

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	No	No	No	University	Use Self Determination Tool	General Counsel
Retrospective Case Study 5 records or Less <i>Includes students and staff with direct access to EMR.</i>	No	No	University Policy	No	No	No – Use Case Auth Form	WVU Health System OR the University (Staff or Academic project)	Use Self Determination Tool	General Counsel
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	No	No	N/A	University	Use Self Determination Tool	General Counsel
Oral Histories (non-clinical) Scholarly and	No	No	University Policy	N/A	No	No	University	Not Needed	General Counsel

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.

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Journal/Documentary Activities ⁴									
Public Health Surveillance (WVU Health System must approve/provide access to EMR)	No	No	University Policy	No	No	No	University	Use Self Determination Tool	General Counsel
Research (federal definition)⁵ – Not Human Subjects Research (NHSR)									
Publicly Available Data	No	Yes	University & Research Office Storage Policy	No	Yes – via Data Protection	No	University	Not Needed	General Counsel
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	General Counsel
Secondary Analysis of Data (If WVUM EMR, Request de-identified data from CTSI) ⁶	No	Yes	University & Research Office Storage Policy	If EMR data = Yes	Yes – via Data Protection	No	University	Via DP Certification	General Counsel

Additional Guidance:

⁴ 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.

⁵ 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

⁶ 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.

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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.
3. Prep to Research ?
 - 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.
4. 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