The students of The Milken Institute School of Public Health (SPH) at The George Washington University are increasingly engaged in rigorous student research that requires approval by the GW Institutional Review Board (IRB). At the same time, we acknowledge that class activities with the objective of teaching proficiencies for specific tools or methods may not require IRB approval. The purpose of this document is to provide SPH faculty and students with guidance on whether or not IRB review is necessary before conducting a given activity. This guidance details the distinctions between research and non-research activities. It is important to err on the side of caution and consult with our SPH Student IRB Liaison at SPHStudentIRB@gwu.edu and/or the GW Office of Human Research at ohrirb@gwu.edu if there is any doubt that an activity requires approval.

Beginning Sept. 1, 2015, if it is clear that a project involves human subjects research (after reviewing Tables 1 and 2), students and their instructors/advisors should proceed with submission of the IRB application for review, available at: http://humanresearch.gwu.edu/IRBforms. Select the New Study Application Form (HRP-200).

In all other cases, students under the supervision of their instructors/advisors must submit the SPH Student Human Subjects Research Determination Form to the Student IRB Liaison at SPHStudentIRB@gwu.edu for pre-review. The faculty advisor/PI must sign the Milken Institute SPH Human Subjects Research Determination Form, which can be found on the SPH Research Portal: http://publichealth.gwu.edu/research/policy-procedure-guidance. Based on the information provided on the form, a determination of whether the proposed activity involves human subjects research will be made. The Student IRB Liaison will inform the student and faculty advisor/instructor of the next steps to obtain IRB approval.

A. Scope. This policy covers all SPH student research involving human subjects within the scope of the School’s educational activities, including, but not limited to:
- Independent Research Projects (e.g., theses, dissertations, and honors projects)
- Coursework or Classroom Activities
- Practicum
- Culminating or Capstone Experiences
- Internships

B. Overview. The SPH supports and encourages undergraduate and graduate student research projects involving human subjects. For Student Human Subjects Research Determination Forms, the SPH Student IRB Liaison will determine if the project is “Not Research” (NR) or “Not Human Subjects Research” (NHSR), and no further review will be necessary. Otherwise, we rely on the GW IRB to make a final determination of whether a proposed activity is: “Human Subjects Research (HSR) Exempt from IRB Review”, “HSR Expedited” or “HSR Requiring Full IRB Review.” These categories are explained on the GW Office of Human Research website: http://humanresearch.gwu.edu/IRBforms. Students may not initiate research recruitment or enrollment, data collection, or data analysis until they receive written approval from the IRB. It is important for students to understand the processes for review and approval of research involving human subjects and to plan accordingly for the time needed to obtain the necessary approvals. Students must complete the same compliance training requirements as any other researcher, including CITI and HIPAA training, before undertaking the research activities in Table 1 and 2. Training requirements are described on the GW Office of Human Research website (refer to OHR Training). Faculty advisors/instructors or PIs of record and the student’s department have the responsibility for: (1) assessing whether student projects/classroom activities involving human participants meet eligibility requirements for IRB review, per Table 1 and 2 below; (2) overseeing the activities; (3) assuring adherence to the ethical principles of research (as outlined in The Belmont Report) and (4) assuring that all certifications or training requirements noted above are completed by students. Failure to obtain proper approvals in advance may jeopardize data, prevent results from being published or presented and could put students and faculty advisors/instructors and the University in violation of...
federal regulations.

C. Student Research Roles. SPH students are typically involved in research involving human subjects in one of two ways: (1) as a research **team member** performing duties of record keeping, data collection or analysis, and/or lab work (as is often the case with GRA positions); and (2) as a student **investigator** who is undertaking an independent research project or assignment in fulfillment of the requirements of his or her degree program or for other educational reasons, supervised by a faculty advisor. This includes activities outlined under Part A, “Scope,” at the beginning of this policy.

- **Student as Research Team Member.** If a student is engaged as a study team member on a human subjects research project led by a PI at GW, the student must be added to the approved IRB research protocol. If a SPH student is listed as a study team member on an IRB protocol at a different institution/organization (as is the case for some Practicum and internship projects), students should provide a copy of the IRB approval letter or other documentation of participation to the appropriate academic department administrator to be retained in the official student file. Students must also comply with the research training requirements of the external sites or institutions/organizations.

