Policy Name: **Informed Consent to Participate in Research Policy and Procedures**		
Approved		
Effective Date: 12/01/2016	**Page 1 of 12**	**Section: HRPP 6.1**
Replaces Policy: Effective 01/27/2012		

I. POLICY

A. Introduction

The purpose of this policy is to detail MUSC expectations for appropriate informed consent to participate in research.

B. Requirement to Obtain Informed Consent

1. Informed consent must be obtained and documented prior to involving any individual in research including invasive screening for eligibility to participate and recording identifiable information unless a waiver of consent is approved by the IRB.

2. Informed consent must be obtained from the individual participating in the research who is 18+ years of age and from the parent(s) of a child less than 18 years of age (see MUSC policy and procedure, Children as Research Subjects). Children between the ages of 12-18 years must give documented "assent".

3. Only those individuals approved by name by the IRB may obtain informed consent.

4. Every informed consent document must be signed and dated by the subject and the individual who obtained the consent.

C. Vulnerable Populations

Special protections are required when obtaining informed consent from vulnerable populations

1. When the study population includes individuals who are possibly cognitively impaired, the IRB must evaluate the proposed plan for assessing that the capacity to consent is adequate and the use of legally authorized representative consent must be approved by the IRB. The IRB must also decide if the assent of the participants is a requirement, and, if so, whether the plan for assent is adequate.

2. When the study population includes pregnant women, the purpose of the research is to improve the mother's health, and the risks to the fetus are minimal, informed consent of both the mother and

father is required unless: 1) the purpose of the research is to meet the health needs of the mother; 2) the father's identity or whereabouts cannot reasonably be ascertained; 3) he is not reasonably available; or 4) the pregnancy resulted from rape (45 CFR 46.204)

D. Emancipated Minor

An "emancipated minor" may only give informed consent when there is documentation that the minor is "emancipated", i.e. a marriage certificate, a rental lease signed by the minor, etc.

E. Legally authorized representative Consent

The IRB must specifically approve informed consent being obtained from a legally authorized representative who must be specifically named rather than from the individual who will be the research participant

F. Required Elements of the Informed Consent

The informed consent must include the following required elements (45 CFR 46.116(a)(1) and 21 CFR 50.25) and must be written in lay language (see MUSC Informed Consent Guidelines):

1. A statement that the study involves research;

2. An explanation of the purpose of the study;

3. A description of the procedures to be followed;

4. Identification of any procedures that are experimental;

5. The expected duration of the subject's participation;

6. A description of any reasonably foreseeable risks or discomforts to the subject;

7. The amount and schedule of payments;

8. A description of any benefits to the subject or to others which may reasonably be expected from the research;

   For VA Research

   a) A statement that in the event of a research-related injury, the VA will provide necessary medical treatment to a participant injured by participation.

b) A statement that a veteran-participant does not have to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans have to pay co-payments for medical care and services provided by VA.

c) When a VA study involves “usual or standard of care” in the protocol or a separate document in the IRB application the researcher must clearly designate the individual or entity (e.g., the appropriate research personnel versus the subject’s health care provider) responsible for relevant aspects of both the research and the usual care.

9. A disclosure of alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

10. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (For FDA-regulated Research, the FDA may inspect the records);

11. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

12. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

13. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent will be provided when appropriate under [45 CFR 46 116 and 21 CFR 50.25]:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

7. For applicable clinical trials, a statement notifying the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank. The statement is: "A description of this clinical trial will be available on http://ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time."

G. Exclusion of Exculpatory Language

Informed consent documents may not include exculpatory language (45 CFR 46.116 and 21 CFR 50.20)

H. Genetic Research

Any genetic research study will include the MUSC genetic research required paragraphs in the informed consent documents as appropriate for:

1. Human Biological Material (HBM) linked to the subject with the potential for recontact,

2. HBM linked to the subject with no intent to recontact, and

3. HBM that is not linked to the subject with no recontact possible (see MUSC Standard Genetic Research Paragraphs)

I. MUSC Standard Paragraphs

Every informed consent will include the appropriate MUSC standard paragraphs regarding the institution's commitment, the sponsor's commitment, and the potential termination of the research by the investigator, and the "volunteer's agreement" (see MUSC Informed Consent Guidelines).

J. Agreement to Disclose Pregnancy Testing Results

If the research study includes children and pregnancy testing, the consent will include the MUSC required paragraphs (see MUSC Standard Consent Guide).

K. English Literacy

Subjects who do not speak/read English will be given an informed consent document understandable to them. (45 CFR 46.116, 46.117 and 21 CFR 50.20)

L. IRB Observation of the Informed Consent Process

The IRB may observe the process of informed consent at any time. For example, observation of the consent process might provide additional protections when research involves adults with diminished decision-making capacity. Observation of the consent process might be performed by the IRB, IRB staff, other individuals in the organization, or by a third party hired by the organization, investigator, or sponsor.

M. NIH Supported Clinical Trials

If a research study is a NIH supported clinical trial with an NIH approved sample informed consent document, any deletion or substantive modification of information concerning risks or alternative procedures contained in the NIH approved sample consent must be justified in writing by the investigator, approved by the IRB and reflected in the IRB minutes.

N. 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”.

If a research is a VA study, the informed consent will incorporate requirements of VHA 1200.05.

O. Long form of Consent Documentation

For the long form of consent documentation, the IRB will determine that the regulatory criteria for the long form of consent documentation are met:

1. The consent document embodies the basic and appropriate additional elements of disclosure.

2. The participant or the participant's legally authorized representative has signed and dated the consent document.

3. A copy of the signed and dated consent document is given to the person signing the consent document.

4. The investigator will give either the participant or the participant's legally authorized representative adequate opportunity to read the consent document before signing and dating the document.

5. For VA research, the consent document is on VA Form 10-1086

P. Short Form of Consent Document

For the short form of consent documentation, the IRB will determine that the regulatory criteria for the short form of consent documentation are met:

1. The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.

2. A written summary embodies the basic and appropriate additional elements of disclosure.

3. There was a witness to the oral presentation.

4. For participants who did not speak English, the witness was conversant in both English and the language of the participant.

5. The participant or the participant's legally authorized representative signed the consent document. If the research is FDA-regulated or VA research, the participant or the participant's legally authorized representative signed and dated the consent document.

6. A copy of the summary has been given to the participant or the participant's legally authorized representative

Q. Consent Process

The following information will be provided to the IRB in order to determine whether the consent process can be approved. This information can be collected as part of the application or be included in the protocol:

1. The person who will conduct the consent interview.

2. The person who will provide consent or permission.

3. Any waiting period between informing the prospective participant and obtaining consent.

4. Steps taken to minimize the possibility of coercion or undue influence.

5. The language to be used by those obtaining consent.

6. The language understood by the prospective participant or the legally authorized representative.

7. The information to be communicated to the prospective participant or the legally authorized representative

NOTE: These policies do not apply to research determined to be "exempt".

R. 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>).

II. DEFINITIONS

Definitions for the following terms used in this section may be found in the HRPP Program Guide Section 1.3 – Definitions of terms

A. Informed consent

B. Legal guardian

C. Legal representative

D. Children

E. Exculpatory language

F. Witness

III. PROCEDURES

A. The principal investigator will submit a description of the informed consent process and the informed consent document when submitting an application packet to the IRB either for full Board (see MUSC Policy and Procedure, Full Board Initial Review) or expedited review (see MUSC Policy and Procedure, Expedited Review).

B. The designated IRB reviewer(s) will assess the process and document for appropriateness, completeness, and understandability.

C. The IRB reviewer(s) will assess the qualifications of those individuals the principal investigator has requested be allowed to obtain informed consent and to give informed consent. The IRB reviewer(s) may request additional documentation of described qualifications. If required by the convened IRB as part of the protocol approval, a witness to the participant's signature or the legally authorized representative's signature sign and date the consent document. This will be communicated to the investigator upon review of the protocol.

D. The following must occur when using the short form consent documentation:

1. The witness will sign and date both the short form and a copy of the summary.

2. The person actually obtaining consent will sign and date a copy of the summary.

3. A copy of the signed and dated short form will be given to the participant or the legally authorized representative.

4. A copy of the signed summary will be given to the subject or the legally authorized representative.

E. Informed consents must be translated into a foreign language by a translator certified by the American Translators Association. The principal investigator will submit documentation that any foreign language informed consent has been translated by a certified translator.

F. If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.

1. After the written consent document and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has

orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.

2. By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that consent was freely given by the subject or the subject's legally acceptable representative.

G. For corporate sponsored studies, ORSP will verify the consistency between the contract agreement and the informed consent. Any discrepancies noted are then addressed with the IRB Administrator or Program Manager.

H. When the informed consent document and process have been approved, the original copy is stamped with the IRB approval date by the IRB staff, and retained in IRB records. A Master Copy with an original IRB approval stamp is provided to the principal investigator. Copies are to be made only from the Master Copy, which is identified by the original IRB date stamp. No copies are to be made from word processing files or from any other copy without the original stamp.

I. VA Protocols:

1. Unless otherwise requested and approved, all VA research subjects medical records will be flagged in the VA electronic medical record (CPRS) per VA regulations. The flag will contain the name of the study, the study investigator, and study contact information. The flag is activated by the RHJVAMC staff after being contacted regarding the subject's enrollment by the investigator/study team.

   The flag will be required for all studies involving investigational medications, devices and/or interventions. Some studies may not require a flag and will be determined on a case by case bases after a request not to flag has been submitted to the IRB by the PI. Examples of studies that may not require a flag include:

   a) Retrospective chart audit studies
   b) Studies involving only one encounter
   c) Participation in the study involves the use of a questionnaire or previously collected biological specimens; and/or
   d) Studies where identification of the patient as a subject in the study would place the subject at greater than minimal risk.

2. In the event of a research-related injury, the VA has to provide necessary medical treatment to a participant injured by participation. Except in limited circumstances, the necessary care will be provided in VA medical facilities. Exceptions to the above include;

   a) Situations where VA facilities are not capable of furnishing economical care; and/or

   b) Situations where VA facilities are not capable of furnishing the care or services required.

3. A veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with Title 38 United States Code USC 1710(f) and 1710(g). Certain veterans will be required to pay co-payments for medical care and services provided by the VA.

4. All regulations pertaining to the participation of veterans as participants including requirements for indemnification in cases of research-related injury pertain to non-veteran participants enrolled in VA-approved research.

5. The Consent Process

   a) If someone other than the investigator conducts the interview and obtains consent, the investigator formally delegates this responsibility and the person so delegated has received the appropriate training to perform this activity.

   b) The participant or the participant's legally authorized representative will sign and date the consent document.

   c) A copy of the signed and dated consent document is given to the person signing the consent document.

   d) IRB approval of the working of the consent document will be document through a stamp on each page of VA Form 10-1086, indicating the date of most recent IRB approval.

   e) If the consent document is amended during the protocol approval period, the consent document must bear the approval date of the amendment rather than the date of the approved protocol.

   f) Investigator must include a progress note in the participant's medical record of the consent. This note should include:

(1) The name of the study;

(2) The person obtaining the participant's consent;

(3) A statement that the participant or the participant's legally authorized representative is capable of understanding the consent process;

(4) A statement that the study was explained to the participant; and

(5) A statement that the participant was given the opportunity to ask questions.

g) The investigator will place additional progress notes in the participant's medical record when;

(1) The participant is entered into the study; and

(2) The participant's participation is terminated

J. Subject Withdrawal

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access, for purposes related to the study, the subject's medical record or other confidential records requiring the subject's consent. However, a research may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

For FDA regulated studies, when participants withdraw from a clinical trial, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.

A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequently to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such a medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.

The researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in

the original consent document). The IRB must approve the consent document.

IV. REFERENCES

A. DHHS Title 45 Subpart 46 (45 CFR 46)

B. FDA 20 CFR 50