Application Instructions:
Secondary Data

General Guidance:

Please consult the sections below for any information that will be applicable for your research.

Washington State Department of Corrections Data (DOC): The DOC will only accept IRB approval from the Washington State IRB (WSIRB) for data requests. You will need to seek separate approval for the use of their data. If you have other components of your research, include only those other components in this application.

Protected Health Information (PHI): PHI is individually identifiable health care information or clinical specimens from an organization considered a "covered entity" by federal Health Insurance Portability and Accountability Act (HIPAA) regulations. University health clinics are covered entities. If you will be obtaining, using, or analyzing PHI, you will need the participants to sign a HIPAA authorization.

A HIPAA authorization form for research is different from the one a clinic uses when patients receive care. Researchers need to have a separate form where the participant authorizes the use and disclosure of their information. You will need to submit your HIPAA authorization form along with your application.

On the application form list the PHI, you will be collecting. PHI that are identifiers can be listed under the identifiers question. PHI that are other variables can be listed in the procedures question.

It is possible to request a waiver of HIPAA authorization for some recruitment procedures. Please contact us if this is necessary for your research.

Student Records: FERPA is a federal law that protects the privacy of student education records. Western has extended the protections of FERPA to include personally identifiable information such as student names, ID numbers, and contact information.

Student education records may not be released without explicit written consent of the student, or with parental permission if the student is under 18 years old, except by provisions outlined in FERPA. Faculty and staff, when acting as an "institutional official" (performing their duties as an employee), can use student education records for "legitimate educational use." For example, teachers can email their students about class activities.

Any access or use of an education record for research, however, requires consent. When obtaining consent to release education records, the consent form must include the following information. Exempt applications with FERPA considerations should be especially aware of these requirements.

Some researchers are interested in pulling lists of student names and contact information for recruitment purposes. They may want to use Canvas, a WWU program email roster, or records from the Registrar's Office. Research recruitment, however, is not explicitly listed in FERPA as a "legitimate educational use." That unfortunately means this is a grey area for compliance.

Teachers should consider the following points if they plan to disseminate research recruitment notices for their own or another person's research using education record based email addresses:

- FERPA is not the jurisdiction of the IRB. While the IRB will give as much counsel and direction as possible, IRB approval of a research application does NOT relate to your responsibilities to FERPA.
- The Registrar's Office is available for counsel, as a second set of eyes. As the authority who investigates FERPA complaints, they are an excellent resource to check with before embarking on a FERPA grey area. The Registrar's Office, however, does not have authority to "approve" or "deny" uses of educational records such as using course email addresses.
- Go at your own risk. If a teacher uses education record based email addresses for research recruitment, then if there is a complaint, it will fall on that teacher to justify the use.

Registrar's Office Requests: If you are intending to request education record information for research (see above), you must submit a written request (email or mail) to the Registrar's Office. Requests are reviewed on a case by case basis to determine if the disclosure is justifiable. The Registrar's Office approval is not guaranteed, so we recommend consulting with them as soon as possible. Documentation of clearance (email or mail) from the Registrar's Office should be attached to the submitted Human Subjects Research Application.

Research Collaboration: If any of the individuals, who provide you with identifiable data or specimens also collaborate on other activities for this research, then they are considered engaged in the research. You will need to ensure that they have received appropriate training in the protection of human subjects.

European Union Data: If your research involves obtaining personal data from the European Union, there are very strict international requirements on the protection of this data that go above our required protections. Please speak to a Research Compliance Officer before submitting your application, so that we can work together to ensure that the right protections are in place.

Application Form Instructions:

This is guidance for how to complete the original Human Subjects Application form when your research involves collection or analysis of secondary data.

Question 2.5 Research Location: Enter where you are requesting or receiving the dataset from. The "Activity at this Location" is where the data is being collected or received.

Question 4.2 Participants: Enter the age range of the participants in the data set, if known. If not known, describe this in your response to this question.

Question 6.1 Consent: If consent was originally obtained or will be obtained for this proposed use of data, check any of the consent options that applied and attach a copy of the consent language (note that we **do not** want to receive copies of signed consent forms). If you don't have or can't locate the original consent language, you can provide some other type of documentation to show that the use is authorized.

If consent was not obtained, or you can't provide documentation that this use is authorized by consent or other means, you will need to either obtain consent for this new proposed use or submit an application for a waiver of consent.

Question 7.1 Procedures: Describe the purpose for which the data was/will be collected. Provide a list of the variables being requested/collected. If you have a data collection form available, you can instead indicate that the form is attached to the application.

Question 10.1 Risks: Describe the risks of the analysis, not the original data collection.

DO NOT SUBMIT THIS INSTRUCTION PAGE