OVERVIEW

A culminating experience (CE) is required by the Council on Education for Public Health, the accrediting body of U.S. schools of public health, for all students completing a Master of Public Health (MPH) degree. The culminating experience “requires a student to synthesize and integrate the knowledge acquired in coursework and other learning experiences and to apply theory and principles in a situation that approximates some aspect of professional practice” (Council on Education for Public Health, Criterion V.B., 2004). Hence, it is designed to ensure that all MPH graduates can integrate and apply the knowledge and skills that they have gained during their graduate training.

Specifically, through the CE the student demonstrates his/her ability to:

- synthesize public health concepts as they relate to a particular topic
- communicate public health information in writing (including appropriate citations)
- communicate public health information orally (including organization of material and presentation effectiveness)
- identify, access, and critically evaluate public health information

Students at the University of Texas School of Public Health (UTSPH) have two options for their culminating experience:

1) A written paper that presents an inquiry into a public health issue or problem. This paper may take many forms including, but not limited to:
   a. Traditional research thesis
   b. Systematic review of the literature
   c. Policy analysis or practice issue
   d. Practice-based report

2) A capstone course

Additional details for the written and capstone course CE options are provided in the following sections of this document.

Students may count 3-6 hours towards the combination of their CE and practicum. Credits for the CE are usually completed during the student’s final year of study.

Both CE options are available to all MPH students. Prior to making a decision about which option to pursue, students should: learn more about each option; consider their own strengths and weaknesses, public health interests, career goals, and plans for further graduate education; and discuss the options with their MPH advisor.

THE MPH CAPSTONE COURSE

The CE capstone course is a three-credit class that required the student to synthesize and integrate information, as well as problem-solve. Prior to taking the capstone course, students must have completed the five core courses (or have a waiver on file) and at least 30 semester credit hours. In addition, they must have completed or be concurrently enrolled in the practicum.
THE MPH WRITTEN CULMINATING EXPERIENCE (WCE)

The WCE provides the opportunity to develop expertise in a specific topic area and to make a contribution to the field of public health. For example, the WCE could result in the publication of a manuscript or the development of a public health program or intervention. Establishing expertise in a specific topic area and producing concrete evidence of that expertise can be an important first step in establishing your career in public health. Students who plan to pursue further academic studies or for whom peer-reviewed publication is important are encouraged to consider the WCE option.

This guide provides an overview of the steps required to complete the WCE. The Office of Research also offers seminars on related topics. For a list of seminar dates, please visit: https://sph.uth.tmc.edu/research/student-research

I. WHAT TYPES OF PROJECTS CAN BE USED FOR THE WCE?

Each WCE project is unique. Whether it is the topic itself, use of a new study design, analysis of new data, application of a new method, or the synthesis of existing literature from a new perspective, all WCE projects must include an original aspect. However, many of the WCE projects undertaken by MPH students at UTSPH fall into one of four general categories:

**Research Thesis**

The traditional thesis option involves investigation of a scientific question using public health methods (e.g. epidemiology, biostatistics, environmental science, behavioral science, management and policy science). The thesis should address an important public health issue and provide a unique contribution to the overall literature on the topic. The specific question to be addressed may be an original question developed by the student or it may be developed in collaboration with the advisory committee and data may be collected as part of the project or be derived from an existing data source. In some cases, simulated data may be used (e.g. to compare analytical strategies).

**Systematic Review**

A systematic review involves the investigation of a specific public health question using published studies. The study question is something that has been addressed in the literature, but has not been resolved (e.g. results have been equivocal or inconsistent across studies). The data for a systematic review is obtained using a formal strategy to search the literature and a structured approach to identifying relevant features of each included study. Various qualitative and quantitative approaches can be used for the systemic review. Table 1 (Supplemental Appendix) illustrates the elements of a systematic review as compared to a research thesis.

The UTSPH library provides several resources related to systematic reviews:

https://sph.uth.edu/current-students/library/guides-to-using-library-resources/

**Policy Analysis or Practice Issue**

A policy analysis involves the review and synthesis of data relevant to a defined public health policy or practice issue, and application of the gained knowledge toward a practical solution to, or recommendations regarding that issue. The data for a policy/practice WCE may be collected as part of the project, or derived from existing data sources, including the published literature and other documents that are in the public domain.
**Public Health Practice**

A public health practice WCE is designed to focus on a specific public health issue faced by the practice community. For example, a public health practice WCE could describe the implementation of a community-based intervention for a particular agency. The project described within the WCE can, but does not have to be, an extension of a student’s practicum. However, it cannot be a description of the practicum experience. When the WCE is based on the practicum experience, it may involve an extension of the practicum project and additional contact time with the practice agency or sponsor.

