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by William R. Brody, M.D., Ph.D.

As you know, Johns Hopkins is an institution founded for the betterment of human life and funded through philanthropy and the public trust. Everything we do rests on Hopkins' unimpeachable reputation for integrity. We all, therefore, have a responsibility to conduct ourselves in an ethical manner. It is important that you never hesitate to come forward if something does not seem right to you. If you have knowledge of, or suspect, unethical or illegal behavior, call the Hopkins Compliance line at 1-877-932-6675 (1-877-WE-COMPLY).

I ask that you carefully review the following revised Statement of Ethical Standards and diligently observe the standards it outlines.

It is essential that the faculty and staff of the Johns Hopkins University maintain the highest standards of integrity and ethical conduct, both in fact and in appearance.

The following principles are the standards of ethical behavior required of Johns Hopkins University faculty and staff.

1. Faculty and staff are expected to obey all federal, state and local laws, including, but not limited to, those pertaining to equal opportunity, non-discrimination and harassment.
2. Faculty and staff must abide by the University's Conflict of Interest Policies and its Conflict of Commitment Policies.
3. Faculty and staff must maintain the confidentiality of information as required under University policies or applicable law, including the confidentiality of



From the
University
President

Johns Hopkins University Statement of Ethical Standards

personnel, student and patient medical records, and proprietary information.

4. **Faculty and staff members may not accept gifts or entertainment that might influence their decision making or compromise their judgment. Faculty and staff should not accept gifts, hospitality, favors or entertainment with a value of more than \$100 from any vendors who have current or pending business arrangements with the University, over which that person has authority or influence. If they are uncertain about the value of an offer or whether the offer can be accepted under this policy, faculty and staff should consult with their immediate supervisor. Ordinary business courtesies, such as occasional business lunches (which should be well below \$100 in cost), are excluded from this policy.**
5. **Faculty and staff should report ethical standards violations as indicated in the relevant University policies; or by contacting the Office of Internal Audits or the Office of Vice President and General Counsel; or by calling the Hopkins Compliance line at 877-932-6675 (877-WE-COMPLY).**
6. **Retaliation against an employee who has in good faith reported an alleged unethical practice will not be tolerated.**

Questions concerning ethical behavior should be directed to one's supervisor, the Office of Internal Audits, or the Office of Vice President and General Counsel. Supervisors seeking guidance should contact these same offices.



From the Vice Dean for Clinical Investigation

The Course on Research Ethics (C.O.R.E.)
by Daniel E. Ford, M.D., M.P.H.

The Johns Hopkins School of Medicine has supported an institution-wide initiative to make certain we conduct clinical research that is scientifically sound and protects the human subjects who are our partners in clinical research. One component of this initiative has been the completion of the accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Another component has been to have all faculty and trainees involved with clinical research complete the Course on Research Ethics (C.O.R.E.).

C.O.R.E. covers issues such as scientific integrity as well as the protection of research subjects. Factual information is covered in the course, but the course also gives us one of the rare opportunities to interact with colleagues from other departments and to reflect on our research. The course format consists of a web-based pre-conference knowledge assessment, a four-hour instructor-led course consisting of lectures and small group discussions, and a post-conference web-based portion to provide practical information on the ethical issues involved in research protocol development and implementation.

All Principal Investigators of active IRB protocols must complete this course **by June 30, 2006**. We are giving you substantial notice because the course dates and class size are limited. We cannot accommodate everyone in the last few months. To make this process as smooth as possible, please register for one of the course dates listed below. Registration is

handled by of the Office of Continuing Medical Education (CME).

All courses are held from 8 am – 12:30 pm in the Turner Concourse. Remaining courses are:

Wednesday, April 19, 2006
 Wednesday, May 31, 2006
 Friday, June 30, 2006



Ask the RSA

Non-Compliance in Research

By Susan Bonura, Research Subject Advocate

Are you a research coordinator? Have you identified issues which you feel should be reported as non-compliance in research? Are you aware that there is a process for reporting issues of non-compliance in research?

