IRB Submission Checklist

All information must be typed, handwritten copies will be returned

Your submission for review should include the following items if applicable:

_____ Copy of CITI Program Completion Report for all personnel involved in the project, including students who are involved with testing or handling data.

_____ Copies of data collection methods (See question 9.a)

_____ Copies of submission materials (See question 12)

_____ Application signed by PI, any Co-PI's, chair/supervisor, and dean (See question 13)

_____ Research Assistants have signed the Research Assistant Confidentiality Agreement

_____ Permissions have been received from facility or agency if necessary to conduct research using students or employees (school districts, medical offices, shopping centers, etc.)

_____ Copies of informed consent forms (parental consent/child assent if minors are involved)

_____ If surveying LMU faculty, staff or students please complete the Permission to survey form. (Only signature of investigator and Professional School VP are needed; others will be requested once the IRB approves the application).

An electronic copy of the completed application and all supporting documents should be submitted to IRB@lmunet.edu. Handwritten or e-signatures will be accepted. *Adobe sign is the preferred signature method.*

The submission of incomplete packets may significantly delay the review process. Forms and policy guidelines are available at: Forms and Guidelines

For questions, comments, or assistance in completing the form, contact the ORGSP at 423-869-6485.

IRB APPLICATION FOR HUMAN SUBJECT RESEARCH

(ORGSP use only) **IRB #** _____

1. PROJECT TITLE

Title of Project: _____

2. TYPE OF REVIEW: *IRB will determine level of review.*

3. PROJECT DATES

a. Anticipated starting and completion dates: _____ to _____

NOTE: Project may not start prior to approval from the IRB.

b. This project may be conducted on an annual basis: ☐ Yes

4. PRINCIPAL INVESTIGATOR INFORMATION

a. Contact Information

Principal Investigator: _____

Department or Affiliation: _____

Telephone: _____ Email: _____

Name of chair/supervisor: _____

Email of chair/supervisor: _____

a. IRB Training and Certification

Have you successfully completed the online IRB training program? CITI? **Proof of completion must be submitted along with this application.* ☐ Yes Date _____

c. Student / Outside Researcher Information

If you are a student, please provide the following as applicable:

Thesis/Dissertation: ☐ Independent Study: ☐ Class Project: ☐ Other: ☐

Course # & Name: _____

Faculty Sponsor: _____ Dept: _____

Faculty Email: _____ Phone: _____

Students and outside researchers must provide their current address:

_____

NOTE: A application by a student researcher must have the following statement signed by a university sponsor:

I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. For student projects, I will take responsibility for informing the student of the need for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.).

Signature of University/Faculty Sponsor | Date

If you are an outside researcher, please provide the following as applicable:

Investigator Name:

Name of Home Institution:

Investigator email: | Phone:

Home Institution IRB Contact: | Dept:

Date of IRB Approval: (Please include copy of approval) | FWA Number

NOTE: A application by outside researcher must have the following statement signed by a university sponsor:

I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I will take responsibility for informing the above-mentioned investigator of the need for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.).

Signature of University/Faculty Sponsor | Date

5. FUNDING

Is this project being funded? ☐ Yes ☐ No

If yes, list the funding source:

6. RESEARCH STATEMENT: In 100 words or less give a short justification for the study:

7. PARTICIPANTS

a. Indicate which, if any, of the following groups will be research subjects (check all that apply):

☐ Minors (under 18)
☐ Students
☐ Non-English Speakers
☐ Institutional Residents
☐ Single Subject Populations (by Race, Ethnicity, Sex, or Religion)
☐ Other (specify):

☐ Senior Citizens (over 65)
☐ Prisoners
☐ Mentally/Physically Disabled
☐ Employees

☐ Terminally Ill
☐ Cognitively Impaired
☐ Pregnant Women
☐ No Special Groups

b. If any of the above groups are selected, state the rationale for using special groups.

c. What is the approximate number of subjects to be recruited?

d. How will the subjects be solicited (check all that apply)?

☐ Advertisements ☐ Letters ☐ Random Calls
☐ Telephone Lists ☐ Notices ☐ Direct Solicitation
☐ Other (specify):

8. INFORMED CONSENT. See Informed consent for detailed information on consent and assent forms, the required consent elements, and to view sample consent forms.

a. Type of Consent/Minor Assent Requested (check all that apply):

(i)	☐	Adult Consent

(ii)	Use of Minors (under 18 years of age)	
	☐	Parent/Guardian Consent
	☐	Child/Minor Assent (Non-readers: Not able to read or not proficient at reading)
	☐	Child/Minor Assent (Proficient readers: Can read & understand a simple assent form)

(iii)	In certain circumstances, a waiver of informed consent/minor assent may be requested. In this case, subjects are not informed or only partially informed about a study. To request that informed consent or assent be waived, indicate category below (check all that apply).	
	☐	Informed consent will not be obtained
	☐	Parental consent will not be obtained
	☐	Child/minor assent will not be obtained
	☐	Partial Consent/Assent: This study involves deception

Justify why informed consent will not be obtained or why deception is necessary for this study. For studies that involve deception please include plans for how and when subjects will be debriefed. If a debriefing statement will not be used, explain why.

b. Method to obtain consent/minor assent.

(i) ☐ Written Consent/Assent (written signature will be obtained from subjects)

(ii) ☐ No Written Consent/Assent Obtained (a written signature will not be obtained from subjects. Documentation of a signature is waived.)

If a waiver of a signature is requested, indicate below how subjects will be informed:

☐ An Information Sheet will be used. Explain rationale below.