Not all WCE projects fit neatly into one of the categories described above. Examples of many different types of WCE proposal can be found in the UTSPH library.

Depending on your background and the type of WCE you decide to pursue, you may want to take a course that will help you to prepare for your project. For example, a proposal writing course that aims to develop scientific/technical writing skills, a course that focuses on systematic reviews, or an independent study class to learn more about your particular topic. However, in most cases it is not necessary to take such courses before you begin your WCE.

II. WHAT IS THE ROLE OF THE STUDENT’S COMMITTEE IN THE WCE?

The student’s WCE committee includes the student, his/her academic advisor and one additional member who will provide expertise in support of the project. The additional member is chosen by the student in consultation with their academic advisor and can come from within or outside of the student’s primary discipline. The second member may also be from outside of the UTSPH.

Students who elect a concentration must have a committee member who represents the concentration. This may be the academic advisor or the additional committee member, if one or both represents the concentration. Otherwise, a committee member representing the concentration must also be included.

Any of the advisory committee members may serve as the Supervisor for the project.

The academic advisor serves as the Chair of the WCE committee.

Additional details about the WCE committee composition for can be found at:

https://sph.uth.tmc.edu/academics/degree-programs/.

Students should also check their Divisional website for information specific to their degree program.

Forms for adding or changing committee membership:

https://sph.uth.tmc.edu/current-students/student-forms/

**What is the student’s role on the committee:** As a member of the committee, the student should coordinate committee meetings. Although students meet with their academic advisory committee twice each year, these meetings are generally insufficient for discussing the details of the WCE. Consequently, additional meetings, specifically for review and discussion of the WCE, are generally required. Such meetings can save the student and other committee members time, and minimize the potential for confusion that can occur when the student must try to integrate multiple (and sometimes conflicting) opinions without the benefit of everyone
talking together. The number and duration of such meetings will depend on the specific project and committee. In general, it may be helpful to have meetings:

- Prior to writing the proposal
- After all committee members have a read a final, or near-final, version of the proposal
- After all committee members have read a final, or near-final, version of the written WCE

Committee meetings are typically scheduled several weeks in advance in order to accommodate the committee members other professional obligations.

The student should also coordinate meetings with individual committee members as needed. In general, the student should meet with the project supervisor at least every other week. The frequency of meetings with other committee members will depend on their role on the project.

What are the roles of the other committee members? The committee members serve many different roles including: scientific advisor, editor, mentor and advocate. Individual members may serve in one or more of these roles. The committee or individual committee members work with the student to develop the proposal, obtain necessary institutional approvals (e.g. IRB, animal welfare), and assist with the execution of the proposed project and completion of the final WCE document. In general, committee members should provide feedback on all written documents and requests within two weeks of submission by the student.

The faculty and other professional members of the committee are responsible for the approval of the scientific integrity of both the WCE proposal and the final written paper.

III. WHAT STEPS ARE INVOLVED IN A WRITTEN CULMINATING EXPERIENCE?

The WCE requires several steps:

- Identification of a project
- Preparation of a proposal
- Review and approval of proposal by WCE committee
- Review and approval of proposal by IRBs, Associated Dean for Research etc.
- Completion of the proposed work
- Preparation of the final WCE document
- Public presentation of the WCE project

Each of these steps is described below. However, as soon as you decide to pursue a WCE - even before you have selected your project - it is important to ensure that you have, or have a plan to acquire, the basic skills required to complete the WCE, including:

Basic writing skills: The UTSPH does not provide course work in basic writing skills. However, such courses are available through several local institutions. Information on writing resources that may be available to UTSPH students can be found at:

http://www.sph.uth.tmc.edu/detail.aspx?id=12933&libID=12934
Scientific writing skills: Students who have limited experience writing scientific materials, or who would like to improve their scientific writing skills should consider taking PH1498-500, Foundations of Academic Scientific Writing in Public Health, or one of the scientific/proposal writing classes offered at UTSPH.

