Purpose:
Informed consent is a fundamental mechanism to ensure respect for persons through provision of purposeful agreement to a voluntary act. The requirement reflects the core principle of autonomy and respect for persons who participate in research studies.

Responsible Personnel:

Background:

Regulation and Guideline Reference(s):

45CFR 46.111
21 CFR 56.111
45 CFR 46.116
21 CFR 50.25
45 CFR 46.117
21 CFR 50.27
45 CFR 46.115
21 CFR 56.115

KUMC References:

KUMC Research Records Retention Policy
7.0 Informed Consent Requirements

7.1 Legally Effective Informed Consent Process and Documentation

I. This standard operating procedure applies to research conducted under the KUMC Federalwide Assurance #00003411. It also applies to all research that is greater than minimal risk, regardless of funding source.

II. Informed consent is a fundamental mechanism to ensure respect for persons through provision of purposeful agreement to a voluntary act. The requirement reflects the core principle of autonomy and respect for persons who participate in research studies.

III. Federal regulations present general guidelines about the informed consent process that apply to all non-exempt studies.

A. Before a subject is included in human subjects research, the investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

B. The investigator should seek consent only when the subject or representative has sufficient opportunity to discuss, ask questions and consider whether or not to participate.

C. The consent process should minimize the possibility of coercion or undue influence. Information presented to potential subjects may not include exculpatory language by which the subject is forced to give up legal rights in order to join the study or language that releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

D. Information about the study should be provided in language that is understandable to the subject or representative.

E. The subject or representative should be provided with information that a reasonable person would want to have in order to decide whether or not to participate.

IV. Consent documents should be revised when deficiencies are noted or when additional information will improve the consent process. If the approval and expiration dates are the only changes, then re-consenting at continuing review is not required.

V. The IRB assures that provisions are made to obtain legally effective informed consent prior to the involvement of the individual in the research. However, there are circumstances in which the IRB may grant a waiver or alteration of informed consent in accordance with Federal regulations.

VI. Documentation of informed consent must be obtained unless alternate procedures are approved by the IRB. The IRB reviews all informed consent documents to assure the adequacy of the information contained in the consent document and adherence to Federal regulations regarding the required elements of informed consent. Required elements are discussed below in section 7.3.11.

VII. The IRB reviews all aspects of the proposed informed consent process by reviewing the application materials including, but not limited to, consent form(s), advertisements, description of consent methods, and qualifications and experience of study personnel.
VIII. The informed consent process begins when the subject is first contacted about the possibility of participation. The investigator must provide a detailed description of the intended method for identifying potential subjects and obtaining informed consent in their initial application. The information in the protocol must match the information in the informed consent document regarding the purpose, procedures, risks, and benefits of the research.

IX. All aspects of the informed consent process and documentation must be approved by the IRB prior to their implementation.

X. Documents used to obtain informed consent must be submitted for review and approval by the IRB prior to use. When applicable, the IRB will affix the approval and expiration dates to approved informed consent documents. Only IRB-approved documents can be used in obtaining consent.

XI. Any proposed changes in the informed consent documents must be submitted as modifications to the IRB for review and approval prior to use.

XII. Unless specifically waived by the IRB, informed consent is documented in writing through the use of a current IRB-approved informed consent document signed and dated by the participant, or by the participant’s legally authorized representative, prior to enrollment or participation in any phase of the research study. A copy of the signed document must be given to the subject or to their representative who provides consent.

XIII. The investigator is responsible for ensuring that the informed consent process in research is an ongoing exchange of information between the research team and the study participants throughout the course of a research study. Informed consent is a continuous process of communication and acknowledgement over time, not just a signed document. Information must be presented in a manner that enables a person to voluntarily decide whether or not to participate as a research subject.

XIV. Unless otherwise approved by the IRB, a written informed consent document will be provided.

7.2 Assessing Capacity to Consent

I. When the potential participant is not able to provide informed consent, permission for the research must be obtained by a legally authorized representative.

II. Children. For children, their parents or guardian are the legally authorized representatives who may grant permission for their participation in research. Only the parents or guardian may grant permission for their child’s participation in research. Assent is to be sought from the child only after permission has been obtained from the parents. Grandparents and other relatives or caregivers may not grant permission for research participation unless they have been named the legal guardian for the child.

III. Decisionally-Impaired Adult Subjects. If a prospective adult subject lacks the capacity to consent, his or her legally authorized representative may grant permission, on their behalf, for their participation in research. Protections and requirements for decisionally-impaired adults are further discussed in SOP 9.5.

7.3 Written Consent Forms

I. Written informed consent shall be sought as follows:

   A. English Language Consents
      As applicable to the study, one or more consent forms should be developed by investigators and included in the IRB submission. The Human Research Protection Program posts consent templates on its website to provide further guidance.

