

Below is the IRB Manual's IRB Application Review Checklist (Appendix I), Informed Consent Checklist, and Sample Consent Form (Appendix G). They assist with determining Chapt. 3 Methodology content, and completing the IRB Application.

APPENDIX I

IRB Protocol #: _____

Date Submitted: _____

Date Completed: _____

IRB APPLICATION REVIEW CHECKLIST

(to be used by the students prior to submission to designated IRB faculty)

Principal Investigator (PI):

Name of CRP or dissertation chair:

Proposal Title: _____

Reviewer: _____

0. Status

_____ If PI requesting Expedited status, request form is attached

_____ Contact information completed

_____ Adviser's name present

_____ Project title clear

_____ Funding source noted if relevant

1. Project Description

_____ Adequate overview of purpose and clear statement of goals of study

_____ Adequate preliminary data to justify study

_____ Appropriate justification for the particular protocol being proposed

2. Source of Participants

- ___ Source and estimated number of participants stated clearly
- ___ Methods of recruitment clearly outlined, including inclusion and exclusion criteria
- ___ All recruitment materials attached to the application
- ___ Recruitment methods, places, times, and recruiting person are appropriate
- ___ Ages, genders, ethnicities stated, and relevance to the research question of the chosen population made clear
- ___ Compensation, if any, is clearly described and not an undue incentive
- ___ Relationship between investigator and participants clearly described, and any potential conflict of interest addressed clearly

3. Research Procedure

- ___ Hypotheses stated clearly
- ___ Design described clearly and adequately
- ___ Design is justified by preliminary data and appropriate to the question asked
- ___ Research procedure clearly described
 - ___ What participants will do
 - ___ What will be done to participants, if relevant
 - ___ Copies and brief descriptions of all instruments, surveys, questionnaires, etc. included in application
 - ___ If development of an instrument is part of the project, specific description of data to be collected, especially data of a sensitive nature, is included
- ___ The amount of time required of participants is clearly stated and is reasonably accurate estimate of the actual time needed; this includes time for follow-up in qualitative studies

4. Deception and coercion

- ___ If deception or coercion is involved, clear justification of why this is needed and the nature of the deception or coercion is stated
 - ___ Debriefing protocol described in detail and is adequate
 - ___ Mechanics of debriefing described, e.g., where, how, by whom

5. Risks and Benefits

- Clear description of potential risks or discomforts to participants, including physical, psychological or social risks
- Clear description of any sensitive data to be collected
- Threat of loss of confidentiality addressed directly, i.e., how specifically private data will be protected
- Clear statement of potential benefits, e.g., compensation, as well as conditions for receiving compensation
- Consequences of choosing not to participate or of withdrawing from the study clearly stated
- If relevant, alternatives to participating in the research are noted

6. Minimizing Risk

- Clear statement of steps taken to minimize each risk noted in previous section
- Steps to minimize risk are adequate

7. Protection of Privacy

- Anonymous study
- Description of steps taken to ensure anonymity
- Confidential study
 - Detailed description of how confidentiality will be ensured
 - Description of how codes or master lists will be stored and protected
 - Protection of transcripts and group confidentiality described clearly

8. Informed Consent

- Procedures for obtaining informed consent from all relevant parties described clearly
- Informed consent form attached

9. Signatures

- All relevant names, signatures, dates are present

INFORMED CONSENT CHECKLIST

- ___ Title of study at the top of the form (both consent and assent if both needed)
- ___ Form is written in the first person
- ___ Form is written at fourth grade reading level or lower
- ___ If non-English speakers are participants; form is in their native language
- ___ How this person was selected, i.e., why he or she is being asked to participate
- ___ Number of participants anticipated—must match application
- ___ Research question and purpose of study explained clearly in lay terms.
- ___ If PI is a graduate student, clear statement of how the research relates to the student's program, e.g., dissertation, thesis, etc.

