

# Data Collection Tool Questions and Response Options

The Data Collection Tool version 2.8.6 included 165 questions organized into 11 sections. Each question allows users to either type a value, select one from defined response values, select one from defined response values and/or type a value, or select one or more from defined response values and/or type a value.

The data collection tool includes conditional logic that helps the user skip question when one response negates the relevance of subsequent questions. Conditional logic is represented below as (*skip to question X*).

## Section 1: User Information

- 1.1. Question: Enter your first name [type a value]
  - a. Response: [type a value]
- 1.2. Question: Enter your last name [type a value]
  - a. Response: [type a value]
- 1.3. Question: Enter the organization(s) that you represent [type a value]
  - a. Response: [type a value]
- 1.4. Question: Select or enter the value that best represents your role related to this dataset [select one or more or type a value]
  - a. Response Value: Associate investigator
  - b. Response Value: Co-principal investigator
  - c. Response Value: Principal investigator
  - d. Response Value: Research study coordinator
  - e. Response Value: IRB representative
  - f. Response Value: Signing official
  - g. Response Value: Legal representative
  - h. Response: [type a value]

## Section 2: Dataset Information

- 2.1. Question: Enter the name of the dataset [type a value]
  - a. Response: [type a value]
- 2.2. Question: Enter the name of the study that generated this dataset [type a value]
  - a. Response: [type a value]
- 2.3. Question: Select or enter the type of data in the dataset [select one or more or type a value]
  - a. Response Value: Administrative
  - b. Response Value: Claims
  - c. Response Value: Clinical
  - d. Response Value: Electronic Health Record (EHR)

- e. Response Value: Environmental
  - f. Response Value: Data generated from biospecimens
  - g. Response Value: Genomic data
  - h. Response Value: Patient generated health data (e.g., PROs, RPM, wearables, devices, sensors)
  - i. Response Value: Survey
  - j. Response: [type a value]
- 2.4. Question: Enter the name of the organization that collected the dataset [type a value]
- a. Response: [type a value]
- 2.5. Question: Enter the name of the organization(s) that funded the collection of this dataset [type a value]
- a. Response: [type a value]
- 2.6. Question: Enter the grant number for the collection of this dataset [type a value]
- a. Response: [type a value]
- 2.7. Question: Does this dataset contain Personally Identifiable Information (PII) for use in individual-level dataset linkage? [select one]
- a. Response Value: Yes
  - b. Response Value: No (*skip to question 2.10*)
  - c. Response Value: I don't know (*skip to question 2.10*)
- 2.8. Question: Select which PII elements the dataset contains [select one or more or type a value]
- a. Response Value: Name
  - b. Response Value: Geographic subdivision smaller than state (e.g., address or zip code)
  - c. Response Value: Elements of dates (except for year) related to birth, death, or medical encounters
  - d. Response Value: Telephone number
  - e. Response Value: Fax number
  - f. Response Value: Email address
  - g. Response Value: Social security number
  - h. Response Value: Medical record number
  - i. Response Value: Health plan beneficiary number
  - j. Response Value: Account number
  - k. Response Value: Certificate or license number
  - l. Response Value: Vehicle identifier and serial numbers, including license plate numbers
  - m. Response Value: Device identifier
  - n. Response Value: Web URL
  - o. Response Value: Internet protocol address
  - p. Response Value: Biometric identifiers (e.g., fingerprint or voice)
  - q. Response Value: Photographic image

- r. Response: [type a value]
- 2.9. Question: Enter the organization that holds these PII elements. [type a value]
  - a. Response: [type a value] (*skip to question 3.1*)
- 2.10. Question: Select or enter the method used to de-identify the dataset. [select one or type a value]
  - a. Response Value: HIPAA - Safe Harbor
  - b. Response Value: HIPAA - Expert Determination
  - c. Response Value: Dataset contains no individual-level data
  - d. Response: [type a value]
- 2.11. Question: Are identifiers accessible outside of the dataset to generate a pseudo-identifier (e.g., hash or token)? [select one]
  - a. Response Value: Yes
  - b. Response Value: No
  - c. Response Value: I don't know

### Section 3: History of Dataset Linkage

- 3.1. Question: Has this dataset previously been linked? [select one]
  - a. Response Value: Yes
  - b. Response Value: No (*skip to question 4.1*)
  - c. Response Value: Information not available/found (*skip to question 4.1*)
  - d. Response Value: I don't know (*skip to question 4.1*)
- 3.2. Question: Select or enter the linkage method [select one or more or type a value]
  - a. Response Value: Privacy Preserving Record Linkage (PPRL)
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 3.3. Question: Enter the name of the project [type a value]
  - a. Response: [type a value]
- 3.4. Enter the name of the dataset or describe the group of datasets [type a value]
  - a. Response: [type a value]
- 3.5. Question: Enter who collected the dataset or group of datasets [type a value]
  - a. Response: [type a value]

