Office of Research Excellence
Guidance for Students: Ethics Oversights of Student Projects

Background:

1. The Office of Research Excellence (ORE) is responsible for providing support and oversight over all research and research-related activities carried out under the auspices of the Milken Institute School of Public Health.
2. All student projects related to program requirements (e.g., dissertation, MPH Culminating Experience (CE) project, MPH practicum, biostatistics consulting practicum, field/lab placement, independent study) require oversight and tracking for reporting purposes and the protection of human subjects.
3. The ORE aims to simplify the process of submitting projects for ethics oversight by use of an online portal. The portal also allows organized tracking of determinations and descriptions of the exciting work in which our students engage.
4. If Faculty Advisors are aware that a student's project will need IRB review, they **do not** need to wait for a determination from the ORE to submit to the GW Office of Human Research (IRB). Projects that require IRB review and approval are to be submitted to the GW IRB through advising faculty. The student is to upload pertinent IRB approval documentation to the portal *after it is obtain*ed.
5. Students may commence their proposed project activities only after obtaining requisite IRB approval or a determination from the ORE that provides clearance to proceed.
6. Categories of projects for which ORE has granted a blanket determination do not need to be submitted through the portal. Faculty Advisors/Practicum Directors should inform students of this and provide them with a copy of the pertinent blanket determination.

Project Submission Process:

1. Students are required to work with Faculty Advisors as they develop their projects.
2. Submission instructions are set out in this document, as well as on the portal landing page.
3. The student will need to request that his/her Faculty Advisor complete and sign the fillable PDF Oversight Endorsement Form that is available on the portal. If the project has a site preceptor, the student must also send this form to the preceptor to complete, endorse, and return to the student. *All sections of the Oversight Endorsement Form are to be completed*.
4. The student will need to assemble all necessary documents in order to enter project information into the portal, including the completed Oversight Endorsement Form. For some programs (e.g., MPH@GW), students may be required to complete the PDF fillable template of the portal fields and receive approval from the Faculty Advisor or Practicum Director before entering project details into the portal. This template is available on the portal landing page and is for informational/reference purposes only.
5. The portal database will generate an email communication to the student and the Faculty Advisor to confirm successful submission.
6. ORE will review and issue a determination within 7-10 business days from receipt of submission. In the event that a response is not received within 7-10 business days, please email sphstudentirb@gwu.edu to make an inquiry.
7. A determination will be emailed to the student and, as applicable, to the Faculty Advisor, Practicum Director, and preceptor. Receipt of an email advising the student to proceed with her/his project

concludes the ORE review process and begins the student's project implementation with faculty support.

Documents Required for Portal Submissions:

1. If the proposed activity is covered by a new or existing GW or non-GW IRB decision, the following are required:
   a. The proposal/project plan approved by the Faculty Advisor or Practicum Director;
   b. Proof of a current, non-expired IRB approval (as relevant, new or existing approval/exempt status) and the modification to include the student as a study team member.
2. For a study reviewed and approved via expedited or full review IRB procedures, the following are required:
   a. Current, non-expired IRB approval, ***plus*** the modification to show that the student has been successfully added as a study team member;
   b. For a study designated by an IRB as Exempt/Non-human subjects research (NHSR), the Exempt/NHSR documentation, ***plus*** a letter from the Principal Investigator that grants the student permission to be part of the study.
3. If the proposed project does not require IRB review or if the Faculty Advisor is unsure about the need for IRB review, students are to prepare the following documents:
   a. The proposal/project plan approved by the Faculty Advisor or Practicum Director;
   b. If applicable, a list of every type of data (variables) to be accessed or collected, whether or not such data would be analyzed;
   c. Any applicable data collection instrument; and
   d. A fully completed and signed Oversight Endorsement Form.