Use of electronic and library resources: The UTSPH library provides formal training on the use of on-line searching techniques and reference management software. In addition, members of the library staff are available to provide one-on-one training and assistance.

http://www.sph.uth.tmc.edu/library/

The Texas Medical Center library also offers classes on a variety of topics:

http://resource.library.tmc.edu/cf/clscalendar.cfm (classes)
http://www.library.tmc.edu/usingthelibrary/etutorials/ (online tutorials)

III-A. Identification of a Project

It is never too early to start thinking about topics for your WCE. There are many potential sources of ideas, including: faculty, staff and students; co-workers and other colleagues; journals; classes; seminars; and professional meetings.

As you begin to think about your WCE topic, it may help to keep a notebook or journal that includes project ideas, notes from discussions and seminars, lists of additional people to talk with, and articles on topics of interest. Once you have identified a potential project, it may be helpful to prepare a short overview, summarizing the relevant background information as well as the aims and significance of the proposed project that can be shared and discussed with your committee members.

The School’s website offers several features that can help you to find out about the research interests of the faculty.

- The online faculty directory includes brief descriptions of each faculty member’s research interests. The directory can be filtered by Division, Campus or Center and can also be searched for specific keywords
  - https://sph.uth.tmc.edu/faculty/
- The Office of Research webpage includes lists of recent publications by the faculty as well as recently funded grants
  - https://sph.uth.tmc.edu/research/office-of-research/

The project that you select should be of interest to you and relevant to your future career goals. However, it should also be feasible to carry-out given available resources and within a reasonable time period. It is very important that you pick a project that fits with your skills (e.g. statistical, qualitative and analytic). Consequently, once you have identified a potential project, it is essential that you discuss both the scientific and practical aspects of the project with your committee members and any others who would play a significant role in the project. Do not be discouraged if your first project idea is determined to be inappropriate, for either scientific or practical reasons. It is not unusual to identify two or three potential projects before an appropriate project is identified. Working through the scientific and practical issues of each
potential project provides valuable experience and perspective and is part of the learning process.

**When should the WCE project be started?** Although it is never too early to start to think about ideas for your WCE project, planning the project and writing the proposal will require the synthesis of knowledge and experiences gained from the MPH program. Consequently, the bulk of the WCE project is undertaken after sufficient public health knowledge and skills have been acquired. The process is generally initiated at least 12 months prior to the deadline for submitting the final documents in the semester that you plan to graduate.

**TIMELINE:** The time required to identify a WCE project is extremely variable. However, it can take several weeks, so it is never too early to start thinking about topics.

### III-B. Preparation of the Proposal

Once you and your committee have agreed on an appropriate project, the next step is to complete a written project proposal.

**What is the purpose of the proposal?** The proposal is a requirement for all students who choose to undertake a WCE and serves several purposes. First, the proposal prepares you for the work that will be required to complete your WCE project. As you write your proposal, you are gaining important background knowledge that will help to guide your project, as well as working through the logistics required to complete each step of the project. The proposal also serves as a contract between you and your committee. It is a statement of the goals that you have agreed need to be met to complete the WCE and move forward towards graduation. Your proposal may also be required to obtain the institutional approvals (e.g. IRB) needed before the project may be initiated.

**Is there a specific format for the proposal?** The UTSPH does not require a specific format for the WCE proposal.

- There are optional templates for the final WCE that you may want to use for the proposal. These templates are for style and “construction”, not content, and can be found at: [https://sph.uth.edu/research/student-research/](https://sph.uth.edu/research/student-research/)
- Check with your committee to determine whether they will require or prefer a specific structure, style (e.g. APA style), and/or reference and bibliography format.
- In general, double-spaced text, with a 12 point font and 1 inch margins is appropriate for the proposal.

**What should the proposal include?** The length and specific content of your proposal will be determined by your committee. In general, proposals are not longer than 15 double-spaced pages (1 inch margins, 12 point font) and include the following sections.

**Background/Introduction and Public Health Significance**

This section should provide a review of the relevant literature. The level of detail that you provide in this section will be determined by you and your committee members. At a minimum, you should provide the background information that a general reader would require to understand the topic of your project and the rationale for the proposed work. This section should also include a discussion of the public health significance of your specific project.
• **Specific Aims/Hypotheses/Objectives**

This section should include a statement of the research question, hypothesis, specific aims or objectives of your project. The best approach for setting up this section will depend on your specific project and should be discussed with your committee. This section may also include a brief discussion of the rationale for the proposed project and/or a brief description of the approach that will be used to meet the stated goals.

