Attachment C – UWL IRB Revision or Report Form

Reason for form submission (check all that apply):

[ ]  Change in lead PI/PD (see section III) [ ]  Adverse event(s)\* (see section V)

[ ]  Change in protocol\* (see section III) [ ]  Continuing review\* (see section IV)

[ ]  Study closure or end date change (see section III)

[ ]  Change to consent form or other protocol materials\* (see section III)

\*Attach any additional documentation

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**Date Completed**: Click or tap to enter a date.

**I. Principal Investigator / Project Director** (currently on file in IRB office)

Name: Click or tap here to enter text.

Person ID or Student ID Number (if known): Click or tap here to enter text.

Email: Click or tap here to enter text.

Name of person completing the form, if not original lead PI/PD: Click or tap here to enter text.

 Email: Click or tap here to enter text.

**II. Project Information:**

Project Title (250 character maximum):

Click or tap here to enter text.

Date of original IRB approval letter: Click or tap to enter a date.

IRB Protocol ID Number (if known): Click or tap here to enter text.

**III. Change to Protocol Questions:**

[ ]  Yes [ ]  No Was the original protocol approved as Exempt?

[ ]  Yes [ ]  No Is this still an active study?

If **NO**, what date did it end? Click or tap to enter a date.

[ ]  Yes [ ]  No Is the end date of the study changing?

If **YES**, what is the new end date? Click or tap to enter a date.

[ ]  Yes [x]  No Are new Co-PIs or personnel being added to the projects?

If **YES**, list the name, person/student ID, email, and affiliation. If they are a UWL employee, also state the department/office. Attach CITI training at the end of the document.

Please begin list here: Click or tap here to enter text.

[ ]  Yes [ ]  No Has or is the lead PI/PD changing?

If **YES**, list the name, person/student ID, email, and affiliation. If they are a UWL employee, also state the department/office. Attach CITI training at the end of the document.

Please begin list here: Click or tap here to enter text.

[ ]  Yes [ ]  No Are there any changes to your research process or procedures?

If **YES**, explain in the text box below or attach your revised protocol.

[ ]  Yes [ ]  No Are there any changes to the consent process, form, or recruitment

materials that were not previously approved?

If **YES**, explain in Section IV and attach a copy of your consent form, marketing materials, or other protocol materials with the changes highlighted.

**IV. Continuing Review Questions:**

[ ]  Yes [ ]  No Have any subjects been enrolled in this study since first review?

 If **YES**, how many? Click or tap here to enter text.

[ ]  Yes [ ]  No Have any subjects been withdrawn or removed from this study since first

review?

 If **YES**, how many? Click or tap here to enter text.

 Reasons for withdrawal and removal must be described in you general

progress report on this study’s activities over the past approved period.

[ ]  Yes [ ]  No Is this research permanently closed to the enrollment of new subjects?

[ ]  Yes [ ]  No Have all subjects completed research-related interventions?

[ ]  Yes [ ]  No Is the research remaining active only for long-term follow-up of subjects?

If **YES**, a summary of the long-term follow-up activities should be provided, but no other documentation is needed.

[ ]  Yes [ ]  No Is data analysis the only remaining research activity?

[ ]  Yes [ ]  No Have any additional risks to subjects been identified?

If **YES**, continuing review will require a full committee review. IRB will schedule your continuing review for the next calendar meeting.

[ ]  Yes [ ]  No Is your study being conducted under an IND or an IDE?

If **YES**, continuing review will require a full committee review. IRB will schedule your continuing review for the next calendar meeting.

To complete your continuing review, you must prepare a general progress report on this study’s activities over the past approval period which should be attached to this form. This report should include:

[ ]  A summary of changes requested and approved. Provide the dates of approval.

[ ]  A report of any adverse events and unanticipated problems reported to the IRB (as

 applicable).

[ ]  A summary of any subject’s complaints and how they were handled.

[ ]  Any new information relevant to the risk/benefits associated with the research.

[ ]  A proposed consent form, assent form, and/or permission form (as applicable) for the

upcoming approval period. Ensure risks/benefits are congruent with any new relevant information.

If you are a requesting an approval period less than 1 year, what end date are you requesting: Click or tap here to enter text.

[ ]  An updated complete protocol that matches all requested and approved changes made in the

 past approval period.

**V. Adverse Events/Unanticipated Problems Questions:**

[ ]  Yes [ ]  No Was the adverse event a risk that was unanticipated and thus missing

from the possible risks of study participation in your original protocol and consent form?

[ ]  Yes [ ]  No Was the incident related, or possibly related to the research?

[ ]  Yes [ ]  No Did the adverse event pose additional risks to subjects or others?

[ ]  Yes [ ]  No Was there a breach of confidentiality or a risk of a breach?

[ ]  Yes [ ]  No Is this research project supported by extramural funding? If yes, list

Award Number(s). Click or tap here to enter text.

[ ]  Yes [ ]  No Does this project have U.S. Food & Drug Administration (FDA)

requirements (e.g., IND, IDE) if applicable?

If **YES** to any of the questions in this section, provide a detailed description of the adverse event in the explanations section below. Include the date(s) and location(s) of the incident. Provide an attachment if additional space is needed.

**VI. EXPLANATIONS:**

Use this space to provide any needed explanations. (2,500 character, including spaces, limit) If you need additional space, please attach an additional page.

Click or tap here to enter text.

**VII. SIGNATURE**

By typing my name below, I agree to continue my compliance with any decisions made by the University of Wisconsin-La Crosse IRB in regard to the above named research project and the standards of professional ethics in my field of study. To the best of my knowledge, the information I have provided in this form is complete and accurate.

Name: Click or tap here to enter text. Date: Click or tap to enter a date.

**NOTE:** You must copy all faculty advisors, thesis committee members, co-PIs, and co-PDs on the email in which you submit your Attachment C.

Are you submitting additional information?

[ ]  Yes, protocol documents (e.g., consent form, marketing materials) – please append starting as page 5 of this document.

[ ]  Yes, continuing review information – please begin below the dotted line.

[ ]  Yes, adverse events information – please begin below the dotted line.

[ ]  Yes, additional information that did not fit in the explanations box – please begin below the dotted line.

[ ]  No

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Click or tap here to enter text.