

## ***Human Subjects Research Policy***

### **WHO MAY BE A PRINCIPAL INVESTIGATOR FOR HUMAN SUBJECTS RESEARCH CONDUCTED AT UMDNJ**

#### ***Definition of Principal Investigator:***

A principal investigator is the individual who assumes full responsibility for a research project, including the supervision of any co-investigators, research assistants, house staff and students. The Institutional Review Board only recognizes one principal investigator per human subjects research study, no matter how many research sites may be involved. Other individuals may be named co-investigators. The principal investigator must possess the expertise, time and commitment to conduct and provide the necessary oversight for all aspects of the study, and must be willing to accept full responsibility for the study. In multi-site studies for which UMDNJ is the coordinating institution, the principal investigator assumes the responsibility for the conduct of the study at each performance site and by each site-specific principal investigator.

#### ***Who may be a Principal Investigator for Human Subjects Research Conducted at UMDNJ:***

The following classes of individual may serve as principal investigator on human subjects studies conducted at UMDNJ:

1. individuals with a paid faculty appointment at a UMDNJ School, other than visiting and per-diem faculty, with the approval of the department Chair; unpaid (volunteer) faculty at a UMDNJ School by exception only, with written justification by the department Chair, and case-by-case approval by the campus IRB Director and IRB Chair

2. individuals in permanent, non-faculty staff positions at UMDNJ, with the approval of the department Chair or pertinent Vice President;
3. students enrolled in a UMDNJ School or Program which has procedures to ensure appropriate close-out of human subjects research on which the student is principal investigator. These procedures include as a requirement for graduation proof of study termination by the IRB. The student's faculty advisor must be named a co-investigator on the study. Students whose School or Program does not have close out procedures in place may only conduct human subjects research as a co-investigator under the supervision of a faculty advisor, who will be named the principal investigator and be held responsible for the conduct of the research and the work of the student.

House staff (interns, residents and clinical fellows) and postdoctoral fellows may not be principal investigators on human subjects studies, but may be named co-investigator under a faculty advisor as principal investigator. The faculty advisor, as principal investigator, assumes all of the responsibilities for the conduct of the research and the work of the intern, resident, clinical fellow or postdoctoral fellow. Exceptions for individual house officers or postdoctoral fellows may be requested by the department Chair to the IRB Director if written procedures are in place to ensure appropriate close-out of the research when the individual leaves the University.

***Responsibilities of a Principal Investigator for Human Subjects Research:***

1. protecting the rights and welfare of the participants;
2. ensuring that the research receives IRB review and approval before any activity begins, including screening procedures;
3. ensuring that all co-investigators and research staff comply with the conditions, findings, determinations and requirements of the IRB;
4. ensuring that all pertinent regulations, laws, guidelines and procedures are observed by all co-investigators and research staff involved in the conduct of the study;

5. identifying all collaborating sites in the protocol, indicating which aspects of the research will take place at each site, and ensuring that there is appropriate IRB review and approval at each site;
6. assuring receipt of IRB approval from all collaborating institutions;
7. ensuring that all co-investigators and study staff submit disclosures of financial and other personal interests in the study to the Research Dean and the IRB;
8. ensuring that the protocol is followed in the conduct of the study, including inclusion/exclusion criteria, number of subjects recruited, obtaining consent, etc.;
9. ensuring that studies receive timely IRB continuing review and approval;
10. obtaining prior IRB review and approval of all changes to the protocol and consent forms, except where necessary to eliminate immediate hazards to subjects or others;
11. reporting to the IRB promptly any unanticipated problems involving risks to subjects or others, and any serious adverse events that are either unanticipated or anticipated;
12. ensuring adherence to all HIPAA requirements;
13. ensuring that the IRB is notified about any monitoring visits or FDA audits in advance of the visit, as well as the results of any such visits.
14. discontinuing all study activities at the end of the IRB-designated approval period;
15. submitting to the IRB all required study-closure documentation upon study completion or discontinuation.