Research Data Source and Risk DUA & Training Requirements Guidance
Clinical and Non-Clinical Human Data

Source	Data	Research Risk Category	Notes	DUA Outgoing
Category: Clinical Data The data is associated with or derived from a healthcare service event (the provision of care as defined by HIPAA). This includes: • All data from or going to the EMR in any WVU Health System clinical data system or repository. • Information ranging from determinants of health and measures of health and health status to documentation of care delivery. • Clinical observational study data collected through surveys, forms, wearables, video and audio recordings. • Communication data associated with texting and emails to provide and collect information related to appointments, participant actions, the status of a device/drug, or general well-being). • The data used to complete retrospective chart studies.				
WVU Health System EPIC	The researcher accesses the EMR and enters information into a spreadsheet, REDCap, etc. The Data Protection form will indicate how the data was received from the medical record.			
	CTSI Provided EMR Identifiable/Coded/LDS	High		Yes
	The researcher directly accesses the EMR and records only de-identified data	High	The researcher must have access to EPIC and permission to access the EMR for research regardless of clinical role. The risk is high as the data was not de-identified by CTSI.	Yes
	De-identified by CTSI	Low		No
WVU Health System Clinical Systems & Services	WVU Health System Enterprise Analytics Department provides Citrix access and data/access to other repositories, clinical databases, and systems.			
	Identifiable/Coded/LDS	High		Yes
	De-identified By the Source	Low		No

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HSC Biospecimen Digital Data	The digital data associated with an approved HSC biospecimen repository.			
	Identifiable/Coded/LDS	High		Yes
	CTSI De-identified	Low		No
	Researcher De-identified	High	If verified by CTSI, the risk can be decreased.	Yes
Clinical data purchased by WVU (University) for research	The data may not be able to be transferred or shared based on the purchase agreement. Since this is not WVU's PHI, HIPAA does not apply (i.e., training to access storage, forms, tracking, and reporting). However, WVU will protect PHI transferred or shared from other entities as high-risk data.			
	Identifiable/Coded/LDS	High		Review
	De-identified - Researcher	High	If verified by CTSI, the risk can be decreased.	Review
	De-identified by the source	Low		Review
Clinical External Source (not purchased)	This source includes data from another medical center or healthcare entity and data shared by a collaborator. It also includes data repositories and online sources subscribed to by the health system and used for research purposes. Since this data is not WVU's PHI, WVU is not the responsible covered entity, and HIPAA does not apply in most situations. WVU will protect identifiable external PHI as high-risk data. DUA requirements from external sources may override the risk ratings for low or medium-risk data.			
	Identifiable/Coded/LDS	High		Review
	De-identified by the source	Low		Review
	De-identified by the researcher	High	If verified by CTSI, the risk can be decreased.	Review
	Anonymous from the source	Low		No
Clinical Internal Source	Clinical data collected internally at WVU or previously purchased by WVU from an external source. Must have approval to use the data for research based on the agreement for the data or from the source. HIPAA may apply; refer to OGC.			
	Identifiable/Coded/LDS	High		Yes
	De-identified by CTSI	Low		No
	De-identified by the Researcher	High	If verified by CTSI, the risk can be decreased.	Review
	Anonymous	Low	Verified by Data Protection and the WVU IRB	No

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Clinical Participant Data Collection	Collecting data directly from research participants.			
	Identifiable/Coded/LDS	High		Yes
	De-identified by CTSI	Low		No
	De-identified by the Researcher	High	If verified by CTSI, the risk can be decreased.	Yes
	Anonymous	Low	Verified by Data Protection and the WVU IRB	No

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Source	Data	Research Risk Category	Notes	DUA Outgoing
Non-Clinical Data: Data collected or derived from a participant in situations that do not meet the definition of clinical research is not subject to HIPAA compliance (includes data collected by WVU-covered entities). However, identifiable research data **is** subject to other state and federal laws and institutional policies for the privacy and confidentiality of research health information.				
Participant Data Collection	Examples: surveys, forms, wearables, video and audio recordings			
	Identifiable with WVU-Sensitive variables	High		Yes
	Identifiable without WVU-sensitive variables.	Medium		Yes
	De-identified	Low		No
	Anonymous	Low		No
WVU Internal Source	Data collected internally at WVU or previously purchased by WVU from an external source. Must have approval to use the data for research based on the agreement for the data or from the source. Internal clinical sources are not included in this source.			
	Identifiable with WVU-Sensitive variables	High		Yes
	Identifiable without WVU-sensitive variables.	Medium		Yes
	De-identified	Low		No
	Anonymous	Low		No
Publicly Available Data	The general public can obtain the data, including identifiers or identifying information. There are no conditions for use, and payment may be required for access. This includes social media that does not require a login and profiles set to public. Combining public data sets may change the risk, and some publicly available data may limit research use.			

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	Not Combined	Low		No
	Combined	Medium		Review
External source (not purchased)	DUA requirements from external sources may override the risk ratings. Examples are purchased data and data shared by a collaborator for research.			
	Identifiable with WVU-Sensitive variables	High		Review
	Identifiable without WVU-sensitive variables	Medium		Review
	Coded by the Source	Medium		Review
	De-identified by the source	Low		Review
	De-identified by the researcher	Medium		Review
	Anonymous from the source	Low		No

Other Factors:

If any of the following are characteristic of the data, then the data risk is elevated as follows:

- Federally Funded Data (future: NSPM-33)– Elevate to medium risk
- Vulnerable Populations – Elevate to high-risk
- Sensitive Topics in Research – Elevate to high-risk
- International Components – Elevate to medium risk
- Intellectual Property (commercial product or service) – Elevate to high risk
- HIPAA, FDA, FERPA, Export Control, GDPR, NIST 800-171 (CUI, CMMC 2.0), FISMA, NIST 800-53 (FIPS), DFARS Clause 252.204-7012, Endangered Species or Other Regulations Apply– Elevate to high risk
- Agreement from the source requires a high level of protection – Elevate as directed by the agreement.
- Federally funded projects under the new Public Access policies will need to be aware of restrictions on sharing data in agreements related to data brought into the University or from the WVU Health System.

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Helpful Information:

Mapping of Research Risk Categories to WVU Information Security Policy Data Classifications

	Sensitive	Confidential	Internal	Public
High	X			
Medium		X	X	
Low				X

WVU Office of Human Research Protection (OHRP) Glossary

Research Data Protection Form and Process