*Revised 24/7/2024*

**STUDENT CHECKLIST: FOR EPIDEMIOLOGY OR BIOSTATISTICS PRACTICUM AND CULMINATING EXPERIENCE**

**Key Definitions – Course Participants**

**Students** – Students identify and develop a topic applying and integrating the knowledge and skills they have gained from their academic work in epidemiology or biostatistics, through the accomplishment of the objectives of the Practicum-Culminating Experience (CE).

**Site Preceptor (SP)** – The individual in the field who will supervises the student’s work and provides input on the student’s performance through an evaluation.

**GW Faculty Advisor** **(GWFA)** – This is a member of the GW Milken Institute School of Public Health (SPH) Department of Epidemiology and Department of Biostatistics and Bioinformatics (DBB) faculty who will work with the student throughout the CE process to ensure that the student’s project and work meet Departmental standards. In some cases, there may also be a GWFA for the Practicum as well as for the CE. The GW Faculty Advisor is responsible for completing the student’s final evaluation, which contributes to a portion of the final grade for the Culminating Experience.

**Practicum Director (PD)** – The Practicum Directors, Joe Schmitthenner and Vivi Alves de Sa, guide students through the Practicum-CE process, verify students, sites and Site Preceptors on the SPH Practicum Website, follow student progress, review student and preceptor evaluations and from them, give the final student grade on the Practicum and CE.

**SAS Coach** – The SAS Coach assists students with data management and analysis. Please contact your Practicum Directorwhen assistance is needed. The SAS Coach is available to help by email or appointment only.

**Process for Registration**

### Students should not register for or begin the Practicum or CE without first having a meeting with one of the PDs; please contact Joseph Schmitthenner, MS at [jschmitthenner@gwu.edu](mailto:jschmitthenner@gwu.edu) at if you’re an Epi student and your last name begins with A – M; or contact Vivi Alves de Sa, MS at vivianne\_a@gwu.edu if your an Epi student and your last name ends in N – Z. Contact Stephanie Lee, MPA, MA at slee@gwu.edu if you are a Biostatistics and Bioinformatics student.

**Epidemiology and DBB Practicum-CE Resource Page**

For a student checklist, course syllabi, evaluations, FAQ sheet, project opportunities and funding awards, etc., please go to the Department of Epidemiology and DBB Practicum and Culminating Experience Resource page at: https://publichealth.gwu.edu/epidemiology-practice-experience**Preparing to Begin the Practicum**

*Mid-program and* ***at least one semester before starting Practicum****:*

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| **Activity:** | **Date Completed:** |
| **1. Before you can begin the Practicum you must complete the following prerequisites:** |  |
| PubH 6002 Biostatistical Applications for Public Health |  |
| PubH 6003 Principles and Practice of Epidemiology |  |
| PubH 6247 (co-requisite) Design of Health Studies |  |
| PubH 6249 (co-requisite) Use of Stat Packages for Data Mgmnt/Data Analysis |  |
| **2. Attend Department of Epidemiology (DEPI) or Department of Biostatistics and Bioinformatics (DBB) mandatory Practicum**  **Orientation sessions** (make sure you RSVP, arrive on time and sign in at the training). |  |
| **3. Prepare resume and cover letter for possible distribution to potential Site Preceptors**  **if looking for a Practicum site.** |  |
| **4. Complete CITI online module for Social and Behavioral Researchers** (https://www.citiprogram.org/  ). Make sure to save your certificate, and send to Student Records |  |
| **5. Schedule an appointment with a Practicum Director (PD)** and meet to identify possible practice area and project. (Joe Schmitthenner, last names with A-M; Vivi Alves de Sa: last names with N-Z). |  |
| **6. Choose a project and Site Preceptor (SP)** with assistance from PD, review of available projects on the Practicum website, and using other resources. Students can also identify their own projects, however, these should be discussed with the Practicum Directors. |  |
| **7. Meet with your SP** to plan your project. If you plan to link your Practicum and Culminating Experience (CE), please let your PD know. |  |

**Starting the Practicum**

*At the beginning of the second half of your program (e.g., September for 2nd year students):*

