U-MIC TRANSCRIPT
Principal Investigator Responsibilities per the HRPP Operations Manual and the Common Rule

The University of Michigan Human Research Protection Program's Operations Manual addresses the roles and responsibilities of researchers, including principal investigators, or PIs. These responsibilities apply to all University research; depending on the research type, other requirements may apply. Past presentations have outlined additional responsibilities and requirements for research subject to FDA or Department of Defense oversight.

The Operations Manual identifies the following categories of individuals as eligible to serve as PIs:

- non-temporary University faculty and staff
- trainees with mentor sponsorship
- and other individuals whose applications are sponsored by University faculty or staff members

Mentors sponsoring trainees or others should be listed as faculty advisors within eResearch.

The PI has primary responsibility

- for knowing and complying with the Common Rule, as well as Institutional policies and procedures
- and for proper study conduct and the fulfillment of all associated obligations

In order to minimize risks and protect subject rights and welfare, the PI must

- design and implement protocols that comply with ethical principles, regulatory requirements, and Institutional policies
- use procedures that are consistent with sound research design; this involves ensuring
    - that there is a reasonable expectation that the study will answer the proposed question
    - and that anticipated knowledge is sufficiently important to justify the research
- promote equitable subject selection
- whenever possible, use procedures already being performed for diagnostic and treatment purposes
- evaluate resources available at research sites
- protect the privacy of subjects and the confidentiality of data
- and provide additional safeguards for vulnerable subjects

PIs must consult with the IRB to ensure that, before they are initiated, all activities meeting the definition of human subjects research undergo review and approval, unless they are determined to be exempt. They must also cooperate with the IRB in fulfilling their obligations for initial and continuing review,

monitoring, record keeping, and reporting; this involves

- providing all information requested by the IRB in a timely fashion
- conducting research as specified in the IRB-approved protocol
- obtaining advance IRB approval of any proposed changes in the research, unless they are necessary to eliminate apparent immediate risks to subjects
- complying with IRB determinations, including directives to terminate participation in designated research activities
- promptly reporting to the IRB any unanticipated problems involving risks to subjects or others and reporting ORIOs and adverse events according to IRB requirements, as well as addressing changes in the study's risk assessment and conveying newly identified risks in the consent materials
- and reporting any potential noncompliance with applicable laws or regulations or IRB requirements, whether by investigators, research staff, or others

As the Operations Manual states, informed consent is not a single event or document, but an ongoing process. Investigators are responsible for

- obtaining and documenting the consent of each subject (or their legally authorized representative) before research begins, unless the IRB has issued a waiver or alteration of consent or a waiver of documentation of consent
- conveying information in language that is understandable to potential subjects
- ensuring that consent is sought under conditions that minimize the possibility of undue influence or coercion
- and including all required elements of consent, as well as additional elements when applicable

The University of Michigan policy on conflicts of interest is available on the Office of the Provost's web site. As long as financial conflicts are reported and managed or resolved, they do not distort—and may even benefit—the research process. The Operations Manual encourages PIs to follow one simple rule regarding conflicts of interest: When in doubt, disclose.

To fulfill their obligations regarding the conduct of research, PIs must

- perform or delegate to qualified research staff all tasks that are necessary to carry out a study
- provide members of the research team with sufficient information and training to facilitate protocol adherence
- cooperate with evaluations, inspections, and audits performed by authorized external reviewers or internal oversight authorities
- inform the IRB of any disapprovals, suspensions, or terminations of a project
- and create and securely maintain accurate records

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PIs and other members of the study team must complete the Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) Human Subjects module. The PI is responsible for ensuring that the appropriate study personnel obtain their PEERRS certification. The U-M IRBs and other HRPP components provide workshops, seminars, and one-on-one training on a variety of research topics.

Contact the IRB for more information about PI responsibilities.

- http://hrpp.umich.edu/om/Part6.html
- http://irb.umich.edu/policies/facultyadvisors.pdf
- http://my.research.umich.edu/peerrs/

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