### Section 4: Institutional Review Board

- 4.1. Question: Is this dataset governed by an IRB Protocol? [select one]
  - a. Response Value: Yes
  - b. Response Value: Yes, but determined to be non-human subject's research (*skip to question 5.1*)
  - c. Response Value: No (*skip to question 5.1*)
- 4.2. Question: How many IRBs are involved with this dataset [select one or type a value]

- a. Response Value: A single IRB
  - b. Response Value: Multiple IRBs
  - c. Response: [type a value]
- 4.3. Question: Enter the name of the IRB of record [type a value]
- a. Response: [type a value]
- 4.4. Question: For a future linkage study, would a requester of this dataset need to receive study-specific approval from an IRB? [select one]
- a. Response Value: Yes
  - b. Response Value: No
  - c. Response Value: I don't know
- 4.5. Question: Does the IRB permit dataset linkage? [select one]
- a. Response Value: Yes (*skip to question 4.9*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 4.9*)
  - d. Response Value: I don't know (*skip to question 4.9*)
  - e. Response Value: It doesn't say (*skip to question 4.9*)
- 4.6. Question: Select or enter the dataset linkage conditions that the IRB applies [select one or more or type a value]
- a. Response Value: The dataset may only be linked with the approval of the IRB of record (*skip to question 4.9*)
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites (*skip to question 4.9*)
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value] (*skip to question 4.9*)
- 4.7. Question: Select or enter the linkage method [select one or type a value]
- a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 4.8. Question: Enter the specific types of research or use [type a value]
- a. Response: [type a value]
- 4.9. Question: Does the IRB permit dataset sharing? [select one]
- a. Response Value: Yes (*skip to question 4.13*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 4.13*)
  - d. Response Value: I don't know (*skip to question 4.13*)
  - e. Response Value: It doesn't say (*skip to question 4.13*)

- 4.10. Question: Select or enter the dataset sharing conditions that the IRB applies [select one or more]
- a. Response Value: The dataset may only be shared as a de-identified dataset (*skip to question 4.13*)
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method (*skip to question 4.13*)
  - c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset (*skip to question 4.13*)
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value] (*skip to question 4.13*)
- 4.11. Question: Enter the review body needed for approval for sharing
- a. Response: [type a value]
- 4.12. Question: Describe the data release process
- a. Response: [type a value]
- 4.13. Question: Does the IRB permit secondary dataset access? [select one]
- a. Response Value: Yes (*skip to question 4.15*)
  - a. Response Value: Yes, with conditions
  - b. Response Value: No (*skip to question 4.15*)
  - c. Response Value: I don't know (*skip to question 4.15*)
  - d. Response Value: It doesn't say (*skip to question 4.15*)
- 4.14. Question: Select or enter the secondary dataset access conditions that the IRB applies [select one or more or type a value]
- a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]
- 4.15. Question: Does the IRB permit secondary dataset use? [select one]
- a. Response Value: Yes (*skip to question 4.18*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 4.18*)
  - d. Response Value: I don't know (*skip to question 4.18*)
  - e. Response Value: It doesn't say (*skip to question 4.18*)
- 4.16. Question: Select or enter the secondary dataset use conditions that the IRB applies [select one or more]
- a. Response Value: This dataset may only be used for an approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic (*skip to question 4.18*)
  - c. Response: [type a value] (*skip to question 4.18*)
- 4.17. Question: Enter the approved purpose
- a. Response: [type a value]

- 4.18. Question: Select or enter the prohibitions [select one or more or type a value]
- a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed
  - e. Response Value: The dataset may not be used for secondary purposes
  - f. Response Value: The dataset may not be used for commercial purposes
  - g. Response Value: The dataset may not be used for any purposes beyond explicit permissions
  - h. Response Value: The dataset may not be sold
  - i. Response: [type a value]

