**Secondary Use of Data Protocol Template**

This document serves as a template for both prospective and retrospective review of data (often referred to in biomedical research as “chart reviews” when reviewing medical records only and referred to as “secondary research” in regulations) when the data has been or will be generated for non-research purposes or a prior research purpose. This template **may not be used** when secondary use of data will be combined with intervention or interaction with participants for research purposes. In those cases, use the Social Behavioral or the Biomedical protocol template.

This protocol template is to be used as a guide and is the preferred template for secondary research. You may add additional information as needed. Complete all sections of the template.

* Information provided in this template is intended to be a prompt, if something does not apply to your study, mark it not applicable.
* Use good version control of your document as you make edits. The version data of the protocol should be changed each time revisions are made.
* Keep an electronic copy of your final draft. You will need to modify this copy when making future changes.
* As of January 2019, the Common Rule (the regulations governing human subject protections) provides the following criteria for approval of Secondary Research for which consent it not required:
  + Secondary research uses of identifiable private information / data (which includes information about biospecimens may be eligible for an exempt determination if the identifiable private information / data is
    - (i) publicly available, *OR*
    - (ii) is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects, *OR*
    - (iii) involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research (i.e. the data is Protected Health Information (PHI) and otherwise meets the technical, administrative and physical safeguards in the HIPAA standards [45 CFR parts 160 and 164])
  + Exempt Category 4 at 45CFR46.104(d)(4) expressly states consent is not required if the study involves secondary research use of identifiable private information or identifiable biospecimens and meets one of the above the criteria for exemption.
  + Note a Waiver of HIPAA authorization may be required for exempt research. Please be sure to complete all of Section 9 of this template to ensure the reviewer has the necessary information for an appropriate determination.
  + Secondary research that does not meet criteria for exemption will be considered for approval under expedited criteria. In this case, additional revisions to the protocol may be needed to account for the consent requirement under expedited criteria (the study will either require that consent be obtained or will have to meet criteria for a waiver of consent). In the event this is necessary additional instruction will be provided.

If you have questions about this form, please contact the Georgetown University IRB office at [IRBoard@georgetown.edu](mailto:IRBoard@georgetown.edu) or the MedStar Health Research Institute IRB office at [ORI.helpdesk@medstar.net](mailto:ORI.helpdesk@medstar.net).

**I. BASIC INFORMATION**

|  |  |
| --- | --- |
| **1. Title of Study**  Include the full protocol title | |
|  | |
| **2. Principal Investigator** | |
| Name: | |
| Institutional Affiliation: | |
| Department: | |
| Phone Number: | |
| Email: | |
| **3.** **Location(s) of Research**  Describe the sites/locations\* for the research and any site-specific regulations or customs affecting the research at those sites.  \*Sites: institution or place where the research is conducted. Location: specific state or country.  In addition, describe any local scientific/ethical reviews completed for those sites and attach the ethics review in the SmartForm. Information on international laws and regulations governing human research is available at: <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html> | |
|  | |
| **4. Anticipated dates of research**  Includes contact with human subjects and analysis of identifiable data. Applications to the IRB must be submitted **prior** to any interactions with human subjects. | |
| Start Date: | End Date: |

**II. STUDY INFORMATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1. Version Number and Date**  Keep a version of this document in a Word format. Version control is important when protocols are being created or revised; it helps to track changes and identify when key decisions were made along the way. Version control allows the study team and regulatory groups to identify which version of a protocol was approved and applicable at a particular time. Versions can be documented by date and/or chronologic numbering each time you submit a modified protocol document. If you have to submit revisions to the protocol, revise this document and note a new version below. | | | | |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
| Initial V1 |  | N/A | N/A |
| V2 |  |  | Yes No |
| V3 |  |  | Yes No |
| V4 |  |  | Yes No |

|  |
| --- |
| **2. Study Specific Abbreviations and Definitions** |
|  |
| **3. GHUCCTS (Georgetown-Howard Universities Center for Clinical and Translational Science)** |

|  |  |
| --- | --- |
| Is this study a GHUCCTS Study? | Yes No |
| Is the project being sponsored or funded by GHUCCTS? | Yes No |
| Does the project utilize GHUCCTS services or facilities (e.g., is the study conducted on the Clinical Research Unit (CRU), is the study supported by a GHUCCTS biostatistician)? | Yes No |

