CENTRAL STATE UNIVERSITY
Wilberforce, Ohio 45384

APPLICATION TO INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

The IRB committee will meet on the fourth Wednesday of each Month*. All applications must be submitted two weeks prior to the scheduled meetings. Notification will be given within one month from the date of application submission. Signed applications must be submitted to irb@centralstate.edu or hand delivered to Central State University, Office of Sponsored Programs and Research, Jenkins Hall, Room 100, Wilberforce, Ohio 45384.

In case of urgency, the committee can be called together. Please allow ten business days for decisions.

* If the Principal Investigator is a student or is not affiliated with an institution of higher education, then a full-time CSU faculty member must assume the role of Co-Principal Investigator or Faculty Sponsor and indicate which one.

Title of Application:			
Anticipated Start Date:		**Anticipated Completion Date:**	

Sponsoring Agency:					
Address:					
City:		**State:**		**Zip:**	

Principal Investigator: Faculty ☐ Student ☐ Staff ☐				**Other:**	
Name:				**Title/Degree:**	
Telephone:		**Fax:**		**Email:**	
Institution:					
Department:					
Address:					
City:		**State:**		**Zip:**	

Co-Principal Investigator ☐ **Faculty Sponsor** ☐ **Project Coordinator** ☐ **Sub-Investigator** ☐					
Name:				**Title/Degree:**	
Telephone:		**Fax:**		**Email:**	
Institution:					
Department:					
Address:					
City:		**State:**		**Zip:**	

Co-Principal Investigator ☐	Faculty Sponsor ☐	Project Coordinator ☐	Sub-Investigator ☐		
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City:		State:		Zip:	

Co-Principal Investigator ☐	Faculty Sponsor ☐	Project Coordinator ☐	Sub-Investigator ☐		
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Co-Principal Investigator ☐	Faculty Sponsor ☐	Project Coordinator ☐	Sub-Investigator ☐		
Name:		Title/Degree:			
Telephone:		Fax:		Email:	
Institution:					
Department:					
Address:					
City:		State:		Zip:	

PLEASE ANSWER ALL QUESTIONS – If a question does not apply to your specific protocol, so indicate with "Not Applicable" or "N/A". If additional space is required, additional pages may be used.

1. **Briefly state, using easily understandable LAY TERMINOLOGY the objectives and the relevance of the study in advancing scientific knowledge, and/or benefits to human health or wellbeing.**

2. Briefly describe methods and/or procedures that involve human subject participation and briefly describe how confidentiality of subjects will be established and maintained.

3. **Describe your research design, data collection strategies, and specific factors (such as independent variables), conditions or groups in your study and any control conditions. Include the setting in which the interaction occurs, and your relationship to this setting.**

4. Describe characters of subject population (include selection criteria and any age, sex, physical, mental and health restrictions):

5. Does the project specifically target subjects who are:

(a) Minors (less than 18 years of age)?
Recruited ☐ Excluded ☐ Permissible/Not Recruited ☐

(b) Pregnant women?
Recruited ☐ Excluded ☐ Permissible/Not Recruited ☐

(c) Prisoners?
Recruited ☐ Excluded ☐ Permissible/Not Recruited ☐

(d) Intellectually or emotionally impaired (developmentally disabled, psychiatric patients, etc.)
Recruited ☐ Excluded ☐ Permissible/Not Recruited ☐

(e) Physically Handicapped (uses wheelchairs, walker, etc.)
Recruited ☐ Excluded ☐ Permissible/Not Recruited ☐

(f) Institutionalized?
Recruited ☐ Excluded ☐ Permissible/Not Recruited ☐

(g) University Students?
Recruited ■ Excluded ☐ Permissible/Not Recruited ☐

6. **Does the study:**

(a) Require the obtaining of parental/guardian consent and/or institutional authorization for access to the subjects if minor, intellectually or emotionally impaired, or institutionalized?

Yes ☐ No ☐

(b) Involve information gathering procedures (personality tests, questionnaire, inventories, surveys, medical record review, observations, etc.) where the subject can be identified by name or code?

Yes ☐ No ☐

Please Explain:

(c) Involve procedures specifically designed to directly modify (coerce) the knowledge, thinking, attitudes, feelings or other aspects of the subjects' behavior?

Yes ☐ No ☐

If yes, please justify:

(d) Involve giving any false information (deliberate deception) to the subject?

Yes ☐ No ☐

If yes, please justify:

7. List all off-campus study sites to be used during this study:

Study Site:					
Address:					
City:		State:		Zip:	
Contact Name:		Phone:			

Study Site:					
Address:					
City:		State:		Zip:	
Contact Name:		Phone:			

Study Site:					
Address:					
City:		State:		Zip:	
Contact Name:		Phone:			

8. If subjects will:

(a) Receive any payment for participation (e.g., money, course credit, medication, free examinations) give details:

(b) Be solicited, explain how. (Attach copy of all advertisements. Note: All advertisements (i.e., brochures, flyers, newspaper, radio, television, videos, etc.)

(c) Be exposed to any procedures that cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, or threat to their dignity, or if the procedure may cause any potential harm, state what provisions have been established to respond to the harmful or adverse conditions that may arise:

9. Will individuals other than the principal investigator, co-investigators, governmental review agencies and sponsoring IRB's be able to identify the subjects in the study? (For example, will editors, general public, colleagues, etc. be able to identify the subjects in reports of publications?)

Yes ■ No □

(a) If yes, explain why the confidentiality of the subjects cannot be maintained.

(b) If no, describe how you plan to codify the subjects to maintain their confidentiality.

(c) HIPAA Privacy: In obtaining the data, please cite authority (subjects' permission to release protected health information (PHI), or right to review patient data) for all individuals who will have access to protected health information (PHI)[1]. (E.g. study coordinator, psychometrist, statistician, or other non-healthcare providers)

10. In your opinion, is the risk to the subject greater than any of the potential benefits that the subjects will obtain?

Yes ☐ No ☐

11. Fill in the number or estimate:

The average amount of time required for subjects participation (in hours per week):				
If questionnaires are involved, the total number of items (see Appendix B for a copy of the survey questions):				
The number of subjects to be involved in study:	Locally:		Nationally:	

[1] 45 CFR 164.501, 164.508(f), 164.512(i), HIPAA Privacy, Office for Civil Rights, HIPAA Technical Assistance - Research

12. **Please state your qualifications to do this project (Note: even if you have filled this out before, this information needs to be on each application that you submit as a matter of record):**

13. **Attachments required to complete your application:**

Please check off those attachments included with your submission. Items in **BOLD** must accompany your application or it will be returned.

- ☐ **Protocol Narrative**
- ☐ **Informed Consent Document**(unless exempt, closed to enrollment, or requesting waiver of written consent)
- ☐ Assent Document (if minor subjects will be included)
- ☐ Data collection instrument
- ☐ **Letter of Permission or IRB approval from Off-Site Institution/Off-Site Research Agreement**
- ☐ Advertisement/Recruitment Materials
- ☐ Sponsor Protocol/Master Protocol
- ☐ Investigator's Brochure
- ☐ "Human Subjects" section of funding proposal
- ☐ Curriculum Vita for all investigators is to be submitted for review by the IRB
- ☐ Has completed the required modules in the CITI training program, which can be found at http://www.citiprogram.org/
- ☐ OMB Form "Assurance Identification/IRB Certification/Declaration of Exemption" (for federally funded research)

14. **Will the project require additional:**

☐ **Space** ☐ **Equipment** ☐ **Professional and/or staff time** ☐ **Resources**

How will this proposal be supported? ☐ **Grant** ☐ **Contract** ☐ **In-house support**

Has a grant or contract been submitted to a funding agency? ☐ **Yes** ☐ **No**

Date submitted (or to be submitted): _____

Name of Agency or Sponsor: _____

NOTE: If you already know that there are items you will need to submit for this protocol that are not yet available (e.g., letters of permission from off-site institutions, data collection instruments, advertisements, etc.), please describe below your anticipated timetable for obtaining and/or developing these documents.
AS PRINCIPAL INVESTIGATOR, I WILL OPERATE IN ACCORDANCE WITH ALL FEDERAL, STATE AND CENTRAL STATE UNIVERSITY REGULATIONS GOVERNING RESEARCH INVOLVING HUMAN SUBJECTS AS STATED IN THE IRB GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS.

I ACKNOWLEDGE RESPONSIBILITY FOR THIS PROJECT AND I ASSURE THAT STUDENTS, RESIDENTS, STAFF AND FACULTY INVOLVED IN THE PROJECT ARE OR WILL BE QUALIFIED TO CONDUCT THIS STUDY IN THE MANNER DESCRIBED HEREIN BEFORE THE STUDY IS INITIATED.

IN ACCORDANCE WITH 45 CFR 46.112,[2] CENTRAL STATE UNIVERSITY EXPRESSLY RESERVES THE RIGHT TO REVIEW FOR APPROVAL OR DISAPPROVAL RESEARCH APPROVED BY THE IRB.

_____ _____
Signature of Principal Investigator Date

This project is consistent with departmental objectives; and adequate space, equipment, professional and staff time, and other resources as stated in this application will be made available if the research is approved.

_____ _____
Signature of Chair/ Chair Designee Date

Note: If this project is being internally funded (Central State University) it also requires the signature of the Dean/Dean's Designee.

If significant changes have been made to this protocol since the grant/contract was submitted and reviewed, the IRB Committee approval is required.

To be completed by the IRB Committee Chair

PLEASE TYPE AND ANSWER ALL QUESTIONS AS COMPLETELY AS POSSIBLE	**IRB ID# _____**
The information provided should address a specific project in its entirety.	**Reviewers _____**
	Date Received _____
In which category does this proposal belong? New (first submission for this application) Revised: Previous IRB# Continuation with changes:	**Date Approved _____** **Not Approved _____**
Type of Review: Expedited ☐ Full ☐	**IRB Chair Signature_____**

[2]**NOTE: No research involving human subjects is to be conducted without the prior written approval of the IRB Committee**