The purpose of this form is to determine whether student projects, research, practicum, or culminating experience activities require review by the GW IRB. If you and your faculty advisor have determined that your project does require GW IRB review then you do not need to submit this form; work instead with your faculty advisor to ensure all IRB approvals are documented and in place prior to initiation of any project activity. This form is only for use by students and faculty in the Department of Epidemiology and Biostatistics.

Please see INSTRUCTIONS on the last page of this form.

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### Section I. DETERMINATION OF RESEARCH

#### I.A. DOES THE PROPOSED ACTIVITY MEET THE FOLLOWING CRITERIA FOR RESEARCH?

1. **Y** □ **N** □ Activities constitute a *systematic investigation* (involving at least 4 subjects or participants) that includes research development, data collection and/or data analysis, and/or evaluation.

2. **Y** □ **N** □ Conclusions or findings will contribute to *generalizable knowledge*—that is, there is a possibility of publishing, presenting, or otherwise applying knowledge gained to a population or audience outside of the local research context/entity (e.g., beyond the classroom or university setting).

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### Section II. DETERMINATION OF THE INVOLVEMENT OF HUMAN SUBJECTS

#### II.A. DOES THE PROPOSED ACTIVITY INVOLVE HUMAN SUBJECTS?

1. **Y** □ **N** □ Collect data through *intervention*¹ or *interaction*² with an individual, including interviews, surveys, physical procedures, manipulations of the subject's environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not).

   ¹. Intervention: Includes both physical procedures by which data are gathered, and manipulations of the subject or subject's environment performed for research purposes.

   ². Interaction: Communication or interpersonal contact between investigator and subject.

2. **Y** □ **N** □ Obtain, view, or otherwise handle any *private information*¹ which identifies individual subject(s) through the use of either *direct identifiers*² (name, address, etc.), or *indirect identifiers* in the form of a code that links back to the identity of subject through an existing key.

   ¹. Private information includes (but is not limited to)
      - Health information, health behaviors or practices
      - Medical records and charts, specimens, data or tissue repositories
      - Employment or educational records, and observations of behavior which the subject could reasonably expect no observation to be taking place.
      - Personal thoughts, feelings, opinions, attitudes, beliefs, etc.

   ². Direct identifiers include (but not limited to) name, street address, audio/video-recordings, telephone, fax, email, texts, SSN, medical record # (other potential identifiers evaluated on a case by case basis).

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### Section III. RESEARCH DESCRIPTION

#### III. A. APPLICANT INFORMATION

**DATE:**

**PROJECT TITLE:**
### III. B. PROPOSED STUDY CHARACTERISTICS

1. Provide a 3-5 sentence, clear summary of the proposed research activity. Please include the purpose and aims of the research. You may submit your proposal if you wish.

*Please note that projects performed under the auspices of the IRB of a non-GW institution require additional procedures. Please consult with your faculty advisor and SPH Student IRB Liaison.*
2. Describe all research activities that will be performed / conducted by or under the supervision of GW faculty, staff, or students. If you are working at another institution, please provide details of what you will be doing as well as a letter of permission from the site PI or preceptor.

3. Describe or list all study procedures to be conducted related to study participants (i.e., screening, recruitment, consenting, enrollment, procedures, use of social media), types of data being collected, sample size, anonymous/identifiable information, and how you will be obtaining data from or about study subjects. If you are conducting a secondary analysis, attach a complete variable list of all the data you will be analyzing.

(Please be sure to attach any survey, interview, or focus group questions, if applicable.)

4. Please answer the following questions about your project:

- Will you have any contact with humans? □ No □ Yes
- Do you work with the dataset as a part of your paid or unpaid work outside of school? □ No □ Yes
- Will you be interacting with any medical or private information (e.g., medical charts, EHR)? □ No □ Yes
- Will you be interacting with any existing electronic data? □ No □ Yes
- Are the data publicly available? If yes, provide URL: □ No □ Yes
- What is the sample size?
- Are your data coded, that is, linked to an individual person through a code that is not itself a direct identifier (e.g., like a randomly assigned participant ID code rather than a medical record number or SSN)? □ No □ Yes
- If your answer to the previous question is “yes,” is there any way you could ever have access to the code-link (e.g., the link between the person's participant ID and the person's direct identifier), even if you are not using it in your analysis? □ No □ Yes

If NO, assurance that you will never have access to the code-link is demonstrated by:

- □ A letter from sponsor
- □ Documentation indicates the link will never be released to you (please attach)
- □ Website information URL:
- □ Other, specify

Check which of the following variables are in your dataset or are being collected (whether or not you will analyze them)

- Names
- Geographical subdivisions smaller than a state (including full zip code)
- All elements of dates beyond year (includes DOB, admission, procedure, death dates, people > 90 years)
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Health plan beneficiary numbers (private, public, or any other)
- Account numbers
- Certificate or license numbers
- Vehicle identifier and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URLs or IP addresses
- Biometric identifiers including finger and voice prints
- Full-face photographs and any comparable images
- Any other unique identifying number, characteristic, or code (e.g., derived from other information that can identify the individual or codes that are not released by the entity responsible for the data)
- Other codes that could identify an individual
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<th>FACULTY PRINCIPAL</th>
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<td>INVESTIGATOR OF RECORD</td>
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I have reviewed the above and concur with the student’s proposal and statements on this form.

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(Forms without faculty signatures will not be reviewed.)
INSTRUCTIONS

How to complete this form:

Complete all sections of this worksheet to assist us in determining whether or not your research project is considered human subjects research as defined by federal regulations. The more detailed information you can provide the more quickly your application will be processed. Students must work with faculty principal investigators on this form and faculty principal investigators must sign the form prior to submission; unsigned forms will not be reviewed. Forms must be typewritten.

How to submit this form:

The completed form should be emailed to kmorrison5@email.gwu.edu.

Form review and response:

Upon review of this form, the faculty principal investigator and the student will typically be contacted within 5 business days by the DEB Student IRB Liaison about the final determination. There are several potential responses:

Please provide more information. Research is complicated and when it comes to ensuring protection of research subjects, we must always be very cautious and thoughtful; many IRB issues are not cut and dry. You may be asked to provide more information to enable a determination about your project.

Not research. Your study may be determined to not be research at all. If this is the case, you will not need to pursue approval by the GW IRB. However, if you have any change to your proposed project, you should check again to ensure that the determination has not changed. Note that if you intend to present your findings outside of your department in any way, or in any publication, the project is considered to be research and this category will not apply.

Non-human subjects determination. If you receive this designation it means that your proposed project is not considered human subjects research and you do not need to pursue approval by the GW IRB. However, if you have any change to your proposed project, you should check again to ensure that the determination has not changed.

Recommendation to refer to the IRB. You may be advised to submit a new study application to the GW IRB. If this occurs, you must work with your faculty principal investigator to do so. At this point, the SPH Student IRB Liaison will no longer be involved. Remember to keep comprehensive files of all of your submissions to, approvals from, and contact from the IRB.

➡️Reminder➡️

You may NOT begin your project until you have received GW IRB approval or a determination by the SPH Student IRB Liaison or IRB that your study does not require GW IRB approval.