

IRB Protocol #: _____

Date Submitted: _____

Date Completed: _____

IRB REVIEW CHECKLIST

PI: _____

Protocol Title: _____

Note: “Please do not reference or attach your proposal to an application” (IRB Handbook p. 34)

<u>ITEM</u>	<u>NO</u>	<u>YES</u>	<u>N/A</u>
1. Is the PI requesting Expedited Status?			
2. If so, is the request for expedited review form attached?			
3. Has the PI completed the appropriate contact information?			
4. Is the PI’s graduate advisor’s name designated?			
5. Is the project title clear?			
6. Is a funding source designated?			
1. PURPOSE OF THE STUDY			
7. Has the PI provided an adequate overview of the study’s purpose and goals?			
8. Are the aims clearly specified?			
9. Are there adequate preliminary data to justify the research?			
10. Is there appropriate justification for this research protocol?			
2. SUMMARY/METHODOLOGY			
11. Are the study hypotheses clearly stated?			
12. Is the scientific design adequate to answer the question?			
13. Is the scientific design described and adequately justified?			
14. Are the rationale and details of the research procedures accurately described and acceptable?			
15. Are the individuals performing the procedures appropriately trained and is the location for performing the procedure acceptable?			

ITEM	NO	YES	N/A
16. Are there adequate plans to inform subjects about specific research results if necessary?			
17. Is the total amount of time it will take for subjects to participate specified?			
18. Does the amount of time match the consent form?			
19. Are the measures adequately described?			
20. Are the measures appropriate to the research design and research questions?			
21. In the case of psychological instruments, are the qualifications of the individuals administering the measures sufficient for the measure?			
22. Are the measures appropriate to the subjects?			
23. Are copies of all study measures included?			
24. Are the methods for recruiting potential subjects well defined?			
25. Are the location and timing of the recruitment process acceptable?			
26. Is the individual performing the recruitment appropriate for the process?			
27. Are all of the recruitment materials submitted and appropriate?			
28. Are there acceptable methods for screening subjects before recruitment?			
29. Is there to be any monetary or material compensation for the subjects?			
30. Are the terms for monetary or material compensation adequately described in both above and in the consent form?			
31. Is there to be any course credit for the subjects?			
32. Are the terms for course credit adequately described in Number 2 and in the Consent form?			
33. If children or adolescents are involved is who is to receive the compensation designated and is this appropriate?			
34. Is there a relationship between the PI and the proposed subjects?			

<u>ITEM</u>	<u>NO</u>	<u>YES</u>	<u>N/A</u>
3. SUBJECT/PARTICIPANT DEMOGRAPHICS			
35. Does number match consent form?			
4. DECEPTION			
36. Is there to be deception in this study?			
37. Has the PI justified the deception?			
38. If deception is part of study, has PI sufficiently described the debriefing and provided a debriefing form?			
5. AUDIO/VIDEOTAPING			
39. Does this protocol involve video or audio taping?			
40. Is the audio/video taping mentioned in consent form?			
6. Confidentiality—A, B, & C			
6. (A)			
41. Are there adequate provisions to protect the privacy and assure the confidentiality/anonymity of the research subject?			
42. Are there adequate plans to store and code the data?			
43. Is the use of identifiers or links to identifiers necessary and how is this information protected?			
44. Will clinical vignettes or interviews be used?			
45. If so, will verbatim excerpts be used?			
46. Is this adequately described in the consent form?			
6. (B)			
47. Does the application address what specific precautions will be taken to safeguard and protect subject's confidentiality while handling the data (audio/video/paper) both in researcher's possession and in reporting the findings? (i.e., coding, removal of identifying data)			
6. (C)			
48. Describe procedures where confidentiality may be broken by law (e.g., child abuse, suicidal intent).			

