Universiti Brunei Darussalam

PAPRSB Institute of Health Sciences

**IHSREC Risk & Sensitivity Assessment (IRSA)**

This document is for you to identify the risk and sensitivity levels of your project.

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| **Title of Project** |
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| **A low risk and low sensitivity project will have all the columns as ‘True’.** | | **Details (if ‘False’)** |
| **1.**  **My study exposes participants to NO MORE than MINIMAL RISK as defined below:**  “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.” (Source: Federal Government, USA) | **True / False** |  |
| **2.**  **My study does NOT involve ANY of the following participant populations:**   1. Economically or educationally disadvantaged persons 2. Mentally disabled, cognitively impaired or legally incompetent persons 3. Children below the age of 18 years 4. Participants recruited directly by their own professors/advisors/coaches/employers 5. Very sick, hospitalized or institutionalized persons 6. Prisoners | **True / False** |  |
| **3.**  **My study does NOT involve ANY of the following procedures:**   1. Use of drugs; ingested, inhaled, or injected substances; devices; or surgical procedures 2. Induction of mental and/or physical stress 3. Deception (i.e. misleading the participant as to the true purpose of the research) 4. Punishment 5. Procedures with risk of physical harm to the subject | **True / False** |  |
| **4.**  **My study does NOT involve ANY of the following:**   1. Data gathering through photographic, video, or sound-recording devices 2. Covert observation in locations where there is a reasonable expectation of privacy, intimacy, or seclusion (e.g. in restroom) 3. Materials commonly regarded as socially unacceptable (e.g. pornographic materials) 4. Procedures that might be regarded as an invasion of privacy (e.g. permission to access academic records) | **True / False** |  |

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| **5.** **Before obtaining any data for this study, either oral or written informed consent will be obtained from each participant as stated below:**   1. Participants will be informed that they may ask any questions and are free to decline participation and/or withdraw participation at any time with no penalty. 2. Informed consent cannot waive a participant’s legal rights nor can it release others from liability for negligence. 3. Participants will be told all relevant details concerning the research procedure and purpose, risks and anticipated benefits, and length of time required for participation. 4. The information about the study will be presented in a clear manner, which allows time for questions and consideration prior to granting or declining informed consent. 5. The presentation of the information will be appropriate to the participant’s maturity, language and cognitive capabilities. If a participant does not understand the information provided, that individual will not be eligible to participate in this study. 6. Under any circumstances, coercion or undue influence will NOT be applied to gain informed consent. [Coercion includes any threats of any negative consequences for failing to participate. Under influence includes excessive payment or rewards and promises of impossible or unlikely benefits.] | **True / False** |  |
| **6.**  **All participants in this study will be guaranteed complete anonymity and confidentiality as defined below:**   1. **‘**Anonymity’ means that a participant’s responses will never be linked to that individual’s name or any other information that could reasonably be used to determine the participant’s identity or the identity of any persons known to the participant. 2. ‘Confidentiality’ means that a participant’s responses could be linked to that individual’s identity, but the researcher promises to prevent anyone besides authorized members of the research team from gaining the participant’s information.   **As my study involves collecting ‘confidential’ data, I have clearly identified in the application who has access to the information and also clarified how confidentiality will be protected.** | **True / False** |  |
| **7.**  **My research does NOT involve obtaining data about potentially sensitive topics as defined below:**  ‘Sensitive’ topics may include, but are not limited to, racial, ethnic or religious prejudices; reports of sexual activity or orientation; illegal activities; substance abuse; mental disorders, emotional disturbances; physical diseases; experiences with mental health treatment or medical treatments. | **True / False** |  |

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