• **Methods**

The content of this section will depend on your specific project. However, all proposals must include details of the methods that will be used to address the study aims/hypotheses or objectives. The methods section should include the following considerations, as appropriate to your proposed work:

- Study design
- Study setting, including locations and dates
- Study subjects
- Sample size calculations and/or study power
- Data collection
- Data analysis, including statistical, laboratory and other methods that you will use to address your study aims, hypotheses or objectives
- Human subjects, animal subjects, and/or safety considerations

The methods section tells the reader exactly “how” you are going to achieve your aims and/or answer your research questions. It is important to be as specific as possible in this section. For example, stating that you will use logistic regression to analyze your data is not sufficient. Rather, you need to state what independent and dependent variables will be used as well as what potential confounders and effect modifiers will be considered. Additional details, such as how variables will be coded, can also be helpful. Further, you should indicate how the analyses will be interpreted (e.g. p-values, odds ratios and 95% confidence intervals).

When organizing the methods section, it is often helpful to re-state each aim and follow it with the details of the specific methods that will be used to achieve that aim. It is also important that you use past and present tense appropriately in this section. For example, if you will analyze previously collected data, sections on study design, setting and subject recruitment should be written in the past tense (e.g. someone collected the data in the past), whereas sections on data analysis should be written in the future tense (e.g. you will analyze the data in the future, after your proposal is approved). It is extremely important that you clearly delineate the work that you will do from the work that has already been done.

• **References/Bibliography**

This section should include complete references for all literature, websites, books, and other materials referenced in your proposal. There is no required format for the references in your proposal. It is, however, recommended that you use reference management software, such as RefWorks.
RefWorks is available free of charge to UTSPH students, and information and training on RefWorks is available through the UTSPH library:

http://www.sph.uth.tmc.edu/detail.aspx?id=13044&libID=13045#refworks

- **Other Sections**

  Your proposal may include other sections as appropriate for your project or as required by your committee. Examples of other sections that you might include are:

  - **Preliminary data:** If you have already started to work on your project, for example as part of your practicum or as a graduate research assistant, you should include a summary of the work that has already been done.
  
  - **Results:** If you include this section, it would provide an outline of how your results will be presented and mock-ups of the tables and/or figures that will be used to present your data.

  Table 2 in the Supplemental Appendix provides additional detail on the contents of each section for different types of WCEs.

  Preparation of your proposal is an interactive process that involves your advisory committee members. As you begin your proposal, you should work with your committee to establish how they will review drafts of your proposal. Often, one member of your committee will serve as a primary reviewer for your initial draft(s), while the other members will review only later drafts or specific sections of the proposal.

  In general, your proposal will require several drafts and edits before it is finalized. It is reasonable to assume that, on average, it will take two weeks for committee members to provide feedback on each of your drafts and that two to four drafts will be required before the proposal is finalized.

  **What approvals are required?** Your proposal must be approved by all advisory committee members and the UTSPH Associate Dean for Research. In addition, your proposal may need to be submitted to and approved by:

  - UTHSC Committee for the Protection of Human Subjects (i.e. IRB)
  
  - Other institutional IRBs (e.g. for data collection at an institution outside of UTHSC)
  
  - UTHSC Animal Welfare Committee
  
  - UTHSC Biosafety/Chemical Safety Committees

  To determine whether your project requires such approvals, as well as for additional information on the approval process, please refer to the UTSPH Research Compliance document included in the Appendix to this Guide and available on the Schools' website:

  https://sph.uth.tmc.edu/research/office-of-research/student-research/

  **What forms must be submitted with the proposal:** Once your committee has signed off on your proposal and you have received all necessary institutional approvals, you will need to submit the proposal and additional documentation (see below) to the UTSPH Associate Dean for Research (ADR) for approval through the Office of Research.

