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

- **Student Services**
  - 713-500-9032
  - 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

https://sph.uth.edu/research/student-research/
RESOURCES

► Completed theses and dissertations
► SPH Library > Databases A-Z > UTSPH Theses & Dissertations
  ► http://libguides.sph.uth.tmc.edu/content.php?pid=357371&sid=2922844

► Proposal examples
  ► Rebecca.Novak@uth.tmc.edu
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    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
Proposal Review Process

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

► All degree programs: CE/Thesis/Dissertation committee approves written proposal

► All degree programs/all proposals: SPH Assistant Dean Review (through the SPH Office of Academic Affairs and Student Services)

► Other reviews, as needed:
  - UTHHealth IRB - CPHS (Committee for the Protection of Human Subjects)
    - iRIS (online system) https://iris.uth.tmc.edu/
  - Outside IRB – 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/
- 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 Approval

► Deadlines [https://sph.uth.edu/research/student-research/important-dates-for-the-cethesisdissertation/](https://sph.uth.edu/research/student-research/important-dates-for-the-cethesisdissertation/)

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

► Proposal submission instructions and forms [https://sph.uth.edu/research/student-research/](https://sph.uth.edu/research/student-research/)
  - Printed copy = SPH submission, to Student Services
  - Electronic copy = online submission in iRIS (UT IRB)
    - Save scanned copies for iRIS application and for your own files
PROPOSAL DEADLINES

► Summer 2017
  - Submission: April 28th
  - Approval: June 9th
    (Summer graduation)

► Fall 2017
  - Submission: August 11th
  - Approval: Early fall
    (Fall graduation)

Proposals must be submitted to SPH Office of Academic Affairs and Student Services no later than last class day of the semester before your intended graduation!
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

- For your benefit

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

► Human subjects research?
  - If in doubt, check!

► MUST have UTHealth IRB approval/exemption
  - Other IRB approvals may also be required
  - Request to rely on outside IRB

► UTHealth IRB Approval (2 options):
  - Student as PI of thesis/student protocol in iRIS
  - Student added to UT faculty active protocol in iRIS
Institutional Review Board (IRB)

- UTHealth Committee for the Protection of Human Subjects - CPHS (UT IRB)
  - [http://www.uthouston.edu/cphs/](http://www.uthouston.edu/cphs/)
- iRIS – online application system
  - [https://iris.uth.tmc.edu/](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
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 (IRB) 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 for 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.”
Benefits must *always* outweigh risks

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?
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 UTSPH students.

  ✔ CITI online: [https://www.citiprogram.org/](https://www.citiprogram.org/)
Office of Academic Affairs
and Student Services

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