

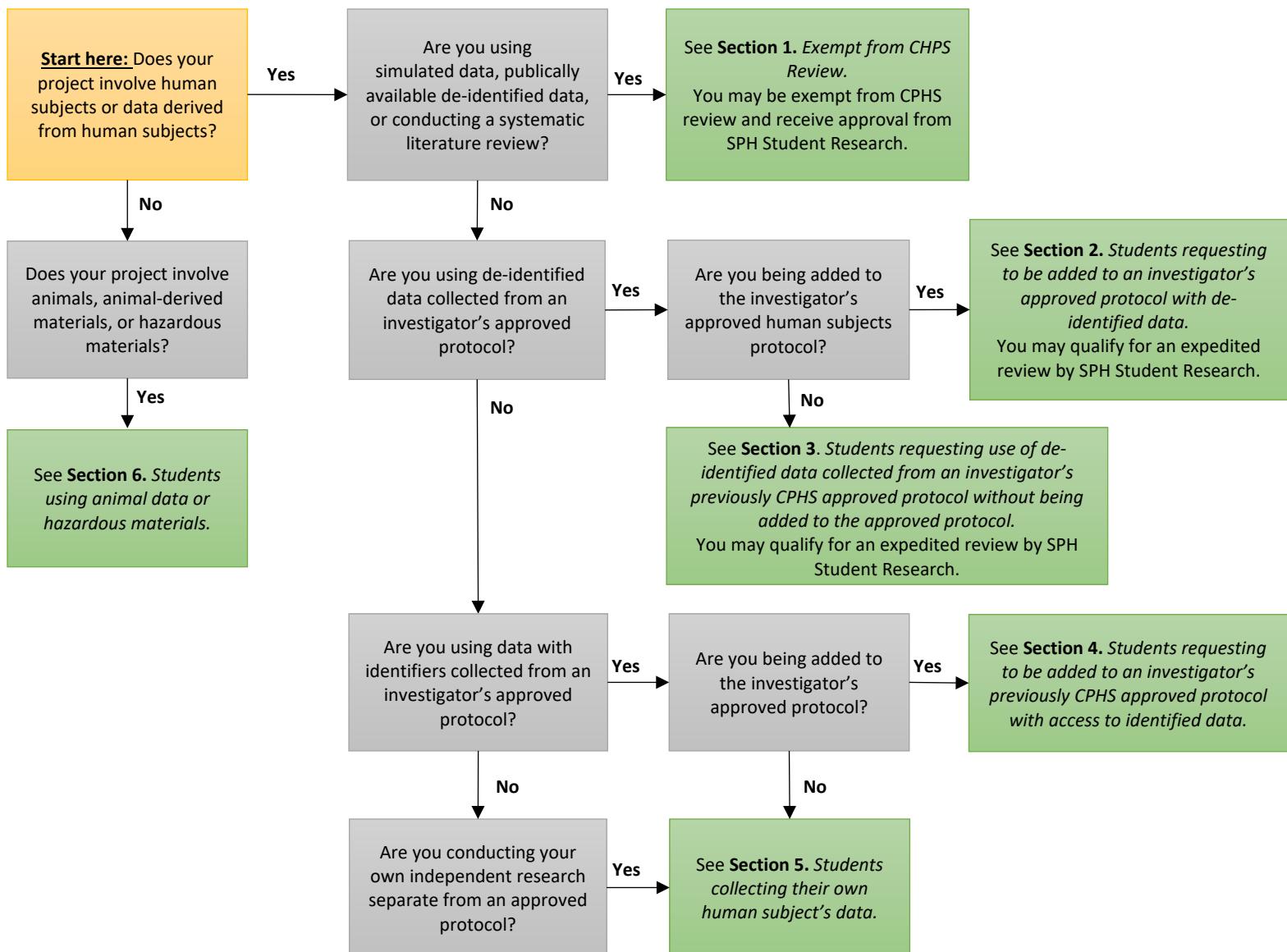
Committee for the Protection of Human Subjects (CPHS) SPH Student Guide and Instructions

Purpose

Students completing research may be required to undergo review and approval based on the data being used. The Committee for Protection of Human Subjects (CPHS) conducts this review on behalf of UTHealth. Students should use the flowchart below to help identify the section number that corresponds with their data type and collection method. Each section outlines the necessary steps and requirements for each scenario.

Students can also reach out to the CPHS helpdesk by contacting CPHS@uth.tmc.edu or calling 713-500-7943.

Students should use the following flow chart to help determine where to start.



This guide includes the following sections:

- Section 1. Exempt from CPHS review.
- Section 2. Students requesting to be added to an investigator's approved protocol with de-identified data.
- Section 3. Students requesting use of de-identified data collected from an investigator's previously CPHS approved protocol without being added to the approved protocol.
- Section 4. Students requesting to be added to an investigator's previously CPHS approved protocol with access to identified data.
- Section 5. Students collecting their own human subject's data.
- Section 6. Students using animal data or hazardous materials.
- Section 7. How to submit your request through the iRIS platform.

