

**Institutional Review Board Office**

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**BSPH IRB OFFICE STUDENT DETERMINATION REQUEST FORM**

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| **DETERMINATION REQUEST FORM:** This form is for students or post-doctoral trainees who are initiating projects as part of their degree or training requirements. It helps the IRB in delivering a preliminary opinion on whether a project requires a new PHIRST application, an amendment to an existing BSPH IRB-approved PHIRST application or can be conducted with no further action.  ETHICAL CONDUCT: The BSPH IRB ensures the ethical conduct of research done by BSPH students and post-doctoral trainees for their degree requirements. All students and post-doctoral trainees must apply ethical principles when interacting with human participants or their data, regardless of whether IRB review is required.  PROJECT ADVISOR: This form may be submitted with a named non-BSPH advisor. If the BSPH IRB Office determines that this student project does not involve human subjects research, you may retain the external advisor as your Project Advisor. If the BSPH IRB Office determines that the project involves human subjects research and necessitates a new PHIRST application, you will need to identify a full-time BSPH faculty member as the named principal investigator for the project, and the external advisor may also be listed on the application and continue to serve as a Project Advisor in collaboration with the BSPH investigator.  **INSTRUCTIONS:** Both the student and the Project Advisor must complete this form.   * **Part A**: Fill in the Student Project and Advisor Information * **Part B**: Complete if you are collecting new data. * **Part C**: Complete if you are doing secondary data analysis of existing data. * To check a box, double click it and select “Checked”. * Reference the Student Research and the BSPH IRB Office [FAQs](https://my.publichealth.jhu.edu/sites/ors/_layouts/15/WopiFrame.aspx?sourcedoc=%7bd27561bc-ed6e-437a-b846-438104377670%7d&action=default) if you have questions as you are filling out this form.   Email the completed form as an attachment in a word document format to the BSPH IRB Office at [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu) and copy your Project Advisor on your email submission. If you have any questions, please email them to the same address.  DETERMINATION REQUEST FORM SUBMISSIONS: Generally, the preliminary review process does not take long, though it could take up to 2 weeks to complete. If no response is received after 2 weeks of submission, please send a follow-up email to the BSPH IRB Office. You may not begin your project until you receive formal IRB determination or approval from the BSPH IRB Office.  CAPSTONE SUBMISSIONS: You assume the risk that the review of your request form will not be completed on time if you fail to submit by the deadlines provided by the MPH Office. MPH Capstone students should refer to the MPH Program Manual for information on program deadlines.  PHIRST APPLICATION SUBMISSIONS: 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 BSPH IRB-approved PHIRST application, you will receive an email notification with further guidance. |

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| **Part A: Student Project and Advisor Information** |
| Name: |
| Email Address: |
| Project Title: |
| Aim/Objective: |
| Funding: |
| Project Purpose & Design: (In 1-2 sentences, briefly describe your project’s goals & describe the methodology or approach for collecting & analyzing data): |

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| **Please identify the academic activity this project fulfills and provide the additional information below:** | | |
| MPH Capstone | | PhD Dissertation |  |
| MPH Practicum | | DrPH Dissertation | |
| ScD Thesis/Project | | DrPH Practicum | |
| ScM Thesis/Project | | Post-Doc Project | |
| MHS Thesis/Project | | Class Project | |
| MSPH Thesis/Project | | Other (Please Explain): | |
| **For Project Advisor to Complete:** | | |
| It is important to recognize that, if you serve as the Project Advisor, you are ultimately responsible for providing oversight 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 (if applicable):  Advisor’s faculty status:  Full-time  Part-time  Adjunct  N/A   * Advisor’s role in the project: * Advisor’s comments:   Please describe the oversight plan you have established with the student investigator (e.g., regular meeting schedule, etc.): | | |  |  |

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| **Part B: New Data Collection** |
| 1. Is this proposed project associated with an active BSPH IRB-approved PHIRST application?   **Yes**  **If yes, please provide the PI name, study title and the IRB number.**  **No** |
| 1. Are you listed as an investigator on an IRB approved active research application or granted an IRB approval or Exempt Determination by an external IRB?   **Yes**   * **If yes, please attach the IRB approval/determination letter, along with any other relevant IRB documents from the external institution’s IRB that includes your name as an investigator or study team member.** * **Please specify whether you are requesting the BSPH IRB to rely on that external IRB or to accept the external IRB’s Exempt Determination.**   **No** |
| 1. Is the purpose of your new data collection “[research](https://publichealth.jhu.edu/sites/default/files/2024-04/nhsr-guidance-10may2022.docx)”? Please explain: |
| 1. Is the information you are proposing to collect from people about them or does it elicit their [personal opinions](https://publichealth.jhu.edu/sites/default/files/2024-04/nhsr-guidance-10may2022.docx)?   **Yes**  **If yes, please explain:**  **No** |
| 1. 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** |
| 1. Describe your role in this project. Provide details about how you will interact with participants in recruitment and/or collecting data (survey, questionnaire, interview, biospecimen collection): |
| 1. What population you will engage in the project, including, as relevant, age, gender, ethnicity, community associations, etc.: |
| 1. Will you conduct the project in a site that requires local permission/approval for access, such as a public school, recreation center, market, health facility, or Native American reservation?   **Yes**  **If yes, please explain**.  **No** |
| 1. How will you introduce your project to the target population? |
| 1. Will you obtain agreement or consent from individuals?   **Yes**  **If yes, please explain how**.  **No** |
| 1. If relevant, please submit as an attachment the survey, questionnaire, interview guide, or a list of the questions that you are proposing to use. |
| 1. What is the time burden for participants in the activity? Please explain: |
| 1. 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** |
| 1. 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** |
| 1. Do you intend to disseminate the results of your project by publication, presentation, or other public dissemination beyond internal BSPH or organizational use? (Note: Presentation within the School is considered an academic activity, not publication or dissemination.)   **Yes**  **If yes, please explain**.  **No** |
| 1. What is your plan for protecting data confidentiality through all phases of the project? |
| 1. Provide your Data Sharing and Management Plan, including your plans for archiving, destroying, or other disposition of the data after completing analysis, if applicable: |

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| **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**  **Literature review of publicly available data in journal articles. No website addresses available.** |
| 3. Are the data from an active BSPH IRB-approved PHIRST application?  **Yes**  **If yes, please provide the PI name, study title and the IRB number**.  **No** |
| 4. Are the data from an IRB approved study at an [external institution](https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/policies-and-guidance/guidance/reliance-agreements-and-single-irb)?  **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. Upload the IRB approval letter that lists your name if available.**  **No** |
| 5. What variables or data points will you need? |
| 6. Do the data include personal identifiers (e.g., names, street addresses, medical record numbers) 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 or organizational 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 project? |
| 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 this determination request form.**  **No**  **If No, please explain.** |

Email the completed form and relevant supporting documentation to the BSPH IRB Office at [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu) and copy your Project Advisor. If you have questions, reach out to the same email.