  All WCE proposals require the following forms/documentation:

  - Student Proposal Cover Sheet
• UTSPH Student Proposal Institutional Approval Document
• Authorship, Publication Plan, and Data Ownership form
• Certification of student’s completion of a course on the protection of human subjects
  o Collaborative Institutional Training Initiative (CITI)
    ▪ https://www.citiprogram.org/

Additional forms/documentation that may be required include:

• Data Handling Procedures (proposals that involve existing data)
• Letter of permission for use of data (proposals that involve existing data that is not publically available)
• Letter documenting that the student is included on, and project is covered under an existing Committee for the Protection of Human Subjects (CPHS) protocol – from the Principal Investigator of the approved protocol (as appropriate)
• UTHSC CPHS documentation that study is exempt or approved (projects using data from humans that is not publically available)
• UTHSC Animal Welfare Committee documentation (project using animals)
• UTHSC Institutional Biosafety/Chemical Safety Committees (as appropriate)
• Certificate of completion from appropriate institutional safety courses (e.g. animals; biohazardous substances, chemical, radioactive materials; microbiological, biological, infectious agents or recombinant DNA)

Students must submit a printed proposal along with signed forms/documents to the Office of Research for approval, as well as an electronic copy of the proposal itself (without the forms). Proposal forms and submission instructions can be found online at the Office of Research: https://sph.uth.tmc.edu/research/office-of-research/

Approval by the ADR requires that all appropriate forms/documents have been submitted and are complete and accurate. If your project requires CPHS or other approvals, and such approvals are pending, you may submit all other documents to the ADR for preliminary review. However, final approval by the ADR will require appropriate documentation from all relevant committees.

What are the enrollment requirements?

You must be enrolled for at least three credit hours during the semester in which the proposal is submitted and in every semester after you submit your proposal until you graduate.

TIMELINE: Completion of the WCE proposal will generally take at least one month and may require several months, depending on the number of revisions required by your advisory committee. Projects that require CPHS or other institutional approvals will generally take longer than those that do not require such approvals.

The WCE proposal must receive written approval by the ADR and all relevant institutional committees NO LATER THAN the Proposal Approval deadline for the semester in which you
intend to graduate. Students should refer to the School’s website for information about other deadlines related to graduation:

https://sph.uth.tmc.edu/current-students/planning-to-graduate/

III-C. Completion of the proposed project

The requirements for this step vary considerably from project to project. While the WCE proposal provides an outline of the work that needs to be accomplished, the student and advisory committee must work together to determine the details of how and when that work will be accomplished.

The successful and timely completion of any project requires communication, organization and time management. Hence, it is essential that you meet with your committee members to develop a work plan and timeline. Issues that should be addressed during this initial meeting include:

- the role of each committee member
  - often, you will work more closely with one member than the others
- meeting schedules
  - how often will you meet with the entire committee? individual members?
  - optimally, you will meet at least every other week with a least one member of the committee
- mechanism(s) for providing updates between meetings
  - e.g. emails, summary reports etc.

As you are working on your project, it is important to adjust your work plan and timeline so that they remain realistic. If your work plan changes substantially, relative to what was included in your approved proposal, it may be necessary to submit a proposal amendment memo for review by the ADR as well as protocol amendments to other relevant committees (e.g. CPHS).

TIMELINE: In general, it will take 1-6 months to complete the WCE project after all appropriate approvals have been received.

III-D. Preparation of the final WCE

The WCE proposal will provide the starting point for your final WCE document. However, you may need to update the Background section to reflect any new developments in the field. In addition, you may need to expand and/or revise the Methods section to accurately reflect the procedures that were used. You will also need to write the sections that were not included in your proposal (e.g. Results and Discussion) and update your references.

Is there a specific format for the final WCE document?

The final WCE document can have one of two general formats:

- WCE without journal article
- WCE with journal article

Templates for these two formats are available at:

https://sph.uth.edu/research/student-research/
These templates are designed to assure that standards of style and document “construction” are met. They are not intended to define the specific content of the WCE. Use of these electronic templates is optional, but they must be consulted for the appropriate construction and content of the final document.

**What should the final WCE document include?**

There is considerable flexibility in the manner in which you present your WCE. In general, the final document will include the following sections:

- **Abstract**
  The abstract is a concise summary (~500 words) of the background, methods, primary results and conclusions of your WCE.

- **Background/Introduction and Public Health Significance** (previously described)

- **Specific Aims/Hypotheses/Objectives** (previously described)

- **Methods** (previously described)

- **Results**

  This section should describe your findings or accomplishments, without comment or discussion. Findings may be presented in tables and figures as well as text.