## Section 5: Consent

- 5.1. Question: Were participants consented for the collection of this dataset? [select one]
- a. Response Value: Yes
  - b. Response Value: No, consent was waived by the IRB (*skip to question 6.1*)
  - c. Response Value: I don't know (*skip to question 6.1*)
  - d. Response Value: No human participants in this dataset (*skip to question 6.1*)
- 5.2. Question: Will minor participants be re-consented when they become adults? [select one]
- a. Response Value: Yes
  - b. Response Value: No
  - c. Response Value: I don't know
  - d. Response Value: There are no minors in this dataset
  - e. Response: [type a value]
- 5.3. Question: Does the consent permit dataset linkage? [select one]
- a. Response Value: Yes (*skip to question 5.7*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 5.7*)
  - d. Response Value: I don't know (*skip to question 5.7*)
  - e. Response Value: It doesn't say (*skip to question 5.7*)
- 5.4. Question: Select the dataset linkage conditions that the consent applies [select one or more or type a value]
- a. Response Value: The dataset may only be linked with the approval of the IRB of record
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites (*skip to question 5.7*)
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value] (*skip to question 5.7*)

- 5.5. Question: Select or enter the linkage method [select one or type a value]
- a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 5.6. Question: Enter the specific type of research or use [type a value]
- a. Response: [type a value]
- 5.7. Question: Does the consent permit dataset sharing? [select one]
- a. Response Value: Yes (*skip to question 5.11*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 5.11*)
  - d. Response Value: I don't know (*skip to question 5.11*)
  - e. Response Value: It doesn't say (*skip to question 5.11*)
- 5.8. Question: Select the dataset sharing conditions that the consent applies [select one or more]
- a. Response Value: The dataset may only be shared as a de-identified dataset (*skip to question 48*)
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method (*skip to question 48*)
  - c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset (*skip to question 48*)
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value]
- 5.9. Question: Describe the data release process
- a. Response: [type a value]
- 5.10. Question: Enter the name of the review body needed for approval for sharing
- a. Response: [type a value]
- 5.11. Question: Does the consent permit secondary dataset access? [select one]
- a. Response Value: Yes (*skip to question 5.13*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 5.13*)
  - d. Response Value: I don't know (*skip to question 5.13*)
  - e. Response Value: It doesn't say (*skip to question 5.13*)
- 5.12. Question: Select the secondary dataset access conditions that the consent applies [select one or more]
- a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]
- 5.13. Question: Does the consent permit secondary dataset use? [select one]

- a. Response Value: Yes (*skip to question 5.16*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 5.16*)
  - d. Response Value: I don't know (*skip to question 5.16*)
  - e. Response Value: It doesn't say (*skip to question 5.16*)
- 5.14. Question: Select the secondary dataset use conditions that the consent applies [select one or more]
- a. Response Value: This dataset may only be used for an approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic (*skip to question 5.16*)
  - c. Response: [type a value]
- 5.15. Question: Enter the approved purpose
- a. Response: [type a value]
- 5.16. Question: Select or enter the prohibitions [select one or more]
- a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed for secondary use
  - e. Response Value: The dataset may not be used for secondary purposes
  - f. Response Value: The dataset may not be used for commercial purposes
  - g. Response Value: The dataset may not be used for any purposes beyond explicit permissions
  - h. Response Value: The dataset may not be sold
  - i. Response: [type a value]

## Section 6: Privacy Board

- 6.1. Question: Is this dataset governed by a Privacy Board? [select one]
- a. Response Value: Yes
  - b. Response Value: No (*skip to question 7.1*)
  - c. Response Value: I don't know (*skip to question 7.1*)
- 6.2. Question: Does the Privacy Board policy permit dataset linkage? [select one]
- a. Response Value: Yes (*skip to question 6.6*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 6.6*)
  - d. Response Value: I don't know (*skip to question 6.6*)
  - e. Response Value: It doesn't say (*skip to question 6.6*)
- 6.3. Question: Select or enter the dataset linkage conditions that the Privacy Board applies [select one or more]



- a. Response Value: The dataset may only be linked with the approval of the IRB of record (*skip to question 6.6*)
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites (*skip to question 6.6*)
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value] (*skip to question 6.6*)
- 6.4. Question: Select or enter the linkage method [select one]
- a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 6.5. Question: Enter the type of research or use
- a. Response: [type a value]
- 6.6. Question: Does the Privacy Board policy permit dataset sharing? [select one]
- a. Response Value: Yes (*skip to question 6.10*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 6.10*)
  - d. Response Value: I don't know (*skip to question 6.10*)
  - e. Response Value: It doesn't say (*skip to question 6.10*)
- 6.7. Question: Select or enter the dataset sharing conditions that the Privacy Board applies [select one or more]
- a. Response Value: The dataset may only be shared as a de-identified dataset (*skip to question 6.10*)
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method (*skip to question 6.10*)
  - c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset (*skip to question 6.10*)
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value] (*skip to question 6.10*)
- 6.8. Question: Describe the review body needed for approval for sharing
- a. Response: [type a value]
- 6.9. Question: Describe the data release process
- a. Response: [type a value]
- 6.10. Question: Does the Privacy Board policy permit secondary dataset access? [select one]
- a. Response Value: Yes (*skip to question 6.12*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 6.12*)
  - d. Response Value: I don't know (*skip to question 6.12*)

