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Science Awards (CTSA), this program envisions “transformational” changes in how universities organize their clinical research activities.

The underlying objective is to provide a “home” for clinical research and clinical researchers within institutions. The perception of Dr. Elias Zerhouni, Director of the NIH (and previously our own GCRC Principal Investigator) is that clinical research activities throughout universities across the country have become too diffuse, too unfocused. Dr. Barbara Alving, now Director of the NCRRI at the NIH, is leading this new initiative on behalf of Dr. Zerhouni. She spent a day visiting us last spring.

The new program asks each institution to apply for one large grant that will combine a series of previously unconnected clinical research activities. The emphasis is on a strong educational component, strong on bench-to-bedside (“translational”) research, interconnectedness and innovation.

The previously independent programs that will become part of the CTSA at each university include the GCRCs, degree-granting programs (in our case the GTPCI), and several other large grants that promote teaching in clinical research. Hopkins is fortunate to already have all the grants that will join together into the CTSA, so our challenge will be to put them together in innovative ways, to organize them so that the whole is much more than the sum of their parts.

Over the next five years or so, the NIH vision is that as many as 60 institutions around the country will be awarded CTSA grants. Each of the existing grants, such as the GCRCs, will become a part of these CTSA programs.



## From the Program Director

### **A New Day for Clinical Research**

by Christopher D. Saudek, M.D.

In mid-October, the NIH issued a Request for Applications that will in essence change the landscape of clinical research for decades to come. Called the Clinical and Translational

Needless to say, there is a great deal of creative thinking and planning stimulated by this new CTSA program here at Hopkins and throughout the country. We feel we are well positioned to take advantage of the new opportunities, and that our university has always stressed positive, collaborative interactions. We look forward, therefore, to the new day in clinical research. It will be different and challenging; but we forecast that it will be bright and sunny for Johns Hopkins.



## Current Issues in the GCRC

### Welcome Dr. Ford

by Gerald Stacy  
Administrative Manager

I am pleased to announce the appointment of Daniel E. Ford, M.D., M.P.H., as the new Principal Investigator for the GCRC. Dan accepts this role as part of his new position as Vice Dean for Clinical Investigation.

Dan is a pioneer in patient-oriented research associated with the interrelationships between mental disorders, particularly depression, and chronic medical conditions. His work has been recognized internationally and his clinical studies have documented depression as an independent risk factor in developing coronary heart disease and describing the long term health risks related to sleep disturbances.

Dan was recently selected by the Robert Wood Johnson Foundation to direct the evaluation of its \$12 million Depression in Primary Care Initiative. He is one of the few generalists who have served on National Institute of Mental Health clinical review groups. For 12 years, Dan has been the Principal Investigator of a training

grant to develop researchers in general internal medicine and he has been a leader in using the Internet for clinical research.

In 1982, Dan came to Hopkins as an Osler resident, joining the faculty of the Division of Internal Medicine in 1988. He holds joint appointments in Psychiatry at the School of Medicine and in Epidemiology and Health Policy and Management at the Bloomberg School of Public Health. He has authored more than 120 publications and book chapters and has served as the associate editor of the *Journal of General Internal Medicine* and as a member of the editorial board of *General Hospital Psychiatry*.

Dan served the GCRC in the past as a member of the adult protocol review subcommittee and as a member of the GCRC Advisory Committee. We are extremely fortunate to have someone of Dan Ford's caliber to fill the shoes of Mike Klag, who has been honored with the appointment as Dean of the Bloomberg School of Public Health. Please join me in supporting Dan in his new role as Principal Investigator for the GCRC.



## From the Vice Dean for Clinical Investigation

### IRB Monitoring Information Sessions

by Daniel E. Ford, M.D., M.P.H.

The Office of Human Subjects Research compliance monitoring program began in June 2004. Over 50 IRB approved protocols have been reviewed by the compliance monitors since that time, and there are several trends that have surfaced during the visits. I am pleased to announce that an educational session has been developed to provide an overview by the compliance monitors of issues that occur during the conduct of an IRB approved research project.

Tips on surviving a monitoring visit, either by the internal monitors or by an FDA inspector, will be provided. The one hour session will be held on Thursday, November 10, 2005, in the Broadway Research Building (BRB) Room G01, at 1:30 p.m. We look forward to seeing you on the 10th, as feedback from attendees will assist us in developing future information sessions.



