

Institutional Review Board

User Guide

Overview:

The Institutional Review Board (IRB) reviews human subjects research at The University of Massachusetts Dartmouth (UMD). Principal Investigators (PIs) planning to conduct human subjects research must prepare an IRB application and research proposal for review. The IRB reviews full board research; exempt and expedited research are reviewed "in house" by the Office of Institutional Compliance. When a study is approved an approval letter is sent to the PI by email. Studies are typically approved for a one-year period. The IRB must approve *any* changes or amendments to an approved study before the researcher implements such changes. PIs wishing to continue research beyond their one-year approval time period must submit a continuing review. If a continuing review is not received by the study expiration date, the study is suspended. Research cannot proceed during the suspension period. However, a continuing review can be submitted during this time. After 30 days a suspended study is terminated or expired. A terminated study is permanently closed.

Defining Human Subjects Research:

The definitions below are the starting point for anyone attempting to determine whether their research requires IRB review or not.

The *first* question to ask is if your project involves human subjects:

Human Subject means a *living individual* about whom the investigator conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information ([45 CFR 46.102F](#))

The *second* question is if your project is actually research as defined by the Common Rule:

Research means a *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities ([45 CFR 46.102d](#)). For more information see the [Office for Human Research Protections](#).

If the answer to both questions is "yes," then you need IRB approval to conduct research. If the answer to one of the questions is "no," then ask yourself these questions:

- Does the activity involve a new drug or a new use for an approved drug (including over-the-counter drugs)?
- Does the activity involve a new medical device or a new use for an approved medical device? (Note that medical devices generally include devices intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, and devices intended to affect the structure or any function of the body of humans or other animals.)
- Will data be submitted to the FDA or held for their inspection?

If the answer to one of the above questions is "yes," then you will need IRB approval to proceed.

[Click here for expedited categories](#)

 [Human Subject Regulations Decision Charts](#)

IRB approval is required before conducting research, expedited or full board research. OIC approval is required before conducting exempt research.

Training:

In order to conduct research, all investigators must complete a training program online.

Please go to www.citiprogram.org to begin your training. If you have not previously logged on, you must register by using the University of Massachusetts – Dartmouth as your participating institution and creating a user name and password. After registering you will be able to select your curriculum. Under the “Select Your Curriculum” category you will be required to answer questions 1, 2, and 4 in order to choose which course applies. Once you have chosen a course that applies to your category of research, click “Continue” and under “My Courses” click “Enter” to begin your training. These courses will take 4 to 6 hours to complete. After completing your course, citiprogram.org will forward your certification to the institution. Your certification will be valid for 3 years and you will be notified by e-mail when you need a renewal.

Faculty Sponsors & Student Research Projects (Thesis, Dissertation, Honors Thesis, Undergraduate Projects):

A faculty sponsor is required for all students conducting human subjects research. Your faculty sponsor must approve your application prior to IRB submission, and remember that your faculty sponsor is your primary contact for human subject concerns and questions.

Exempt Research:

There are several categories of research that are exempt from this policy. Even though exempt research does not require formal IRB review, exempt research must still be submitted to the OIC for approval.

PIs that will be conducting exempt research should complete the Exempt Application. PIs should email the completed application, consent documents, site letters, questionnaires, survey documents, and any other attachments to the Office of Institutional Compliance (OIC) for review.

Exemption determinations are valid for one year. Prior to implementing any changes or modifications, the PI must obtain OIC approval for the amendment(s). PIs who wish to continue their research projects beyond the first year are responsible for submitting continuing reviews before the one-year expiration date.

[Click here for exempt categories](#)

Expedited and Full Board Research Proposals:

PIs that are conducting non-exempt research must complete to the OIC a research proposal. The research proposal consists of the following documents: the completed IRB application, the research protocol, consent forms, site letters, questionnaires, surveys, interview questions, etc.

Expedited review does not require a full convened IRB meeting and is done administratively by the OIC in conjunction with the IRB committee. Non-exempt, minimal-risk research is eligible for expedited review.

Studies requiring full board reviews are greater than minimal risk. Full board review is a convened meeting of the institutional review board to review research proposals. PIs conducting full board research should budget six to eight weeks for IRB approval because of the complicated process in reviewing research proposals.

Timeline:

Different types of studies have different timetables for review. For example, expedited and exempt studies are reviewed as received by OIC. Exempt studies, posing minimal risk to human subjects, take approximately 2-3 weeks to approve from the date received by OIC. Expedited studies take approximately 2-4 weeks to approve from the date received by OIC. It is important to remember that both exempt and expedited studies are reviewed "in house." Therefore, the full board meeting and agenda dates and deadlines are not applicable to exempt and expedited studies. Full board studies are reviewed monthly. Each meeting has a corresponding agenda deadline. A study must be submitted on or before the agenda deadline to be reviewed by the board at that month's meeting.

Notification of determinations reached at the full board meetings are mailed to PIs within two weeks after the meeting date.

