Subject: Procedure for Waiver or Exception of Informed Consent for Human Subjects Research

Procedure:
This procedure provides guidance on obtaining a waiver of informed consent; and requesting approval for exception from informed consent in emergency research from the Institutional Review Board(IRB).

I. Investigator Responsibilities.
   A. Waiver of informed consent in public benefit or service programs or for minimal risk research
      1. The Investigator will assess the proposed research to determine if it meets regulatory requirements for a waiver of informed consent.
      2. The Investigator will complete and submit for review a request for waiver or alteration of consent
   B. Exception from informed consent requirements for emergency research
      1. The Investigator is responsible for providing all study documents and any additional materials requested by the IRB to prepare and conduct community consultation and public disclosure of the proposed research.
      2. The Investigator will prepare and submit to the IRB materials in preparation for public disclosure following completion of the research.
      3. The Investigator will establish an independent data and safety monitoring committee to exercise oversight of the clinical investigation.
      4. When the Investigator is unable to locate a legally authorized representative the Investigator will attempt to contact, within the therapeutic window, the participant’s family member who is not a legally authorized representative, to ask whether he or she objects to the individual’s participation. A summary of efforts to contact the legally authorized representative and family members is made available to the IRB at the time of continuing review.

II. IRB Committee Responsibilities.
   A. The IRB Reviewers will consider the request for a waiver of informed consent and the Investigator’s justification verifying and documenting that regulatory conditions are applicable to the proposed research activities.
   B. If the IRB Reviewers agree with the Investigator’s justification and documentation for waiver or alternation of the consent process, they will document on the Reviewer’s Comment Form that they agreed with the Investigator’s justifications.
   C. If the IRB Reviewers do not agree with the Investigator’s justification but agree for other reasons that waiver or alteration of the consent process is allowable and appropriate, they must document on the Reviewer’s Comment Form, their own protocol specific findings that justify the waiver or alteration of consent.
   D. If the IRB reviewers do not agree that waiver or alteration of the consent process is allowable and appropriate they will document such on the Reviewer’s Comment Form.
   E. Exception from informed consent requirements for emergency research requires additional protections for the rights and welfare of the participants including, but not limited to the following:
      1. Consultation with representatives of the communities in which the investigation is conducted and from which the participants are drawn;
      2. Public disclosure of plans for the investigation and its risks and expected benefits to the communities in which the research is conducted and from which the participants are drawn;
      3. Public disclosure at the completion of the research to inform the
community and researchers of the study. This may include the
demographic characteristics of the research population and study results
F. When amendments are made to a currently approved research study, the waiver
of informed consent is reassessed by the IRB Committee, Chair or his or her
designee, and a determination made as to whether the conditions for the waiver
have been altered, necessitating the rescinding of the waiver. If this occurs, the
IRB also determines whether currently enrolled participants must be re-consented
by the Investigator.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will conduct a pre-review of the request for waiver of consent to verify that
the study meets the criteria for a waiver of informed consent. If the RCA
determines that the study does not meet the criteria for a waiver, the Investigator is
contacted for further clarification or guidance on drafting an informed consent
document
B. Pre-review changes are sent to the Investigator by the RCA.
C. Once the pre-review revisions are received from the Investigator, the RCA will
forward the study and informed consent documents for review by the appropriate
process (expedited or IRB Committee review).
D. Appropriate database entries are completed.