- e. Response Value: It doesn't say (*skip to question 6.12*)
- 6.11. Question: Select or enter the secondary dataset access conditions that the Privacy Board applies [select one or more]
  - a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]
- 6.12. Question: Does the Privacy Board policy permit secondary dataset use? [select one]
  - a. Response Value: Yes (*skip to question 6.15*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 6.15*)
  - d. Response Value: I don't know (*skip to question 6.15*)
  - e. Response Value: It doesn't say (*skip to question 6.15*)
- 6.13. Question: Select or enter the secondary dataset use conditions that the Privacy Board applies [select one or more]
  - a. Response Value: This dataset may only be used for the approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic (*skip to question 6.15*)
  - c. Response: [type a value] (*skip to question 6.15*)
- 6.14. Question: Enter the approved purpose
  - a. Response: [type a value]
- 6.15. Question: Select or enter the prohibitions [select one or more]
  - a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed for secondary purposes
  - e. Response Value: The dataset may not be used for secondary purposes
  - f. Response Value: The dataset may not be used for commercial purposes
  - g. Response Value: The dataset may not be used for any purposes beyond explicit permissions
  - h. Response Value: The dataset may not be sold
  - i. Response: [type a value]

## Section 7: Data Use Agreement

- 7.1. Question: Is a DUA required for dataset linkage, sharing, and secondary access and use? [select one]
  - a. Response Value: Yes
  - b. Response Value: No (*skip to question 8.1*)
  - c. Response Value: I don't know (*skip to question 8.1*)
- 7.2. Question: Enter the name of the DUA

- a. Response: [type a value]
- 7.3. Question: Select or enter the organization providing the dataset [select one]
  - a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data repository
  - d. Response Value: Government organization
  - e. Response: [type a value]
- 7.4. Question: Select or enter the data receiving organization [select one]
  - a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data requester
  - d. Response Value: Government organization
  - e. Response Value: Data repository
  - f. Response: [type a value]
- 7.5. Question: Does the DUA permit dataset linkage? [select one]
  - a. Response Value: Yes (*skip to question 7.9*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 7.9*)
  - d. Response Value: I don't know (*skip to question 7.9*)
  - e. Response Value: It doesn't say (*skip to question 7.9*)
- 7.6. Question: Select or enter the dataset linkage conditions that the DUA applies [select one or more]
  - a. Response Value: The dataset may only be linked with the approval of the IRB of record (*skip to question 7.9*)
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites (*skip to question 7.9*)
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value] (*skip to question 7.9*)
- 7.7. Question: Enter the specific types of research or use
  - a. Response: [type a value]
- 7.8. Question: Select or enter the linkage method [select one]
  - a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 7.9. Question: Does the DUA permit dataset sharing? [select one]
  - a. Response Value: Yes (*skip to question 7.13*)
  - b. Response Value: Yes, with conditions

- c. Response Value: No (*skip to question 7.13*)
  - d. Response Value: I don't know (*skip to question 7.13*)
  - e. Response Value: It doesn't say (*skip to question 7.13*)
- 7.10. Question: Select or enter the dataset sharing conditions that the DUA applies [select one or more]
- a. Response Value: The dataset may only be shared as a de-identified dataset (*skip to question 7.13*)
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method (*skip to question 7.13*)
  - c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset (*skip to question 7.13*)
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value] (*skip to question 7.13*)
- 7.11. Question: Enter the name of the review body needed for approval for sharing
- a. Response: [type a value]
- 7.12. Question: Describe the data release process
- a. Response: [type a value]
- 7.13. Question: Does the DUA permit secondary dataset access? [select one]
- a. Response Value: Yes (*skip to question 7.15*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 7.15*)
  - d. Response Value: I don't know (*skip to question 7.15*)
  - e. Response Value: It doesn't say (*skip to question 7.15*)
- 7.14. Question: Select or enter the secondary dataset access conditions that the DUA applies [select one or more]
- a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]
- 7.15. Question: Does the DUA permit secondary dataset use? [select one]
- a. Response Value: Yes (*skip to question 7.18*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 7.18*)
  - d. Response Value: I don't know (*skip to question 7.18*)
  - e. Response Value: It doesn't say (*skip to question 7.18*)
- 7.16. Question: Select or enter the secondary dataset use conditions that the DUA applies [select one or more]
- a. Response Value: This dataset may only be used for the approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic (*skip to question 86*)

