EXPEDITED AND FULL BOARD PROTOCOL

Form for Expedited and Full Board Review

For use of this form, see UNCA IRB SOP-3.5 and 3.6 Expedited and Full Board Review

Project Title: _____

Principal Investigator (PI): _____ University Affiliated: __Yes __No

Department or Organization: _____ Phone #: _____

Email: _____

Co-Principal Investigator (Co-PI): _____ University Affiliated: __Yes __No

Department or Organization: _____ Phone #: _____

Email: _____

Student Co-PI (S-Co-PI): _____ University Affiliated: __Yes __No

Email: _____

NOTE: If more you need to identify more personnel, please complete the Project Personnel Continuation form located at the end of this application. Include their CITI certificates when submitting the protocol.

Proposed Start Date: _____

Types of Data (*Choose All That Apply*)	**Reason for Research Conducted** *(Choose All That Apply)*
____ Primary Data ____ Secondary Data __ Hospital/Clinic chart review __ Purchased Data Base __ Other	____ Faculty Research ____ Undergraduate Course Number: _____ ____ Graduate Course Number: _____ ____ Master Project/Thesis: _____ ____ Student Research Presentation (e.g. UGR) ____ Other: _____
Type of Research *(Choose One)*	
____ Quantitative ____ Qualitative ____ Mixed-Methods	
Research Design *(Choose One)*	**Research Involves External Organization**
____ Experimental ____ Quasi Experimental ____ Non-Experimental	____ No ____ Yes: _____ (Approval Documentation Must be Provided)

I hereby certify that upon approval of this proposal by the IRB, no changes will be made without approval of the IRB, and that any problems, adverse reaction, or unforeseen conditions encountered in the use of human subjects will be immediately reported to the Chair of the IRB. I further agree to supply the IRB with all requested reports and a Certificate of Compliance upon completion of the project.

_____ _____

Principal Investigator's Signature Date

I. Project Introduction/Overview

Please provide your statement of purpose, significance of study, and relevant supporting literature

II. Research Question and/or Research Hypothesis

Please provide concise answers

III. Setting *Is the study conducted in, or recruited from the following categories?*

____ Schools (private/public P-12) ____Hospital/Clinic ____ College ____ General Public ____Other

Please describe setting used:

IV. Subjects

a. Characteristics of Subject Group *Are any of the subjects in the following categories?*

____ Pregnant ____ Fetus ____ Children ____ Mentally Impaired ____ Legally Restricted ____Other

Please describe subjects used:

b. Health of Subject Group *Check the physical and mental health of the subjects for inclusion in this study.*

Physical Health: ____ Poor ____ Good ____ Excellent ____ Unknown

Mental Health: ____ Poor ____ Good ____ Excellent ____ Unknown

Please state the necessity of using these particular groups:

c. Subject Inclusion Criteria:

Please provide concise and complete inclusion criteria:

d. Subject Exclusion Criteria:

Please provide concise and complete exclusion criteria:

e. Recruitment of Subjects: *Check which one applies to the recruitment of your subjects.*

____ Recruitment of UNCA class, students, or personnel ____ Outside agencies, schools, organizations, or data base ____ Open call for particpants (general public)

Please describe how you will recruit participants and attach copies or script (if recruiting orally) of the recruitment material (e.g. flyers, advertisements, letters, etc.):

f. Sampling Plan: *Check which one applies.*

____ Random Sampling ____ Stratified Sampling ____ Convenience Sampling ____ Other

Please provide a rationale for your sampling plan:

g. Sample Size

Please provide the total number of expected participants and rationale.

V. Instruments (Upload all instruments to be used in IRBNet)

Please describe all means used to collect data and attach the instruments to be used (e.g. interview questions, surveys, assessments, etc.):

VI. Procedures

Please describe the procedures used to collect data based on identified instruments and total time investment of the participant:

VII. Analysis

Please describe how you will analyze the data collected:

VIII. Risk to the subjects *Identify the following risk categories and your perception of the level of risk involved*

Please note that Health & Human Services (HHS) states that there is always risk to the subject and have defined the categories of risk as follows.

____ Physical ____ Psychological ____ Social ____ Legal ____ Economic

Please describe the risk in detail:

Perceived level of risk _____ Less than minimal ____ Minimal
_____ Greater than Minimal

IX. Mitigation of Risk to the Subject

a. Researcher Mitigation

Please describe how the researcher will try to mitigate the risk (a mitigation has to be supplied for every identified risk):

b. Research Gain

Please describe the importance of the information gained in relationship to the risk:

c. Equity and Equality

Please describe how the researcher will ensure equity and equality for the participants:
[To treat "equitably" means to treat fairly; to treat "equally" means to treat in exactly the same way.

Research should strive for equitable distribution of the risks and potential benefits of the research. This means that investigators are treating the groups involved in the research fairly and justly. It does not necessarily mean that all groups are equally represented, but that their representation is fair and just based on the risks and potential benefits associated with the research.]

X. Compensations and Benefits

a. Are you offering any compensations to individuals for participating in your study? *If yes, please describe.* ____ Yes ____ No

b. Benefits to individual *Outside of any compensation offered what are the benefits for the individual for participating?*

c. Benefits to society

How will participating in this study benefit society?

