**IRB File #:** Please enter file number here.

**Principal Investigator(s):** First and Last Names of Principal Investigator(s) here.

**Project Title:** Enter Project Title Here

**Current Expiration Date:** MM/DD/YYYY – if previously extended use most recent expiration date here.

***If IRB Approval Expired or Will Expire:*** No research related activities may occur after the protocol expiration date. If the study has expired or will expire while waiting for IRB review, the following information should be included in the space below:

* If your project has expired, please describe any study activities that have occurred during the lapse in approval
  + Provide an explanation for what led to the delayed submission of the Continuing Review (CR) form
* If your research is greater than minimal risk and activities need to occur during the lapse for the benefit or safety of participants, an exception request should be submitted.

Enter documentation here for project if it has an expired, or will soon expire.

# Continuing Review Submission Requirements:

* Research that requires Convened/Full Annual Continuing Review is due 6 weeks prior to expiration.
* Research that qualifies for Expedited Annual Continuing Review is due at least 2 weeks prior to expiration.
* Incomplete submissions will be returned for edits regardless of expiration date.
* Please check any of the boxes below that apply to your project.

No concerns raised and no negative impact to subjects in the last 12 months.

This project will continue for another year.

# Documents:

One Copy of each of the following documents are required for continuing approval for all research:

* Completed version of this Continuing Review Form, (Paper submissions require PI signature)
* Progress Report: Please include a cover letter that includes the following information:
  + All IRB submissions require a narrative summary of the study activities that occurred during the approval year including notable comments, notable subject experiences, any delays in study activities, and expected activities for the coming year.
* All IRB submissions require a summary of any planned/outstanding modifications that will be submitted to the IRB for review including the planned timeline for submission and the impact the modifications have for enrolled subjects, as applicable.

# Who should the IRB contact with questions?

**Name:** First and Last Name

**Cell/Telephone:** (xxx) xxx-xxxx

**Email:** Click or tap here to enter text.

# Subject Enrollment Reporting - (Items A – H)

Please be mindful that enrolling beyond the approved target is considered a deviation. If you have enrolled subjects beyond your target and plan to continue consenting subjects, please submit a modification to revise your enrollment target and plan.

## A. Total target Enrollment for LCC Investigators:

(Please list the maximum number of subjects approved by the IRB to be consented LCC investigators. If no maximum was set, please enter “No Target Set.”)

Click or tap here to enter text.

## B. Target enrollment for next 12 months

CONSENTED SUBJECTS BREAKDOWN: (Even if subjects do not sign their name to a form they are

considered consented if an IRB approved process was completed to gain their permission to voluntarily participate)

Click or tap here to enter text.

## C. Number of subjects consented at LCC since the last Continuing Review:

Click or tap here to enter text.

## D. Number of subjects consented at LCC since the initiation of the study:

SUBJECT STATUS BREAKDOWN: When responding to these items please only account for subjects enrolled at LCC. Do not account for individual subjects in multiple categories. E+ F+ G + H = D. Provide any required clarification in your progress report.

Click or tap here to enter text.

## E. Number of subjects actively participating in study procedures:

Click or tap here to enter text.

## F. Number of subjects participating only in follow up procedures:

Click or tap here to enter text.

## G. Are there any subjects who provided consent that are no longer participating (no further study related contact required) for reasons other than completion?

YES  NO

If Yes: Please provide a summarized list below of subjects that did not complete the study but have ended participation since enrollment began. Include the reasons other than completion and the number of inactive subjects in each category. (Categories to consider: determined ineligible after consent, lost to follow up, voluntary withdrawal, withdrawal by the PI, disease progression, adverse event, ETC…)

Click or tap here to enter text.

# Participant Recruitment since the last continuing review

## 1. If you have changed your subject recruitment procedures please describe what has been successful versus not.

Please discuss your plans for the upcoming year, including any changes to the recruitment plan to improve recruitment and increase enrollment.

Click or tap here to enter text.

# Risk-Benefit Assessment

Is there any new information to report that would alter the IRB’s previous determination that risks to subjects are minimized AND risks to subjects are reasonable in relation to anticipated benefits, if any?

YES  NO

If yes: Please describe the new information the IRB should consider that may alter the previous

determinations for these two IRB approval criteria:

Click or tap here to enter text.

# Continuing Review Form Completion

By signing this form, the principal investigator and the person completing the form (if other than the investigator) certify that he/she has disclosed to the IRB all relevant information that might affect re-approval of this study.

**Principal Investigator Signature:** PI Signature Here **Date:** Click or tap to enter a date.

**Name of Person Completing this Form:** Click or tap here to enter text.

**Signature of Person Completing This Form:** Signature Here **Date:** Click or tap to enter a date.

# THIS SECTION FOR EXPEDITED AND ADMINISTRATIVE IRB USE ONLY

# APPROVED VIA EXPEDITED IRB REVIEW:

**Issues Identified – Referred to IRB staff with instructions**

Click or tap here to enter text.

**Signature of Expedited Approver:** Approver Signature Here **Date:** Click or tap to enter a date.

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