Date Rec’d Amendment # \_\_\_\_\_\_\_\_\_\_\_\_\_

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| ORANGEonWHITE | SYRACUSE UNIVERSITY INSTITUTIONAL REVIEW BOARDAMENDMENT REQUEST FORM |

An Amendment Request form must be submitted for review and approval **PRIOR** to initiation of **any** changes to your originally approved protocol. The IRB will assign the amendment number for your request. Answer each question as applicable on the amendment request form and make sure to include all necessary documentation as indicated. More than one change can be requested on the form. Initial review of your amendment request generally requires 5-10 business days from the date it is received by the IRB Office. Should modifications and/or clarifications be requested by the IRB, additional review time may be required.

**IRB#**:

**Current Protocol Title:**

**Current Principal Investigator:**

[ ]  **Change in protocol title**

* New Protocol Title:

[ ]  **Change in principal investigator (PI) and/or addition of a co-investigator (Co-PI)**

(Requires signature of new PI and/or Co-PI)

For Expedited and Full Board research: The required CITI training must be completed *prior* to submission of the amendment request form. If CITI training has been completed at another institution, a copy of the CITI training certificate must be attached. For Exempt research: CITI training is not required.

* Research qualifications:

* Name of new Principal Investigator and/or Co-PI:

**Signature of NEW PI/Co-PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_ (\***Only sign here when requesting a change in PI and/or Co-PI**)

[ ]  **Addition of research staff**

For Expedited and Full Board Amendment Requests: Required CITI training must be completed *prior* to amendment submission. If CITI training has been completed at another institution, a copy of the CITI training certificate must be included with this request. CITI training is not required for Exempt amendment requests.

* Name(s) of new research staff:
* Research qualifications for each person added to the study.

[ ]  **Removal of research staff**

* Name(s) of research staff to be removed:

[ ]  **Consent Form changes**

**[ ]  Revised consent/s- intended to replace the currently authorized document/s.**

* Submit one hard copy of each revised document with changes highlighted. **AND**
* Submit one clean (un-highlighted) hard copy of each revised document for IRB date stamping upon approval.

**[ ]  New consent/s-intended to be used in addition to the currently authorized document/s.**

* Submit one clean hard copy of each new document for IRB date stamping upon approval.
* Include the form number /label in the footer of each new document.
* Submit a revised/updated consent log including the addition of each new document.

[ ]  **Assent Form changes**

 **[ ]  Revised assent/s-intended to replace the currently authorized document/s.**

* Submit one hard copy of each revised document with changes highlighted. **AND**
* Submit one clean (un-highlighted) hard copy of each revised document for IRB date stamping upon approval.

**[ ]  New assent form/s-intended to be used in addition to the currently authorized documents.**

* Submit one clean hard copy of each new document for IRB date stamping upon approval.
* Include the form number /label in the footer of each new document.
* Submit a revised/updated consent log including the addition of each new document.

[ ]  **Change in total number of subjects.**

* Currently authorized total:
* New anticipated total:

[ ]  **Addition of Research Site(s)**

You must include a letter of cooperation and/or IRB approval for each site. The letter must be on official letterhead and signed by the research site official/person in authority.

* Name of site(s):

[ ]  **Change in Methods**

[ ]  **Change in and/or addition of Research Instruments/Tools (**surveys, questionnaires, interview guide questions, etc.) - Attach a hard copy of appropriate document/s.

[ ]  **Change in Recruitment Materials/Methods** – Attach a hard copy of revised recruitment materials.

[ ]  **Revisions intended to replace currently approved/authorized recruitment materials.** [ ]  **New recruitment materials intended to be used in addition to the currently approved materials.**

(Recruitment materials must: state the purpose of the research; indicate that solicitation is for

 research purposes; include the eligibility requirements; indicate the time commitment for participation;

 include the location of the research; include information regarding who to contact for further

 information; and, when applicable, information regarding the incentive/compensation.)

[ ]  **Sponsor Change** (funded projects)

* Name of new sponsor:
* Contact information:

[ ]  **Other- Describe**:

**Please provide a response for each question listed below. Failure to answer these questions will delay the review of your amendment request.**

**How does this change your currently approved protocol? Provide a brief summary of the change(s).**

**What is your justification/rationale for the change?**

**Does the change(s) affect the risks or benefits to participants?**

**[ ]  No.**

**[ ]  Yes. If *yes* provide rationale:**

**Could the requested amendment relate to participants willingness to continue to take part in the research?**

**[ ]  No.**

**[ ]  Yes. If *yes* provide rationale:**

**Should currently enrolled participants be notified of the changes described by this amendment?**

**[ ]  No.**

**[ ]  Yes. If *yes* provide rationale:**

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_ Date** \_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:** **Date:**

**(\***Amendment **forms must be signed by the Principal Investigator** currently listed in the approved protocol**.)**

The amendment request form can be submitted electronically via e-mail – orip@syr.edu .

If you have questions regarding submission of this form or amendment request requirements, please contact the IRB office at 443.3013.