## Ask the RSA

### Health Literacy Month

by Jeannette Cooke, RSA Assistant

October is Health Literacy Month<sup>1</sup>, which means it is the perfect time to learn what it is, who it impacts, and how to improve it. Health literacy is not only the ability to read health information (consent forms, insurance policies, etc.), but also the ability to understand and use health information to make appropriate healthcare decisions<sup>2</sup>. Limited health literacy is linked to poor health status, which is why improving health literacy has become part of the national agenda<sup>3</sup>. In fact, improving health literacy is an objective under the larger focus area of health communication in *Healthy People 2010*, with the goal being to use communication strategically to improve health<sup>4</sup>.

Approximately 90 million Americans, have difficulty understanding and using healthcare information<sup>5</sup>. Limited health literacy can be experienced by anyone who uses the healthcare system; even healthcare professionals can have limited health literacy in areas outside their specialty. Certain groups are more at-risk for having limited health literacy, including those individuals that have poor basic literacy skills and low socioeconomic status<sup>5</sup>. The elderly, minorities, and immigrants may be affected<sup>5</sup>.

Other factors that can impact health literacy are cultural factors, certain health conditions, experience with the healthcare system, and the level at which health information is communicated<sup>5</sup>.

Most health information is written at the 10<sup>th</sup> grade level while the average American reads at an 8<sup>th</sup> grade level<sup>2</sup>. There is often a mismatch between the level at which physicians communicate and the level at which patients comprehend, which can lead to medication errors and adverse outcomes. In fact, medication errors and hospitalizations related to low literacy cost the healthcare system \$50 to \$73 billion per year<sup>2</sup>. Individuals with limited health literacy are not likely to use preventive services and practice health promoting behaviors, which increases the likelihood of illness and contributes to these costs.

Health literacy not only impacts clinical care, it also impacts research. In research, the most important exchange of information occurs during the consent process, which is ongoing throughout the study and involves not only the consent form, but also a discussion of the study. During the initial consent process, participants are provided with information about the study and asked to decide whether or not they want to enroll. Participants with limited health literacy may not understand the information that is presented to them, which could impact their decision to participate. For example, participants may not understand randomization and think that by joining the study they will receive the study drug, when really there is a chance they will not. This puts pressure on researchers to not only present information to participants in an understandable way, but also assess whether the participants did, indeed, understand the information<sup>6</sup>. The key to improving health literacy is to improve communication<sup>2,3,4,5</sup>.

The first step to improving health literacy in research is to write a consent form according to the JHM IRB guidelines, which can be found at

<http://irb.jhmi.edu/Guidelines/informedconsentguidance.html>. The JHM IRB suggests that the reading level of a consent form should be no higher than an 8<sup>th</sup> grade reading level and instructions are available on their website for checking the readability of a consent form using Microsoft Word. Check the following website for alternative words to use when preparing consent forms: <http://www.stanford.edu/dept/DoR/compliance/h/s/medical/glossary.html>.

If the study involves multiple visits, a lengthy consent form, or complex procedures, researchers may wish to create supplemental materials to use along with the consent form, such as a chart, timeline or calendar visually showing the course of the study visits or a simple picture showing how a study procedure is performed. Supplemental materials could also include a brochure that highlights the risks of the study and the procedures. Information for creating understandable printed material can be found at <http://www.hsph.harvard.edu/healthliteracy/materials.html>. Researchers may want to provide participants with the research brochure created by the Office of Human Research Protections, available at <http://www.hhs.gov/ohrp/outreach>, which details the questions participants should ask. Remember to obtain IRB approval for all supplemental materials.

Besides creating appropriate consent forms and supplemental materials, researchers should gauge participants' understanding of the study, both before and after the study is discussed. The consent dialogue should be started by asking participants what they already know about the study and why they want to join the study. This dialogue gives researchers the opportunity to correct any misconceptions or expectations participants may have. Before participants sign the consent form, use the teach-back method to determine if participants really understand the study<sup>2</sup>. The teach-back method is essentially asking participants specific questions about the

material reviewed, such as the side effects of the study medication. Review any aspects of the study that participants have not understood. During the discussion, remember to allow plenty of time, speak slowly, use plain language, and encourage questions<sup>2</sup>. For more information on obtaining "truly" informed consent visit: [http://informedconsent.disted.mcw.edu/PI\\_RTM/default.htm](http://informedconsent.disted.mcw.edu/PI_RTM/default.htm).

