

This request is from a WVU Non-Covered Entity, the data source is External Data Source with Identifiers. Several Data Information and identifiable data variables will be included. Data Transfer is required. Clinical Trial Agreement and Sponsored Research Agreement Data Agreements are in place/pending.

1. Department *
Select a department from the drop-down.
2. Department Head or Chair *
Select a department head or chair from the drop-down. For this test, select yourself (if available).
3. Principal Investigator *
Select a principal investigator from the drop-down. For this test, select yourself (if available).
4. Research Project Title *
Enter any text for the research project title (For example, *Script 14 - <Initials>*. In my case, *Script 14 – GWS*).
5. Are you collecting, using or storing any of the following identifiable data variables?
Select all that apply.
Select **Surgery or Procedure Dates** and **Medical Test Dates**
6. Are you collecting, using or storing any of the following additional data variables?
Check all that apply.
Select no boxes/leave empty.
7. Does the research involve Sensitive Topics?
Check all that apply.
Select no boxes/leave empty.
8. Indicate the source of the data: *
Definitions: (7 definitions with several hyperlinks are listed).
Select **External Data Source**
9. Provide the source of the data. *
Enter any text for the source of data (For example, *The Moon!*).
10. Will the data be de-identified during the research project? *
Please see [here](#) for a definition of De-identified Data.
Select **Yes**
11. Select the De-identification method. *
Select **HIPAA Safe Harbor – Preferred Method**
12. Will an honest broker be used? *

Honest Broker (HIPAA): A neutral intermediary (person or system) between the individual whose tissue and data are being studied, and the researcher. More information is available [here](#).

Select **Yes**

13. Will WV CTSI act as the honest Broker? *

Select **Yes**

14. Select the WVU entity to which your department belongs. *

The following list represents the WVU departments (entities) that must comply with the HIPAA Privacy Rule. Please select your department if it is on the list; if it is not on the list, select None of the above. More information is available [here](#).

Select **None of the above**

15. Is Data Transfer/Sharing required for your project? *

Data Sharing: A collaborative agreement exists for data to be shared by multiple institutions/organizations throughout a research project. Data transfer likely occurs more than once. Does not include obtaining/receiving data as part of service provided by a third-party vendor where a purchase agreement exists.

Select **Both**

16. Are there international components or involvement with the research? *

Select **No**

17. Is the software, service, or communications product you will use to collect data, obtain samples, distribute survey links, pay participants, or communicate with participants on the WVU Approved Technology for Research List? *

This list is maintained.

Select **Yes**

18. Will participants be compensated? *

Select **No**

19. Do you plan to request the procurement of a new (not currently owned or approved by WVU) product or service for data storage or analysis from ITS? *

Examples include: analytics, machine learning AI, cloud storage services, high performance computing, etc.

Select **No**

20. Research Information

Describe how data will be used in your research? *

Enter any text for the data usage title (For example, *Data will be used in research oh so well*).

21. WVU Protocol Number (if available)

Leave blank.

22. Does the project have a Funding Source? *

Select **No**

23. Data Use and Storage

How long will the identifiable research data be kept? *

Data **must** be kept for a minimum of three (3) years after study completion but may be kept longer.

Enter any text for the time (For example, *Data will be kept for 5 years.*).

24. Will anyone other than the PI, research team members, or IRB have access to the identifiable data (e.g., sponsor/funding source, other collaborators)? *

Select **No**

25. Will physical copies (i.e. paper copies) of the data be stored during the project? *

Select **No**

26. What is the plan for data at the conclusion of the project? *

Select **The data will be destroyed**

27. Provide details for the destruction plan. *

Enter any text for the destruction plan (For example, *Hard drives and digital data will be fully formatted and no paper copies will exist.*).

28. Will the WVU ITS High Risk Data Collection and Storage Plan meet the needs of your project? *

Select **Yes, I will use the ITS Approved Plan**

29. Are any of the following in place or pending? *

Select **Clinical Trial Agreement and Sponsored Research Agreement**

30. Researcher Attestation

Select **By checking this box, I agree that the information I provided is correct and will comply with the protection requirements on the Data Protection Certificate throughout the research project. If change occurs with the data requirements, I will submit a new Data Protection form.**

31. In the upper right corner Actions panel

Select **Submit**

RESULT:

Your form was successfully submitted notification is present.

Email notification will be received (within a few minutes):

Email subject “Data Protection Certificate”.

Email body will state “Hello <name>,”

Your Data Protection Certification request has been approved! Please see the attached Data Protection Certificate for your Protection Plan details.”

The attached PDF will be titled “Data Protection Certificate - <name>.pdf”

The header will state “High Risk”

Another email notification will be received (within a few minutes):

Email Subject “Researcher in your department received a Data Protection Certificate”

Email body will state “Please be advised that a Data Protection Certificate was issued to Principal Investigator <name> for the project <project title>.”

A copy of the certificate is attached. No action is required on your part. This message is only to inform you that Sensitive, High Risk data will be handled by members of your department and has protection requirements.

The data protections required by the University are indicated on the certificate and must be followed. For more detail, please consult with the PI named above.

Have a great day!”

The attached PDF will be titled “Data Protection Certificate - <name>.pdf”

The header will state “High Risk”