International University of Leadership

Where Leaders Are Born!

Doctoral Dissertation Research Protocol Approval Form

Hints and help:

- Complete all sections about your research proposal.
- Submit your completed application to the IRB office within the Office of Research and Doctorare Programs (ORDP). E-mail the entire proposal with any attachments such as surveys and recruiting flyers to irbprotocol@iulf.education. To facilitate tracking, please include in the file name 1) your last name and 2) one or two key words describing its subject.
- Print off, sign, and send this front page to the IRB at IUL email.
- Training in the conduct of human subject research is critical and investigators must demonstrate their knowledge and awareness through the completion of appropriate coursework. As of January 1, 2007, the IRB adopted the CITI "Course in The Protection of Human Research Subjects" (https://www.citiprogram.org) as the primary means of training and as a requirement of protocol approval. Please provide documentation of your training with this application; you may be asked to pursue additional training appropriate to your proposal.
- More information about the IRB at IUL is available at the main web page, there are sample protocols and consent forms, links to training materials, policies and procedures, etc.
- For other assistance, contact the Compliance Associate within ORGS,

Investigator information	Primary investigator: Doctoral Candidate, Faculty and Student	Other Investigators: Faculty, Advisor or Mentor co-investigators, etc.
Name:		
Affiliation to IUL -University:		
Affiliation to Partner University:		
Phone contact (office or cell):		
Email contact:		
Title of protocol:		
Anticipated Starting date:	Estimated completion Date:	
Date submitted:	☐new protocol ☐amendment ☐renewal	
Vulnerable subjects (risks), please indicate if any?:		

DECLARATION BY ALL PARTICIPANTS: This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the Belmont Report. I/We agree to abide by the policies and procedures of the IRB at IUL, including obtaining appropriate training in human subject research for myself and those involved in its conduct. I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB. I/We will inform the IRB of any adverse events that occur or of a need to modify the study design. I/We understand that approval, when granted, is valid for up to one year and will submit a renewal for its continuation if needed.

(send this signed page to the IRB office)	Signature	Date
Primary investigator:		
all others, including advisors:		

IRB office use	Review type:		
Date of submission:	Assigned to:	training:	approval date:
Protocol #:			renewal date:
Copies:	final:	e-mailed:	
This protocol has been reviewed and approved for conduct by the IRB, International University of Leadership Chair, IRB Date			

General information:

Provide below brief details of the proposed research. Use lay language and avoid technical terms

1. Purpose - Why are you conducting this study? What are the objective(s) and goal(s)?

2. Outline specifically the relationship of your proposed research to other, previous scientific investigations in the field**.** Provide full citations (APA style is a good format).

3. Summarize the study design. Describe in detail all procedures to be performed with human subjects. What will be done? Include when and where the research will occur and who will conduct it. Define terms, abbreviations, and procedures for the understanding of the IRB reviewer.

4. What is your intent of the research study (hypothesis or research question of the study)?

5. Is the project a systematical investigation, including research development, testing and evaluation?

6. **Participants**: describe your subjects and methods of recruiting them. Also describe anything that would cause you to exclude a particular subject, and why.

7. **Procedures**: describe your data collection methods, such as "Survey" or "Public observation," etc.

8. Will you collect subject identities in conjunction with the data? If so, how will you prevent disclosures?

9. Will the subject's participation be recorded (audio/video)?

10. How will you store the data after you complete the research (data retention schedule)?

11. Will the subjects be offered an incentive to participate or compensated for their time?

12. Does your research pose risk of harm to subjects? Describe any foreseeable risks and your plan to reduce or eliminate them.

13. Will the research utilize existing or secondary data which contains individually identifiable private information?

14. Can subjects reasonably expect a direct benefit from participation? Describe any foreseeable benefit to the subjects.

15. How will society benefit from your research? Is the project designed to contribute to generalizable knowledge?

Affiliation to Institutions:

1. Are you collaborating with another group such as a school, community association, government agency, etc.? Is IRB approval necessary, or being obtained, elsewhere (domestically or internationally)? Is the project being sponsored or supported through a grant, contract, or other financial arrangement? Describe as appropriate

2. Financial interest – Do you, as an investigator involved with the project, or any family member (spouse or dependent child) have a financial interest in this study? If yes, describe.

3. Are you a doctoral candidate or student? Is this project part of a classroom experience or a dissertation project part of a program? Has your advisor/mentor reviewed your IRB application? Describe as appropriate

4. Do you have any pre-existing relationships of any kind with the subjects (participants) or institutions involved in conducting this study? If so, please describe them.

5. If you are not affiliated with IUL, which partnering institution or campus initiated this study?

Data Collection Process:

1. What data about the subjects will be collected? How will it be coded or identified? Will social security numbers be used? What will become of the data at the end of the study (returned, destroyed, archived)?