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| --- |
| **4. Are all study team members listed on the application associated with the Medstar Health or Georgetown University workforce?** |
| **Yes  No**  If no, provide a detailed scope of work for external investigators. This should explain, at a minimum, what data will be accessible to external investigators and how access will be provided. Please note if sharing MedStar / Georgetown data with external collaborators a data agreement will likely be needed. It should also be noted that in most cases the GU / MH IRBs will not make exempt determinations for external investigators. It is expected each institution/organization will obtain an independent determination. |
| **4. Ownership and location of secondary data:**  Include the legal name of the entity that possesses the proposed study data and physical location of facilities/covered entities from which data will be collected.   * This section would be applicable if you are a MedStar or Georgetown University Employee completing this work as a student in program outside of Georgetown University and have submitted your protocol to your educational program’s IRB. |
|  |
| **5. IRB Review History:** Has this or will this protocol be reviewed by another IRB? |
| **Yes  No**  If yes please provide IRB study identification number, the name of the reviewing Institution and IRB committee (if applicable), the date of review, the outcome of the review and IRB contact information. |
| **6. Study Objectives:**  What is the question to be answered? Describe the purpose, specific aims or objectives and hypotheses as concise as possible. |
|  |
| **7. Background:**  Describe relevant prior experience. Consider 3 paragraphs:  1. Why is this important.  2. What does current literature say about the topic?  3. What gaps in current knowledge will this study fill?  Describe any relevant preliminary data with citations |
|  |
| **8. Data review study type(s),** choose all that apply: |
| **Retrospective Data Collection/Analysis** (Retrospective means the data is already in existence when the project is submitted to the IRB for initial review)  **Prospective Data Collection/Analysis** (Prospective means that not all data is in existence when the project is submitted to the IRB for initial review. If this is checked, consider if consent is needed or if there is a request for a waiver) |
| **Provide the date range for records that will be reviewed:** |
| Click to enter a date to Click to enter a date |

