

Appendix C

Application for IRB Review and Certification of Compliance: Full Application Form Checklist

Full IRB Review (Level 3) Application, High Risk

(Full Board Review) Application Form Checklist

To the Principal Investigator of a research project:

- 1. Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*
- 2. Please be advised that research projects involving interaction with human participants must have an Informed Consent Form(s) attached. If a minor or incapacitated individual of any age is involved, parent/guardian permission must be noted and included.*
- 3. Parental permission does not negate the child's right to chose to not participate.*
- 4. If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*
- 5. If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB)-- then written permission from the participating institution's IRB must be attached to your IRB application.*
- 6. If you are conducting the research outside of the United States, attach a letter of assurance that where the research is being conducted.*

Please check: The attached Application for Certification of Compliance contains

- Institutional Permission Letter (where research is taking place)
- Assurance of Adherence to Governmental Regulations concerning Human Subjects (if Research project is conducted outside the US)
- Letter(s) of Informed Consent
- Parent/guardian Permission Letter (must have provision for written signature)
- Oral statement of Assurance (used with minors)
- Data-gathering instruments (s): Observation, Interview, Survey, other
- Conflict of Interest Disclosure Statement
- CITI completion documentation for both Principal Investigator and Faculty Research Supervisor
- Principal Investigator and Faculty Research Supervisor's signatures

***Application for IRB Review and Certification of Compliance
Full Cover Sheet***

*Full Review (Level 3) Application, High Risk
(Full Board Review)*

IRB# _____
Date Logged: _____

Principal Investigator/Researcher's Name: _____

Student ID Number: _____

Type of Research Project (CRP, Dissertation, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Email Address: _____ Telephone Number: _____

Faculty Research Supervisor/CRP/Dissertation Committee Chair's Name: _____

College: Business Psychology and Behavioral Sciences
 Education Health Sciences OTHER _____

Program of Study: _____ Degree _____

Project Proposed Start Date: _____ Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in subject(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or final completion date of project. I also attest that I will treat human participants' data ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator/Researcher _____ / _____
Date

Approval Signature - Faculty Research Supervisor/CRP/Dissertation Committee Chair:

Date

IRB Certification Signature:

Date

The above named research project is certified for compliance with Argosy University's requirements for the protection of human research participants with the following conditions:

1. Research must be conducted according to the research project that was certified by the IRB.
2. Any changes to the research project, such as procedures, consent or assent forms, addition of participants, or study design must be reported to and certified by the IRB.
3. Any adverse events or reactions must be reported to the IRB immediately.
4. The research project is certified for the specific time period noted in this application; any collection of data from human participants after this time period is in violation of IRB policy.
5. When the study is complete, the investigator must complete a Completion of Research form.
6. Any future correspondence should be through the principal investigator's research supervisor and include the assigned IRB research project number and the project title.

NOTES:

- Please complete this cover and the Application in detail. Every question must be answered. Please type your answers.
- Attach the appropriate documents and submit the entire application materials under the cover of a completed Application Checklist to the CRP or Dissertation Chairperson.
- Do not proceed with any research work with participants until IRB Certification is obtained.
- If any change occurs in the procedure, sample size, research focus, or other element of the project impacts participants, the IRB must be notified in writing with the appropriate form (see ancillary forms).
- Please allow 30 days after receipt of a complete application for processing.
- **DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION**

***Application for IRB Certification of Compliance:
Full Application***

Full IRB Review (Level 3) Application, High Risk or Involving Vulnerable Populations

Vulnerable populations include children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons.

Please completely answer the requested information (NA is not acceptable for any question). **DO NOT** attach your research proposal – answer each specific question in the area provided.

1. Purpose of the Study:

2. Brief but detailed summary of the project, including methodology:

3. Subject/participant Demographics:

a. Anticipated Sample Size:

b. Special Ethnic Groups (describe):

c. Institutionalized	Y	N	Protected Group (describe)
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d. Age group:

e. General State of Health:

f. Other details to describe sample group:

4. Will deception be used in the study? Y N (please describe)

5. Will audio or videotapes be used in the study? Y N (please explain)

7. Review by institutions outside of Argosy University/name of the campus. (Attach copies of permission letters, IRB certifications, and any other relevant documents).

8. Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent.

9. If written or oral informed consent is required, describe the manner in which consent and/or assent was obtained for each category).

(a) Adult Participants (18 years and older – written consent required).

(b) Child Participants (under 18 – parent/guardian consent and participant assent required).

(c) Institutionalized participants (parent/guardian/conservator consent with appropriate participant assent).

10. Describe any possible physical, psychological, social, legal, economic or other risks to participants (Attach another page if needed).

a. Describe the precautions taken to minimize risk to participants.

b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies).

11. Potential benefit of the study:

a. Assess the potential benefit(s) of the study for the participants:

b. Assess the potential benefits(s) to the professional community:

Attach any other required forms, including the principal investigator and faculty research supervisors' CITI completion forms, the principal investigator's Conflict of Interest form, tests, institutional permission slips, etc., related to this study. Failure to do so will result in delayed processing of the application.