**Instructions:**

This document serves as a template for both prospective and retrospective review of data (often referred to in biomedical research as “chart reviews” and referred to as “secondary research” in regulations) when the data was previously generated for a non-research or a prior research purpose.

This protocol template is to be used as a guide. You may use a different format, order, or add additional information as needed.

* Information provided in this template is intended to be a prompt, if something does not apply to your study, delete it.
* Delete all instructional text from the final copy, indicated by red font.
* Use good version control of your document as you make edits.
* Keep an electronic copy of your final draft. You will need to modify this copy when making future changes.
* The revised Common Rule, the regulations governing human subject protections, went into effect in January 2019. **Why does this matter?** It expanded the exemption categories for chart reviews to include data that does not already exist and some types of identifiable data.
  + Under the revised rule a secondary review of data may be eligible for determination of exempt status if the 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 is still required for exempt research.
  + Secondary research or chart reviews that do not meet criteria for exemption will need to be reviewed and approved under expedited review, which requires consent or authorization or a waiver of consent/authorization to be approved by the IRB

**Protocol Title:** Include full protocol title as listed in the IRB application

**Principle Investigator:** Include the principle investigator’s name as listed in the IRB application

**Location of secondary data (charts) to be reviewed:** Include the legal name and physical location of facilities/covered entities from which data will be collected.

**Are all investigators listed on the application members of the workforce of the facilities/covered entities where the data will be abstracted/reviewed?**

**Yes No** If no, explain how authority to access data will be requested and what agreements (if applicable) will be executed:

**IRB Review History:** If you have submitted this protocol for review to another IRB, provide the previous study identification number and provide details of the review including the IRB name, date of review, and IRB contact information.

* This section would be applicable if you are a student or outside investigator belonging to another institution and have submitted your protocol to your home institution.
* This section may also be relevant if you are doing secondary research on data from a previously approved study. If this applies, explain the situation.
* If not, delete this section.

1. **Study Objectives:** What is the question to be answered? Describe the purpose, specific aims or objectives and hypotheses as concise as possible.
2. **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.
3. **Chart review study type(s),** choose all that apply:

**\_\_\_\_\_ Retrospective Chart Review** (Retrospective means the data is already in existence when the project is submitted to the IRB for initial review)

**\_\_\_\_\_ Prospective Chart Review** (Prospective means that not all data is in existence when the project is submitted to the IRB for initial review)

**Provide the date range for records that will be reviewed: (Provide dates in the following format** mm/dd/yyyy to mm/dd/yyyy)

1. **Selection of subjects:** 
   1. **Local number:** Estimate the total number of records you need to collect to conduct the study. This will be the total number you are approved by the IRB to enroll. If you need more subjects, an amendment will be required. So be sure not to underestimate. This is the number of records you need to pull, not just the number of records that once reviewed would meet inclusion/exclusion criteria.
   2. **Study wide number:** If multisite, include total number of subjects to be enrolled across all sites.
   3. **Inclusion Criteria:** This is your search criteria used to pull the records from the data source.
   4. **Exclusion Criteria:** 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.
   5. **Age Range:**
2. **Study Methods:** Chart reviews 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 collect and record in terms of private identifying information.
   1. Chart review level of identifiers needed:

**\_\_\_\_\_\_** 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.***

**\_\_\_\_\_\_** 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. ***I do plan to contact subjects***.

* 1. Identifiers recorded for this study (if applicable):

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name/Initials |  | Unique ID Numbers: Student ID, Health Plan Beneficiary Number, Medical Record Number, Account Number, etc. |
|  | Address |  | Certificate/license Number |
|  | City |  | Vehicle Identifiers |
|  | County |  | Device Identifiers |
|  | Precinct |  | Web Universal Resource Locators (URL) |
|  | Zip Code |  | Internet Protocol Address Numbers |
|  | Telephone Number |  | Biometric Identifiers (including finger or voice prints) |
|  | Fax Number |  | Full Face Photographs and Comparable Images |
|  | E-Mail Address |  | Any Other Unique Identifying number, characteristic or code |
|  | Social Security Number |  | All dates (except year) that are directly related to an individual (e.g. date of birth, graduation date, admission/discharge date) |

* 1. Source (location) of records to be reviewed: Be sure to include all sources, i.e. any databases uses or information from previous research study (indicate IRB #) + medical records.
  2. Describe how the charts to be reviewed will be identified: How do you get the list of names/medical record numbers to go and access the person’s record? List search criteria
  3. Describe who will identify charts to be reviewed: Are you using a third party to pull the records for you? If so, specify.
  4. 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).
  5. Describe the process for de-identification: Describe in detail the methodology to de-identify the data or delete this section if you do not plan to de-identify the data set.
  6. 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.

1. **Data Confidentiality and Data Security**
   1. Describe how data (both paper and electronic) will be stored to safe-guard confidentiality (e.g. in a locked cabinet, password protected computer)
   2. Specify who will have access to collected patient data
   3. Clarify how long data will be stored and how it will be destroyed when no longer needed
2. **Risks and Benefits:**
   1. Risks: Describe risks, for example a confidentiality breach is a risk associated with chart review research
   2. Benefits: The subject’s whose charts are reviewed are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.
3. **Data management and Statistical Considerations**
   1. Proposed sample size (number of records to be reviewed):
   2. Proposed time period to be evaluated
   3. Specify how data will be analyzed and by whom
   4. Describe the data analysis plan, including any statistical procedures.
   5. Provide a power analysis
   6. Describe procedures used for quality control of collected data
   7. Describe steps taken to secure the data (i.e. training, authorized access, password protect, encryption, separation of identifiers and data) during storage, use and transmission.
4. **Request for a Waiver of HIPAA Authorization:** regardless of IRB review category, for a chart review study involving Protected Health Information (PHI) a Waiver of HIPAA Authorization forthe use or disclosure of PHI needs to be requested and obtained. The following elements from 45 CFR 164.512 (i) (1) (i) must be met for the IRB to waive the requirement:
   1. A waiver of HIPAA authorization is being requested the following must be addressed:
      1. 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 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.)*
      2. Discuss how the research could not practicably be carried out without the requested waiver or alteration;
      3. 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 its 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?*

**APPENDIX A: DATA COLLECTION FORM**

1. **Unique Subject Code**
2. **List all elements to be collected during the chart review or provide a data collection/case report form as an attachment**