

Research Utilizing Electronic Health Record (EHR) Data Sets IRB SUBMISSION TIPS

Projects that only involve secondary data analysis from electronic health records (EHR) require IRB review because the definition of “human subject” at 45 CFR 46.102(f) includes living individuals about whom an investigator obtains identifiable private information for research purposes.

[Exempt category 4\(iii\)](#) includes the secondary use of data if all abstracted data is regulated by HIPAA (meaning that subjects’ personal health information is being used or disclosed). The data can be recorded in an individually identifiable manner (e.g. a master list can be maintained, etc.), and both prospective and retrospective data can be used. For this exempt category to apply, **HIPAA must apply to ALL individuals whose individually identifiable or coded data is recorded.**

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 must be trained in the protection of human subjects. WMed uses CITI a web-based human research courses to satisfy this requirement. Visit <https://med.wmich.edu/cititraining> for instructions or contact IRB Staff at 269-337-4345 for assistance.
- Because the IRB has a responsibility to assess investigator qualifications as part of their mandate to protect the rights and welfare of research participants the IRB strongly recommends investigators provide a current CV with their submission. You can upload your CV into the [electronic system](#) or send it to irb@wmed.edu and it will be uploaded for you.

IRB Application/Submission Packet:

The [IRB application](#) has built-in logic designed to route you to applicable sections according to how the questions are answered. If they are not answered correctly, you may not be routed properly. The following are the 12 sections with tips for selecting the appropriate answers specific to requests for EHR data sets.

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 obtain and maintain data be sure to add Theresa McGoff as the Data Manager.

4. Site Information

4.2 Did you utilize the Project Request and Triage Form during protocol development? If so, select “Yes” and select research services as applicable. This helps us keep track of who has been involved prior to submission.

4.3 Select covered entity where medical records/data will be obtained (i.e. Bronson, Borgess).

4.4 Select applicable data source. Be sure to answer “Yes” when the WMed Virtual Data Warehouse (VDW) is involved. Note all data pull requests for EHR, when the data will be transferred to WMed, are required to go through the VDW.

5. Research Determination

5.6 Select “No” to both questions.

5.7 Select “No” for the first question and “Yes” for the second question.

5.8 Select “Yes” for studies accessing medical records. This is relevant even if you and your study team will receive de-identified records because the data manager will see identifiers.

6. FDA-Regulated Products “No”

7. Funding Sources “No”

8. Risk Level Involved “Yes” Minimal Risk

9. Research Procedures & Techniques

- 9.1 Select the first option, “Does the research procedure involve the review of medical records (e.g. chart review)?”
- 9.2 Answer “Yes” for review of medical records. There is a brief description for retrospective and prospective data collection. Indicate the desired START date for record collection and the desired END date for record collection. Please note the start and end dates in this section must match the record collection dates in the protocol. Include when the data will be de-identified. Answer Yes/No question regarding collecting sensitive information. Please note that if this is answered YES, additional questions will display to be completed.

10. Study Subjects

- 10.1 Include the maximum number of subjects/medical records anticipated enrolling/accessing for this study. Enter the inclusion/exclusion criteria and include ICD 10 codes and CPT codes if applicable/available. Again, this information should be consistent with the protocol. If there is any question, please consult the VDW data manager.
- 10.4 If applicable, select the population targeted as subjects. Questions based on the subject population will display.
If children are the subjects:
- 10.5 Provide a rationale for inclusion and additional safeguards to protect their rights and welfare.
- 10.6 Select “A waiver of parental permission is being requested” and explain provisions made for children whose parents have not given consent for participation. Example: Given the retrospective design of this study, and results presented in aggregate with no PHI disclosed, there is minimal risk involved for subjects. Therefore, parental permission may be waived.
- 10.7 Select “No” and provide justification. Example: Given the retrospective design of this study, and results presented in aggregate with no PHI disclosed, there is minimal risk involved for subjects. Therefore, assent will not be obtained.

11. Use of Protected Health Information (HIPAA)

- 11.1: Review the list of PHI elements. If you are uncertain if PHI is being accessed, select Yes. Please note collecting a medical record number is a HIPAA element and would require a HIPAA waiver of authorization
- 11.2 Select “No”, that written HIPAA authorization will not be obtained from study participants.
- 11.3: Select applicable box, for secondary use of existing data sets a Full Waiver is required
- 11.4: - 11.9: This information should be well described in the data management plan section of your protocol. You may reference the applicable sections of the protocol in response to these questions.

12. Participant Privacy & Data Confidentiality

- 12.1: Check all that apply. Typically, option #4 applies to a secondary use of data. The collection of information about participants is limited to the amount necessary to achieve aims of the research.
- 12.2: Check all that apply. Likely option #2 Data and/or specimens WILL be labeled with a code that the research team can link to personal identifying information (coded).
- 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: If storing data in the VDW, select option #9 “other” 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 (template specific to data review 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)

Please note, it is very helpful to include version dates on submission documents.

Once the IRB reviews the protocol, you will receive a determination letter from the IRB outlining the category of exemption and the conditions of the waiver of HIPAA authorization. **Be sure to review the letter.** If the parameters of the determination are incorrect or if you have questions, please call the IRB at 269-337-4345.