to speak to someone about the Immune System Blood Study.

If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University Office of Research Integrity toll free at 1-866-600-6789.

Example 5 – Simplified Model with Information Provided in Bullet-list Format

Scenario: A research study designed to determine the optimal placement of a prototype device that measures how an experienced adult smoker smokes and samples waterpipe tobacco smoke in real-time.

The study will involve experienced water pipe tobacco smokers using a water pipe without the device and also with the device installed in various components of the water pipe. In addition, demographic information, including medical history, smoking history, and marijuana and alcohol use history will be collected in order to ensure participants meet inclusion/exclusion criteria and also so that the participant sample can be characterized precisely.

Key Features:

- minimal risk
- Non-pregnant adults who self-identify as experienced smokers.

Analysis:

This consent form reduces the elements of consent to a list of bullets addressing the required elements of informed consent.

Selected elements of consent are not included in accordance with previously approved SACHRP recommendations. Omission of these elements does not require a waiver from the IRB. Omitted elements include the following:

- alternatives to participation
- benefits
- research related injury

Due to the technical aspects of this study even experienced waterpipe users may benefit from a consent process that includes tools such as a waterpipe outfitted with the device.

There are no additional risks introduced by the research for experienced adult water pipe tobacco smokers, therefore risks are not included in the consent document. However, as this study involves administration of tobacco, some IRBs may determine that the research is greater than minimal risk. In this case, we have made an assumption that the study is minimal risk in non-pregnant adults who self-identify as experienced smokers.

To proceed under this approach, the IRB would need to grant a waiver of documentation of consent, which it could do under 45 CFR 46.117(c)(2) as 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.

CONSENT TO PARTICIPATE IN RESEARCH

Title: REALTIME water pipe tobacco smoke sampling device

IRB Number:

Investigator:

- The purpose of this research study is to test a device called REALTIME that will sample tobacco smoke from a water pipe.
- You do not have to participate in this study. If you choose to participate you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in this study.
- You will be asked questions about your general health, smoking history, and marijuana and alcohol use.
- If you are a woman you will need to provide a urine sample that will be tested immediately for pregnancy. If you are pregnant you cannot participate.
- All information will be confidential. There is always a small risk of accidental disclosure.
- Your participation will require three, 2-hour sessions separated by at least 48 hours. You may not use any tobacco products or nicotine containing products (like gum or the patch) for at least 12 hours before each session. You will take a simple breath test to make sure that you have complied with these restrictions. We will also ask you to stop eating 1 hour before each session.
- In each session you will be asked to smoke a water pipe in the laboratory. We want you to smoke as you normally would and we will use your preferred brand/brand of tobacco. The water pipe will be loaded only once in each session, and we ask that you use it for at least 45 minutes, though you may take as many or as few puffs as you like during that period. The water pipe will be started with a single charcoal disk, but you may add additional ½ disks as you like.
- You will receive \$30 after the first session, \$70 after the second, and \$100 after the third session.
- You can contact Dr. Smith with any questions about the study at 987-654-3210
- If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University Office of Research Integrity toll free at 1-866-600-6789.

Example 6 – Simplified Consent Language with Documentation of Consent

The study will involve individual interviews and focus groups to discuss issues related to religion. Participation may last up to one year. Interviews and focus group discussions will focus on the experiences of adults in relation to religious certainty, doubt and questioning.

Key Features:

- minimal risk
- adults
- study will pose potentially sensitive questions in a focus group setting

Analysis:

Given the subject matter and the real and perceived sensitivity regarding religious beliefs and the fact that the study involves focus group discussions, we believe it would be appropriate to include more than the minimal amount of information related to privacy and confidentiality concerns.

Selected elements of consent are not included in accordance with previously approved SACHRP recommendations. Omission of these elements does not require a waiver from the IRB. Omitted elements include the following:

- alternatives to participation
- benefits
- research related injury

A signature block for documentation and a separate endorsement for recording is included. IRBs could elect to waive written documentation.

The complete regulatory language regarding “penalty or loss of benefits to which the subject is otherwise entitled” (45 CFR 46.116(a)(8)) is not used in an effort to simplify consent and eliminate confusion. There is a presumption that “penalty” can be interpreted to include loss of benefits.

You are being asked to be in a research study by investigators at XYZ University. We are studying the experiences of Americans in relation to religious certainty, doubt, and questioning. We are also interested in the nature of faith and the nature of religion in America in the 21st century.

If you agree to be in our study we will talk with you for several hours. You will also be asked to be in small focus-group discussions. You do not have to be in the study if you don’t want to: it is your choice. You can also agree to be interviewed but not be in a focus group. You can change your mind at any time and there will be no penalty. You and [name] will decide together how many interviews you will have, and when they will occur. The interviews may happen over the span of a year, if you agree.

