I. INTRODUCTION

This purpose of this policy is to detail the procedure for approving a Waiver or alteration of the consent process and the waiver of consent documentation.

II. PROCEDURES

A. A Principal Investigator may request a waiver or alteration of the required elements of the informed consent process by completing the appropriate questions in the eIRB system.

B. The request is reviewed by the IRB, the IRB Chair or the IRB Chair's designee.

1. The proposed consent procedure which does not include, or which alters some or all of the requirements of informed consent process set forth in the federal regulations [45 CFR 46.116 (a) and (b)] may be approved or the requirement to obtain informed consent or parental permission may be waived provided the IRB finds and documents that:

    a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine [45 CFR 46.116(e)]:

        (1) Public benefit or service programs;

        (2) Procedures for obtaining benefits or services under those programs;

        (3) Possible changes in or alternatives to those programs or procedures; or

        (4) Possible changes in methods or levels of payment for benefits or services under those programs;

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

c) The research is not subject to FDA regulation; and

d) The research is not subject to DoD regulation or the Secretary of the Department of Defense has approved a waiver.

2. The consent procedure which does not include, or which alters, some or all of the elements of informed consent may be approved or the requirements to obtain informed consent waived provided the IRB finds and documents that [45 CFR 46.116(f)]:

a) The research involves no more than minimal risk to the participants;

b) The waiver or alteration will not adversely affect the rights and welfare of the participants;

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

d) **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;**

e) Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation;

f) The research is not subject to FDA regulation; and

g) The research is not subject to DoD regulation or the Secretary of the Department of Defense has approved a waiver.

3. Waiver of Documentation of the Informed Consent Process

a) The following stipulations must be true before waiving the requirement for the investigator to obtain a signed informed consent document for some or all of the participants ([45 CFR 46.117(c)(1)].

(1) The only record linking the participant and the research would be the consent document.

(2) The principal risk would be potential harm resulting from a breach of confidentiality.

(3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(3) Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or a written statement describing the research will be provided to participants (e.g., copy of consent document, study information sheet);

4) The research is not subject to FDA regulations.

b) The following stipulations must be true before waiving the requirement for the investigator to obtain a signed informed consent document for some or all of the participants true [45 CFR 46.117(c)(2)] [21 CFR 56.109(c)(1)]

(1) The research presents no more than minimal risk of harm to participants.

(2) The research involves no procedures for which written consent is normally required outside of the research context.

c) The IRB, the IRB Chair or the IRB Chair's designee reviews: a) a copy of the consent document or written statement of information for inclusion of all required and appropriate additional elements of disclosure and b) considers whether to require the investigator to provide subjects with a written statement regarding the research.

4. Waiver of Consent Process – Permission is not a reasonable requirement

a) The research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

b) An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

c) The research is not FDA-regulated.

III. FDA Regulations

A. FDA regulations do not allow waiver of any informed consent requirements except in emergency use situations.

B. When following FDA regulations, the IRB is allowed to waive the requirement to document the consent process by determining that the regulatory criteria for waivers are met as follows.

1. The IRB reviews a written description of the information that will be provided to subjects.

2. The IRB considers requiring the researcher to provide subjects with a written statement regarding the research.

IV. MEMORANDUM OF UNDERSTANDING

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

V. ADDITIONAL IRB RESPONSIBILITIES

A. If waiver or alteration of informed consent, signed informed consent, or elements of informed consent is requested, the reviewer(s) will document if the proposed research study meets the requirements for waiver approval. If not, the reviewer or IRB administrator will communicate this denial of waiver to the principal investigator and ask for necessary revisions to the informed consent process/document.

B. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,

- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>)

C. VA Research

For VA research, the IRB will document the reason for waiver when it waives the requirement to obtain written documentation of the consent process.