XI. Consent Procedures

Federal regulations require precautionary measures to be taken to insure the protection of human subjects on physical, psychological, social, economical and other issues. This includes the use of “informed consent” or ‘wavier of informed consent” procedures.

a. Type of Informed Consent *If applicable, which one(s) applies to your study?*

____ Electronic Survey Consent *Script must be provied*

Note: Many minimal risk survey research involves the use of virtual survey platforms such as Google Docs, Qualtrics, or Survey Monkey. For these types of projects, consent is best conducted by using the first questions of the survey as the informed consent. The full text of the consent can be

included with a "I agree" or "I do not agree" checkbox acknowledging the potential participant has read and understood the document. By clicking "I agree," potential subjects will be directed to the rest of the survey. By clicking, "I do not agree", the individual cannot move forward and is free to close out the platform. Any time implied consent is obtained with this approach, a print or email option should be available to the participant.

____ Oral Consent *Script must be provied*

____ Written Consent *Consent form must be provided; please use our consent template.*

____ Assent In conjuction with parental consent for children 7-17. Assent form should be a Flesh-Kicaide reading grade level 5-7.

_____ Oral

_____ Written

____ Parent Consent/Permission *In conjunction with parental consent for children 7-17. Assent form should be a Flesh-Kicaide reading grade level 5-7.*

b. Type of Waiver of Consent *If applicable, which one(s) applies to your study?*

____ Implied Consent Waiver* *Consent description must be provided; please use our implied consent template.*

Note: *Implied consent is defined as a situation where the lack of an objection to research participation is considered to be the equivalent of an affirmative declaration of informed consent. In other words, if the subject fills out the questionnaire and does not say "No" to filling out the questionnaire, it means that the subject consents to be a participant.*

____ Secondary Data Waiver* *Consent was given: 1) to hospital/clinic upon initial collection under HIPPA guidelines and study does not necessitate additional consent or further contact with human subject; 2) data purchased has been scrubbed of all human subject identifying features and contact information; or 3) data is part of public domain. No further documentation needed.*

Please provide a rationale for a waiver request below:

____ *Yes* ____ *No* Will this waiver adversely affect the rights and welfare of the participants?

____ *Yes* ____ *No* Would this research be practicably conducted without the waiver of consent?

____ *Yes* ____ *No* Will participants be provided with any information on this study after participation?

c. Are your subject(s) minors or mentally impaired? ____ Yes ____ No

*If yes, Please describe how and by whom permission will be granted. *Subject Assent form must accompany Parent/legal guardian's Permission/consent form.*

d. Do subject(s) have a cognitive limitation/impairment and/or a language/literacy barrier? ____ Yes ____ No

Please describe the limitation/impairments and/or barrier and how you plan to ensure participants understanding for informed consent.

e. Will subject(s) be provided copies of all consent documentation including implied consent description? ____ Yes ____ No

If consent/assent documentation is not provided to participants please justify why.

XII. Disclosure *Check which one applies.*

Federal regulations require precautionary measures to be taken to insure the protection of human subjects on physical, psychological, social, economical and other issues. This includes the use of "informed consent" procedures.

____ Full-disclosure ____ Less than Full Disclosure ____ Necessary Deception

Please describe how you will disclose the study to the participants. If less than full disclosure or necessary deception is chosen, please justify the need for such action. All studies using less than full disclosure or necessary deception must provide a debriefing script or handout explaining to the participants the true purpose of the study and need for deception.

XIII. Data Confidentiality

The IRB is responsible for evaluating proposed research to ensure adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. Researchers must include adequate provisions to maintain the confidentiality of research data.

a. Does this data fall within: _____ Public Domain *(Ex: public record document, public access documents, court transcripts, etc.)* ____ Confidential Domain *(Ex: data only accessible by through permission of the institution and/or subject being studied)*

b. Data Access

*Please describe **all parties** who will have access to the data.*
Please provide (in an attachment) evidence of human subject training/confidentiality agreement for those who have access.

c. Subjects' anonymity/confidentiality

How do you plan to protect the individual subjects' anonymity/confidentiality?

d. Data Storage

How, where and for how long will the data be stored? (Please not that for IRB purposes all data must be stored for a minimal of three years.)

e. Data Deletion

How will the data be destroyed? (Please address all data sources, e.g. video, audio-visual, interview, questionnaires, consent forms, electronic data, etc.)

XIV. HIPAA (Health Insurance Portability & Accountability Act)

If you answer "Yes" to any of the following questions, your project is subject to HIPAA and you must complete the HIPAA Supplement (available from the Office of Research and Sponsored Programs and IRBNet) and attach it to the application.

____ Yes ____ No	Will health information be obtained from a covered entity (a health plan, health care clearing house, or a health care provider who bills health insurers (e.g. hospitals, doctor's offices, dentists, the UNCA Student Health Center, UNCA Counseling Services, etc.)?
____Yes ____ No	Will the study involve the provision of health care in a covered entity?
____ Yes ____ No	If the study involves the provision of health care, will a health insurer or billing agency be contacted for billing or eligibility?

CONTINUATION: PROJECT PERSONNEL

Project Personnel: ______________________________ University Affiliated: __Yes __No
Department or Organization: ______________________ Phone #: ______________
Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

Project Personnel: ______________________________ University Affiliated: __Yes __No
Department or Organization: ______________________ Phone #: ______________
Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

University Affiliated: __Yes __No
Project Personnel: ______________________________
Department or Organization: ______________________ Phone #: ______________
Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

Project Personnel: ______________________________ University Affiliated: __Yes __No
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Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

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Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

Project Personnel: ______________________________ University Affiliated: __Yes __No
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Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

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Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

Project Personnel: ______________________________ University Affiliated: __Yes __No
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Email: ________________________
Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________

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Status: _____ Faculty _____ Staff _____ Student _____ Other: ______________________