Renewal Form
Institutional Review Board
347 S. Gladstone Ave
Aurora, IL 60506

Researcher: ____________________________  Date: ____________________________

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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.

1. ENROLLMENT:

Yes___  No___  Was this project undertaken?

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

Yes___  No___  Number of subjects who withdrew prematurely:___________ (Please attach a brief summary of the reasons for withdrawal.)

Yes___  No___  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.

Yes___  No___  Anticipated end date (all subject enrollment, data collection, and data analysis is complete): __/__/____.

Yes___  No___  Have any non-AU IRBs reviewed this protocol? Who?

Yes___  No___  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:
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