

RESEARCH INVOLVING HUMAN SUBJECTS  
AMENDMENT/ADDENDUM/MODIFICATION FORM

- 1) Amendments/modifications requiring changes to the consent documents:
  - a) Submit one copy of the IRB approved and stamped consent document currently in use;
  - b) Submit one copy of the document(s) that reflects changes due to the modification (highlight changes with a marker, bold type, shaded type, etc.);
  - c) Submit one unmarked copy of the revised document for the IRB to stamp with the new approval date.
  - d) All submissions must be typewritten or word-processed.
  - e) Do not submit advertisements, recruitment flyers or news releases under this form. Submit under a separate memo.
  - f) Submit application materials to: The Office of Research Affairs, 544 AcFac
  - g) Direct All Questions to: 312-942-5498
  
- 2) Amendments/modifications requiring changes to the protocol:
  - a) Submit one copy of the new version of the protocol plus the required amendments or one copy of the grant.
  - b) Submit one copy of the currently approved and stamped consent document for reference.
  - c) All submissions must be typewritten or word-processed.
  - d) Do not submit advertisements, recruitment flyers or news releases under this form. Submit under a separate memo.
  - e) Submit application materials to: The Office of Research Affairs, 544 AcFac
  - f) Direct All Questions to: 312-942-5498
  
3. Sign and date the amendment form.

**Failure to submit the appropriate materials could result in delay of IRB review.**

**RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER  
AMENDMENTS/ MODIFICATIONS TO APPROVED PROJECTS**

**ORA#:** \_\_\_\_\_

**PRINCIPAL INVESTIGATOR:** \_\_\_\_\_  
**DEPARTMENT ADDRESS AND TELEPHONE:** \_\_\_\_\_  
**EMAIL ADDRESS:** \_\_\_\_\_  
**FAX NUMBER:** \_\_\_\_\_  
**ALTERNATE CONTACT FOR QUESTIONS:** \_\_\_\_\_

**PROJECT TITLE:** \_\_\_\_\_

**NUMBER OF SUBJECTS ENROLLED TO DATE:** \_\_\_\_\_  
**This study remains open to enrollment:**  Yes  No

**Assurance**

I the undersigned assure that, to the best of my knowledge, the procedures and activities involving humans in research included in this application are completely and accurately described. I also assure that, if applicable, this description of procedures and activities is consistent with those proposed in grant application(s) submitted to funding agencies outside this institution to support this project. All protocol activities will be performed in accordance with Rush-Presbyterian-St. Luke's Medical Center, State and Federal regulations. No activities involving the use of human subjects will be initiated without prior review and approval by the Rush-Presbyterian-St. Luke's Medical Center's Institutional Review Boards.

\_\_\_\_\_  
Signature of Principal Investigator/Date

**FOR ORA/IRB Use Only:**  
**Approved by IRB Chair /Designated IRB Reviewer - Signature/Date** \_\_\_\_\_

**MODIFICATION/AMENDMENT INFORMATION**

Check box(es) which apply to this modification

- Change in protocol (this includes changes in inclusion/exclusion criteria, data collection, laboratory studies, etc)
- Change in total number of subjects
- Change in investigator/co-investigator(s)
- Change in consent/information documents
- Other (for example, change in title)

1) Describe the changes planned for this protocol

These changes may be procedural, administrative, consenting documents, etc.  
Be detailed. Please explain why these changes are necessary.

2) Do the proposed changes impact the risks to subjects enrolled or to be enrolled in this study?

\_\_\_\_\_

