



**Yale University School of Medicine
Human Investigation Committee
Request To Classify Research Project as Not Involving Human Subjects**

This form should be used to submit to the HIC research project descriptions that are considered by a Yale University investigator not to be subject to human subjects regulations. Research projects may be classified as “not involving human subjects” if they involve obtaining, collecting and/or using coded, non-identifiable, or anonymous private information or human biologic specimens.

For more information see <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

This form cannot be used for studies that are considered exempt under federal human subject regulations.

Title of Research Project:

Name of Principal Investigator : _____

Position or Association with Yale University: _____

Other Investigator(s): _____

(Individuals who are not full-time Yale faculty are not permitted to serve as principal investigators on Yale research studies. Students may serve as a Principal Investigator under the guidance of a Faculty Advisor. The name of the faculty advisor must be listed on this form.)

Campus Address:

Campus phone:	Fax:	Pager:	E-mail:
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Correspondent Name:	E-mail:
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Campus phone:	Pager:
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Please complete the following questions:

- 1) Purpose of the study (Please attach a project description):
- 2) Proposed start date: _____ Anticipated study completion date: _____
- 3) Number of coded, non-identifiable, or anonymous private data sets or human biologic specimens that will be used for this project:
- 4) From what sources will the coded, non-identifiable, or anonymous private data sets or human biologic specimens be obtained from for analysis or analyses? (examples: YNHH, Pathology Department, An Institution other than Yale University or YNHH)
Investigators are reminded to submit a Form 14 along with this form if specimens are requested of the Yale Pathology Department.
- 5) Does the person conducting the study have a doctor/patient or other health care provider relationship with the subjects? Yes No *If, yes, describe how the identity of the subject will be kept unknown to the investigator.*
- 6) Have the requested coded, non-identifiable, or anonymous private data or human biologic specimens been previously collected? Yes No

7) Please check the appropriate category that applies to your research.

Activity is considered research but does NOT involve identifiable human subjects:

- Project requires the collection /analysis of data regarding health facilities or other organizations or units which are not individual persons.
- Project requires data and or specimens from deceased persons.
- Project requires using unlinked anonymous data or specimens. Please note that all the following requirements needs to be met in order for this category to apply:
 1. No contact with human subjects is involved for the proposed activity
 2. Data or specimens are/were collected for another purposes
 3. No extra data/specimens are/were collected for this purposes
 4. Identifying information either was not obtained or has been removed so that data cannot be linked or re-linked to identifiable human subjects.

Please note: Continuing HIC oversight is not required for studies that are considered Non-Human Research Subjects. Nevertheless, investigators and research staff are expected to adhere to ethical principles and federal and state standards that govern Human Subjects Research as well as Yale University Policies and Procedures.