



UNIVERSITY POLICY

SUBJECT: ACADEMIC AFFAIRS

TITLE: HUMAN SUBJECTS RESEARCH:
PROTECTION OF HUMAN SUBJECTS

CODING: 00-01-20-90:00

ADOPTED: 11/01/95

AMENDED: 04/18/06

LAST REVIEWED: 04/18/06

I. PURPOSE

To set University policy that will ensure, through the University's Human Subjects Protection Program (HSPP), that human subjects research (1) conducted by UMDNJ faculty, staff, house officers, students or other agents, **or** (2) conducted on UMDNJ premises, **or** (3) otherwise conducted under UMDNJ auspices, is conducted in conformance with all applicable Federal, State and other regulations (including 45 CFR 46,164 and 21 CFR 50, 56), and with the Federal Wide Assurances (FWAs) filed by the University with the Office for Human Research Protections (OHRP). The University's mission includes dedication to the pursuit of excellence in research, including human subjects research; the broader purpose of this policy is therefore to foster and help ensure the ethical conduct of and the attainment of excellence in human subjects research.

II. ACCOUNTABILITY

Under the direction of the President and the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, the Deans and the Executive Director of Human Subjects Protection shall ensure compliance with this policy, and the Research Deans, Campus Institutional Review Board (IRB) Chairs and Campus IRB Directors shall implement this policy through the University's HSPP. The Executive Director of Human Subjects Protection shall implement the HSPP, which includes education and training, IRB review, and monitoring of approved research. The Executive Vice President for Academic and Clinical Affairs or designee shall be the University's Institutional Official under the University's three FWAs.

III. APPLICABILITY

This policy shall apply to (1) human subjects research sponsored by UMDNJ; (2) human subjects research directed or performed by any UMDNJ faculty, housestaff, other employee, student, volunteer or other agent in connection with his or her institutional responsibilities or educational program, whether or not the research is carried out on UMDNJ premises; (3) human subjects research conducted by any individual, regardless of institutional affiliation, using any property or facility of UMDNJ; and (4) human subjects research using UMDNJ's non-public information to identify or contact human research subjects or prospective subjects, regardless of affiliation of investigator or location of the research. This policy shall apply to all such research, regardless of sponsorship or if the research is unsponsored. Only a UMDNJ IRB has the authority to make a final determination of exemption of research from further review.

IV. REFERENCES

- A. Records Management [00-01-10-50:00](#)
- B. Standards for Privacy of Individually Identifiable Health Information [00-01-15-05:00](#)
- C. Access of Individuals to Protected Health Information [00-01-15-10:00](#)

D.	Uses and Disclosures of Health Information with and Without an Authorization	00-01-15-15:00
E.	Accounting of Disclosures of Health Information	00-01-15-20:00
F.	Request for Amendment of Individual Health Information	00-01-15-25:00
G.	Requests for Restrictions of Uses and Disclosures of Protected Health Information	00-01-15-30:00
H.	Facsimile (Fax) Machine Transmittal of Confidential, Sensitive or Protected Health Information	00-01-15-35:00
I.	Disclosures of Personally Identifiable Health Information to Business Associates	00-01-15-40:00
J.	Protected Health Information-Destruction and Disposal	00-01-15-45:00
K.	Protection of Sensitive Electronic Information (SEI)	00-01-15-50:00
L.	Research Misconduct	00-01-20-60:00
M.	Human Research Subjects: Medical Care	00-01-20-85:00
N.	Investigator Conflict of Interest	00-01-20-89:00

V. DEFINITIONS

- A. **Human Subject:** an individual, living or deceased, about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information.
- B. **Research:** systematic investigation designed to develop or contribute to scientific knowledge, including the generation of data for publication.
- C. **Human Subjects Research:** research involving human subjects; the use of human organs, human tissues, human body fluids, human cell lines, and human materials for stem cell research; and the use of clinical records or data derived from clinical records, including individual case reports. Research involving human cell lines obtained from human cell repositories that comply with U.S. Department of Health and Human Services regulations for the protection of human subjects will NOT be subject to this policy; these repositories must have Institutional Review Board oversight under an FWA approved by OHRP, and it must be documented that recipient-investigators are denied access to identities of donor-subjects and to information through which identities of donor-subjects may be ascertained.
- D. **Behavioral Research involving Human Subjects:** research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factor evaluation or quality assurance methodologies.

