Milken Institute School of Public Health
THE GEORGE WASHINGTON UNIVERSITY

GUIDANCE FOR FACULTY ADVISORS AND PRACTICUM DIRECTORS: ETHICS OVERSIGHT OF STUDENT PROJECTS

BACKGROUND
1. The Dean's Office of Research Excellence (ORE) is responsible for providing 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 obtained.
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 the ORE has granted a blanket determination do not need to be submitted through the portal. Faculty Advisors/Practicum Directors are to inform students of this and provide them with a copy of the pertinent blanket determination.
7. Faculty Advisors and Practicum Directors may approach ORE to discuss blanket determinations for certain types of projects.

THE PROJECT SUBMISSION PROCESS
1. Students are required to work with Faculty Advisors as they develop their projects.
2. Detailed submission instructions are available in written guidance for students, 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 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.

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6. The ORE will review the submission and issue a determination within 7-10 business days. In the event that a response is not received within 7-10 business days, please email Paul Ndebele at pndebele@gwu.edu to make an inquiry.
7. A determination will be emailed to 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 an existing, 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 project does not require IRB review or if the Faculty Advisor is unsure about the need for IRB review, faculty are to advise students to prepare the following documents for a portal submission:
   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
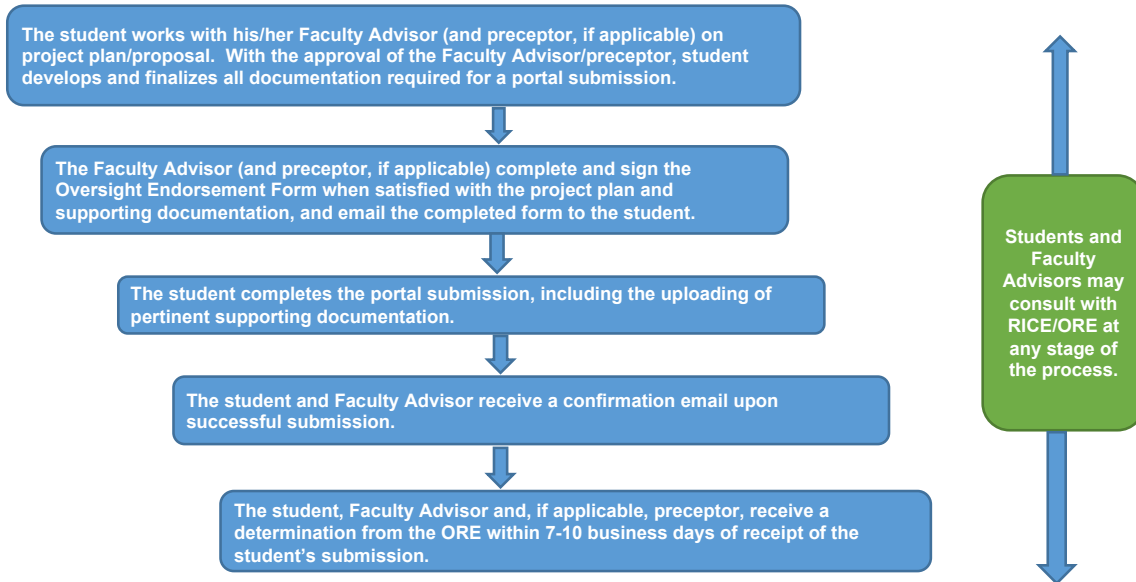The ORE may issue one of the following four determinations:
1. **Non-human subjects research**; the student may proceed with proposed activity.
2. **No further IRB review required per existing IRB approval**; the student may proceed with proposed activity.
3. **Not research**; the student may proceed 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. Faculty Advisors and students are to familiarize themselves with the portal. 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

Student Projects Portal Submission Process

The student works with his/her Faculty Advisor (and preceptor, if applicable) on project plan/proposal. With the approval of the Faculty Advisor/preceptor, student develops and finalizes all documentation required for a portal submission.

The Faculty Advisor (and preceptor, if applicable) complete and sign the Oversight Endorsement Form when satisfied with the project plan and supporting documentation, and email the completed form to the student.

The student completes the portal submission, including the uploading of pertinent supporting documentation.

The student and Faculty Advisor receive a confirmation email upon successful submission.

The student, Faculty Advisor and, if applicable, preceptor, receive a determination from the ORE within 7-10 business days of receipt of the student's submission.

Students and Faculty Advisors may consult with RICE/ORE at any stage of the process.

CONTACT INFORMATION

Faculty Advisors and students may contact the Research Integrity, Compliance and Ethics (RICE) Unit within ORE with questions regarding the portal submission process and requirements:

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 held on Wednesdays from 2:00 to 4:30pm in the RICE Unit, 7th Floor, Suite 722, Milken Institute School of Public Health

Thank you for your work to support our students.

APPENDIX

The Oversight Endorsement Form (3 pages) that follows is for informational purposes only. In preparing a portal submission, students are to download this fillable PDF form from the portal.

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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		

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GWSPH Advisor/Practicum Director	Name:		
	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:		