



EDUCATIONAL GUIDE BEHAVIORAL AND SOCIAL SCIENCE RESEARCH APPLICATION

*NOT ALL QUESTIONS WITHIN THE APPLICATION CONTAIN AN EDUCATIONAL NOTE.
THE NUMBERS AND LETTERS CORRESPOND WITH THE QUESTIONS ON THE APPLICATION.*

SECTION I

4. **FUNDING SOURCE**

All research must have a source of funding. Examples of other funding sources may be departmental funds, Clinical Research Center Support grants, or personal funding.

7. **STUDY SITES:**

- A. Study sites are defined as all internal or external locations, such as a clinic, laboratory, school, center, church, other community site where Oakwood University investigators or staff interact with subjects, collect data or solicit consent (e.g. Oakwood Adventist Academy, New Life S.D.A. Church, Mason Courts)
- B. This section should specify study sites at institutions that are under the oversight of external IRBs (e.g., other academic centers or hospitals, other universities).

SECTION II

PURPOSE OF THE STUDY AND THE BACKGROUND

2. **BACKGROUND AND RATIONALE**

This section should clearly support the purpose of the study, contain appropriate key literature citations, and should not exceed three pages in length but should be more than one paragraph.

CHARACTERISTICS OF THE SUBJECT POPULATION (3-8)

3. **ACCRUAL**

- A. For multi-center studies provide the total expected number of subjects
- B. Summarize briefly the statistical consideration or other considerations which determine the total number of subjects. For studies with a separate protocol document, summarize briefly here and reference the statistical information in the protocol document.
- C. Subjects may be consented but fail screening or they may voluntarily withdraw or be involuntarily withdrawn by the investigator. Thus, depending upon the nature of the study, more subjects may need to be initially consented in order to obtain the number necessary to achieve the scientific objectives of the research. The stated number of subjects to be consented is a maximum number which cannot be exceeded without IRB approval.

4. **GENDER OF THE SUBJECTS**

- A. YES. Equitable inclusion of both male and female subjects in research is important to ensure that they receive an equal share of the benefits of research and that neither group bears a disproportionate burden. Therefore, subjects of both genders should be included in research unless there are sound medical or scientific reasons.
- B. YES. Individuals of childbearing potential should not be routinely excluded from participating in research unless there are sound medical or scientific reasons not to include them.
- C. YES. Individuals who are pregnant or breast-feeding should not be routinely excluded from participating in research unless there are sound medical and/or scientific reasons not to include them.

5. **AGE RANGE OF SUBJECTS**

- A. The lower and upper end of the age range must be stated.
- B. Participation of adult subjects in research should not be age-restricted unless there is sound scientific and/or medical justification. The age of majority in Alabama is 19 years of age.

- C. NO. Children should not be routinely excluded from participating in research unless there are sound medical or scientific reasons not to include them.

6. RACE AND ETHNICITY

YES. Within the limitations imposed by the prospective subject population of the study site(s), research should include sufficient enrollment of persons of diverse racial and ethnic backgrounds in order to ensure that the benefits and burdens of research participation are distributed in an equitable manner.

7. VULNERABLE SUBJECTS

- A. Pregnant individuals, fetuses, prisoners, and children are defined by federal regulations as vulnerable populations requiring specific additional protections. Inclusion of these populations requires that the research satisfy requirements of 45 CFR 46 subparts B (pregnant women and fetuses), C (prisoners), and D (children). In addition, research involving decisionally impaired persons must satisfy 45 CFR 46.111(b).

Note: If any subject becomes pregnant or incarcerated after enrollment in the research and their inclusion has not been approved by the IRB, contact the ORA for advice. If the study becomes open to any of the other vulnerable populations specified above, a Request for Change and the required addendum must be submitted before enrollment.

- B. **Yes.** Populations that may be considered vulnerable to coercion or undue influence such as economically or educationally disadvantaged persons are placed at increased risk of coercion or undue influence, thereby requiring appropriate additional protections per 45 CFR 46.111(b).

8. INCLUSION CRITERIA

The inclusion criteria should be based on the study objectives and the need to minimize risk.

9. EXCLUSION CRITERIA

The exclusion criteria should be based on the study objectives and the need to

METHODS AND PROCEDURES (10-11)

10. METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS

- A. The study design must be scientifically sound and help ensure minimization of risk to subjects.
- B. This section should describe the research with enough specificity so that the IRB can understand what will be done to human subjects. Include flow charts and diagrams as necessary.
- C. A research protocol may involve interventions that are: 1) strictly experimental (e.g., administration of a new psychological assessment instrument), or 2) administration of standard assessments performed exclusively for research purposes. It is important for this section to distinguish between interventions that are experimental and standard procedures carried out solely for research purposes versus those procedures that are considered standard and would be performed regardless of research participation.
- D. Statistical methods must be appropriate in consideration of the scientific objectives of the study.

