Research Utilizing Existing Educational Records

Research involving the secondary use of student educational records requires IRB review. In most cases, the IRB may review the research under Exempt Categories 1 and 4, which include studies conducted in an established or commonly accepted educational setting involving normal educational practices. Please note that access to educational records under these exemptions is only granted to individuals involved as part of their normal activities at the medical school.

IRB Requirements to be Completed Prior to Submission:

- All investigators and key personnel who participate in the design, conduct, and/or reporting of human subjects research are required to complete training in the protection of human subjects. WMed utilizes CITI, a web-based platform offering human research courses, to fulfill this requirement. For instructions, visit https://wmed.edu/cititraining, or reach out to the IRB Staff at 269-337-4345 or irb@wmed.edu for assistance.
- As part of its responsibility to assess investigator qualifications and ensure the protection or research participants' rights and welfare, the IRB strongly recommends that investigators submit a current CV with their application. You can either upload your CV directly into the electronic system or email it to irb@wmed.edu and it will be uploaded for you.

IRB Application/Submission Packet:

The IRB application includes built-in logic that directs you to the relevant sections based on your responses to questions. If the questions are not answered correctly, you may not be routed to the appropriate sections. Below are the 12 sections along with tips for selecting the correct answers.

1. **General Information**

2. **Add Departments**

3. **Assign Key Study Personnel (KSP) Access to the Study**
   Note: If you are utilizing the WMed Virtual Data Warehouse (VDW) to serve as the honest broker please include this person in the list of key study personnel.

4. **Site Information**
   4.2 Did you utilize the Project Request and Triage Form during protocol development? If so, select "Yes" and choose the applicable research services. This helps us keep track of who has been involved prior to submission.
   4.3 Select the appropriate site(s) where the education is being conducted.
   4.4 Does your project involve the collection of data? Should be answered "Yes". Select applicable source "Student or Resident or "other" and enter the data source.
   4.12 Select the population to be included if applicable (i.e. student data, resident/fellow data or faculty data).

5. **Research Determination**
   5.6 Select "No" to question one (intervention) and "No" to question 2 (interaction).
   5.7 Select "No" to question one (no observation) and "Yes" to question 2 (data provided for specific purposes in which the individual can reasonably expect it will not be made public),
   5.8 Select "yes"

6. **FDA-Regulated Products** "No"

7. **Funding Sources** If funding has been awarded, answer "Yes" and provide the source of the funding (e.g. WMed student grant)

8. **Risk Level Involved** "Yes" Minimal Risk

9. **Research Procedures & Techniques**
   9.1 Select the second option, "Does the research procedure involve Secondary data or biospecimen use NOT collected for THIS study"
   9.3 Select "Yes", this project involves ONLY re-using private information that has been collected for some other primary or initial activity.
   - Include a description of the data set(s) to be analyzed
   - Include who is providing the data to you
   - Indicate what type of data set you will be using: Restricted Access Data Set
   - Is a data use agreement required? Answer "Yes" or "No"
   - Include the list of variables contained in the data set

10. **Study Subjects**
   10.1 Include the maximum number of subjects/records anticipated to be enrolled. Enter the inclusion/exclusion criteria.
   10.4 Select the targeted population if applicable (e.g. students, residents or fellows, employees or staff). Note: Once a targeted population is selected, additional sections will appear, requiring you to provide rationale for including the population, outline additional safeguards to protect their rights and welfare, and describe plans to mitigate the perceived risk of coercion or undue influence.
   10.12 Indicate category of students: WMed or Other
   - Describe the research plan, including the rational for including the population, the additional safeguards in place to protect their right and welfare, and the strategies to mitigate any risk of coercion or undue influence.
   - Will educational records be protected under FERPA? Answer "Yes" or "No".
   - If applicable describe how the research complies with FERPA.

11. **Use of Protected Health Information (HIPAA)**
   This should be answered as "No".

12. **Participant Privacy & Data Confidentiality**
   12.1: Check all that apply. Typically, option #2 and 4 may apply.
   12.2: Check all that apply. Option #2 applies to confidential records that will be labeled with a code linking to personally identifiable information (coded). This typically involves the use of an honest broker to de-identify the data before it is shared with the study team. Option #3 applies to the receipt of a de-identified dataset.
   12.3 Indicate where data will be stored. If electronic, select "Local Server" for studies that will be stored in the VDW or SP.
   12.5: Select option # 1 if a linking code will be maintained until completion of the study.
   Select option #6 when no direct identifiers are being collected.
   Select option # 9 "other" if storing data in the VDW and include this summary: The data set (and any copies of the data set) will be stored in the VDW SharePoint Hub for two years following the data the investigator is granted access. If data needs to be maintained

past the two-year timeframe, a modification request will be submitted to track data for another two years

13. Attach the appropriate documents as follows:

- Study Protocol (Educational Studies available at https://wmed.edu/node/723)
- Data Collection Form (i.e. REDCap; Excel with data variables)
- Any other documents that may apply to the study and/or acquisition of data (i.e. data use agreement)

Submit the final (clean) version of all documents with no track changes visible and be sure to include the version date.

Once the IRB reviews the protocol, you will receive a determination letter outlining the category of exemption or other depending on the level of risk. **Please review the letter carefully**. If the parameters are incorrect or if you have questions, contact the IRB at 269-337-4345.