**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 |