OAKWOOD UNIVERSITY

INSTITUTIONAL REVIEW BOARD

BEHAVIORAL AND SOCIAL SCIENCE RESEARCH APPLICATION

SECTION I

1. STATUS:

☐ New Submission
☐ Revised protocol, IRB #____; version # or date _____

2. TITLE OF PROTOCOL:

3. RESPONSIBLE PERSONEL

A. PRINCIPAL INVESTIGATOR (PI):

Name:		**Position:**	
Department:		**Campus Zip:**	
Address:			
Email Address:			
Phone:		**Pager**	

*Note: This individual assumes **overall** responsibility for 1) development and submission of this IRB application, 2) obtainment of legally effective informed consent and assent (as applicable) from prospective subjects by all authorized personnel listed on this IRB application, 3) the performance of research interventions, 4) conduct of the research in full compliance with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, the HIPPA Rule, applicable state law, HRPP policies, the provisions of the protocol as approved by the IRB, and 5) the presentation or publication of the data. Only **one** PI can be named on the IRB application. Co-PIs (e.g. on NIH grants) must be listed as Secondary Investigators.*

If the PI is a student, a faculty advisor must be listed and must sign the Faculty Certification in Section II.10. The faculty advisor assumes responsibility for overall supervision of the student's research.

B. SECONDARY INVESTIGATOR (SI)

Names	Position	Department

Note: The SI(s) may also be termed co-investigators and share responsibility with the PI for: 1) development and submission of the application to the IRB, 2) obtainment of legally effective informed consent/assent from prospective subjects (as applicable), 3) performance of research interventions, 4) conduct of the research in full compliance with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, the HIPPA Rule, applicable state law, HRPP policies, the provisions of the protocol as approved by the IRB, and 5) the presentation or publication of the date.

C. PARTICIPATING PERSONNEL:

Names	Position	Department

Note: These individuals are not involved in the development and submission of the application to the IRB, but may be involved in conducting procedures and obtainment of legally effective informed consent/assent. All participating personnel must have sufficient knowledge about the protocol to facilitate effective interaction with the subject.

D. DATA/ADMINISTRATIVE PERSONNEL:

Names	Phone	Email

Note: These individuals do not have direct contact with subjects, but may have access to the subject's protected health information (PHI) or identifiers and may be directly involved in data management, research budget management and statistical support. These individuals usually do not serve as a contact for the O.U. IRB.

4. FUNDING SOURCE: Check **all that apply and provide the source of the funding.**

☐ **Grant – Provide source:**

☐ **Commercial – Provide company name:**

☐ **Other – Provide source:**

☐ **Oakwood University Departmental Funds**

5. Contract: Is there a contract or agreement associated with this study?

☐ Yes

☐ No

6. FUNDING AGENCY DEADLINE FOR IRB APROVAL: _____

7. STUDY SITES: Provide the names and locations of all study sites where this research will be conducted under the oversight of the O.U. IRB. See Educational Guide

8. PRINCIPAL INVESTIGATOR'S ASSURANCE

The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:

