Dental Research Administration

Graduate Student Research Process
MS and PG Students
Department Overview

• Dental Research Administration (DRA) serves as a resource center to assist all researchers (faculty, staff, and students) in conducting quality research projects while observing Institutional Review Board (IRB) and Tufts University School of Dental Medicine (TUSDM) regulations.

• TUSDM requires that all research studies be reviewed and approved in DRA for overall compliance, including but not limited to human and animal subjects’ safety and protection, clinical care regulations, and financial compliance.
Department Overview

• To facilitate the approval process, DRA provides project development services including but not limited to: study design, grant editing and submission, contract negotiation, budget development, IRB submission, statistical analysis, and general consultation.

• All projects, whether or not they require IRB review (i.e., certain types of case reports involving less than three cases) are submitted to the DRA office for review and internal tracking.
Institutional Review Board (IRB)

An 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.

Any studies involving human subjects, human samples (i.e., blood, cells), or human data (i.e., medical record information) is considered human subjects research and must be reviewed and approved by the IRB.
Institutional Review Board (IRB)

Here at Tufts, we have two IRB offices. The IRB on the Boston campus focuses on biomedical research, while the IRB on the Medford campus focuses on social, behavioral and educational research (excluding that which involves HIPAA).

Tufts Medical Center and Tufts University IRB
- On the Boston campus
- Reviews clinical studies and any research involving protected health information under HIPAA regulations

Social, Behavioral and Educational Research IRB
- On the Medford campus
- Reviews social, behavioral and educational research not involving HIPAA information (e.g., survey about student opinions)
MS Student

- Follow MS handbook guidelines at all times
- Determine a project and committee members, including a statistician
- Communicate regularly with committee members
- Work with DRA to develop your protocol
- Get final protocol approved by your PI
- Review supporting/submission documents from DRA
- Be ready to respond to all inquiries from the IRB in a timely manner
MS Student Budget

• Check with AGE Office
• Typically maximum of $2000 covered by AGE Office
• Budget form will need to be completed and submitted
PG Certificate Student Process

• Determine who your mentor/Principal Investigator (PI) will be
• Determine a project and co-investigators, including a statistician
• Contact DRA to initiate the submission process
• Work with DRA to develop protocol
• Get finalized protocol approved by your PI
• Review supporting/submission documents from DRA
• Be ready to respond to all inquiries from the IRB in a timely manner
Checklists

• Checklists to assist with developing your study.

• Checklists exist for different types of studies:
  • Survey Study, Bench/Laboratory Study, Clinical Study, Record Review Study, Qualitative Interview and/or Focus Group Study

• Categories in the checklists include:
  • Initial Project Development
  • Subjects/Groups
  • Variables
  • Further Elements of Study Design
  • Logistical Concerns
  • Protocol
  • IRB Considerations

• Checklists are available at the following link: https://sites.tufts.edu/dentalresearch/resources/protocol-development/
Protocol

• **What is a research protocol?**
  • A document that details the conduct of a research study and includes the operational details of the study. It describes the background, rationale, objectives, design, methodology, statistical evaluation of the data, and organization of your project.

• **Why do I need a written protocol?**
  • Forces investigators to clarify their thoughts and to think about all aspects of the study
  • Serves as a guide for a team working on research – helps to ensure the study is performed similarly by different people over time
  • An essential component of submissions for IRB and funding approvals
  • Serves as a guide to start writing a manuscript when study is completed
Protocol Templates

• Templates to assist with writing your protocol.

• Templates for different types of studies:
  • Survey Study, Bench/Laboratory Study, Clinical Study, Record Review Study, Focus Group Study

• Templates include several sections (varying according to the type of study). Some of the sections include:
  • Introduction/Background
  • Research Aims/Hypothesis
  • Significance
  • Materials and Methods
  • Data Analysis
  • For studies including human participants or data, other sections include risks/benefits, confidentiality, etc.

• Templates are available at the following link: https://sites.tufts.edu/dentalresearch/resources/protocol-development/
Principal Investigator (PI)

- A Principal Investigator (PI) is the individual responsible for carrying out a scientifically sound, ethical research study consistent with the research plans approved by an IRB.

- PI’s role:
  - Responsible for entire study
  - Responsible for completion of and safe maintenance of all documents
  - Retains all original correspondence from the IRB and a copy of all correspondence submitted to the IRB
  - Submits a copy of the approved IRB letter to DRA
  - Retains a copy of education certificates for all research team members

- Students may not be a PI.

- Faculty members serving as PI’s are responsible for students’ research activities during the conduct of clinical research.
  - PI’s must ensure that only official research team members may perform clinical procedures that are conducted solely for research purposes.
Finding a Mentor/PI

- Review Bates-Andrews Research Day abstract book (available from DRA) to see if there is a PI who has done research you are interested in.
  - Bates-Andrews Research Day is a research day where TUSDM students who have conducted research can present their results.

- Tufts University School of Dental Medicine Research Database
  - This resource provides mentor information about types of research that they conduct, fields of interest, contact information, and research interests.
  - [http://sites.tufts.edu/tusdmresearchdatabase/](http://sites.tufts.edu/tusdmresearchdatabase/)
Pre-IRB Submission

• Complete IRB mandatory educational requirements for all personnel involved in the research
  • PI, Co-Investigator, any person who is involved in the conduct of a research study must complete the online CITI education modules
  • Send copy of completion report to coordinator in DRA

• Meet with DRA for assistance with:
  • Protocol development – study design, statistics
  • Conveying pertinent information for IRB paperwork
  • Funding and budgetary considerations

• A coordinator will complete IRB forms; you will convey pertinent information for the IRB paperwork and supporting documentation (e.g., informed consents, recruitment material, etc.)
Pre-IRB Submission

For all funded studies, work with one of our specialists to determine what steps need to be taken for funding applications.

Corporate Funded Studies

- Do not start negotiating with sponsors without notifying DRA
- Pharmaceutical and medical device manufacturer conduct (105 CMR 970.000)
  - Every gift donated in form of cash, materials and/or equipment to Tufts University needs to be recorded by the Materials Committee
  - Dental Research Administration will keep on file
- To prevent internal competition from within the dental school, the PI should notify DRA director before entering into grant negotiations and donations with the company
- After discussions with the company are complete, the PI should obtain a letter of intent from the company, stating that the company wishes to participate in the project
Accessing Records for Research

Proper procedures must be put in place before accessing AxiUm records for the purpose of research.

When accessing records for research, the IRB must grant you a waiver of HIPAA Authorization to access patient protected health information without contacting the patient.

IT can grant you research access to records upon IRB approval.

If you need to do a preliminary review of records to see if there is enough information to conduct a study, you can submit a “Review Preparatory to Research Form” to the IRB.

• Upon reviewing the records, if you have enough information, a full protocol with the sample size must be submitted to the IRB for approval.
IRB Submission

- A DRA coordinator will prepare submission package
- Each investigator will sign a conflict of interest form
- All paperwork will need to be signed by principal investigator (PI)
- DRA director will review paperwork for compliance with all TUSDM policies prior to final approval for submission to IRB
- DRA coordinator will make a copy of each submission for study files
- All IRB communication will go directly to study PI
- DRA will assist with any revisions requested by the IRB and will resubmit the paperwork
- PI keeps DRA informed of approval status and any need for revisions
Types of Review

New Studies

There are three types of review that can be applied to new research study applications. It is important to understand that none of the types of review is superior or inferior to the other. The type of review is strictly dependent on the research study design and the nature of the research. The IRB makes the final determination which category each study qualifies for.
Types of Review

- **Exempt** – Usually minimal risk studies; typically take about 7-10 **business days** for the initial review, which does not necessarily include approval. On average, about 3 to 3.5 weeks for approval.

- **Expedited** - As defined by federal regulations, do not extend beyond minimal risk. Multiple types of studies; can include some clinical studies depending on their nature. Studies involving radiation, x-rays for research, and inclusion of vulnerable populations do not qualify for expedited review.

- **Full Review** - For almost all clinical studies
  - Can take 6-8 weeks for initial review, and possibly longer
  - This includes items noted during pre-review which an IRB coordinator may request clarification on or supporting documents for

- The Scientific Review Committee (SRC) will review selected clinical research studies to ensure that they meet an acceptable standard of scientific rigor and merit. Occurs prior to IRB review.
IRB/Tufts Regulations

• No study procedures may begin until letter of approval or exemption is received from the IRB

• For clinical studies, recruitment, screening, and enrollment may only begin upon:
  • Receipt of the Notice of IRB Approval (sent to PI)
  • Finalization of any contracts (i.e., Grants and Contracts) and Financial Forms approval by Tufts Vice-Provost

• DRA Review Policy
  • The Tufts IRB has determined that all submissions, including initial, revisions, continuing reviews, and any other updates must be submitted to DRA for review prior to submission to IRB
DRA Clinical Study Support

• Study Preparation
  • A DRA coordinator will meet with Research Team for a study initiation visit to organize study logistics (required forms, charts, storage areas, data tracking systems, advertisement postings, etc.)

• Consenting subjects
  • A DRA coordinator will provide instruction on consenting subjects and be available for the first couple of appointments until the research team is comfortable with the process

• Monitoring and Audits
  • A DRA coordinator will periodically check in with you about your study; they will review charts, conduct continuing review audits, and answer any questions. You will be able to contact your coordinator at any time if you have a question before your scheduled appointment.
Division of Biostatistics & Experimental Design

• Members of the Division:
  • Matthew Finkelman, PhD
  • Britta Magnuson, DMD
  • Sarah Pagni, MPH, PhD
  • Tamar Roomian, MS, MPH

• Missions of the Division:
  • Collaborate with students and faculty on research projects
  • Teach pre-doctoral and post-doctoral students
  • Seek external funding for research

• We provide research support to MS students!
What do we do for MS Students?

- Each of you will have a thesis committee
- Most of you will have a statistician (Dr. Pagni or Dr. Finkelman) on your committee
- Dr. Magnuson also serves on thesis committees
More Specifically...

1. We help with aspects of **study design**. Examples:

   a) “Who should I include/exclude in my study?”
   b) “Should I use a split-mouth design?”
   c) “What sample size should I get for my study?”
More Specifically...

• In every study, we have to determine how big your sample size should be in order for your results to be precise/reliable.

• The required sample size depends on the study:
  • You’ll learn more in Basic Biostatistics B.

• We can help you find the right sample size for your study, as well as discussing other elements of study design!
More Specifically...

2. We help with randomization

- Comparing the effectiveness of Treatment 1 vs. Treatment 2
  - Each subject will only get one treatment
  - You need to determine randomly who gets each treatment

- We can work with you to determine who gets 1 and who gets 2!
3. We help with your statistical plan

• Each of you will determine what stats to use in your study, based on your Biostats coursework
  • Before carrying out the study, you will write a description of how you will analyze the data (“statistical plan”)
  • This description will be a section of your protocol

• We can go over it with you and provide feedback before you submit the protocol!
More Specifically...

4. We help with your data formatting

• Most of you will enter your data into Microsoft Excel
More Specifically...

- How should you format the data? It matters.
  - When you do the analysis, the computer will expect the data to be formatted in a certain way.

- We can help you figure out the format that’s right for you, before you collect the data!
More Specifically…

5. We help as you:
   • Perform your statistical analysis
   • Interpret the results

• If you run into obstacles while analyzing your data, come to your stats committee member (Dr. Pagni or Dr. Finkelman), and we will help you solve the problem!

• Once you’ve completed the final analysis, we will go over what everything means!
More Specifically...

6. We help you figure out the best way to present your results

- Writing your thesis
- Writing a paper to submit to a journal
- Making a poster/PowerPoint presentation for a conference
In summary

• All MS students have access to statistical support

• We enjoy working with you!
Questions? Comments?

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