The institutions have established an avenue for reporting such concerns. It's the Johns Hopkins Compliance Line, an independently administered, toll-free anonymous hot line at **1-877-WE COMPLY (1-877-932-6675)**. See also <http://hrnt.jhu.edu/compliance/?SMSESSION=N>. You may also report non-compliance to the IRB at 410-955-3008.

The JHM-IRB has posted new policies which describe how issues of non-compliance are addressed by the IRB. See the *Organization Policy on Investigator Non-Compliance* at http://irb.jhmi.edu/Policies/103_7.html and the *Organization Policy on Complaints from Research Participants, Investigators and Research Staff, the Community, etc.* at: http://irb.jhmi.edu/Policies/109_3.html.



Helpful Hints for Successful Protocol Approval

Current Hints

by Shernice Madison, Administrative Assistant

1. Be sure to check the GCRC website for the latest version of our application:
<http://www.hopkinsmedicine.org/gcrc/>
2. Call with your questions prior to finalizing your application. Our main number is 4-2717. The Research Subject Advocate can be reached at 4-6323. The Administrative Assistant for protocol review can be reached at 5-5176.



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New Newsletter on Patient Safety Available

On Guard is a monthly newsletter about patient safety for employees of Johns Hopkins Medicine. *On Guard* is a different kind of publication that's lifting the veil on how patients have been harmed and sharing the lessons learned from these incidents and what we're doing to prevent them from recurring. Read the latest version online at:

<http://www.insidehopkinsmedicine.org/safety/on-guard/>.



FDA Announces Exploratory IND Guidance

FDA is providing guidance on how to conduct exploratory IND studies. These types of studies are prior to phase I studies and involve very small amounts of drugs, fewer subjects and hopefully less risk. To access the guidance, see: <http://www.fda.gov/bbs/topics/news/2006/NEW01296.html>

Amendment Request Form

An Amendment Request Form, is now available on the CHR website, and must be completed and submitted to the Office for Research Subjects when requesting an amendment(s) to approved research studies. To access the form, see: <http://www.jhsph.edu/chr/AppsForms/Forms/Request%20for%20amendment.doc>

DAID Requirement for Research Involving Children

DIADS (Division of AIDS), NIAID requires documentation of the IRB designation of a risk/benefit category for studies involving children. The documentation will be required to complete DAID's protocol registration for all research involving children or adolescents and applies to all new and continuing reviews by the IRB.

The CHR statement of approval includes this designation for studies involving children and adolescents it reviews. The CHR approval letter may be submitted to DAIDS in support of this requirement.

Enrolling Foster Children in Research

Enrolling foster children involves special consent requirements. CHR is currently drafting the policy for research involving foster children. Until finalized, SPH investigators who wish to enroll foster children must first contact CHR for specific guidance before proceeding to enroll foster children.

Office for Research Subjects Brown Bag Series

The Office of Research Subjects (ORS) offers monthly presentations and open conversation from 12:15-1:15 p.m. The Brown Bags are informal talks connecting the ORS with faculty, staff and students who conduct human subject research.

The next presentation will be held on Wednesday, March 29th, Room W3008. The topic will be Introduction to PHIRST: Public Health Institutional Review Submission and Tracking: The New Electronic Database for Submitting Applications to the ORS. The presenter will be Stephanie Gaudreau, Education Coordinator, ORS.

For additional information on these Brown Bag lectures, see: <http://www.jhsph.edu/chr/NewsAnnounce/BrownBag/default.html>.



New Human Subject Protections Resource Page

Visit the Office of Human Research Protection's new human subject protection resource page at <http://www.hhs.gov/ohrp/related.html>, to find links to reference documents, historical materials and Common Rule departments and agencies.

OHRP encourages all in the research community to use this reference page.

Continuing Education Events

OHRP is co-sponsoring the following unique education events during 2006:

- Tuesday, May 16 in Notre Dame, Indiana: *Bridging the Regulatory Gap Biomedical & Social/Behavioral Research Are Closer Than You Think.*
- Thursday and Friday, June 1 and 2 in Denver, Colorado: *Special Populations/Special Research Situations.*
- Monday and Tuesday, September 25 and 26 in Durham, North Carolina: *Crossing the Line: How Much Risk is Acceptable?*

Details about these events can be accessed at: <http://www.hhs.gov/ohrp/education/conference.html#upcoming>.



