***Human Participant Ethics Protocol Worksheet***

FOR DRAFTING ETHICS APPLICATION – DO NOT SUBMIT

COPY & PASTE APPLICABLE FIELDS INTO MRHP WEBFORM

\*\*\**Please note that not all application questions are included on this worksheet. This worksheet is intended to provide a general overview of the human ethics application and as well as being a tool to help facilitate collaborative efforts.\*\*\**

*Sections 0-4 is a series of ‘Yes’ or ‘No’ questions. Depending on your answer, further explanation may be requested.*

**0 – Identification – This section will ask for basic identification information, names of collaborators and/or students as well as the start/end date.**

**1 - History of the Protocol**

**2 – Location – This section will ask for information pertaining to the location of the research as well as the involvement of any other research ethics board(s).**

**3 - Agreements and Reviews – This section will ask for information pertaining to funding, agreements and scholarly**

 **review(s).**

**4 - Potential Conflicts – This section will ask for information pertaining to any potential conflicts of interest, restrictions**

 **on information, researcher relationships, collaborative decision making and terms of reference.**

**5 - Project Summary**

**Rationale**

Describe the purpose and scholarly rationale for the project:

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**Methods**

Describe formal/informal procedures to be used:

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**6 - Participants and Data – This section will ask for information pertaining to sample size, vulnerability, recruitment and compensation.**

 Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion

 criteria. Where the research involves extraction or collection of personally identifiable information, please describe where the information will be obtained, what it

 will include, and how permission to access said information is being sought.

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**7 - Investigator Experience**

Please describe the community members research team status (eg. employees, volunteers, or participants). What training will they receive?

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**Investigator Experience with this type of research**

Please provide a brief description of the previous experience for this type of research by the applicant, the research team, and any persons who will have direct contact with the applicants. If there is no previous experience, how will the applicant and research team be prepared?

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**8 - Possible Risks and Benefits**

**Possible Risks – (Complete as Applicable)**

Psychological/Emotional Risks:

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Physical Risks:

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 Social Risks:

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 Legal Risks:

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Potential Benefits

 Benefit Description:

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**9 - Consent**

Consent Process Details:

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Capacity/Competency Assessment Process

 Process Details by which Capacity/Competency will be assessed and alternate sources of consent:

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Assent Process

 Participant Assent Process Details:

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 **10 - Debriefing and Dissemination**

 Information Feed Back Details following completion of a participant’s participation in the project:

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Procedural details which allow participants to withdraw from the project:

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What happens to a participant’s data and any known consequences related to the removal of said participant?

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List reasons why a participant cannot withdraw from the project (either at all or after a certain period of time):

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**11 - Confidentiality and Privacy**

Data Protection

Describe how the data will be protected through the research phase and subsequent dissemination of results:

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Describe how the data will be retained, and its final disposal or storage. Please provide reason if data will be stored for an indefinite length of time.

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**12 - Level of Risk and Research Ethics Board**

Explanation/Justification details for the group vulnerability and research risk listed above:

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**13 - Application Documents Summary**

**14 - Applicant Undertaking**