- I certify that I, and all listed research personnel, have the necessary qualifications and expertise to conduct this study in a manner which fully protects the rights and welfare of research subjects.
- I certify that all listed Secondary Investigators have been given a copy of this IRB application and any other relevant study related documents and have agreed to be a Secondary Investigator.
- I certify that all listed Secondary Investigators and other involved research personnel will be given a copy of the final IRB approved application and any other relevant study related documents.
- I recognize that as the PI it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will comply fully with the IRB-approved protocol, all applicable federal regulations, state laws, and HRPP policies.
- I recognize that it is my responsibility to ensure that valid informed consent/assent has been obtained, as appropriate, from all research subjects or their legally authorized representative (LARs). I will ensure that all research personnel involved in the process of consent/assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to HRPP policies, applicable federal regulations, and state law.
- I certify that the minimum amount of protected health information (PHI) necessary will be used and disclosed to conduct this research study (if applicable). I will implement reasonable safeguards to protect the PHI at all times.
- I will promptly inform the IRB of any unanticipated problems involving risk to the subjects or to others, as required within the time frame defined by HRPP policies.
- I will analyze each reported problem to determine if it impacts the risk benefit relationship of the study, the safety of the subjects, or informed consent.
- I will promptly inform he IRB if I become aware of 1) any complaints from research subjects, LARs, or others about research participation, 2) violations of federal regulations or state law, 3) violations of the HIPAA Rule, or 4) violations of HRPP policies.
- I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.
- I certify that there are, or will be adequate resources and facilities to safely initiate, carry out and complete this research at the study sites specified in Section I.7. This includes sufficient staff, funding, space, record keeping capability, and resources necessary to address any unanticipated problems involving risk to the subject or others. If the necessary resources become unavailable I will promptly notify the IRB.
- I will promptly inform the IRB of any significant negative change in the risk/benefit relationship or the research as originally presented in the protocol and approved by the IRB.
- I understand that continuing review by the IRB is required at least annually in order to maintain approval status. I will maintain IRB approval as long as this study is active.
- I will maintain all required research records on file and I recognize that representatives from the IRB, OHRP, HHS, and other Federal Departments or Agencies may inspect these records in accordance with granted authority.
- I certify that I and all other personnel listed in Section I of the IRB Application have disclosed all potential financial conflicts of interest as required and are in full compliance with the O.U. Conflict of Interest Policy. I further certify that all potential financial conflicts of interest are appropriately managed in order to ensure protection of the rights and welfare of patients.
- I understand that failure to comply with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, the HIPAA Rule, applicable state law, HRPP policies, and the provisions of the IRB-approved protocol may result in suspension or termination of IRB Approval or my research project and/or other administrative or legal actions.

_____	_____	_____
Printed Name of Principal Investigator	Signature of Principal Investigator	Date

9. CERTIFICATION OF FACULTY ADVISOR
If the PI is a student

My signature certifies that I have reviewed this IRB application and I approve it for submission to the IRB. I assume responsibility for the overall supervision of this research. I will advise the student on the responsible conduct of research including compliance with all applicable federal regulations, state laws, and HRPP policies.

_____	_____	_____
Printed Name of Faculty Advisor	Signature of Faculty Advisor	Date

10. PRINCIPAL INVESTIGATOR FINANCIAL INTEREST DISCLOSURE

A. ***As the PI, I certify that I am in full compliance with the O.U. Conflict of Interest Policy and I declare:***

1)

☐ I have no financial interest in this research.

OR

☐ I have a financial interest in this research. I have completed the *O.U. Disclosure of Potential Conflict of Interest Form* and obtained all required signatures. The original disclosure form is attached to this application. Note: *A COI management plan for the PI conflict of interest must be developed before this application will be reviewed by the IRB.*

2)

☐ I understand that if there is any change in my financial interest during the course of this research**,** I will update and submit the *O.U. Disclosure or Potential Conflict of Interest Form* within five (5) business days from the time the change becomes known.

B. ***As the PI who is ultimately responsible for the proper conduct of this research, I also certify that:***

☐ No Responsible Personnel have a financial interest in this research.

11. SCIENTIFIC/SCHOLARLY MERIT AND RESOURCE REVIEW CERTIFICATON

Note: Research proposals must undergo substantive scientific/scholarly merit and resource review ***prior to submission*** *of the application to the IRB. This IRB Application must provide evidence of this review. IRB applications submitted without this certification will* ***not*** *be reviewed by the IRB.*

The chairperson, authorized delegate, or appointed review committee of the PI's department or division is responsible for review of the research proposal ***prior*** *to submission. A Chairperson/delegate who is also listed as study personnel in Section I of this application cannot provide certification.*

My signature certifies that this application has been reviewed for scientific/scholarly merit and available resources. It has been determined that the application merits consideration by the IRB based upon the following:

1) **The proposal has an acceptable level of scientific/scholarly merit which justifies the use of human subjects.**

2) **The proposal has a sound research design which will achieve the stated objectives.**

3) **The PI has the necessary qualifications and experience to conduct this research.**

4) **The PI has, or will have, the necessary funding to support this research.**

5) **There is adequate physical space required for the research interventions at all study sites specified in Section I.8. In addition, there is adequate laboratory and clerical support, data storage capability, and any other resources necessary to complete this research.**

6) **At all study sites specified in Section I.7, there are provisions to respond promptly to unanticipated problems involving risk to the subject or others.**

7) **I will promptly notify the IRB if the necessary resources to support this research become available.**

I am not listed as study personnel in Section I of this application.