2. If applicable, have you submitted a copy of the survey or questionnaire to the IRB? Provide the URL for electronic surveys (it will be tested during IRB review; discard those data before 'going live').

3. Who will have access to the data? To whom will the raw data be disclosed? How will the data be kept protected and secure? (*researcher must provide a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information*.)

4. Does the research project have provisions or plans for the ongoing monitoring of data collection to ensure safety of subjects? If so, describe the plan.

5. For studies involving medical records, explain compliance with the HIPAA privacy rule (Health Insurance Portability and Accountability Act) and disclosure of protected health information (PHI).

6. How many subjects (or participants) will be involved in the research project? It is acceptable to have a range, but it must be a close approximation.

7. Briefly describe the subject group(s).

8. What are the benefits, if any, to the subjects from participating in this study?

9. Describe the control and/or comparison group(s), if any in your study?

9. Will the subjects be compensated? If yes, in what way (token of appreciation, money, gift, cash card, course credit, etc.)?

Section 1, Human Subject Research Determination

Answer the questions below:

1. Will your investigation gather information about living human individuals?
■ Yes ☐No

2. Will you be interacting with the respondents or intervening in their daily routine, including via the internet or over the phone?
☐ Yes ☐No

3. Are you collecting data that would allow you or another researcher to identify the participants (examples: Name, Social Security Number, phone number, mailing address, email, medical record number or any other number or code that pertains specifically to an individual)?
☐ Yes ☐No

4. Is the data collected considered to be private information, which the participant expects will not be made public, or collected within a context which an individual would not otherwise expect to be observed or recorded (such as in their home)?
☐ Yes ☐No

If you answer "NO" to EACH of questions 1-4, your research does not involve human participants and HRPP review is not required.
If you answer "YES" to one or more of the above questions, your research involves human participants and you need to complete question 4 below.

5. Are you conducting an investigation, a searching inquiry to gather facts, or an examination of a phenomenon?
☐ Yes ☐No

6. Is it systematic, involving a system, method, or plan that will be employed consistently throughout data collection?
☐ Yes ☐No

7. Will your findings be presented beyond the university setting, such as presented at a conference, or published in a peer-reviewed journal **or** used in a dissertation?
☐ Yes ☐No

8. Will your conclusions be presented as representative of the larger population from which your sample was recruited? (Mark 'No' if the data collected applies only to the sample population)
☐ Yes ☐No

If you answer "NO" to questions 5-8, your study is not research and HRPP review is not required.
However your study may qualify for non-regulatory review.
If you answer "YES" to one or more of questions 5-8, your study is research.
Continue to Section 2.

Section 2, Screening questions

Federal regulations specify that certain types of research pose low risk to participants, and therefore MAY qualify for EXEMPTION under federal regulations. To determine if your study is exempt, answer the following screening questions.

1. Will participants be asked to report their own or others' sexual experiences, alcohol or drug use, and will their identities be known to you?
☐ Yes ☐No

2. Are the participants' data directly or indirectly identifiable, and could these data place subjects at risk for criminal or civil liability, or might they be damaging to subjects' financial standing, employability or reputation?
☐ Yes ☐No

3. Will you be recording the subjects' participation by video or audio for reasons **other** than transcription?
☐ Yes ☐No

4. Are any participants confined in a correctional or detention facility, including involuntary assignment to community-based alternatives to incarceration (drug treatment facilities, etc.)?
☐ Yes ☐No

5. Are participants involved who may not be legally/mentally/cognitively competent?
☐ Yes ☐No

6. Are personal records (medical, academic, etc.) used with identifiers and without written consent?
☐ Yes ☐No

7. Will alcohol or drugs be administered to the subjects?
☐ Yes ☐No

8. Will blood/body fluids be drawn from participants?
☐ Yes ☐No

9. Will specimens obtained from an autopsy be used?
☐ Yes ☐No

10. Are live fetuses subjects in this research?
☐ Yes ☐No

If you answer "YES" to any of the above questions, then your research is NOT exempt and you need to fill out the non-exempt application.
If you answer "NO" to all the above questions, your research may be exempt.
Complete Sections 3-4

Section 3, Exemption categories and determinations

EXCEPTIONS:
The exemption categories listed below do not apply when the research includes the following:

- Prisoners,
- Survey or interview techniques which include minors as participants,
- Observation of minors where the investigator participates in the activities being observed,
- Food and Drug Administration (FDA) regulated research.

This applies to exemption categories that include projects for which the data will be submitted to or held for inspection by the FDA, or research for which the investigator gathers data on participants who serve as controls for participants who receive FDA-regulated drugs or medical devices, other than in the course of medical practice.

