**Office of Research Administration - Institutional Review Board**

Modification of Approved Human Subjects Research

*Version November 1, 2012*

This application is to seek approval for a modification to a currently approved study. Any proposed changes to previously approved human subjects research must be reviewed and approved by the IRB prior to implementation. This includes modifications to the study, inclusion or exclusion criteria, recruitment methods, research personnel, or *any* new or revised study materials. Approval is required for all modifications whether initiated by the investigator or external sponsor.

Include the items indicated, where applicable:

* *Check* the relevant items below and include one copy of all checked items 1-5 in the order listed.
* Also include one additional collated set of copies for items 1 and 2.

**Applications will be returned if these instructions are not followed.**

|  |  |  |
| --- | --- | --- |
| Check | Item | Total No. of Copies |
| □ | 1. A concise summary of the requested modification using this form. List and describe each proposed change to aid in IRB review. Add pages as necessary. Provide a concise summary of changes when submitting an updated Investigator Brochure or Master Protocol. | 2 |
| □ | 2. New or revised consent forms, questionnaires, surveys, recruitment materials, advertisements, etc. One copy should have changes highlighted by underlining, and the other clean copy will be used for stamping. | 1 highlighted& 1 clean |
| □ | 3. If you have made substantive changes to the study design or procedures, submit a revised full IRB application with changes highlighted by underlining. If you are making changes only to the first page, just submit that page. | 2 |
| □ | 4. The sponsor's document describing the amendment, if any. | 1 |
| □ | 5. If adding personnel, include name, location (UNC or specific outside location), role, and email address for each person who should receive electronic copies of IRB correspondence to PI.  | 1 |

**1 List and describe each proposed change:**

**2. Is this modification being submitted in response to an** **unanticipated problem/adverse event or new findings?** \_\_\_yes \_\_\_no

If yes, explain, including whether these events or findings are relevant to participants’ willingness to continue.

**3. Do any of the proposed changes increase risk?** \_\_\_yes \_\_\_no If yes, explain.

**Principal Investigator**:       **Faculty advisor:**

 (if applicable)

**IRB study #:**       **Date:**

**Title of Study:**

Signature of Principal Investigator or designee Date

Signature of Faculty Advisor (if applicable) Date

|  |
| --- |
| **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**