




JOHNS HOPKINS  
M E D I C I N E

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Vice Dean for Research

## CLINICAL INVESTIGATION NOTICE

Date: January 12, 2001

TO: Faculty and Staff Conducting Human Subjects Research

FROM: Chi Van Dang, M.D., Ph.D.  
Vice Dean for Research 

RE: Changes in JCCI/JHBMC IRB Guidelines and Forms

The Office for Human Research Protections (OHRP) contacted The Institutions in October 2000, regarding the guidelines of the JCCI and JHBMC IRB. The OHRP requested clarification and changes in the guidelines they believed were required to assure The Institutions were in compliance with federal regulations. In addition, they requested changes in the standard consent form boiler plate section. As a result of our review of OHRP's request, changes in several sections of the guidelines have been made and posted on the Internet. Please review the Guidelines changes that contain the December 2000 revision date. The Guidelines are available on line at:  
<http://infonet.welch.jhu.edu/research/jcci>

The consent form boiler plate language has been changed. The changes include: 1) a new paragraph entitled "Questions About Your Rights as a Research Subject;" 2) the paragraph entitled "In Case of Injury" has been revised; and 3) the Paragraph entitled "Joining of Your Own Free Will" contains the new sentence "If you refuse to join this study, you will not suffer any penalty or loss of benefits to which you are otherwise entitled." There is a new signature line on the consent form. It is to be used in cases where the JCCI/JHBMC IRB approve a study with use of surrogate consent for adult subjects who are not competent to provide informed consent.

The new application form has been revised. The face page states "If funding will be from any federal agency (Public Health Service, DOD, etc.), a copy of the complete grant application must be submitted with this application. The OHRP has taken a strong position on enforcing the regulations that IRBs must review the complete funding application, in addition to review of the protocol. The protocol submitted to the JCCI/JHBMC IRB must match the grant submission, even if portions will not be done immediately. The JCCI/JHBMC IRB will now begin accepting protocol applications and consent forms on a disk, or by e-mail, in Microsoft Word format only. However, electronic submission must be accompanied by a printed, signed first page of the application, as electronic signature ability is not available at this time.

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In September, an announcement was made regarding the NIH requirement for training in human subjects research. At the School of Medicine, this requirement now has been extended to all research projects, regardless of funding source. As of March 1, 2001, all individuals listed on a protocol application (as either an investigator or co-investigator, individuals who are delegated responsibility to obtain informed consent, individuals listed on FDA 1571 and 1572 forms, and individuals who recruit subjects into a research protocol) are expected to have completed the training requirement. The JCCI/JHBMC IRB staff will have the ability to verify training has been completed. Final approval of applications that list individuals who have not completed training will be held by staff until training is verified. The on-line training module is available at: <https://secure.lwserver.net/jhmrcrct>. Federal employees (NIA GRC staff or NIDA staff) who participate in JCCI/JHBMC IRB protocols do not have to complete the SOM training course to fulfill the requirement. Federal employees may meet the requirement by completing the NIH approved on-line training course.

Questions regarding the changes made in the JCCI/JHBMC IRB guidelines or forms, or the training requirement, may be directed to Barbara Starklauf, Assistant Dean/Administrator, Human Subjects Committees, at Ext. 5-3008.

CVD:bls

cc: Legal Counsel – JHHS and JHU  
Administration – JHBMC, JHH, SOM, SON, KKI, HCGH, APL