McLaren HEALTH CARE		Policy Title:	Obtaining Informed Consent from Research Subjects
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Administrative Responsibility:	Corporate Research Integrity Manager Institutional Official, HRPP		

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"*

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, generally this requires that 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, 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 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).

4.8. Preemption -The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

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 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 the criteria for waivers or alterations are met.

5.2.3. The investigator or designee must obtain consent using an IRB approved informed consent document, script, or other IRB-approved consent materials.

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 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 the consenter can answer questions to help provide understanding, the consenter must have appropriate expertise, 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. telephone; or

5.2.8.6. fax.

5.2.9. Informed consent should be obtained face to face, whenever possible, to facilitate the exchange of information. If the study design allows for obtaining informed consent via phone, fax, e-mail or any other means, 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 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 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. The status of the representative to serve as LAR must be established.

5.3.2.3.1. 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:

5.3.2.3.1.1. Driver's License

5.3.2.3.1.2. State ID

5.3.2.3.1.3. Birth Certificate

5.3.2.3.1.4. Passport

5.3.2.3.1.5. Proof of shared residence

Common Rule Requirements

5.3.2.4. *The prospective subject or the legally authorized representative must be 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 the information.*

5.3.2.5. *Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.*

5.3.2.6. *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 legally authorized representative's understanding of the reasons why one might or might not want to participate.*

5.3.2.7. 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 to participate and that minimize the possibility of coercion or undue influence.

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

5.3.2.8.1. 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.

5.3.2.8.2. 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).

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

5.3.2.10. 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 may 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, complaints, or problems; to obtain answers to questions about their rights as a research participant; to provide suggestions or input, 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

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 trial must be registered on clinicaltrials.gov under FDAAA801: "A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site 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."

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

5.4.1.17.1. 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

5.4.1.17.2. 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 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 risk to subjects is not well known.)

5.5.1.2. A statement that if the subject is or becomes pregnant, the 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 and procedures for orderly termination of participation by the subject.

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

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

5.5.1.8. The amount and schedule of all payments to subjects.

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).

5.5.1.12. When appropriate, the consent describes the plan for returning individual research results to participants, including anticipatable incidental or secondary findings.

5.5.1.13. For research not subject to FDA-regulations, the consent describes any possibility for and/or limitations on a subjects ability to withdraw data or specimens.

5.5.1.14. When appropriate, the consent describes the possibility for partial withdrawal (e.g., stop intervention but continue follow up).

5.5.1.15. For research protected under a Certificate of Confidentiality (CoC), the consent describes the protections the CoC affords, and any restrictions or exceptions to those protections.

5.5.1.16. For research that may trigger mandated reporting requirements (e.g., communicable diseases, abuse or neglect, threats to self or others, etc.), the consent discloses this possibility.

5.5.1.17. For organizations subject to Joint Commission requirements, the consent captures the name of the person who provided the consent information and the date the form was signed.

5.5.1.18. For research subject to ICH-GCP requirements, the consent includes:

5.5.1.18.1. The approval of favorable opinion of the IRB.

5.5.1.18.2. The probability for random assignment to each treatment.

5.5.1.18.3. The participant's responsibilities.

5.5.1.18.4. When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.

5.5.1.18.5. When there is no intended clinical benefit to the participant, the participant should be made aware of this.

5.5.1.18.6. A statement that the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing the consent form, the participant or the participant's legally authorized representative is authorizing such access.

5.5.1.18.7. If the results of the trial are published, the participant's identity will remain confidential.

5.5.1.19. The IRB may require that additional information be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

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 the 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 informed consent form meeting all the requirements described in this policy. The investigator shall give the subject or the subject's LAR adequate opportunity to read the consent form before it is signed; alternatively, the form may be read to the subject or the subject's LAR.

5.6.6.2. A short form stating that all required elements of informed consent have been presented orally to the subject or the subject's LAR, and key information was presented first to the subject, before other information, if any, was provided.

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

5.6.6.2.3. There must be a witness to the oral presentation. When applicable, the witness must be an individual who is fluent in both English and the language understandable to the subject or the subject's LAR.

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

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

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

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

5.6.6.2.8. 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.

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

5.6.6.3.1. 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.

When ICH-GCP is applicable Documentation of the Consent Process Includes:

5.6.7. Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.

5.6.8. Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the person who conducted the informed consent discussion.

5.6.9. If a participant 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.

5.6.9.1. After the written consent document and any other written information to be provided to participants is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant'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.

5.6.9.2. 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 participant or the participant's legally acceptable representative, and that consent was freely given by the participant or the participant's legally acceptable representative.

5.6.10. Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written consent document and any other written information provided to the participants.

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
*(**Note:** The provisions described in this section 5.7.1 do not apply to research subject to the **pre-2018 Common Rule or to DOJ-regulated research**. These provisions do not appear in FDA regulations, however, the FDA does not consider records review or oral communication with potential subjects prior to obtaining consent to be part of a clinical investigation, therefore waivers are not required. See FDA Draft Guidance for more information.)*

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 the investigator excludes 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 involving 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 and consent may only be waived for research that is regulated by the FDA when the requirements outlined in 5.9.2 are satisfied. The provisions described in 5.9.3 do not apply to FDA-regulated research.

5.9.2. The IRB may approve a consent procedure that does not include, or 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:

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.

Note: This criterion does not apply to FDA or DoD regulated research or to research subject to the pre-2018 Common Rule.

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 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 programs.

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 and documenting 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. The oral or written information provided to participants must include all required and appropriate additional elements of consent unless the IRB also approves an alteration of consent using the criteria described in 5.9.

5.10.1.3. 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 principal 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.) (Note: this provision may not be used for FDA-regulated research); 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. (Note: this provision may be used for FDA-regulated research); or

5.10.2.3. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more that minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that consent was obtained. (Note: this provision may not be used for FDA-regulated research or research subject to the pre-2018 Common Rule).

5.10.3. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide a written statement regarding the research.

5.11. Consent Monitoring

5.11.1. In reviewing the adequacy of informed consent procedures for proposed research, the IRB may determine 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, assuring 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 involving 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 the 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 consent monitoring is required, the IRB chair and the Corporate Research Integrity Manager 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 or Clinical Trial Consent Form (only applicable to research subject to the 2018 Common Rule)

6.1. For each clinical trial conducted or supported by a federal department or agency, one IRB-approved consent form used to enroll subjects must be posted by the awardee or by the Federal department or agency component conducting the trial on a publicly available Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. When MCH is the prime awardee, the MCH investigator is responsible for ensuring this requirement is met.

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

6.3. At this time, two publicly available federal websites that will satisfy the consent form posting requirement have been identified: ClinicalTrials.gov and a docket folder

on Regulations.gov (Docket ID: HHS-OPHS-208-0021). Additional websites may be identified in the future.

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 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: 3/25/13, 11/20/15, 11/14/21

10. Supersedes Policy: None

11. Approvals:

MHC Institutional Review Board initial approval: 1/18/13

MHC Institutional Review Board acknowledgment: 12/4/15, 3/3/17

Signature on File *1/31/23*

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Justin Klamerus, MD, MMM Date
Executive Vice President/Chief Medical Officer
Institutional Official of Research