Retrospective Chart Review Guidance and Instructions
Tips for an efficient IRB review

The IRB office aims to efficiently process applications for retrospective chart reviews. Please provide sufficient details in your application form to facilitate a quicker review. The following pointers address the most common sources of delay:

1. The IRB has developed a form that serves as both the IRB application and your research protocol. A separate research protocol is not needed. The document is posted on our website at:
   http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/forms.html

2. Please make sure that your entire project is retrospective in nature. Retrospective research uses data/specimens that exist at the time the project is submitted to the IRB. If your project has both retrospective and prospective components, please consult with the IRB office about the correct protocol template and application.

3. In section F, an actual number of charts you plan to review must be named in the application. If you are unsure of the number, provide an approximation. If you are reviewing less than 50 charts, the IRB office will work with you to meet additional HIPAA requirements for accounting of disclosures in the medical record.

4. In Section G, provide justification for waiving the informed consent requirement. Because obtaining informed consent is the default requirement for human subjects research, investigators must demonstrate that their project meets regulatory criteria for a waiver. The federal criteria for waiving consent are broad. To assist you in your response, please consider the following points:

   **Why is the research no more than minimal risk to subjects?**
   - Are you using data that was already collected for clinical care?
   - Will patients have to undergo any new procedures to generate your data?
   - Are you collecting data on sensitive topics (such as diagnosis of psychiatric disorder or communicable diseases, abuse, illegal conduct, etc.)?
   - Have you minimized the personal identifiers that will be kept with the data?
   - Are the data being stored on secure university servers?
   - Will access to the data be limited to members of the study team?
   - What steps have you taken to minimize the risk of breach of confidentiality?

   **Why are the rights and welfare of subjects not adversely affected by waiving consent?**
   - Are the data being collected from procedures that would occur regardless of the research?
   - Are you going to learn anything new about these patients that would impact their ongoing care?
   - Would any study data be used for making treatment decisions?
   - Are any results from your study going to be placed in the patient’s medical record?

   **Why can the research not practicably be carried out without a waiver of consent?**
   - Are you still having clinical contact with the patients whose records you will access? (if so, then consent would be feasible)
   - Could you answer your research question with data from only those patients who are able to provide informed consent?
   - Would contacting subjects to obtain consent cause undue burden or potential harm?

   **Are there any circumstances in which you would provide the subjects with additional pertinent information after your analysis?**
   - Would your project generate information that patients should know about for their ongoing care?
   - Will any information from the project be placed in the patient’s medical record?
   - Would patients obtain a direct personal benefit from learning of your results?
5. In Section H, investigators must provide sufficient details to demonstrate that the risk of confidentiality breach has been minimized. Your description should address the following issues:
   - Describe your plan for secure storage of the data
   - State exactly where data will be stored
   - Discuss how you will restrict access so that data will only be available by approved individuals.
   - Discuss how you will ensure that data are not re-used for another purpose
   - Demonstrate that any identifiers kept with the data are the minimum necessary to accomplish the research.
   - Discuss any plans to send study data outside KUMC and how this will be securely accomplished.
   - If applicable, state where you will keep the master list that contains patient identities. (The master list should be kept separately from the study data.)
   - Estimate the length of time you will need to keep the master list. It must be destroyed when it is no longer needed.
   - Confirm that once the analysis is complete, all identifiers will be removed from study data.

6. Please ensure that everyone on your study team is current on human subjects training and conflict of interest disclosure. These items are a frequent source of delay in approval.

7. When you have completed the protocol form, please follow the instructions on first page of the form about uploading all required documents into the electronic IRB system. If you have questions or difficulty with system access, please contact the IRB at humansubjects@kumc.edu or 913-588-1240.