



Instructions for completion of the Continuing Review Form (CRF)  
HSL Institutional Review Board (IRB)

All research activities approved by the HSL IRB are subject to continuing review. DHHS and FDA rules require re-evaluation of approved research at intervals that are appropriate to the degree of risk. At the time of the initial review, the IRB will determine how often it should re-evaluate the research project and set a date for its next review. The Principal investigator will receive notice by the IRB of the impending project continuing review, and the deadline for submission of this review to the IRB. **If an investigator fails to meet the deadline, the IRB maintains the authority to suspend or terminate approval of the research.**

Continued monitoring of approved research by the IRB is as important as the initial review and approval. The continuing review form provides a scheduled progress report to the IRB by the research investigator. The IRB must reassess the research, and the progress of the research, at the time of the continuing review to 1) continue approval of the research; 2) require modifications to the research; 3) suspend the research or 4) terminate its approval of the research.

The following information is provided to offer guidance to investigators for completion of CRF.

*Please answer each question. If a question is not applicable, please put N/A in the box.*

Section 1 - Principal Investigator

Identify Principal Investigator and co-investigators and contact information.

Section 2 - Protocol Information

Identify the Exact Title of the Protocol (as submitted to the funding agency); the funding agency; the funding period (start date and end date) and the location of the research activity, i.e., where will the research be conducted.

Section 3 – Protocol Status

A. This section pertains to studies that have never enrolled human subjects as part of the protocol.

**B. Pending/No Enrollment** – If no subjects have been enrolled anywhere, please provide an explanation regarding the lack of accrual and justification for continuation of the project.

Active Enrollment – Recruitment is ongoing and subjects are actively being recruited into the study.

Closed to Enrollment – *More than one response* may be applicable in this section. Please be sure to select all that apply to the research protocol. If the study is permanently closed to enrollment of subjects please be sure to include the *date of closure*.

Completed - All research activities are completed and termination of the research protocol is requested. *Please submit a final report and/or summary of the research.* If no subjects were ever enrolled anywhere, and the study will not proceed, please check the termination of the research protocol box.

Section 4 – Participant information If the protocol did not involve human subject enrollment, skip to Section 6.

Please complete Part A and B

- A. Please provide the *total* number of participants enrolled into the study
- B. Please provide the requested information for participants enrolled during the last approval period.

Section 5 – Adverse Events or Unexpected Problems If the protocol did not involve human subject enrollment, skip to Section 6.

Part A – Please check the appropriate box if adverse events or unexpected problems occurred during the past approval period. Definition of Adverse Event = An undesirable and unintended, although *not necessarily unexpected* result of therapy or other intervention (e.g. headache following spinal tap or intestinal bleeding associated with aspirin therapy). Please provide a *detailed* explanation of the event/s or problem/s that occurred and when (*the date*) the IRB was notified. If the IRB was not notified, please explain why this was not done.

Part B – Please check the appropriate box regarding Data Safety Monitoring Board (DSMB) or Safety Officer, and be sure to indicate the date of the last DSMB review. *Investigators are required to submit DSMB reports to the HSL IRB at the time they are made available to the investigator.*

Section 6 – Protocol Amendments or Revisions

Part A – Please check the appropriate box if amendments or revisions to the protocol have been made since the last full IRB approval. If yes, please provide the date of IRB approval of the *amendment or revision* to the protocol. Please note that requests for new amendments or revisions must be submitted *separately* from the continuing review.

Part B – Please check the appropriate box if the informed consent form has been changed since last review by the IRB.

Part C – Please check the appropriate box if any new personnel are working on this study *since the last approval period*. Please indicate whether they have taken the mandatory

Human Subjects Protection Training. Human Subjects Protection Certificates must be submitted for all personnel with human subjects responsibilities

Section 7 – Research Findings

Please submit a brief summary of any research findings to date

Section 8 – HIPAA Waiver

Please check the appropriate box if a HIPAA waiver has been granted by the HSL IRB for this protocol.

If a HIPAA waiver has been granted, please indicated whether you wish to renew the HIPAA waiver and if there have been any changes to the PHI being accessed/collected. If there have been changes, please list them.

*For further information regarding HIPAA waivers for research purposes at HSL, or to determine if your research protocol is eligible for/ or requires a HIPAA waiver, please see the separate HSL IRB instructions and application form for HIPAA waivers.*

Section 9 – Recent Findings

Please check the appropriate box if there has been any new information that might effect the willingness of subjects to continue participating in the research. If yes, you must indicate your plan to communicate these findings to research subjects. You must also provide justification as to why the research should proceed.

Section 10 – Required Signatures

The principal investigator must sign and date the completed continuing review form. The principal investigator should review the form to be sure all items have been answered appropriately.

Additional items to be included with the completed continuing review form.

- Two clean (unstamped) copy of the current informed consent form
- All recruitment materials, i.e. flyers, advertisements, radio/tv scripts, etc.
- A copy of any questionnaire or protocol form revised since the last IRB review. Please highlight the sections that have been revised

*Revised 1/25/2007*