  If the project has been, or will be submitted for publication, the journal article (conforming to the style of the journal to which it has been/will be submitted) may be included as a chapter within the results section. Any additional findings, not included in the article, should be included as a separate chapter in the results section.

- **Discussion/Conclusions/Recommendations**

  In this section, the results of your project should be discussed relative to what is already known about the topic. In addition, the conclusions and/or recommendations that can be made based on the results of the project should be stated. Finally, the strengths and limitations of the project should be described.

- **References/Bibliography** (previously described)

**What institutional approvals are required?**

The final WCE must be approved and signed by all student advisory committee members. One or two revisions are often required before the final WCE is approved. The final WCE document must also be reviewed by the Office of the ADR to ensure that it conforms to all structural requirements. The ADR format review will be completed online, after the student advisory committee has approved the document.

**TIMELINE:** The final WCE must be submitted to the Office of Research by the deadline indicated on the SPH calendar for the semester you intend to graduate. Students should refer to the School’s website for information about this and other deadlines related to graduation:

[https://sph.uth.tmc.edu/current-students/planning-to-graduate/](https://sph.uth.tmc.edu/current-students/planning-to-graduate/)

As with all of the steps in the thesis, the time required to complete the final written document can be quite variable.
III-E. Public presentation of the WCE project

For all MPH students entering in the Fall of 2005 or later, successful completion of the WCE includes a public presentation. This presentation may be based on either the proposal or on the completed project. The decision as to when to conduct the oral presentation is determined by the student and the advisory committee. Presenting the project at the proposal stage has the advantage of allowing for input from individuals outside of your committee, which may be helpful as you move forward with your project, and can help to reduce your workload as you approach graduation.

Although there is not a specific format for the public presentation, it is suggested that you use a standard software package (e.g. PowerPoint) to develop your talk. You should provide drafts of your slides to your advisory committee, and practice your talk at least once with your advisory committee members. Additional practice sessions with other students or colleagues can also be helpful. You should be able to present your work without, or with minimal reference, to written notes and be prepared to answer questions from the audience. It is also important that you are able to go through your entire presentation in the allotted time.

The time and venue for the presentation are determined by the student’s advisory committee and Division. Options include presentation as part of a School or Division-wide seminar or an individually scheduled public presentation. This requirement is BEST completed at least two weeks prior to the last day of class in the semester that the student plans to graduate. The final DEADLINE for completion is no later than the last class day. The activity must be documented by a public invitational flyer that is distributed at least two weeks before the last day of class.
IV. WHAT IS THE GENERAL TIMELINE FOR COMPLETION OF THE WCE?

There is no set time for the completion of the WCE. The amount of time required to complete the WCE is determined by the specific project and the time that the student devotes to the project. In general, this process will require at least six and up to 17 months.

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<tr>
<th>Activity</th>
<th>Timeline</th>
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<tr>
<td><strong>Selection of a project</strong></td>
<td>1-3 Months</td>
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<tr>
<td>• Discussion of ideas with committee members</td>
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<td>• Approval of concept by all committee members</td>
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<tr>
<td><strong>Preparation/committee approval of the proposal</strong></td>
<td>1-3 months</td>
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<td>• Draft proposal</td>
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<td>• Review of proposal by committee members</td>
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<td>• Revision of proposal (several revisions may be necessary)</td>
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<td>• Committee approval</td>
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<td><strong>Other institutional approvals of proposal (if required)</strong></td>
<td>Generally &lt; 6 weeks</td>
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<td><strong>ADR approval of proposal</strong></td>
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<td><strong>Conduct of the project</strong></td>
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<td>• Data collection</td>
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<td>• Analysis</td>
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<td><strong>Preparation/committee approval of the final WCE document</strong></td>
<td>1-2 months</td>
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<td>• Update background, methods, bibliography as needed</td>
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<td>• Write results and discussion</td>
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<td>• Prepare figures and tables</td>
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<td>• Submit to committee members</td>
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<td>• Review by committee members</td>
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<td>• Revisions as necessary (several may be required)</td>
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<td>• Committee approval</td>
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<td><strong>Formatting review of final WCE document</strong></td>
<td>&lt; 1 month</td>
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<td><strong>Total</strong></td>
<td>6-17 months</td>
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*Proposals requiring full IRB review may take longer.
APPENDIX