VI. POLICY

- A. Requirements:

1. The University is responsible for the compliance with all applicable laws and regulations of human subjects research to which this policy applies (see Section III above). Therefore the University and its administrative officers must maintain adequate administrative involvement with and oversight of all policies and procedures relating to this research. This administrative oversight shall be vested in the University's Office of Human Subjects Protection under an Executive Director. The Campus IRB Directors will be responsible for the administrative support of the Campus IRBs which review human subjects research for the schools and units of UMDNJ.
2. All proposed human subjects research to which this policy applies (see Section III above) must be reviewed and approved by a University IRB as established under a UMDNJ FWA. The pertinent Campus IRB for review and approval shall be determined by the investigator's institutional affiliation, appointment, enrollment or employment. However, with the approval of the Executive Vice President for Academic and Clinical Affairs and the appropriate Research Dean, and/or Dean, cooperative IRB authorization agreements with other institutions may be entered into. The HSPP is responsible for working with the requesting investigator/institution to assure that appropriate site visits and reviews are conducted prior to executing an IRB authorization agreement.
3. The Executive Vice President for Academic and Clinical Affairs and the Vice President for Academic Affairs, through the Executive Director of the HSPP and in collaboration with the Research Deans and the Campus IRB Directors, shall exercise administrative oversight of all policies and procedures involved in reviewing, approving, conducting, monitoring and documenting human subjects research in order to ensure that the rights and welfare of human subjects are being protected and that the schools and units of the University are in compliance with their FWAs. This administrative oversight shall consist of the following activities and responsibilities:
 - a. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall be responsible for the development, periodic review and revision of written policies and procedures, including applicable forms, for the conduct of human subjects research covered by this policy, and shall ensure that all individuals proposing and/or performing such research are aware of these policies and procedures. These policies and procedures shall ensure compliance with the requirements for human subjects research set forth in Federal, state and other regulations, in this policy and by the Campus IRBs.
 - b. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the orientation and training of investigators proposing and of all personnel conducting human subjects research covered by this policy. Training designed to enhance the development of high quality protocols shall be encouraged, and training in good research practices and in methods for minimizing risk shall be provided. In addition, the Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall communicate widely the University's policies and procedures for protecting human subjects to department chairs, research administrators, clinical care staff and appropriate institutional officials. A statement of principles, such as the Belmont Report, shall be included in material used in orientation and training, and shall be made part of the Campus IRB policies and procedures regarding human subjects research.
 - c. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall be responsible for the establishment of an IRB under an FWA to review and approve all human subjects research, as defined above, at each campus.

