Form A
Request for Institutional Review and Assurances

(To be completed for all research requests)

PLEASE NOTE: ALL PERSONS INVOLVED IN RESEARCH MUST COMPLETE A TRAINING MODULE FOR HUMAN PARTICIPANT RESEARCH AND SUBMIT THE CERTIFICATE WITH PAPERWORK

Investigator(s): List all Faculty, Staff, and/or Students conducting this research:

	Name	**Location**	**Phone**
P.I.	_____	_____	_____
Co-P.I.	_____	_____	_____
Co-P.I.	_____	_____	_____
Co-P.I.	_____	_____	_____

Faculty Sponsor (if applicable)_____

Designate one person as the primary contact to receive IRB communications and provide an address.

_____ _____

Name of Primary Contact **Address**

Title of Research Project:

Location(s) at which research is to be conducted (provide name and address):

Funding Source (if applicable):

Anticipated Dates of Study: From __ / __ / ____ To __ / __ / ____

Anticipated Number of Human Research Subjects:

Students _____ Parents _____ Teachers _____Others (describe)_____

* Is this an application for **INITIAL REVIEW**? ○ Yes ○ No

* Is this an application for annual **CONTINUING REVIEW**? ○ Yes ○ No

Date of Initial approval:

1. Will this study include **MINORS** as research subjects? ○ Yes ○ No
2. Will this study involve **DECEPTION** of human subjects? ○ Yes ○ No

3. Will subjects be **PAID**? ◯ Yes ◯ No
4. Will this study involve materials that may be **HAZARDOUS** to human subjects? ◯ Yes ◯ No
5. Will this be a **DRUG STUDY**? ◯ Yes ◯ No
6. Will this study include **PRISONERS** as research subjects? ◯ Yes ◯ No
7. Will this study include subjects who have a **COGNITIVE IMPAIRMENT** that interferes with the ability to provide informed consent? ◯ Yes ◯ No
8. Will this study include **PREGNANT WOMEN** as research subjects? ◯ Yes ◯ No
9. Will this study include **HUMAN TISSUES** as the subjects of research? ◯ Yes ◯ No

---

The following section pertains ONLY to an annual Continuing Review:

A.Provide a brief summary of the progress of the research.

B.Findings from this research
Do the findings or results thus far indicate a change in any of the following:

a. The current risk-potential benefit assessment based on study results ◯ Yes ◯ No
b. Alternatives to subject participation in the research ◯ Yes ◯ No
c. Subject willingness to continue participating in the research ◯ Yes ◯ No

IF you answered **YES** to any of the above (a-c), please describe details further including any need for amendment to the research.

C.Summary of recent literature

Has any literature published or presented since the last IRB approval demonstrated an impact on the risk, potential benefits, alternatives, and willingness to continued participation?
◯ N/A. There has not been any recent literature published or presented since the last IRB review.
◯ No.
◯ Yes. IF YES, an amendment is: ◯ Pending ◯ Submitted ◯ Approved ◯ Not required

D.Subject participation

a. Have any complaints been received about the research since the last IRB approval? ○ Yes ○ No

b. Have any recruited persons declined to participate in the research after being approached since the last IRB approval? ○ Yes ○ No

c. Have any subjects dropped out, been lost to follow up, or been withdrawn from the research after initial enrollment? ○ Yes ○ No

IF you answered **YES** to any of the above (a-c), please describe details.

E. Research Compliance

a. Have any unanticipated problems involving risks to subjects occurred since last IRB approval? ○ Yes ○ No

b. Have any adverse events occurred at a higher level than documented in the research protocol? ○ Yes ○ No

c. Has there been any IRB disapproval, suspension, or termination of this research since the last IRB approval? ○ Yes ○ No

d. Has an audit of this research been conducted by a federal agency or sponsor since the last IRB approval? ○ Yes ○ No

IF you answered **YES** to any of the above (a-d), please describe details further.

FOR BOTH INITIAL AND CONTINUING REVIEWS, PLEASE SIGN BELOW:

I certify that the above information is correct: I have read and approved of the protocol:

_____ _____

Investigator Date Faculty Sponsor (if appropriate) Date

If you answered "No" to Questions 1-9, you *may* qualify for an exemption from full IRB review; proceed to Form B. If you answered "Yes" to *any* of Questions 1-9, you *must* complete the information required on Form C.

Investigator's Assurance

I certify that the information provided in this application for review is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants, conduct of the study and the ethical performance of the project. I agree to comply with all IRB policies

and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the Lewis University IRB certified protocol.
- No changes will be made in the protocol or consent form until approved by the Lewis University IRB.
- Legally effective informed consent will be obtained from human participants if applicable.
- Adverse events will be reported to the Lewis University IRB in a timely manner.

I further certify that the proposed research is not currently underway (except for those protocols of research previously approved and currently seeking renewal) and will not begin until approval has been obtained.

Principal Investigator's Signature_____ Date_____

Faculty Sponsor's Assurance for Student or Guest Investigators

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

- I agree to meet with the investigator on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I insure that the investigator will promptly report significant or untoward adverse effects to the Lewis University IRB in a timely manner.

If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the Lewis University IRB by letter of such arrangements. I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Faculty Sponsor's Signature_____ Date_____

The faculty sponsor must be a member of the Lewis University faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.