



**Yale University School of Medicine
Human Investigation Committee
Request for Approval of Medical Record Review**


Questions to determine if the study qualifies as Medical Record Review:

1. Will the medical information to be accessed be limited to only records of decedents?
 No Yes → (If yes, stop completing this form and 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 records.

*For additional information consult the HIC website at
<http://www.med.yale.edu/hic/hipaa/guide/impact.html#decedent>.*

2. Will the information collected be used to create a data archive for future research?
 No Yes → (If yes, stop completing this form and complete the HIC Application to Involve Human Subjects in Research Biologic Material and/or Data Repository).
3. Are there plans to contact subjects for follow-up or to collect any information using assessment tools or other means to complete the information that is not currently available in the chart? No Yes → (If yes, discontinue filling out this form and complete the HIC Protocol Application Form).

If you answered “No” to all of the above questions, complete the following form:

	<p>Yale University School of Medicine Human Investigation Committee Request for Approval of Medical Record Review</p>
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Title of Research Project: _____

A. Investigator and Project Information

Principal Investigator*: _____

PI's Association or Status with Yale: Faculty Student/Fellow Other: _____

List all other investigators and study personnel:

**Principal Investigators who are students or trainees must have the guidance of a Faculty Advisor. The Faculty Advisor must be a full-time Yale Faculty member and must be named on this form. (Both the PI and the Faculty Advisor must sign below)*

Campus Address:			
Campus phone:	Fax:	Pager:	E-mail:
Correspondent Name:		E-mail:	
Campus phone:		Pager:	

B. Principal Investigator Assurance

As the Principal Investigator or Faculty Advisor of this research project, I certify the following:

- The information provided in this application is complete and accurate.
- I assume full responsibility for the protection of human subjects and the proper conduct of the research.
- Subject confidentiality will be of paramount concern, and every effort will be made to protect subjects' rights and welfare.
- The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.
- All members of the research team will be kept apprised of research goals.
- I will obtain approval for this research study and any subsequent revisions prior to initiation.
- I am in compliance with the requirements set forth in the Yale University Faculty Handbook and qualify to serve as the Principal Investigator of the project or have acquired the appropriate approval from the Dean's office or Office of the Provost, or Yale New Haven Hospital general counsel.
- My signature below provides written assurance that subjects' Protected Health Information (PHI) will not be used or disclosed except as required by law, for authorized oversight of research or for conducting secondary research only if that research has been reviewed and approved by the HIC.

Signature of PI

Date

C. Faculty Advisor Assurance

As the **faculty advisor** of this research project, I certify that:

- The information provided in this application is complete and accurate.

- This project has scientific value and merit and that the student or trainee investigator has the necessary resources to complete the project and achieve the aims.
- I will train the student investigator in matters of appropriate research compliance, protection of human subjects and proper conduct of research.
- The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.
- The student investigator will obtain approval for this research study and any subsequent revisions prior to initiating the study or revision and will obtain continuing approval prior to the expiration of any approval period.
- The student investigator will report to the HIC any serious injuries and/or other unanticipated problems involving risk to participants.
- I am in compliance with the requirements set forth by the [University](#) and qualify to serve as the faculty advisor of this project.

Signature of Faculty Advisor (If Applicable)

(Print or Type Name)

Date

1. Funding source: (Specify Federal, Private, Industry or Department source, etc. If grant funded, provide the “M” number from the ProSum, and the grant number, if known.)
2. Purpose of the study: (describe briefly, including hypothesis, research plan and possible risks and benefits.)

3. Sources of data? Please check as appropriate:

- Films/X-rays
- Computer/Database(s) records
- Pathology/Laboratory slides or records
- YNHH Labs, Name _____
- Yale University Labs, Name _____
- YCC Tumor Registry/Co-Path **Note:** If the YCC Tumor Registry is to be accessed, the Yale University School of Medicine/Yale–New Haven Hospital Cancer Data Repository (Tumor Registry) Request For Information form must be completed this form can be found at <http://www.yalepath.org/CaDR/data.htm>
- Other types of record (*please specify*) _____

4. Estimated number of subjects whose information will be reviewed or databases that will be reviewed:
5. Criteria for inclusion/exclusion:

6. Probable Duration of study: (Please state the expected duration of the project, including all data analysis activities)
7. Indicate the estimated time frame of the data that will be accessed: From: _____
To: _____

8. Will patient names or protected health information (PHI) be recorded on any medium?
 No Yes

If yes:

- o List the identifying information to be recorded. Note that only the minimum information necessary to conduct the research should be used.
- o Identify the type of medium that will be used to record the PHI and the plans for maintaining confidentiality and security of the data.
- o Also indicate who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored.

Note: Investigators are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media. Identifiers and code keys must be stored in a secure manner, e.g., Yale network servers. If identifiers are stored on moveable media then investigators must use encryption methods to protect access to these files or other methods as appropriate for the types of information stored on these devices.

9. Will the data and/or identifiers be destroyed when no longer needed for research purposes? Yes
 No

If No, please explain why data must be retained, for how long, and how it will be secured.

10. Waiver of Consent/Waiver of HIPAA Authorization: Will you request either a waiver of consent, or a waiver of documented consent, for this record review? If so, please address the following:
- a) Does the research pose greater than minimal risk to subjects?
 - b) Will the waiver adversely affect subjects' rights and welfare?
 - c) Describe why it would be impracticable to obtain the subjects consent and authorization for use or disclosure without the waiver.
 - d) Are there any plans to provide subjects with additional pertinent information after their records have been reviewed? No Yes
If yes,
 - e) How will pertinent information be returned to subjects, if appropriate at a later date?

Note: IRB approval for medical record review does not permit contact with subjects. If the review generates a need for subject contact, a separate request for IRB approval must be submitted.

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the “accounting for disclosures log”, by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

By signing this protocol application, the investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

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

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

<i>FOR HIC USE ONLY</i>	
_____ Approval date	_____ HIC Staff Signature
THIS APPROVAL DOES NOT AUTHORIZE PATIENT CONTACT	