- **Student as Investigator.** A student may not serve as PI for human subjects research and must enlist a faculty member to be the PI of record. At GW, only regular faculty and research faculty (with limited exceptions) may serve as a PI for research protocols involving human subjects. This includes the activities outlined under Part A, “Scope,” at the beginning of this policy.

D. Submitting for IRB Determination or Review. After reviewing Tables 1 and 2 for guidance (on page 3), if it is clear that the project involves human subjects research, students and their instructors/advisors should proceed with submission of the required **IRB form** for review. The IRB Form is available on the GW Office of Human Research website: [New Study Application Form (HRP-200)](New%20Study%20Application%20Form%20(HRP-200)). The same form is used for all IRB submissions, whether the proposed activity qualifies as “Human Subjects Research (HSR) Exempt from IRB Review”, “HSR Expedited” or “HSR Requiring Full IRB Review.”

**In all other cases,** students under the supervision of their instructors/advisors must submit the “**SPH Student Human Subjects Research Determination Form**” to [SPHStudentIRB@gwu.edu](mailto:SPHStudentIRB@gwu.edu) for pre-review. The faculty advisor/PI must sign off on the [Student Human Subjects Research Determination Form](Student%20Human%20Subjects%20Research%20Determination%20Form). Based on the information provided on the form, a determination of whether the proposed activity involves human subjects research will be made and the faculty advisor/instructor and student will be informed.

**Important note:** When relevant for the scenarios in Tables 1 and 2, we encourage the submission of the IRB forms or the SPH Student Human Subjects Research Determination Form on behalf of **groups of students rather than multiple individual student submissions.** Students and faculty PIs will be notified about determinations or reviews via email, with requests for supporting documentation as appropriate. The length of time required for IRB review after the date of submission varies. Review of the SPH Student Human Subjects Research Determination Form will typically take less time than an IRB review. Generally faculty and their students should plan as follows:

- Pre-review (if needed) by the SPH Student IRB Liaison for NR or NHSR: 3-5 Business Days
- HSR Exempt from IRB Review: 5-7 Business Days
- HSR Expedited IRB: Varies
- HSR Requiring Full Quorum IRB Review: Varies
# TABLE 1: STUDENT INDEPENDENT RESEARCH COMMON SCENARIOS

<table>
<thead>
<tr>
<th>Scenario</th>
<th>IRB Review Required</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESEARCH involving direct human interaction or a manipulation of their environment (e.g., in person, via mail, email, web survey, or telephone), or data from human subjects for which the researchers will have access to private identifiable information.</td>
<td>IRB review is required</td>
<td>Submit the application form to the IRB. <a href="https://example.com">New Study Application Form (HRP-200)</a></td>
</tr>
<tr>
<td>RESEARCH involving secondary analysis of data, records or specimens that are publicly available, including de-identified data.</td>
<td>IRB review is not required</td>
<td></td>
</tr>
<tr>
<td>RESEARCH activities using any departmental/University subject pools (e.g., Psychology, Business, Political Science, Public Health, University listservs), regardless of the type of data.</td>
<td>IRB review is required</td>
<td>Submit the application form to the IRB. <a href="https://example.com">New Study Application Form (HRP-200)</a></td>
</tr>
</tbody>
</table>