Printed Name of Reviewer	**Position**
Signature of Reviewer	**Date**

SECTION II

Instructions: In order to review your proposal, the IRB must have the following information pursuant to its charge by federal regulations for the protection of human subjects. Each subpart must be titled using numbered **boldface subheadings** as described below and addressed independently in the listed sequence without reliance on information covered under other subparts. Attachment of applicable sections of the grant application or detailed protocol is not acceptable as a substitute for the completion of each subpart.

The IRB Application must provide sufficient information to facilitate an effective review by all members of the IRB including non-specialists. There is an educational guide to this application available on the IRB website titled "**Educational Guide – Behavioral-Social Science Research**." Questions that have an educational note that explain the information requirements will be referred to the Guide with the statement "See Educational Guide – Behavioral-Social Science Research." Applications that do not allow for an effective review may be returned to the investigator, without IRB review, for revision and resubmission.

If a question is clearly not applicable, this should be stated with rationale provided as necessary. Information should be provided by site for all studies involving more than one site for which the O.U. IRB is the only IRB of record.

PROTOCOL ABSTRACT

Provide a brief (less than 400 words) abstract of the research protocol. This summary should include: 1) the title of the protocol, 2) a *brief* description of the purpose of the study, 3) eligibility criteria, 4) interventions and evaluations, and 5) follow-up.

PURPOSE OF THE STUDY AND THE BACKGROUND (1-2)

1. PURPOSE OF THE STUDY

What are the specific scientific objectives (aims) of the research?

2. BACKGROUND AND RATIONALE

Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill. *See Educational Guide – Behavioral-Social Science*

CHARACTERISTICS OF THE SUBJECT POPULATION (3-8)

3. ACCURAL

- **A. What is the number of subjects that must complete the study and be evaluable in order to achieve the scientific objectives of the research?** *See Educational Guide – Behavioral-Social Science*
- **B. What is the statistical or other justification for the number of subjects needed to complete the study?** *See Educational Guide – Behavioral-Social Science*
- **C. What is the maximum number of subjects that will be consented at all sites under the oversight of the O.U. IRB and what is the justification for this number?** *See Educational Guide – Behavioral-Social Science*

4. GENDER OF THE SUBJECTS

- **A. Are there any enrollment restrictions based on gender?**
  - ☐ **No**
  - ☐ **Yes. Provide justification.** *See Educational Guide – Behavioral-Social Science*
- **B. Are individuals of childbearing potential excluded from participation in this study?**
  - ☐ **No**

☐ **Yes. Provide justification.** *See Educational Guide – Behavioral-Social Science*

C. Are pregnant or breast feeding individuals excluded from participation?

☐ **No**

☐ **Yes. Provide justification.** *See Educational Guide – Behavioral-Social Science*

5. AGE RANGE OF SUBJECTS

A. **What is the age range of the adult subjects?** *See Educational Guide – Behavioral-Social Science*

B. **What is the rationale for selecting this age range?** *See Educational Guide – Behavioral-Social Science*

C. **Will children (18 years of age or younger) be included in this research?**

☐ **No. What is the justification for excluding children from participating in this research? See Educational Guide – Behavioral-Social Science**

☐ **Yes.** Complete and attach *Addendum D.*

6. RACE AND ETHNICITY

Are there any subject enrollment restrictions based upon race or ethnic origin?

☐ **No**

☐ **Yes. Explain the nature of the restrictions and provide justification.**

See Educational Guide – Behavioral-Social Science

7. VULNERABLE SUBJECTS

A. Will any of the following vulnerable populations be included in this research

No	Yes	Vulnerable Population	Complete:
		Pregnant individuals	Addendum B not required
		Prisoners	Addendum C
		Children	Addendum D
		Decisionally-impaired persons	Addendum E

B. Will any other vulnerable population be specifically recruited for enrollment in this research?

☐ **NO**

☐ **YES. Complete Addendum F.**

See Educational Guide – Behavioral – Social Science

8. INCLUSION CRITERIA

What are the specific inclusion criteria? *See Educational Guide – Behavioral-Social Science*

9. EXCLUSION CRITERIA

What are the specific exclusion criteria? *See Educational Guide – Behavioral-Social Science*

METHODS AND PROCEDURES (9-10)

10. METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS

A. Describe the study design. *See Educational Guide – Behavioral-Social Science*

B. Describe sequentially all procedures, interventions and evaluations to be applied to subjects. *See Educational Guide – Behavioral-Social Science*

C. Identify any procedures, interventions, and evaluations to be applied to subjects. *See Educational Guide – Behavioral-Social Science*

D. Describe briefly the statistical methods used to analyze the data. *See Educational Guide – Behavioral-Social Science*

11. CONFIDENTIALITY AND PRIVACY

A. Where will research data be stored and how will it be secured? *See Educational Guide – Behavioral-Social Science*

B. Will any of the following subject identifiers be obtained from records and/or directly from the subject or their LAR and maintained (at any time) in association with the research data?

