

Data Protection and IRB Protocol Submission Guidance Not Research and Not Human Subjects Research (NHSR) Projects

| Activity | IRB Protocol Required Y/N | Data Protection Process Required | Data Storage Policy ¹ | CTSI Approval for EMR ² Use | HSC ITS Approval | HIPAA Waiver | Responsible Entity for Activity | IRB NHSR Letter of Determination (Publication) | Data Agreements |
|---|--|--|----------------------------------|---|----------------------------------|---|---|--|-------------------|
| Not Research³ These activities could: use PHI, be Academic Program Related, or be WVU Health System (WVUM) Directed | | | | | | | | | |
| WVU Health System - QI, EBP & Program Evaluation | No | No | WVU Health System | No | No | No | WVU Health System | Use Self Determination Tool | WVU Health System |
| WVU Employee/ Student QI, EBP & Program Eval – University Initiated –Dept should approve the project. | No | No | University Policy | If EMR Use = Yes Use iLab ⁴ | Yes = EMR ⁵ | No | University | Use Self Determination Tool | OSP ⁶ |
| Retrospective Case Study 5 records or Less <i>Includes students and staff with direct access to EMR.</i> | No | No | University Policy | No | Yes = EMR | No – Use Case Auth Form CTSI/Upload copy to EPIC ⁷ . | WVU Health System OR the University (Staff or Academic project) | Use Self Determination Tool | OSP |
| WVU Classroom/Educational Activity <i>Based on Intent. It can include Retrospective. Case Studies(5 or less) if CTSI is used to obtain the data.</i> | No | No | University Policy | If EMR Use = Yes, Use iLab to request data from CTSI. | YES = EMR | N/A | University | Use Self Determination Tool | OSP |

¹ Data storage options for projects that are NOT considered research can be discussed with the IT group that supports your department.

² EMR – Electronic Medical or Dental records from any clinical system owned by the WVU Health System (a separate legal entity from the University).

³ The “Not Research” activities using EMR data should be approved by the academic unit. Accessing the data should be discussed and approved with the WVU Health System, as research policies for human subjects research do not apply.

⁴ Use the [CTSI iLab Request](#) to obtain WVU Health System EMR data.

⁵ Contact [HSC ITS](#) or [WVU ITS](#) to request information on the appropriate storage of PHI for projects that are not considered research.

⁶ [WVU Office of Sponsored Programs](#) provides services for data agreements for projects that are NOT considered research and research.

⁷ If the participant can’t sign the Case Authorization Form, the [WVUM Privacy Office](#) must approve access for both WVUM and WVU staff and students

Data Protection and IRB Protocol Submission Guidance Not Research and Not Human Subjects Research (NHSR) Projects

| Activity | IRB Protocol Required Y/N | Data Protection Process Required | Data Storage Policy ¹ | CTSI Approval for EMR ² Use | HSC ITS Approval | HIPAA Waiver | Responsible Entity for Activity | IRB NHSR Letter of Determination (Publication) | Data Agreements |
|---|--|--|---|---|----------------------------------|---|---------------------------------|--|-----------------|
| Oral Histories (non-clinical) Scholarly and Journal/Documentary Activities ⁸ | No | No | University Policy | N/A | No | No | University | Not Needed | OSP |
| Public Health Surveillance (WVU Health System must approve/provide access to EMR) | No | No | University Policy | No | Yes | No | University | Use Self Determination Tool | OSP |
| Research (federal definition)⁹ – Not Human Subjects Research (NHSR) | | | | | | | | | |
| Publicly Available Data | No | Yes | University & Research Office Storage Policy | No | Yes – via Data Protection | No | University | Not Needed | OSP |
| Deceased Person Data Collection | No | Yes | University & Research Office Storage Policy | Yes | Yes – via Data Protection | HIPAA Decedent Form for WVUM EMR Data | University | Via DP Certification | OSP |
| Secondary Analysis of Data Request de-identified data from CTSI ¹⁰ | No | Yes | University & Research Office Storage Policy | If EMR data = Yes | Yes – via Data Protection | No | University | Via DP Certification | OSP |

⁸ In this context, an Oral History is the collection and use of information that focuses directly on the individuals about whom the information is collected.

⁹ Research is defined in the Privacy Rule as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501

¹⁰ Secondary Analysis of Data – If EMR is directly accessed by PI, then the activity is considered Human Subjects Research. If the PI will be receiving PHI from CTSI or WVU Health System clinical data source, the activity is considered Human Subjects Research.

Data Protection and IRB Protocol Submission Guidance Not Research and Not Human Subjects Research (NHSR) Projects

Additional Guidance:

1. Use the [Self Determination Tool](#) to verify the category of the project/activity.
2. Not Research Activities and Projects:
 - Data storage for the “Not Research” activities should follow the [University’s Information Security Policy](#) and HIPAA Hybrid Entity Designation policies as applicable. Since these activities are **not** considered Research, the Research Office process and policies for Research Data Management do not apply unless an agreement is needed; then, OSP processes apply. Please get in touch with the IT department that supports your department or function for assistance.
 - CTSI’s role for the “Not Research” activities relates to the WVU/WVU Health System contractual role as the Honest Broker for the WVU Health System medical records. This review includes a privacy component and ensures that WVU, “the University,” is using and managing the data according to agreements. CTSI does not review and approve access to medical records for WVU Health System-sponsored activities.
 - WVU Students, WVU employees, and Affiliate student access to WVU Health System Medical and Dental records for activities categorized as “Not Research” will request access to the EMR data through [CTSI using iLAB](#). If you have questions regarding EMR access for projects that are not considered research, refer to your Department Head or Instructor.
3. Need Help?
 - [WVU Office of Human Research Protections](#) - Research/Not Research IRB Review Determinations
 - [WVU Research Office – Data Protection Support](#) – Data Protection Process for NHSR and Human Subjects Research
 - [WV Clinical and Translational Science Institute](#) –EMR use for non-clinical activities sponsored by WVU
 - [WVU Research Office – Office of Sponsored Programs](#) – Data Agreements
 - [WVU Information Technology Services](#) - Enterprise Information Security and IT services
 - [WVU Health Sciences Information Technology Services](#) – HIPAA PHI and IT services for WVU Health Sciences