UNION UNIVERSITY
INSTITUTIONAL REVIEW BOARD

PROTOCOL CHECKLIST

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

Recommendation:

☐ Full Approval	No changes needed; approved as is.
☐ Pending Approval	Requires simple concurrence by the investigator; minor changes are needed. The changes may be reviewed by the Chair or designated reviewer.
☐ Deferred	Requires substantive clarifications, protocol modifications or consent revisions. The protocol must be sent back to the full committee.
☐ Disapproved	

Protocol Checklist:		**Comments:**
Are risks to subjects minimized?	☐ Yes ☐ No	
Are procedures consistent with sound research design?	☐ Yes ☐ No	
Are research risks to subjects reasonable in relation to anticipated benefits?	☐ Yes ☐ No	
Is selection of subjects equitable, given the purpose of the research and the setting in which the research will be conducted?	☐ Yes ☐ No	
If appropriate, does the protocol make adequate provisions for monitoring data collected to ensure safety of subjects?	☐ Yes ☐ No	
Are there adequate provisions to protect the privacy of subjects and maintain confi-dentiality of data?	☐ Yes ☐ No	
If there are vulnerable populations (minors, pregnant women, economically or educa-tionally disadvantaged, mentally disabled) involved, are additional safeguards included in the study to protect these subjects?	☐ Yes ☐ No	

Will assent be sought (if applicable) and appropriately documented in accordance with federal regulations.	☐ Yes ☐ No	
Will consent be sought and appropriately documented in accordance with federal regulations?	☐ Yes ☐ No	

Consent Checklist:		
Does the informed consent:		**Comments**
include a statement that explains the purpose of the research, length of time subject is expected to participate, and description of procedures?	☐ Yes ☐ No	
include a description of any benefits of the research to society and/or to the individual?	☐ Yes ☐ No	
include a description of any potential risks to the subject, including physical, psycholog-ical, social harm, discomfort, or inconvenience?	☐ Yes ☐ No	
include a description of how confidentiality of records identifying the subject will be maintained?	☐ Yes ☐ No	
include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled?	☐ Yes ☐ No	
include a statement that the subject may withdraw from the study at any time without penalty?	☐ Yes ☐ No	
include who to contact 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 at (731) 661-5580 for answers to questions regarding their rights as research subjects.	☐ Yes ☐ No	

Other General Comments: