



Bon Secours Richmond Health System (BSRHS) IRB CONTINUING REVIEW OR CLOSURE FORM

PRINCIPAL INVESTIGATOR:	
EMAIL:	
ADDRESS:	
RESEARCH COORDINATOR:	
EMAIL:	
IRB APPROVAL EXPIRATION DATE:	
TITLE OF PROJECT:	

ANSWER ALL QUESTIONS

1. If you have planned for inclusion of data on any of the following VULNERABLE POPULATIONS, check that apply: <input type="checkbox"/> CHILDREN <input type="checkbox"/> PREGNANT WOMEN <input type="checkbox"/> FETUSES (OR FETAL TISSUE) <input type="checkbox"/> NEONATES	
2. Has your project begun? (If YES, proceed to question #4. If NO, proceed to QUESTION #3.)	<input type="checkbox"/> YES <input type="checkbox"/> NO
3. If your project has NOT begun, do you want to CLOSE your project?	<input type="checkbox"/> YES <input type="checkbox"/> NO
4. Since initiation of your project: how many subjects have been enrolled?	Local _____ Total Sites _____
5. Do subjects represent the population described in the Initial IRB application? If NO, attach an EXPLANATION: (a) include planned steps to ensure that the population is represented and implementation timeline, or (b) submit an amendment to the protocol to modify the subject population.	<input type="checkbox"/> YES <input type="checkbox"/> NO
6. Are you still enrolling subjects? If not, on what date did you stop enrolling subjects?	<input type="checkbox"/> YES <input type="checkbox"/> NO ____/____/____
7. Do you plan to continue to enroll subjects?	<input type="checkbox"/> YES <input type="checkbox"/> NO
8. Do you plan to continue research interventions or research interactions with subjects?	<input type="checkbox"/> YES <input type="checkbox"/> NO
9. Since the last IRB review, have adverse events changed the profile of risks to participants or others? If YES, attach a SUMMARY of changes. [Refer to Question #9]	<input type="checkbox"/> YES <input type="checkbox"/> NO
10. Since the last IRB review, have protocol deviations or unanticipated problems introduced unforeseen risks to participants or others? If YES, attach a SUMMARY. [Refer to Question #10]	<input type="checkbox"/> YES <input type="checkbox"/> NO
11. Since the last IRB review, have any participants withdrawn from the research? If YES, attach a SUMMARY of the number and reason for withdrawal. [Refer to Question #11]	<input type="checkbox"/> YES <input type="checkbox"/> NO
12. Since the last IRB review, have participants or others complained about the research? If YES, attach a SUMMARY of the number and nature of complaints. [Refer to Question #12]	<input type="checkbox"/> YES <input type="checkbox"/> NO
13. Since the last IRB review, have there been relevant publications? If YES, attach a SUMMARY of recent literature. [Refer to Question #13]	<input type="checkbox"/> YES <input type="checkbox"/> NO
14. Since the last IRB review, have there been any interim findings? If YES, attach a SUMMARY of the interim findings. [Refer to Question #14]	<input type="checkbox"/> YES <input type="checkbox"/> NO
15. Since the last IRB review, have there been any multi-center trial reports? If YES, attach a COPY of all multi-center trial reports.	<input type="checkbox"/> YES <input type="checkbox"/> NO

16. Since the last IRB review, have there been data safety monitoring board (DSMB) reports? YES NO
If YES, attach a COPY of DSMB reports. If not available, provide contact information for the DSMB.

17. Since the last IRB review, have there been any changes in study personnel? YES NO
If YES, attach a summary including names and contact information. [Refer to Question #17]

18. Since the last IRB review, have participants experienced any benefits? YES NO
If YES, attach a SUMMARY of benefits. [Refer to Question #18]

19. In the opinion of the principal investigator, have the risks or potential benefits of this research changed? YES NO
If YES, attach a SUMMARY of those changes. [Refer to Question #19]

20. Since the last IRB review, have there been any amendments to the research? YES NO
If YES, attach a SUMMARY description of amendments. [Refer to Question #20]

21. Have you been audited by the FDA for this project since your last report? YES NO
If YES, attach a COPY of the FDA Audit Report.

22. In the opinion of the principal investigator, are steps to protect the confidentiality of data adequate? YES NO
If NO, attach an AMENDMENT to change these steps. [Refer to Question #22]

23. STORAGE OF INFORMED CONSENT DOCUMENTS

Note below the exact location, method of storage, names and titles of individuals (other than IRB and federal officials) having access to informed consent documents. Periodic audit of study files by BSRHS IRB staff may be conducted.

The IRB cannot approve the continuation of studies that omit this information.

24. Do you, the principal investigator, or any people responsible for the design, conduct, or reporting of this study receive any financial remuneration for consulting, teaching, or any other duties from the sponsor, a Contract Research Organization (CRO), or any intermediary associated in any way with this research study? YES NO

25. Do you wish to close the study? YES NO
 IRB oversight may end following request for closure only under the following circumstances and conditions:
 No further interaction/intervention with subjects or access to identifiable information. AND
 (a) All data analysis is complete with data/samples de-identified to remain de-identified; OR
 (b) Data de-identified with no codes or keys to allow for identification in the future. This applies to multi-center research where de-identified data is provided to a sponsor who authorizes closure.

26. Please check ALL CHANGES you are submitting with this continuing review:

PROTOCOL REVISION/AMENDMENT

- AMENDMENT TO CONSENT/ASSENT DOCUMENT(S)
- AMENDMENT TO RECRUITMENT ADVERTISEMENT(S)
- INVESTIGATIONAL DRUG BROCHURE AMENDMENT
- PACKAGE INSERT
- RESEARCH FUNDING CHANGES
- New PI/SUB-INVESTIGATOR CV/BIOSKETCH <http://grants.nih.gov/grants/funding/phs398/biosketch.pdf> AND Training Certification
- OTHER (please specify):

(1) FOR PROTOCOL AMENDMENT, SUBMIT RESEARCH PLAN OR SYNOPSIS AS FOLLOWS:

- Clean copy of **revised** Research Plan or Synopsis
- Redline copy of revised Research Plan or Synopsis, OR a detailed description of proposed changes.
- Explanation of why changes are being made, **and**
- The most recent IRB-approved Research Plan or Synopsis

(2) AMENDMENT TO CONSENT/ASSENT DOCUMENT(S)

Submit: (a) copy of red-line/strike-out version(s) of the CONSENT/ASSENT FORM(S) OR DETAILED DESCRIPTION OF PROPOSED CHANGES, (b) clean copy of the revised consent/assent form(s), (c) explanation of why changes are being made, **AND** (d) the most recent IRB approved stamped consent/assent form(s). [Version number or Date, and Page numbers **MUST** be included]

(3) AMENDMENT TO ADVERTISEMENT

Submit: (a) copy of red-line/strike-out version of the ADVERTISEMENT OR DETAILED DESCRIPTION OF PROPOSED CHANGES, (b) clean copy of the revised advertisement, (c) explanation of why changes are being made, **AND** (d) the most recent IRB-approved stamped advertisement. [Version number or Date, and Page numbers **MUST** be included]

(4) AMENDMENT TO INVESTIGATIONAL DRUG BROCHURE

Investigational drug brochure amendment or package insert, list of changes made, indicating consideration of the risk/benefit ratio, and any changes proposed in the conduct of the project (amendment to the protocol and/or consent/assent document(s)).

(5) RESEARCH FUNDING PROPOSAL

Federal regulations require IRB approval of NEW, RESUBMISSION, or COMPETING CONTINUATION FEDERAL RESEARCH FUNDING PROPOSALS. If there is a new, resubmission, or competing continuation BSRHS federal research funding proposal associated with this research project, you must include a copy of your **ENTIRE** proposal (exclusive of appendices) with this submission.

(6) NEW PRINCIPAL INVESTIGATOR OR MEDICALLY RESPONSIBLE INVESTIGATOR

If requesting a change in the principal investigator, the CONTINUING REVIEW FORM must be signed by the currently approved Principal Investigator (PI). **NOTE:** All documents that reference the current PI should be revised to reflect the new PI and included with this submission for approval, e.g. protocol, informed consent form(s), advertisement(s), etc. Check appropriate boxes on this form.

I, hereby, certify that every subject in this study has completed the informed consent process as approved by BSRHS IRB.

SIGNATURE OF PRINCIPAL INVESTIGATOR:		DATE OF SIGNATURE:	
PRINTED PI NAME:			