



YALE UNIVERSITY SCHOOL OF MEDICINE
HUMAN INVESTIGATION COMMITTEE
Request to Close a Research Study Involving Human Subjects
Form 5-C

47 College Street, Suite 204
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Telephone: 203/785-4688
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Use this form when requesting to close a research study operating under the purview of the Human Investigation Committee (HIC.)

Please note that a protocol cannot be closed by the Principal Investigator simply because no additional subjects will be enrolled or because the participation of subjects has ended. Even when only data analysis or long term follow up is being conducted, a [Request for Reapproval \(HIC Form #5R\)](#) must be submitted to the HIC for approval to ensure continuing compliance with federal regulation and University policies.

Additionally, any protocol that includes a secondary aim or component that involves the banking of biological specimens or data for a time period that exceeds the duration of the primary protocol cannot be closed. The protocol must remain open for as long as the biological samples or data are being retained for future research purposes by Yale researchers. Alternatively, investigators may create a new protocol that focuses on the banking and secondary uses of biological samples or data. See – <http://www.info.med.yale.edu/hic/forms/forms/RepositoryProtocolAppFormFinal.doc>.

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|---|-------------|--|----------------|
| HIC Protocol Number | | | |
| Title of Research Project: | | | |
| Principal Investigator: | | Yale Academic Appointment: <input type="text" value="Select from list"/> | |
| Campus Address: | | | |
| Campus Phone: | Fax: | Pager: | E-mail: |
| Protocol Correspondent Name & Address: | | | |
| Campus Phone: | Fax: | E-mail: | |

Signature of Principal Investigator

Date of Request for Closure

1. Reason for request to close study:
 - _____ Project never started
 - _____ Completed per protocol
 - _____ Study closed by sponsor
 - _____ PI no longer at Yale
 - _____ Other: _____

2. If the study is being closed by the sponsor, please give a brief summary of the reason for closing and provide communication from the sponsor regarding closure (letter, e-mail, etc).

3. Summarize the results obtained in the study. Indicate whether the results were consistent with what was expected. Attach abstracts or any publications.

4. Date enrollment closed:
 - a. Have all subjects completed all research interventions? (e.g., drug regimens, questionnaires, cognitive therapy sessions, etc.) Yes No
 - b. Is long term follow-up of the subjects completed? Yes No
 - c. Is data analysis complete? Yes No
 - d. If data analysis is **not** complete, is it being conducted only by the sponsor?
Yes No

5. How many different classes of subjects (e.g., cases vs. controls) were being recruited into the study? If applicable, refine the responses below by specifying the number enrolled by category of subject, study arm or study phase.
 - a. What was the total number of subjects that were projected to be enrolled in this study? (The number noted in the initial protocol application.)
 - b. What was the total number of subjects enrolled?

- c. What was the total number of subjects that completed the study?
6. In total, how many serious and unanticipated events that were possibly, probably, or definitely related to the study occurred?
- a. Was each reported to the HIC and other organizations as appropriate? Yes No
N/A
- b. Are there any updates to previously reported serious adverse events that should be reported to the HIC? Yes No If yes, please describe.
7. Have there been any unanticipated problems other than the adverse events cited above in #7 that involved risk to subjects or others? Yes No If yes, please describe.
Are there any updates to previously reported unanticipated problems that should be reported to the HIC? Yes No If yes, please describe.
8. Have there been any complaints from subjects relating to the study? Yes No If yes, describe the complaint(s) and resolution.
9. Were the research data collected, recorded and secured in accordance with the standards noted in the approved protocol? Yes No If no, please explain.
10. Were the methods and procedures used to safeguard the confidentiality of subjects and their data as outlined in the approved protocol adhered to? Yes No If no, please explain the mechanisms that will be implemented to ensure the proper use and continued protection of these data.
11. **Plans for retaining or destroying research data.** Researchers are reminded that subject permission must be obtained to retain personally identifiable research data for future research purposes. Researchers are also reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media, (e.g., laptops, compact discs, jump drives, thumb drives). Further, University policy prohibits unauthorized access and disclosure of confidential information; therefore, deleting data or reformatting disks is not sufficient for removing personally identifiable information or data from equipment used during the conduct of a research study. Zeroing, degaussing or another method must be used to remove these types of identifiers or data. See Disposal of Media Containing Confidential or Protected Health Information under Procedure 1609: Media Controls found at <http://mire.med.yale.edu/hipaapolicies/>
- a. What are the plans for retaining the research data?
- b. What are the plans for destroying the research data?

12. Has the use and/or distribution of protected health information been consistent with the use and distribution noted in the current HIPAA Research Authorization form that was reviewed and acknowledged by the HIC and/or the HIPAA Waiver that was approved by the HIC? Yes No If no, explain why it has not been.
13. Was this study monitored by a Data and Safety Monitoring Board (DSMB) or a Data and Safety Monitoring Committee? Yes No If yes, name the Board or Committee and attach the final summary report.
14. Did the principal investigator of this study hold an IND or IDE for the conduct of this study? Yes No N/A If yes, attach a copy of the final FDA annual report and notice to the FDA of termination.
15. When appropriate (e.g., for projects studying health issues and outcomes in New Haven, and CTSA awarded projects), describe the method whereby subjects who participated in the research project will be informed of the research outcome or results.
16. For studies that involve or include a repository for biological specimens and/or data:
- a. How many specimens and/or individual data sets have been collected in total?
 - b. Were individual or personal identifiers withheld or distributed in accordance with the repository procedures outlined in the initial protocol? Yes No
 - c. Has the disposal/destruction of the subject identifiers as approved in the repository protocol been achieved? For examples, have data and/or specimens been destroyed? Specimens used until exhausted? Stored indefinitely? Yes No
17. For studies that are only Medical Record or chart reviews:
- a. How many records have been reviewed in total?
 - b. Has the disposition of data as approved in the protocol been achieved? Yes No
 - c. If the protocol did not specify disposition, describe what will be done with the data generated from the medical record review.

FOR HIC USE ONLY

Reviewed by the HIC on: _____

By: _____