Lipscomb University Institutional Review Board: Review Template

Reviewer Name: _____ **Date:** _____

Principal Researcher(s): _____

Project Title: _____

Study Description: ☐Dissertation Research ☐Grant Proposal ☐Master's Thesis Research ☐Faculty Research ☐Undergraduate Research ☐Other:

Review Type: ☐Exempt ☐Expedited ☐Full Review

Systemic Review Process Instructions (for reviewers): *(1) Read the research proposal form (2) Read the consent document (3) Read the supporting material (4) Read the consent document again (5) Complete the review template*

A. Identification Information, Specific Aims/Objectives, & Background

A1. Is the identification information complete and proposal type accurately identified? A1. ☐Yes ☐No

A2. Are all of the required attachments listed below included in the submitted proposal? A2. ☐Yes ☐No

Required Attachment	Included	Not Included	N/A
Informed consent	☐	☐	☐
Assent form	☐	☐	☐
All instruments/tests/questionnaires	☐	☐	☐
NIH/CITI certificate for each researcher/faculty advisor	☐	☐	☐
Letters of cooperation from participating institutions	☐	☐	☐
Multimedia release form	☐	☐	☐

A3. If the proposal is student research, is the advisor copied to the emailed proposal submission? A3. ☐Yes ☐No ☐N/A

A4. Are the specific aims/objectives clearly specified? A4. ☐Yes ☐No

A5. Is there appropriate justification for this research protocol? A5. ☐Yes ☐No

B. Informed Consent/Assent (☐An informed consent was not required for this study)

B1. Is the scientific design adequately described in the informed consent? B1. ☐Yes ☐No ☐N/A

B2. Are the objectives likely to be achievable within the given time period? B2. ☐Yes ☐No ☐N/A

B3. Are there adequate provisions for monitoring data described? B3. ☐Yes ☐No ☐N/A

B4. Are all of the following elements of informed consent contained in the consent document? B4. ☐Yes ☐No ☐N/A

Required Elements

☐Research Purpose & Procedures ☐Risks & Discomforts ☐Potential Benefits

☐Provisions for Confidentiality ☐Contacts for Additional Information ☐Voluntary Participation

☐Right to Discontinue Participation Without Penalty

Required When Applicable

☐Unforeseeable Risks ☐Termination of Participation by the Investigator ☐Additional Costs

☐Consequences of Discontinuing Research Participation ☐Notification of Significant New Findings

☐Approximate Number of Subjects ☐Alternative Procedures or Treatments

☐Handling of Research-Related Injury

B5. Is the process of obtaining consent adequately described in the research proposal? B5. ☐Yes ☐No ☐N/A

B6. Is the assent form acceptable (assent is not required if any of the parameters below are met)? B6. ☐Yes ☐No ☐N/A

☐The child is not capable of assent

☐The research offers a prospect of direct benefit not available outside of the research

☐Parental permission is not required by law in this context and is not necessary to protect subjects

B7. Is the waiver or modification of consent possible? B7. ☐Yes ☐No ☐N/A

C. Inclusion/Exclusion Criteria for Subjects

C1. Are inclusion and exclusion criteria clearly specified and appropriate? C1. ☐Yes ☐No ☐N/A

C2. Are the methods for recruiting potential subjects acceptable and well defined in the proposal? C2. ☐Yes ☐No ☐N/A

C3. If vulnerable groups (e.g., children, minorities) are included or excluded, is this justified? C3. ☐Yes ☐No ☐N/A

C4. Is the choice of subjects appropriate for the question being asked? C4. ☐Yes ☐No ☐N/A

C5. Is the principle of distributive justice (i.e., risk is spread evenly among those who may benefit from the research) adequately incorporated into the inclusion and exclusion criteria for the research protocol? C5. ☐Yes ☐No ☐N/A

C6. Is the selection process equitable (i.e., people groups are not unnecessarily favored or excluded)? C6. ☐Yes ☐No ☐N/A

