

Data Protection and IRB Protocol Submission Guidance

Activities That Do Not Meet the Federal HHS Definition of Research and Not Human Subjects Research (NHSR)

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	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	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 –COI Notification	University
Retrospective Case Study 5 records or Less <i>Includes students and staff with direct access to EMR.</i>	No	No	University Policy	Notification	No	No – Use Case Auth Form	WVU Health System OR the University (Staff or Academic project)	University
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	University
Oral Histories (non-clinical) Scholarly and Journal/Documentary Activities ⁴	No	No	University Policy	N/A	No	No	University	University

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 Health Information Management department, as research policies for human subjects research do not apply.

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.

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Public Health Surveillance (WVU Health System must approve/provide access to EMR)	No	No	University Policy	No	No	No	University	University
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	University
Deceased Person Data Only	No	Yes	University & Research Office Storage Policy	Yes	Yes – via Data Protection	HIPAA Decedent Form for WVUM EMR Data	University	University
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	University

Additional Guidance:

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 the PI directly accesses EMR, then the activity is considered Human Subjects Research. If the PI receives PHI(identifiers) from CTSI or WVU Health System clinical data source, the activity is considered Human Subjects Research.

Sponsored Projects – A notification will be sent to COI