Western Connecticut State University

Institutional Review Board

Office of Sponsored Research & Admin Services

321 Warner Hall, 181 White St.

Danbury, CT 06810 Secretarial contact: 203-837-8740

irb@wcsu.edu Web: www.wcsu.edu/irb

Application for Review of Research Involving Human Subjects

ENTIRE PROPOSAL (INCLUD. SIGNATURES & ALL APPENDICES) SHOULD BE SUBMITTED AS 1 .DOC FILE ATTACHMENT TO irb@wcsu.edu

WCSU Institutional Review Board's (IRB) role is to review all proposed research by/on/at WCSU faculty, staff, or students to ensure the research meets Federal standards for safety & protection of human subjects. In compliance with U.S. Code of Federal Regulations, Department of Health & Human Services (DHHS) Title 45 Part 46, WCSU's IRB has registered approval (Federalwide Assurance/FWA) from Office of Human Research Protections (OHRP) and requires all researchers to submit protocol for review (see www.wcsu.edu/irb). WCSU IRB discusses any concerns with investigator/s before issuing a final decision. ***Researchers are encouraged to attend IRB meetings to address concerns directly.*** *During normal academic semesters, deadlines for Full proposals are the 1st of each month; Expedited/Exempt proposals are accepted on rolling basis.*

FOR COMMITTEE USE ONLY

___Not/Approved as

IRB Chair's Approval: Date:

Before submitting research for IRB review, everyone involved must complete Human Subjects Collaborative Institutional Training Initiative (CITI) certification, (accessible at www.wcsu.edu/irb/) or equivalent. List anyone responsible for the method, recruitment, consent, and/or involved in data collection, analysis, or follow-up. *Student- or non-WCSU-affiliates: list non-visiting WCSU faculty/staff as project sponsors.*

1. PRINCIPAL INVESTIGATOR/S:

a. If PI is a student, **FACULTY SUPERVISOR:**

2. DEPARTMENT:

3. EMAIL/S:

4. PROJECT TITLE:

5. IS THE RESEARCH DEVELOPED WITH A GRANT? ☒ **NO** ☐ **YES**

a. If yes, indicate grant source:

6. IS THIS A NEW RESEARCH PROJECT?

☐ **YES** ☐ **NO**

a. If NO, any modifications to the original proposal?

☐ **No** ☐ **Yes**

b. Protocol # of prior approval:

7. RESEARCH SUMMARY: In lay language, *briefly* summarize the objectives/relevant details of the research.

8. INTENDED DISSEMINATION: : *Indicate your intended goal/s for the results of this study (Check all that apply).*

☐ None; data collection for internal program assessment purposes only *(i.e., "I am the only one who will use/see this data")*

☐ Class project/paper/presentation ☐ Conference/Journal submission (academic or trade)

☐ Other: please describe

9. PERFORMANCE SITES: *Including WCSU sites, describe ALL the research sites for this protocol. Where, specifically, will the research activities occur? For each non-WCSU site, describe each site's (a) possession of an IRB & your stage in their approval process, (b) permission for this research to be conducted (append approvals as applicable), and (c)contact info.*

a. **Will you collect data in/during class or other formal programming?**

☐ **NO** ☐ **YES**

If YES, *#10 must detail (a) planned nonparticipant alternatives, (b) where (e.g., classroom, private area) both non/participants will be located/affected during study, & (c) rationale/method to assure nonparticipants' standing not affected (also note in #12 & #13 below).*

10. PARTICIPANTS & RECRUITMENT: *Describe number & characteristics of target sample participants and how they'll be recruited. Indicate any special/vulnerable populations included. Address if: any researchers are associated with subjects (e.g., students, employees, patients) & any specific agencies are providing access to subjects or their data. Who/how will contact subjects? Detail solicitations (e.g., posters, internet), personal interactions, resources (e.g., phone, class, registry, referral); append recruitment materials.*

