
Yale University Institutional Review Boards Procedure

100FRXX Request for Determination that a Research Project Does Not Involve Human Subjects

Research projects may be classified as “not involving human subjects” if they involve obtaining, collecting or using human data or specimens that are coded or do not include personally identifiable private information. For more information, see Yale IRB Policy 100 and <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>

Title of Research Project: _____

Name of Principal Investigator: _____

Position or Association with Yale University: _____

Other Investigators: _____

Campus Address: _____

Campus Phone: _____ **Fax:** _____ **Pager:** _____

Email: _____

Correspondent Name: _____ **Email:** _____

Campus Phone: _____ **Pager:** _____

Please complete the following questions:

1. State the study hypothesis and give a brief description of methodology, including estimated numbers and sources of data or specimens:

2. Please indicate the following (check applicable description)

Project requires the collection/analysis of data regarding health facilities, businesses or other organizations or units which are not individual persons.
If you have checked this box, you do not need to complete the next section of this request.

Project requires data or specimens from deceased persons and no data about or specimens from living individuals will be collected..
*If you have checked this box, you do not need to complete the next section of this request. For studies involving protected health information, you must complete the Request for Access to Protected Health Information for a Research Purpose located at the HIC website at <http://info.med.yale.edu/hic/forms/forms/Form5032RequestAccessPHI.doc>
When completed, this form is to be given only to the holder of the record.*

Project requires using only de-identified human data or specimens. *See list below for identifiers. Specimens/data may or may not be coded. **Please note: all of the following requirements need to be met in order for this category to apply:***

- No contact with human subjects by the PI for this study is involved for the proposed activity
- Data or specimens are/were collected for another purpose and no extra data/specimens are/were collected for this purpose
- Identifying information either was not obtained or has been removed so that data cannot be linked or re-linked to identifiable human subjects by the PI for this study. *Note: A code kept by the original researcher is allowed, but the PI for this study can have no means to identify individual human subjects.*

FOR YALE SCHOOL OF MEDICINE ONLY:

Project requires using human data or specimens with limited direct HIPAA identifiers, such as dates and zip code: *Specimens may or may not be coded. **Please note: all of the following requirements need to be met in order for this category to apply:***

- No contact with human subjects by the Yale researcher is involved for the proposed activity
- Data or specimens are/were collected for another purpose
- There is a data use agreement in place for a limited data set
(See <http://info.med.yale.edu/hic/forms/forms/DUA.doc>)
- A copy of the data use agreement is attached.

Please note: Continuing IRB oversight is not required for studies that are considered Not Human Subjects Research.

Identifiers for data or specimens relating to an individual or their family member:

names; postal address information, other than State; all elements of dates (except for years) related to individuals (including date of birth, admission date, discharge date, age over 89) telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images; any other characteristic or information that could be used alone or in combination to identify an individual.