



UNION UNIVERSITY

INSTITUTIONAL REVIEW BOARD

REVIEW SHEET

Date:		Reviewers:		
IRB #:		Principal Investigator:		
Review Type:	Initial <input type="checkbox"/>	Expedited <input type="checkbox"/>	Exempt <input type="checkbox"/>	Continuing <input type="checkbox"/>
OHRP Completion Certificate Submitted: <input type="checkbox"/> Yes <input type="checkbox"/> No Signed Assurances Page Submitted: <input type="checkbox"/> Yes <input type="checkbox"/> No				

Recommendation:

<input type="checkbox"/> Full Approval	No changes needed; approved as is.
<input type="checkbox"/> Pending Approval	Requires simple concurrence by the investigator; minor changes are needed.
<input type="checkbox"/> Pending Approval	Requires substantive clarifications, protocol modifications or consent revisions.
<input type="checkbox"/> Disapproved	Should be reviewed by the full Institutional Review Board.

- 1. Purpose of the Study:** *Must provide a description of the project that includes a statement, grounded in the pertinent body of research literature, that describes the purpose and importance of the proposed research project.*

2. Methods and Procedures: *Must describe the study design and all procedures, step by step, to be applied to subjects.*

3a. Human Subjects – Characteristics: *Should include anticipated number of subjects, age range, gender, ethnicity, health status, limitations, or if it is a vulnerable population.*

3b. Human Subjects – Recruitment: *Should include how subjects will be identified and recruited.*

3c. Human Subjects – Selection: *Should include criteria for inclusion and exclusion of subjects.*

3d. Human Subjects – Compensation or Incentives: *Should include any form of incentives used, if any.*

4. Potential Risks: *All physical, psychological, social, legal or other potential risks should be described.*

5. Potential Benefits: *Researcher should describe any potential benefits of the study to the subject and/or society, if any.*

6. Assessment: *Researcher should justify research based on the risk/benefit assessment.*

7. Confidentiality: *Must describe how confidentiality of data and privacy of subject's participation will be maintained. Must include where data will be stored, who will have access to the data, and what will happen to the data after the study is completed.*

8. Informed Consent: *Does the researcher use the required format? Are all the elements of consent included in the consent form?*

9. Suggestions Not Related to IRB Approval of Protocol/Editorial Notes: