



On The Research Subject



A Newsletter from the Johns Hopkins GCRC Research Subject Advocate Program

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From the Program Director

The Research Subject Advocate Program
by Christopher D. Saudek, MD

First, my congratulations to Susan Bonura, the GCRC Research Subjects Advocate (RSA), for putting together this Newsletter. And to Drs. Jim Casella and Wendy Post, RSA Faculty Advisors, for developing the program so effectively with Susan.

There is no question that in coming years there will be closer and closer scrutiny of issues surrounding participation of human subjects in clinical research. A moral philosophy and a science have developed around the conduct of clinical research, looking far more thoughtfully at issues such as coercion, risk/benefit, consent

and conflict of interest. No doubt a mountain of paperwork has also developed. But we are lucky to have an RSA program funded to help all investigators at every step.

While it is impossible to eliminate risk altogether, in research or in life, it is essential to minimize risk, and imperative that research subjects understand for what they are volunteering. The GCRC staff and the RSA will help investigators design the best protocol, go through peer review of that protocol and consent forms, and see that the paperwork is in order. The RSA will work in close contact with the IRBs. Susan Bonura will also be developing programs (such as this Newsletter) to help the people who actually do the consenting and implement the protocols work in an effective, compassionate way.

Last spring, we were visited by the Director of the GCRC programs from the NIH, Dr. Anthony Hayward. He described the RSA program nationally as 75 individual experiments, by which he meant that each GCRC around the country could fashion its own program and see what works. We feel we have designed a viable, productive RSA program here at Hopkins, one we will be proud to show as a model of its kind.

In less than a year, the GCRC will submit our five-year competitive renewal, and have our major site visit. A few investigators will present their work at a site visit next November, but every protocol will be reviewed, and I have no doubt that the reviews will focus most specifically on human subjects issues. So we will need your help in seeing to it that each of your protocols has all the i's dotted and t's crossed, all the human subjects questions

thoroughly answered. Any imperfection in this section of your protocol puts you in jeopardy as well as the whole GCRC.

The Research Subjects Advocate program is designed to help each of us meet all the human subjects and regulatory requirements. So I encourage you to bring your human subjects questions or problems to Susan Bonura, and to see that as individuals and as a GCRC, we are doing everything possible to run ethical, excellent clinical research.



Current Issues in the GCRC

by Florence Perry, GCRC Administrator

The GCRC at Johns Hopkins Hospital has seen its share of change since our successful competing renewal in 1998. We've grown considerably during this grant cycle, and are in many ways a stronger GCRC.

Our next renewal is due October 1, 2003, followed by a site visit November or December 2003. The most important component of our success is the caliber of our investigators. You make us one of the strongest, largest, and most successful GCRCs in the country. As we begin our 42nd year of funding, we are depending on our investigators to help us secure another successful renewal. This will involve reviewing your Human Subjects sections as requested by our RSA, Susan Bonura. We also encourage you to use the facilities, and get the protocols humming. So enroll, admit, schedule, and keep up the good work you do. And when you publish, don't forget to cite the GCRC grant, M01-RR00052 from the National Center for Research Resources/NIH.



Ask the RSA

by Susan Bonura, MPA, CCRP

On May 17, 2001, the NCCR stipulated that each GCRC have a Research Subject Advocate (RSA).

The role of the Research Subject Advocate is to assist investigators with human subjects' protection, consent forms, and compliance issues. All adverse events and severe adverse events are to be reported to the RSA at the same time they are reported to any of the JHM IRBs or to the WIRB. The RSA will conduct occasional study audits to help investigators assure total human subjects compliance.

The RSA program is supported by **Jennifer Morrow**, the RSA secretary, who tracks consent form status, human subjects training, and the protocol review process.

The primary responsibility of the Research Subject Advocate is to provide assurance to the Principal Investigator of the General Clinical Research Center that appropriate efforts are being made throughout any clinical research activity at the GCRC to protect the participating individuals and to ensure that their safety receives the highest priority.

Other RSA responsibilities:

- Ensure that the IRB- and GAC-approved monitoring plan is fully implemented and that the protocol carried out at the GCRC complies with the IRB- and GAC-approved protocol.
- Ensure that GCRC investigators send expedited adverse event (AE) reports in a

timely fashion to the IRB, GCRC and appropriate Federal agencies.

