

Rush-Presbyterian-St. Luke's Medical Center
Institutional Review Board
CONTINUING REVIEW APPLICATION



Please complete this form, sign and return it to the Office of Research Affairs, 544 AcFac.

Please attach a copy of the consent document currently in use.

Please attach a clean copy of the current consent documents for a stamp of re-approval.

If this project is permanently closed to accrual, there is no need to submit the consent documents.

If consent was waived for this project, please note on the review form.

All incomplete submissions will be returned to sender. If you have any questions, contact the Office of Research Affairs by phone at 942-5498, fax 942-2874 or in person in Room 544 Academic Facility.

PLEASE ALLOW AT LEAST 4 WEEKS FOR THE CONTINUING REVIEW PROCESS.

ORA#:

INVESTIGATOR:

DEPARTMENT:

TITLE OF STUDY:

PERSON TO CONTACT WITH QUESTIONS:

EMAIL:

PHONE:

FAX:

INVESTIGATOR ASSURANCE:

The information given in response to the questions in this application is accurate. I assure the IRB that the use of human subjects has been conducted in accordance with the previously approved protocol and conditions.

Principal Investigator Date

Sponsor Date
(if PI is a student)

Rush-Presbyterian-St. Luke's Medical Center
Institutional Review Board
CONTINUING REVIEW APPLICATION

1. Is the protocol permanently closed to the enrollment of new subjects? Yes No
b.) Have all subjects completed all research-related interventions? Yes No
c.) Does the study remain active only for long-term follow-up? Yes No
2. Are all remaining research activities limited to data analysis? Yes No
3. Total number of subjects enrolled at Rush: _____
Number of withdrawals at Rush: _____
Number of subjects lost to follow-up at Rush: _____
4. Number of subjects enrolled since last IRB review: _____
5. Are any of the following special populations being studied? Yes No
If yes, indicate which groups:
 Minors Fetuses/Abortuses Pregnant Women Prisoners
 Economically/Educationally Disadvantaged Cognitively Impaired
 Other _____

6. Summarize all serious adverse events or unanticipated problems involving subjects at Rush-Presbyterian-St. Luke's Medical Center. If there have been no adverse events to report, please state so.

6a. Have adverse events been reported that have occurred **at Rush** been reported to the IRB for review and consideration?
 Yes No None to report

6b. Have adverse events been reported that have occurred **at other sites** been reported to the IRB for review and consideration?
 Yes No None to report

6c. Is this research study monitored by an Independent Data Safety Monitoring Board (DSMB)?
 Yes No

If YES, list the name and location of the DSMB:

**Rush-Presbyterian-St. Luke's Medical Center
Institutional Review Board
CONTINUING REVIEW APPLICATION**

7. Review the consent document. Does it continue to accurately reflect the study's procedures, processes, risks and benefits?

Yes Closed to further enrollment, consent no longer necessary, Consent Waived by IRB, No , If not, why not?

8. Progress Report:

Summarize the preliminary results of the research or attach copies of abstracts or articles that have been generated due to this research project.

8a. Has any of the new information been shared with the research subjects enrolled in the study?

Yes No, If not, why not? No information to report