



# On The Research Subject



A Newsletter from the Johns Hopkins GCRC Research Subject Advocate Program

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ethical clinical researcher. We are lucky, as clinical investigators, to be engaged in one of the most important, ethical and valued of professions. We should look on the changing regulations and requirements not as obstacles but as a new part of the fabric of excellent clinical research. Let's embrace the new rules and get on with the research.



## Current Issues in the GCRC



## From the Program Director

An Approach to Compliance  
by Christopher D. Saudek, MD

Guidelines, requirements, documentation, legislation... and now HIPAA. It makes the head spin. But the GCRC has people who can help you. Susan Bonura, the Research Subjects Advocate, reviews the Humans Subjects sections, and is available to advise you or even to walk you through what's needed. Flo Perry is also a source of good advice and encouragement on HIPAA issues. Both Susan and Flo are reachable at 4-2717.

I suggest that we approach these compliance issues without losing the broader view, which is that the essence of ethical clinical research is the

HIPAA and Clinical Research  
by Florence Perry, GCRC Administrator

It's been heading our way for some time now, and it's almost here. Clinical investigators are encouraged to review the HIPAA training module as soon as possible. If you wait until April, you've waited too long. PIs with active protocols enrolling participants on or after April 14<sup>th</sup> will be required to create an Authorization for Use and Disclosure of Health Information for Research form and have it reviewed and approved by the IRB before April 14<sup>th</sup>. There are new requirements surrounding research databases as well.

Please be certain to review the web site, <http://www.insidehopkinsmedicine.org/hipaa/>, or the JHM IRB web site, <http://www.hopkinsmedicine.org/irb/jhmirb/> for details.



## Advice from the RSA Faculty Advisor

An Approach to Compliance  
by James Casella, MD

In the inaugural newsletter from the GCRC Research Subject Advocate (RSA) Program, Chris Saudek, M.D., and Susan Bonura, the RSA, combined to describe this new position, created by the National Center for Research Resources (NCRR). It is worth taking a minute to expand a bit on why this new position was mandated, as it is important to carrying out the intended mission of the RSA. As the Hopkins community is well aware, the role of human subjects in biomedical research has come under increasing scrutiny over the last few years. Traditionally, issues regarding human subjects have been considered to be the province of Institutional Review Boards (IRBs); however, in 1998, a report by the Office of the Inspector General of the Department of Health and Human Services concluded that IRB review and informed consent requirements might not guarantee adequate protection for human subjects. In a recent letter to GCRC Principal Investigators, Anthony Hayward, the Director of the Division of Clinical Research, NCRR, commented that the RSA position was created “in response to public concern over the safety of participants in clinical trials.”

Clearly, a number of forces are creating an impetus to take a fresh look at how human subjects are protected in clinical trials, and the GCRC sees the RSA position as one opportunity to move in the direction of innovation. The RSA (also called Data and Safety Monitor at some institutions) is charged with ensuring that all

reasonable steps are taken to maximize the safety of clinical trials. This includes being familiar with all federal regulations and policies that govern human research. The RSA is expected to assist investigators with maintaining compliance with these regulations and policies. The RSA is responsible for making sure that all protocols conducted in the GCRC have a data and safety monitoring plan that is approved by the GCRC advisory committee, and that all adverse events are reported promptly to the IRB and Federal agencies.

At Hopkins, we have asked the RSA to be particularly sensitive to always taking the perspective of the patient. Many people will read a consent form, for example. The RSA is charged with looking at how the individual will perceive their experience in the study, based on reading this important document, as well as ensuring that all aspects of human safety are clearly explained. In the event that something goes awry, the RSA should be available to meet with the patient and investigators as necessary, to address concerns, and facilitate resolution of any problems. With time, we plan to begin to look at new ways to ensure that descriptions of research are actually understood by patients in the way that they are intended.

As with many newly created positions, there is the potential for overlap, or the appearance of overlap, with existing personnel and institutional bodies. In the worst case, this can be perceived as increasing the bureaucratic load for the investigator. This is something we are continually striving to avoid, and will need ongoing investigator input to succeed in doing so. For example, comments by the RSA are prepared on all GCRC protocols undergoing review. These comments are first reviewed with the protocol review committee and its chairman, after which they are forwarded to the investigator as part of the protocol review committee letter to the investigator. In this way, we hope that the investigator will not feel the effects of two serial,

possibly conflicting reviews, and have the need to respond to both. This also allows any human subject safety issues to be discussed in the presence of individuals with a variety of expertise. In our early experience, we have found that having many eyes look at the same situation is more an advantage than a disadvantage in the case of human subjects concerns. In the event of serious disagreement with the committee, the RSA will have the authority to address human subjects' issues directly with the investigator. Throughout the process, we must continue to consider human subject safety as an integral part of the research, and resist any urge to see the review of human subjects' issues as an administrative add-on.

When should you make use of the RSA? We would hope that the RSA would come to mind in any case where an investigator has concerns regarding human safety issues, or needs assistance in preparing human subjects sections or reporting adverse events occurring in the GCRC. The RSA is continuously available for "pre-review" of protocols and human subjects sections prior to full scientific review of the application by the protocol review committee, in much the same way that statistical pre-review is now offered by statisticians. This may be particularly helpful in cases where there are high risks in a given protocol, or when vulnerable populations are to be studied.

We are lucky to have a highly energetic and capable RSA in the person of Susan Bonura, and the services of Wendy Post, M.D., the other RSA Advisor, and I encourage all GCRC investigators to use Susan's services to improve and facilitate our clinical research activities at Hopkins. Please let us know if any of you have suggestions about how to continue to develop this important position.



## *Ask the RSA*

Women, Minorities and Children  
by Susan Bonura, MPA, CCRP

Public Law 103-43 requires that women and minorities be included in clinical research studies. This law further specifies that women and minorities be included in Phase III clinical trials and these trials must be designed to permit valid analysis. Cost is not allowed as an acceptable reason for exclusion of women and minorities. NIH will support outreach efforts to recruit and retain women and minorities and their subpopulations in clinical studies.

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research is available at [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm)

It is the policy of NIH that children (i.e., individuals under the age of 18, per Maryland state law) must be included in all human subjects' research, conducted or supported by the NIH (i.e., all GCRC studies), unless there are scientific and ethical reasons not to include them.

Proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

Please refer to the full policy, available on line at [www.nih.gov/grants/guide/notice-files/not98-024.html](http://www.nih.gov/grants/guide/notice-files/not98-024.html) for complete details.



## Helpful Hints for Completing a GCRC Application



by Jennifer Morrow, RSA Secretary

1. If you have any questions while you are filling out the application, call us and we will try to help you. Don't just guess.
2. Make sure that you are using the correct version of the application, protocol summary and human subjects section.
3. Provide us with an electronic version of the protocol summary and human subjects section when you submit your application. You may either e-mail them to us or put them on a disk.
4. Check the deadlines for submission and try to get everything to us as soon as possible.
5. Make sure that you give us the correct number of copies.

### PRE-REVIEW SERVICES AVAILABLE

We would hope that the RSA would come to mind in any case where an investigator has concerns regarding human safety issues, or needs assistance in preparing human subjects sections or reporting adverse events occurring in the GCRC. The RSA is continuously available for "pre-review" of protocols and human subjects sections prior to full scientific review of the application by the protocol review committee, in much the same way that statistical pre-review is now offered by statisticians. This may be particularly helpful in cases where there are high risks in a given protocol, or when vulnerable populations are to be studied.

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