Possible Determinations:

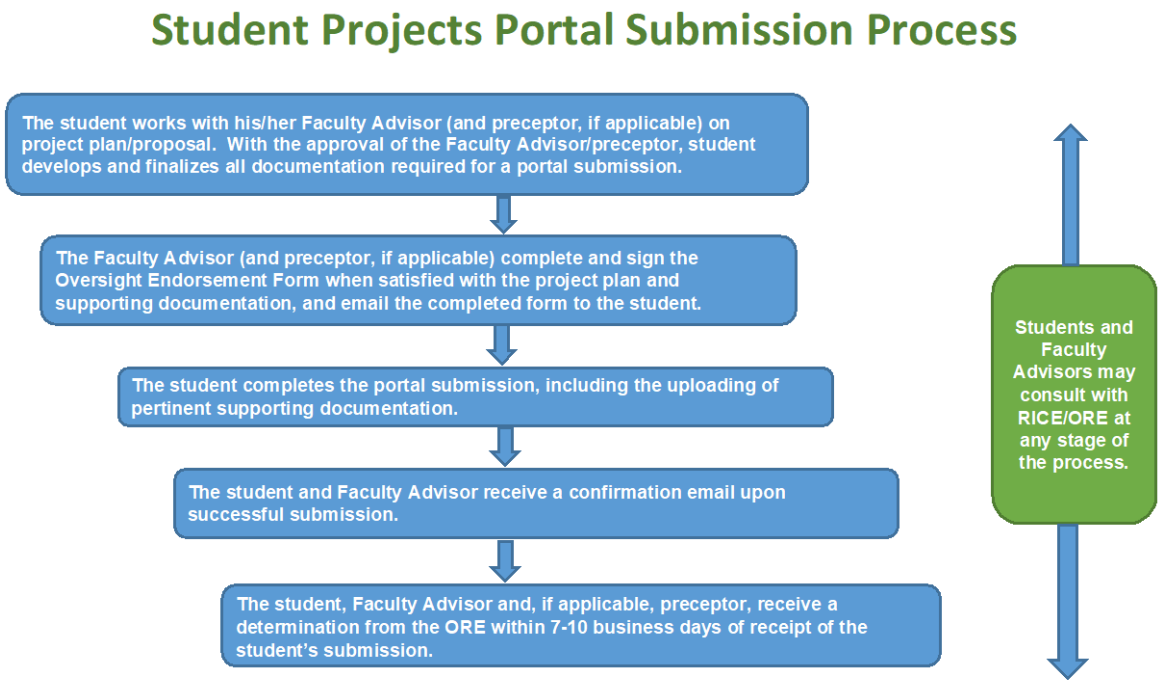
The ORE may issue one of the following four determinations:

1. **Non-human subjects research**; the student may proceed with proposed activity.
2. **No further IRB review required per existing IRB approval**; the student may proceed with proposed activity.
3. **Not research**; the student may proceed with proposed activity.
4. **Project must be submitted to IRB for review and approval**; the student is to submit applicable IRB documentation to the portal when received.

Useful Tips:

1. Students should familiarize themselves with the portal. Additionally, to avoid review delays, students should ensure that their submissions sufficiently describe the project's primary purpose, methodology, data sources, and variables.
2. Students and Faculty Advisors are advised to plan ahead, as projects that require IRB review and approval need time for processing through the IRB. The process can take up to three (3) months. Research on sensitive topics or involving vulnerable populations requires IRB review and approval.
3. If a student leaves the portal and wishes to complete the submission later, s/he is advised to write down the "Return Code" to return to the draft. The Return Code can be obtained by clicking "Save and return later." Once submitted, a "Return Code" can no longer be used.
4. Students are required to submit separate portal submissions for MPH CE and practicum projects.

