



On The Research Subject



A Newsletter from the Johns Hopkins GCRC Research Subject Advocate Program

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From the Program Director

The GCRC as an Institutional Resource

by Christopher D. Saudek, M.D.

Let's step back and take a long view of the GCRC. It is an "institutional" resource, meaning that it belongs to no one investigator and no one department. Its overall mission is to provide infrastructure that supports outstanding clinical investigation.

We favor protocols that are investigator-initiated and have outside peer-reviewed sources of funding, but we can support investigators who are working toward future outside support, and

also industry-initiated research (the latter billed to the industry sponsor).

Within the academic health center, the GCRC is one of the few federally supported programs that is *not* specifically tied to a given department, project, disease or investigator. So the GCRC has a special role to play.

How does this "institutional infrastructure support" turn into real benefits to the individual clinical investigator? Let me count the ways:

- **Space:** You don't have to worry about borrowing or renting clinical exam rooms. The out-patient GCRC spaces (adults on Carnegie 3 behind the Moore Clinic, Pediatrics as part of the PCRU) are well-equipped and attractive. Drop by anytime to see these well-designed facilities.
- **Staffing:** Each of the GCRC units: out-patient and in-patient, adult, pediatric and Kennedy-Krieger's NBRU, are staffed by trained, competent and enthusiastic research staffs. They work with investigators or individual research coordinators to assist in any way they can. Phlebotomy, vital signs, questionnaires, even Dexa scans. They don't recruit or schedule subjects, but they provide other excellent services.
- **Admissions:** For approved investigator-initiated studies, the GCRC actually supports the entire costs of research admissions. This was the original mission of GCRCs in the 1960's, providing a haven where investigators could admit without fear of insurance hassles or sacrificing research protocol implementation to demands of clinical care. While out-patient research has increased, we continue to support over 1,000 in-patient days a year.
- **"Ancillary" Testing:** The GCRC pays for regular laboratory and other tests done as part

of approved protocols. We cannot support an investigator's own laboratory or a specialized research test not available to patients in general; but this leaves a very large number of ancillary tests that we do support.

- **Biostatistical Consulting:** An outstanding team of biostatisticians, led by Dr. Josef Coresh, are available to discuss all of your statistical concerns. Don't just come to them for t-testing or power calculations—use them also for in-depth consideration of study design, hypothesis testing and so on. They speak our language.
- **Computing Facilities:** Mr. David Holmack runs an outstanding computing facility, available to help you set up data storage capabilities and any number of other computing needs.
- **Nutrition:** Ms. Susan Oh and her excellent staff can help you prepare dietary elements of a protocol and then pay for and implement the diets. No protocol with a nutritional aspect is too small or too large for them.
- **Imaging:** Many imaging studies are supported by the GCRC, with the NBRU at Kennedy Krieger's fMRI being the most advanced and available.
- **Human Subjects Advocacy:** With the plethora of questions and requirements related to human subjects, our Human Subjects Advocate, Ms. Susan Bonura (also editor of this news sheet!) and her new staff member, Jeannette Catalano, can help you navigate through the complexities. Give them a call.

And so you see, the GCRC is an institutional, cross-departmental resource; and, it is an infrastructure. And it has the potential to provide you, the individual investigator, with exceptional resources tailored to your specific needs, which will assist you in completing your study and furthering scientific discovery. Use us!



GCRC Requirements

An Exchange

by Gerald Stacy, GCRC Administrator

In exchange for the services and facilities offered by the GCRC to investigators, as described in Dr. Saudek's article above, we require specific forms and documents throughout the course of your study. Initially, we request a GCRC application, full protocol, copies of awards, contracts, other funding, and initial IRB approval notice with IRB stamped consent forms. During the course of your study, we request copies of any IRB documents, including protocol revisions/amendments, changes to the consent forms, quarterly reports to the WIRB, annual renewals for the JHM IRBs and the BSPH CHR, adverse event reports, data and safety monitoring reports, and protocol deviation or violation reports. Annually, we request a summary of your project including any publications, number of subjects enrolled to date, and updates to your funding/other support. At the conclusion of your study, we request that you credit the GCRC in publications.



From the Office of Human Subjects Research

New Issues: Research MRI Screening for Metal/Metal Exposure

Skull x-rays are now required for all studies which include MRI if the subject indicates possible exposure to metal (metalworkers, welders, etc.). If the MRI is for research only,

the radiation exposure of the x-ray changes the review procedure for the study and the protocol must be reviewed by the Radiation Safety Committee.

The PI has two options:

1. Exclude all individuals who say “yes” to possible exposure to metal (via protocol amendment), OR
2. Amend the protocol by describing a screening process for exposure to metal and the added risks of radiation involved in the skull x-ray. These changes must be made to both the protocol and consent form.



From the Vice Dean for Clinical Investigation

Studies Involving Stored Blood and Tissues

by Michael J. Klag, M.D., M.P.H.

There has been an explosion of interest in studying blood and tissue specimens associated with specific diseases and with disease and aging processes. This is an exciting field of research and conduct of such studies will bring great advances in care and treatment. As exciting as the research is, however, it is imperative that investigators collect specimens under IRB approved protocols and conduct future research on existing specimens in a protocol that the IRB has approved and is HIPAA compliant.

