DEFIANCE COLLEGE
To Know ◆ To Lead ◆ To Serve ◆ To Understand

Office Use Only
IRB Tracking # _____
_____ Exempt Review
_____ Full Review

Institutional Review Board

Investigator's Summary Description of Research
Involving the Use of Human Subjects

PROJECT TITLE:		
SUBMISSION DATE:	**PROPOSED START DATE:**	**PROPOSED END DATE:**
DEPARTMENT:		
PRINCIPAL INVESTIGATOR (PI)/FACULTY RESEARCH ADVISOR:		
PI CONTACT (E-MAIL):		
STUDENT RESEARCHER:		
STUDENT RESEARCHER CONTACT (E-MAIL):		
OTHER RESEARCHERS		
RESEARCH INVOLVES EXTERNAL ORGANIZATION?	**REASON FOR RESEARCH CONDUCTED**	
____ No: ____ Yes: _____ (Approval Documentation Must be Provided)	____ Faculty Research ____ Student Project: (Class Name and #) _____ ____ Independent Student Research: _____ ____ Other:_____	
DOES ANY MEMBER OF THE RESEARCH TEAM WORK OR VOLUNTEER AT THIS GROUP?	**HAVE YOU REQUESTED EXTERNAL FUNDING?**	
____ No ____ Yes: _____ (Approval Documentation Must be Provided)	____ No ____ Yes: _____ (Approval Documentation Must be Provided)	
Please explain whether the member of the research team, while fulfilling his/her normal work or volunteer obligations at this group, will have access to information about subjects and/or interact with subjects:		

I hereby certify that all the information contained herein is accurate. I understand that it is my responsibility to protect the rights and welfare of my subjects. I will protect the confidentiality of the information provided by my subjects unless I have obtained their written permission to disclose this information to others. 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.

Faculty Advisor: As a faculty advisor I understand that it is my responsibility to ensure that I and all students working on this project have received the training needed to conduct the study and to safeguard the wellbeing of the subjects with whom they interact..

_____ _____
Principal Investigator's Signature Date

_____ _____
Faculty Advisor's Signature Date

Defiance College IRB Proposal

Consent/assent forms, instruments, recruitment material and other requested documentation to be attached as appendixes to this proposal

1. Project Introduction/Overview

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

2. Research Question and/or Research Hypothesis

Please provide concise answers

3. Data *Is the study conducted in, or recruited from the following categories?*

Will this project involve a pre-existing data set?	____ Yes (Include source) ____ No
If yes, did the subjects give permission for their information to be used for research purposes?	____ Yes ____ No
Will this project involve observations of public behaviors?	____ Yes ____ No

4. Subjects

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

_____	_____	_____	_____	_____	_____
Pregnant women or fetuses	Economically or Educationally Disadvantaged	Children (Under the age of 18)	Seniors (Adults over the age of 65)	Victims of Crime or other traumatic experiences	Mentally /Physically Impaired/Learning Disabilities

Please describe subjects used:

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

____ Recruitment of DC 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.):

c. Sampling Plan: ☑*Check which one applies.*

____ Random Sampling ____ Stratified Sampling ____ Convenience Sampling ____ Other

Please provide a rationale for your sampling plan:

d. Sample Size
Please provide the total number of expected participants and rationale.

5. Instruments (Attach all instruments to be used)

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

6. Procedures

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

Will samples of blood or other bodily fluids be obtained from subjects? ____ Yes* _____No
**If yes, please describe how the sample will be obtained, who will obtain it, and how :*

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

____ Physical ____ Psychological ____ Social ____ Legal ____ Economic

Please describe the risk in detail:

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

8. 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:

9. Compensations and Benefits

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

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?

10. 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" procedures.

a. Type of Consent	☑*Which one(s) applies to your study?*
____ Oral Consent	*Script must be provied with short consent form*
____ Written Consent	*Consent forms must be provided*
____ Assent _____ Oral _____ Written ____ Parent Consent/Permission	*Assent form should be provided*

b. 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.*

c. 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.

d. 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.

11. 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.

12. Data Confidentiality

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.)