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| **Activity:** | **Date Completed:** |
| **1. Develop and submit Practicum plan/APEx Proposal**  Working with the SP and GWFA (if applicable), develop an APEx Proposal for submission on the SPH Practicum website. Your PD must approve the plan before you post it online. In posting the plan online, you will be prompted for information required for approval. Your Preceptor will also be asked some additional questions on an Endorsement Form in order to fully Endorse your project  ***\****If planning to do an internationally based Practicum, be sure to inquire about procedures to register and obtain approval from the GW International Program. |  |
| **2.** All students participating in projects related to school requirements (dissertation, MPH culminating experience (CE), MPH Practicum, Biostatistics Consulting Practicum, Field Lab Experience, independent study, etc.) require oversight of their projects. This is not only for human protection / IRB reasons but also so the Department can monitor what types of projects are being conducted by students and ensure proper oversight. Please refer to **Appendix A of this document** for a full description of this process. |  |
| **3.** **Complete the required modules in the Dept of Epidemiology and DBB Skills Building Modules Blackboard Community**  Practicum course registration can take place at any time during the semester.Concurrent with the Practicum, students are required complete a series of skills building modules in the **Dept of Epidemiology and DBB Skills Building Modules Blackboard Community. All new MPH students are automatically registered in the Skills Building Modules Blackboard Community. If it does not appear on the bottom of your Blackboard home page, please contact one of the Practicum Directors to let them know.** |  |
| **4. Begin the Practicum**  Once you receive Student Project Oversight approval, and online approval of your APEx plan on the SPH Practicum website from your preceptor and PD, you may begin your practicum. It is not required to log your hours, but there is an optional tracking hours sheet available if needed. |  |
| **5. Complete a mid-Practicum attestation on the SPH Practicum website**: The attestation should be completed by the student after approx. 60 hours. |  |
| **6. Complete final Practicum evaluation on SPH Practicum website. Your Site Preceptor will also need to complete a final evaluation** |  |

**Beginning the Culminating Experience**

*Students can register for the CE concurrent with or after the Practicum.*

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| **Activity:** | **Date Completed:** |
| **1. If you decide you want the focus of your Culminating Experience to be different from the**  **topic and site for your Practicum, then work with PD to find another activity for the**  **Culminating Experience**. A GWFA will be assigned to you based on your research topic. If your Practicum and CE are linked, you should begin doing the CE steps described below while still working on your Practicum. |  |
| **2. Draft Concept Paper** **based on your Culminating Experience topic** (refer to PubH  6015 syllabus available on Practicum Resource website -Share the draft with your PD who will use it identify a GWFA for you. |  |
| **3. Register for the Culminating Experience (CE) course (PubH 6015).**  *\*Registration should occur in the semester you intend to finish and present the CE.* You  will need to send your PD an RTF to register for the CE. |  |
| **4. Work with your GWFA’s and Site Preceptor and when they indicate you are ready, begin work on the proposal.** (If you are working on a GWFA’s project, then the GWFA is precepting you and both roles are combined.) |  |
| **5. Be sure to provide your PD with the final version of the Concept Paper.**  It will be placed in your electronic folder. |  |
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**Expanding the CE Concept Paper into a Proposal/Obtaining IRB Approval**

*After finalizing the Concept Paper and beginning the practice activity:*

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| **Activity:** | **Date Completed:** |
| **1. Expand Concept Paper into full a Proposal** (refer to PubH 6015 syllabus). |  |
| **2. Once approved by GWFA and SP, provide final version of the Proposal to**  **the PD and it will be filed electronically**. |  |
| 5. All students participating in projects related to school requirements (dissertation, MPH culminating experience (CE), MPH Practicum, Biostatistics Consulting Practicum, Field Lab Experience, independent study, etc.) require oversight of their projects. This is not only for human protection / IRB reasons but also so the Department can monitor what types of projects are being conducted by students and ensure proper oversight. Please refer to **Appendix A of this document** for a full description of this process. |  |
| **6. Once your project receives IRB authorization or exemption, alert your GWFA and SP and you may begin work on project.** |  |
| **7. Check in with your Site Preceptor and GW Faculty Advisor on a regular basis**  (e.g., at least once a month). |  |
| **8. Register for the Culminating Experience (CE) course (PubH 6015)** during the  semester in which you plan to complete the CE and present the findings. Please send your PD an RTF to to register for the CE. |  |