Site Letters:

Research conducted upon private-premises or off the UMD Campus likely requires approval of the host site. The site letter must grant permission for the researcher to conduct research at that site. The letter should be as formal as possible (use letter head). The letter should be signed by a party responsible for research and/or the conduct of similar activity at the site. For example, school district letters are typically signed by the superintendent for schools in that district. Letters from private institutions should be signed by a director, executive, owner, or other appropriate official.

[Click Here For Site Letter Template](#)

Informed Consent:

Investigators shall give the human research subject sufficient opportunity to consider whether or not to participate for the purpose of minimizing the possibility of coercion and undue influence. Investigators also cannot waive liability in consent forms. In addition, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The basic elements of informed consent include:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and to whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject

may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

[Click Here For Informed Consent Templates](#)

Waiver of Informed Consent:

The IRB may waive the requirements for obtaining informed consent/authorization or approve a consent/authorization procedure which does not include, or which alters, some or all of the elements of informed consent/authorization listed above, provided that all of the following four conditions are met:

- The research involves no more than minimal risk to the subjects.
- The waiver or amendment will not adversely affect the rights and welfare of the subjects.
- The research cannot practicably be carried out without the waiver or amendment.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Documenting Informed Consent:

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the subject or representative. The investigator must give the subject or representative adequate opportunity to read the form or the investigator can present the elements of informed consent orally provided that a short form written consent document stating that the elements of informed consent has been presented.

Waiver of Consent Form:

If the only record linking the subject and research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality then the IRB may waive the requirement for the investigator to obtain signed consent.

In addition, if the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context then the IRB may waive the requirement for the investigator to obtain signed consent.

Non-English Language Informed Consent and other Documents:

If the informed consent and other documents are not professionally translated to the non-English language version, the following procedures must be performed when submitting non-English versions for the Informed Consent for IRB approval:

- Create an original Informed Consent document in English (English version).

- Translate the English version into the spoken language (non-English version) of the research participants.
- The non-English version must then be translated back into English to ensure that all statements are accurate and reflex the statements made in the English version.
- The PI must attest in writing to the accuracy of the translation(s).

Recruitment:

A recruitment plan is considered part of the informed consent process, and as such, any recruitment script or posting must be reviewed and approved by an IRB prior to posting or beginning solicitation (if the project is human subjects' research). Further, selection of participants must be fair, and risks and benefits must be justly distributed.

- Computer and internet-based procedures for advertising and recruiting potential study participants (e.g., internet advertising, e-mail solicitation, banner ads) must follow the IRB guidelines for recruitment that apply to any traditional media, such as newspapers and bulletin boards.
- Investigators are advised that unsolicited e-mail messages to multiple users are prohibited unless explicitly approved by the appropriate University authority. All messages must show accurately from where and from whom the message originated, except in the rare, specific cases where anonymous messages are invited.

Compensating Research Subjects:

The guidelines outlined below are meant to assist investigators in determining a reasonable amount of compensation that can be given to research participants and also place some boundaries on what is and is not "reasonable." The "reasonableness" of a particular sum of money or other form of payment should be based upon the time involved, the inconvenience to the subject, any cost(s) participants incurred while participating, and should not be so large as to constitute a form of coercion.

During the initial review of a research protocol, the IRB is required to review both the amount of compensation proposed and the method and timing of disbursement to assure that neither are coercive or present undue influence. The following are some additional guidelines:

1. Any compensation should not be contingent upon the subject completing the study, but should accrue as the study progresses.
2. Unless it creates undue inconvenience or an undue influence, compensation to subjects who withdraw from the study should be made at the time they would have completed the study, had they not withdrawn.
3. Compensation given as a "bonus" or incentive for completing the study is acceptable to the FDA, providing that the amount is not coercive. The IRB is responsible for determining if the incentive amount is not so large as to be coercive or represent undue influence.

4. The amount of compensation should be clearly set forth in the informed consent/authorization document.

Also please note: The University of Massachusetts Dartmouth Institutional Review Board discourages the payment of finder's fees (monetary or in kind) in any form, due to the potential that such a practice could be perceived as coercive and bordering on unethical research subject recruitment. In addition, several professional associations and groups have stated that this practice is unethical.

Confidentiality, Anonymity, and Privacy:

Researchers should design systems for confidentially coding data. Master-code sheets connecting participating ID codes and participant names should be securely stored, password protected, and/or encrypted. Data should be made anonymous and master-code sheets should be destroyed as early as possible. In order to pose minimal risk to research subjects, design human subject research to be anonymous whenever possible.

Investigators must be cautious and mindful of potential risks if collecting sensitive data from participants in public spaces. Investigators should also be mindful of privacy as it relates to recruitment – sometimes simply volunteering as a study participant may reveal private details. In addition, investigators need to be cautious about data collected or transmitted over the internet and the resulting privacy implications.

Individually Identifiable:

“Individually Identifiable” means the subject’s identity is readily ascertainable by the investigator or associated with the information. For example, the structure of social network, search terms, purchase habits, and movie ratings on Netflix may all uniquely identify an individual.

