

**ST. VINCENT HOSPITAL RESEARCH & REGULATORY AFFAIRS  
STUDY AMENDMENT FORM**

IRB STUDY NUMBER:  
RESEARCH PROPOSAL TITLE:  
AMENDMENT NUMBER:

**SECTION I: INVESTIGATOR INFORMATION**

**Principal Investigator:** \_\_\_\_\_ **Department:** \_\_\_\_\_

*(Last, First, Middle Initial)*

Address: \_\_\_\_\_ Phone: \_\_\_\_\_ E-Mail: \_\_\_\_\_

**Contact Information:**

Name: \_\_\_\_\_ Address: \_\_\_\_\_ Phone: \_\_\_\_\_

Fax: \_\_\_\_\_ E-Mail: \_\_\_\_\_

Research Proposal Title:

Sponsor/Funding Agency: \_\_\_\_\_ Sponsor Amendment No. \_\_\_\_\_

**SECTION II: AMENDMENT DESCRIPTION**

**This form must be typed and returned to Research & Regulatory Affairs Department, 8402 Harcourt Road, Suite 208, Indianapolis, IN 46260. Note: To check a box on this form, double-click the box and select "Checked" under "Default Value."**

1. Describe the proposed change(s) and rationale for the change(s):
  
2. Is the study sponsored?
  - No.
  - Yes. Check the appropriate line below and provide with this amendment, as applicable:
    - a copy of the sponsor's amendment, if the amendment came from the sponsor.
    - a copy of your notice to the sponsor of this change, if you initiated the amendment.
    - a copy of the approved amendment will be sent to the sponsor.
  
3. Will the proposed change(s) affect the risk:benefit ratio for subjects?
  - No.
  - Yes. Please describe the affected risks and benefits below.
  
4. Do the proposed changes affect any of the following documents?
  - Advertisement  Protocol
  - None of the Above  Other, Please describe:
  
5. Do the proposed changes affect the informed consent statement?
  - Informed consent or written documentation of informed consent has been waived for this study.
  - No. Skip to item 6 below.
  - Yes. Answer items A. and B. below.
    - A. Check the appropriate line below. One approved copy will be returned for your files.
      - The new informed consent statement is in addition to the current one.
      - The new informed consent statement is to replace the current one. A copy of the new informed consent with **changes tracked** must accompany the amendment proposal. If there are multiple consents associated with the study, please indicate which informed consent statement is being replaced.
  
    - B. Do the changes to the new informed consent statement require re-consenting of existing subjects?
      - No. Skip to item 6 below.
      - Yes. The study must continue to meet the HIPAA Authorization requirements. Please provide updated HIPAA Authorization Form completed with proposed amendment changes.

IRB STUDY NUMBER:  
RESEARCH PROPOSAL TITLE:  
AMENDMENT NUMBER:

6. Amendment includes:
- |  |   |
|--|---|
| <input type="checkbox"/> Informed Consent,* dated:   | <input type="checkbox"/> Notice to Sponsor, dated:    |
| <input type="checkbox"/> Protocol,* dated:           | <input type="checkbox"/> Advertisement,* dated:       |
| <input type="checkbox"/> Sponsor’s Amendment, dated: | <input type="checkbox"/> HIPAA Authorization,* dated: |
| <input type="checkbox"/> Other*, dated:              |   |

\* Only include these documents if they were checked in items 4 or 5 above (as being changed because of the amendment).

Note: listing document dates are optional and only necessary if required by the investigator or sponsor.

**NOTE TO INVESTIGATORS:** Study amendments *may not* be instituted until written approval from the St. Vincent Institutional Review Board is given. **Unless changes to previously approved research are minor, all amendments must be reviewed at a full IRB meeting.**

Do you consider these changes to be:

- Minor (minimal risk): Minimal risk is defined in 21 CFR 56 (102)(i) as risk which “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” These are studies which would ordinarily be considered very low risk for patients.

Submit (2) copies of the following documents with all changes highlighted if they were checked in items 4 or 5 above: informed consent statement(s), authorization and advertisement(s). Submit (1) copy of the following documents with all changes highlighted if they were checked in item 5 above: summary safeguard statement, protocol, and other documents.

- Major (substantive): This includes any study which does not meet the definition of minimal risk listed above. Submit (2) copies of documents with all changes highlighted if they were checked in items 4 or 5 above.

Signature of Principle Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

**SECTION III: IRB APPROVAL**

The amendment of this protocol, including other documentation noted in item 6 above, for use of human subjects has been reviewed and approved by the St. Vincent Institutional Review Board.

Authorized IRB Printed Name: \_\_\_\_\_

Authorized IRB Signature: \_\_\_\_\_ IRB Approval Date: \_\_\_\_\_

Authorized IBC Printed Name: \_\_\_\_\_

Authorized IBC Signature: \_\_\_\_\_ IBC Approval Date: \_\_\_\_\_

(if applicable)