

DEPARTMENT: Yale University Human Investigation Committee
POLICY NUMBER:
SECTION: Submission of Research Protocol Applications
REVIEW RESPONSIBILITY: HIC Leadership and Yale Pathology
ORIGINAL CREATION DATE: January 1, 2007
REVISIONS:

Policy on the Submission of Protocols Requiring Access to Data Maintained by the Informatics Program of the Yale Department of Pathology and Yale New Haven Hospital Tumor Registry

I. Purpose:

Tumor registries and clinical repositories are a rich source of data that may be used by University researchers to evaluate the pursuit of a potential research hypothesis and/or advance scientific interests. The University is committed to the protection of the individually identifiable information maintained in these repositories and as such wishes 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 requiring access to data maintained by the Yale Pathology Department in the Yale Cancer Data Repository (Tumor Registry) and Yale Pathology CoPath system.

II. Clarifications and Definitions:

The Informatics Program in the Department of Pathology maintains two data sets with significant research value. These are described briefly below. However, it is not necessary for investigators to specify which data set they wish to get information from. The Pathology Informatics program will determine, based on the specifics of the data requested, which system will best meet the data request need. In the future, additional data sources may fall under the management of the Pathology Informatics program. In that event, this policy will apply to access to that data as well.

Cancer Data Repository – This repository is an HIC-approved assembly of existing and on-going clinical data concerning cancer patients or patients with reportable benign tumors treated or diagnosed at Yale New Haven Hospital (YNHH) or Yale Cancer Center (YCC). The data set is based on the “Tumor Registry” data set formerly managed in Therapeutic Radiology and now managed by YNHH. The Pathology Informatics program is enhancing this data set and building a web application to allow approved users access to this information for purposes of clinical investigation.

CoPath System – This is the production clinical information system used by the Department of Pathology. It is maintained by the Pathology Informatics program. In general, because of the production nature of this system, it is generally not used for research.

Preparatory to Research – An activity performed prior to the development of a research protocol that is aimed at reviewing data to assist in the formulation a hypothesis,

determining the feasibility of conducting the study, determining cell size, or other similar use.

Yale University School of Medicine/Yale New Haven Hospital Cancer Data Repository Request for Information Form – The form completed by an investigator that allows the HIC to make the determination as to 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.

III. Policy Statement:

1. Investigators wishing to access data that is maintained within the Cancer Data Repository and/or Tumor Registry and/or the Yale Pathology CoPath Systems for research purposes are required to obtain approval of the research protocol and sign off by the HIC on the *Yale University School of Medicine/Yale New Haven Hospital Cancer Data Repository Request for Information Form* (form) (<http://www.yalepath.org/CaDR/data.htm>) prior to initiating any requests to access the data.
2. Investigators requiring more data from any of the data sources maintained by the Pathology Informatics program (more information about specific individuals or additional data sets) in relation to an already approved protocol or a research project determined to be exempt by the HIC are required to obtain sign off by the HIC on the *Yale University School of Medicine/Yale New Haven Hospital Cancer Data Repository Request for Information Form* (form) (<http://www.yalepath.org/CaDR/data.htm>) prior to initiating any requests to access the data.
3. This policy does not pertain to requests by investigators to conduct activities considered preparatory to research.

IV. Procedure:

1. The investigator, knowing specific data from the Cancer Data Repository/tumor registry or CoPath system is required, completes the form by indicating the search parameters and the individually identifiable data elements. The investigator must submit the form to the HIC with the request to review a new protocol application.
2. Alternatively, if an investigator determines that more data (more information about specific individuals or additional data sets) is required for an already approved protocol or a research project determined to be exempt by the HIC, he/she must complete the form by indicating the additional search parameters and/or individually identifiable data elements. Note the request to obtain additional identifiable information about individuals and/or increasing the targeted number of records may require a formal amendment to an already approved protocol (<http://info.med.yale.edu/hic/forms/index.html>).
3. The HIC reviews the protocol and the form and determines whether the search parameters and individually identifiable data elements are consistently represented in both documents.

4. 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 and the Pathology Informatics Program.