Research activities are exempt from the federal regulation 45 CFR 46.101(b) for the protection of human participants when the ONLY involvement of human participants falls within one or more of the categories below. Check the appropriate categories that apply to your research study:

1. ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   i. Research on regular and special educational instructional strategies, or
   ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   i. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
   ii. Any disclosure of the human participants ' responses outside the research could reasonably place the participants at risk of criminal or civil liability; or
   iii. Be damaging to the participants ' financial standing, employability, or reputation.

PLEASE NOTE: According to 45 CFR 46.401(b), this exemption does NOT apply to survey or interview procedures when the participants are children.

3. ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) of this section, if:
   i. The human participants are elected or appointed public officials or candidates for public office; or
   ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the participants.

PLEASE NOTE: According to the Office for Human Research Protections (OHRP), "to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; participants must consent to participation in research."

5. ☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

i. Public benefit or service programs;
ii. Procedures for obtaining benefits or services under those programs;
iii. Possible changes in or alternatives to those programs or procedures;
iv. Possible changes in methods or levels of payment for benefits or services under those programs.

6. ☐ Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If you mark one or more of the six exemption categories above, complete the remainder of the application and submit to IUL HRPP. The IRB committee will determine whether or not your research qualifies for exemption. Do NOT begin data collection without exemption certification from IRB committee.

Justification of Exemption Category

You must justify how your study qualifies for exemption by addressing the critical elements of the exemption category you choose. The critical elements for each category are:

Category 1: Specify whether 1(i) or 1(ii) applies and briefly explain.

Category 2: Assure that condition 2(i) will be met and briefly explain how; and assure that condition 2(ii) applies; and attach a copy of test/survey/interview questions or items.

Category 3: Explain why conditions 2(i) and 2(ii) cannot be met; and attach a copy of test/survey/interview questions or items; and either assure and briefly explain that condition 3(ii) applies, or explain subject's public office and how it precludes anonymity (i.e., 3(i)).

Category 4: Briefly explain the nature of the existing data/documents and briefly explain either their public availability or the procedures to ensure anonymity and confidentiality.

Category 5: Briefly explain method by which the project is reviewed and approved by a federal department/agency head; and identify and describe which of the 5(i) – 5(iv) categories apply.

Category 6: Assure that condition 6(i) will be met; and assure via documentation regarding approved safety levels that condition 6(ii) will be met.

Section 4, Investigator's responsibilities and assurances

Indicate that you have read and will comply with each statement.

1. ☐ I certify that the information provided in this application, and in all attachments, is complete and correct.

2. ☐ I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.

3. ☐ I agree to comply with all IUL policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.

4. ☐ I certify that:

- The study will be performed by qualified personnel according to the information contained in this application.
- The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
- Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the IUL Office and to the Campus Director
- I am familiar with the latest edition of the IUL Manual for the Protection of Human Research participants, available at www.irb.iulf.education, and I will adhere to the policies and procedures explained therein.
- Student and co-investigators on this study have received adequate training and are knowledgeable about the regulations and policies governing this research.
- I agree to ensure adequate supervision of all research study personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.

5. ☐ I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until exemption has been certified.

Name:_____ Date: _____

How to Submit:
Attach the application and supporting materials (recruiting materials, survey questions, interview guide, etc.) to an email sent to info@aulm.us .
Please allow for up to 10 business days for review of your application determination.

International University of Leadership
1507, S Hiawassee Rd,
Orlando, Florida USA 32835

This is an example of an informed consent form (or cover letter) for a confidential survey

Dear Employee,

I am a Doctoral Candidate at IUL conducting a research study. You are being invited to participate in this research study, which the IUL Institutional Review Board (IRB) has reviewed and approved. This cover letter is designed to provide you, as a human subject, with information about this study.

This survey is related to new employee orientation training. We want to hear your thoughts and feelings on this topic. This research will be used for the purpose of determining the impact of new hire orientation training programs in the work place. The entire survey should only take five (5) minutes of your time. Your participation is strictly voluntary. There are no penalties or negative consequences of your employment for declining to participate. You may discontinue your participation at any time without any negative consequences. However, as a token of my gratitude for your participation, I have provided refreshments at Starbucks after completion of the survey.

Please read each question carefully and then indicate how you feel towards each statement by circling or filling-in your response. We ask that you please read all items very carefully. It is critical that you give your true feelings in your responses.

All your responses are completely confidential. Returning your survey implies your consent as a participant and authorizes me to share the data and information provided in the research with employers on their orientation programs.

I am available to answer any of your questions related to this study at student@iulf.education. If you have any questions or complaints about the informed consent process of this research study or your rights as a subject, please contact the Compliance Office within IUL Office of Research and Graduate Studies at (407) 801-5140, which has approved the conduct of this research study.

Thank you in advance for your valuable time and information. I appreciate your candid responses.

Sincerely,

Business Student