

**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><b>ITEM</b></u>   | <u><b>NO</b></u> | <u><b>YES</b></u> | <u><b>N/A</b></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?   |                  |                   |                   |
| <b>1. PURPOSE OF THE STUDY</b>   |                  |                   |                   |
| 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?   |                  |                   |                   |
| <b>2. SUMMARY/METHODOLOGY</b>  |                  |                   |                   |
| 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? |                  |                   |                   |

| <b>ITEM</b>  | <b>NO</b> | <b>YES</b> | <b>N/A</b> |
|--|-----------|------------|------------|
| 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?  |           |            |            |
| 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> |
|--|-----------|------------|------------|
| <b>3. SUBJECT/PARTICIPANT DEMOGRAPHICS</b>   |           |            |            |
| 35. Does number match consent form?  |           |            |            |
| <b>4. DECEPTION</b>  |           |            |            |
| 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?  |           |            |            |
| <b>5. AUDIO/VIDEOTAPING</b>  |           |            |            |
| 39. Does this protocol involve video or audio taping?  |           |            |            |
| 40. Is the audio/video taping mentioned in consent form?   |           |            |            |
| <b>6. Confidentiality—A, B, &amp; C</b>  |           |            |            |
| <b>6. (A)</b>  |           |            |            |
| 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?  |           |            |            |
| <b>6. (B)</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) |           |            |            |
| <b>6. (C)</b>  |           |            |            |
| 48. Describe procedures where confidentiality may be broken by law (e.g., child abuse, suicidal intent).   |           |            |            |

| <b><u>ITEM</u></b>   | <b><u>NO</u></b> | <b><u>YES</u></b> | <b><u>N/A</u></b> |
|--|------------------|-------------------|-------------------|
| <b>7. EXTERNAL REVIEW</b>  |                  |                   |                   |
| 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?   |                  |                   |                   |
| <b>8. CONSENT</b>  |                  |                   |                   |
| 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?                          |                  |                   |                   |
| <b>9. CONSENT—DESCRIPTION FOR EACH POPULATION APPLICABLE</b>   |                  |                   |                   |
| a) Adults  |                  |                   |                   |
| b) Children  |                  |                   |                   |
| c) Institutionalized individuals   |                  |                   |                   |
| <b>10. (A) MINIMIZING RISK</b>   |                  |                   |                   |
| 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?   |                  |                   |                   |
| <b>10. (B) CORRECTING HARM</b>   |                  |                   |                   |
| 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?  |                  |                   |                   |

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

**CONSENT FORM CHECKLIST**

| <b>ITEM</b>   | <b>NO</b> | <b>YES</b> | <b>N/A</b> |
|---|-----------|------------|------------|
| 72. Does the title of the study appear at the top of the consent/assent form?   |           |            |            |
| 73. Is the consent/assent form written in first person?   |           |            |            |
| 74. Is the number of potential subjects clearly specified?  |           |            |            |
| 75. Does the amount of time in application match the consent form?  |           |            |            |
| 76. Is the consent/assent form written in simple lay language?  |           |            |            |
| 77. Is the consent/assent form written in the native language of the potential subject?   |           |            |            |
| 78. Does the consent/assent form state the general purpose of the study, what the researcher expects to learn?  |           |            |            |
| 79. In the case of student researchers, does the consent/assent form state how the study relates to your program of work (project, thesis, dissertation)?                               |           |            |            |
| 80. Does the consent/assent form state if the study is confidential or anonymous? It cannot be both.  |           |            |            |
| 81. Does the consent/assent form indicate that in cases of detected abuse, this information must be reported to proper authorities? (only in confidential studies)                      |           |            |            |
| 82. Does the consent/assent form indicate to the subject his/her right to choose to participate?  |           |            |            |
| 83. Is there a statement indicating why and how this subject was selected as a possible participant? Are the population and sample clearly identified?                                  |           |            |            |
| 84. 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)? |           |            |            |
| 85. Is there a statement which addresses possible discomforts and inconveniences that the participant might expect?   |           |            |            |
| 86. Does the consent/assent form describe any participant risks that are involved in the project?   |           |            |            |
| 87. 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?              |           |            |            |

| <b>ITEM</b>  | <b>NO</b> | <b>YES</b> | <b>N/A</b> |
|--|-----------|------------|------------|
| 88. 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? |           |            |            |
| 89. Is the subject's confidentiality explained in the consent/assent form?   |           |            |            |
| 90. 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?                 |           |            |            |
| 91. Are compensation and costs included in the project, and are they identified specifically for the subject?  |           |            |            |
| 92. Does the consent/assent form indicate where the subject can contact the PI and/or research advisor with questions?   |           |            |            |
| 93. Address/Phone Number/ Email Address?   |           |            |            |
| 94. In the case of faculty member PI s, is there someone else identified as a contact person, i.e., department head, section leader, etc.?   |           |            |            |
| 95. 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?   |           |            |            |
| 96. Does the consent/form indicate to the subject that he/she can withdraw at any time from the project?   |           |            |            |
| 97. Does the form indicate any procedures that might be necessary for ordinary withdrawal from a complex study?  |           |            |            |
| 98. Are situations where the subject's participation can be terminated described?  |           |            |            |
| 99. Does the consent/assent form indicate to the subject that he/she is entitled to a written copy of said form?   |           |            |            |
| 100. Does a statement exist expressing that the subject's signature indicated a willingness to participate?  |           |            |            |
| 101. If the study is online, does a statement exist indicating that taking the online survey is giving approval?   |           |            |            |
| 102. Does the consent/assent form have a place for the subject's signature, investigator's signature and date?   |           |            |            |
| 103. Does a parental consent form have a blank line for the child's printed name?  |           |            |            |
| 104. Is there a child's assent form (required for children ages 7-18)?   |           |            |            |