- c. Response: [type a value]
- 7.17. Question: Enter the approved purpose
  - a. Response: [type a value]
- 7.18. Question: Select or enter the prohibitions [select one or more]
  - a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed for secondary purposes
  - e. Response Value: The dataset may not be used for secondary purposes
  - f. Response Value: The dataset may not be used for commercial purposes
  - g. Response Value: The dataset may not be used for any purpose beyond explicit permissions
  - h. Response Value: The dataset may not be sold
  - i. Response: [type a value]

## Section 8: Data Submission Agreement

- 8.1. Question: Is the dataset governed by a data submission agreement or institutional certification? [select one]
  - a. Response Value: Yes
  - b. Response Value: No (*skip to question 9.1*)
  - c. Response Value: I don't know (*skip to question 9.1*)
  - d. Response Value: Not yet, but will be in the future (*skip to question 9.1*)
- 8.2. Question: Enter the name of the data submission agreement or institutional certification
  - a. Response: [type a value]
- 8.3. Question: Select the most accurate description of this policy [select one]
  - a. Response Value: Data submission agreement (*skip to question 8.7*)
  - b. Response Value: NIH Institutional Certification
  - c. Response Value: Other (*skip to question 8.6*)
  - d. Response: [type a value] (*skip to question 8.7*)
- 8.4. Question: Select the research data use limitation [select one]
  - a. Response Value: General Research Use (GRU)
  - b. Response Value: Health/Medical/Biomedical (HMB)
  - c. Response Value: Disease-specific (DS)
- 8.5. Question: Select any modifiers [select one or more]
  - a. Response Value: IRB approval required (*skip to question 8.7*)
  - b. Response Value: Publication required (*skip to question 8.7*)
  - c. Response Value: Collaboration required (*skip to question 8.7*)
  - d. Response Value: Not-for-profit use only (*skip to question 8.7*)

- e. Response Value: Methods (*skip to question 8.7*)
- f. Response Value: Genetic studies only (*skip to question 8.7*)
- 8.6. Question: Is this an agreement or certification? [select one]
  - a. Response Value: Institutional Certification
  - b. Response Value: Agreement
- 8.7. Question: Who is the assigning party? [select one]
  - a. Response Value: Certification organization
  - b. Response Value: Data coordinating center
  - c. Response Value: Data provider
  - d. Response Value: Data repository
  - e. Response Value: Government organization
  - f. Response Value: Principal investigator
  - g. Response: [type a value]
- 8.8. Question: Who is the assigned party? [select one]
  - a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data repository
  - d. Response Value: Government organization
  - e. Response Value: Principal investigator
- 8.9. Question: Does the data submission agreement or institutional certification permit dataset linkage? [select one]
  - a. Response Value: Yes (*skip to question 8.13*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 8.13*)
  - d. Response Value: I don't know (*skip to question 8.13*)
  - e. Response Value: It doesn't say (*skip to question 8.13*)
- 8.10. Question: Select the data linkage conditions that the data submission agreement or institutional certification applies [select one]
  - a. Response Value: The dataset may only be linked with the approval of the IRB of record (*skip to question 8.13*)
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites (*skip to question 8.13*)
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value] (*skip to question 8.13*)
- 8.11. Question: Enter the type of research or use
  - a. Response: [type a value]

- 8.12. Question: Select or enter the linkage method [select one]
- a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 8.13. Question: Does the data submission agreement or institutional certification permit dataset sharing? [select one]
- a. Response Value: Yes (*skip to question 8.17*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 8.17*)
  - d. Response Value: I don't know (*skip to question 8.17*)
  - e. Response Value: It doesn't say (*skip to question 8.17*)
- 8.14. Question: Select the dataset sharing conditions that the data submission agreement or institutional certification applies [select one]
- a. Response Value: The dataset may only be shared as a de-identified dataset (*skip to question 8.17*)
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method (*skip to question 8.17*)
  - c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset (*skip to question 8.17*)
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value] (*skip to question 8.17*)
- 8.15. Question: Enter the name of the review body
- a. Response: [type a value]
- 8.16. Question: Describe the data release process
- a. Response: [type a value]
- 8.17. Question: Does the data submission agreement or institutional certification permit secondary dataset access? [select one]
- a. Response Value: Yes (*skip to question 8.19*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 8.19*)
  - d. Response Value: I don't know (*skip to question 8.19*)
  - e. Response Value: It doesn't say (*skip to question 8.19*)
- 8.18. Question: Select the secondary dataset access conditions that the data submission agreement or institutional certification applies [select one]
- a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]

