# PURPOSE

To describe the process for using WVU Health System Data for research purposes.

# OVERVIEW and SCOPE

This SOP applies to all Research conducted under the auspices of WVU. The WVU Health System and West Virginia University are separate legal entities. By legal agreement, the Health System permits the University to use its data for research purposes. This applies to all University employees, dual assignment employees, sponsored employees/students, and students regardless of access to the data for clinical purposes.

The scope of data includes:

*WVU Health System data includes:*

Electronic Medical Records (EMR) : Data from medical records systems, including those from Epic and all other systems that contain electronic medical and dental records, including imaging systems.

Images: Images are provided by WV CTSI, the Honest Broker. The procedures below outline the process for obtaining images to support Research.

Clinical Registries/Repositories: using clinical registries and data repositories requires adherence to the agreement between the Health System and the University and, like EMR data, requires approval from WVU Health Systems to use the data.

Bio-specimens:

The scope of activities includes:

Research is defined by the [federal definition of Research,](https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions) including Research designated as Not Human Subjects Research (NHSR).

The activities included in NHSR are:

* Research using publicly available data
* Research using ONLY deceased person data (living person data cannot be in scope) – HIPAA Decendent Form is required for data from the EMR systems.
* Secondary analysis of data (data can be derived from a WVU Health System source) but must be de-identified by the Honest Broker (WV CTSI) – All data must be de-identified. A *HIPAA Waiver of Authorization is not required as viewing the EMR directly to obtain the data is not permitted for the category of research.*

This SOP excludes activities that are not considered Research under the federal definition. The activities are listed below. *Note that access to the WVU Health System data is required*. However, access is not approved by research procedures, nor is oversight provided by research procedures.

* WVU Health System Quality Improvement, Evidence-Based Practice, and Program Evaluations
* University Quality Improvement, Evidence-Based Practice, and Program Evaluations
* University Retrospective Chart Studies (five records or less) – Requires a Case Study Authorization Form
* University Classroom and Educational-Based Activities
* Oral Histories (non-clinical) – Supporting Scholarly and Journal/Documentary Activities.
* Public Health Surveillance

# PROCEDURES

* 1. Obtain permission (an email from the data owner ) to use registries and repositories owned and managed by WVU Health Systems before starting any research. Approval for using systems containing EMR data is part of the Data Protection process.
  2. Complete the Data Protection Form and upload the email with permission if applicable.
  3. The Data Protection Form will provide the next steps to obtain the images if images are used.
  4. If there are questions related to individual privacy or the Research, you may be contacted by WV CTSI Honest Broker team members.
  5. Approval to use the data is in the form of the Data Protection Certificate.
  6. Complete a HIPAA Waiver of Authorization Form if you will view EMR records, and you will NOT obtain Informed Consent from individuals. This is required even if you are not recording identifiers and will not use identifiers in your research.
  7. Complete the Decendent Form if you use descendent data from the EMR.
  8. Complete the steps to request image data and other data.

# REFERENCES

WVU Research Human Data Protection Process

WV CTSI

HIPAA Honest Broker

WVU Health System Health Information Management

WVU Information Security & Privacy

HIPAA Waiver of Authorization

HIPAA Decendant Form

Case Study Authorization Form

**History of Revisions to SOP**

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| --- | --- | --- |
| Effective Date | Nature of Revision(s) | Name |
| 6/5/23 | Created the new SOP | R. Casteel |