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National Jewish Health Research Database

Pearlanne Zelarney, MS, Research Data Curator

Rick Hum, BS, Research Database Project Coordinator

The 2004 National Jewish Academic Strategic Plan first identified the need for a comprehensive research data repository integrated with an institutional biobank. It became a reality on June 7, 2010 as the National Jewish Health Research Database (RDB) – a part of the Integrated Bioinformation and Specimen Center - available to all research and clinical personnel.

The RDB provides access to EMR data on over 85,000 patients and research subjects in a single, searchable repository. Its phenotypic data includes allergy history, demographics, diagnoses, medications, lab tests, imaging reports, and vital signs/findings. These data are further integrated with clinical research databases (e.g. from the ILD Program) and the institutional Biobank data. The Biobank currently stores biosamples from over 2,350 patients/subjects.

Researchers can use the RDB to perform retrospective studies of defined patient populations. They can also gather data for pilot studies, combine data from various collaborative studies, and review medical record information to identify patients who may qualify to participate in future research studies. The RDB also links a rich set of phenotypic data to samples in the Biobank.

The first step in searching the RDB is to request a “*Fishing License*” at <https://rdb.njc.org/r2prd/ep/request.cfm>. This allows you to create queries and get counts. For instance, you could ask “how many NJH patients have lung nodules and have donated blood samples to the BioBank?” As of 12/1/2010, the answer is approximately 380 unique subjects.

If this is a sufficient number of subjects for your research and you want more data to prepare a well-developed protocol, you can request access to the actual data for these subjects through a *Preparatory to Research HIPAA authorization (HIP-018)*, available in the Forms Management site on the Spyderweb.

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How to Access the NJH Research Database when a Different IRB is the IRB of Record

Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

The NJH-IRB has received a number of inquiries about institutional requirements for access to protected health information (PHI) for research studies approved by external IRBs. Access to the RDB or medical records could be for such purposes as recruitment or supplemental information from a subject's medical record.

The process to access these resources for external IRB approved studies is similar to the process currently used for NJH-IRB approved studies. That is, when wishing to access PHI from the RDB for recruitment or supplemental data, research staff may use the *Supplemental Access to NJH Repositories form*. Submit requests for approval to me in Room M109.

When a waiver of authorization might be needed, such as when screening potential subjects for a study, the *IRB Waiver of HIPAA Authorization (HIP-020)* should be completed. Upon completion both of these forms, they should then be sent to me for

review. During the process of reviewing these completed forms, I may need to review the IRB application, the informed consent document or the protocol. I will request these as necessary. When I approve these forms, I will send them to you and the appropriate repository manager.

While implementing this process, I may have to modify it as I become more familiar with the research community's needs and my continued review of the HIPAA regulations to determine what is required and how can we best meet compliance requirements without creating too many bureaucratic hurdles.

For more information, contact:

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How to Complete the Continuing Review Report Form for Data/Specimen Studies

Deb Clayton, MA, IRB Regulatory Affairs Monitor

When conducting a chart review or using data obtained from the National Jewish Health Research Database, it is sometimes confusing as to what enrollment information should be reported at continuing review.

In the study status box of the report, you should check all of the boxes that pertain to the study on which you are reporting. Also, check the "Other" box and list the data source in the blank provided.

If the IRB approved an actual number of charts or cases that could be reviewed, enter that number in the total approved for enrollment. If no number was specified, enter "N/A."

In the cumulative enrollment table, enter the number of charts and/or data that were reviewed during the review period. That number should be

added to the previous enrollment total reported for the new cumulative total.

If demographic information is provided in the data source, that should be reported as you would report for a study enrolling actual subjects. If that information is not collected, leave the demographics tables empty and note that the information is not collected in the last section of the report form.

Feel free to call anytime with any questions! Have a great 2011!

For more information, contact:

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On the Compliance Radar

Sherri Gabbert, PhD, Clinical Research Quality Assurance Analyst

The RDB at National Jewish Health makes it easier and more secure to access data and banked specimens for secondary research purposes. One feature of the RDB is the ability of RDB staff to act as “honest brokers” for datasets that require subject specific PHI and/or updating over time.

What’s an honest broker? An honest broker can be an information system or an individual or a combination of both. The honest broker is positioned between human specimens and data sources and the researchers to control access to subject PHI and protect the privacy of subjects while facilitating research. Importantly, the honest broker must have no conflict of interest for any research project using the RDB.

The RDB is structured to be an automated honest broker that compiles data but it also assigns an anonymous subject ID, an ASID, to each patient/subject which can be used to populate a coded dataset. The ASIDs used to create the dataset are linked to PHI. The ASID list or “code key” can be retained by an RDB staff member who would provide updates at the request of the researcher. In this case, the RDB staff member who retains the ASID list used to generate the

dataset acts as an honest broker. Here’s the punch line: this arrangement results in a dataset that constitutes non-human subject research!

What are the advantages to researchers working with data and/or specimens? Faster, safer access to identified, clinically annotated data that can be updated for as long as the research is active. The RDB is already IRB-approved and the researcher can designate an RDB staff member – okay, it’s Pearlanne Zelarney – to act as the honest broker for their research. The researcher can then submit to NJH IRB for a non-human subject determination based on the use of an honest broker – okay, Pearlanne.

There are plans being developed to expand this service within the RDB in anticipation of increasing demand for clinical data necessary for clinical-translational grant awards.

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IRB Education Schedule

Deb Clayton

Please join the National Jewish Health IRB for the following educational sessions. The schedule was revised:

01/11/2011	Non-Human Subjects Research	Sherri Gabbert, PhD	10:30 - 11:30 am
02/01/2011	Research vs. Nonresearch	Wendy Charles	10:00 - 11:30 pm (90 min)
03/01/2011	Investigators’ Responsibilities in Research: Two Physician-Researcher Perspectives	Richard Weber, MD & Phillip Corsello, MD	10:00 - 11:30 am (90 min)
04/05/2011	Conflicts of Interest in Research and how they are Managed		10:30 - 11:30 am
05/03/2011	Informed Consent: Policy, Process and Documentation (includes: exculpatory language and subject compensation)	Deb Clayton	10:00 - 11:30 pm (90 min)
06/07/2011	Unanticipated Problems	Wendy Charles	10:30 - 11:30 am

All sessions are in Heitler Hall.

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