Section 1. Exempt from CPHS review.

Students that believe the data they will be using qualifies for an exemption from CPHS review may qualify for an expedited review by the SPH Student Research Office. This includes the research that uses the following types of data:

- Simulated data
- Publicly available de-identified data
- Systematic literature review

Required documentation: Students should complete the following forms and submit them to SPHStudentResearch@uth.tmc.edu to request an expedited review.

1. A copy of the student's CITI Training completion certificate. This training must have been completed within 3 years. *Note: students who completed this requirement as part of SPH New Student Orientation may submit the same certificate if dated within the last 3 years.
2. SPH Student Research [Institutional Approvals Form](#) (students should complete Section 1a)
3. A copy of the student's research proposal

Outcome: Students who are granted an exemption will receive an approved copy of their SPH Student Research Approvals form signed by the School of Public Health. A copy of the approved form will be kept with the student's file to document approval of the exemption. Once students receive this approval, they are permitted to move forward with their intended research plan.

Section 2. Students requesting to be added to an investigator's approved protocol with de-identified data.

Students that are requesting to be added to an investigator's previously CPHS approved protocol in order to have access to collected de-identified data may qualify for an expedited review by the SPH Student Research Office.

The protocol's Primary Investigator must submit a change request to CPHS to add the student to the protocol. CPHS will review this request and provide approval with an outcome letter to the Primary Investigator. The Primary Investigator will share this outcome letter with the student. The student must submit a copy of this outcome letter as mentioned below.

Required documentation: Students should complete the following forms, collect the required documents and submit them to SPHStudentResearch@uth.tmc.edu to request an expedited review.

1. A copy of the student's CITI Training completion certificate. This training must have been completed within 3 years. *Note: students who completed this requirement as part of SPH New Student Orientation may submit the same certificate if dated within the last 3 years.
2. SPH Student Research [Institutional Approvals Form](#) (students should complete Section 1b)
3. Letter of permission to use de-identified data from the CPHS approved protocol. This letter should be written by the protocol's Primary Investigator and addressed to the SPH Office of Student Research. A [template permission letter](#) can be found on the mySPH Student Research webpage.
4. A copy of the approved outcome letter written by CPHS to the protocol's Primary Investigator stating that the student has been added to the research protocol.
5. A copy of the student's research proposal

Outcome: Students who are granted an exemption will receive an approved copy of their SPH Student Research Approvals form signed by the School of Public Health. A copy of the approved form will be kept with the student's file to document approval of the exemption. Once students receive this approval, they are permitted to move forward with their intended research plan.

Section 3. Students requesting use of de-identified data collected from an investigator's previously CPHS approved protocol without being added to the approved protocol.

Students that are requesting to use de-identified data collected from a previously CPHS approved protocol may qualify for an expedited review by the SPH Student Research Office. In this request, students are not requesting to be added to the CPHS approved protocol, only to use data collected from this protocol.

Required documentation: Students should complete the following forms, collect the required documents and submit them to SPHStudentResearch@uth.tmc.edu to request an expedited review.

1. A copy of the student's CITI Training completion certificate. This training must have been completed within 3 years. *Note: students who completed this requirement as part of SPH New Student Orientation may submit the same certificate if dated within the last 3 years.
2. SPH Student Research [Institutional Approvals Form](#) (students should complete Section 1b)
3. Letter of permission to use de-identified data from the CPHS approved protocol. This letter should be written by the protocol's Primary Investigator and addressed to the student and should include that the data has been de-identified. A [template permission letter](#) can be found on the mySPH Student Research webpage.
4. A copy of the student's research proposal

Outcome: Students who are granted an exemption will receive an approved copy of their SPH Student Research Approvals form signed by the School of Public Health. A copy of the approved form will be kept with the student's file to document approval of the exemption. Once students receive this approval, they are permitted to move forward with their intended research plan.

Section 4. Students requesting to be added to an investigator's previously CPHS approved protocol with access to identified data.

Students that are requesting to be added to an investigator's previously CPHS approved protocol in order to have access to collected data must submit their request to CPHS through the iRIS platform.

The protocol's Primary Investigator must submit a change request to CPHS to add the student to the protocol. CPHS will review this request and provide approval with an outcome letter to the Primary Investigator. The Primary Investigator will share this outcome letter with the student. The student must submit a copy of this outcome letter as mentioned below.

Required documentation: Students should complete the following forms, collect the required documents and submit them to the iRIS platform for CPHS review.