Expectations of participants

- ___ Clear explanation of the procedures involved, including taping, instrument to be used, etc. That is, exactly what the participants will do or have done to them.
- ___ Statement of how participants will be assigned to groups, if relevant
- ___ Length of time required, is realistic, and matches application; includes follow-ups if relevant
- ___ Statement that participants have the right to choose not to participate, and to withdraw at any time
- ___ Statement that if child or dependent adult abuse is detected, that will have to be reported
- ___ Potential risks or discomforts clearly stated, along with estimates of likelihood of each risk
- ___ Benefits, including possible compensation, clearly stated, or if none, so state
- ___ Impact on potential benefits, e.g., compensation, if participant withdraws or chooses not to participate
- ___ If the study involves withholding standard treatments, alternatives clearly stated

Compensation (includes class points or other non-monetary rewards)

- ___ Statement of exact nature of compensation, if any
- ___ Clear statement of conditions for obtaining compensation, including alternatives, if person wishes to have the compensation (e.g., class points) but not participate
- ___ Clear statement of when and how compensation will be disbursed

Obtaining Results of Study

- ___ Procedure for requesting summary of results is clearly stated, and any forms involved are included here and in application
- ___ Procedure is not unduly onerous for the participant
- ___ For qualitative studies, statement that all participants will receive the summary

Privacy Protection

- ___ For anonymous studies: Clear statement of how anonymity will be ensured
- ___ For confidential studies:
 - ___ Clear, detailed description of how privacy of records will be ensured

- ___List given of names of all persons who have access to the records
- ___Statement of how audio or video tapes will be protected, and when they will be destroyed, if relevant

Contact Information

- ___Statement that decision to participate will not affect relationship with any cooperating agency
- ___Information for contacting PI and adviser if relevant
 - ___Name
 - ___E-mail if relevant
 - ___Phone number (home phone number is NOT recommended)
- ___Statement of Certification by relevant IRB(s)
- ___Contact information for IRB chair (name, phone, e-mail)

Signatures

- ___Investigator's signature and date
- ___Participant's signature and date
- ___Parent's or guardian's signature and date for children and disabled adults
- ___If children 7-18 are involved, assent form meeting above criteria and written at a child's level of understanding, must be included
- ___Separate signature block giving consent for taping, if relevant
- ___Statement that the participant is entitled to a copy of the consent form

APPENDIX G SAMPLE CONSENT FORM

- 1) This template is intended to be a guide for investigators unsure of what a consent form is.
- 2) Not all studies are the same and, thus, it is assumed that the template will be modified to fit each study.
- 3) Consent forms are required to be written in first person of the subject.
- 4) If the consent form is longer than one page then page numbers (1 of?) and "Date ___ Initial ___" are required to be included on the bottom of each page.
- 5) Refer to consent form check list.

CONSENT FORM (Insert Title of Study)

I have been asked to participate in a research study (*Insert general statement about study*). I was selected to be a possible participant because (*Explain how subject was identified*). A total of (*Insert number of test subjects*) people have been asked to

participate in this study. The purpose of this study is (*Explain research question and purpose in lay language*).

If I agree to be in this study, I will be asked to (*Explain tasks and procedures: Subjects should be told about video or audio taping and if participation will be effected if subject does not want to be video or audio taped, assignment to study groups*) This study will only take (*Insert length of time for participation, frequency of procedures, etc.*) The risks associated with this study are (*Risk must be explained, including the likelihood of the risk*). The benefits of participation are (*Insert benefit(s), if no benefits, state that fact here.*)

I will receive (*Insert payment or reimbursement information, if no monetary compensation, state that fact here.*) *If subjects receive class points or some other token, include that information here and alternative task incase subject does not want to participate in study but wants to obtain class points. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw.*) This study is (*anonymous or confidential can not be both and describe how this will be accomplished*). The records of this study will be kept private. No identifiers linking me to the study will be included in any sort of report that might be published. Research records will be stored securely and only (*Insert names of individuals who will have access to this data*) will have access to the records. (*If tape recording or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be erased.*)

My decision whether of not to participate will not affect my current or future relations with Argosy University (*include any other cooperating institutions, insert names here*). If I decide to participate, I am free to refuse to answer any of the questions that may make me uncomfortable. I can withdraw at any time with out my relations with the university, job, benefits, etc., being affected. I can contact (*Insert your name and contact information and advisors name and contact information*) with any questions about this study.

I understand that this research study has been reviewed and Certified by the Institutional Review Board, Argosy University – (*Insert location*). For research-related problems or questions regarding participants' rights, I can contact the Institutional Review Board through the IRB Chair at (*Insert contact info*).

I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I have been given a copy of this consent form. By signing this document, I consent to participate in the study.

Signature: _____ Date: _____

Signature of Investigator: _____ Date: _____