- Track and review all AEs with RSA faculty advisors:
 - ✚ James Casella, M.D., Professor of Pediatrics and Oncology
 - ✚ Wendy Post, M.D., Assistant Professor, Cardiology
- Help investigators come into compliance with the requirements.
- Perform audits as requested.
- Review all new protocols: pediatric, adult and NBRU for human subject safety issues.
- Ensure the GCRC application includes the appropriately completed human subjects section, especially inclusion of women, children and minorities and Data and Safety Monitoring Plans.
- Ensure the GCRC application includes the Targeted/Planned Enrollment Table.
- Ensure the GCRC application includes a proposed or approved consent.
- IRB approval is obtained before research can be conducted in the GCRC (Adult In-patient - Osler 5, Adult Out-patient - Carnegie 3, PCRU - Blalock 3 and NBRU - Kennedy Krieger).
- Attend all GCRC Advisory Committee (GAC) meetings.
- Attend all Protocol Review Subcommittee (PRS) meetings: Adult, Pediatric, and NBRU.
- Remind Principal Investigators and study coordinators of expiration dates (consent and protocol) in order to ensure that research is not conducted in the GCRC on expired protocols.
- Request and review updated human subjects' information for the 2003 continuing grant renewal.
- Observe the consent process and educate investigators and study coordinators on the requirements for informed consent.
- Develop standard operating procedures for the RSA position.

- Develop and distribute brochures explaining the RSA program to research subjects.
- Communicate effectively with investigators and study coordinators.
- Assist patients or staff with the resolution of any patient or staff generated questions regarding participation of human subjects in studies.

We welcome investigators to take advantage of the important resource our Research Subject Advocacy program provides. Contact Susan at 4-2717.



Helpful Hints for Completing a GCRC Application

by Jennifer Morrow, RSA Secretary

1. When submitting a new GCRC application, make sure that you submit all of the required parts. (Application, protocol summary, human subjects section, etc...)
2. Read the Application Instructions.
3. Follow the new format for the Human Subjects section.
4. Make sure that you have used the proper format for the protocol summary and that all of the sections have the proper headings.
5. Double check the Targeted Enrollment Table to make sure that the numbers add up correctly.

PRE-REVIEW SERVICES AVAILABLE

The RSA would be glad to review any consent forms and research proposals and suggest changes prior to review by the IRB, if an investigator so desires. This may be particularly helpful if the study involves vulnerable populations, or is likely to raise complex human subjects protection issues. To speed the review, Investigators are encouraged to review their proposals with the RSA in time for revision before submission to the GCRC review committee.

Contact: Susan Bonura, RSA
Phone: (410) 614-6323
Fax: (410) 614-7610
E-mail: susanb@jhu.edu

**Principal Investigator & GCRC Advisory Committee Chairman:**

Michael J. Klag, M.D.
 Vice Dean for Clinical Investigation

Program Direction:

Christopher D. Saudek, M.D.
 (410)955-2132
csaudek@jhu.edu

Michael Cataldo, Ph.D.
 (443) 923-2850
cataldo@kennedykrieger.org

Charles W. Flexner, M.D.
 (410) 955-9712
flex@erols.com

Michael A. Levine, M.D.
 (410) 955-6463
mlevine@jhu.edu

Pamela L. Zeitlin, M.D., Ph.D.
 (410) 955-2035
pzeitli@jhmi.edu

Administration:

Florence C. Perry
 (410) 614-2717
fperry@jhu.edu

Neurobehavioral Research Unit
 Bridget Johnson
 (443) 923-2852
johnsonb@kennedykrieger.org

Nurse Managers:

Adult Outpatient Unit
 Phyllis Pentz, RN, BSN
 (410) 614-2244
ppentz@jhu.edu

Pediatric Clinical Research Unit
 Mary Ann Sartain, RN, MSN
 (410) 955-5245
Msartain@jhmi.edu

Adult Inpatient Unit
 Erin Turner, RN, MSN
 (410) 955-5875
eturner2@jhmi.edu

Research Subject Advocate:

Susan Bonura, MPA, CCRA
 (410) 614-6323
susanb@jhu.edu

Research Nutrition Manager:

Susan Oh, MS, MPH, RD
 (410) 955-5189
susanoh@jhmi.edu

Informatics Systems Manager:

David G. Holmack
 (410) 955-0409
david.holmack@jhu.edu