**Wheaton College**

**Institutional Review Board**

**Project Renewal / Final Report**

**DATE**: [CURRENT DATE]

**TO**: [PI NAME]

**IRB REFERENCE #: [**IRBNET ID NUMBER**]**

**TITLE**: [TITLE]

**EXPIRATION DATE**: [PROJECT EXPIRATION DATE]

Federal regulations **REQUIRE** that the IRB conduct continuing review of IRB-approved ongoing research. **If you plan to continue this research beyond the expiration date, approval from the IRB is required.** This form constitutes part of this requirement. Please check the appropriate boxes and upload this form, along with any additional documentation, to IRBnet (see instructions at end of document).

 1) Check One: [ ]  Continuing Report (required to continue) [ ]  Final Report (data collection is complete & onlydata
 data collection) (answer #2-10) analysis of unidentified data remains) (answer #2-7)

 2) Has the project been initiated? Yes [ ]  No [ ]  If yes, is it active now? Yes [ ]  No [ ]

 3) How many subjects have participated to date on campus? \_\_\_\_\_ At other sites? \_\_\_\_\_

 4) Have changes in the scientific literature, or interim experience with this or related studies, changed your assessment of potential risks
 or benefits to study subjects? Yes [ ]  No [ ]  *If “yes”, attach explanation.*

5) Did any subject enrolled on this protocol have a serious adverse reaction? Yes [ ]  No [ ]

If “yes” did the subject(s) withdraw before completing the project? Yes [ ]  No [ ]

If “yes” were there deaths unrelated to the protocol? Yes [ ]  No [ ]  deaths possibly related? Yes [ ]  No [ ]

*If you have not yet notified the IRB of serious, or unusual reactions or deaths, a completed Adverse Event Report, which can be found on IRBnet, must be uploaded with this form.*6) Did any subjects have mild or moderate adverse events? Yes [ ]  No [ ]  *If “yes” provide a list of all events.*

7) Did any subjects enrolled on this protocol have complaints? Yes [ ]  No [ ]  **If “yes” specify nature of complaints:**

8) Do you plan to make any changes in the project protocol? Yes [ ]  No [ ]

**NOTE: ANY MODIFICATIONS TO YOUR PROTOCOL NEED TO BE SUBMITTED TO THE IRB AND MUST BE APPROVED BY THE IRB PRIOR TO INITIATION OF THE CHANGES** (except where necessary to avoid an immediate, apparent hazard to a subject.) Minor modifications in recruitment, protocol, anticipated risks or benefits may be submitted in a letter. **SIGNFICANT CHANGES** (changes in study population, additional measurements or increased risk above minimal) **REQUIRES SUBMISSION OF APPLICATION FORM AND PROPOSED NEW CONSENT FORM.**

9) Have changes to the Informed consent document been made since the IRB reviewed your protocol? Yes [ ]  No [ ]

 *If “yes” attach a copy of the modified Informed Consent Documents (with changes highlighted).*10) Have any changes been made to the personnel on the project? Yes [ ]  No [ ]
 *If “yes,” please list names and CITI #.*

**To upload this form to IRBNet:**

DO NOT create a new project.  Instead, log into IRBNet.org, and click on the appropriate project. Then select “Designer” (on the left), “then “Attach New Document,” then “Create New Package,” then “Attach New Document” (again). Choose your document type, upload this form, and “Sign this Package” (on the left). Finally, select “Submit this Package” (on the left), select the IRB, select the correct submission type, and click submit.