**JHSPH IRB OFFICE DETERMINATION REQUEST FORM:**

***Primary (New) Data Collection***

This determination request form may be used for all students or post-doc-initiated projects when it may be useful to have the IRB’s preliminary opinion on whether a project requires a new application or an amendment adding you to an existing JHSPH IRB-approved study.

JHSPH IRB is responsible for the ethical conduct of the research that JHSPH students conduct in satisfaction of their degree requirements. All students and post-docs should apply ethical principles in their interactions with human participants and/or their data regardless of whether IRB review is required.

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| **INSTRUCTIONS**   * **Check Boxes**  1. Double left [CLICK] the check box 2. Select “Checked” to enter a check mark  * **Students and Post-Docs**  1. Complete the questions in Section A 2. Email the completed form to your project advisor  * **Project (Capstone or Other) Advisor**  1. Review the information that the student has provided. 2. In Section B, describe your role in project management and overseeing data collection. 3. Email this form to the IRB Office email address at [jhsph.irboffice@jhu.edu](mailto:jhsph.irboffice@jhu.edu) from your email address or students may submit from their email address and should copy their advisor on the email submission. |

**CAPSTONE SUBMISSIONS:** You assume the risk that the review of your application will not be completed on time if you fail to submit your application by the deadlines provided by the MPH office.

**PHIRST APPLICATION SUBMISSION DEADLINES:** If the IRB Office reviews this determination request form and determines that you must submit a new PHIRST application or an amendment to an existing IRB-approved study, MPH Capstone students must do so by the date when the Capstone Info form is due. Please refer to the MPH Program Manual.

**Section A. *To be completed by student***

**Student’s Name:**

**Student’s Email:**

**Student’s Phone #:**

1. What degree activity will this project fulfill?

MPH Capstone

ScD Thesis or Project

ScM Thesis or Project

MHS Thesis or Project

MSPH Thesis or Project

PhD Dissertation

DrPH Dissertation

Post-Doc Project

Class Project

Other (Please explain):

1. Please provide your specific project title:
2. Describe your project objective:
3. Did the project originate from a course activity or from a practicum experience? If yes, please explain:
4. Will your project involve new collection of personal information from/about individuals? **Yes  No**
5. Will you interact with people in this project? That is, will you interview them, give them a survey, or collect biological specimens? If yes, provide details below:
6. Describe where your study will take place and the population you wish to recruit for the study (including, as relevant, age, gender, ethnicity, community associations, etc.).
7. Describe how you plan to introduce your study to the population, how you plan to recruit individuals, and how you plan to obtain informed consent from the study participants.
8. Do you plan to collect data using an anonymous online survey/questionnaire? **Yes  No**
9. Will any of the data you plan to collect include sensitive topics such as use of illegal drugs, sexual behavior, or communicable disease status? If yes, provide details:
10. Will any of the data you plan to collect be FROM individuals but not ABOUT them, e.g., are your sources ALL “key informants” who are providing information based on their professional capacity or based upon their knowledge of a certain community’s practices or needs (e.g., not personal information about themselves or others)? If yes, provide details:
11. If the study site is not in the United States, identify your collaborators in the host country and how you will obtain local permissions, and if needed, IRB or ethics committee approval there.
12. Will your research be supervised by another PI at an external (non-JHU) institution? If yes, please explain:
13. Are you listed as an investigator on an existing IRB approval for this project at another institution? If yes, please explain:
14. Please explain your data security plan to protect the data.
15. Please describe the oversight plan you have established with your advisor.
16. The University has a data custody policy that requires ensuring the protection of the data from the time you receive it through destruction/return of the data when a project is completed. Please explain what will happen to the data you propose to use after you complete your project.
17. Do you intend to share the results of your project by publication, presentation, or other public dissemination beyond your class project? (Note: Presentation within the School is considered an academic activity, not publication or dissemination.)  **Yes  No**

* If **YES**, please submit a copy of the survey, questionnaire, interview guide, or a list of the questions that you are proposing to use.
* If **NO**, please provide the specific name of the collaborating agency, department, NGO or class project involved in this activity.

**SECTION B. *To be completed by capstone advisor or, for non-capstone students, other project advisor***

**Advisor’s Name:**

**Advisor’s email:**

**Advisor’s phone #:**

**Advisor’s JHSPH/SOM/Homewood/Other JHU Department:**

**Advisor’s comments:**

1. What is your role in the project?
2. How will you oversee the data collection?
3. What is your faculty status here at JHSPH?  Full-time  Part-time  Adjunct

It is important to recognize that, if you will serve as the Primary Investigator, you are ultimately responsible for all aspects of this project. If you do not believe you can provide adequate oversight, you should not agree to this use of secondary data.