**III. HUMAN SUBJECTS**

|  |  |
| --- | --- |
| **1.** **Selection of** **Subjects** | |
| 1. **Local sample size (number of individuals for whom you will collect data locally):** Estimate the number of individuals about whom you need to collect data to conduct the study. If conducting a medical records review remember to consider you may review records for some individuals that do not meet inclusion criteria. These individuals still count towards the sample size because you are accessed their records for research purposes. The sample size will be the total number you are approved by the IRB to “enroll” (in the case of medical records review the total number of patient records you are approved to access). Therefore, it is suggested that you slightly overestimate the sample size to account for some screen failures. If you find that additional records must be reviewed to collect sufficient data you will need to submit a modification to increase the sample size before accessing additional records. | |
|  | |
| 1. **Study wide sample size (number of individuals for whom data will be collected at all sites:** If multisite, include total number of subjects to be enrolled (about whom data will be collected) across all sites. | |
|  | |
| 1. **Age Range of participants:** | |
|  | |
| **3.** **Criteria for inclusion or exclusion** | |
| 1. What criteria will be used to include individuals’ data in the study?   This is your search criteria used to pull the records from the data source. | |
|  | |
| 1. What criteria will be used to exclude individuals’ data from the study?   If you will exclude certain populations include scientific justification for that exclusion. For example, if excluding men or women a scientific justification may be that the disease being studied is not found in men/women. | |
|  | |
| **III. STUDY METHODS:** | |
| Secondary use of data can fall under several IRB review levels, depending on what is being accessed by the study team and what is being recorded. In your submission be specific about what you will collect and record in terms of private identifying information. Please select the most appropriate option from each section below. Please note: If you intend to contact participants as a part of this research, you will be required to use a different protocol template (see the IRB website for options or contact the IRB office for guidance). | |
| **1.** **Level of identifiers needed for secondary research:** | |
| I will be recording data from the source in such a manner that the identity of the human subjects ***cannot*** readily be ascertained directly or through identifiers linked to the subjects, I will not contact the subjects, and I will not re-identify subjects.  I will be recording data from the source in such a manner that the identity of the human subjects ***could*** readily be ascertained directly or through identifiers linked to the subjects and the study does not involve Protected Health Information (PHI). ***I will not contact the subjects***.  I will be recording data from the source in such a manner that the identity of the human subjects ***could*** readily be ascertained directly or through identifiers linked to the subjects, however the data involves Protected Health Information and the protocol otherwise conforms to the technical administrative and physical safeguards in HIPAA regulations. ***I will not contact the subjects.*** | |
| **2. Identifiers recorded for this study (if applicable):**  If any of the items below are checked, you are also collecting health information and if you are a member of a covered entity, you must complete section 9 **Request for a Waiver of HIPAA Authorization.** | |
| |  |  |  |  | | --- | --- | --- | --- | |  | Name/Initials |  | Social Security Number | |  | Address (all geographic subdivisions smaller than state, including street address, precinct, city, county, and zip code) |  | All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89) | |  | City |  | Certificate/license Number | |  | Vehicle identifiers and serial numbers, including license plate numbers |  | Unique ID Numbers: Student ID, Health Plan Beneficiary Number, Account Number, etc. | | |  | Telephone Number |  | Device identifiers and serial numbers | |  | Fax Number |  | Web Universal Resource Locators (URL) | |  | E-Mail Address |  | Internet Protocol (IP) Address Numbers | |  | Medical Record Number |  | Biometric Identifiers (including finger or voice prints) | |  | Photographic image - Photographic images are not limited to images of the face. |  | Any other characteristic that could uniquely identify the individual, including a characteristic, number, or code | | |
| **3.** **Source (location) of records to be reviewed:**  Be sure to include all sources of records to be reviewed (e.g., databases used, information from previous research study (indicate IRB #), medical records) | |
|  | |
| **4. Describe how records to be reviewed will be identified:**  Describe how will you obtain the list of names/medical record numbers of potential participant and list the search criteria. | |
|  | |
| **5. Describe who will identify records to be reviewed:**  Are you using a third party to pull the records for you? If so, specify. | |
|  | |
| **6. Describe the process for recording data from those eligible:**  Describe the process by which you record data and include your study collection data sheet (often an excel or REDCap file showing the fields of data that will be collected). If the data will be provided to you by someone other than the study team member (such as an honest broker), describe that process. | |
|  | |
| **7. List all data elements to be collected or upload a form to the IRB application that includes a complete list of all data elements that will be collected.** | |
|  | |
| **8.** **Data confidentiality and Security**  Please review and complete Georgetown University Information Services (UIS) guidance and requirements found in [Appendix A](#_APPENDIX_A). Appendix A is a useful reference in completing this portion of the application. | |
| 1. Describe how data (both paper and electronic) will be stored to safe-guard confidentiality (e.g., in a locked cabinet, password-protected computer) | |
| 1. Where will data be stored? Describe the steps taken to secure the data from the initial point of data collection to the ultimate storage location. Include where and how data will be collected and stored, for how long, who will be responsible for data security, and who will have access. Will the data be moved in the course of the research? Who (what role) is responsible for managing data integrity? | |
| 1. If the data will be stored in a repository with the intent to share data with other researchers and/or use the data for future research, describe where and for how long the data will be stored, who can obtain the data, and how data release will be requested and provided. | |
| 1. Which of the following describes the nature of the data (See [Appendix B](#_APPENDIX_B) for definitions): | |
| The data will be associated with Personal Identifiers  The data will be deidentified but coded (a code links it to identifiers)  The data will be completely deidentified and not linked to identifiers  The data will be collected anonymously |
| 1. Describe the process for de-identification: Describe in detail the methodology to de-identify the data or mark as N/A if not pertinent to your project. | |
| 1. Describe the process for re-identification: State if there is any method in which subjects could possibly be re-identified. Include any safety measures in place to prevent re-identification. If you do not plan to re-identify data, please check box below to attest you and your study team will make no attempts to re-identify study data. | |
| 1. Study team will make not attempt to re-identify study subjects. | |

