The purpose of this OPTIONAL worksheet is to help provide sufficient detail for your project to be reviewed by the SPH IRB Determination Office. This is not a required form. If you already know your project requires IRB approval, please work with your GW Faculty Advisor/PI to complete the required forms. If you do not know the answer to the questions below, please also work with your Faculty Advisor before submitting. You may NOT begin your study until you have received either IRB approval or a determination by the SPH that your study is not human subjects research.

Date completed

Student name

GW PI name

Study title

Have the data already been collected?

Yes

No

Do you work with the dataset as a part of your paid or unpaid work outside of school?

Yes

No

Which of the following applies to your project? Check all that apply:

- My practicum or CE only
- Only as an SPH requirement to graduate
- I only want to present to the department
- I want to submit a paper, abstract, oral, or poster
- Program improvement or quality assurance
- I don't want to publish but my preceptor does
- Online / blog post / social media
- GW or local research day
- Other, specify

Is the dataset publicly accessible through directly downloading data online?

Yes

No

What are the name and URL of the dataset?

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?)

Yes

No

Is there any way you would ever have access to the code-link (the link between the person's participant ID and the person's direct identifier)?

Yes

No

If no, how will you be prevented from having access to the code-link?
Assurance that you will never have access to the code-link is demonstrated by:

- I am attaching a letter from the data owner or sponsor indicating that I will never be provided access to the code-link under any circumstances.
- The documentation indicates that the code-link is never released per the sponsor's IRB or regulatory oversight. (Provide specific page number or area of documentation to support this.)
- I do have access but I am not going to use that information.
- Other, specify.

Are your data coded yet still identifiable with direct or indirect identifiers in the dataset and/or you have access to the code-link?

- Yes
- No

Which of these direct identifiers are in your dataset? (Even if you will not be analyzing them)

- Names
- Geographic subdivisions smaller than a state (incl. full zip code)
- All elements of dates beyond year (includes DOB, admission, procedure, death dates, people > 90 yrs, etc.)
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifier and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URLs
- Biometric identifiers including finger and voice prints
- Full-face photographs and any comparable images
- Any other unique identifying number, characteristic, or code except as permitted (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
- I have confirmed that none of these are in the dataset.

Is the subject matter of this study sensitive? This might include HIV, STI, sexual behavior, low prevalence conditions, vulnerable populations, etc.)

- Yes
- No

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Once you have completed this optional worksheet and the SPH IRB Determination Form, please work with your GW Faculty Advisor and receive his or her signature. The SPH IRB determination form and this form may then be given to Ms. Kayla Morrison (kmorrison5@gwu.edu) for processing. If you already know you need to go through IRB for an exempt, expedited, or full review, you do not need to do this process; you may prepare the forms with your Advisor instead. Completed forms must also be sent through Ms. Morrison to obtain the required Departmental signatures. All Department of Epidemiology & Biostatistics IRB determinations and IRB submissions must be processed by Ms. Morrison. If you have any questions, please contact your Advisor, Practicum/CE Director, Ms. Morrison or Dr. Magnus (manyadm@gwu.edu).