



Office of the Vice President For Research
Human Subjects Protections
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DEPARTMENTS: **Institutional Review Boards of the University of Medicine & Dentistry at Newark, New Brunswick-Piscataway and Stratford**

SUBJECT: **Institutional Review Board Requests to the Human Subjects Protection Program for Review of Research Protocols**

Background

To fulfill the mandate of a Federal Wide Assurance filed with the federal Office of Human Research Protections, the University of Medicine & Dentistry of New Jersey has pledged to ensure that the conduct of human subjects research under the auspices of the University shall meet all Federal and Institutional requirements for human subjects protection.

The Institutional Review Boards of each of the three (3) campuses of Newark, New Brunswick-Piscataway and Stratford are obligated to complete a thorough and substantive continuing review of all research. If, at any time during the review of human subject research activities, new information becomes available which is of concern to the IRB as relates to the conduct of human subjects research studies, the Committee is obligated to act upon those concerns.

Purpose

This procedure shall detail the manner in which a request for a review of research stud(ies) from the local Institutional Review Board shall be initiated through actions of the local IRB director and subsequently submitted to the University's Human Subjects Protection program as necessary.

Accountability

Under direction of the Executive Director for Human Subjects Protection, the Directors of each of the three (3) campus Institutional Review Boards shall implement this procedure.

Applicability

These procedures shall apply to all human subjects research covered under the UMDNJ *Human Subjects Research: Protection of Human Subjects* policy.

Procedures

The Institutional Review Boards may at any time request a review on ongoing human subject research.

This shall involve an initial IRB protocol file review and based on this preliminary assessment, the local campus Director may schedule a meeting with the Principal Investigator of the research protocol(s) of concern.

The Director, in consultation with the Chair of the local Institutional Review Board, will refer any additional investigation activities judged necessary to the Office of Human Subjects Protection.

Process for notification of the Human Subjects Protection Program:

- A. The Director of the local campus IRB shall send a written request to the Executive Director of the HSP Program which contains the following information:
1. A description of the nature of Committee concern(s)
 2. A brief history of the IRB review
 3. A copy of the minutes of the corresponding IRB Committee meeting(s)
 4. A summary of the results of the Director's initial inquiry

A standardized short form for requests to the Human Subjects Protection program is attached as an addendum to this procedure statement and will be available to the local IRB Directors on the Human Subjects Protection website at:

<http://www.umdj.edu/hsweb>.

- B. The Senior Analyst of Human Subjects Protection program will then begin a review of the research protocol(s) of concern. This review will be either a full data-point review or a single-issue review and shall be based on the results of the preliminary investigation.

- C. The Senior Analyst of the HSP program, in consultation with the Executive Director, will design a protocol-specific evaluation and will review any / or all of the following materials:

1. IRB Protocol Files
Review will begin prior to the on-site visit. This preliminary data gathering will drive the protocol-specific design of the evaluation.
2. On-Site Research Regulatory Files
3. On-Site Subject Research Records
Review will be designed as appropriate based on a case-by-case evaluation of research-specific IRB concerns.
Inpatient and outpatient clinical medical records and / or research study records of enrolled subjects, as applicable
 - i. Valid, legally-effective consent with appropriate documentation procedures
 - ii. Inclusion / exclusion criteria
 - iii. Screening tests and laboratory results
 - iv. Monitoring and clinic visits
 - v. Adverse events
 - vi. Clinical and / or departmental Standard Research Operating Procedures

Procedures (cont.)

- vii. Research record storage and data handling practices
 - viii. Where investigational drugs and / or devices are part of the research studies, match accountability identified by the principal investigator with all IRB submissions
 - ix. Where behavioral and social science research studies are evaluated, match on-site documentation to the IRB-approved protocol.
- D. Following a preliminary evaluation, the Senior Analyst will notify the IRB Director and the Committee Chair of both a timeframe for completion of the review and a projected date for submission of a draft preliminary summary.
- E. The Senior Analyst of the Human Subjects Protection program will notify the Principal Investigator a minimum of five (5) days prior to the IRB-requested review and arrange a mutually convenient time for the review of all appropriate research records.
- F. A 'Notification of Review' will be sent to the Principal Investigator to confirm the arranged meeting and to request that all subject records, regulatory files and sponsor and IRB correspondence be made available.
- G. The Principle Investigator shall be asked to provide a space for the review of research documents, and arrange for both the PI and his / her research staff to be available during the review to assist with answers to questions regarding the conduct of the research stud(ies).
- H. The Senior Analyst will produce a review report to the Committee within two (2) weeks of the completion of the review of the research protocol(s).
- I. The HSP review report to the Committee will be hand-delivered to the Director of the campus Institutional Review Board, with copies to the Chair(s) of the Institutional Review Board and the Executive Director of the Human Subjects Protection program.
- J. Further review or additional investigation by the Human Subjects Protection program will commence at the request of the Committee through the IRB Director to the HSP program and will follow the same notification procedures as outlined above.
- K. Appropriate notification of and / or preparation of formal reports to all appropriate Federal regulatory agencies and University Institutional Officials will be prepared through the Office of Human Subjects Protection on a case-by-case basis and will be conducted as mandated by the applicable federal regulations and the Institutional Federal-Wide Assurance.
- L. Review procedures and results are subject to the UMDNJ Confidentiality Policies and Procedures.

M. References:

Institutional Policies and Procedures:

Human Subjects Research: Protection of Human Subjects,
00-01-20-90:00
Human Subjects Research: Medical Care,
00-01-20-85:00
Investigator Financial Disclosure and Conflict of Interest,
00-01-20-89:00
Misconduct in Science, 00-01-20-60:00
UMDNJ Guidelines for Investigators in Scientific Research,
revised October, 2002
University Hospital Confidentiality Statement for Information Security

Standards for Privacy of Individually Identifiable Health Information,
00-01-15-05:00
Access of Individuals to Protected Health Information,
00-01-15-10:00
*Uses and Disclosures of Health Information with & without an
Authorization*,
00-01-15-15:00
Accounting of Disclosures of Health Information,
00-01-15-20:00
Requests for Amendment of Individual Health Information,
00-01-15-25:00
*Requests for Restriction of Uses & Disclosures of Protected Health
Information*,
00-01-15-30:00
*Facsimile (Fax) Machine Transmittal of Confidential, Sensitive or
Protected Health Information*,
00-01-15-35:00

Federal Regulations:

Title 45 Public Welfare (DHHS)
Part 46: Protection of Human Subjects
Parts 160 and 164, Subparts A and E:
Standards for Privacy of Individually Identifiable Health Information
Title 21 Food and Drugs
Part 50: Protection of Human Subjects
Part 54: Financial Disclosures
Part 56: Institutional Review Boards
Title 21 Good Clinical Practice
Parts 312 and 314: Investigational New Drugs
Parts 803, 812 and 814: Investigational Devices

Department of Health and Human Services (DHHS) Guidance:

*Protecting Personal Health Information in Research, Understanding the
HIPAA Privacy Rule*, NIH Publication Number 03-5388
Note: Specific Privacy Rule Requirements are found in the relevant laws
and regulations.

N. Signatures:

Prepared by: _____ Date: _____

Susan M. Torok-Rood RN, MSJ
Senior Analyst, Human Subjects Protection
University of Medicine & Dentistry of New Jersey

Approved by: _____ Date: _____

Barbara LoDico BS, CIP
Executive Director, Human Subjects Protection
University of Medicine & Dentistry of New Jersey

Date(s) amended: _____