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| **IV. RISKS AND BENEFITS:** |

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| **1. Potential Risks:**  A risk is a potential harm. Risks can be physical, psychological, sociological, economic, or legal, and include pain, stress, invasion of privacy, embarrassment, or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible, for example by robust data security measures. Describe any potential risks associated with participation in this study. Also consider if the data to be collected or the subject of the study may be considered “sensitive” in nature. |
|  | |
| Is participation in the study or the data to be collected potentially damage to financial standing, employability, or educational advancement or reputation, or relationships with other people (e.g., family relationships, employer/employee relationships).  **Yes  No** | |
| Could participation in the study lead to civil or criminal liability for participants?  **Yes  No** | |
| **2.** Potential **Benefits:**   * Describe the potential benefits to subjects or to others that may be reasonably expected to result from the research. It is likely that Secondary Research will not result in direct benefit to subjects for this proposed research; however, society and investigators are likely to benefit from the knowledge gained. * Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be gained. Will the research study benefit future populations? | |
|  | |
| **V. DATA MANAGEMENT AND STATISTICAL CONSIDERATION:** | |
| 1. Rationale for proposed sample size to be analyzed (Is this a pilot study or was statistical calculation used for the sample size?): | |
|  | |
| 1. Proposed time point for data analysis (Will data be analyzed only once or at different time points?): | |
|  | |
| 1. Specify how data will be analyzed and by whom: | |
|  | |
| 1. Describe the data analysis plan, including any statistical procedures: | |
|  | |
| 1. Provide a power analysis: | |
|  | |
| 1. Describe procedures used for quality control of collected data: | |
|  | |
| 1. Describe steps taken to secure the data (i.e., training, authorized access, password protection, encryption, separation of identifiers and data) during storage, use, and transmission: | |
|  | |

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| **V. REQUEST FOR A WAIVER OF HIPAA AUTHORIZATION:** |

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| --- |
| **Will the proposed research involve the use of protected health information (PHI)?**  **Yes  No (if no, skip this section)** |
| Secondary use of data involving Protected Health Information (PHI) requires a Waiver of HIPAA Authorization forthe use or disclosure of PHI. The following elements from 45 CFR 164.512 (i) (1) (i) must be met for the IRB to waive the requirement. If a waiver of HIPAA authorization is being requested address each of the following: |
| Discuss how the use or disclosure of protected health information in the research involves no more than minimal risk to privacy of individuals, based on, at least, the presence of the following elements: |
| 1. Describe the plan to protect any identifiers from improper use and disclosure: |
|  |
| 2. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law: | |
|  | |
| 3. Provide assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be otherwise permitted (*Example:* *This study involves reviewing non-sensitive data. The only risk to this study is confidentiality risk, which is minimized through using standard HIPAA provision and data security. All MedStar HIPAA policies will be followed. Study documents are saved on password-protected drives, no identifiable data will be transferred from the covered entity and access is restricted to personnel listed on the IRB-approved study.)*: |
|  |
| Discuss how the research could not practicably be carried out without the requested waiver: |
|  |
| Discuss how the research could not practicably be conducted without access to and use of the protected health information (*Note: There may be ethical, scientific or logistical rationales**to justify the practicability standard such as  (i) the consent procedure would itself create additional threats to privacy that would otherwise not exist, by identifying an individual as having or experiencing what is being studied by virtue of their signature on a consent form identifying the condition or event or  (ii) there is a risk of inflicting significant psychological, social or other harm by contacting individuals or families or  (iii) scientific validity would be compromised if consent were required because it would introduce bias to the sample selection by limiting the review to those individual who consented to use of their data when researchers may need to understand the experience of all experienced what is under study. For example, a study assessing flu outbreaks and their relationship to vaccination rates needs to understand the health and vaccination status of all individuals in a region or*  *(iv) a logistical rationale - are these subjects still accessible, still being seen in the clinic? Are they lost to follow up? Are the numbers so large that it would not be practical or feasible to contact every possible individual?* |
|  |

