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| OFFICE USE | **Date Received:** | **Date Verified Complete:** |

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| 1. PROJECT TITLE (Attach Abstract please) | **IRB NUMBER** |
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| 2. PRINCIPAL INVESTIGATOR (or Advisor) | | | | |
| Name (Last, First, MI): |  | E-mail: |  | |
| **If any contact information has changed since last IRB review – provide below:** | | | | |
| University Academic Title: |  | College : | |  |
| Department Name : |  |  | |  |
| Campus Mailing Address: |  | Fax: | |  |
| Phone: |  | Emergency phone: | |  |
| Is there a change in the Principal Investigator? | | Yes  No | | |

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| **3. CO-INVESTIGATOR(S) & PERSONNEL (UWP only-include students who have access to personally identifiable data or subject contact )** | | |
|  | | |
| Are there any changes in UWP study personnel? | Yes  No |
| If yes, list below:  Name (Last, First, MI):  Title/Dept: | |  |  | Phone: |  |
| E-mail: | |  |  | Fax: |  |
| Name (Last, First, MI):  Title/Dept. | |  |  | Phone: |  |
| E-mail:   |  | | --- | | **4. EXTERNAL CO-INVESTIGATOR(S) & PERSONNEL (UWP only-include students who have access to personally identifiable data or subject contact )** | | |  |  | Fax: |  |
| Are there any changes in external study personnel?  Yes  No | | |
| If yes, list below:  Name (Last, First, MI):  Title/Dept: | |  |
| E-mail: | |  |
| Name (Last, First, MI):  Title/Dept. | |  |
| E-mail: | |  |

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| **5. FINANCIAL CONFLICT OF INTEREST** | |
| ***All UWP investigators and key personnel must have a current COI disclosure (updated as necessary for the proposed research) before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights and royalties from such rights*** | | |
| 1. Have all UWP investigators and key personnel completed the required COI disclosure? | Yes  No | |
| 1. Does any UWP investigator (including principal or co-investigator), key personnel,or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research? | Yes  No | |

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| **6. FUNDING OR OTHER SUPPORT** | | | |
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| 1. What is the current funding status of the research? | | | None  Funded |
| **If funded** 🡪 Specify sponsor |  | | |
| 1. Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study? | | | Yes  No |
| **If Yes** 🡪 Specify support and provider: | |  | |
| 1. Is there a new, revised, or renewal grant application since the last IRB review? | | | Yes  No |
| **If Yes** **🡪** ***Forward a copy of the current grant application with this submission. The University is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded.*** | | | |

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| |  |  |  |  | | --- | --- | --- | --- | | **7 RESEARCH PROGRESS** | | | | | 1. Summarize any IRB-approved amendmentsor changes made to the research since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation. | | | N/A | | 1. Discuss significant new findings (e.g., affecting risks, benefits, or alternatives), if any, that could affect participants’ willingness to continue in the research and how participants have been or will be informed. | | | N/A | |  | | | | | b. Projected or actual completion date: |  | (month and year)  ***Indicate “ongoing” for repository research or program protocols*** | | |  | |

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| **8. PARTICIPANT POPULATION AND DATA COLLECTION** | | | | | | | |
| Are you requesting an increase in the total number of participants? | | | | | | Yes  No | |
|  | Age(s): | |  |  | | | |
| 1. Specify the participant population(s) – check any for which you do not currently have IRB approval: | | | | | | | |
|  |  | Adults | | |  | Pregnant women/fetuses | |
|  |  | Children (< 18 years) | | |  | Neonates (uncertain viability/nonviable) | |
|  |  | Adults with decisional impairment | | |  | Student research pools (e.g., psychology, linguistics) | |
|  |  | Non-English speaking | | |  | Specify: |  |
|  |  | Prisoners  b) What is the projected or actual date for data completion collection­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  | Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols) | |

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| **9. RECRUITMENT & INFORMED CONSENT PROCESS** | | | | |
| 1. Are there any changes in participant recruitment procedures If yes explain\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | Yes  No | |
| **If Yes** **🡪**Will recruitment materials still be used? | | | Yes 🡪 ***Provide copies of the current recruitment materials***  ***(ads, radio/TV scripts, internet solicitations, etc.).***  No N/A | |
| 1. How WILL informed consent or assent BE obtained? Check all that apply. ***Provide blank copies of all current documents***. | | | | |
|  |  | Assent – Form |  | Parental Permission – Form |
|  |  | Assent – Verbal Script |  | Parental Permission – Verbal Script |
|  |  | Informed Consent – Form |  | Translated Consent/Assent – Form(s) |
|  |  | Informed Consent – Verbal Script |  | Waiver or Alteration of Consent Process |
|  |  | Informed Consent – Addendum |  | Waiver of Consent Documentation |
| 1. Is deception of participants’ part of the research? | | | Yes  No | |
| **If Yes 🡪 *Provide copy of current debriefing script or other information sheet(s) used to inform participants.*** | | | | |

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| **10. RISK ASSESSMENT** | | |
| 1. Since the last IRB review (initial or continuing), did any unanticipated problems involving risks to subjects or others or adverse events occur in research at UWP or at a site(s) approved by UWP IRB? | | |
|  |  | Yes |
|  |  | No |
| If yes, explain below | | |
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| **11. PARTICIPANT COMPLAINTS & VOLUNTARY WITHDRAWALS** | |
| 1. Have any participants made complaints about the research since the last IRB review? | Yes  No |
| If Yes 🡪 List and describe each complaint and any actions taken to resolve the complaint(s). | |
|  | |
| 1. Have any participants voluntarily withdrawn from the research since last IRB review? ***Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.*** | Yes  No |
| If Yes 🡪 List and describe each withdrawal and any actions taken (e.g., changes to the research or consent process) in response to the withdrawal(s). | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **12. PRINCIPAL INVESTIGATOR’S (or Advisor’s) ASSURANCE** | | | | | | I agree to follow all applicable policies and procedures of the University of Wisconsin Parkside and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:   * Perform the research as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources; * Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the currently IRB-approved consent form(s) and process; * Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others; * Provide significant new findings that may relate to the subjects’ willingness to continue to participate; * Inform the IRB of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the UWP IRB (except where necessary to eliminate apparent immediate hazards to participants); * Complete and submit a Continuing Review of Human Subjects Research application before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities; * Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants; * Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University; * Inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.   I verify that the information provided in this Continuing Review of Human Subjects Research application is accurate and complete. | | | | | |  |  |  |  |  | | Signature of Principal Investigator (or Advisor) | Date | |  |  |  |  |  | |  | Printed name of Principal Investigator (or Advisor) |  |  |  | | |

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| **UW-PARKSIDE USE ONLY** |

**Minor Changes** (adding non-vulnerable subjects, adding or deleting personnel, etc.)

**Major Changes** (changes in procedure, methods, informed consent, adding vulnerable populations, etc.)

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**Reviewer Date Reviewer Date**

**IRB Action:**

**Approved**  **Approved, contingent**  **Disapproved**

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**IRB Administrator Date IRB Chair Date**