- 8.19. Question: Does the data submission agreement or institutional certification permit secondary dataset use? [select one]
- a. Response Value: Yes (*skip to question 8.22*)
  - b. Response Value: Yes, with conditions
  - c. Response Value: No (*skip to question 8.22*)
  - d. Response Value: I don't know (*skip to question 8.22*)
  - e. Response Value: It doesn't say (*skip to question 8.22*)
- 8.20. Question: Select the secondary dataset use conditions that the data submission agreement or institutional certification applies [select one]
- a. Response Value: This dataset may only be used for an approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic (*skip to question 8.22*)
  - c. Response: [type a value] (*skip to question 8.22*)
- 8.21. Question: Enter the approved purpose
- a. Response: [type a value]
- 8.22. Question: Select or enter the prohibitions [select one or more]
- a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed for secondary purposes
  - e. Response Value: The dataset may not be used for secondary purposes
  - f. Response Value: The dataset may not be used for commercial purposes
  - g. Response Value: The dataset may not be used for any purposes beyond explicit permissions
  - h. Response Value: The dataset may not be sold
  - i. Response: [type a value]

## Section 9: Other Governance Policies

- 9.1. Are there other agreements, certifications, contracts, determinations, policies, or processes that have rules about dataset linkage, sharing, or secondary access and use? [select one]
- a. Response Value: Yes
  - b. Response Value: No (*skip to question 10.1*)
  - c. Response Value: I don't know (*skip to question 10.1*)
- 9.2. Question: Enter the name of the policy
- a. Response: [type a value]
- 9.3. Question: Select the type of document or source for governance information [select one]
- a. Response Value: Agreement
  - b. Response Value: Certification
  - c. Response Value: Contract (



- d. Response Value: Determination
  - e. Response Value: Policy
  - f. Response Value: Process
  - g. Response: [type a value]
- 9.4. Question: Select or enter the assignee party [select one]
- a. Response Value: Coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data requester
  - d. Response Value: Principal investigator
  - e. Response Value: Repository
  - f. Response: [type a value]
- 9.5. Question: Select or enter the assigning party [select one]
- a. Response Value: Coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Government organization
  - d. Response Value: Principal investigator
  - e. Response Value: Repository
  - f. Response: [type a value]
- 9.6. Question: Select or enter the assigner [select one]
- a. Response Value: Certification organization
  - b. Response Value: Government organization
  - c. Response Value: Data provider
  - d. Response Value: Data coordinating center
  - e. Response Value: Principal investigator
  - f. Response: [type a value]
- 9.7. Question: Select or enter the assignee [select one]
- a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data repository
  - d. Response Value: Government organization
  - e. Response Value: Principal investigator
  - f. Response: [type a value]
- 9.8. Question: Select or enter the contracted party [select one]
- a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data requester
  - d. Response Value: Data repository

- e. Response Value: Principal investigator
  - f. Response: [type a value]
- 9.9. Question: Select or enter the contracting party [select one]
- a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data repository
  - d. Response Value: Government organization
  - e. Response Value: Principal investigator
  - f. Response: [type a value]
- 9.10. Question: Select or enter the party that is receiving this determination [select one]
- a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data requester
  - d. Response Value: Data repository
  - e. Response Value: Principal investigator
  - f. Response: [type a value]
- 9.11. Question: Select or enter the party that is issuing this determination [select one]
- a. Response Value: Data provider
  - b. Response Value: Government organization
  - c. Response Value: IRB
  - d. Response Value: Privacy board
  - e. Response Value: Data repository
  - f. Response Value: Review committee
  - g. Response Value: Data coordinating center
  - h. Response: [type a value]
- 9.12. Question: Select or enter the party that is subject to this policy [select one]
- a. Response Value: Coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data requester
  - d. Response Value: Government organization
  - e. Response Value: Principal investigator
  - f. Response Value: Repository
  - g. Response Value: Not applicable
  - h. Response: [type a value]
- 9.13. Question: Select or enter the party that is defining or enforcing the policy [select one]
- a. Response Value: Coordinating center
  - b. Response Value: Data provider

