



## **GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

### **1.0 INTRODUCTION**

Union University, in accordance with its Multiple Project Assurance (MPA) filed with the Department of Health and Human Services, and 45 CFR Part 46 establishes the Institutional Review Board for the Protection of Human Subjects (IRB).

The IRB is responsible for reviewing research involving human subjects to ensure that such research is consistent with the principles of (a) respect for persons, (b) beneficence, and (c) justice, as set forth in the Belmont Report (1979). "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Title 45 CFR 46.102(l)). Additionally, the IRB follows all applicable Federal, state, and University regulations. These include but are not limited to 45 CFR Part 46, 21 CFR Parts 50 and 56 and the Union University Multiple Project Assurance (MPA) for research involving human subjects.

### **1.1 Criteria for IRB approval of research**

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

- (1) Risks to subjects are minimized:
  - (a) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
  - (b) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- (3) Selection of subjects is equitable.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative and informed consent will be appropriately documented or appropriately waived.
- (5) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects and that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

### **1.2 Non-compliance**

In accordance with 45 CFR Part 46, the IRB is required to report instances of serious or continuing non-compliance, and any suspension or termination of IRB approval to the Provost, Federal Office for Protection from Research Risks (OPRR), and, in the case of Federally supported research projects, the appropriate Department or Agency head.

Additionally, non-compliance with this policy by faculty/staff members may result in one or more of the following:

- Official reprimand
- Removal from graduate faculty status
- Suspension of research privileges at Union University
- Termination of employment

Non-compliance with this policy by students may jeopardize awarding of the degree being sought.

## 2.0 **SCOPE OF REVIEW**

IRB review and approval is required for any research involving human subjects (including human subjects' data) that is (a) conducted by University faculty, staff, or students; (b) performed with or involves the use of facilities or equipment belonging to the University. Research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

### 2.1 Research methods courses

Courses in research methods and all class assignments which involve research with human subjects require IRB approval even if the class exercise does not seem to qualify as "true research" - when, for example, the results are not intended for publication, will not advance work in another area, or will not contribute to generalized knowledge. For such classes, the instructor should submit a Request for Class Project Waiver of IRB form for IRB approval. Individual student forms would need to be submitted to the IRB if their project falls outside the scope of the approved protocol, or if subsequent to the class, it was decided to use the data for generalized knowledge.

Research methods courses that collect data with invasive techniques or with ionizing radiation are required to be reviewed by the IRB even if the collected data is not intended to be generalized or publishable.

### 2.2 Research conducted by students

Students conducting research using human subjects or their data, either on or off University property, as part of the requirements for completing a degree are required to have the project reviewed by the IRB. A faculty advisor must mentor all student projects. The faculty advisor is ultimately responsible for all aspects of adherence to IRB policy. As such, the advisor should assist in the generation and review of all materials to be submitted to the IRB. The advisor will be responsible for all project termination documentation if the student leaves the University before the documentation is completed.

### 2.3 Dissertation requirements

The graduate student's dissertation committee must approve the study before it is submitted to the IRB for review.

### 2.4 Research conducted at another institution

Research conducted at, or in affiliation with, another institution must be reviewed by the IRBs of both Union University and the other participating institution(s). An institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

### 2.5 Research conducted in a foreign country

Research conducted in a foreign country must also be reviewed by the IRB. When research takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in these guidelines. In these circumstances, if the IRB determines that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in these guidelines, the IRB may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in these guidelines.

For projects requiring an informed consent document, both an English and a native language document must be generated. Approval to waive a signature on an informed consent may be given (a) if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, (b) that the research presents no more than minimal risk of harm to subjects, and (c) provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

### 3.0 **LEVELS OF REVIEW**

There are three levels of review, as determined by the degree of risk to subjects. Applications will be screened for exempt, expedited, or full IRB review. The level of review is determined by the IRB.

#### 3.1 Exempt Review

A project that is exempt presents little or no risk to participants. Exempt review consists of review by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. If the project is declared non-exempt, the protocol will then be sent for expedited or full board review. An IRB approval document must be obtained prior to initiating the research. Any changes to the protocol must be submitted and approved by the IRB.

Examples of research that may be exempt from Federal regulations include:

- Research using existing or archived data, documents, records, or specimens may be exempt from Federal regulations. Existing data means the items existed before the research was proposed or was collected prior to the research for a purpose other than the proposed research. The data must be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research conducted in established or commonly accepted educational settings, involving 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, 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.
- Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, and observational procedures may be exempt from Federal regulations 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 remains anonymous; (2) 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 (3) 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, but that the IRB determines there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(Note: Exemption is not allowed for interviews with children or observations of children in which the investigator participates in the activity being observed.)

- 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. 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.
- Secondary research for which consent is not required. Secondary research refers to research with materials originally obtained for non-research purposes or for research other than the current research proposal. Secondary research uses of identifiable private information or identifiable biospecimens may include: (a) identifiable private information or biospecimens that are publicly available; (b) information, which may include information about biospecimens, is recorded 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) investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health." Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).
- Taste and food quality evaluation and consumer acceptance studies if: (a) wholesome foods without additives are consumed or (b) 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.
- Storage or maintenance of identifiable private information or biospecimens for secondary research. The exemption can only be used when (a) there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials and (b) the IRB determines there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Secondary research for which broad consent is required. The use of identifiable private information or identifiable biospecimens if the following criteria are met: (a) broad consent was obtained from the subjects for the secondary research use of their identifiable materials, (b) documentation or waiver of documentation of informed consent was obtained, (c) the IRB determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, and (d) investigators cannot include the return of individual research results to subjects in the study plan. Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.

### 3.2 Expedited review

If the research meets the definition of minimal risk and involves only procedures listed in one or more of the categories below it may be reviewed by expedited procedures. Expedited review consists of review by two members of the Institutional Review Board. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Clinical studies of drugs and medical devices for which an investigational new drug application or an investigational device exemption application is not required.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means (e.g., hair and nail clippings, sputum specimen collected after saline mist nebulization, to name a few).
- Collection of information or biospecimens through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves (e.g., body weight, electrocardiograph, ultrasound, moderate exercise when appropriate).
- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as for medical treatment or diagnosis). Note: some research in this category may be exempt from HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
- Collection of information from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note: some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.

### 3.3 Full board review

Any research that involves more than minimal risk requires review by the full board.

### 3.4 Continuing review

Research that presents significant physical, social or psychological risks to subjects is subject to continuous review at least every 12 months. Continuing review will not be required in instances where such review does little to protect subjects (e.g., where data collection is complete and only data analysis is still being performed). An application for continuing review is scrutinized at the same level as the initial review.

#### 4.0 **REVIEW PROCESS**

After review at the appropriate level one of the following actions will be taken:

- Approved as submitted and research may begin
- Approved, pending receipt of minimum clarifications, protocol modifications, or consent revisions
- Deferred, pending receipt of additional information or major revisions
- Not approved

Investigators will be notified by email of any revisions that are required, or of other information needed before final approval can be obtained. Research may begin only after revisions have been made and approved by the IRB. Upon final approval (when all concerns of the reviewers have been satisfied), the investigator will receive an approval document signed by the chairperson, or an experienced IRB member designated by the chairperson and, if applicable, the approved informed consent document that has been stamped by the IRB indicating the expiration date. A copy of all documentation is archived in the IRB Office.

There may be occasions where the IRB will require verification from sources other than the investigators that no material changes have occurred since previous IRB review, such as the experience of the investigator or if an investigator has a history of non-compliance.

Initial review applications are submitted to the IRB, and are reviewed to determine if they are complete. If they are not, they are sent back to the investigator to complete. Complete applications are assessed as to level of review (exempt, expedited, or full) based on risks to subjects, subject population, or if medical equipment or drugs are used.

##### 4.1 Exempt review process

Exempt review consists of review by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. There is no deadline for submitting an application for exempt review. Investigators should allow 1-2 weeks for the review process, and longer if revisions are required. When the review is received from the IRB chairperson or designated reviewer, the investigator is advised via email either of the approval or of any revisions required before final approval can be obtained. A list of all applications approved through the exempt process is submitted to the full board and documented in the minutes.

##### 4.2 Expedited review process

Expedited review consists of review by one or more IRB members. There is no deadline for submitting an application for expedited review. Investigators should allow 2 weeks for the review process, and longer if revisions are required. Any of the reviewers can require that an application be submitted to the full board for review if they feel the risks are more than minimal, or for any other reason. When reviews are received from the designated reviewers, the investigator is advised via email either of the approval or of any revisions required before final approval can be obtained. A list of all applications approved through the expedited process is submitted to the full board and documented in the minutes.

##### 4.3 Full board review process

Full board review consists of review by all members of the IRB. Applications are due by noon on the deadline date (usually 2 weeks prior to the meeting date), and are distributed to each member at that time to allow adequate time for review. The meeting dates are posted on the IRB website at <http://www.uu.edu/research/irb/>. At convened meetings of the IRB, applications are approved, approved with revisions, deferred, or disapproved. The investigator is advised via email of the

decision, of any revisions that are required, or of other information needed before final approval can be obtained. Full board actions require the presence of a quorum of the voting members, defined as a majority of the membership including at least one member whose primary concerns are in a nonscientific area. Regulations may require that a consultant or expert be added to the IRB when reviewing some research. Meetings are scheduled on a regular monthly basis, and investigators may be asked to attend. Investigators will be excused from the meeting prior to the vote of the IRB.

#### 4.3.1. What to submit (if applicable)

- Initial Review form
- Copy of consent document(s), cover letter, or script
- Copy of survey, questionnaire, or interview guides/scripts (include documentation of permission to use/adapt a survey or questionnaire (if applicable)).
- Copy of any recruitment advertisements
- Signed Assurances page which includes the signature for the investigator and the advisor

#### 4.4 Continuing Review

Research that presents significant physical, social or psychological risks to subjects is subject to continuous review at least every 12 months. Continuing review is not required for: (a) research that is eligible for expedited review, (b) exempt research conditioned on limited IRB review, (c) research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable, and (d) research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

##### 4.4.1 What to submit

- Continuing Review form
- Clean copy of the proposed informed consent document (to be re-stamped by IRB)

#### 4.5 Adverse Events

Adverse events are unexpected problems whose nature, severity, and frequency are not described in the information provided to the IRB or to participants. Examples include unexpected complications with a subject, missteps in the consent documentation, or breaches of confidentiality. Adverse events should be reported to the IRB within 10 working days. These reports usually receive expedited review, but in some cases the full IRB is involved. Sometimes a study must be suspended to ensure subjects' safety. All reports of adverse events, and any suspension or termination of IRB approval will be reported to the Provost, the Federal Office for Protection from Research Risks, and, the appropriate Department or Agency head.

##### 4.5.1 What to submit

- The facts of the case, including the date and a description of the subject.
- Whether the event is related to the study's procedures or drugs or to the subject's underlying disease or condition.
- The steps that have been taken to address the problem.
- Whether the event is likely to recur; and whether the event provides new information about the study's risks that should be conveyed to participants, in a revised consent form.

#### 4.6 Changes to Protocol after Approval

All proposed changes to the approved research activity must be reported promptly to the IRB for review. Any changes to the approved research during the period for which IRB approval has already been given may not be initiated without IRB review except when necessary to eliminate apparent immediate hazards to the subject. Any revised informed consent document(s) must be re-stamped. Approval of the change is given for the same period as the most recent review.

#### 5.0 **SPECIAL POPULATIONS**

The Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, persons with a mental disability, or persons who are economically or educationally disadvantaged. In general, these special regulations allow IRBs to approve research with these special populations that is of minimal risk or that will benefit the subjects directly.

##### 5.1 Students as research subjects

In order to avoid coercion, instructors should not use their own students as research subjects. If class credit is offered to participate in research, it must be at a level appropriate to the degree of risk. Detail must be given as to how credit will be pro-rated for early withdrawal. An alternative method of receiving the same credit must be provided for students who do not wish to participate in the research. A copy of recruitment materials must be submitted with the application.

##### 5.2 Children as research subjects

Any research that involves children as subjects must take into consideration the benefits, risks, and discomforts inherent in the research. Generally, research using children as subjects should involve no more than minimal risk. Permission of parents or guardians must be obtained, as well as assent of the child. Failure to object to the research should not be construed as assent. (Note: Exemption is not allowed for interviews with children or observations of children in which the investigator participates in the activity being observed.)

##### 5.3 Prisoners as research subjects

The primary issues surrounding the participation of prisoners in research is whether prisoners have a real choice regarding their participation in research, whether their situation prohibits the exercise of free choice, and whether his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. Any study involving prisoners as subjects must be reviewed by an IRB that includes a prisoner or prisoner representative with appropriate background and experience to serve in that capacity.