Summary of Submission Process



Contact Information:

The Research Integrity, Compliance, and Ethics (RICE) Unit within ORE will assist students with questions regarding the portal submission process and requirements. Students may contact the RICE Unit as follows:

1. Paul Ndebele at pndebele@gwu.edu (phone: 202-994-1271) or Hina Shaikh at hshaikh@gwu.edu (phone: 202-994-0857)
2. Weekly walk-in hours are available on Wednesdays from 2:00 to 4:30pm at the Milken Institute School of Public Health, 7th Floor, Suite 722

APPENDIX

1. Supplement 1: The Oversight Endorsement Form is for informational purposes only. In preparing a portal submission, students are to download this fillable PDF form from the portal.
2. Supplement 2: The GWSPH Student Project Oversight Form is for informational purposes only. In preparing a portal submission, students may download this form from the portal.

Thank you for your participation in this important educational milestone.

Prepared by: *Hina Shaikh, JD MPH, and Paul Ndebele, PHD, Research Integrity, Compliance and Ethics Unit, Office of Research Excellence*

Approved by: *Adnan Hyder, MD MPH PHD, Senior Associate Dean for Research, Office of Research Excellence*

Date: *26 May 2020*

Supplement 1

Form to be completed and signed by Site Preceptor (for Practicums and field work) & GWSPH Advisor/Practicum Director

Oversight Endorsement Form

Student and Project Information				
Student's full name				
Student's email address				
Project title				
Briefly describe the student's planned activities:				
Please complete the following by checking the applicable box.		**YES**	**NO**	**N/A**
Permissions and approvals				
The student has permission to work at this organization.				
The student has permission to use the dataset(s) specified in his/her proposal.				
The student is permitted to independently share findings beyond GWSPH program requirements.				
The student will use a dataset that is publicly accessible (i.e., free of charge and does not require registration or passwords in order to access the dataset).				
If yes, please describe:				
This project has current IRB approval from GWU or another institution.				
If yes, please provide the student with the IRB approval letter and, if applicable, documentation that s/he is on the IRB membership roster for the applicable study.				
Project purpose				
The intention of this project is to support our existing public health practices (e.g., surveillance, data entry).				
The intention of this project is to disseminate findings and contribute to the scientific literature (e.g., paper, conference).				
Types of data access				
The student will access sensitive data.				

If yes, please describe:			
Please complete the following by checking the applicable box.	**YES**	**NO**	**N/A**
The student will have access to individual or private information.			
If yes, please describe:			
The student will have access to direct (e.g., medical record number, email address) and/or indirect (e.g., date of birth, date of procedure) identifiers.			
If yes, please describe:			
The student will have access to code-links that connect coded information/data with identifiable information (e.g., via a log, consent form, database).			
If yes, please describe:			
Other significant information about the project:			
By signing below, I confirm that I have reviewed the student's project plan and endorse its implementation.			
Signatures			
Site Preceptor	Name:		
	Email address:		
	Phone number:		
Site Preceptor's title			
Site Preceptor's signature		Date	
Organization name and physical address			
	Name:		

GWSPH Advisor/Practicum Director	Email address:		
	Phone number:		
GWSPH Advisor/Practicum Director's title and department	Title:		
	Department:		
GWSPH Advisor/Practicum Director's signature		Date	
For MPH@GW Program			
MPH@GW Academic Advisor	Name:		
	Email address:		

Supplement 2

This form is for reference only. MPH@GW program students must complete and send this form to their GWSPH Advisor for review.

Welcome to the GWSPH Student Project Oversight Portal

- All student projects outside of activities limited to the classroom need to be entered into the portal. This helps us keep track of the great work our students are doing.
- This includes CEs, practicum and field lab placements, independent studies, final projects, and other projects for school credit.
- This process allows the Dean's Office of Research Excellence (ORE) to support your educational journey while ensuring compliance with GWU policies.
- This portal is managed by ORE. For general questions about the process, please email sphstudentirb@gwu.edu.
- **In order to ensure full compliance with regulations and GWU policies, you may not begin your project until you have received a determination by email that you are approved to do so.**

How the Process Works

Work with your GWSPH Advisor or Practicum Director on your proposal.
To make a submission through this portal, your GWSPH Advisor must endorse your project by signature on the provided Oversight Endorsement Form. All practicum projects and other field work must be supervised by a Site Preceptor, whether located at GWU or elsewhere. If you have a Site Preceptor, s/he also must complete the Oversight Endorsement Form that is embedded below and directly on the second page of the portal.