- c. Response Value: Government organization
  - d. Response Value: Repository
  - e. Response Value: Review committee
  - f. Response: [type a value]
- 9.14. Question: Select or enter the party that carries out this process [select one]
- a. Response Value: Data coordinating center
  - b. Response Value: Data provider
  - c. Response Value: Data repository
  - d. Response Value: Government organization
  - e. Response Value: Principal investigator
  - f. Response: [type a value]
- 9.15. Question: Select or enter the party that carries out this process [select one]
- a. Response Value: Data coordinating center
  - b. Response Value: Data provider
- 9.16. Response Value: Data requester
- a. Response Value: Data repository
  - b. Response Value: Principal investigator
  - c. Response: [type a value]
- 9.17. Question: Does this policy permit dataset linkage? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 9.18. Question: Select the data linkage conditions that this policy applies [select one or more]
- a. Response Value: The dataset may only be linked with the approval of the IRB of record
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value]
- 9.19. Question: Select or enter the linkage method [select one]
- a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 9.20. Question: Enter the specific types of research or use
- a. Response: [type a value]
- 9.21. Question: Does this policy permit dataset sharing? [select one]

- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 9.22. Question: Select the dataset sharing conditions that this policy applies [select one or more]
- a. Response Value: The dataset may only be shared as a de-identified dataset
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method
  - c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value]
- 9.23. Question: Describe the review body needed for approval for sharing
- a. Response: [type a value]
- 9.24. Question: Describe the data release process
- a. Response: [type a value]
- 9.25. Question: Does this policy permit secondary dataset access? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 9.26. Question: Select the secondary dataset access conditions that this policy applies [select one or more]
- a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]
- 9.27. Question: Does this policy permit secondary dataset use? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 9.28. Question: Select the secondary dataset use conditions that this policy applies [select one or more]
- a. Response Value: This dataset may only be used for the approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic

- c. Response: [type a value]
- 9.29. Question: Enter the approved use
  - a. Response: [type a value]
- 9.30. Question: Select or enter the prohibitions [select one or more]
  - a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed for secondary purposes
  - e. Response Value: The dataset may not be used for secondary purposes
  - f. Response Value: The dataset may not be used for commercial purposes
  - g. Response Value: The dataset may not be used for any purposes beyond explicit permissions
  - h. Response Value: The dataset may not be sold
  - i. Response: [type a value]

## Section 10: Laws

- 10.1. Question: Do local, state, or federal laws apply to this dataset? [select one]
  - a. Response Value: Yes
  - b. Response Value: No
  - c. Response Value: I don't know
- 10.2. Question: Select the applicable federal laws [select one]
  - a. Response Value: CIPSEA: Confidential Information Protection and Statistical Efficiency
  - b. Response Value: FERPA: Family Educational Rights and Privacy Act
  - c. Response Value: HIPAA Privacy Rule
  - d. Response Value: The Common Rule: 45 CFR 46 Part A
  - e. Response Value: The Federal Privacy Act (of 1974)
  - f. Response Value: The Public Health Services Act
- 10.3. Question: Select or enter the CIPSEA rules that apply to the dataset [select one or more]
  - a. Response Value: Prohibits participant re-identification
  - b. Response Value: Permits data sharing with approved researchers who are designated agents
  - c. Response Value: Guarantees confidentiality of participants and contributing organizations
  - d. Response Value: Permits secondary data use for research
  - e. Response Value: Penalizes confidentiality violations
  - f. Response Value: Supersedes the Freedom of Information Act (FOIA) such that data collected under CIPSEA are not subject to FOIA
  - g. Response: [type a value]
- 10.4. Question: Select or enter the FERPA rules that apply to the dataset [select one or more]
  - a. Response Value: Permits sharing identified data for approved purposes [excludes research]

- b. Response Value: Permits sharing of de-identified data
  - c. Response: [type a value]
- 10.5. Question: Select or enter the HIPAA rules that apply to the dataset [select one or more]
- a. Response Value: Permits sharing of a deidentified dataset for research purposes
  - b. Response Value: Permits sharing of limited dataset for research without participant consent by entering into a data use agreement with a recipient organization
  - c. Response Value: Defines a limited dataset as a dataset where 16 categories of direct identifiers have been removed
  - d. Response Value: Defines Safe Harbor and Expert Determination as the allowed methods for deidentification
  - e. Response Value: Permits use of limited dataset for research without participant consent by entering into a data use agreement with a recipient
  - f. Response Value: Permits data use for research with either 1) individual authorization (consent) or 2) IRB or a Privacy Board approval of waiver of consent requirement
  - g. Response Value: Data de-identified according to HIPAA standards are no longer subject to HIPAA and can be used for research without participant consent
  - h. Response: [type a value]
- 10.6. Question: Select the HIPAA designated type of dataset [select one]
- a. Response Value: Deidentified dataset
  - b. Response Value: Limited dataset
  - c. Response Value: Fully identified dataset
  - d. Response Value: I don't know
- 10.7. Question: Select or enter the Common Rule rules that apply to the dataset [select one or more]
- a. Response Value: Permits sharing of de-identified data
  - b. Response Value: Permits human subjects research use of data with PII with either 1) participant consent or 2) IRB or a Privacy Board approval of consent waiver
  - c. Response: [type a value]
- 10.8. Question: Select or enter the Privacy Act of 1974 rules that apply to the dataset [select one or more]
- a. Response Value: Permits collection of data that includes PII by federal agencies that have published a system of records notice (or "SORN") in the Federal Register
  - b. Response Value: Permits sharing of data with PII if federal agencies take the data into their SORN
  - c. Response Value: Permits federal agency use of the data with PII if the federal agencies take the data into their SORN
  - d. Response: [type a value]
- 10.9. Question: Select or enter the Public Health Services Act rules that apply to the dataset [select one or more]
- a. Response Value: Permits data collection