Information Sheet Guidance Initiative

The U.S. Food and Drug Administration announced its Information Sheet Guidance Initiative to update its process for developing, issuing and making available guidance intended for institutional review boards (IRBs), clinical investigators, and sponsors. You can learn more about the information sheet guidance initiative and the newly revised information sheets by visiting *In the News* at www.fda.gov/oc/gcp.

Clinical Trial Data Monitoring Committees

FDA has announced the availability of a second draft guidance document entitled "Guidance for Clinical Trial Sponsors: Establishment and

Operations of Clinical Trial Data Monitoring Committee." This draft guidance addresses the roles, responsibilities, and operating procedures of DMCs, and describes certain reporting and recordkeeping responsibilities including the following: (1) Sponsor notification to the DMC regarding waivers of expedited reporting, (2) DMC reports of meeting minutes to the sponsor, (3) sponsor reporting to FDA on DMC safety-related recommendations, (4) standard operating procedures (SOPs) for DMCs, (5) DMC meeting records, and (6) DMC reports to the sponsor.

A copy of this draft guidance can be found at <http://www.fda.gov/OHRMS/DOCKETS/98fr/01d-0489-gdl0002.pdf>. For more information about this draft guidance and/or to comment on this draft guidance, please visit <http://www.fda.gov/ohrms/dockets/>, the FDA Docket Management web page.



2006 Initial Review Submission Form Available

The revised version of the WIRB Initial Review Submission Form is now available on the web at http://www.wirb.com/shell.php?content=content/quick_download_forms#1.

The following changes have been made to the form:

- questions have been eliminated
- the "additional sites" listing has been broken out onto its own page
- the signature line on the last page has been eliminated
- question 1f has been added for investigators who do research at

institutions which have special requirements for their WIRB studies

- question 32, regarding audio-visual materials, has been changed
- human subject protection training requirements in question 10 have been updated

The WIRB will continue to accept the 2005 version of the form until March 31, 2006. Beyond that date, submitters will be asked to complete and submit the 2006 version.

Investigator Confirmation of Board Requirements

DHHS regulation 45 CFR 46.109(d) states “An IRB shall notify investigators and the institution in writing of modifications required to secure IRB approval of the research activity....” Based on this regulation, effective October 1, 2005, investigators approved for new research studies are required by WIRB to confirm their acceptance of the requirements imposed by the Board. No action is required for studies approved prior to October 1, 2005.

For further information about these new requirements, contact Client Services at clientservices@wirb.com.



SAVE THE DATE: Friday, June 2, 2006
4th Annual ACRP Chapter Symposium

The popular Baltimore/Washington Chapter of ACRP Symposium date has been announced. The 4th Annual Symposium will be held on Friday, June 2, 2006 at the Columbia Hilton in

Columbia Maryland. Topics include new technologies and their impact on research, globalization of clinical research, recruitment of minorities, informed consent readability, and hidden costs in research. This symposium is sure to be informative and an excellent networking opportunity. The agenda and registration forms will be available soon. For more information, contact Deborah Grady at DGRADY@epi.umaryland.edu, or see <http://www.acrpnet.org/chapters/balt/index.html>.



Adverse Event Reporting for Human Subjects in Research

The next Washington D.C. "National Capital Area" SoCRA Chapter meeting is scheduled for April 10 at 6:30 pm with a “meet and greet” and discussion of chapter business. Speaker begins at 7 pm. RSVP to: mcdonaldc@nmrc.navy.mil. The meeting topic is, “The need for better adverse event reporting for human subjects in research.” A summary of this topic can be found at: <Y:\4-10-06 meeting\Shamoo The Need for Better Adverse Events Reporting DIA Today 05.pdf>. 1 SoCRA CE Credit available. The meeting will be held at the Shock Trauma Auditorium at the University of Maryland Medical Center, Baltimore. For more information, contact SoCRA at SoCRAMail@aol.com



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