**VI. COLLABORATING or MULTI-SITE STUDIES**

|  |
| --- |
| **1. Is this study a Multi-site or Collaborative study?\*** |
| YES  NO (if NO, skip the remainder of questions)  \*Collaborating Institution(s)  A Collaborating Institution is an institution engaged in portions of the outlined research project.  \*Multi-site Study  A multi-site study is a study that follows a single protocol but is conducted in more than one place, each of which is under the direction of one or more separate investigators. (Please Note: A study that utilizes one or more Research Locations at your institution would likely not be considered a multi-site or collaborative research study in this system. Please contact the IRB office for any questions about your study scenario.) |
| **2. Name of Collaborating Institution(s) and/or Site(s) for Multi-Site Studies**  List each collaborating institution or Multi-Site Study and indicate the corresponding activities conducted there with the appropriate letter(s) from the list below:   1. The entire protocol will be conducted at the site outside GU (if this is selected no other letters need to be added) 2. Obtain information by intervening or interacting with living individuals for research purposes 3. Obtaining identifiable private information about living individuals 4. Obtaining the voluntary informed consent of individuals to be subjects 5. Making decisions about subject eligibility 6. Studying, interpreting, or analyzing identifiable private information or data/specimens for research purposes 7. Studying, interpreting, or analyzing coded (linked) data or specimens for research purposes 8. Other: please specify   EXAMPLE:  Name: XZY University  Research Activities: B, E, H-the collaborator will recruit participants by review of the EMR at their site and provide to the PI at GU |
|  |

**Appendix A**

**Information Services Guidance on Data Storage and Security**

Please complete the following checklists from Georgetown University Information Systems. Definitions of Terms are included below the checklist for your reference and accurate completion.

**Indicate in the chart below what type of data is being collected, stored, transmitted, and/or shared.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Collected** | **Stored** | **Transmitted** | **Shared** |
| **Protected Health Information (PHI)** |  |  |  |  |
| **Personally Identifiable Information (PII)** |  |  |  |  |
| **Identified** |  |  |  |  |
| **Deidentified (includes no PHI or PII)** |  |  |  |  |
| **Limited Data Set (LDS)** |  |  |  |  |
| **Data from vulnerable populations\*** |  |  |  |  |

\* Pregnant Women, Neonates, Children, Prisoners, Mentally Disabled, Cognitively Impaired, Economically or Educationally Disadvantaged

**Address the following data security questions. All “NO” responses require further explanation as to why data security requirements are not being met.**

|  | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| Computer software is in place to protect against malware (GU employees can visit [Georgetown University Software Webstore](https://georgetown.onthehub.com/WebStore/Welcome.aspx) to ensure you have the appropriate software) |  |  |  |
| All operating systems and software updates and patches are applied regularly |  |  |  |
| The data collected is only the minimum data necessary to answer the research question |  |  |  |
| Codes are stored separately from the corresponding de-identified data |  |  |  |
| Encryption and password protection are in place on all portable devices used to access data |  |  |  |
| Two Factor Authentication is used for all systems accessing research data |  |  |  |
| Any external service/supplier contracts and data use agreements have been reviewed and approved by appropriate institutional offices |  |  |  |
| Physical and technical safeguards in place for electronic and paper data during collection, storage, transmission, and destruction must be in alignment with Georgetown University/Medstar policies and procedures |  |  |  |
| Email will not be used to collect, store, or transmit sensitive human subject research data or Protected Health Information (PHI) |  |  |  |
| Secured, non-public Wi-Fi will always be used with this data |  |  |  |
| Computer screens will be locked when not in use |  |  |  |
| Data will be securely destroyed at the end of the retention period [(GU policy on secure data destruction)](https://security.georgetown.edu/data-security/data_destruction/) |  |  |  |