<u>ITEM</u>	<u>NO</u>	<u>YES</u>	<u>N/A</u>
7. EXTERNAL REVIEW			
49. Is permission required by people or institutions outside of Argosy University? (e.g. hospital, school)			
50. Are all copies attached copies of permission letters and any other relevant documents on letterhead or identifiable email?			
51. Is IRB certification required from other institution(s)?			
52. Is a copy of IRB certification attached?			
8. CONSENT			
53. Is informed Consent attached?			
54. Is an Assent form necessary? Is it attached?			
55. If consent is not necessary (e.g., anonymous interview), how you will inform all participants of the elements of consent?			
9. CONSENT—DESCRIPTION FOR EACH POPULATION APPLICABLE			
a) Adults			
b) Children			
c) Institutionalized individuals			
10. (A) MINIMIZING RISK			
56. Are the steps taken to minimize risk described?			
57. Are the steps taken to minimize risk adequate?			
58. Is there more that could be feasibly done to minimize risk?			
59. Does the protocol sufficiently describe potential risks and discomforts to participants?			
60. Are these risks disclosed in the consent form?			
61. Does this protocol involve invasive or sensitive procedures?			
10. (B) CORRECTING HARM			
62. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies)			
63. Are appropriate referrals made?			
64. If a referral sheet for mental health services is referenced, is it included?			

<u>ITEM</u>	<u>NO</u>	<u>YES</u>	<u>N/A</u>
ADDITIONAL RISK/BENEFIT QUESTIONS			
65. Does this protocol involve sensitive subject matter?			
66. Are the direct benefits to the research participant described?			
67. Are alternatives to participating in the research described?			
68. Are the consequences for withdrawing from the study described?			
69. Does this description match the consent form?			
70. Is the level of compensation unduly coercive?			
11. BENEFITS			
71. Are potential benefit(s) of the study for the participants addressed?			
72. Are potential benefits(s) to the professional audience in the study addressed?			

CONSENT FORM CHECKLIST

ITEM	NO	YES	N/A
Does the title of the study appear at the top of the consent/assent form?			
Is the consent/assent form written in first person?			
Is the number of potential subjects clearly specified?			
Is the consent/assent form written in simple lay language?			
Is the consent/assent form written in the native language of the potential subject?			
Does the consent/assent form state the general purpose of the study, what the researcher expects to learn?			
In the case of student researchers, does the consent/assent form state how the study relates to your program of work (project, thesis, dissertation)?			
Does the consent/assent form state if the study is confidential or anonymous? It cannot be both.			
Does the consent/assent form indicate that in cases of detected abuse, this information must be reported to proper authorities? (only in confidential studies)			
Does the consent/assent form indicate to the subject his/her right to choose to participate?			
Is there a statement indicating why and how this subject was selected as a possible participant? Are the population and sample clearly identified?			
Does the consent/assent form clearly explain the procedure to be followed in implementing the project (time, frequency, nature of information, questions asked, observations made)?			
Is there a statement which addresses possible discomforts and inconveniences that the participant might expect?			
Does the consent/assent form describe any participant risks that are involved in the project?			
If there are any benefits to the subject, are they identified in the consent/assent form? Otherwise, does it state that there are no personal benefits to the subject?			
If the project requires that any standard treatment be withheld, is this clearly designated in the consent/assent form? If alternative treatments are available, are they described?			

ITEM	NO	YES	N/A
Is the subject's confidentiality explained in the consent/assent form?			
Is the use of any tapes or other materials (such as audio tapes, videotapes, photos, use of data for other purposes) explained and the final disposition made clear?			
Are compensation and costs included in the project, and are they identified specifically for the subject?			
Does the consent/assent form indicate where the subject can contact the PI and/or research advisor to have questions answered?			
Address			
Phone Number			
E-mail address			
In the case of faculty member PI s, is there someone else identified as a contact person, i.e., department head, section leader, etc.?			
Does the consent/assent form have the AU-C IRB statement along with the address, telephone number and e-mail address of the IRB Chair?			
Does the consent/form indicate to the subject that he/she can withdraw at any time from the project?			
Does the form indicate any procedures that might be necessary for ordinary withdrawal from a complex study?			
Are situations where the subject's participation can be terminated described?			
Does the consent/assent form indicate to the subject that he/she is entitled to a written copy of said form?			
Does a statement exist expressing that the subject's signature indicated a willingness to participate?			
If the study is online, does a statement exist indicating that taking the online survey is giving approval?			
Does the consent/assent form have a place for the subject's signature, investigator's signature and date?			
Does a parental consent form have a blank line for the child's printed name?			
Is there a child's assent form (required for children ages 7-18)?			

