**Institutional Review Board**

**Assessment of Risk**

Taken from the CITI course for Assessing Risk – SBE

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| **Considerations for Assessing Risk** |
|[ ]  Probability of Harm (likelihood that a specific harm might occur) |
|[ ]  Magnitude of Harm (severity of harm should it occur) |
|[ ]  Risks of harm specific to time, situation, and culture |
|[ ]  Subject Population |

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| **Possible Categories of Risk (check all that may apply)** |
|[ ]  Invasion of Privacy |
|  |[ ]  Personal information is accessed or collected without the subjects’ knowledge or consent |
|  |[ ]  A subject’s participation in a study is revealed despite assurances that this would not happen |
|[ ]  Breach of Confidentiality |
|  |[ ]  Information obtained by researchers could adversely affect subjects if disclosed outside the research setting |
|  |[ ]  Confidentiality is compromised through an unauthorized release of data, negatively impacting the subjects’ psychological, social, or economic status |
|[ ]  Study Procedures |
|  |[ ]  Taking part in research can put the subject at risk |
|  |[ ]  A potential for a breach of confidentiality exists from the subjects themselves (e.g., focus group) |
|  |[ ]  Nature of the research inquiry without proper protections can pose risk of harm to subjects |
| *If any of the above categories of risk are checked, how is the researcher working to minimize those risks?*Comments: Click or tap here to enter text. |

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| **Ways to Minimize and Manage Risk (check all that apply)** |
|[ ]  When the Primary Source of Risk is Data |
|  |[ ]  Data is collected anonymously |
|  |[ ]  The PI/Researcher uses as few direct identifiers as practical |
|  |[ ]  The PI/Researcher removes all direct identifiers as soon as possible |
|  |[ ]  Codes are substituted for identifiers |
|  |[ ]  Code lists and data files are maintained in separate secure locations |
|  |[ ]  Accepted methods to protect against indirect identification, such as aggregate reporting or pseudonyms, are used |
|  |[ ]  Computer passwords are used and protected |
|  |[ ]  The PI/Researcher encrypts transmitted and stored data |
|  |[ ]  Data on computers are accessed and stored without internet connections |
|  |[ ]  Procedures involving transferring direct identifiers between persons are minimized |
|  |[ ]  Obtain a Certificate of Confidentiality |
|  |[ ]  Obtain IT security guidance regarding the most secure means of obtaining, transferring, analyzing, and storing data |
|[ ]  When the Primary Source of Risk is the Consent Document |
|  |[ ]  The consent form is the only document that links the participants to the study |
|  |[ ]  Apply for a waiver of the requirement to document consent [ ]  N/A |