If your proposed activity is covered by a new or existing GWU or outside IRB decision or approval, you will need to upload the following documents:

- Proposal/project plan approved by your GWSPH Advisor/Practicum Director; and
- Proof of an existing IRB decision, as relevant (new or existing approval/exempt status/modification to include student on study roster). If the study was reviewed and approved via expedited or full review IRB procedures you will need the current IRB approval, PLUS the modification to show that you were successfully added to the study roster. If the study is designated Non-Human Subjects Research (NHSR) by an IRB, you will need the NHSR designation documentation, PLUS a letter from the PI granting you permission to be part of study.
- Oversight Endorsement Form completed and signed by your GWSPH Advisor/Practicum Director and, if applicable, Site Preceptor.

If your proposed activity does not require IRB review or if you are not sure about the need for IRB review, please have the following documents ready for uploading:

- Proposal/project plan approved by your GWSPH Advisor/Practicum Director;
- List of every type of data (variables) you will have access to or collect (whether or not you would analyze them) and any surveys or other instruments to be used for data collection, if applicable; and
- Oversight Endorsement Form completed and signed by your GWSPH Advisor/Practicum Director and, if applicable, Site Preceptor.

**Note: For MPH@GW program students, your Advisor must review and the MPH@GW Practicum or CE Director must sign the Oversight Endorsement Form.

When all the information and documents have been entered, it's time to submit! You will receive a confirmation email when your submission has been received. **If you have not received a confirmation email, you have not successfully submitted through this portal.** Please ensure that you have correctly submitted.

ORE will send you a determination by email within 5 to 7 business days of your completed submission, exclusive of holidays. Your determination will be one of the following:

- Non-human subjects research; you may proceed with your proposed activity.
- Not research; you may proceed with your proposed activity.
- No further IRB review required per existing IRB approval; you may proceed with your proposed activity.
- Project should be submitted to IRB for review; please submit applicable IRB approvals and documentation to the portal when received.

Tips for Preparing Your Submission

- Although most student projects are determined to be non-research or research that does not require IRB review, it is important to allow enough time in case it does. In the event that you are required to apply to the GWU IRB, it may take up to three months to complete IRB review. Please plan accordingly.
- If your GWSPH Advisor knows that the project needs GWU IRB approval but has not yet applied for review, work with her/him to submit to the GWU IRB. You do not need to wait for instructions from this oversight process to submit to the GWU IRB; you may wait until you have IRB approval to submit through this portal.
- **If you leave the portal and wish to complete the worksheet later, please write down your unique "Return Code" to return to your draft.**

If you have questions regarding the submission process and requirements, please email sphstudentirb@gwu.edu. For technical issues and support, please email Joseph Schmitthenner at jschmitthenner@gwu.edu.

Section I: Background Information	
First Name:	
Last Name:	
Email Address:	
GWID:	
Date:	
Department:	
Degree:	
Program of Study: (Please specify your program or track (e.g. Epidemiology))	
GWSPH Advisor or Practicum Director Name:	