- b. Response Value: Permits data sharing with approved researchers who are designated agents
  - c. Response Value: Permits data use for purposes described in participant consent
  - d. Response: [type a value]
- 10.10. Question: Do other laws apply to this dataset? [select one]
- a. Response Value: Yes
  - b. Response Value: No
  - c. Response Value: I don't know
- 10.11. Question: What is the name of the law?
- a. Response: [type a value]
- 10.12. Question: Does the law permit dataset linkage? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 10.13. Question: Select the dataset linkage conditions that this law applies [select one or more]
- a. Response Value: The dataset may only be linked with the approval of the IRB of record
  - b. Response Value: The dataset may only be linked with the approval of data contributing sites
  - c. Response Value: The dataset may only be linked using a specific linkage method
  - d. Response Value: The dataset may only be linked for specific types of research or use
  - e. Response: [type a value]
- 10.14. Question: Select or enter the linkage method [select one]
- a. Response Value: PPRL
  - b. Response Value: Clear text
  - c. Response: [type a value]
- 10.15. Question: Describe the specific types of research or use
- a. Response: [type a value]
- 10.16. Question: Does the law permit dataset sharing? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 10.17. Question: Select the dataset sharing conditions that this law applies [select one or more]
- a. Response Value: The dataset may only be shared as a de-identified dataset
  - b. Response Value: The dataset may only be shared following the Safe Harbor de-identification method

- c. Response Value: The dataset may only be shared if approved by a review body
  - d. Response Value: The dataset may only be shared as a limited dataset
  - e. Response Value: The dataset may only be shared within a defined data release process
  - f. Response: [type a value]
- 10.18. Question: Describe the data release process
- a. Response: [type a value]
- 10.19. Question: Enter the name of the review body
- a. Response: [type a value]
- 10.20. Question: Does the law permit secondary dataset access? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 10.21. Question: Select the secondary dataset access conditions that this law applies [select one or more]
- a. Response Value: The dataset may only be accessed in a data enclave
  - b. Response Value: The dataset may only be accessed in a controlled environment
  - c. Response: [type a value]
- 10.22. Question: Does the law permit secondary dataset use? [select one]
- a. Response Value: Yes
  - b. Response Value: Yes, with conditions
  - c. Response Value: No
  - d. Response Value: I don't know
  - e. Response Value: It doesn't say
- 10.23. Question: Select the secondary dataset use conditions that this law applies [select one or more]
- a. Response Value: This dataset may only be used for the approved purpose
  - b. Response Value: This dataset may only be used for research on a specific topic
  - c. Response: [type a value]
- 10.24. Question: Enter the approved purpose
- a. Response: [type a value]
- 10.25. Question: Select or enter the prohibitions [select one or more]
- a. Response Value: Individuals in the dataset may not be re-identified
  - b. Response Value: The dataset may not be linked
  - c. Response Value: The dataset may not be shared
  - d. Response Value: The dataset may not be accessed for secondary purposes
  - e. Response Value: The dataset may not be used for secondary purposes



- f. Response Value: The dataset may not be used for commercial purposes
- g. Response Value: The dataset may not be used for any purposes beyond explicit permissions
- h. Response Value: The dataset may not be sold
- i. Response: [type a value]

## **Section 11: Other Governance Information**

11.1. Question: Is there any other governance information that applies to this dataset and could not be entered above? [select one]

- a. Response Value: Yes
- b. Response Value: No

11.2. Question: Enter the governance information related to dataset linkage, sharing, and secondary access and use

- a. Response: [type a value]