We know that religious doubt can be a very sensitive topic. You do not have to share any information that you are not comfortable sharing. You can stop the participating in conversation at any time. Also, some people may be upset or angry if they hear others in the focus groups expressing views different from their own.

We will be careful to keep your information confidential, and we will ask you and all the focus group members to keep the discussion confidential as well. There is always a small risk of unwanted or accidental disclosure. The conversations and the focus groups will be recorded and transcribed only with your permission. Any notes, recordings, or transcriptions will be kept private by the primary investigator (name). The files will be encrypted and password protected. You can decide whether you want your name used.

If you have questions or concerns at any time about the research, you can contact [PI name] at ____ .

If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University Office of Research Integrity toll free at 1-866-600-6789.

Name: _____

I give my consent to participate in this study:

Signature

Date

I give my consent to have discussions recorded:

Signature

Date

Example 7 and 8 – Two Approaches to Simplified Consent

Examples 7 and 8 provide two approaches to informed consent for a research study to assess the benefits of a peer mentoring program.

Either approach would be acceptable for this scenario.

Key Features:

- minimal risk
- adults

Analysis:

Each of these examples is intended for the same research scenario and present the same information but in different formats. One example is formatted like a letter and could be provided in advance of the consent discussion. The second example is an outline that the researcher would use to guide the consent discussion. The documents could also be used together as part of one longer consent process, in which prospective subjects receive the letter version (Example 7), but the in-person consent discussion is guided by script (Example 8).

Both examples begin with an introduction of the researcher. In each example this is appropriate. If the information is transmitted in by letter (example 7), it would be appropriate to begin the communication with a formal introduction of the researcher and the project.

Selected elements of consent are not included in accordance with previously approved SACHRP recommendations. Omission of these elements does not require a waiver from the IRB. Omitted elements include the following:

- alternatives to participation
- benefits
- research related injury

To proceed under this approach, the IRB would need to grant a waiver of documentation of consent, which it could do under 45 CFR 46.117(c)(2) as 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.

Example 7 - Letter format:

Dear Participant,

My name is [] and I am a faculty member in the Community Leadership Development Center at the University of the Midwest. I am conducting a study of first generation students to assess the academic and social benefits of peer mentoring.

I am looking for student participants who are currently serving as a mentor or mentee and would be willing to discuss their experiences. If you agree to take part in this study, you will be asked to participate in a focus group to discuss your experience as either a mentor or mentee in the center's peer mentorship program.

Participation is voluntary and you may skip any questions you do not wish to answer. You can also stop participating at any time without penalty. Your decision to participate will have no impact in your participation in mentoring programs.

Your responses may help us understand more about first generation college students and the types of programs that will impact their academic achievement.

There will be separate sessions for mentors and mentees. The sessions for the focus group will be between 30-45 minutes, will be voice-recorded, and conducted in Research Hall. Names will not be recorded. Due to the nature of a focus group, I cannot guarantee privacy as other subjects present in the group will know what was said and by whom. The recordings will be destroyed once the analysis is complete. You will not be paid for taking part in this study, nor will you receive course credit.

If you are interested in participating or have questions about the study, please feel free to contact at 800-555-1234, email@domain.com. If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University Office of Research Integrity toll free at 1-866-600-6789.

Example 8 – Bulleted List of Talking Points to be Followed by the Individual Conducting the Consent Process

Informed Consent Script

- Introduction: My name is [] and I am a faculty member in the Community Leadership Development Center at the University of the Midwest.
- Purpose: I am conducting a study of first generation students to assess the academic and social benefits of the new peer mentorship program provided by the center.
- Requirements for participation: I am asking for student participants who are currently serving as a mentor or mentee. If you agree to take part in this study, you will be asked to participate in a focus group to discuss your experience as either a mentor or mentee in the center's peer mentorship program.
- Study procedures: There will be separate sessions for mentors and mentees. The sessions for the focus group will be between 30-45 minutes, will be voice-recorded, and conducted in Research Hall. Names will not be recorded. Due to the nature of a focus group, I cannot guarantee privacy as other subjects present in the group will know what was said and by whom. The recordings will be destroyed once the analysis is complete. You will not be paid for taking part in this study, nor will you receive course credit.
- Voluntary: Participation is voluntary and you may skip any questions you do not wish to answer. You can also stop participating at any time. Your decision to participate will have no impact in your participation in mentoring programs.
- Goal: Your responses may help us understand more about first generation college students and the types of programs that will impact their academic achievement.
- Contact: If you are interested in participating or have questions about the study, please feel free to contact at 800-555-1234, email@domain.com. If you have any complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University of the Midwest Office of Research Integrity toll free at 1-866-600-6789.