☐ **No**
☐ **Yes. Respond to the following:**

1) Indicate the subject identifiers that will be recorded:

☐ Name
☐ Postal address information: street address, city, county, precinct, ZIP code
☐ All elements of dates (except year) related to an individual (e.g. birth, admission, discharge)
☐ Telephone numbers
☐ Fax numbers
☐ Electronic mail addresses
☐ Social Security numbers
☐ Medical Record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ Device identifiers and serial numbers
☐ Web Universal Resource Locaters (URLs)
☐ Internet Protocol (IP) address numbers
☐ Biometric identifiers, including finger and voice prints
☐ Full face photographic images [and any comparable images]
☐ Any other unique identifying number, characteristic, or code

2) What is the justification for recording the specific identifiers listed above? *See Educational Guide – Behavioral-Social Science*

3) How long will the subject identifiers be maintained in association with the research data?

C. Will research data that contains subject identifiers be disclosed to anyone at O.U. who is <u>not</u> listed in Section I of this application?

☐ **No**
☐ **Yes.** Identify by name. *See Educational Guide – Behavioral-Social Science*

D. Will research data that contains subject identifiers be disclosed to any investigators <u>outside</u> of O.U.?

☐ **No**
☐ **Yes. Respond to the following:**

1)Identify the investigator by name and affiliation.

2)Specify the subject identifiers which will be associated with the data.

3)Explain the necessity for this disclosure. *See Educational Guide –*

E. Will research data that contains subject identifiers be disclosed to any commercial sponsor, contract research organization (CRO)?

☐ **No**

☐ **Yes. Respond to the following:**

1)Identify by name and affiliation.

2)Specify the subject identifiers which will be associated with the data.

3)Explain the necessity for this disclosure. *See Educational Guide – Behavioral-Social Science*

F. Will research data that contains subject identifiers be disclosed to any other external organization or entity?

☐ **No**

☐ **Yes. Identify by name.**

G. For what duration of time will research data be subject to disclosure to the persons or groups identified above? *See Educational Guide – Behavioral-Social Science*

H. What provisions will be in place to protect the subject's privacy? *See Educational Guide – Behavioral-Social Science*

I. Does this research involve data banking at O.U. for future use for purposes that are not integral to the current research?

☐ **No**

☐ **Yes.** Complete *Addendum I.*

RISK/BENEFIT ASSESSMENT (11-17)

12. POTENTIAL RISKS

What are the potential risks associated with <u>each</u> research intervention? If data are available, estimate the probability that a given harm may occur and its potential reversibility. *See Educational Guide – Behavioral-Social Science*

13. RISK CLASSIFICATION

What is the overall risk classification of the research? *See Educational Guide – Behavioral-Social Science*

☐ **Minimal risk**

☐ **Greater than minimal risk**

14. MINIMIZATION OF RISK

A. Will the research utilize procedures in order to obtain data which will be performed on the subjects in the course of their normal life?

☐ **No**

☐ **Yes. Describe the procedures. See Educational Guide – Behavioral-Social Science**

B. Describe how potential risks will be minimized and how the subjects of the research will be monitored by the investigators and other research personnel to ensure their safety. *See Educational Guide – Behavioral-Social Science*

C. Describe the data monitoring plan. Specifically:

1) Who will perform the ongoing data and safety analysis?

2) What is the frequency of data analysis?