**Completion of the Culminating Experience (Final Report/Manuscript and Oral Presentation)**

*After finalizing the Proposal and obtaining IRB approval, if necessary:*

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| **Activity:** | **Date Completed:** |
| **1. Complete all analysis for Culminating Experience** working with SP and GW Faculty Advisor. |  |
| **2. Prepare Final Report/Manuscript** (refer to PubH 6015 syllabus). |  |
| **At least 4 weeks in advance of Oral Presentation** | |
| **3. Submit complete final draft of the Report/Manuscript to SP and GW Faculty Advisor for review and comment.** |  |
| **4. Make any required edits and revisions as needed to Report/Manuscript.** |  |
| **5. Obtain Site Preceptor's approval of your final draft and approval to present**  (forward email to PC). |  |
| **6. Obtain GW Faculty Advisor's approval of your final draft and approval to present** (forward email to PC). |  |
| **7. Begin preparing Oral Presentation.** (15 minutes for the presentation, 5- minutes for questions; refer to PubH 6015 syllabus). |  |
| **At least 2 weeks in advance of Oral Presentation** | |
| **8. Schedule oral presentation at your CE site with your site preceptor and colleagues. If you are working with a DEB faculty member who is your site preceptor and GWFA, please make arrangements to present for the GWFA in advance as well.** |  |
| **9. Send email to PC to schedule GW oral presentation with GW Faculty Advisor.** |  |
| **10. Write abstract (using template provided in CE syllabus) and send to GW Faculty Advisor**  **and SP for review and approval.** |  |
| **11. Send approved abstract to PD once date of oral presentation is scheduled.** |  |
| **12. Invite SP and others to presentation.** |  |
| **13. Send CE final evaluation form to SP** |  |
| **14. Submit draft of PowerPoint oral presentation to GW Faculty Advisor and**  **SP for review and approval.** |  |
| **At least 1 week in advance of Oral presentation** | |
| **15. Submit revised version of PowerPoint oral presentation to GW Faculty Advisor, SP, and PC**. |  |
| **16. Submit electronic copy of Concept Paper, Proposal, and Final Report/ Manuscript with the required title page to the** PD, GW Faculty Advisor, and SP(refer to PubH 6015 syllabus appendix)**.** |  |
| **17. On the scheduled date: Present Oral Presentation for GW Faculty!** |  |
| **To ensure you get Credit the Practicum and CE, please be sure to do the following:** | |
| **Practicum:**   1. **Make sure your Site Preceptor (SP) has approved your Practicum Plan** 2. **Be sure to complete the Midpoint Attestation.** 3. **Please make sure that your SP has completed the Final Site Preceptor Evaluation Form on the SPH website.** 4. **Complete the Final Student Evaluation Form of your SP on the SPH website and review.** |  |
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| **Culminating Experience (CE):**   1. **If you have not already done so, submit electronic versions of Concept Paper, Proposal, Final Report or Manuscript, and PowerPoint presentation to PD, GWFA and SP.** 2. **Have SP complete and submit the MPH Culminating Experience Student Performance Evaluation, and return it to the PD.** 3. **Complete CE Student Final Evaluation and submit it to the PD.** 4. **Close out the study with the applicable IRB, if necessary.** |  |

**Students who are graduating must present by the date the semester officially ends to be able to graduate within that semester. The exact date can be obtained from Student Records. Presentation dates are set by the faculty and announced during the first weeks of each semester.**

**CONGRATULATIONS!** Enjoy the satisfaction of reaching your goal!

**DEPARTMENT OF EPIDEMIOLOGY AND DBB STUDENT PROJECT OVERSIGHT PROCESS**

# Background

* All students participating in projects related to school requirements (dissertation, MPH culminating experience (CE), MPH Practicum, Biostatistics Consulting Practicum, Field Lab Experience, independent study, etc.) require oversight of their projects. This is not only for human protection / IRB reasons but also so the Department can monitor what types of projects are being conducted by students and ensure proper oversight.
* Before beginning any school project involving seeing or handling data derived from humans, students must complete the determination process and have a determination about next steps made.
* Student requirements for project oversight are not always the same as faculty requirements. For example, certain types of studies may be considered non-human subjects research (NHSR) for faculty but due to their sensitive subject area, exempt review is required for students.
* Approval for the project itself is not implied by the completion of the determination project; students still need to work with faculty and staff to ensure the project is approved and meets academic requirements.
* It is the faculty advisor’s responsibility to ensure that students have a determination on file for projects that meet academic program requirements. Students cannot begin their projects until process is completed. Faculty advisors are ultimately responsible for each of the students that they advise on research projects.

