

UMDNJ

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY HUMAN SUBJECTS PROTECTION PROGRAM (HSPP)

Routine Review of Ongoing Research Activities	Date Issued: May, 2003
	Date Revised: June 26, 2007
Approved by: Executive Director, HSPP	Effective Date: June 26, 2007

I. Purpose

To provide guidelines for the routine audits of all IRB-approved human subjects research activities covered under the *UMDNJ Human Subjects Research: Protection of Human Subjects* policy for which a UMDNJ IRB is the IRB of record.

II. Accountability

Under the direction of the Vice President for Academic Affairs or designee, the HSPP audit staff shall implement these procedures to support the University's responsibility for ensuring compliance with federal and state regulations and Institutional policies governing human subject research.

III. Implementation

- 1) An HSPP auditor will obtain a list of all ongoing, IRB-approved human subjects research and identify a target number of studies on each of the three University campuses of Newark, New Brunswick / Piscataway and Stratford to be scheduled for routine audit.
- 2) A representative number of studies will be scheduled for routine audit on each campus based on the current total of IRB-approved studies. All studies will be categorized as to type of research involved and the general risk to the safety, welfare, or rights of study participants.
- 3) In consultation with each campus IRB Director, priority for routine audit will be given to studies that:
 - a) require either full board or expedited review;
 - b) are clinical trials involving an FDA-regulated product (drug, device or biologic);
 - c) are investigator-initiated research activities; or
 - d) are conducted by faculty or investigators from schools / departments / performance sites not recently selected for routine audit.
- 5) An HSPP auditor shall prepare for the routine review of each study with a review of the full IRB protocol file including initial and continuing review submissions and approvals, amendments and all correspondence to and from the PI, sponsor and IRB. Comparison to the IRB protocol file and IRB-approved protocol as well as adherence to federal regulation,

good clinical practice guidelines & recommendations, applicable state law and institutional policies will serve as the standard against which the routine review is conducted.

- 5) The HSPP auditor will notify the Principal Investigator(s) by sending a *Notice of Review* a minimum of ten (10) days prior to the routine review and arrange a mutually convenient time for review of all appropriate research records including:
 - a) regulatory files
 - b) participant research / medical records: inpatient medical and outpatient clinical / research records of enrolled subjects will be reviewed as necessary, according to the protocol-specific design of each study
 - c) electronic data, where applicable
- 6) The *Notice of Review* to each PI shall request that all participant records, regulatory files and sponsor and IRB correspondence be made available for the routine review of each study.
- 7) An informal pre-review discussion will be scheduled with the Principal Investigator of each study. The PI may include any members of the research staff s/he chooses. The pre-review discussion will include a description of some or all of the following:
 - a) study protocol, procedures and timelines
 - b) study population and any special needs of the research participants within this population
 - c) recruitment and consent processes
 - d) reporting of unanticipated problems / adverse events
 - e) individuals involved in the conduct of the research activities and delegation of duties
 - f) location of research records, research data and source documents
 - g) protections in place to provide for limited access to study data, confidentiality of research records (hard-copy and electronic), and participant privacy
- 8) The HSPP auditor will accompany study staff or the principal investigator on a brief walk-through of the research site and then initiate on-site inspection of study records with a review of the Principal Investigator's regulatory file.
- 9) The HSPP auditor will inspect on-site research records for the presence of / adherence to the following, if applicable:
 - a) a valid, legally-effective, appropriately executed consent form and ancillary documentation
 - b) appropriate recruitment of participants with respect to protocol-specific inclusion / exclusion criteria
 - c) source documentation of protocol-specific study procedures, interventions, study visits, and follow-up
 - d) source documentation of exposure to study drug, device or biologic and outcome
 - e) test-article accountability (drug, device, biologic)
 - f) source documentation of adverse events and unanticipated problems including reports to sponsor, IRB and federal agencies, where necessary
 - g) study-specific site SOPs, departmental research-related SOPs and documentation of PI supervision of the conduct of the study e.g.) in-services or regularly-scheduled research meetings

- 10) The Principal Investigator shall be asked to provide a space for the review of research records and arrange for research staff to be available during the routine review to assist with answers to questions regarding the conduct of the selected study.
- 11) The HSPP auditor will produce a report to the Institutional Review Board following completion of the analysis of on-site data collection.
- 12) Review procedures and results are subject to UMDNJ Institutional policies and procedures.
- 13) Studies currently reviewed by the Western Institutional Review Board (WIRB) shall not be covered under this policy for routine review by the University's HSPP.

UMDNJ will instead receive copies of on-site reviews initiated through WIRB. The Executive Director of HSPP will review and acknowledge receipt of each WIRB report and retain copies of these WIRB reports with study documents filed with the UMDNJ HSPP. The Executive Director shall retain independent discretion to request that UMDNJ's HSPP perform its own directed review, as appropriate.

IV. References

UMDNJ Policies pertaining to Human Subjects Research:

Human Subjects Research: Protection of Human Subjects	00-01-20-90:00
Human Research Subjects: Medical Care	00-01-20-85:00
Investigator Conflict of Interest	00-01-20-89:00

Other pertinent UMDNJ policies:

Access of Individuals to Protected Health Information	00-01-15-10:00
Accounting of Disclosures of Health Information	00-01-15-20:00
Disclosures of Personally Identifiable Health Information to Business Associates	00-01-15-40:00
Facsimile (Fax) Machine Transmittal of Confidential, Sensitive or Protected Health Information	00-01-15-35:00
Protected Health Information: Destruction and Disposal	00-01-15-45:00
Protection of Sensitive Electronic Information (SEI)	00-01-15-50:00
Records Management	00-01-10-50:00
Requests for Amendment of Individual Health Information	00-01-15-25:00
Requests for Restriction of Uses and Disclosures of Protected Health Information	00-01-15-30:00
Research Misconduct	00-01-20-60:00
Standards for Privacy of Individually Identifiable Health Information	00-01-15-05:00
Uses and Disclosures of Health Information with and without an Authorization	00-01-15-15:00

University Research Guidelines:

■ Guidelines for Investigators in Scientific Research

Federal Regulations

Office for Human Research Protections (OHRP)

45 CFR 46

■ **Subpart A:** Common Rule

■ **Subpart B:** Additional Protections for Pregnant Women, Human Fetuses & Neonates

■ **Subpart C:** Additional Protections for Prisoners Involved in Research

■ **Subpart D:** Additional Protections for Children Involved in Research

Food and Drug Administration (FDA) Title 21

■ 21 CFR 11: Electronic Records; Electronic Signatures

■ 21 CFR 50: Protection of Human Subjects, Informed Consent

■ 21 CFR 54: Financial Disclosure

■ 21 CFR 56: Institutional Review Boards

■ 21 CFR 312: Investigational New Drugs

■ 21 CFR 314: FDA Approval to Market a New Drug (NDA)

■ 21 CFR 600: Biologics, general

■ 21 CFR 601: Biologics, licensing

■ 21 CFR 812: Investigational Devices

■ 21 CFR 814: Medical Devices, Pre-Market-Approval (PMA)

■ 21 CFR 860: Medical Devices, Classification Procedures

HIPAA Regulations

■ Privacy Regulations, 45 CFR 160 and 45 CFR 164 (subparts A + E)

■ Security Regulations, 45 CFR 164

International Conference on Harmonisation (ICH) Guidelines

Applicable State Laws and Regulations