Explain any “NO” responses here:

**Georgetown University Specific Policies**

|  | **Yes** | **No** | **N/A** |
| --- | --- | --- | --- |
| For surveys, Qualtrics and RedCap– the GU-approved survey systems for which we are licensed – will be used |  |  |  |
| GU Box will be used as the data storage repository for Research Data |  |  |  |
| Data will be shared via GU Box or another secure method such as Secure File Transfer Protocol (SFTP). Data will be encrypted during transmission |  |  |  |
| I have read and will comply with the [UIS Research Data Protections Guidelines](https://security.georgetown.edu/research_data_protection_guidelines/) |  |  |  |

Explain any “NO” responses here:

**Appendix B**

**Definitions**

* **Protected Health Information (PHI):**

Protected health information includes all individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. ‘Protected’ means the information is protected under the HIPAA Privacy Rule. Protected health information is defined in the Code of Federal Regulations and applies to health records, but not education records which are covered by other federal regulations, nor records held by a HIPAA-covered entity related to its role as an employer. In the case of an employee-patient, protected health information does not include information held on the employee by a covered entity in its role as an employer, only in its role as a healthcare provider.

PHI does not include individually identifiable health information of persons who have been deceased for more than 50 years.

Below is the list of 18 identifiers defined by federal regulations:

* + - 1. Names;
      2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
      3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
      4. Phone numbers;
      5. Fax numbers;
      6. Electronic mail addresses;
      7. Social Security numbers;
      8. Medical record numbers;
      9. Health plan beneficiary numbers;
      10. Account numbers;
      11. Certificate/license numbers;
      12. Vehicle identifiers and serial numbers, including license plate numbers;
      13. Device identifiers and serial numbers;
      14. Web Universal Resource Locators (URLs);
      15. Internet Protocol (IP) address numbers;
      16. Biometric identifiers, including finger and voice prints;
      17. Full face photographic images and any comparable images; and
      18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)
* **Personally Identifiable Information (PII):**

The term “personally identifiable information” refers to information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, etc. alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother’s maiden name, etc. (OMB, 2007)

PII can also be a combination of data from which, taken together, the identity of a person can reasonably be known. For example, if the complete birthdate is given as well as the gender, then even the school or street location would be enough to link information provided in a study about an individual to the specific individual. A study subject might disclose private information as part of the study, and/or a study test result might generate private information. In some Human Subjects Research studies, the only identifying information is the consent form or, even without a consent form, the identifying information is that co-subjects in the study observe private information about another co-subject.

PII is protected by state and local data breach laws, and includes:

* + Social Security Number
  + Place of Birth
  + Dependents
  + Bank account numbers
  + Income tax records
  + Driver’s license numbers
  + Credit card numbers
  + Passport numbers
* **Anonymous Data :**

Data that was collected without identifiers and that were never linked to an individual. Coded data are not anonymous.

* **De-identified Data :**

The term “de-identified” or “anonymized” should be used only to describe data that:

* Previously contained identifiers, which have been stripped, and no “code” linking the data back to identifiers still exists, such that the dataset cannot be “re-identified” by anyone.

Data is not “de-identified,” but “coded” and “indirectly identifiable” if:

* Researchers have “coded” the data and store the code separately from the research dataset, or the data provider has the “key” to “coded” data, even if the researchers do not, or anyone can “re-identify” the data by linking the dataset to direct identifiers.
* **Limited Data Set:**

A Limited Data Set is a set of data in which 16 categories of identifier have been removed.

The following identifiers of the study subjects, or of the study subjects’ relatives, employers, or household members, can be included in a limited data set:

* 1. All elements of dates, such as birth date, admission date, discharge date, and date of death;
  2. Town or city, state, and ZIP Code

The following identifiers of the study subjects, or of the study subjects’ relatives, employers, or household members, must be removed from a limited data set:

1. Names;
2. Addresses, other than town or city, state, and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate / license numbers;
11. Vehicle identifiers and serial numbers (including license plate numbers);
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.