



USUHS FORM 3204B
RESEARCH INVOLVING HUMAN
TISSUE/SAMPLES (continuing/annual review)

REA Date Stamp

SECTION I. PROTOCOL INFORMATION

Protocol No.: _____

Principal Investigator: _____

Department: _____ Phone _____

E-Mail: _____ Payer or Other Phone Number _____

Project Title: _____

SECTION II. STATUS OF THE STUDY {Mark the status of the study (a-g) and note the specific information that must be submitted}.

- a. _____ **No human tissue/samples collected in this study** – termination requested. [Complete section III only].
- b. _____ **Tissue/sample collection for this study is pending** – continued approval requested. [Submit Sections III and IV (2, 8, 10 and 11)].
- c. _____ **Active with ongoing tissue/sample collection and/or data analyses: Tissue/sample collection not completed.** [Submit Sections III and IV (1 and 3-11)].
- d. _____ **Active with ongoing tissue/sample analysis and/or data analysis only: Tissue/sample collection completed.** [Submit Sections III and IV (1 and 3-9)].
- e. _____ **Completed.** Date of Completion _____ [Submit Sections III and IV (1 and 3-9) as a final human participant use report.

SECTION III. CERTIFICATION OF PRINCIPAL INVESTIGATOR

Signature certifies that the above titled research has been/will be conducted in full compliance with the DHHS/FDA Regulations and USUHS IRB requirements/policies governing human participant research. It is understood that IRB continuing review is required in order to maintain study approval and that **ANY** changes in the study/methodology which affect the participants must be approved by the IRB prior to implementation. Alternatively, if the study has never been initiated and you are requesting termination (II[a] above), your signature verifies this request. If the study is completed (II[g] above), the information provided on this form represents an accurate final human research report.

Signature of Principal Investigator

Date

SECTION IV. SUMMARY OF RESEARCH (use additional sheets as necessary)

DEMOGRAPHIC INFORMATION

1. **Target Collection Number:** What is the target collection number approved by the IRB? _____
2. **Non-accrual:** If no tissue/samples have been collected since the last IRB review, the reason(s) for non-accrual must be provided.
3. **Source(s) of tissue/samples (USUHS and non-USUHS):** _____

	No. of samples collected from USUHS sources	No. of samples received from non-USUHS sources	No. of samples analyzed	No. of samples remaining to be analyzed
Since last review:				
a. archived				
b. prospectively collected				
Study totals to date:				
a. archived				
b. prospectively collected				

STUDY RESULTS

4. **Study Progress/Results:** Provide a brief summary of study progress/results (preliminary or final) obtained in the study. If the study is part of a cooperative group or multi-center trial, a copy of the most recent group-wide progress report must be attached.

ADVERSE EVENTS AND PROBLEMS

5. **Unanticipated adverse event(s):** From initial approval of the study to the present, has any participant enrolled in your study suffered an unanticipated adverse event? If the answer is yes, specify the total number of events, date(s) and summarize briefly the overall nature and significance of the adverse event(s).

PARTICIPANT WITHDRAWAL

6. **Involuntary participant withdrawal:** Was any tissue/sample withdrawn from your study because of medical complications or other problems? If the answer is yes, provide a brief description of the medical complication/problem for each participant who was involuntarily withdrawn.
7. **Voluntary participant withdrawal:** Did any participant voluntarily request withdrawal of his/her tissue/sample from your study for non-medical reasons? If the answer is yes, provide a brief description of any known reason(s) for each participant who voluntarily withdrew from the study.

CURRENT RISK/BENEFIT ASSESSMENT

8. **Current Risk/Benefit Assessment:** Has anything occurred since the last IRB review that may have altered the risk/benefit relationship? If the answer is yes, provide a current assessment, in your opinion, of the risk/benefit relationship based upon study results, adverse events, or other factors.

INFORMED CONSENT EVALUATION

9. **Informed consent process:** Did any problems occur relative to the obtainment and documentation of informed consent since the last IRB review? If the answer is yes, please provide a brief description of the problems.
10. **Informed consent document:** Is the approved informed consent document still acceptable (i.e., the information contained in the document is accurate and complete and there is no new information that should be disclosed to the participant)?
- a. **For tissue/samples collected via a USUHS protocol:** *If in your opinion the approved informed consent document is still acceptable, this must be stated and a clean copy of the form(s) must be submitted with this form on USUHS letterhead for a continuing approval stamp.* If, revisions are necessary to the USUHS informed consent document, this must be stated and a new USUHS Form 3204 must be submitted along with this annual review.
- b. **For tissue/samples collected via a collaborative effort from another study and/or institution:** *Submit the most recent, IRB-approved consent document and IRB approval memo from that study and/or institution.*
11. **Equity or consultative relationship:** Have any investigators developed an equity or consultative relationship with a non-USUHS source related to this protocol which might be considered to be a conflict of interest? *(If yes, please append a statement of disclosure.)*