- i. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Director shall ensure that IRB membership is in accordance with Federal regulations, that the Campus IRB conducts an appropriate review of research utilizing the required elements of review and consent, and functions autonomously in accordance with all applicable regulations. The Campus IRBs also shall function as the privacy boards for the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Executive Director of the HSPP shall advise the Campus IRB Directors and Campus IRB Chairs concerning adherence to all applicable regulations, and shall work with the Campus IRB Directors and Campus IRB Chairs to ensure that all applicable regulations are being observed. If the Executive Director of the HSPP or the Campus IRB Chair or the Campus IRB Director is unable to ensure compliance of the Campus IRB with all applicable regulations, he or she shall inform the Executive Vice President for Academic and Clinical Affairs and the Vice President for Academic Affairs, who shall take appropriate action.
- ii. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the appropriate initial orientation and training, as well as periodic continuing education, of current and new IRB members in human subjects research regulations, institutional policies and procedures, and other relevant matters. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall encourage and support the attendance by IRB members at workshops and other educational opportunities focused on IRB functions.
- iii. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the preparation of written procedures and guidelines to be followed by the IRBs when conducting their initial and continuing reviews of research, and for reporting their findings and actions to the investigator.
- iv. The Executive Director of the HSPP in collaboration with the Research Dean and the Campus IRB Directors shall be responsible for providing the IRBs with sufficient meeting space and staff to support their review and record-keeping duties. Designated, confidential storage space to maintain IRB records shall be provided.
- v. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the adequate documentation of IRB activities, including maintenance of all research protocols reviewed (including IRB applications, funding submissions such as grants and sponsor contracts, Investigator Financial & Other Personal Interests Disclosure Forms, sponsor protocols, informed consent documents, etc.), agenda and minutes of IRB meetings, records of continuing review activities (including study modifications, advertising and recruitment activities, adverse reactions and/or adverse events, etc.), copies of all correspondence between the IRB and investigators, and statements of new findings provided to subjects.
- vi. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure that all records pertaining to an IRB-approved protocol are accessible to the pertinent study investigators as appropriate, to IRB members, to authorized

representatives of the sponsor of the research, and to appropriate Federal regulatory agencies.

- d. New applications from investigators wishing to undertake human subjects research, reports of progress of approved research in the frequency prescribed by the IRB, requests for periodic IRB review and for continuing approval, and proposed changes to ongoing protocols shall be forwarded to the Campus IRB by the Campus IRB Director and IRB Staff. The decisions of the IRB and the administrative status of applications shall be communicated in writing to the investigators by the Campus IRB Chair or designee.
 - i. The Campus IRB may require that applications for human subjects research be scientifically reviewed prior to final IRB review.
 - ii. A pertinent school representative, such as the Dean, Research Dean or department chair, shall review all new applications for human subjects research and decide whether the institution will permit the research. Human subjects research may proceed **only** following approval by the Campus IRB, the UMDNJ school or unit, and the research site (hospital, clinic, office, etc.).
 - iii. In addition to the principal investigators, the department chair and Research Deans shall receive certifications of IRB review and approval of all human subjects research.
- e. External regulatory agency (e.g., FDA, OIG) communications and reports, and sponsors' site-visit and monitoring reports about research covered under this policy shall be sent to the Campus IRB Director by the investigator for review by the Campus IRB.
- f. The Campus IRB Chair or designee shall promptly inform the Executive Director of HSPP and the pertinent Research Dean of any significant or material finding or action with regard to the human subjects research being conducted by UMDNJ individuals or on UMDNJ premises, including but not limited to injuries to human subjects or other unanticipated problems involving risks to human subjects or to others. The Research Dean shall promptly inform the Dean. If of sufficient seriousness, the Executive Director of HSPP shall inform the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, the OHRP, and the research sponsor.
- g. Allegations and complaints regarding inappropriate conduct of human subjects research and/or non-compliance by investigators with Federal regulations, institutional policies or IRB requirements shall be reported to the Executive Director of the HSPP, the Research Dean, the Campus IRB Chair and Campus IRB Director, and shall be documented in writing. The Campus IRB Chair or designee shall investigate the facts of any allegation. At the end of the fact-finding process, the Campus Executive IRB shall make a determination of the merits of the allegation. If, after fact-finding, the allegation demonstrates merit, the Campus IRB Chair or designee shall inform the Executive Director of the HSPP and the pertinent Research Dean, and the Campus IRB Director shall undertake a full investigation. After the fact finding and investigative process, if a finding of serious noncompliance is determined by the Campus Executive IRB, the Executive Director of the HSPP shall report such finding to the pertinent Research Dean who shall inform the Dean, the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, OHRP and the research sponsor.

