

St. Luke's Health System  
Institutional Review Board Review (IRB)

## POST IRB APPROVAL SUBMISSION FORM

(For submission of any material to the IRB, post initial approval, with the exception of adverse events. Please contact Francine Winkle at (208) 381-4717 for information on submitting adverse events.)

1. **DATE:**
2. **STUDY NAME:**  
**IRB NO.:**
3. **ITEM(S) OF CHANGE WITH BRIEF DESCRIPTION:**  
Please submit items of change in triplicate.

4. **Has there been any change in research personnel?** If yes, please list below

Name and Title	Study Position	Address	Phone/Fax	Email	Add or Remove?

5. **ENROLLMENT STATUS OF STUDY:**

Total number of subjects enrolled from your site: \_\_\_\_\_  
Status of the subjects enrolled: (The numbers below should add up to the total number of subjects enrolled.)  
# of subjects active in the study: \_\_\_\_\_  
# of subjects in long-term follow-up: \_\_\_\_\_  
# of subject deaths: \_\_\_\_\_  
# of subjects that withdrew consent : \_\_\_\_\_  
Reason for withdrawal: \_\_\_\_\_  
# of subjects that completed participation: \_\_\_\_\_  
Other: \_\_\_\_\_

6. **ARE THERE ANY CHANGES TO THE CONSENT FORM?** YES  NO

-Please attach three copies of the revised pages of the consent form clearly indicating the changes. Place a strike through for items deleted and an underline for items added. Please do not highlight changes.  
-Please attach three copies of the final version of the consent form you would like to have approved.

7. **NAME & CONTACT NUMBER OF THE PERSON SUBMITTING THIS CHANGE.**

8. **SIGNATURE:** \_\_\_\_\_