RESEARCH COMPLIANCE

UNIVERSITY OF TEXAS SCHOOL OF PUBLIC HEALTH
All research conducted by the faculty, students and staff of the University of Texas School of Public Health (UTSPH), including research projects and analyses of research data that are conducted as part of UTSPH courses, must be reviewed and approved or exempted by the appropriate Institutional committees before the research is initiated. At the University of Texas Health Science Center (UTHSC), these committees, which fall under the Office of Research, monitor research compliance related to: Human Subjects Protection, Care and Use of Animals and Environmental Health and Safety.

UTHSC Office of Research: [http://www.uthouston.edu/index/research.htm](http://www.uthouston.edu/index/research.htm)

UTHSC Compliance Programs: [http://www.uth.tmc.edu/research/compliance/index.htm](http://www.uth.tmc.edu/research/compliance/index.htm)

It is the responsibility of the investigator (or course instructor) to ensure that a research project has received all necessary approvals prior to initiating a study, and to require all project staff and/or students to receive appropriate training before initiating any research related activities. It is also the investigator’s responsibility to obtain approval for any additions or changes to the study, before they are implemented, as well as to maintain all necessary approvals through completion of the study.

This document provides UTSPH investigators with general information regarding the Institutional training that is available, and the oversight that is required for different types of research. In addition, general questions regarding training and oversight may be directed to Ms. Rebecca Novak at the UTSPH Office of Research. However, investigators should visit the appropriate website for the most up-to-date and complete information, and/or contact the appropriate programmatic official in the UTHSC Office of Research, to ensure that they have obtained all necessary training and approvals before initiating any research project.

Rebecca Novak: x9055 or Rebecca.Novak@uth.tmc.edu

**Student Research:** The information included in this document relates to students as well as faculty and staff. Additional information related specifically to student research is provided at the end of the document.
Human Subjects Protection

Committee for the Protection of Human Subjects (CPHS)

The CPHS is the Institutional Review Board (IRB) for the UTHSC. CPHS reviews proposed research as it applies to the individuals being asked to participate as research subjects in order to determine if adequate measures are in place to protect autonomy, safety, emotional health, and financial considerations.

CPHS: http://www.uth.tmc.edu/orsc/cphs.html

Most of the research conducted by UTSPH investigators will require review by CPHS. Some examples of research that does not require CPHS review include:

Research Using Animals: Research that is exclusively conducted using animals or animal-derived materials does not require CPHS review. However, such research does require review by the Animal Welfare Committee (see below).

Research Using Publicly Available Data: Research involving publicly available data (e.g. census data, labor statistics) does not require CPHS review. Investigators should contact the CPHS if they are not sure whether their data qualifies as “publicly available”.

Research Using Simulated Data: Research based solely on data obtained through computer simulations does not require CPHS review.

Research Using Published Literature or other Publically Available Documents: Research that is based entirely on published literature (e.g. systematic literature reviews) or other documents that are in the public domain (e.g. policy analyses) does not require CPHS review.

Exempt Status: Many research projects are exempt from CPHS review. However, the investigator cannot make the decision regarding exempt status. Studies that may be exempt must be submitted for review and determination of exempt status by CPHS.

Information on exempt research: http://www.uth.tmc.edu/orsc/guidelines/exempt.html

Training: All individuals participating in research that involves human subjects must receive appropriate training before initiating any research activities, and must receive updated training as necessary.

Courses that satisfy the UTHSC requirement for education on the protection of human subjects are offered online by the Collaborative Institutional Training Initiative (CITI).

In addition to the above requirement, all principal investigators of sponsored projects must attend an Investigator Responsibility Briefing, conducted by Dr. Peter Davies, Executive Vice President for Research.

Information on CITI: http://www.uth.tmc.edu/orsc/training/CITI.html

Link to CITI: https://www.citiprogram.org/default.asp?language=english
**Applications:** The UTHSC CPHS uses an online application. All applications, including those for studies that may be exempt from CPHS review, are submitted through the Integrated Research Information System or iRIS.