Custody of Research Data:

All Research Data shall be preserved in the custody of, or as arranged by, the Principal Investigator on behalf of the University. The Principal Investigator is charged with the integrity, preservation and security of Research data, appropriate marking and reporting of all University intellectual property that may be included in, or derived from, the Research Data. In the case of incapacity of the Principal Investigator, that individual’s supervisor will take custody of that individual’s Research Data until other appropriate arrangements are made for alternative custody.

Storage of Research Data:

When storing benign research information and access should be limited to those individuals who have a specific research need to access the information. Requirements for storing data include:

- making use of complex passwords
- encryption
- not sharing accounts
- limiting system accounts to those with a specific need
- not responding to offers or links in unsolicited email
- not surfing web sites that are likely to try to download malware (e.g., illegal file sharing or pornography sites)

Retention of Research Data:

The Principal Investigator of each Research program must ensure that Research Data documenting the methods and accuracy of data collection and interpretation is retained. Research Data disclosed or referenced in publications, including the primary experimental results, must be retained for a minimum of three (3) years to allow analysis and replication by others. In addition, any of the following circumstances may justify longer periods of retention:

- data must be kept for as long as may be necessary to protect any intellectual property resulting from the work
- if any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained until such charges are fully resolved
- if a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work

Beyond the periods above, destruction of the research record is at the discretion of the PI or the laboratory/department head. Research Data will normally be retained in the administrative unit where generated. Research Data must be retained in a University facility unless specific permission to do otherwise is granted by the Provost.

Access to Research Data:

The University has the right to access Research Data for all Research that is either performed at the University, supported by University administered funds, or conducted using University facilities, provided such access shall be for reasonable cause, at reasonable times and after reasonable notice, except in the event of a bona fide emergency. The University's right of access shall continue regardless of the location of the Principal Investigator or of the Research Data.

Information or data that would violate the confidentiality of sources or subjects involved in the Research shall not be disclosed except in accordance with law or regulation.

Transfer of Research Data:

When required by law, regulation or contract, or to fulfill other obligations, the University may transfer title or custody of Research Data and records at its discretion. In such cases, the University, insofar as possible, will ensure access by Principal Investigators, Investigators and other appropriate individuals to that Research Data.

Ownership of Research Data and University Disposition:

Consistent with federal policy and prevailing high education practice, Research Data belongs to the University. In the event that Investigator data retention and maintenance practices are found to be contrary to this Policy, the University may make disposition of these Research Data and related property rights in a manner that is consistent with law and policy.

Internet Research:

Internet-based research is research which utilizes the internet to collect information through an online tool, such as an online survey; studies about how people use the internet, e.g., through collecting data and/or examining activities in or on any online environments; and/or, uses of online datasets, databases, databanks, repositories. The internet is a powerful means for data collection, analysis, and transmission. However, with this power comes unique and possibly unknown risks. Research conducted over the internet is not anonymous. Privacy expectations are ambiguous. Internet research increases the complexity of obtaining a signed informed consent. In addition, internet research raises concerns about data security, participant authentication, data destruction, server / cloud storage, and recruitment. Please submit all human subjects research utilizing the internet for review.

Closing a Study:

A PI closes their study on or before the study expiration date. All studies which approval has lapsed are expired and then terminated. Lapsed studies cannot be closed. Closing a study requires PIs to submit a closure report. This is a very short form that summarizes your research project; the PI and (if one exists) faculty sponsor sign the closure report. A study should be closed when human subject interactions have ended and subjects are not identifiable. If a risk to confidentiality remains despite all research being concluded (i.e. subjects can be identified in your data as you analyze and write) then you should not close the study.

NON-COMPLIANCE WITH IRB POLICIES, PROCEDURES, OR DECISIONS

THE IRB CANNOT RETROSPECTIVELY APPROVE RESEARCH. DO NOT BEGIN RESEARCH WITHOUT IRB APPROVAL.

Human subjects research that deviates from the policies, procedures, stipulations, or decisions of the IRB is subject to further inquiry by the IRB. Initially, OIC may send the investigator(s) in question a notice requesting the suspension of all research activities while the issue of non-compliance is reviewed, consistent with Federal Mandate 45 CFR Part 46.113. This initial notice will also include a statement detailing the rationale for the IRB's action. Finally, OIC will investigate allegations of non-compliance.

Areas reviewed during a non-compliance inquiry include: the category of original review (**e.g.** Exempt, Expedited, Full Board), the type (e.g. general, serious, and continuing) and nature of the non-compliance, how investigators deviated from approved protocol, or failed to follow IRB procedure. They also include the history of non-compliance for the PI, CO-PI, and/or faculty sponsors, how the event was reported to the IRB, *what steps if any the investigator took to rectify the non-compliance, and finally the implications for participants and the informed consent process.*

Complaints:

PIs may bring forward to the Associate Provost for Graduate Studies and Research Development (Alex Fowler), IRB Chairs (Dr. Scarano, & Dr. Neto), or Director of OIC (Andrew Karberg), concerns or recommendations regarding the human research protection program, including the IRB review process.