

		Policy Title:	Obtaining Informed Consent from Research Subjects
Effective Date:	March 3, 2017	Policy Number:	MHC_RP0115
Review Date:	March 3, 2017	Section:	Research Integrity
Revised Date:	May 20, 2020	Oversight Level:	Corporate
Administrative Responsibility:		Corporate Research Manager Institutional Official	

1. Purpose

1.1. The purpose of this policy is to describe the requirements for obtaining and documenting informed consent of research subjects.

2. Scope

2.1. This SOP applies to MHC IRB review of and consent process performed by investigators, key personnel, and research staff in non-exempt human subject research and clinical investigations.

3. Definitions

3.1. Refer to Appendix I “Definitions” for additional information.

4. Policy

4.1. When employees or agents of McLaren Health Care and its subsidiary hospitals conduct human subject research at a McLaren institution, informed consent will be obtained in compliance with all applicable federal and state regulations and the requirements of the McLaren Human Research Protections Program (MHC HRPP).

4.2. No investigator conducting research under the auspices of the MHC HRPP may involve a human being as a subject in research without obtaining the legally effective informed consent of the subject or the subject’s legally authorized representative unless a waiver of consent has been approved by the IRB.

4.3. A subject must have the capacity to consent to his or her own participation in a research activity if s/he demonstrates an appreciation:

4.3.1. That the activity is research.

4.3.2. Of the risks and benefits of a study.

4.3.3. Of the study procedures and requirements.

4.3.4. Of the alternatives that are available if not participating.

4.3.5. That, by choosing not to participate, this decision will be accepted without penalty.

4.4. The investigator must formally and prospectively designate in the application for IRB approval, anyone other than the PI that will conduct the informed consent process and obtain informed consent from a subject or the subject's representative.

4.5. The IRB will ensure, as part of its review, that the information in the consent document and process is consistent with the research plan and, when applicable, the HIPAA authorization.

4.6. The IRB will evaluate the informed consent document, the consent process, and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from participants.

4.7. Emergency medical care - Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe.

5. Procedure

5.1. The following procedures describe the requirements for obtaining consent from participants in research conducted under the auspices of MHC HRPP.

5.2. Basic Requirements:

5.2.1. The investigator or a designee is required to obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to entering a subject into a study, gathering data on a subject, and/or conducting any procedures required by the research plan, unless consent is waived by the IRB.

5.2.1.1. Vulnerable Populations:

5.2.1.1.1. At the time of initial review, the IRB will consider the scientific and ethical reasons for including vulnerable subjects in research.

5.2.1.1.2. The IRB may require that additional safeguards be put into place for vulnerable subjects, such as those without decision-making capacity.

5.2.1.1.3. Children who are wards of the state or any other agency, institution, or entity may only be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, if such research is related to their status as wards or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

5.2.1.1.3.1. If the research meets the conditions above, an advocate must be appointed for each child (the same individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in loco parentis.

5.2.1.1.3.2. The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is

not associated in any way (except as a member of the IRB) with the research, the investigators, or the guardian organization.

5.2.2. The IRB is allowed to waive parental permission if it is determined that the criteria for waivers or alterations are met.

5.2.3. The investigator or designee must obtain consent using a IRB approved informed consent document.

5.2.4. When informed consent is required, it must be sought prospectively and properly documented.

5.2.5. The investigator or designee (consenter) must carry out the informed consent process by:

5.2.5.1. disclosing to the prospective human subject the information needed to make an informed decision;

5.2.5.2. facilitating the understanding of what has been disclosed (e.g. asking open ended questions to validate understanding); and

5.2.5.3. promoting the voluntariness of the decision about whether or not to participate in the research.

5.2.6. Informed consent is the process of exchanging information, including reading and signing the informed consent document. It is not just a signature on a form. This process begins when the consenter initially approaches a subject and continues through the completion of the study. It is the critical communication link between the prospective human subject and the consenter.