C7. Is the individual performing the recruitment appropriate for the process? C7. ☐Yes ☐No ☐N/A

Comments:

D. Research Procedures	
D1. Are the rationale and details of the research procedures accurately described and acceptable	D1. ☐Yes ☐No
D2. Is there a clear differentiation between research procedures and standard care?	D2. ☐Yes ☐No ☐N/A
D3. Are the individuals performing the procedures appropriately qualified?	D3. ☐Yes ☐No ☐N/A
D4. Is the location of where the procedure will be performed acceptable?	D4. ☐Yes ☐No ☐N/A
D5. Are there adequate plans to inform subjects about the specific research results if necessary?	D5. ☐Yes ☐No ☐N/A
E. Potential Risks, Discomforts, and Benefits for Subjects	
E1. Are the risks and benefits adequately identified, evaluated, and described?	E1. ☐Yes ☐No
E2. Are the potential risks minimized and the likelihood of benefits maximized?	E2. ☐Yes ☐No
E3. Is the risk/benefit ratio acceptable for proceeding with research?	E3. ☐Yes ☐No
E4. If children are involved, which regulatory category of risk/benefit below does the protocol fall within, and are all the criteria within the category adequately addressed? ☐Research presenting no greater than minimal risk to children ☐Research involving an intervention/procedure presenting more than minimal risk that offers the prospect of direct benefit or may contribute to the well-being of the individual child ☐Research involving an intervention or procedure that presents only a minor increase over minimal risk, yet does not offer any prospect of direct benefit or contribute to the well-being of the child	E4. ☐Yes ☐No ☐N/A
F. Compensation and Costs for Subjects	
F1. Is the amount or type of compensation or reimbursement reasonable?	F1. ☐Yes ☐No ☐N/A
F2. Are there adequate provisions to avoid out-of-pocket expenses by the research subject, or is there sufficient justification to allow subjects to pay?	F2. ☐Yes ☐No ☐N/A
F3. If children or adolescents are involved, is the person receiving the compensation appropriate?	F3. ☐Yes ☐No ☐N/A
G. Privacy and Confidentiality	
G1. Are the provisions to protect the privacy and confidentiality of the research subjects appropriate?	G1. ☐Yes ☐No ☐N/A
G2. Are there adequate plans to store, secure, and de-identify data?	G2. ☐Yes ☐No ☐N/A
G3. Is the use of identifiers or links to identifiers necessary and how is this information protected?	G3. ☐Yes ☐No ☐N/A
H. Written Materials, Measures, & Assessments	
H1. Are all materials meant to be read by participants written at the appropriate grade level?	H1. ☐Yes ☐No ☐N/A
H2. Are all materials meant to be read by participants written in a clear and comprehensible manner?	H2. ☐Yes ☐No ☐N/A
H3. Are all materials meant to be read by participants consistent with what is described in the research proposal and informed consent/assent forms?	H3. ☐Yes ☐No ☐N/A
I. Drugs, Biologics, and Devices ☐This section is not applicable to this study	
I1. Is the status of the drug/biologic/device(s) described and appropriate?	I1. ☐Yes ☐No ☐N/A
I2. Are the drug/biologic/device(s) dosage and route of administration appropriate?	I2. ☐Yes ☐No ☐N/A
I3. The drug/biologic/device(s) safety and efficacy data are sufficient to warrant the proposed phase of testing.	I3. ☐Yes ☐No ☐N/A
I4. Is the significant risk or non-significant risk status of the drug/biologic/device(s) described and appropriate?	I4. ☐Yes ☐No ☐N/A

Comments:

Status of Research Review

☐**Research approved**: Researcher should be free to proceed with data collection.

☐**Conditional approval**: Researcher should proceed with data collection provided that the required modifications (see comments) are in place. A research proposal form with the *Request for Amendment to Approved Research* box checked should be submitted within 30 days.

☐**Additional information is needed before a decision can be made**

☐**This proposal has been denied**