#### 6.0 **INFORMED CONSENT**

The process of informed consent is central to the protection of human subjects involved in research. Informed consent involves more than signing a form. The prospective subject or the legally authorized representative must understand the study and be provided with information that a reasonable person would want to have in order to make an informed decision about whether to participate. Subjects should be given the opportunity to discuss, ask questions, and consider whether or not to participate in the research study. The consent document should be written in language appropriate to the intended audience, avoiding jargon and technical or scientific terms. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal



rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

6.1. Basic elements of informed consent

Federal regulations identify basic elements of informed consent, which must be addressed in consent documents. The following information must be provided to each subject:

- (a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (b) a description of any reasonably foreseeable risks or discomforts to the subject;
- (c) a description of any benefits to the subject or to others which may reasonably be expected from the research;
- (d) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (e) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (Note: confidentiality can only be maintained within the limits allowed by law and should be stated as such. Do not promise strict confidentiality unless participation is anonymous);
- (f) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained (Note: a statement must be included that Union University does not have any funds budgeted for compensation for injury, damages, or other expenses);
- (g) an explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of a research-related injury to the subject; for answers to questions regarding the research subjects' rights, the Chair of the Institutional Review Board should be contacted at 731-661-5580.
- (h) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- (i) if research involves the collection of identifiable private information or biospecimens, a statement that either (a) identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens might be used for future research studies or distributed to another investigator without additional informed consent, or (b) the subject's information or biospecimens will not be used for future research studies (even if identifiers are removed).
- (j) When appropriate, the IRB may ask that additional information be provided to each subject.

6.2. Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in 6.1. Check with the IRB Office concerning the elements of Broad Consent.

6.3. General Waiver or Alterations to Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (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) if the research involves using identifiable private information or biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identified, but protected format; and
- (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Note: If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements for broad consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

#### 6.3.1. Waiver of Signed Informed Consent

The IRB may approve a waiver of the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- (a) the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality;
- (b) 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;
- (c) the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

## 7.0 **DEFINITIONS**

**ADVERSE EVENT** An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).

**ANONYMOUS** data collection means that even the researcher does not know the identity of the subjects.

**BROAD CONSENT** pertains to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.

**CONFIDENTIAL** data collection means that the researcher knows the identity of the subjects either directly or through the use of a master list used for coding but will not release identifying information when sharing the data with others.

**HUMAN SUBJECT** means a living individual about whom an investigator (whether professional or student) conducting research: (a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates human subject information.

**INTERACTION** includes communication or interpersonal contact between investigator and subject.

**INTERVENTION** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

**MINIMAL RISK** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults. [See 45 CFR 46.303(d)]

**PRINCIPAL INVESTIGATOR** is an employee, faculty member, or student who accepts responsibility for the research.

**PROTOCOL** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**RATIONALE** A statement, grounded in the pertinent body of research literature, that describes the purpose and importance of the proposed research project.

**RESEARCH** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalized knowledge [Federal Policy §46.102(d)].

**RETROSPECTIVE STUDIES** Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

**SECONDARY RESEARCH** refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for non-research purposes, such as materials that are left over from routine clinical diagnosis or treatments.

**VULNERABLE POPULATIONS** Special consideration is given to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled person, or economically or educationally disadvantaged persons.

## CHECKLIST

1. \_\_\_\_\_ Has the Institutional Review Board Tutorial been completed?
2. \_\_\_\_\_ Is there approval from the School of Education Research Review Committee or Nursing Review Committee (if applicable)?
3. \_\_\_\_\_ Is the appropriate form completed (initial or continuing review)?
4. \_\_\_\_\_ Is the Initial Review application complete? Is every question answered thoroughly?
5. \_\_\_\_\_ Have any survey instruments or recruitment ads been attached to the application?
6. \_\_\_\_\_ Is there more than minimal risk involved in this study? If yes, this project must be submitted for full board review.
7. \_\_\_\_\_ Do the project benefits outweigh the project risks?
8. \_\_\_\_\_ If any compensation is associated with this study, is it pro-rated over the course of the study?
9. \_\_\_\_\_ Is the assurances page signed by both the researcher and the advisor?
10. \_\_\_\_\_ Has the Informed Consent document(s) been attached to the application (if applicable) and written at a 6<sup>th</sup> grade level?
11. Are the elements of consent given in Section 6.1 of the Guidelines present in the Informed Consent document?
12. \_\_\_\_\_ Does the purpose of the study and the description of the project in the consent form match what is stated in the protocol?