11. CONFIDENTIALITY AND PRIVACY

- A. Research data must be stored and secured in a manner which fully protects confidentiality. This section should describe how data is stored and secured at all stages of collection and analysis, including hard copy and/or electronically on local computers or shared secure drives. For example, hard copies must be stored in a secure location (e.g., locked room and file cabinet) and all electronic copies, which include PHI, must be protected. Indicate that all mobile devices (e.g., laptops, flash drives) which contain PHI are encrypted in order to minimize the potential for breach. In addition, all research data should be stored with a backup system.
- B. YES. 2) In order to help protect confidentiality the least number of subject identifiers should be recorded.
- C. YES. This section does not include persons who have access to research data solely for patient care.
- D. YES. 3) The number of subject identifiers associated with research data provided to outside investigators must be minimized to the greatest extent possible.
- E. YES. 3) The number of subject identifiers associated with research data provided to outside investigators must be minimized to the greatest extent possible.
- G. Generally, research data is subject to disclosure for the duration of the research and until data analysis is complete.

- H. Privacy refers to persons and their interest in controlling access to themselves whereas confidentiality is about protecting data. In order to protect a subject's privacy an investigator should consider, for example, any or all of the following depending upon the nature of the research: 1) obtaining consent in a private conference room or area, 2) ensuring that no unauthorized personnel are present, and 3) ensuring that the subject's name or other identifiers are not visible to non-study personnel.

RISK/BENEFIT ASSESSMENT (12-18)

12. POTENTIAL RISKS

A risk is a potential harm (injury) associated with the research that a reasonable person would likely consider significant. Risks can be generally categorized as physical, psychological, sociological, economic and legal.

13. RISK CLASSIFICATION

The PI should review each research intervention and then determine the overall risk classification for the study based upon the following factors: 1) existing data concerning risk, 2) evaluation of subject susceptibility and vulnerability to possible harm and discomfort, and 3) the steps taken to minimize risk. The estimation of risk is, therefore, procedure-specific, population-dependent, and collective.

Minimal risk means "The probability (of occurrence) and magnitude (seriousness) of harm or discomfort associated with the research are not greater than those ordinarily encountered in daily life (of the average person in the general population) or during the performance of routine physical or psychological examinations or tests." Minimal risk, therefore, is used to define a threshold of anticipated harm or discomfort associated with the research that is low.

Greater than minimal risk means the possible harms and discomforts of the research involving the proposed study population are greater than those ordinarily encountered in the daily life of the average person in the general population or during the performance of routine physical or psychological examinations or tests.

14. MINIMIZATION OF RISK

YES. Risks to subjects must be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

- B. All human subject research requires procedures to ensure subject safety that are based upon the risks, complexity and nature of the research. In general risks may be minimized by utilizing alternatives (procedures that have less risk), precautions (procedures to decrease the likelihood that harms will occur) and contingencies (procedures to deal with harms if they occur). The specific plan for minimizing risk; therefore, may include such items as interventions to respond to

psychological distress (e.g., counseling); scheduled follow-up visits; and phone calls or other communications with the subject.

- C. 2) All human subject research should have appropriate data monitoring procedures to ensure subject safety in consideration of the risks, complexity, and nature of the research. This section should describe procedures for monitoring the data obtained during the course of the research. Information obtained during data monitoring will help determine when a change in protocol may be necessary to minimize risk or subjects should be withdrawn from the research.
- D. This section should describe the specific criteria by which the investigator would withdraw subjects from the research. The criteria will depend upon the nature of the research and the risk level.
- E. Stopping rules refer to specific criteria for early termination of the study. This section should describe the specific rules for early termination of any study where stopping rules are necessary for subject safety.
- F. Auditing refers to a retrospective review of compliance with the protocol which is usually carried out by study personnel. All research should have an appropriate auditing plan based upon the nature and risks of the research. Reports of any protocol violations discovered during auditing should be submitted to the IRB as required

15. POTENTIAL BENEFITS TO THE SUBJECT

Any statement concerning the prospect of direct subject benefit should be fully supported by the protocol and the literature citations in the background section.

