Proposal # \_\_\_\_\_\_\_\_\_\_ Expires: \_\_\_\_\_\_\_\_\_ IRB office

Renewal Form

Institutional Review Board

347 S. Gladstone Ave

Aurora, Il 60506

Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please answer each of the following questions, attach documents as requested, and return this form to the IRB Office ***as soon as possible***. The project being reviewed is listed below. Please review and correct this title as needed.

Project Title

1. **ENROLLMENT:**

Yes\_\_\_ No\_\_\_ Was this project undertaken?

Exact Number of subjects enrolled in this project since the last IRB review (initial approval or last renewal):\_\_\_\_\_\_\_\_\_\_\_\_

Number of subjects who withdrew prematurely:\_\_\_\_\_\_\_\_\_\_\_\_ (Please attach a brief summary of the reasons for withdrawal.)

Exact number of subjects enrolled in this project since its inception (including subjects who

withdrew prematurely):\_\_\_\_\_\_\_\_\_\_\_

Yes\_\_\_ No\_\_\_ Are there any risks to subjects who withdrew prematurely? (if yes, please detail as an attachment)

Yes\_\_\_ No\_\_\_ Has all subject enrollment ceased?

Yes\_\_\_ No\_\_\_ Data collection with existing subject continues. (All projects must have continuing approval

during data collection.)

Yes\_\_\_ No\_\_\_ Only data analysis continues. (All projects must have continuing approval during data analysis.)

Yes\_\_\_ No\_\_\_ Do you plan to continue this project (continuing to enroll/collect data/analyze data)? If no, this

project will be archived.

Anticipated end date (all subject enrollment, data collection, and data analysis is complete):

\_\_\_/\_\_\_/\_\_\_.

Yes\_\_\_ No\_\_\_ Have any non-AU IRBs reviewed this protocol? Who?

Date of last approval \_\_\_/\_\_\_/\_\_\_ ***Please forward a current approval letter.***

2. **MODIFICATIONS:**

Yes\_\_\_ No\_\_\_ Have there been any modifications to the procedures, consent form(s), process or change in

Researchers since the last review that have not been reviewed and approved by the IRB? ***If yes***  ***please indicate in the box below***. Explain whether any of the modifications might affect the risk or

benefits to subjects or the subjects’ desire to continue to participate in this project.

**Indicate changes here:**

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**3**. **UNANTICIPATED PROBLEMS:**

Yes \_\_\_ No \_\_\_ Have there been any unanticipated problems or adverse events since the last review,

including those that have been reported? Problems could include unanticipated side

effects or complications from subjects, loss of confidential data, and injuries to subjects.

( **If yes, attach a summary of the events and describe the resolution.)**

**4. CONSENT DOCUMENTS:**

Attach copies of the most recent IRB approved consent forms that you are currently using with this project, sending the most recent versions that have been date stamped by the IRB. (If modifications are also being requested, submit appropriately revised informed consent documents).

**5. RESEARCHER ASSURANCES:** The signature (faxed or scanned version acceptable) of the Researcher is

required before this application can be processed. Other researchers who are responsible for these assurances are encouraged to sign.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the

conduct of this study, and the ethical performance of this project.

I agree to comply with all AU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher (faculty member) Date