1. A copy of the student's CITI Training completion certificate. This training must have been completed within 3 years. *Note: students who completed this requirement as part of SPH New Student Orientation may submit the same certificate if dated within the last 3 years.
2. A completed [Master's Thesis Committee Form](#) or [Doctoral Dissertation Committee Form](#).
3. SPH Student Research [Institutional Approvals Form](#) (students should complete Section 1b)
4. A copy of the approved outcome letter written by CPHS to the protocol's Primary Investigator stating that the student has been added to the research protocol.
5. A copy of the approved outcome letter written by CPHS to the student confirming that the student has been added to the research protocol.
6. A copy of the student's research proposal.

Students also review [Section 7. How to submit your request through the iRIS platform](#) for a step-by-step guide to submitting required information and documents for CPHS review.

Outcome: Students who are approved by CPHS will receive an outcome letter from CPHS. Students must submit a copy of this outcome letter along with the documentation listed above to SPHStudentResearch@uth.tmc.edu. The School of Public Health will then sign and approve the student's SPH Institutional Approvals Form. A copy of the approved form will be kept with the student's file. Once students receive this approval, they are permitted to move forward with their intended research plan.

Section 5. Students collecting their own human subject's data.

Students conducting their own research separate from an approved protocol are required to undergo a full review by CPHS. This review requires the following forms and should be submitted through the iRIS platform.

Required documentation: Students should complete the following forms, collect the required documents and submit them to the iRIS platform for CPHS review.

1. A copy of the student's CITI Training completion certificate. This training must have been completed within 3 years. *Note: students who completed this requirement as part of SPH New Student Orientation may submit the same certificate if dated within the last 3 years.
2. A completed Committee form.
3. SPH Student Research [Institutional Approvals Form](#) (students should complete Section 1c)
4. A copy of the approved outcome letter written by CPHS to the student confirming that the student has been approved for the research protocol.

5. A copy of the student's research proposal.

Students also review [Section 7. How to submit your request through the iRIS platform](#) for a step-by-step guide to submitting required information and documents for CPHS review.

Outcome: Students who are approved by CPHS will receive an outcome letter from CPHS. Students must submit a copy of this outcome letter along with the documentation listed above to SPHStudentResearch@uth.tmc.edu. The School of Public Health will then sign and approve the student's SPH Institutional Approvals Form. A copy of the approved form will be kept with the student's file. Once students receive this approval, they are permitted to move forward with their intended research plan.

Section 6. Students using animal data or hazardous materials.

Students conducting research or collecting data derived from animal subjects or hazardous materials are required to undergo a full review. This review requires the following forms and should be submitted through the iRIS platform.

Required documentation: Students should complete the following forms, collect the required documents and submit them to the iRIS platform for review.

1. A copy of the student's CITI Training completion certificate. This training must have been completed within 3 years. *Note: students who completed this requirement as part of SPH New Student Orientation may submit the same certificate if dated within the last 3 years.
2. SPH Student Research [Institutional Approvals Form](#) (students should complete Section 1c)
3. A copy of the student's research proposal

Students also review [Section 7. How to submit your request through the iRIS platform](#) for a step-by-step guide to submitting required information and documents for AWC review.

Outcome: Students who are approved by the Animal Welfare Committee (AWC) will receive an outcome letter from AWC. Students must submit a copy of this outcome letter along with the documentation listed above to SPHStudentResearch@uth.tmc.edu. Once students receive their outcome letter, they are permitted to move forward with their intended research plan.

Section 7. How to submit your request through the iRIS platform.

Students should use the following steps below to submit their request to IRB for approval, unless exempt.

1. Log in to [iRIS](#) with your UTHealth username and password
2. Click on "Add a New Study" and complete the walk-through process. *If you cannot see "Add a New Study," you might need to click on the "Compatibility view" button on your browser (located to the right of the URL).* As you complete your application, be sure to complete the fields below as noted:
 - a) "Department" field, question #2 – complete with your major department or campus.
 - b) "Principal Investigator (PI)" field – list your Faculty Advisor/Committee Chair's name
 - c) "Faculty Advisor" field – list one SPH committee member; **do not** list as "Co-Investigator"

- d) "Study Contact" field – list Travis Crook as an additional contact (this action will forward a copy of your IRB approval letter to SPH)
- e) "Department Signature" field – list your Department Chair's name

3. Supporting documentation – after the application questions have been answered, you must include the supporting documentation mentioned in the appropriate sections above to your iRIS submission packet under "Study Documents." Consent documents or letters of information can be placed under "Informed Consent." Include the following documents:
 - SPH Student Research [Institutional Approvals Form](#) (students should begin at section 1c)
 - A protocol using the [Protocol Template – Observational Study](#), available on the CPHS website
 - Survey or interview questions
4. Submit completed application – click "Send" when the application has been completed and the supporting documentation has been attached. You will be required to include an electronic signature using your iRIS username and password.