The RSA Program in the GCRC is always willing to provide guidance on writing consent forms and to serve as an independent witness during the consent process. We have an IRB approved pamphlet on all GCRC units available to inform research subjects of their rights and the role of the RSA. We have the American Medical Association literacy toolkit, which you can review at our office in Carnegie 446 or by visiting <http://www.ama-assn.org/ama/pub/category/9913.html> for an electronic version. The RSA is working with the School of Nursing to put the finishing touches on a new consent training course, which will cover how to write an appropriate consent form and the communication process that needs to take place in order to obtain informed consent. The course is expected to be available in November. Please contact us for more information regarding any of the services offered by the RSA Program. The Committee on Human Research in the School of Public Health is having a lecture on December 7<sup>th</sup> from 12:00 PM - 1:30 PM in Room W3030 on "Meeting Health Literacy Challenges in Informed Consent". To learn more about health literacy and improving communication visit the following websites: <http://www.hsph.harvard.edu/healthliteracy/index.html>, <http://www.aed.org/ToolsandPublications/iom/>, and <http://www.plainlanguage.gov/>.

#### References:

1. <http://www.healthliteracy.com/hlmonth/>
2. <http://www.ama-assn.org/ama/pub/category/9913.html>

3. <http://www.ets.org/Media/Research/pdf/PICHEATH.pdf>
4. <http://www.healthypeople.gov/document/HTML/Volume1/11HealthCom.htm>
5. <http://www.nap.edu/books/0309091179/html>
6. <http://irb.jhmi.edu/Guidelines/informedconsentguidance.html#consent17>



## Helpful Hints for Successful Protocol Approval

### **Protocol Review Subcommittee Deadlines** by Shernice Madison, Administrative Assistant

Please be reminded of the remaining 2005 deadlines for review of new applications by the GCRC's Protocol Review Subcommittees:

#### Adult Protocol Review Subcommittee

November 16<sup>th</sup> for the December 7<sup>th</sup> meeting  
December 14<sup>th</sup> for the January 4<sup>th</sup> meeting

#### Pediatric Protocol Review Subcommittee

November 22<sup>nd</sup> for the December 13<sup>th</sup> meeting  
December 20<sup>th</sup> for the January 10<sup>th</sup> meeting

#### Neurobehavioral Research Unit Subcommittee

November 29<sup>th</sup> for the December 13<sup>th</sup> meeting  
December 27<sup>th</sup> for the January 10<sup>th</sup> meeting

#### SKCCC CRO Subcommittee

The CRO reviews new protocols weekly.

Before submitting your application, check the GCRC website to ensure that you have used the most recent version of the application. See <http://www.hopkinsmedicine.org/gcrc/> for further information including the number of copies to be submitted.



### **COMING SOON! - CHR Online Submission**

The CHR is about to enter the era of electronic submission, review and management of research projects involving human subjects with the introduction of PHIRST – Public Health Institutional Review, Submission & Tracking! Their new online system will make all aspects of the CHR process easier and more efficient. Stay tuned in the coming months for updates and details about PHIRST as they become available.

### **Enrolling Wards of the State in Human Subjects Research**

CHR is currently drafting policy for enrolling children who are wards of the State in human subject's research. HHS regulations require that an independent advocate that will act in the best interest of the child be involved in research that is greater than minimal risk and has no direct benefit. The requirement for an independent advocate is also required for certain other research involving children as wards of the State that is only approvable by the Secretary, DHHS.

Until CHR policy is final, you must contact CHR prior to enrolling any child who is a ward of the State. If foster children are already enrolled in a CHR approved study, please notify CHR as soon as possible.

CHR staff will provide guidance on the Federal requirements as they apply to research involving foster children.

### **Revised CHR Application and Research Plan Template**

The CHR application and research plan

templates have been revised. Please check the CHR website to make sure that you submit the most recent CHR application to ensure that your application is complete. Incomplete applications will not be processed and will cause a delay in reviewing your application. The most recent version of the application can be found at the following web address: <http://www.jhsph.edu/CHR/AppsForms/>.



