JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

BSPH IRB OFFICE STUDENT DETERMINATION REQUEST FORM

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 BSPH IRB-approved study.

BSPH IRB is responsible for the ethical conduct of the research that BSPH 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.

INSTRUCTIONS

This determination form is to be completed by both the student and the advisor on the project.

- Student Project and Advisor Information – **Complete Part A**
- For New Data Collection – **Complete Part B**
- For Secondary Data Analysis of Existing Data – **Complete Part C**
- For Check Boxes – Double left [CLICK] the check box and select "Checked" to enter a check mark

Students may email this determination form to the BSPH IRB Office email address at bsph.irboffice@jhu.edu from their email address, copying their advisor on the email submission.

If you have questions about this form, please send them to: bsph.irboffice@jhu.edu

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 BSPH 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, you will receive an email notification with further guidance. MPH Capstone students must do so by the date when the Capstone Info form is due. Please refer to the MPH Program Manual.

Part A: Student Project and Advisor Information

Name:
Email Address:
Project Title:
Aim/Objective:
Funding:

Please identify the academic activity this project fulfills and provide the additional information below:

☐ MPH Capstone	☐ DrPH Dissertation
☐ ScD Thesis/Project	☐ Post-Doc Project
☐ ScM Thesis/Project	☐ Class Project
☐ MHS Thesis/Project	☐ Practicum Project
☐ MSPH Thesis/Project	☐ Other (Please Explain):
☐ PhD Dissertation	

For Capstone/Project Advisor to Complete:

It is important to recognize that, if you will serve as Capstone Advisor or, for non-capstone students, a Project Advisor, 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 role. Please provide the following information:

Advisor's Name:
Advisor's email:
Advisor's phone #:
Advisor's BSPH/SOM/Homewood/Other JHU Department:
Advisor's faculty status: ☐ Full-time ☐ Part-time ☐ Adjunct
Advisor's role in the project:
Advisor's comments:

Please describe the oversight plan you have established with the student investigator.

Part B: New Data Collection

1. Is the proposed activity associated with an active research study approved by the BSPH IRB?

   ☐ **Yes**

   If yes, please provide the study title and the IRB number.

   ☐ **No**

2. Are you listed as an investigator in an active research application approved or given an IRB approval or Exempt Determination by an External IRB?

   ☐ **Yes**

   If yes, please clarify whether you are asking the BSPH IRB to rely on that External IRB or to accept the External IRB's Exempt Determination.

   ☐ **No**

3. Is the purpose of your new data collection "research"?

4. Is the information you are proposing to collect from people will be about them or does it elicit personal opinion? [*Is the information collected <u>from humans and about them including personal opinions</u> OR <u>from humans but NOT about the person or about how they think about the research topic</u>? Key informant interviews (KII) collect information from humans with no risk to the respondent with respect to employment or political stigma. The information should be limited to professional opinions about health services or programs without any of those risks. Interviews collecting information on personal opinions (as opposed to professional opinions) are not KII.*]

   ☐ **Yes**

   If yes, please explain:

   ☐ **No**

5. Will your data collection occur outside the U.S.? If yes, identify your local collaborators and what local approvals you will obtain:

   ☐ **Yes**

   If yes, please explain:

   ☐ **No**

6. Describe your role in this project. In particular, provide details about whether you will interact with the individuals via recruitment and/or collecting data via survey, questionnaire, interview, biospecimen collection:

7. What population you will engage in the project, including, as relevant, age, gender, ethnicity, community associations, etc. Provide details:

8. Will you conduct the activity in a public school, recreation center, market, foreign health clinic, Native American reservation, or other site that requires local permission/approval for access?

☐ **Yes**

If yes, please explain.

☐ **No**

9. How will you introduce your project to the target population?

10. Will you obtain agreement or consent from individuals?

☐ **Yes**

If yes, please explain how.

☐ **No**

11. If relevant, **submit the survey, questionnaire, interview guide, or a list of the questions** that you are proposing to use.

12. Will you collect information of a sensitive or personal nature?

☐ **Yes**

If yes, please explain.

☐ **No**

13. What is the time burden for participants in the activity?

14. Do you or anyone on your study team intend to record personal identifiers or create links between the study data and a study ID?

☐ **Yes**

If yes, please explain.

☐ **No**

15. After this one activity is over, do you have plans for follow-up assessments, related activities or scale-up of interventions and in what contexts**?**

☐ **Yes**

If yes, please explain.

☐ **No**

16. Do you intend to disseminate the results of your project by publication, presentation, or other public dissemination beyond internal BSPH use? (Note: Presentation within the School is considered an academic activity, not publication or dissemination.)

☐ **Yes**

If yes, please explain.

☐ **No**

17. What is your plan for protecting data confidentiality through all phases of the study?

18. Provide your Data Sharing and Management Plan, including your plans for archiving, destroying, or other disposition of the data after completing analysis:

Part C: Secondary Data Analysis of Existing Data

1. Describe your data source(s) and what permissions/approvals are required for access:

2. Are the data publicly available?

☐ **Yes**

If yes, provide the website address:

☐ **No**

3. Are the data from a BSPH-IRB approved research study?

☐ **Yes**

If yes, is the study currently active? Please provide the IRB study title and the study number.

☐ **No**

4. Are the data from an IRB approved study at an external institution?

☐ **Yes**

If yes, identify the institution and the status of the study (actively collecting data?) and whether you are listed on the approved research protocol.

☐ **No**

5. What variables or data points will you need?

6. Do the data include personal identifiers or links/codes that connect the data to individuals?

☐ **Yes**

If yes, will you have access to those links/codes?

☐ **No**

7. Is it possible that you could re-identify the individuals?

☐ **Yes**

If yes, please explain.

☐ **No**

8. Will you have access to PHI (Protected Health Information) from a U.S. based health care provider, billing organization, or data center like CMS? Please see the list of identifiers below to help with your response.

☐ **Yes**

If yes, please explain.

☐ **No**

• Name • Geographic information smaller than state • Elements of dates (birth date, admission date, date of death, ages greater than or equal to 90 years of age • Telephone numbers • Fax numbers • Electronic mail addresses • Social security numbers • Medical record numbers • Account numbers	• Certificate or license number • Vehicle identifiers and serial numbers including license plate • Device identifiers and serial numbers • URLs • IP address numbers • Biometric identifiers • Full face photographic images and comparable images • Health Plan beneficiary numbers • Any other unique identifying number, characteristic or code

9. Do you intend to disseminate the results of your project by publication, presentation, or other public dissemination beyond internal BSPH use? (Note: Presentation within the School is considered an academic activity, not publication or dissemination.)

☐ **Yes**

☐ **No**

10. What is your plan for protecting data confidentiality through all phases of the study?

11. Provide your Data Sharing and Management Plan, including your plans for archiving, destroying, or other disposition of the data after completing analysis:

12. Do you have a Data Use Agreement or a Letter of Permission for use of the data?

☐ **Yes**

If yes, please submit a copy of it with your determination request form.

☐ **No**