5.2.7. To ensure that the consenter can answer questions to help provide understanding, the consenter must have appropriate training and be knowledgeable about the study.

5.2.8. The informed consent process can occur via one or more modes of communication, for example;

5.2.8.1. face to face interaction;

5.2.8.2. mail;

5.2.8.3. email;

5.2.8.4. electronic device such as eConsenting;

5.2.8.5. teleconsent

5.2.8.6. telephone; or

5.2.8.7. fax.

5.2.9. Informed consent should be obtained face to face, whenever possible. If the study design allows for obtaining informed consent via phone, fax, e-mail or any other electronic devices, the IRB must approve this method.

5.2.10. Informed consent must be obtained prior to enrolling a subject in a study and/or conducting research procedures, unless consent is waived by the IRB.

5.2.11. Sample or draft consent documents may be developed by a sponsor or

cooperative study group. However, the IRB-of-record is the final authority on the content of the consent documents that are presented to prospective study subjects.

5.3. Informed Consent Process

5.3.1. Only individuals approved by the IRB can obtain consent.

5.3.2. Informed consent must be obtained under the following circumstances:

5.3.2.1. Informed consent may only be obtained from subjects who have the legal and mental capacity to give consent.

5.3.2.2. The decision-making capacity of a potential research subject should be evaluated when there are reasons to believe that the subject may not be capable of making voluntary and informed decisions about research participation.

5.3.2.3. For subjects lacking this capacity, consent must be obtained from a legal guardian or a legally authorized representative.

5.3.2.3.1.1. Proof of LAR may include information related to the potential participants wishes in regards to research.

5.3.2.2.2. If no legal documentation exists (i.e. advanced directive, durable power of attorney), proof of identity and, when possible, proof of relationship to the potential participant should be obtained. This could be, but is not limited to:

5.3.2.2.2.1. Driver's License

5.3.2.2.2.2. State ID

5.3.2.2.2.3. Birth Certificate

5.3.2.2.2.4. Passport

5.3.2.2.2.5. Proof of shared residence

5.3.2.4. The informed consent process shall be sought under circumstances that provide the subject (or legally authorized representative) with sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

5.3.2.5. The informed consent information must be presented in language that is understandable to the subject (or legally authorized representative).

5.3.2.5.1. To the extent possible, the language should be understandable by a person who is educated to 10th grade level and layman's terms shall be used in the description of the research.

5.3.2.6. For subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the subject (or the subject's legally authorized representative).

5.3.2.6.1. In accordance with this policy, the IRB requires that the informed consent process include a reliable translator when the prospective subject does not understand the language of the person who is obtaining consent.

5.3.2.7. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This include information about the purpose, the risks, the benefits, and alternatives. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

5.3.2.8. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate

5.3.2.9. The informed consent process may not include any exculpatory language through which the subject is made to waive, or appear to waive any of the subject's legal rights; or through which the investigator, the sponsor, the oorganization or MHC employees or agents are released from liability for negligence or appear to be so released.

5.3.2.10. The PI must insure that the prospective subject or the LAR is provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5.3.2.11. The individual who obtained the informed consent should be the signatory for the documented process.

5.4. Basic Elements of Informed Consent

5.4.1. To be valid, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

5.4.1.1. A statement that the study involves research.

5.4.1.2. An **explanation** of the **purposes** of the research.

5.4.1.3. The expected **duration** of the subject's participation

5.4.1.4. A description of the **procedures** to be followed.

5.4.1.5. Identification of any **procedures which are experimental**

5.4.1.6. A description of any reasonably **foreseeable risks or discomforts** to the subject.

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

5.4.1.8. Disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject.

5.4.1.9. A statement describing the extent, if any, to which **confidentiality of records** identifying the subject must be maintained.

5.4.1.10. 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.

5.4.1.11. An explanation of **whom to contact** on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject;

5.4.1.12. Contact information for the IRB to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant in the event the research staff could not be reached; or in the event the subject wishes to talk to someone who is unaffiliated with a specific research study.

5.4.1.13. Contact information for the investigator to obtain answers to questions about the research study, such as scientific issues, how to do any part of it or to report an injury.

5.4.1.14. A statement that participation is voluntary, refusal to participate or the subject's decision to discontinue participation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled;

5.4.1.15. For **FDA-regulated studies**, the possibility that the Food and Drug Administration may **inspect the records** needs to be included in the statement regarding subject confidentiality.

5.4.1.16. If the research involves the collection of identifiable private information or identifiable biospecimens, the informed consent must contain one of the following:

5.4.1.16.1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

5.4.1.16.2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

5.5. Additional elements of informed consent

5.5.1. One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

5.5.1.1. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable. (e.g.: when the research involves investigational test articles or other procedures in which the risks to subjects is not well known.)

5.5.1.2. A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable. (e.g. the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices,

or other procedures involved in the research is not well known.)

5.5.1.3. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent. (e.g.: when there are anticipated circumstances under which the investigator may terminate participation of a subject.)

5.5.1.4. Any costs to the subject that may result from participation in the research. (i.e., when it is anticipated that subjects may have additional costs.)

5.5.1.5. The consequences of a subject's decision to withdraw from the research.

5.5.1.6. Procedures for orderly termination of participation by the subject when the protocol describes such procedures

5.5.1.7. 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.

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

5.5.1.9. A statement that the subjects biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

5.5.1.10. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

5.5.1.11. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of human germline or somatic specimen with the intent to generate or exome sequence of that specimen).

5.6. Documentation of Informed Consent

5.6.1. Except as provided in Section 5.7 and 5.8 of this document, informed consent must be documented by the use of a written consent form approved by the IRB and must be signed and dated (including in an electronic format) by the person performing consent discussion and by the subject or the subject's legally authorized representative at the time of consent.

5.6.2. If the investigator plans to use audio or videotapes, computer video presentations, or written materials, to promote understanding, these materials must be provided to the IRB for review. If audio or video recordings are used to document assent, provisions to ensure the security of the recordings must be described to the IRB.

5.6.3. Any forms intended to document assent must be reviewed and approved by the IRB prior to their use.

5.6.4. A written copy of the signed and dated consent form must be given to the person signing the ICF and the original copy must be retained in the research records.

5.6.5. The investigator or designee should enter a checklist or progress note in the research record describing consent process and statement that subject received a copy of the signed consent.

5.6.6. The consent form may be either of the following:

5.6.6.1. A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the subject or the subject's legally authorized representative, but the subject or subject's legally authorized representative must be given adequate opportunity to read it before it is signed; or

5.6.6.2. A short form may be used if the common language of local study participants is English, but the potential exists to enroll a subject or subjects that do not speak fluent English. In order to use the short form, all of the following must be in place:

5.6.6.2.1. The oral presentation and the written short form document must be in a language understandable to the subject;

5.6.6.2.2. There must be a witness to the oral presentation;

5.6.6.2.3. The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject or the subject's legally authorized representative. The interpreter may serve as the witness

5.6.6.2.4. The IRB must approve a written summary of what is to be said to the subject (the IRB-approved English language informed consent document may serve as the summary);

5.6.6.2.5. The short form document is signed by the subject;

5.6.6.2.6. The witness must sign both the short form and a copy of the summary;

5.6.6.2.7. The person obtaining consent must sign a copy of the summary;

5.6.6.2.8. A copy of the summary and a copy of the short form must be given to the subject or representative.

5.6.6.2.9. The original signed summary and the original signed "short form" should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

5.5.1.6 The IRB must receive all foreign language versions of the short form document as a condition of approval.

5.5.1.6.1 Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

5.7. Screening, Recruiting, or Determining Eligibility

5.7.1. An IRB may approve research in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or

determining the eligibility of prospective subjects or the subject's legally authorized representative, if either is met:

5.7.1.1. the investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; or

5.7.1.2. the investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

5.7.2. Investigators do not have to request waivers of consent when 5.6.1 is met but must still describe the activities in the application or protocol submitted to the MHC IRB.

5.7.3. Nothing in 5.6.1 negates the requirement to obtain consent, or a waiver of consent, before involving a subject, nor does it negate the requirements of other rules, such as HIPAA, when applicable.

5.8. Subject Withdrawal or Termination

5.8.1. For a variety of reasons, a subject enrolled in a research study may decide to withdraw from the research or an investigator may decide to terminate a subject's participation in research regardless of whether the subject wishes to continue participating.

5.8.2. In these circumstances, questions sometimes arise about:

5.8.2.1. whether the investigator may use, study, or analyze already collected data about the subject who withdraws from the research or whose participation is terminated by the investigator; and

5.8.2.2. whether the investigator can continue to obtain data about the subject and if so, under what circumstances.

5.8.3. Investigators must plan for the possibility that subjects will withdraw from research and include a discussion of what withdrawal will mean and how it will be handled in their research protocols and informed consent documents.

5.8.4. Regulatory requirements regarding the retention and use of data after subject withdrawal or termination differ between research subject to FDA regulations and that not subject to FDA regulations.

5.8.4.1. Under applicable FDA law and regulations, data collected on human subjects enrolled in an FDA-regulated clinical trial up to the time of subject withdrawal must remain in the trial database in order for the study to be scientifically valid.

5.8.4.2. For research not subject to FDA regulations, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.

5.8.5. When seeking informed consent from subjects, the following information regarding data retention and use must be included:

5.8.5.1. For FDA-regulated clinical trials, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal must remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

5.8.5.2. For research not subject to FDA regulations, the investigator should inform subjects whether the investigator intends to either:

5.8.5.2.1. retain and analyze already collected data relating to the subject up to the time of subject withdrawal; or

5.8.5.2.2. honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.

5.8.6. Sometimes, a subject wants to withdraw from the primary interventional component of a study, but is willing to allow the investigator to continue other research activities described in the IRB-approved protocol and informed consent document that involve participation of the subject, such as:

5.8.6.1. obtaining data about the subject through interaction with the subject (e.g., through follow-up interviews, physical exams, blood tests, or radiographic imaging); or

5.8.6.2. obtaining identifiable private information from the subject's medical, educational, or social services agency records or from the subject's healthcare providers, teachers, or social worker.

5.8.7. When a subject's withdrawal request is limited to discontinuation of the primary interventional component of a research study, research activities involving other types of participation for which the subject previously gave consent may continue.

5.8.7.1. The investigator should ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study.

5.8.7.2. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.

5.8.8. If a subject withdraws from the interventional portion of the study, but agrees to continue follow-up of associated clinical outcome information as described in the previous paragraph, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents would be required.

5.8.9. If a subject a) withdraws from the interventional portion of a study, (b) does not consent to continued follow-up of associated clinical outcome information, and (c) does not request removal of their data, the investigator must not access for purposes related to the study the subject's medical record or

other confidential records requiring the subject's consent.

5.8.10. An investigator 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

5.9. Waiver or Alteration of Informed Consent

5.9.1. The IRB is allowed to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of the consent process are met.

5.9.2. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

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

5.9.2.2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

5.9.2.3. The research could not practicably be carried out without the waiver or alteration; and

5.9.2.4. If the research involves using identifiable private information or identifiable biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format

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

5.9.3. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

5.9.3.1. 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:

5.9.3.1.1. Public benefit or service programs.

5.9.3.1.2. Procedures for obtaining benefits or services under those program.

5.9.3.1.3. Possible changes in or alternatives to those programs or procedures; or

5.9.3.1.4. Possible changes in methods or levels of payment for benefits or services under those programs; and

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

5.10. Waiver of Documentation of Informed Consent

5.10.1. The IRB is allowed to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of the consent process are met.

5.10.1.1. When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants.

5.10.1.2. When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers requiring the researcher to provide participants with a written statement regarding the research.

5.10.2. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following:

5.10.2.1. The only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality. Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the subject is talking to researchers.); or

5.10.2.2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (i.e. non-sensitive surveys, questionnaires and interviews); or

5.10.2.3. 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.

5.10.3. In cases in which the documentation requirement is waived, the IRB requires the investigator to provide a written summary of the information to be communicated to the subject with their submission.

5.11. Consent Monitoring

5.11.1. In reviewing the adequacy of informed consent procedures for proposed research, the IRB may determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, or that subjects are truly giving informed consent.

5.11.2. Such monitoring may be particularly warranted for:

5.11.2.1. High risk studies.

5.11.2.2. Studies that involve particularly complicated procedures or interventions.

5.11.2.3. Studies involving highly vulnerable populations (e.g., ICU patients,

children).

5.11.2.4. Studies involving study staff with minimal experience in administering consent to potential study participants, or

5.11.2.5. Other situations when the IRB has concerns that consent process is not being conducted appropriately.

5.11.3. Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project.

5.11.4. If the IRB determines that consent monitoring is required, the IRB chair and the Director of Corporate Research Administration will develop a monitoring plan and submit it to the IRB for approval.

5.11.5. The consent monitoring may be conducted by IRB staff, IRB members or another party, either affiliated or not with the institution. The PI will be notified of the IRB's determination and the reasons for the determination.

5.11.6. Arrangements will be made with the PI for the monitoring of the consent process for a specified number of subjects. When observing the consent process, the monitor will determine whether:

5.11.6.1. The informed consent process was appropriately completed and documented,

5.11.6.2. The participant had sufficient time to consider study participation,

5.11.6.3. The consent process involved coercion or undue influence,

5.11.6.4. The information was accurate and conveyed in understandable language, and

5.11.6.5. The subject appeared to understand the information and gave their voluntary consent.

5.11.7. Following the monitoring, a report of the findings will be submitted to the IRB, which will determine the appropriate action to be taken.

6. Posting of Clinical Trial Consent Form

6.1. One IRB-approved consent form must be posted to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

6.2. This requirement may be satisfied by either the awardee or Federal department or agency.

6.3. The Federal department or agency may determine if certain information should be redacted.

6.4. Federal guidance or instruction regarding implementation of the posting requirement was no available at the time the SOP went into effect. The prime awardee should consult with the grant officer regarding how to satisfy this requirement.

7. Responsibilities

7.1. IRB:

7.1.1. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate including consideration of state and local law, and organizational policy.

7.1.2. The IRB will evaluate the informed consent document, the consent process, and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from participants.

7.2. Investigator

7.2.1. The investigator and research staff must have adequate procedures in place for assessing and ensuring subjects' capacity, understanding, and informed consent or assent.

7.2.2. The investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to procedures unless (1) the research is exempt under 45 CFR 46.101(d); (2) the IRB finds and documents that informed consent can be waived (45 CFR 46.116(f) or 46.117(c)); or (3) the IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

7.2.3. The investigator will obtain consent from all eligible subjects ensuring equal access for potential participants.

8. References:

8.1. 21 CFR 56

8.2. 21 CFR 50

8.3. 45 CFR 46

8.4. Appendix I "*Definitions*"

9. **Previous Revisions:** March 25, 2013, November 20, 2015, March 3, 2017, (supplement - MHC_0500 SOP Transition and IRB Review of Research Subject to Revised 2018 Common Rule)

For those studies receiving approval prior to the implementation of the Revised Common Rule (approved prior to January 21, 2019), the previous regulations apply. For more information regarding the regulations applicable to these studies, please see March 3, 2017 version.

10. **Supersedes Policy:** None

11. Approvals:

MHC Institutional Review Board initial approval: January 18, 2013

MHC Institutional Review Board acknowledgment: December 4, 2015, March 3,
2017, January 18, 2019

Michael McKenna, MD
Executive Vice President/Chief Medical Officer
Institutional Official of Research

Date