16. POTENTIAL BENEFITS TO SOCIETY

Societal benefit generally refers to the advancement of knowledge. This section should reflect a degree (i.e., importance) of the potential societal benefit that is supported by the protocol and the literature citations in the background section. The potential benefits should not be overstated.

17. RISK-BENEFIT RELATIONSHIP OF THE RESEARCH

The potential risks of the research must be outweighed or balanced by the potential benefit to the subject and/or to society. Analysis of the risk/benefit relationship of the research should only consider those risks and benefits that may result directly from the research interventions. This section should clearly document why the risk to subjects involved in the research are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

18. ALTERNATIVES TO PARTICIPATION

This section should include a reasonably detailed description of the alternatives that could be of benefit to the prospective subjects should they elect not to participate in the protocol. In most cases, the alternative is to not participate in behavioral or social science research.

FINANCIAL OBLIGATIONS AND COMPENSATION (19-20)

19. **FINANCIAL OBLIGATIONS OF THE SUBJECT**

YES. In most behavioral and social science research projects, subjects should not incur any financial burden from participating in the research.

20. **COMPENSATION TO THE SUBJECT FOR PARTICIPATION**

YES. Compensation may be monetary or, depending on the nature of the research, may consist of other forms of compensation such as gift cards, free goods, toys, or other items. Any compensation must be justified and not constitute undue inducement of the subject to participate in the research. A prorated system of financial compensation is required in most circumstances. The IRB has a strict policy for financial compensation, particularly in consideration of the possibility that economically disadvantaged subjects may be vulnerable to coercion or undue influence. Refer to HRPP Policy 3.7.

SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT (22-29)

22. **METHOD OF SUBJECT IDENTIFICATION AND RECRUITMENT**

- B. YES. All prospective subjects have a right to privacy. Therefore, research personnel must have ethical access to the names of prospective subjects. This means that the individuals involved have a professional relationship with the prospective subjects. If neither condition is met, the investigator must obtain the services of someone who does have such access and can contact prospective subjects on behalf of the investigator and obtain permission to release their names.
- C. An initial, personal invitation to prospective subjects about participating in the research must come from one or more of the research personnel who have ethical access. If none of the research personnel have ethical access, the investigator must obtain the services of someone who does.

Note: The identification and recruitment of subjects must be ethically and legally acceptable and free of coercion or undue influence. In addition, the recruitment procedure should be designed to facilitate equitable selection of subjects with particular attention paid to the recruitment of study participants of both genders and from different

racial or ethnic groups. In addition, the investigator should be particularly cognizant of the special problems of research involving vulnerable subjects.

Note: If advertisements or fliers are to be used, they must be submitted to the IRB and approved before use.

- D. "Appropriate diversity" means a distribution of subjects by gender and race/ethnicity which reflects the geographical recruitment area and objectives of the study. Depending on the nature of the research, the IRB may choose to require a specific plan to assure adequate enrollment of minorities.

23. **CAPACITY TO CONSENT**

- B. YES. When a research protocol is not designed with the intent to enroll decisionally- impaired individuals but there is, nevertheless, a reasonable likelihood that some subjects could lose the capacity to continue to provide valid informed consent during the study (i.e., participation in an ongoing consent process), the investigator should utilize the IRB "Assessment of Capacity to Consent to Participate in Research Form" (available on the IRB website). This form is designed to assist the investigator in determining whether or not the subject has the capacity to consent. If a subject lacks that capacity, an LAR must provide consent in order for the subject to continue participating in the research.

24. **PROCESS OF INFORMED CONSENT FOR COMPETENT ADULT SUBJECTS**

- A. Prospective subjects should be approached sufficiently far in advance of their involvement in research to enable them to have time to make an informed decision to participate in the study. This helps minimize the possibility of coercion or undue influence.
- B. The environment where informed consent will be obtained should be a private and quiet location, conducive to discussion and thoughtful consideration by the prospective subject with consideration given to the need to minimize the possibility of coercion or undue influence.
- C. This section should identify by name and describe the specific responsibilities of research personnel who will be involved in the process of consent (e.g., explanation of the research, demonstration of a procedure...). Individuals involved in the process of consent should take all necessary steps to minimize the possibility of coercion or undue influence. In addition, no exculpatory language should be used which suggests or implies in any way the subject is waiving any of their legal rights or appears to release the investigator, sponsor, or the institution from liability for negligence.

