

# HIC

## REQUESTS FOR RESEARCH USE OF HUMAN SPECIMENS (TISSUE, BODY FLUIDS, ETC.)

Information to help define requirements for protocol submission:

Please read the "Human Investigation Committee Guidelines for Preparation of Protocols for Review by the HIC", and the "Interim Policy on the Use of Pathological Tissue Specimens for Research Purposes". Answer all of the following questions and submit this worksheet with your HIC Protocol. If you are requesting information only, you may be eligible to complete HIC Form #12, Medical Records Review Short Form.

Title of project:

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Principal Investigator:

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<i>Last name</i>	<i>First name</i>
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- Yes  No 1. Will the subject(s) have a medical procedure performed solely for research specimen collection?

If you answer YES, you must get informed consent from the subjects, regardless of whether samples will be labeled with subject identity or not. There are certain exceptions for procedures considered to be minimal risk. See HIC Guidelines, Appendix I.

- Yes  No 2. Will you receive and/or store specimens in a way such that the subject is, or could be, identified (e.g., labeled with or coded for name, unit number, pathology number, etc)?

If you answer YES, you may be required to obtain informed consent from subjects. A requirement for informed consent might be waived if you are using only coded samples or information and the code is not accessible or provided to you without further HIC review. Waiver might also be considered for identified patients if there is very nearly no likelihood of injury to the interests of the subjects or their relatives (see questions 6 through 11 below) AND a requirement for informed consent would make the accomplishment of the research goal impracticable. Please discuss both of these topics.

If you answer YES, skip to question 3.

If you answer NO, you will not be able to request more of any specific sample, nor will you be able to get any more descriptive information about the subject or the sample.

If you answer NO, you may request a waiver of informed consent. Request for waiver of informed consent will most often be granted under these conditions; however, see questions 1, 5 and 13.

If you answer NO, please sign the following statement.

I make assurance that I will not attempt to discover, or in any way retain, the identity of the person(s) from whom these samples were obtained. I will inform all members of my research group of this assurance, and take responsibility for compliance with the restriction.

*Signature of Principal Investigator*

- Yes  No 2b. If you answered NO to question 2a, do you anticipate or are you aware of circumstances such that seemingly anonymous “unlinkable” specimens or data might, in fact, be able to be linked to the subject?

If, after reading the commentaries in the Definitions section of the Interim Policy, you answer YES to this question, please describe any such circumstances in detail.

- Yes  No 3. Will you use store specimens for future use?

Any use of specimens not mentioned in the current protocol must be approved by the HIC. If consent for samples is obtained, banking and general types of future use must be explained to the subject.

- Yes  No 4. Are you a health care professional and/or have responsibility for maintaining medical records containing personal identifiers (apart from doing the research mentioned in the current application)?

If you answered YES to question 2, and if you answer NO to this question, please explain in detail how you will responsibly handle confidential patient information.

In order to be able to review medical record information, you must be an authorized individual; see HIC Guidelines. Students and non-authorized individuals who are principal investigators must have a faculty sponsor sign below.

I accept responsibility for confidentiality of the records involved in this project.		
<i>Last name</i>	<i>First name</i>	<i>Signature of Faculty Sponsor</i>
<i>Name of Faculty Sponsor</i>		

- Yes  No 5. Have any of the investigators had a face-to-face or other direct professional contact with the subject(s) involved in this project?

If you answer YES, you must get informed consent from all subjects you see professionally, regardless of whether samples will be labeled with subject identity. If you have not had contact with the subjects for a long time, please explain, and this requirement for informed consent will be evaluated by the HIC.

- Yes  No 6. Is your proposed research limited to a disease that the subjects and/or their families already know that they are affected by?

If you answer NO, please discuss the relative risks of this research to the subjects and their families.

- Yes  No 7. Will results of this research be included in medical records?

If you answer YES, and if requirement for informed consent is not waived, the reporting of results should be explained in the consent document. The implications (social, economic, and legal) of having such information should be disclosed. Also note that you lab should address CLIA '88 regulations for clinical tests.

If you answer NO, and requirement for informed consent is not waived, the consent document should make it very clear that the research results will not be included in medical records, and explain why.

If you answer NO, and if you obtain unexpected results that you think should be included in the medical record, you must first contact the HIC for advice.

- Yes  No 8. Will this research yield new information or a new diagnosis relevant to the subjects' current medical care?

If you answer YES, please discuss the relative risks of this research to the subjects and their families. If you are working with identified or coded samples or information, there is a presumption in favor of an informed consent requirement.

- Yes  No 9. Will you report results of this research to the subject and/or his or her physician?

If you answer YES, there is a presumption in favor of an informed consent requirement. As part of the informed consent document, the implications (social, economic, and legal) of having such information should be disclosed. Your lab should address CLIA '88 requirements.

If you answer NO, and requirement for informed consent is not waived, the consent document should make it very clear that the results will not be reported to the subjects or their physicians, and explain why.

If you answer NO, and if you obtain unexplained results that you think should be reported to the subject or his or her physician, you must first contact the HIC for advice.

- Yes  No 10. Will this research help refine or alter the subjects' current prognosis or treatment?

If you answer YES, and if you are working with identified or coded subject samples or information, please explain how your results will be used. Informed consent may be required; please discuss the likelihood of injury to the subjects and their families. Also discuss the practicability of obtaining informed consent from the subjects. If requirement for informed consent is not waived, the consent document must make it very clear how research results will be used or reported.

- Yes  No 11. Will this research yield information about germline mutations?

If you answer YES, and if you are working with identified or coded subject samples or information, there is a presumption in favor of an informed consent requirement. If you request a waiver of this requirement, please discuss the likelihood of injury to the subjects and their families. Also discuss the practicability of obtaining informed consent from the subjects.

If you answer NO, and are working on somatic mutations, please explain how you will be able to distinguish between somatic and germline mutations in your assay system.

- Yes  No 12. Do you request approval for use of human samples and/or information from sources other than Yale-New Haven Medical Center (solely or in addition to samples/information from YNHH)?

If you answer YES, please be aware that the other sources might also require approval from their own institutional Review Board. Any such use of outside tissues or identifiable subject information by Yale investigators must be reviewed and approved by the Yale HIC. Also note that approval from other IRBs does not guarantee approval from the Yale HIC.

Yes  No 13. Do you request approval for use of tissues/information from abortions?

If you are requesting tissue or other samples from database, fetuses, and/or minors, please contact the HIC Office for further information. Also see the HIC Guidelines on "Special Problems in Research", especially the discussion on "Research Involving Children".

PLEASE NOTE: Any uses of tissues that are not mentioned in this current protocol must be submitted to and approved by the HIC before research is performed.

P.I. Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Form Approved/Revised: 5/02