GWSPH Advisor or Practicum Director Email Address:	
Do you have a non-GWSPH Site Preceptor for your Project?	Yes ☐ No ☐
Site Preceptor Name (if applicable):	
Site Preceptor's Email Address:	
Name of Site Preceptor's Organization:	
Site receptor's Organization Address	
Section II: Project Overview	
Title of Project:	
Type of Project:	○ MPH Practicum ○ MPH Culminating Experience (CE) ○ MS Thesis ○ Final Project ○ Independent Study ○ Classroom project (research or evaluation done in a class with intent to publich) ○ Field/Lab Placement ○ Biostatistics Consulting Practicum ○ Other, please specify in the field below
If Other, please specify the nature of your project:	
If this is for a class, what course is this project for?	
Please include a copy of your Proposal/Practicum Plan	
Note: You may only submit through the portal after uploading your approved proposal or Practicum Plan, as appropriate. If your project is currently with the GWU IRB for review please complete this submission after you have obtained approval from the GWU IRB.	
Has your project already undergone IRB review?	Yes ☐ No ☐
If yes, please continue. If no, please skip to Section IV	
Section III: Proposed activity covered by new or existing IRB approval/decision	
Study Principal Investigator's name as per IRB Records:	
Indicate the IRB approval/decision date:	

Indicate the IRB Protocol expiration date:	
Study/site location:	
IRB Approval/Study Number:	
Study Title as approved by IRB:	
OVERSIGHT ENDORSEMENT FORM: Your Site Preceptor and GWSPH Advisor or Practicum Director must complete this form (embedded on the Student Project Oversight Portal) to verify that you (1) have permission to work at the organization; (2) have permission to use relevant data; and (3) if applicable, would not have access to private identifiable information. Note: All projects require this form to be completed and signed by both your Site Preceptor and GWSPH Advisor or Practicum Director.	
NOTE: You can successfully submit only after uploading a copy of the IRB approval/decision letter.	
Please provide a copy of the IRB approval/decision letter	
Please upload a letter from the Principal Investigator verifying that you are a member of the research team or the approval or modification from the listed IRB confirming that you are a research team member	
Please upload any other supporting documents, e.g., for determinations of non-human subjects research or exempt status	
Please provide any other relevant documentation.	
I certify that the information given by me is accurate to the best of my knowledge, I am familiar with and understand the GWU policies concerning academic honesty, research misconduct and research involving human participants, and I agree: 1. To accept responsibility for the scientific and ethical conduct of this project; 2. To notify my faculty advisor/practicum director/preceptor of any plan to introduce changes to my project and, if necessary, report such changes to the ORE in accordance with GWSPH requirements; and 3. To immediately report to my faculty advisor/practicum director/preceptor and ORE any serious adverse reactions and/or unanticipated effects on volunteers and others which may occur as a result of this project	
Signature:	
Student Projects Requiring Determinations by ORE Oversight Team	
Section IV: Project Characteristics	
Please describe your project in 2-3 sentences:	

What is the nature of your project? Check all that apply:	○ Literature review limited to peer-reviewed and grey literature ○ Systematic review ○ Meta-analysis (study that combines data from other studies) ○ Secondary analysis using publicly available dataset with individual-level data that does NOT require a password or special access ○ Secondary analysis using publicly available dataset with individual-level data that REQUIRES a password or special access ○ Secondary analysis using publicly available dataset with aggregate data (e.g., from public health reports) ○ Secondary analysis using non-publicly available dataset (e.g., dataset provided by an investigator or organization) ○ Synthesis of existing aggregate reports (no individual-level data) ○ Work involving surveys, focus groups, or interviews ○ Work on an interventional study or trial ○ Work with lab animals ○ Work with specimens in a lab ○ Monitoring/evaluation ○ International primary data collection ○ Quality Assurance/quality improvement (QA/QI) ○ None of the above (Please check all that apply)
What activities would you do in connection with this project? Please check all that apply	○ Accessing electronic medical records, health data, or individual-level data ○ Accessing physical medical records, health data, or individual-level data ○ Interacting with a community-based organization, agency or clinic ○ Interacting with individual subjects in any way (including online, on the phone, in person, or via focus groups, interviews, or survey questionnaires)