See Educational Guide – Behavioral-Social Science

D. Describe the <u>specific withdrawal</u> criteria. If *none*, provide an explanation. *See Educational Guide – Behavioral-Social Science*

E. Describe the specific <u>stopping rules for the research.</u> If *none*, provide an explanation. *See Educational Guide – Behavioral-Social Science*

F. Describe the auditing plan for the research (i.e., who will conduct the audit and how often). If *none*, provide an explanation. *See Educational Guide – Behavioral-Social Science*

15. POTENTIAL BENEFITS TO THE SUBJECT
What are the anticipated benefits (if any) to the subjects that may reasonably be expected from participation in the research?
See Educational Guide – Behavioral-Social Science

16. POTENTIAL BENEFITS TO SOCIETY
What are the anticipated benefits (i.e., value) to society that may reasonably be expected to result from this research? *See Educational Guide – Behavioral-Social Science*

17. RISK-BENNEFIT RELATIONSHIP OF RESEARCH
What is the risk-benefit relationship of the research? *See Educational Guide – Behavioral-Social Science*

18. ALTERNATIVES TO PARTICIPATION
What are the alternatives available to the prospective subject in the <u>non-research</u> setting which may be of reasonable benefit to the individual? *See Educational Guide – Behavioral-Social Science*

FINANCIAL OBLIGATIONS AND COMPENSATION (18-19)

19. FINANCIAL OBLIGATIONS OF THE SUBJECT
Will the subject incur any financial obligations as a result of participating in the study?
- ☐ **No**
- ☐ **Yes. Provide additional detail and justification for increased financial obligations to the subject.** *See Educational Guide – Behavioral-Social Science*

20. COMPENSATION TO THE SUBJECT FOR PARTICIPATION
Will the subject receive any compensation for anticipation?
- ☐ **No**
- ☐ **Yes. Describe the form of compensation, dollar amount (if applicable) and the prorated compensation plan (if applicable).** *See Educational Guide – Behavioral-Social Science*

PRIOR REVIEW (20)
21. PRIOR IRB REVIEW

A. Has this study (or one substantially similar) been previously submitted to the O.U. IRB and then withdrawn by the investigator for any reason?
- ☐ **No**
- ☐ **Yes. Respond to the following:**
  - **1) Describe why the study was withdrawn**
  - **2) Describe changes made to the research plan prior to the current submission.**

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and not granted approval?

☐ **No**
☐ **Yes. Provide details of the disapproval including the name of the reviewing IRB, date of review, and reasons for disapproval.**

SUBJECT IDENTIFICATION, RECURITMENT AND CONSENT/ASSENT (21-28)

22. METHOD OF SUBJECT IDENTIFCATION AND RECRUITMENT

A. How will prospective subjects be identified (e.g., previous research participants, support groups, school records, databases)?

B. Does the PI, secondary investigator(s) or participating personnel have ethical access to the names of prospective subjects?

☐ **No. Describe how these names will be obtained.**

☐ **Yes. Describe the ethical access.** *See Educational Guide – Behavioral-Social Science*

C. How will prospective subjects be recruited (e.g., personal contact, advertisements, fliers)? *See Educational Guide – Behavioral-Social Science*

D. What efforts will be made to achieve appropriate study population diversity? *See Educational Guide – Behavioral-Social Science*

23. CAPACITY TO CONSENT

A. At the time of initial consent, will all subjects have the capacity to give informed consent?

☐ **Yes**
☐ **No.** Complete *Addendum E.*

B. Is there a reasonable likelihood that some subjects may lose the capacity to continue to provide informed consent during the course of the study?

☐ **No**
☐ **Yes.** Complete *Addendum E. See Educational Guide – Behavioral-Social Science*

24. PROCESS OF INFORMED CONSENT FOR COMPETENT ADULT SUBJECTS

A. When will the prospective subject be approached relative to their actual participation in the study? *See Educational Guide – Behavioral-Social Science*

B. What is the location where informed consent will be obtained, and how will the environment be conducive to discussion and thoughtful consideration? *See Educational Guide – Behavioral-Social Science*

C. Who will be involved in the process of consent and what are their responsibilities? *See Educational Guide – Behavioral-Social Science*

D. How much time will be allotted to the process of consent? *See Educational Guide – Behavioral-Social Science*

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence? *See Educational Guide – Behavioral-Social Science*

F. How will informed consent be obtained from a non-English speaking subject? *See Educational Guide – Behavioral-Social Science*

G. How will it be determined that the subject understood the information presented? *See*

Educational Guide – Behavioral-Social Science

H. Will there be a formal process of *on-going* re-consent (over and above re-consent associate with changes in protocol)?