The JHM IRBs and WIRB have seen an increase in the number of applications that appear to involve collection and storage of blood or tissue for future unspecific research, but the application neglects to provide adequate information to allow the IRB to judge the appropriateness of the

future research. Often, a consent form references collection or storage of specimens, but the protocol lacks a description of the plans to study the specimens, how long they will be stored, and whether there are limits to future testing that would be done on the material. The flip side is found in applications that provide appropriate detail in the protocol about collection and storage of specimens for future research, but the consent form lacks this information.

I wish to remind you that both the protocol and the consent form must explain procedures for future study of blood and tissue specimens when this activity is part of the project. Please review your applications before submission to make sure that the protocol and consent forms are consistent in this area. In addition, under HIPAA requirements, future research involving stored specimens may not proceed without the subject's privacy authorization for the future research (approved at Hopkins by the IRB) or a waiver by the IRB of that subject's authorization for the future research.

If you have any questions about this topic, please contact staff in the Office of Human Subjects Research or a member of the JHM IRBs for assistance.

JHM IRB Guidance for Clinical Investigators



JHM IRB Routine Monitoring Visits

The Office of Human Subjects Research was expanded in 2004 to include a Compliance group. This group consists of the Regulatory Team and Monitoring Staff. The Compliance

group will plan monitoring visits of research protocols approved by the JHM IRB 1-5. The visits primarily are intended to ensure the conduct of approved research at Johns Hopkins proceeds according to the approved protocol. Routine visits will be conducted periodically. For complete information on study monitoring by The Office of Human Subjects Research, see: <http://irb.jhmi.edu/Guidelines/MonitoringVisits.html>.



Ask the RSA

An excerpt from the FDA Information Sheets on Screening Tests Prior to Study Enrollment

For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. While the investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research.

Informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research.

For complete guidance from the FDA, see:

<http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening>.



The Investigational Drug Service (IDS)

Research: How the Pharmacist Fits In
by Kathleen Truelove, RPh
Investigational Drug Pharmacist

The Investigational Drug Service (IDS) at the Johns Hopkins Hospital has two principal divisions: oncology and non-oncology. The Oncology Center's IDS has a staff of 4 pharmacists and one technician and is located in the Weinberg Building. The non-oncology component, the Research Pharmacy, is located in Osler 100, right across from Hurd Hall, with a staff of 7 pharmacists and one technician. The Research Pharmacy includes the AIDS Clinical Trials Group pharmacist, Andi Weiss, and Hye Kim, who works with the HIV Vaccine Trials Network. We work with drug studies all over the hospital, and even some around the country and around the world! IDS pharmacist Vivian Rexroad works with Hopkins projects in Uganda, India, and Ethiopia, setting up and supervising local research pharmacies. Vivian is also a member of the School of Public Health's IRB. Another IDS pharmacist, Kathleen Truelove, is a member of the School of Medicine's IRB -1 and both Vivian and Kathleen are liaisons from the hospital's Pharmacy and Therapeutics Committee to their respective IRBs.

All inpatient drug studies must be dispensed by the pharmacy and are coordinated by IDS, which directly dispenses the study drug for some and sets up procedures for the inpatient pharmacies

to dispense for others. How is it determined whether the IDS or an inpatient pharmacy dispenses drugs for a particular study? The only studies dispensed by the inpatient pharmacies are those in which subjects are enrolled on an emergent basis, such as stroke, MI, infection, or sickle cell crisis, or other reasons why support is needed during “off – hours”. Investigators may control and dispense their own drug for outpatient drug studies if the drug is packaged in a patient specific manner and no manipulation is required. An example would be tablets packaged in numbered, patient specific kits. For studies where the investigator controls the drug, IDS audits drug storage, labeling, and record keeping. Such audits are conducted when the study is first submitted to the IRB, after the first couple of subjects have been enrolled, and subsequently at yearly intervals until a final audit when the study is over.

Research pharmacists can also assist investigators with preparation of randomization schemes and blinding drug, especially for investigator initiated protocols. Drug information sheets for study subjects is another service offered, along with one on one, in - person counseling for subjects in regard to issues such as potential side effects and adherence to the drug regimen.

In summary, our mission is to provide pharmacy support to Hopkins investigators. If we can be of help, please contact us. For the oncology IDS, the phone number is 2 - 1036; for non – oncology, the Research Pharmacy’s phone number is 5 – 6337.

Revised HIPAA Web Site

The Johns Hopkins HIPAA website has been updated and redesigned to be more operationally focused and user friendly. Please visit the new site—you may learn something you didn’t previously know.

<http://www.insidehopkinsmedicine.org/hipaa/>



Helpful Hints for Successful Protocol Submission

New Submission Deadlines

by Shernice Madison, Administrative Assistant

The application deadlines for both the Adult and Pediatric Protocol Review Subcommittees (PRS) have been revised. The new deadlines for the remainder of 2004 are as follows:

ADULT PRS

- August 18
- September 22
- October 20
- November 17

PEDIATRIC PRS

- July 27
- August 31
- September 28
- October 26
- November 30

The deadlines for the **NBRU PRS** remain the same and are as follows:

- July 27
- August 31
- September 28
- October 26
- November 30



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