

DEPARTMENT:	Yale University Human Investigation Committee
POLICY NUMBER:	
SECTION:	Submission of Research Protocol Applications
REVIEW RESPONSIBILITY:	HIC Leadership and YNHH
ORIGINAL CREATION DATE:	October 11, 2006
REVISIONS:	October 23, 2006

Policy on the Use of Excess Clinical Samples for Research

I. Purpose:

The Clinical Laboratories in the Department of Laboratory Medicine at Yale-New Haven Hospital house a variety of blood, urine, sputum and other specimens, analyzed for clinical purposes. Requests are often made to use left-over or excess specimens for research purposes. YNHH and Yale University are committed to the protection of the individually identifiable information which may accompany these specimens, and as such, wish to ensure that investigators access only that information that is relevant to specific research interests. This policy addresses the Human Investigation Committee (HIC) requirements relating to submission of research protocols requesting use of excess clinical samples for research.

The purpose of this policy and the Use of Excess Clinical Samples for Research Form (http://info.med.yale.edu/labmed/education_research/clinical_research.html) is to allow the HIC to certify to the YNHH Clinical Laboratories whether or not information being requested by an investigator falls within the scope of the research protocol which is pending evaluation, has already been approved, or has been deemed exempt by the HIC.

II. Definitions:

Excess clinical samples: Left-over specimens, after clinical utility is met, destined for discard

Anonymous: No direct identifiers and no code available to link back to individuals.

De-identified: Data that contains none of the 18 identifiers listed in the HIPAA definition.

Coded: Samples or data that are linked to identifiers via a key or 'code' that is retained by laboratory personnel, such that no identifiers accompany the samples or data.

Human subject: a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

III. Policy Statement:

1. Investigators wishing to request excess clinical samples for research use are required to complete the YNHH clinical laboratories' form ("Form") (<http://info.med.yale.edu/labmed/clinicalresearch/>) prior to initiating any requests of the Laboratories in the Department of Laboratory Medicine at YNHH. This form is also available on the HIC website <http://info.med.yale.edu/hic/forms/index.html>.
2. If the use involves human subject research, HIC review is required, and the form must be submitted to the HIC, referencing the existing protocol, or accompanied by a new protocol application or exemption request. (<http://info.med.yale.edu/hic/forms/index.html>)
3. Investigators requiring identifiers must specify what identifier(s) is (are) required. Investigators are reminded to request only the minimum amount of identifiers necessary to accomplish the research project.
4. This policy does not pertain to requests by investigators to conduct activities considered preparatory to research, e.g., determining whether there is sufficient cell size to conduct a research project.

IV. Procedure:

1. The investigator requesting use of excess clinical samples from the YNHH Clinical Laboratories, completes the Form by indicating the parameters/criteria for selecting samples, and the data elements requested for each case. If individually identifiable data elements are required, the investigator must submit the Form to the HIC with the request to review a new protocol application, amendment request, e.g. if additional information or data is being requested for review, or exemption request. Investigators should address whether informed consent and HIPAA research authorization (<http://info.med.yale.edu/hic/hipaa/index.html>) are necessary or feasible. (If waivers are requested, these requests must be submitted to HIC as well.)
2. The HIC reviews the protocol and the Form to determine whether the search parameters and individually identifiable data elements are consistently represented in both documents. The HIC further determines whether informed consent and HIPAA research authorization is required. If this is not practicable, the HIC may waive these requirements. Waiver of HIPAA authorization will necessitate tracking by the Clinical Laboratories.
3. When the HIC approves the protocol, the HIC representative completes the appropriate section of the Form and forwards a signed and stamped copy of the form to the Principal Investigator who is responsible for presenting the Form to the YNHH Clinical Laboratories when requesting samples. If a waiver of consent and HIPAA Research Authorization is granted by the HIC, these findings will be noted in the HIC approval letter and the signed form(s).