☐ **No**

☐ **Yes. Describe** *See Educational Guide – Behavioral-Social Science*

25. INFORMATION PURPOSELY WITHHELD

Will any information be purposely withheld from the subject/LAR during the research or after completion of the research?

☐ **No**

☐ **Yes. Please complete the following:**

A. What specific information will be withheld?

B. What is the justification for this non-disclosure?

C. Will information that has been withheld eventually be shared with the subject/LAR?

☐ **No. Provide justification**

☐ **Yes. When and how will information be shared (e.g., after completion of his/her participation in the research or after completion of the research project in its entirety)?** *See Educational Guide – Behavioral-Social Science*

26. DOCUMENTATION OF CONSENT AND ASSENT

Identify, by name, the investigator(s) and participating personnel who will document obtainment of informed consent/assent from the subject or the subject's LAR (i.e., sign the consent form.) *See Educational Guide – Behavioral-Social Science*

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

Indicate the type of consent forms, assent forms, and study information sheets to be used in this research: *See Educational Guide – Behavioral-Social Science*

☐ **Adult consent form**
☐ **Legally authorized representative (LAR) consent form**
☐ **Parental consent form**
☐ **Youth Study Information Sheet**
☐ **Child Study Information Sheet**
☐ **Adult assent form**
☐ **Addendum consent form**
☐ **Other:**

28. WAIVER OR ALTERATION OF INFORMED CONSENT

Is a waiver or alteration of consent requested?

☐ **No**
☐ **Yes.** *See Educational Guide – Behavioral-Social Science*

29. WAIVER OF A SIGNED CONSENT FORM

Is a waiver of the requirement to obtain a signed consent form requested?

☐ **No**
☐ **Yes.** Complete the *Addendum M. See Educational Guide – Behavioral-Social Science*

RESOURCES (30)

30. DESCRIBE THE RESOURCES AVAILABLE TO SAFELY CONDUCT THIS STUDY AT ALL STUDY SITES SPECIFIED IN SECTION I.8. *See Educational Guide – Behavioral-Social Science*

LITERATURE REVIEW (31)

31. REFERENCES

Provide a full listing of the key references cited in the background (Section II.2).The references should clearly support the stated purpose of the study. *See Educational Guide – Behavioral-Social Science*

SUBMISSION DEADLINE

Note: Incomplete submissions may result in delay of IRB review

A. Full Board Review: The IRB meets monthly, on the third Tuesday of each month, with the exception of January, June, July, and August. No more than 2 applications (i.e., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.oakwood.edu.

B. Expedited Review: Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Please call IRB Chair, 256.726.7293, for assistance in determining if your study meets the requirements for expedited review.

SUBMISSION CHECKLIST

A. *Number of Copies/Packets:*

- ☐ 1 Original "packet" printed single-sided and paper-clipped.
- ☐ 5 "packets" (Materials in each packet must be printed consecutively front-to-back and each packet is stapled together as one item.) *Note: If this study qualifies for expedited review only **1** copy is required.*

B. *Each "packet" must contain the following items in this specific order"*

- ☐ Behavioral and Social Science Research Application
- ☐ Certificates indicating completion of government approved training for Protection of Human Subjects for ALL responsible personnel\
- ☐ Informed consent form(s), adult assent form(s), youth/child study information sheets
- ☐ Subject recruitment material
- ☐ Copy of all questionnaires, surveys, assessment tools, and other relevant materials

C. *3 copies of each of the following documents (each copied separately front-to-back and stapled) (as applicable):* *Note: If this study qualifies for expedited review only **1**copy of each document is required.*

- ☐ Detailed protocol (*if applicable*)
- ☐ Grant Application

D. *1 copy of the following forms (as applicable)*

- ☐ *IRB Review Fee Form* for all commercially sponsored research projects
- ☐ *O.U. Disclosure of Potential Conflict of Interest Form* for the Principal Investigator if a financial interest has been declared in Section I.10. *Note: A COI management plan for the PI conflict of interest must be developed before this application will be reviewed by the IRB*
- ☐ *O.U. Disclosure of Potential Conflict of Interest Form* for any responsible personnel with a financial interest declared in Section I.10. *Note: Completed O.U. Disclosure of Potential Conflict of Interest Forms must contain all required signatures. Send completed forms to the IRB Chair.*