Reviewer Name: XXXXXXXXX
PI Name: XXXXXXXXX
Training Done: Yes
Protocol #: XXX-XXXX
Protocol Title: XXXXXXXXX
Review Type Requested: Expedited, Category X

I agree that this project poses minimal risk to subjects and qualifies for expedited review under one of the following categories (mark all categories that apply):

**Category 1:** Clinical studies of drugs and medical devices only when the following conditions are met:

- Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
- Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used according with its cleared/approved labeling.

**Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- from other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**Category 3:** Prospective collection of biological specimens for research purposes by non-invasive means.

**Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
**Category 5:** Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

**Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

**Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research in perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

This project does not qualify for expedited review because:

- The specific circumstances of the proposed research pose greater than minimal risk to subjects, and/or
- The research involves procedures that do not fall under the expedited review categories listed above.

**If the first option above is checked**, indicate the reason why you have determined this protocol poses greater than minimal risk to subjects:

More information is needed before a determination can be made. See comments below.

**Reviewer Signature:**
Signed: ________________________________ Date: ____________

Reviewer: Please mail the completed form to the Office of Sponsored Programs and Research, Tower House, Room B9 or fax to 516-686-1235.