IRB Retrospective Chart Review Protocol Outline

Notes:

- For studies involving secondary data analysis only.
- Please use this to ensure that all the applicable points are addressed in your existing protocol document or in a supplemental document.

1. Title Page:
   - Full study title
   - Name, Title(s), and Department of Principal Investigator
   - Funding Source(s)
   - Protocol version number and version date

2. Background and significance:
   - Description of problem/condition to be explored; what hypothesis is the study specifically intended to test?
   - Preliminary studies and existing literature that support or illustrate need for the study
   - What is ultimate intended purpose and audience(s) for the results of the study?

3. Study Design
   a. Sample
      - Source of records (be specific). Be sure to note if the sample includes any vulnerable populations (pregnant women, minors, or prisoners)
      - Date range (in MM/DD/YYYY-MM/DD/YYYY format) from which chart data will be reviewed
      - Inclusion criteria, including age range
      - Exclusion criteria
      - **Please <u>do not</u> include estimated number of charts to be reviewed** (to avoid unnecessary violations of HIPAA via reviewing too many charts); though estimated *minimum* number of charts may be included in the Data Analysis section below

   b. Informed Consent
      - Do you wish to request a waiver of informed consent for this research use of the record? Please address how your request meets the following criteria:
        - The research involves no more than minimal risk to the subjects.
        - The waiver or alteration will not adversely affect the rights and welfare of the subjects.
        - The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)
        - Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary).

   c. HIPAA
      - Will you be recording identifiers from charts? A list of HIPAA identifiers is attached
      - If you are recording identifiers from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, you will need to request a HIPAA waiver. Please address how your request meets the following criteria:
        - The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
          - An adequate plan to protect the identifiers from improper use and disclosure;

        - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research.
        - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity.
    - The research could not practicably be conducted without the waiver or alteration
    - The research could not practicably be conducted without access to and use of the protected health information.

d. Procedures
    - Procedures for medical record review
        - Data to be collected
        - How will data be obtained (if other than the EMR)

e. Risks to participation
    - Include breach of confidentiality
    - ***Do not state that there are no risks***

f. Benefits to future subjects or science

g. Data analysis
    - Plans for data management and statistical analysis
    - Formal sample calculations, if applicable (may include minimum number of charts needed, but avoid giving exact number to be used, to avoid HIPAA issues)

4. Confidentiality
    a. All sensitive data and data that contains HIPAA identifiers, when electronic, must be stored on a hard drive, disk, or thumb drive that is encrypted – not solely password-protected or kept in a locked office.

    b. Plan to protect privacy of subjects and confidentiality of data obtained from the medical record (e.g., photos, imaging, biomedical data with identifiers). The plan needs to answer the following questions:
        - What identifiers will be kept with the data?
        - If codes, where will the key linking the codes to identifiers be kept?
        - Will other parties help create and/or host the database?
        - How will data be securely stored?
        - Will other parties help with statistical analysis, and if so, will identifiers be stripped off first?
        - What are plans for protecting the data or disposing of it once the study is completed?

5. References/Bibliography