UNION UNIVERSITY
INSTITUTIONAL REVIEW BOARD

PROTOCOL REVIEW

Date:			Reviewer:	
IRB #:			Principal Investigator:	
Review Type:	Full Board ☐	Expedited ☐	Exempt ☐	Continuing ☐

Recommendation:

☐Full Approval	No changes needed; approved as is.
☐Pending Approval	Requires minimum clarifications, protocol modifications, or consent revisions.
☐ Deferred	Requires substantive clarifications, protocol modifications, or consent revisions. Returned to original reviewers for second review and approval.
☐ Disapproved	

PROTOCOL CHECKLIST

Evaluation Area		Comments
Is a sound purpose statement provided that summarizes the research project's main goal(s)? Does it align with the research questions?	☐Yes ☐No	
Does the rationale for the study include a brief description of the relevant and cited literature to convey significance?	☐Yes ☐No	
Are research questions or hypotheses researchable and consistent with the proposal title and purpose statement?	☐Yes ☐No	
Is selection of subjects equitable, given the purpose of the research and the setting in which the research will be conducted? Are inclusion/exclusion criteria clearly described?	☐Yes ☐No ☐Yes ☐No	
Are recruitment procedures (for participants and/or research sites) adequately described and consistent with protection of human subjects? If applicable, have recruitment documents been submitted?	☐Yes ☐No	
Does investigator have a role and/or relationship to potential participants or the research site?	☐Yes ☐No	

Are procedures consistent with sound research design and include a step-by-step explanation of procedures that will be performed with human subjects?	☐Yes ☐No	
Are data analyses/statistical procedures (whether quantitative or qualitative) appropriate to answer each research question or test the hypothesis?	☐Yes ☐No	
Are research risks to subjects reasonable in relation to anticipated benefits?	☐Yes ☐No	
Are risks to subjects and procedures for minimizing risks adequately described (including physical, psychological, social harm, discomfort, or inconvenience)?	☐Yes ☐No	
If there are vulnerable populations (minors, pregnant women, economically or educationally disadvantaged, intellectually disabled, prisoners) involved, are additional safeguards included and described in the study to protect these subjects?	☐Yes ☐No ☐N/A	
Are potential benefits of the research to the individual and society adequately described?	☐Yes ☐No	
Are there adequate provisions to protect the privacy of subjects and maintain confidentiality of data (during and post-study)? Ex., use of pseudonyms, coding of identifiers.	☐Yes ☐No	
Have all instruments been submitted and protocols used for data collection described (if applicable) Have the proper permissions to use/adapt instruments been obtained (if applicable)? Are instruments properly cited?	☐Yes ☐No ☐Yes ☐No	
Are Child Assent procedures described and consistent with the elements of consent in 6.1 of Guidelines for the Protection of Human Subjects in Research?	☐Yes ☐No ☐N/A	
Are Informed Consent procedures described and consistent with the elements of consent in 6.1 of Guidelines for the Protection of Human Subjects in Research?	☐Yes ☐No	

INFORMED CONSENT CHECKLIST

Does the informed consent:		Comments
Include a statement that explains the purpose of the research? Does it match the intended purpose given in the research protocol?	☐Yes ☐No	
Include a description of the procedures (what the participant is being asked to do or provide) and length of time the subject is expected to participate?	☐Yes ☐No	
Include a description of all potential risks to the subject (including physical, psychological, social harm, discomfort, or inconvenience)?	☐Yes ☐No	
Include a description of any benefits of the research to the individual and society?	☐Yes ☐No	
Include a description of compensation or token of appreciation provided to participants (if any)?	☐Yes ☐No	
Include a statement that participation is voluntary and refusal to participate will involve no penalty or loss of current benefits?	☐Yes ☐No	
Include a statement that the subject may withdraw from the study at any time without penalty (unless data are submitted anonymously)?	☐Yes ☐No	
Include a description of how confidentiality of research records will be maintained (during and post-study)?	☐Yes ☐No	
Include who to contact (and how) for answers to questions or in the event of a research-related injury or emergency?	☐Yes ☐No	
Include a statement that subjects may contact the Chair of the Institutional Review Board for answers to questions regarding their rights as research subjects? Contact information provided?	☐Yes ☐No	

Other General Comments: