WCE/Thesis/Dissertation Proposal Preparation and IRB Basics

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Written CE, Thesis, or Dissertation

- Culmination of academic degree
- Opportunity for independent research
- Safe, positive, guided experience
  - Faculty
  - Staff
  - UTHealth IRB (CPHS)
STUDENT RESEARCH
Office of Academic Affairs
and Student Services

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  RAS 2nd floor / East

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Proposal Preparation and IRB Basics

- Proposal Development - Resources
- Submitting your proposal for Review and Approval
- Human Subjects/IRB Application
RESOURCES

- CE, Thesis, and Dissertation Guides
  https://sph.uth.edu/research/student-research/
RESOURCES

► SPH Writing Support Services
  - SPHWritingHub@uth.tmc.edu
  - SPH Library - RAS E-125
  - 713-500-9121

► Full text of theses and dissertations – ProQuest
  - SPH Library > Databases A-Z > UTSPH Theses & Dissertations
    [link]

► Examples of proposals – in office or by email
  - Rebecca.Novak@uth.tmc.edu
  - 713-500-9055
  - RAS E-229
WCE/Thesis/Dissertation COMMITTEE

► Committee is formed by the student
  ▪ Current students > Student Forms > Degree program
    ► PhD/DrPH: Doctoral Dissertation Committee Forms
    ► MPH: MPH/MS Thesis Supervisor Appointment; Optional Member Appointment
    ► MS: MPH/MS Thesis Supervisor Appointment; MS Committee Appointment

► Timing

► Roles
  ▪ Student is a full member of his/her committee
  ▪ Faculty roles
Proposal Review Process

► Doctoral students: Oral defense of dissertation proposal *first*
  [https://sph.uth.edu/current-students/student-forms/](https://sph.uth.edu/current-students/student-forms/)

► All students: WCE/Thesis/Dissertation committee approves your written proposal

► All students: SPH Assistant Dean Review through the SPH Office of Academic Affairs and Student Services

► Other reviews, as needed:
  - UTHealth IRB - CPHS (Committee for the Protection of Human Subjects)
    - iRIS online application [https://iris.uth.tmc.edu/](https://iris.uth.tmc.edu/)
  - Outside IRBs – local, hospital, DSHS, CDC, etc.
  - International IRB/Ethical Review Committee (ERC)
  - Other UT Institutional committees - Biological Safety Committee, Animal Welfare Committee, Chemical Safety Committee, Radiation Safety Committee
UTSPH Policy

All student CE/Thesis/Dissertation proposals must be approved by the Assistant Dean for Academic Affairs and Student Services prior to beginning data collection or analysis.
Timeline

► Create a timeline for your project

- CE/Thesis/Dissertation Guide - example timeline
  [https://sph.uth.edu/research/student-research/](https://sph.uth.edu/research/student-research/)
- Check deadlines for the semester you plan to graduate

► Allow enough time for review and approval

  ✓ SPH Review
    - Allow 2 weeks/Proposal submission deadline

  ✓ UT CPHS (IRB)
    - Approximately 2 weeks for Exempt status
    - Approximately 3 weeks for Expedited review
    - Approximately 4 weeks for Subcommittee review
PROPOSAL DEADLINES

► Spring 2017
  - Submission: December 9
  - Approval: February 3rd

► Summer 2017
  - Submission: April 28
  - Approval: June 9

Proposals are due no later than the last class day of the semester prior to your intended graduation date!
Proposal Approval

- Deadlines
  https://sph.uth.edu/research/student-research/important-dates-for-the-thesisdissertation/

- Proposals may be submitted at *any time* during *any semester* in which you are enrolled

- Continuous Enrollment Policy
  https://sph.uth.edu/academics/academic-affairs/#tab-3

- Proposal forms and submission instructions:
  https://sph.uth.edu/research/student-research/
  - Printed copy + signed forms = SPH submission
  - Electronic copy + scanned forms = UTHealth IRB submission in iRIS
Authorship Agreement

► Discuss publication and authorship issues with committee members and data owner(s) early on in proposal development stages

► This agreement is not a contract

► It is for your benefit

► Maintain a copy for your files!
Institutional Review Board (IRB)

► UTHealth IRB = Committee for the Protection of Human Subjects (CPHS)
  ► http://www.uthouston.edu/cphs/

► iRIS – online application system for CPHS approval
  ► https://iris.uth.tmc.edu/

► No submission deadline for initial review

► UTHealth username/password + UTHealth email
  ► iRIS Helpdesk (technical support) 713-500-7960
  ► CPHS (IRB questions) 713-500-7943
  ► UT-HSC Helpdesk (password) 713-500-4848
Institutional Review Board (IRB)

► Human subjects research
  - If in doubt, ask!

► MUST have CPHS approval (not just outside IRB approval)
  - Outside IRB approvals may be required also

► CPHS Approval (2 options):
  - Student submits application as PI of the thesis
  - Student is added to UT faculty’s active protocol
Investigator/IRB Relationship

Communication with the IRB takes place for the duration of your research.

- **Initial Review/Approval/Exemption**
- **Change Request** – Changes/amendments must be submitted to, and approved by, the IRB before they are carried out
- **Continuing review** – Annually (unless Exempt)
- **Study Closure Report** – Submit closure report in iRIS after dissertation is completed
Does My Project Need IRB Review?

- UT CPHS reviews all UTSPH projects involving human participants and/or use of human-derived data/samples, including:
  - **Primary data collection** - Interviews, surveys, interventions, observational studies
  - **Existing data, de-identified** - Exempt status
  - **Existing data, with identifiers** - Expedited review/approval
    - Names, addresses, social security numbers, etc.
    - PHI (Protected Health Information) – HIPAA
  - **Publicly available data** – Exempt status (you must submit an application to receive Exempt status in iRIS)

- UT CPHS does *not* need to review:
  - **Systematic review of literature** (use of published literature)
  - **Simulated data only**
Research with Human Subjects

► **Research** (45 CFR 46):
  - “A systematic investigation designed to develop or contribute to generalizable knowledge.”

► **Human Subject** (45 CFR 46):
  - “… a living individual about whom an investigator (whether professional or student) conducting research obtains:
    (1) data through intervention or interaction with the individual, or;
    (2) identifiable private information.”
IRB Application

► Benefits must always outweigh the risks to participants
  ➢ Three possible categories
    ▪ Benefit to individual participant (direct benefit)
    ▪ Benefit to community/group (in the future)
    ▪ Benefit to society (in the form of knowledge gained)

► What are the potential Risks?
  ▪ You must describe risks, even if minimal or no risk
  ▪ Studies using existing data: loss of confidentiality

► Privacy — (Where will the interview or survey take place?)

► Confidentiality — (How will data or records be maintained? Who will have access to hard copies/electronic data?)
IRB Application

► Informed Consent
  ▪ Process begins with recruitment
    ► who, what, when, where, how?

► Compensation ("incentives")
  ▪ Must not appear as coercive

► Experience of participants
  ▪ Explain exactly what will happen from the perspective of the participant, step by step, in order for them to take part in your research. Include time commitment.
Surveys and Interviews

► Conduct surveys anonymously whenever possible
  ▪ Consent is implied with completion of survey
  ▪ Letter of invitation (instead of consent form)
    ► No link back to subject; confidentiality is maintained

► Is this a vulnerable population?
  ▪ Certificate of Confidentiality

► Are sensitive questions being asked?
HIPAA and Research


- Researchers who receive or use data from covered entities for research activities must comply with the Privacy Rule to ensure security of PHI.

- If data source is not a covered entity, then HIPAA does not apply; variables are not referred to as “PHI”
What is a Covered Entity?

► “Covered entity” (covered under HIPAA) means a health care provider, health plan, or a health care clearinghouse which...

► Electronically transmits billing or payment transactions for services or insurance coverage
What is Protected Health Information (PHI)?

- Identifies a patient/participant
- Information might relate to past, present, or future physical or mental condition of a patient

Includes:

- Paper or electronic records
- Pictures, videos, or other images
- Research data
- Oral information
HIPAA Tips

► Limit PHI used or disclosed to only the amount necessary to accomplish the purpose of that use or disclosure

► Use *minimum necessary* information to accomplish your research goals
Protection of Human Subjects Education Requirement

- **Federal policy**: Certification required for all key personnel conducting human subjects research, regardless of funding source.

- **UTHSC policy**: Certification required for all key and non-key personnel involved in human subjects research, regardless of funding source.

- **UTSPH policy**: Certification required for all students.

  ✔ **CITI online**: [https://www.citiprogram.org/](https://www.citiprogram.org/)'
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