11. RESEARCH PROCEDURES/DATA: *Using LAYMAN'S LANGUAGE, describe what researchers & participants will do (e.g., dates/durations, treatments/meetings/measures) & participants' total commitments.* ***Attach as appendices copies of all instruments.***

a. **Will you be collecting or using** (e.g., pre-existing) **any protected health information?**

"Yes" if, during *either recruiting or data collection*, you'll use or have access to such info related to (a) past/present/future health or conditions of, (b) provision of health care to, (c) or payments for the provision of health care to *living or deceased* individual/s. ☐ **YES** ☐ **NO**

12. DATA HANDLING: *Explain who collects/handles data in terms of:* ***(a)*** *How confidentiality (or anonymity) maintained during/after data collection (if applicable, confidentiality/security for emailed data, web interface, computer server, other networked info);* ***(b)*** *How subjects tracked/coded/ID'd (e.g., use recording, storage, etc.); and* ***(c)*** *What inducements/rewards offered.* Note: Current CT BOR policies do *not* guarantee privacy of info stored physically, remotely, or otherwise on WCSU computers (e.g., laptop, Dropbox, drives). To maintain truth of any claims to participants regarding anonymity/confidentiality, researchers should NOT connect any data-storage to any CSU network. It's the primary researcher's responsibility to store data actually securely if such assurances are made to participants.

13. CONSENT: CSU research policy requires comprehensive, written documentation comprehended and validated by the subject (or an authorized representative) as the principal consent method. Children 8-17 should sign written assent forms (those under 8yrs. may assent orally or passively, depending on maturity), with guardians separately consenting on child's behalf (i.e., 2 different forms). *Describe steps to minimize coercion, when/where consent obtained, how often, by/from whom. Append forms minimally including (a) procedure, (b) location, (c) date/time commitment, (d) alternate activity, (e) risk/incentive, (f) researcher & IRB contact info, (g) Protocol # and approval expiration.*

14. RISKS: *Risks include ANY potential discomfort re. emotions, psyche, physical well-being, privacy, dignity, reputation, employability, &/or criminal/legal status. If your protocol involves ANY of these potential risks to participants (actual or perceived) psychological comfort, it DOES involve more than "minimal risk"; indicate as such below & detail how addressed.*

a. **Is there anything in your study that presents more than "minimal risk" to participants?**

☐ **NO** ☐ **YES**

If YES, *detail all known and/or potential risks to subjects and describe all steps taken to minimize them.*

b. **Will *any* individually identifiable info be published/shared/otherwise disseminated?**

☐ **NO** ☐ **YES**

***If YES,** explain. Participants must provide explicit consent/assent for such usage.*

15. BENEFITS: *Describe study's expected benefits to subjects or society. Provide evidence that benefits outweigh any potential risks.*

16. INVESTIGATOR ASSURANCES: *By inserting your signature/s below, you agree to the following:*

- I certify that the info provided in this application, and in all attachments, is complete and correct.
- I understand that I have ultimate responsibility for (a) protecting the rights and welfare of my human subjects, (b) the conduct of this study, and (c) the ethical performance of this project.
- I agree to comply with all WCSU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research including:
  - Obtaining legally effective informed consent or assent from human subjects as required.
  - Reporting unanticipated problems, adverse events, & new info that may affect the proposed risk-benefit assessment to the WCSU IRB Office (203-837-8470; irb@wcsu.edu).
  - Maintaining ethical, safety, and/or regulatory training & study implementation of any student/guest investigators on this project.
- I agree that any changes to the project will be submitted to the Institutional Review Board for review prior to implementation.
- *I further certify that the proposed research has not yet been done, isn't currently underway, and will not begin until WCSU IRB approval has been obtained.* I realize that some changes may alter the approval status of this project.

Include actual, handwritten signatures of all involved (anyone named in #1); scan/photo your sig. & then insert/paste image file/s below.

For student projects, student is PI and Faculty Sponsor is an additional investigator.

Primary Investigator: Date

Investigator: Date

[Add more as needed…]

17. APPENDICES

[Insert relevant documentation here. See website for example templates]