	○ International data collection or international data source ○ Implementing or evaluating an intervention (e.g., biomedical or behavioral) ○ Sensitive topics (e.g., HIV, STIs, sexual behavior, minors, smoking, substance abuse, incarcerated individuals, vulnerable populations such as cognitively impaired persons) ○ Supporting existing work at an organization, agency, or clinic that is ongoing to meet the needs of the site (e.g., surveillance, service provision) ○ Supporting work at an organization, agency or clinic that is being done specifically for eventual research purposes (e.g., research in existing agencies) ○ Surveillance system or Department of Health information ○ Working with animals ○ Biohazards/lab-based research ○ Vulnerable/Special populations (e.g., pregnant women, human fetuses and neonates, children, cognitively impaired persons, prisoners, veterans, students, and employees) ○ Situations that could be hazardous to you or others in any way ○ None of these
Section V: Use of Data	
Will you have access to or will you be using any existing data? (This includes collecting electronic data or using existing data) **If No, please proceed to Section VI*	Yes ☐ No ☐
Is this data from a publicly available dataset?	Yes ☐ No ☐
Do you work with this data as part of your paid or unpaid work?	Yes ☐ No ☐

Are your data coded? Meaning are they linked to an individual person through a code that is not itself a direct identifier (e.g., a randomly assigned participant ID rather than a medical record number or social security number)?	Yes ☐ No ☐
If your answer to the previous question is "Yes", is there any way you could ever have access to the code-links (the link between the person's participant ID and the person's direct identifier), even if you would not use them in your analysis?	Yes ☐ No ☐
Note: If No, please provide assurance that you would never have access to any code-links via the materials mentioned. Please check all that apply and attach those relevant	○ Oversight Endorsement Form completed and signed by the person providing the data ○ Documentation verifying that code-links would never be released to you ○ Website information. Please specify in the field below ○ Other, please specify in the field below
If applicable, please provide the specific URL for the confidentiality policy and assurance that you would never have access to the code-links	
If Other, please specify and upload appropriate materials	
Will you interact with any medical records or private information (e.g., medical charts, electronic health records)?	Yes ☐ No ☐
What is the sample size of the data that you would use for this project?	
Which of the following variables would be available to you (whether or not you would analyze them)? Please check all that apply:	○ Names ○ Geographical subdivisions smaller than a state (including full zip codes) ○ All elements of dates beyond year (includes: DOB, admission, procedure, death dates, people > 90 years) ○ Telephone numbers ○ Fax numbers ○ Email addresses

	○ Social Security Numbers ○ Health plan beneficiary numbers (private, public or and other) ○ Account numbers ○ Certificate or license numbers ○ Vehicle identification or serial numbers (including license plate numbers) ○ Device identifiers or serial numbers ○ Web URLs or IP addresses ○ Biometric identifiers, including fingerprints and voice recordings ○ Full-face photographs and any comparable images ○ Any other unique identifying number, characteristic, or code (e.g., derived from other information that can identify the individual or codes that are not released by the entity responsible for the data) ○ Other codes that could identify an individual
In connection with this project, which of the following do you plan to do? Please check all that apply:	○ Share within the organization where I will work, as a report and/or presentation ○ Submit to a conference ○ Share locally beyond the organization where I will work but not in scientific literature ○ Other, please specify in the field below
If Other, please specify	
Please upload the list of variables you will be using in your study	
Do you or your Site Preceptor/GWSPH Advisor plan to eventually publish the findings from this project in a peer-reviewed journal?	Yes ☐ No ☐
Section VI: GWSPH Advisor/Practicum Director Approval	
OVERSIGHT ENDORSEMENT FORM: Your Site Preceptor and GWSPH Advisor or Practicum Director must complete this form (embedded on the Student Project Oversight Portal) to verify that you (1) have permission to work at the organization; (2) have permission to use relevant data; and (3) if applicable, would not have access to private identifiable information. Note: All projects require this form to be completed and signed by both your Site Preceptor and GWSPH Advisor or Practicum Director.	
Other significant information about the project (please list and/or attach any other significant information about the project.	