

Yale University
Human Investigation Committee
School of Medicine
47 College Street, Suite 204
P. O. Box 208010
New Haven, Connecticut 06520-8010

Telephone: 203/785-4688
Fax: 203/785-2847

REQUEST FOR APPROVAL OF MEDICAL RECORD REVIEW

Title of Project: _____

Principal Investigator: _____

Dept: _____

Address: _____

Telephone: _____

Email: _____

P.I.'s Association or Status with Yale: _____

Other Investigator(s): _____

(The Faculty Handbook requires that the principal investigator is employed full-time by the University and holds an appointment as assistant professor, associate professor, professor, research scientist/scholar, or senior research scientist/scholar. Exceptions require approval by the department chair, and the dean of the School of Medicine. The form for requesting special permission is available at the HIC website <http://info.med.yale.edu/hic/forms/index.html>, and includes instructions for submission.

Students, postdoctoral appointees, fellows and other trainees may serve as a PI provided that the protocol design and conduct is appropriate for the trainee's level of knowledge, training and skill and that the trainee performs the research under the oversight of a designated faculty sponsor. The HIC Protocol Application Form, "Application to Involve Human Subjects in Research", includes instructions on serving as PI on a project with a faculty sponsor.

Associate Research Scientists may either conduct research under the oversight of a faculty sponsor, as described above, or may request special approval to serve as PI.)

I agree that the information requested for the research purpose described will be used only for those research purposes. I accept responsibility for protecting the confidentiality and security of this information and will destroy identifiers if required.

Faculty Sponsor: _____

Please print or type

Signature

Date

Telephone

Investigators requesting a waiver of informed consent or who plan to use in-patient, psychiatric, drug, or alcohol records must comply with other university policy and federal regulations.

Please consult HIC guidelines (<http://info.med.yale.edu/hic>)

1) Purpose of review of medical records:

2) From what sources will records be obtained for review? (examples: YNHH, YMG, Diagnostic Imagery)

3) Does the person conducting the medical record review have a doctor/patient or other health care provider relationship with the subjects?

If yes, what is the nature of the relationship?

If no, is this study considered an activity preparatory to research?

(A request for a Waiver of HIPAA Authorization for recruitment purposes must be attached if activity is not preparatory to research and the person conducting the medical record review does not have a treating relationship with the subject.)

4) Number of subjects:

5) Criteria for inclusion/exclusion:

6) Duration of study:

7) Will patient names or other information (ie: PHI) identifying the individual patient be recorded?

If yes, please detail plans for maintenance of confidentiality.

8) Is it practicable for the investigator to obtain the subject's written consent prior to reviewing of the subject's medical record? If no, please explain. If yes, attach consent form and HIPAA research authorization form, if necessary. (*Please see Guidance for Investigators on our website <http://info.med.yale.edu/hic>*)

9) Will a waiver of informed consent adversely affect the rights or welfare of the subjects?
Please explain.

10) If appropriate, will subjects be provided with additional pertinent information after their records have been reviewed? If no, please explain.

11) Does this medical record research involve more than minimal risk to the subjects? If the answer to question #7 is yes and questions #8 and #9 are no, then a Request for Waiver of HIPAA Authorization may be required to use PHI in the research project. (*Please see our website <http://info.med.yale.edu/hic> for details.*)

12) Funding requested? (Specify Federal, Private, Industry or Department source. Indicate proposal title, proposal number and submission date as appropriate.)

PLEASE SUBMIT THE ORIGINAL PLUS ONE COPY OF COMPLETED FORM TO HIC OFFICE, 47 COLLEGE ST., SUITE 204. IF YOU HAVE ANY QUESTIONS, PLEASE CALL 785-4688.

For HIC Use Only

Date Approved

Human Investigation Committee

THIS APPROVAL DOES NOT AUTHORIZE PATIENT CONTACT

Form Approved/Revised: 4/07
(Date)