**Data Module & Confidentiality Form**

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| --- |
| Research Study Title …………………………………………….. |
| PI …………………………………………….. |
| Phone …………………………………………….. |
|  |
| Address ………………………….…………………….. |

If your **ONLY** research procedure is **analysis of data or specimens** and you are not planning to prospectively collect biospecimens solely for research purposes, this is the appropriate protocol template to use. (For example, medical record review, you plan to analyze data or biospecimens that were collected in prior research studies or data that are available from internet based records, government datasets, etc.)

This form should only be submitted for projects that are research with human subjects (see below on this page for discussion of when analysis of data/specimens requires IRB review).

**Are the data/specimens identifiable? If the data/specimens are de-identified, do not use this form.**

If your project **solely** involves analyzing **de-identified** data and/or specimens, and is not part of a larger-scope project that is human subjects research, you do not need IRB review to analyze de-identified data/specimens. If you need bioethics committee approval on that the research is not dealing with human subjects. Then you **do not need to complete this form.**

*Please respond to the following statements]*

1. CHARACTERISTICS OF DATA/SPECIMENS TO BE ANALYZED
2. What datasets/specimens do you plan to analyze, who will provide you with the data/specimens, and who originally collected the data/specimens?

*[List the specific data elements that will be collected or, if preferred, you may attach the list of specific data elements as an appendix to this protocol]*

Click or tap here to enter text.

1. Explain if the data/specimens were collected in a previous research study, collected as part of a government program or as part of an organization’s standard operations, or for other purposes.

*[if the data have been approved before, provide the approval number. If you are accessing specimens from a biobank/biorepository, specify which biobank/biorepository will be providing the specimens.]*

Click or tap here to enter text.

1. Internet links to databases.

*[If you plan to analyze multiple datasets, describe each dataset separately and explain who holds each dataset. If you already have access to certain database before this research then explain how you had this access ]*

1. Describe whether use of the data/specimens requires any special permissions, restrictions, and/or agreements

*[Describe clearly if any data sharing agreement is taking place while this study is continuing. ]*

1. Are any identifiers associated with the data/specimens? Yes No

If ‘yes’, please provide the following for each identifier:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Name | Phone number | residential addresses | ID number |
| 1 | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| 2 |  |  |  |  |

1. If the data/specimens are already have identifiers associated with them now, please indicate if they are going to be removed at any phase through out this study.

Click or tap here to enter text.

1. if the data/specimens are going to be stored with a code, please indicate if this code will be shared among team members and where it will be stored.

Click or tap here to enter text.

1. ACCESS, SECURITY, AND MANAGEMENT
2. Where and how will you access, transmit and store the data/specimens?

*[describe if there is any restrictions imposed on data handling methodologies, i.e. storing data and accessibility. ]*

Click or tap here to enter text.

1. What will you do with these data/specimens after completing the study?

*[describe how you are going to destroy the data/specimens after completing the study . ]*

Click or tap here to enter text.

1. Is there any plans to store data/specimen for long term beyond the scope of this study?

Yes No , If ‘yes’, please indicate clearly for what purposes.

Click or tap here to enter text.

1. Explain if there is any relevant information and how you plan to protect the confidentiality of the data/specimens.

Click or tap here to enter text.