Guidelines for Requesting a Waiver of Informed Consent for Retrospective Chart Reviews

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In order for the IRB to waive informed consent, the IRB must find and document all of the following:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

When completing the request for a waiver of informed consent – all answers to the above questions must be “yes” and there must be a description of *why* the answer is “yes”.

**Here is an example of how these criteria/questions might be answered depending on the details of your study. Please use this as a guide and only use these responses if they are applicable to your study.**

**Example Explanations for “Yes” Answers to the Following Criteria/Questions**

The research involves no more than minimal risk to the subjects.

This is a medical record review. All data that is accessed or collected for this study will be in existence prior to submitting the original IRB protocol. The data will not include any sensitive information (Sensitive meaning - when disclosed could have adverse consequences for subjects or others, place them at risk for criminal or civil liability, or damage their financial standing, employability, insurability, or reputation). In order to protect confidentiality, one patient identifier will be kept on a master sheet to assign the patient a unique study identifier. This master sheet will be kept on an encrypted and password-protected network drive, separate from the data collection tool. Access to the master sheet will be limited to only study personnel as defined by this protocol. Once data analysis is finalized, the master sheet will be destroyed. All data collected will be stored on a secured server that is password-protected with access limited to only study personnel.

The waiver of alteration will not adversely affect the rights and welfare of the subjects

The research will not impact clinical care decisions or access to clinical care because the clinical care has already been completed for the timeline specified for the data that will be collected.

The research involves using identifiable private information, and the research could not practicably be carried out without using such information in an identifiable format

This chart review study requires the collection of data that is not retrievable as a deidentified report in Cerner and therefore requires a manual chart review.

The research could not practicably be carried out without the waiver or alteration

Since the data for this study already exists and the relevant healthcare visits have been completed, the chart review will not change the care already received. It would be difficult to contact individuals directly when there is no existing relationship between the researchers and the subjects. Subjects are not expected to be contacted and could they perceive it as an invasion of privacy.

Whenever appropriate, the subjects will be provided additional pertinent information after participation

If an incidental finding is noted during the course of a medical chart review that reveals something of relevance to the ongoing care of the patient - the principal investigator will ensure that a medical provider notifies the subject.