Register for iRIS training: [http://www.uth.tmc.edu/orsc/training/iRISTrainReg.html](http://www.uth.tmc.edu/orsc/training/iRISTrainReg.html)

Link to iRIS: [http://iris.uth.tmc.edu](http://iris.uth.tmc.edu)
Care and Use of Animals

Center for Laboratory Animal Medicine and Care (CLAMC)

The CLAMC provides training related to the oversight, care and use of experimental animals, to ensure that the individuals involved in these activities are qualified to accomplish these tasks in a humane and scientifically acceptable manner.

CLAMC: http://www.uthouston.edu/animal-research/training/

Animal Welfare Committee (AWC)

All research using animal subjects or animal derived materials must be submitted to the AWC, the Institutional Animal Care and Use Committee, for the UTHSC. Faculty with approved animal use protocols must assure the AWC that personnel will be or are adequately trained. Training is provided through CLAMC.

AWC: http://www.uthouston.edu/animal-research/awc.htm
Environmental Health and Safety

**Safety, Health, Environment and Risk Management (SHERM)**

Training in basic laboratory safety as well as radiation, chemical and biosafety is provided by SHERM.

SHERM: [http://www.uthouston.edu/safety/](http://www.uthouston.edu/safety/)

**Radiation Safety Committee**

Radiation Safety Committee approval must be obtained prior to the use of radioactive materials or other sources of radiation.

**Chemical Safety Committee**

Chemical Safety Committee approval must be obtained prior to using acutely toxic chemical agents, including those listed by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP) as suspected or confirmed carcinogens, or for which toxicological/epidemiological studies have indicated that the chemical has reproduction, acute, and or reactive hazard(s). In addition, any hazardous chemical that is used in such a way as to present the potential for an exposure above the Occupational Safety and Health Administration’s Permissible Exposure Limits (PEL) or the American Conference of Governmental Industrial Hygienist’s Threshold Limit Values (TLV), requires committee review.

**Institutional Biosafety Committee**

Institutional Biosafety Committee approval must be obtained prior to using microbiological/infectious agents and/or recombinant DNA molecules in research.

Additional information about these Committees as well as application materials can be obtained at: [http://www.uthouston.edu/safety/](http://www.uthouston.edu/safety/)
Student Research

**Faculty Research:** Many UTSPH students participate in research that is being conducted by UTSPH faculty. A student’s involvement in such projects must be approved by all appropriate committees. In general, students can be added to an existing, approved protocol by submitting a change request to the appropriate committee.

**Classroom Projects:** Instructors who include a research project or analysis of existing research data for any purpose (e.g. to explore statistical methods or other methodological issues) as part of a course should obtain appropriate CPHS approvals. In general, applications for class projects that involve contact with, or analysis of data from human subjects should be submitted to CPHS (through iRIS), by the course instructor. Briefly, the application would include: the class objectives; types of research activities that will be included in the course; description of faculty oversight for the project; and an acknowledgement that any student activities that exceed the boundaries of the class would need to be submitted as individual projects (e.g. if a student were to expand a class project for use as a culminating experience). Students who wish to expand on a classroom project (e.g. for use in a written culminating experience) should contact CPHS to determine whether additional project approvals will be required. Questions regarding classroom projects should be directed to Cynthia Edmonds (Cynthia.L.Edmonds@uth.tmc.edu), Director of Research Support Services, UTHSC.

**Student Research:** Many UTSPH students engage in an independent research project, such as the MPH written culminating experience, MS thesis, and PhD/DrPH dissertation. As for all UTSPH research projects, student projects must be reviewed by the appropriate Institutional committees before the research is initiated.

It is the responsibility of the student and his/her research committee to determine which approvals are required and to apply for, obtain and maintain all such approvals. Ms. Rebecca Novak in the UTSPH is available to help students determine what approvals may be required for a specific project. However, the student should visit the appropriate website for the most up to date and complete information and/or contact the appropriate programmatic official in the UTHSC Office of Research to ensure that they have obtained the appropriate training and approvals before initiating their project. Students undertaking a written culminating experience, thesis or dissertation project must complete all required training and obtain all necessary committee approvals before their project will be approved by the UTSPH Associate Dean for Research.

In general, the approval processes for student projects are identical to those of faculty projects. However, if a student is conducting a project that falls under or is closely-related to an existing, UTHSC CPHS approved protocol, it may be possible for the study PI to obtain the appropriate approval for the student’s work by submitting a change request or protocol amendment for the existing approved protocol.