



Office of the Vice Provost

Mailing Address:
136 Harrison Avenue
Boston, Massachusetts 02111

Research Administration at Tufts University

Normally, a Tufts Medical School faculty member should submit proposals for funding through the institution at which the research will be done. Faculty members based at affiliated hospitals will normally use the office of research administration at their home hospital for grant submissions and administration as well as for regulatory compliance. Under unusual circumstances, such as when a funding agency will only consider applications from a university, a Tufts Medical School faculty member who is based at an affiliated hospital may make special arrangements with the Office of Research Administration to have the grant administered at Tufts. This will require agreement of the home institution.

Proposals and applications for outside funding of research to be administered by Tufts University must be submitted through the Office of Research Administration. The office will review the terms and conditions of the award to determine that it is something that Tufts can accept and will assure that the proposal meets sponsor requirements.

Research funds are normally disbursed to the institution from which the application was submitted. When funding is approved, the University Office of Sponsored Programs will set up an account from which money will be spent. The PI will be the person with authority to approve expenditures from that account. All expenditures must be in accordance with University policy and sponsor requirements.

The Office of Research Administration is located within the Office of the Vice Provost at 75 Kneeland Street, 9th floor. More information is available on our website at <http://www.tufts.edu/central/research/>

Human Subjects in Research

*Research plans that propose the use of living human subjects, tissues or materials from living humans, or **data on humans** must be reviewed and approved or granted an exemption by the IRB before the research begins.*

Is it Research?

- A systematic investigation
- Designed to develop or contribute to generalizable knowledge
- No bright-line test, factors to consider
- Do you plan to publish the results?
- Can include research development, testing, evaluation, pilot studies
- Err on the side of caution

Are there human subjects involved?

- A living individual ABOUT whom an investigator conducting research obtains
 - data through intervention or interaction with the individual or
 - identifiable private information (includes observation of behavior in non-public setting)

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Are there human subjects involved? (cont'd)

- Does not always require that you interact with a person
 - Identified/Identifiable secondary data
 - Blood/tissue samples
 - Small part in someone else's research that will result in authorship

When can human subject research be exempt from IRB review?

- MUST request exemption from IRB – cannot determine this yourself
- Research conducted in **established or commonly accepted educational settings, involving normal educational practices**. An example of this would be a comparison of the effectiveness of two instructional strategies.
- Research involving the use of **educational tests, survey procedures, interview procedures, or observation of public behavior UNLESS the information is recorded in a personally identifiable way AND disclosure would place the subject at risk of criminal or civil liability or be damaging to financial standing, employability, or reputation EXCEPT when children are subjects**. Passive observation of public behavior involving children is exempt.
- Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior where subjects are **elected or appointed officials or candidates for public office**.
- Research involving the collection or study of **EXISTING data, documents, records, or specimens if the sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers or codes**. Note: Even brief use of identifier or code disqualifies the exemption.
- Research and demonstration programs designed to study, evaluate, or examine **Federal public benefit or service programs** (sponsored by the program/government).
- Taste and food quality evaluation and consumer acceptance studies involving **wholesome foods** without additives or additives or chemicals below established "safe" levels.

When can human subject research review be expedited? Expedited review uses the same standards as full committee review. The difference is that it is done by one committee member outside of regular meeting time and is therefore normally faster.

- Minimal Risk
- Falls in designated categories, for example,
 - Materials have been collected or will be collected for non-research purposes
 - Data to be collected from existing voice or image recording
 - On individual or group behavior characteristics
 - Most survey instruments
 - Minor changes in previously approved research during approved period
 - Continuing review in certain circumstances

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What if there is no federal funding?

- Tufts University's Federal-Wide Assurance requires that all research involving human subjects be reviewed by the IRB. There is no difference between federal and non-federal funded research.

What about student research?

- Same rules apply.
 - If it is research
 - If it involves human subjects
 - If it does not fall into an exempt category
 - It must have IRB review

Continuing Review

- Study must be reviewed at annual intervals (or more often if desired by IRB) for as long as it continues.

Adverse Event Reporting

- Informed Consent form lists risks.
- Reporting to IRB required when an unanticipated risk happens or for serious event.

What is the authority of the IRB?

- The IRB is the only body that can approve human subject research
- Institution can disapprove something that the IRB approves but cannot approve something they disapprove
- Responsible for protecting subjects

Consequences of not going to IRB

- Non-compliance
- Reportable to OHRP
- Suspension of research
- May not be able to publish
- Other sanctions

Research will not be approved unless:

- risks to subjects are minimized;
- risks to subjects are reasonable in relation to anticipated benefits;
- selection of subjects is equitable;
- informed consent is adequate and appropriately documented;
- where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
- where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
- appropriate safeguards have been included to protect vulnerable subjects.

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Informed Consent Normally Includes the Following:

- Statement that the study is research
- Explanation of the purpose of the research
- Expected duration of participation
- Description of procedures
- Identification of any experimental procedures
- Description of any reasonably foreseeable risks or discomforts
- Description of any benefits to the subject or to others that might be reasonably expected from the research
- Disclosure of appropriate alternative treatment or courses of action, if any, that may be advantageous to the subject, including no treatment
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the sponsor, the IRB, their agents, the FDA, or other regulatory agencies.
- For research involving more than minimal risk, an explanation as to whether compensation and/or medical treatment are available in the event of research-related injury. If so, the terms and the compensation or treatment must be detailed and the subject must be given the name and number of a person not directly involved in the conduct of the study to contact in the event of injury.
- The name of a person to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact if the subject sustains injury.
- A statement that participation is voluntary, that the subject may discontinue participation at any time, and that refusal to participate or withdrawal will not involve a penalty or loss of benefits to which the subject is otherwise entitled.
- Statement, when appropriate, that the study may involve risks that are known or currently unforeseeable.
- Any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research, including whether such costs may be billed to a third party payor.
- The consequences of the subject's decision to withdraw from the research and procedures for safe and orderly termination of participation.
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue to participate, will be provided to the subject.
- The approximate number of subjects involved in the study.

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Vulnerable Populations

- Federal regulations require that special consideration be given to protecting the welfare of particularly vulnerable populations:
 - Children
 - Prisoners
 - Pregnant women
 - Decisionally impaired persons
 - Economically or educationally disadvantaged persons
- In general, must be minimal risk or possible direct benefit.
- Special safeguards in informed consent.

Responsibilities of Investigators

- Obtaining IRB Approval
- Protecting Human Subjects
- Adhering to Highest Ethical Standards
- Complying with Regulations
- Following Prescribed Protocol
- Using Approved Version of Consent Form
- Keeping Accurate and Complete Records
- Protecting Privacy
- Present Consent Form in Manner Conducive to Understanding
- Report Adverse or Unexpected Events

For more information or to contact the IRB administrator, please consult our website at <http://www.tufts.edu/central/research/HumanCare.htm>

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