Submitting Your Research Study to the Institutional Review Board

Research on human subjects is any research in which the investigator obtains information about a living individual through intervention or interaction with the individual (such as **administering medication**or having the person **fill out a survey**), or from identifiable private information that should be protected (including **observation of behavior** in a nonpublic setting).  It also includes any research that used personal information such as **identified/identifiable secondary data** or **blood/tissue samples**.

An Institutional Review Board (IRB) is a federally mandated organization of scientific and non-scientific persons, whose charge is to review research studies involving human subjects to ensure subject safety and welfare. While responsibility for the conduct of a research study ultimately lies with the Principal Investigator, an IRB’s goal is to ensure that any research study under its jurisdiction is in compliance with federal, state, and institutional regulations.

Here at Tufts, we have two IRB offices.

[**Tufts Health Sciences IRB**](https://viceprovost.tufts.edu/about-tufts-irb)

* Reviews clinical studies and any research involving protected health information under HIPAA regulations

[**Social, Behavioral and Educational Research IRB**](https://viceprovost.tufts.edu/about-sber-irb)

* Reviews social, behavioral and educational research not involving HIPAA information (e.g., survey about student opinions)

**Before submitting ANYTHING to the IRB, you must send it through Dental Research Administration (DRA) first.**

For general questions about IRB issues, please contact:

Sarah Anderson

MPH, Senior Research Coordinator

617-636-3865

[**sarah.anderson@tufts.edu**](mailto:sarah.anderson@tufts.edu)

or

Ann-Marie Billig

Research Affairs Specialist

617-636-3715

[**Ann-Marie.Billig@tufts.edu**](mailto:Ann-Marie.Billig@tufts.edu)

**Your Principal Investigator/ Professor should be your primary source of information about how to develop a realistic protocol and how to go about getting the protocol approved by the IRB.**  A student may not be listed as the principal investigator (PI).  The PI must be a Tufts faculty member. The student may be listed as a co-investigator, but your PI has primary responsibility regarding IRB issues.

There are IRB educational requirements that need to be completed by all students engaged in human subject research and should be completed prior to submitting a protocol to the IRB, including [Collaborative Institutional Training Initiative](https://tufts.app.box.com/s/4bg0k94dt9kwhaztopnfff78huus20g5) (CITI Program) and [Good Clinical Practices](https://tufts.app.box.com/s/yj5vrp5p5c23w9yym6ugq0kd5b2d6g66) (GCP).  These are reading modules that can be viewed on your time, with follow-up exams. Please email Ann-Marie for instructions on how to access these trainings within the Tufts Learning Management System.

**To get started**, please view the annotated [IRB protocol templates](https://sites.tufts.edu/dentalresearch/resources/protocol-development/) and [study design checklists](https://sites.tufts.edu/dentalresearch/resources/protocol-development/), and select that best fits your proposed study activities.

* For Student Research Fellowship Program participants, please follow the [SRFP Research Approval Flow Chart](https://tufts.box.com/s/kcah95w7fdoidsifaeo64ozxkcrvcpbl)
* For MS/DSc students, please follow the [MS/DSc Research Approval Flow Chart](https://tufts.box.com/s/uxrni7kpigu1nx1f64ojasdhxscnp0rh)
* For all other research, work with [Biostatistics](https://sites.tufts.edu/dentalresearch/resources/biostatistics/) and your study team to complete the protocol template

Once you have completed the protocol template to the best of your abilities, please email it to [Ann-Marie Billig](mailto:ann-marie.billig@tufts.edu)/[Sarah Anderson](mailto:Sarah.Anderson@tufts.edu), who will assist you with the IRB submission process, including the preparation of any needed supplementary documents, collection of conflict of interest forms, and uploading all documents to eIRB.

After your study has been submitted, the IRB will review the study package. After reviewing the required documents, the IRB office will decide whether your protocol requires full IRB review or not. Full IRB review normally takes six to eight weeks, while a determination of exemption can often be done in about two- four weeks. **Timeliness of approval of your study to begin research activities will greatly depend on study team responsiveness to DRA’s emails regarding IRB queries!**

Upon IRB approval, DRA will schedule a study initiation visit with your team to review the IRB-approved protocol and study documents and discuss study logistics.