### **Request for Public Comment on Draft OHRP Guidance Document**

The Office for Human Research Protections (OHRP) is soliciting public comment on a draft guidance document for Institutional Review Boards, investigators, research institutions, Department of Health and Human Services agencies that conduct or sponsor human subjects' research, and other interested parties, entitled, "Guidance on Reporting and Reviewing Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others." See <http://www.hhs.gov/ohrp/requests/com101105.html>.

Comments should be submitted by 1/13/06 to OHRP by email at [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov). Please include the term "Draft guidance on reporting adverse events" in the subject field.

Comments may also be submitted by mail to:

CAPT Michael Carome, M.D.  
 U.S. Public Health Service  
 Associate Director for Regulatory Affairs  
 Office for Human Research Protections  
 1101 Wootton Parkway, Suite 200  
 Rockville, MD 20852

### **Frequently Asked Questions (FAQs) to Clarify Issues Related to Research Involving Children**

OHRP announces the availability of a new set of Frequently Asked Questions (FAQs) to help clarify issues related to research involving children. These FAQs can be accessed from the OHRP's Policy and Guidance page under the header "children," then "Research with Children FAQs"

<http://www.hhs.gov/ohrp/policy/index.html>.

The FAQs may also be accessed from the HHS homepage (<http://www.hhs.gov>), by selecting "Questions" at the top right of the page and then on the "Questions and Answers" page under the "Category" drop-down menu, selecting "Human Research," and sub-menu, selecting "Research With Children."

OHRP plans to continue expanding the number of FAQs on human subject protection issues.

### **Guidance on Institutional Review Board Review of Clinical Trial Websites**

OHRP has issued guidance on Institutional Review Board (IRB) Review of Clinical Trial Websites,

<http://www.hhs.gov/ohrp/policy/clinicaltrials.html>. The guidance, which applies to HHS-conducted or -supported research, describes the circumstances for which IRB review of clinical trial websites is required and provides some points to consider in the review process. It also describes the circumstances for which IRB review of clinical trial websites is not required.

The guidance document can be accessed from the OHRP website Policy and Guidance page, <http://www.hhs.gov/ohrp/policy/index.html> under the guidance topic, Clinical Trial Websites.



### **WIRB Guide for Researchers**

The Western Institutional Review Board (WIRB) provides "A Guide for Researchers" containing general information about conducting research and using WIRB for review of research. The information is intended to provide practical guidance about submission questions, IRB review and oversight, as well as other topics that

may be of interest to investigators and research staff. The guide can be accessed at the WIRB website ([www.wirb.com](http://www.wirb.com)) under the "Info for Investigators" tab.



**JOHNS HOPKINS**  
M E D I C I N E



# Make that consent informed!

November 11 & 18, 2005  
8:00 am – 12:15 pm

"Make that consent informed!" is a full day program, offered over 2 consecutive mornings. It is designed to provide practical skills, knowledge, and resources for those administering the informed consent process.



**Register Soon!  
Space is Limited.**

## Course Objectives

- Recognize the importance of informed consent in protecting human research volunteers.
- Understand the ethical principles of informed consent
- List the elements of a legally effective informed consent
- List the components of the consent process.
- Develop standard operating procedures for managing the consent process.
- Practice obtaining informed consent.
- Identify special consenting situations and create appropriate solutions.
- List resources for current informed consent research and changes in policy.

## Who should attend?

- New research coordinators
- Any member of a research staff with responsibility for obtaining consent
- Seasoned research coordinators who want a refresher
- Supervisors of research staff who will be obtaining consent

## Date and Time

Fridays

November 11 & 18, 2005

*Attendance both mornings and submission of a newly created consent form are required for course completion.*

8:00 am – 12:15 pm

## Cost \$500

Includes Continental breakfast each day and optional use of the JHU SON computer lab on designated day.  
JHU employees may use tuition remission.

## Location

Johns Hopkins University  
School of Nursing  
525 N. Wolfe Street  
Baltimore, MD 21205

To register for the **Make that consent informed!** or to find out more about the Research Coordinator Training Program, please go to:

<http://www.ijhn.jhmi.edu/ResearchCoordinator>

If you have additional questions, contact us at:

RCTP@son.jhmi.edu / 443.287.4745 voice / 410.614.8972 fax

The program is jointly sponsored by The Johns Hopkins University Schools of Nursing, Medicine, and Public Health and is administered by The Institute for Johns Hopkins Nursing



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