# Process

* + All students participating in projects related to school requirements (dissertation, MPH culminating experience (CE), MPH Practicum, Biostatistics Consulting Practicum, Field Lab Experience, independent study, etc.) require oversight of their projects. This is not only for human protection / IRB reasons but also so the Department can monitor what types of projects are being conducted by students and ensure proper oversight.
  + Before beginning any school project, students must complete the determination process and have a determination about next steps made.
  + It is the faculty advisor’s responsibility to ensure that students have a determination on file for projects that meet academic program requirements. Students cannot begin their projects until a determination is made. Faculty advisors are ultimately responsible for each of the students that they advise on research projects.
  + Process to comply with Student Project Oversight:
  + Once Practicum Director (PD) approves practicum plan, they will advise student to complete the Student Project Oversight form here: https://cri-datacap.org/surveys/index.php?s=T3783HC8Y4
  + Final determinations will be sent to the student, faculty advisor, and PDs
  + RTF forms for the Practicum, CE, Field Lab Experience, Final Project, or Independent Study, students will not be approved until a determination has been made and all relevant approvals are in place.

# Types of Determinations by the Epidemiology and Biostatistics Departmental Liaison

There are several possible outcomes of the determination process:

* **Please provide more information.** Research is complicated and when it comes to ensuring protection of research subjects, we must always be very cautious and thoughtful; many IRB issues are not cut and dry. You may be asked to provide more information to enable a determination about your project.
* **Not research.** Your study may be determined to not be research at all based on human subjects regulations. If this is the case, you will not need to pursue approval by the GW IRB. However, if you have any change to your proposed project, you should check again to ensure that the determination has not changed. Note that if you intend to present your findings outside of your department in any way, or in any publication, the project is considered to be research and this category will not apply.
* **Non-human subjects determination.** If you receive this designation it means that your proposed project is not considered human subjects research and you do not need to pursue approval by the GW IRB. However, if you have any change to your proposed project, you should check again to ensure that the determination has not changed.
* **Recommendation to refer to the IRB.** You may be advised to submit a new study application to the GW IRB. If this occurs, you must work with your faculty principal investigator to do so. At this point, the Departmental IRB Liaison will no longer be involved. Remember to keep comprehensive files of all of your submissions to, approvals from, and contact from the IRB. Submit the final IRB approval into the Student Project Oversight Portal.

# Student Project Types

The following are the most common types of projects students work on. After each one, the type of documentation required before starting the project is described.

# Existing Information

Scenario I:

* Student is working only with one or more of the following types of non-human data: 1) Literature Reviews and Reviews of Public Health Reports/Papers (such as for a meta-analysis), 2) Existing Aggregate Data, 3) laboratory data involving bacteria or viruses, but not human cell lines, tissue or samples, and 4) animal data.
* Required documentation: NHSR determination from Departmental IRB Liaison.

# Secondary Data Analysis

Scenario II:

* Student is working with public access dataset covered under PHS law and publicly downloadable.
* Required documentation: NHSR determination from Departmental IRB Liaison or IRB.

Scenario III:

* Student is working with another (non-PHS) publicly downloadable dataset which appears to be NHSR.
* Required documentation: NHSR determination from Departmental IRB Liaison or IRB.

Scenario IV:

* Student is proposing analysis of more complex data that may involve sensitive topics or have identifiers
* Liaison collaborates with IRB regarding approval submission.
* Required documentation: IRB approval letter or letter from IRB indicating NHSR or exempt approval.

Scenario V:

* Student is participating on existing IRB approved study with NHSR or exempt status.
* Required documentation: IRB approval letter or letter from IRB indicating NHSR or exempt approval.

Scenario VI:

* Student will be receiving data that are stripped of direct and indirect identifiers.
* Required documentation: NHSR determination from Departmental IRB Liaison or IRB.

# Primary data collection

Scenario VII:

* Student will be conducting or participating in primary data collection with GW faculty member as study PI.
* Departmental Liaison refers to GW IRB.
* Required documentation: IRB approval letter that indicates student is an approved study team member.

# Working with other institutions and/or existing studies

Scenario VIII:

* Student will be conducting or participating in primary data collection with non-GW faculty member as study PI at another institution.
* Departmental Liaison refers to GW IRB in order to determine process. Potential options are: a) concurrence with their IRB determination; b) request to submit GW IRB application; c) determination of non-engaged research status. C
* Required documentation: IRB approval letter that indicates student is an approved study team member at other institution and documentation of approval from GW IRB.