Request for Waiver or Alteration of Informed Consent

IRB/Hatton #:

PI:

Sponsor:

Protocol #:

Protocol Version/Date:

Research Title:

1. This form is being used to request the following:

- ◯ Waiver of Informed Consent
- ◯ Alteration of Informed Consent

2. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents the following. Please check ALL of the following that apply:

- ☐ The research involves no more than minimal risks to subjects
- ☐ The research could not practicably be carried out without the requested waiver or alteration
- ☐ 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
- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects
- ☐ Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

3. Explain why the research could not practicably be carried out without the waiver or alteration of informed consent:

4. If the research involves a medical record/chart review*, indicate if the research involves retrospective chart review AND/OR prospective chart review:

- ☐ Retrospective chart review
- ☐ Prospective chart review
- ☐ Not applicable

*The distinction between retrospective chart review and prospective chart review is important. This may influence whether obtaining informed consent from subjects is practicable. In truly retrospective research, it is often not practicable to find and contact all of the targeted subjects to obtain informed consent (and only locating and consenting a part of the subject population may impact analysis and the scientific validity of the study). In prospective chart review research, there is typically an opportunity to engage potential subjects and obtain informed consent since they will be coming in “prospectively” for regular care visits.

5. It is understood that non-research medical records are identifiable and that researchers often request access to identifiable non-research medical records for research purposes. Explain why the research could not practicably be carried out without using identifiable private information or identifiable biospecimens:

6. Indicate if the research plans to the use identifiable private information or identifiable biospecimens from any individuals who REFUSED CONSENT when asked to provide BROAD CONSENT:

◯ The research WILL NOT use identifiable information or biospecimens from individuals who REFUSED BROAD CONSENT.

◯ The research MAY use identifiable information or biospecimens from individuals who REFUSED BROAD CONSENT. The IRB CANNOT approve a waiver of informed consent for for individuals who REFUSED BROAD CONSENT.

PI Signature:

Date: