



INSITUTIONAL REVIEW BOARD

UNIVERSITY OF SOUTH ALABAMA

ANNUAL RENEWAL / FINAL REPORT FORM

- Annual Renewal – study is ongoing**
- Final Report – no further contact with participants will occur** *(no copies required)*

Protocol IRB# _____ Principal Investigator: _____
 Date Submitted: _____ Date of prior approval: _____
 Project Title: _____

If Annual Renewal, please check the appropriate category below and attach the required copies for each submission:

- For expedited review (See Guidelines Part VI for explanation of expedited review):
Submit two copies of this form, two copies of the most recent version of the IRB approved stamped consent, and two copies of the most current protocol and investigator’s brochure (if applicable).
- For full board review (See Guidelines Part VI for explanation of full board review):
Submit thirty copies of this form, thirty copies of the most recent version of the IRB approved stamped consent, and three copies of the most current protocol and investigator’s brochure (if applicable).

The IRB is required by the federal government to obtain the following information in order to approve a request for a renewal of approval and/or conduct a continuing review of a research project.

- | | | |
|--|----------|----------|
| 1. Total number of patients enrolled since study opened | _____ | |
| 2. Number of patients screened and enrolled in past year | _____ | _____ |
| | Screened | Enrolled |
| 3. Number of subjects by race <u>screened</u> for entry into study since the start of the project | _____ | _____ |
| 4. Number of subjects <u>screened</u> by gender since the start of the project | _____ | _____ |
| | Male | Female |
| 5. Number of subjects by race <u>entered</u> into the study since last IRB review | _____ | _____ |
| 6. Number of subjects by gender <u>entered</u> into the study since last IRB review | _____ | _____ |
| | Male | Female |
| 7. Has there been any amendments/revisions since the last IRB approval? <input type="checkbox"/> NO <input type="checkbox"/> YES | | |
| If yes, briefly explain. | | |

8. Have there been any serious adverse event (on-site) reports since the last IRB approval? NO YES
If yes, briefly explain.

9. Brief summary to date. What preliminary findings or evaluations of the study have you received?