☐ Oral Consent will be obtained. Explain rationale below.

☐ Electronic Consent

9. DATA & CONSENT COLLECTION

a. Data collection methods (check all that apply):

☐ Questionnaire or Survey	☐ Archival Data
☐ Web or Internet	☐ Intervention
☐ Interview	☐ Focus Groups
☐ Observation	☐ Testing/Evaluation
☐ Video or Audio Taping	☐ Instruction/Curriculum
☐ Computer Collected Task Data	☐ Physical Tasks
☐ Other:	

b. Will the data be collected with identifiers? ☐ Yes ☐ No

If yes, will the data be rendered anonymous for analysis? ☐ Yes ☐ No

Will the data be rendered anonymous for reporting? ☐ Yes ☐ No

c. Describe how consent forms and other study material (e.g., data instruments, interview questions) will be distributed and collected and how confidentiality/anonymity will be maintained throughout both the consent and data collection process.

d. Describe security of the data, including where the consent forms and other study material will be stored, who will have access, and how and when the material will be destroyed. Note that signed consent forms must be retained for **three years** after the end of the study. State who will maintain the consent forms for the specified three years. (Note: faculty/staff sponsors may retain the original or a copy of signed consent forms including those collected from student projects.)

10. METHODOLOGY: Describe in detail how the research will be conducted making sure to address (1) how subjects will be identified and the process of contacting, selecting and excluding subjects; (2) how consent will be obtained, and if children will be used, describe

how parental consent and child assent will be obtained; and (3) how data will be collected, including how data instruments, if used, will be distributed and collected, and the location where the study will take place.

11. RISK FACTORS: A research participant is considered to be at risk if he or she may be exposed through the procedures of the planned experiment to the possibility of physical or mental harm, coercion, deceit or loss of privacy. The most obvious examples of placing participants at risk of harm include administration of unusual physical exertion, deceit and public embarrassment or humiliation. Coercion may be present when the potential participants are not able to exercise their right to decline participation, particularly when the researcher is in a relationship of greater power over the participants.

a.	Risk Criteria	**CHECK ONE**			
	Deceit, coercion, or possible embarrassment/humiliation		Yes		No
	Experimental drugs will be used.		Yes		No
	Potential for medical problems exist.		Yes		No
	Participants may experience physical discomfort.		Yes		No
	Participants may experience mental discomfort.		Yes		No
	Electrical equipment will be used.		Yes		No
	Participants will be tape recorded, photographed, or videotaped.		Yes		No

b. Does any part of this activity have the potential for coercion of the subject? If yes, explain and describe the proposed safeguards. ☐ Yes ☐ No

c. Assess the likelihood and seriousness of risks (physical, mental, or other) to the subjects. Describe alternative methods that would not entail comparable risks and why these were not used.

d. Description of the anticipated benefits to subjects and contributions to general knowledge in the field of inquiry:

e. If the research subjects will be compensated or rewarded, indicate the type and amount of compensation and the milestone for each payment. If subjects are being recruited from LMU classes, indicate whether students are receiving course credit (regular or extra credit) and, if so, what alternatives are offered to those students who do not wish to participate in the research.

12. SUBMISSION MATERIAL

The IRB must review copies of all final material presented to subjects. The IRB cannot approve a project without a complete and accurate application and final copies of all supporting materials. Please indicate below what materials have been attached to this application (check all that apply):

- ☐ Recruitment material (flyer, announcement, oral script, email, letter, etc.)
- ☐ Data instruments (surveys, interview questions, tests, web-survey, etc.)
- ☐ Informed consent
- ☐ Debriefing statement
- ☐ Video clips, music CDs, photos, etc.
- ☐ Other: (specify) _____

13. CERTIFICATION STATEMENT

In making this application, I certify that I have read and understood Lincoln Memorial University's policies and procedures governing research with human participants (specifically, those as described in Lincoln Memorial University's Institutional Review Board Policy*). I shall comply with the letter and spirit of those policies and will not undertake the research without IRB approval. Furthermore, I am aware that certain departments may have their own standards for conducting research, and it is up to me to familiarize myself with them. I further acknowledge my obligation to: (1) obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations; and (2) report immediately all adverse effects of the study on the participants to the Chairperson of the Institutional Review Board and the Chairperson or Supervisor of my Department.*

Principal Investigator signature	**Date**
Chair/Supervisor/Director signature	**Date**

Your signature verifies that (1) this application and attachments are accurate, clear, and complete; (2) permission has been granted to use instruments developed by others.

Dean Signature	**Date**

Your signature indicates that you have reviewed and approved of this research.

CO-INVESTIGATORS:

a. Name:		Title:	
Signature:		Affiliation:	
b. Name:		Title:	
Signature:		Affiliation:	

13.1 IRB CHAIR APPROVAL

IRB Chair Reviewed as:	**Date**

Exempt Expedited Full

Category:_____

14. SUBMISSION INFORMATION

Original application with signatures and all supporting materials should be emailed to IRB@lmunet.edu. Handwritten or e-signatures will be accepted. *Adobe sign is the preferred signature method.*

The submission of incomplete packets may significantly delay the review process. Forms and policy guidelines are available at:

Guidelines and forms

For questions, comments, or assistance in completing the form, contact the ORGSP at 423-869-6485.

Office of Research, Grants and Sponsored Programs
Lincoln Memorial University
IRB – Grant Lee 108
6965 Cumberland Gap Parkway
Harrogate, TN 37752