- D. The amount of time allotted to the process of consent is dependent upon the nature and complexity of the study and the need to minimize the possibility of coercion or undue influence. In some studies (e.g., complex research) a delayed consent procedure should be incorporated into the protocol in order to afford the subject an opportunity to discuss participation in the study with family, friends, counselors, or other confidants before they sign the consent form. In all cases subjects should be encouraged to take the consent form home before signing whenever they are uncomfortable about participation in the research.
- E. Subjects such as those who are educationally disadvantaged, have limited reading skills, are economically disadvantaged, or are disabled may be vulnerable to coercion or undue influence to participate in research. Additional protections during the process of consent may include but are not limited to appointment of a subject advocate, involvement of the subject's family or friends, use of a short form (verbal) consent, reading the consent to the subject, and use of teaching aids.
- F. Use of an interpreter is allowed for a limited number of non-English speaking subjects along with the use of a short form in accordance with HRPP policy #5.6. However, if it is anticipated that a substantial number of subjects will not speak English, a translated consent form should be used. Translated consent forms must be back-translated for assessment of the accuracy of the translation. Youth and child study information sheets are not required to be routinely translated; documentation of assent is added to the parental consent form.
- G. All investigators have a legal and an ethical obligation to ensure that the prospective subject has sufficient knowledge and comprehension of **all** of the elements of informed consent to enable him/her to make an informed and enlightened decision whether or not to participate in research. The fact that an individual is prepared to sign the informed consent form and has no unanswered questions does not necessarily represent sufficient evidence of an adequate level of comprehension. Some investigators, therefore, choose to determine the level of a person's comprehension by questioning the individual concerning his/her understanding of **all** the elements of informed consent. This section should clearly document that the investigator has an adequate plan in place to assure existence of an acceptable level of comprehension of **all** the elements of consent.
- H. YES. HRPP policies, federal regulations and sound ethical practice require that subjects have the opportunity to withdraw from the research at any time. In certain cases, it may be appropriate to seek active re-consent from subjects. A subject's preferences and interests may change over time, even in the absence of material changes in the research protocol. Therefore, investigators should consider obtaining re-consent, or at least reaffirmation of the subject's willingness to continue participation, on a routine basis. In most cases, such re-consent

need only be verbal agreement on the part of the subject after questioning by the investigator or research team member. In rare cases, more formal re-consent (for example, quarterly or at the time of each research intervention) may be appropriate.

25. C. YES. Research projects may produce results that will not be shared with the subject during the course of the research for scientific or other reasons. This section should clearly document what information will be withheld, why and how long. Upon conclusion of the research, it may be appropriate to advise subjects that research results are available upon request.

26. **DOCUMENTATION OF CONSENT AND ASSENT**

Any individual who is authorized by the IRB to document the obtainment of informed consent/assent from the subject/subject's LAR must have the necessary expertise as well as sufficient knowledge about the protocol and IRB consent requirements. The PI is ultimately responsible for ensuring the obtainment of valid consent/assent from all subjects or their LAR. Only individuals who are listed in this section and approved by the IRB are authorized to document consent and assent.

27. **CONSENT FORM, ASSENT FORMS, AND STUDY INFORMATION SHEETS**

Consent forms, assent forms, and study information sheets must conform to the IRB-required format and reading level. Refer to the model parent/guardian informed consent form and sample study information sheets found on the IRB website.

28. The IRB seldom waives the requirement for informed consent in Biomedical Research. However, under certain limited circumstances, as defined by HHS regulations at 45 CFR 46.116(d) and the HIPAA Privacy and Security Rules as applicable, an IRB may waive the requirements to obtain informed consent, or approve a consent procedure which does not include or which alters some or all of the elements of informed consent.

29. **WAIVER OF A SIGNED CONSENT FORM**

45 CFR 46.117(c) permits the IRB to waive the requirement for a signed consent for some or all subjects if it finds either 1) the only record linking the subject with the research would be the consent document and the principal risk would be a potential harm resulting from a breach of confidentiality. In this case each subject must be asked whether they want documentation linking them with the research and the subject's wishes will govern, or 2) 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.

RESOURCES (30)

30. This section should clearly describe the available resources necessary to safely carry out the research to completion and maintain compliance with all applicable regulations and IRB requirements. This would include: 1) the necessary funding before initiation of the research, 2) access to the physical space required for the interventions, 3) adequate clerical support, 4) data storage capability and security, 5) availability of personnel or services necessary to respond promptly to unanticipated problems involving risk to the subject or others and, 6) any other resources necessary to complete the study.

LITERATURE REVIEW (31)

31. **REFERENCES**

The IRB understands that the full protocol may contain a very extensive listing of references. However, to assure that the full IRB has sufficient information to complete their review this application must contain at least the key references.