# TABLE 2: CLASS PROJECTS, PRACTICA, CE AND OTHER COMMON SCENARIOS

<table>
<thead>
<tr>
<th>Scenario</th>
<th>IRB Review Required</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROJECTS/ASSIGNMENTS involving secondary data analyses that are assigned as time-limited educational/training exercises, using data that is either publicly available, de-identified or otherwise impossible to be linked to personal identities.</td>
<td>IRB pre-review required</td>
<td>Submit the Student Human Subjects Research Determination Form to determine if the activity is considered HSR. If IRB review is not pursued, activities must be limited to class project use and cannot be published/presented/disseminated beyond the classroom (including presentation at GW Research Day, blogs, or other external formats).</td>
</tr>
<tr>
<td>PROJECTS/ASSIGNMENTS involving secondary data analyses that are assigned and conducted as educational/training exercises, and that use data sets that include private identifiable information and codes that link to identifiers. The students or instructor/advisor may have access to the identifiers or the codes.</td>
<td>IRB review is required</td>
<td>Submit the application form to the IRB. <a href="https://example.com">New Study Application Form (HRP-200)</a></td>
</tr>
<tr>
<td>PROJECTS/ASSIGNMENTS that involve collecting primary data through direct interaction with humans (e.g., in person, via mail, email, web surveys, departmental/University subject pools or telephone) for the purpose of education/training in student research skills. Examples include learning how to conduct interviews, surveys, focus groups, needs assessments in the context of research.</td>
<td>IRB pre-review required</td>
<td>Submit the Student Human Subjects Research Determination Form to determine if the activity is considered HSR. If IRB review is not pursued, activities must be limited to class project use and cannot be published/presented/disseminated beyond the classroom (including presentation at GW Research Day, blogs, or other external formats).</td>
</tr>
<tr>
<td>PROJECTS/ASSIGNMENTS that involve collecting primary data through direct interaction with humans (e.g., in person, via mail, email, web surveys, or telephone) for the purpose of education/training for practice proficiency or professional development. Examples include taking client histories, conducting interviews, or performing “in-house” evaluations as requested by the practicum/internship/CE site.</td>
<td>IRB pre-review required</td>
<td>Submit the Student Human Subjects Research Determination Form to determine if the activity is considered HSR. If IRB review is not pursued, activities must be limited to class project use and cannot be published/presented/disseminated beyond the classroom (including presentation at GW Research Day, blogs, or other external formats).</td>
</tr>
</tbody>
</table>
Policy: Student Research and Human Subjects Determination
Approved by: Kimberly Horn, Associate Dean of Research
Date: 1/21/14 rev. 5/2/14, 8/31/15

For additional details about the various types of IRB reviews, refer to: GW IRB Review Types. To reiterate, it is not necessary to submit the SPH Student Human Subjects Research Determination Form if it is clear that a project involves human subjects research – in that case, students and their instructors/advisors should proceed with submission of the required IRB form for review - New Study Application Form (HRP-200). In all other cases, students must submit the Student Human Subjects Research Determination Form for pre-review to SPHStudentIRB@gwu.edu.

E. Useful Definitions
Keep the following definitions in mind as you complete the “SPH Student Research Determination Form”- these criteria serve as guideposts for the IRB in its review and determination and should help you in your planning for the timeline for your research:

Exempt—The code of federal regulations identifies distinct categories of research as being exempt from the Federal Policy for the Protection of Human Research Subjects. Refer to http://www.hhs.gov/ohrp/policy/exmpt-pb.html. Generally, projects might be considered exempt from IRB review when the following conditions are satisfied: (1) the project involves no more than minimal risk to subjects; (2) the project does not involve sensitive topics; (3) the project does not involve participants from vulnerable populations as participants; (4) the project involves the voluntary participation of individuals without any coercion or pressure being placed upon them by the researcher; and (5) private, identifiable information is not recorded by the PI or other team members.

Expedited—Studies that do not fall into one of the exempt categories may be expedited if two criteria are met: (1) the study must be 'minimal risk'; and (2) the study must fall into one of several specific categories designated by the federal government—refer to http://www.hhs.gov/ohrp/policy/exprev.html.

Minimal Risk—Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Sensitive Topics—Any interview, survey or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following sensitive topics will likely require IRB review and approval as HSR:
- sexual orientation
- incest, rape, sexual molestation
- deviant sexual behaviors or attitudes regarding sexual conduct
- practices of contraception, previous abortion and/or pregnancy
- substance use and/or abuse including, but not limited to, alcohol, cigarette smoking, marijuana, steroids, amphetamines, narcotics and any prescription medication legally or illegally obtained
- mental health (e.g., suicide, depression, obsessive compulsive behaviors, gambling, eating disorders)
- traumatic experiences of an individual, including war or combat experiences of veterans,
- illegal activities, involvement in criminal behavior, immigration status, if undocumented,
- opinions about supervisors or other employees or students
- health information, including HIV status, health screenings, insurance status
- other damaging or stigmatizing information

Vulnerable Populations—Vulnerable populations include children, pregnant women or fetuses, prisoners, educationally or economically disadvantaged persons, persons at high risk of incarceration or deportation, cognitively-impaired, and in some instances, students (regardless of age).

Acknowledgments: This policy credits and was adapted from The Johns Hopkins School of Public Health, Policy 103.2, 9/18/08; University of Toledo IRB Guidance for Student Research and Class Projects, 8/27/2008; University of Texas at El Paso (UTEP) Classroom Research Project Checklist; the University of Pittsburgh Institutional Review Board Student Research Guide, U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) materials; and the GW Office of Human Research Principal Investigator Considerations for Student Research document, 08/04/2011.