Chart Review Guidance and Instructions

1. What is the difference between a retrospective and prospective chart review?

   A **Retrospective Chart Review** evaluates patient data that is *existing* at the time the project is submitted to the IRB for initial review.

   A **Prospective Chart Review** evaluates patient data that does not yet exist at the time the project is submitted to the IRB for initial review.

2. Should I request exempt, expedited or full board review?

   **Exempt:** Exempt review should only be requested if the information to be collected already exists and data will be recorded in such a manner that subjects cannot be identified, either directly or indirectly (Exempt Category #4). As data must exist at the time the project is submitted to the IRB, this limits exempt review to retrospective chart reviews. In the majority of cases, chart reviews do not qualify for exempt status because most investigators need to retain identifiers at least through the data collection process. Even if an investigator plans to eventually discard all identifiers once data collection is complete, this is not sufficient for the project to qualify for exempt review.

   **Expedited:** Expedited review can be granted for retrospective and prospective chart reviews under expedited category #5 which is defined as: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Most chart reviews fall into this category.

   **Full Board:** While rare, full board review may be required for both retrospective and prospective chart reviews. Some circumstances under which this occurs is if the investigator plans to collect sensitive data, or if the chart review results in a change in care for the patients whose data is being collected.

3. What type of consent should I apply for?

   **Waiver of Consent:** Waiver of consent is the most frequently requested type of consent for both retrospective and prospective chart reviews. In order for the IRB to approve a waiver of consent, the IRB must be satisfied that the following criteria are met:

   (1) The research involves no more than minimal risk to the subjects;
   (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   (3) The research could not practically be carried out without the waiver or alteration; and
   (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Waiver of Documentation of Consent: This type of consent is not usually requested for a chart review. Under a waiver of documentation of consent, an investigator must still obtain consent from the subject. However, the investigator does not need to obtain a signed consent form from subjects if the IRB agrees that the following criteria are met:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (note: Certificate of Confidentiality may apply).

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Written Consent: In certain instances the IRB may determine that written consent is required if the investigator is unable to justify why it’s impracticable to conduct the research without a waiver. This is more often the case for prospective chart review studies, but sometimes occurs in retrospective chart review studies. For example, an investigator wishes to review the charts of all of his patients he refers onward for a colonoscopy to collect outcome measures. The IRB may determine that the investigator should obtain written consent since he will have the chance to obtain consent from the patients during their clinic visit with him.
CHART REVIEW PROTOCOL TEMPLATE
TITLE HERE

Principal Investigator:
Address:
Site(s) where study will be performed:
Protocol Version Date:

1.0 Introduction - Background and Rationale (include references)

2.0 Hypothesis/Key Questions (the hypothesis being evaluated; the key questions being asked in the research)

3.0 Objectives (Primary endpoints of study, listed and numbered individually)

4.0 Selection of Patients
   4.1 Inclusion Criteria:
   4.2 Exclusion Criteria:
   4.3 Age Range:

5.0 Is this a retrospective or prospective chart review?
   5.1 ______ Retrospective Chart Review (Investigator plans to collect and evaluate only data that is pre-existing at the time the project is submitted to the IRB for initial review.)
       Data collection will be limited to information existing in the records between mm/dd/yyyy to mm/dd/yyyy (end date must come before the submission date of the project to the IRB)

5.2 ______ Prospective Chart Review (Investigator plans to collect and evaluate data that does exist at the time the project is submitted to the IRB for initial review)
       Data collection will be limited to information existing in the records between mm/dd/yyyy to mm/dd/yyyy*

*If there is no end date, please explain why:

6.0 Study Methods
   6.1 Source (location) of records to be reviewed:
   6.2 Describe how the charts to be reviewed will be identified:
   6.3 Who will identify charts to be reviewed (PI? Sub-investigator?)
7.0 Confidentiality of Data
7.1 How will data (both paper and electronic) be stored to safeguard confidentiality? (e.g. in a locked cabinet, password protected computer?)
7.2 Who will have access to harvested patient data?
7.3 How long will harvested patient data be stored? How will it be destroyed when it is no longer needed?

8.0 Consent: describe the type of consent to be obtained and justification for the choice (written, waiver, verbal):

9.0 Statistical Considerations
9.1 Proposed sample size (number of records to be reviewed) and sample size justification (power analysis if applicable)
9.2 Proposed time period to be evaluated:
9.3 How will data be analyzed and by whom?

10.0 Appendices: The following appendices must be attached to the protocol
10.1 Appendix A: Data Collection Form (DCF): (to be used for recording the data that will be extracted during the chart review. This form should not contain any direct or indirect identifiers except for a unique subject code.)

10.2 Appendix B: Coded Identifier List (CIL): (this form should serve as the link between the unique subject code you and any identifiers you will need to conduct this chart review study [e.g., name, medical record number, date of birth, address, telephone number, social security number])

11.0 References

APPENDIX A: DATA COLLECTION FORM

1. Unique Subject Code
2. List all elements to be collected during the chart review

APPENDIX B: CODED IDENTIFIER LIST

1. Unique Subject Code
2. List all identifiers to be collected or used in this study (e.g., name, medical record number, date of birth, address, telephone number, social security number)
## APPENDIX #: CODED IDENTIFIER LIST (TEMPLATE ONLY-Modify as required for your study)

<table>
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<tr>
<th>Subject Name</th>
<th>Medical Record #</th>
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