   B. Non-English Consent Forms
Whenever the investigator expects to enroll non-English speaking subjects, the IRB requires the use of a foreign-language translation of the informed consent document. The translator must certify their expertise in the language. The IRB must approve the translated consent form prior to its use.

C. Short-Form Consent

1. There are times when a non-English speaking subject is unexpectedly found to be eligible for enrollment. In this case, investigators will not have an IRB-approved translation of the consent form. In such cases, investigators may use a written "short form" in the subject's native language as written documentation of the consent process, accompanied by an oral translation of the complete English version of the informed consent document.

2. The translator may be a qualified hospital/clinic staff member or a professional translator. Family members may not serve in this role.

3. The short form indicates that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When the short form is used, investigators must ensure that:
   a. The short form being used is the approved version supplied by the IRB Office;
   b. The IRB-approved English version of the consent form is used in the investigator's and translator's discussion with the potential subject;
   c. A witness is present at the oral presentation who is fluent in both English and the subject's native language; the translator can serve as the witness;
   d. The short form is signed and dated by the subject or the legally authorized representative;
   e. The witness signs both the short form and the English version of the consent form;
   f. The person obtaining consent signs the English version of the consent form.
   g. A signed copy of both the short form and the English version is given to the subject or the representative.

D. As soon as feasible, the English version of the consent form should be fully translated into the subject's language along with all other subject-facing documents. The subject will be re-consented when the fully translated consent form is available.

II. Elements of Informed Consent

A. Federal regulations specify the standard elements of legally effective informed consent. Unless otherwise authorized by the IRB, research investigators at a minimum shall provide the following information to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

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

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

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

5. A statement describing the extent, if any, to which confidentiality of records identifying the
subject will be maintained. For FDA-regulated research, a statement that informs subjects that FDA might inspect the records;

6. For research involving greater 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.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; an explanation of who to contact for concerns or complaints about the research; and

8. 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.

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

   a. 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

   b. 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.

B. When appropriate, the research investigator shall provide one or more of the following additional elements of information to each subject:

1. A description of standard care for the condition under study and how the proposed investigational treatment or procedure differs from standard care.

2. 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;

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

4. Any additional costs to the subject that may result from participation in the research and a clear delineation of which costs are medically indicated and those which accrue as a result of the research;

5. The amount and schedule of any payments to subjects.

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

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;

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

9. A statement that the subject's 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;

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

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

12. Notification that the sponsor, oversight agencies and FDA (as applicable) may inspect identifiable records to verify the accuracy of the information collected.

13. For applicable clinical trials, the paragraph that states, "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."

14. Any study-specific information relevant to state law, as specified in SOP 18.3

C. Consent forms must begin with a 'concise and focused presentation of 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.'

D. Until federal guidance is published, the beginning section of KUMC consent forms should be organized as follows:

1. The beginning section should be labeled as Key Information.

2. The section should be very brief, typically one – two pages, and not exceed three pages. Individual topics should be addressed in short paragraphs, not more than three – five sentences.

3. The Key Information section should be written in plain language using short declarative sentences.

4. At minimum, the Key Information should address the following topics:
   a. The fact that consent is being sought for research and that participation is voluntary
   b. The purpose of the research, i.e., the problem the study seeks to solve
   c. The expected duration of the subject's participation
   d. A summary of the procedures to be used specifically for research
   e. A summary of key risks specific to research participation. This paragraph should include the most common risks subjects will encounter along with a brief discussion of the most serious potential risks.
   f. A description of the benefits that may accrue to the subject
   g. Alternative choices if the subject decides not to join the study
   h. Contact information for the principal investigator and the IRB.

5. Additional topics should be addressed when applicable to the study:
   a. A brief description of how the intervention or investigational treatment works
   b. A description of how research participation would differ from the standard care the subject otherwise would experience
   c. A description of randomization or the criteria by which subjects will be assigned to study
d. Other study-specific information the subject should be aware of, such as particular impact on quality of life, significant time commitment, costly or uncomfortable procedures, or considerations about why the subject might not want to participate in the study.

6. The Key Information section should conclude with a statement that refers the subject or legally authorized representative to the remainder of the document for more detailed explanations.

7. The remainder of the consent form should begin with the header "Detailed Information."

8. Any information presented in the Key Information section does not have to be repeated in the remainder of the document.

E. The KUMC IRB will not require a separate Key Information section for consent forms that are less than eight pages in length, exclusive of the HIPAA privacy section.

III. Documentation of Consent

A. Except when the requirement is waived by the IRB, informed consent will be documented by the use of a written, IRB-approved consent form that is signed and dated by the subject or the subject's legally authorized representative.

B. A signed copy must be given to the person signing the form. The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent described above. This form may be read to the subject or the subject's legally authorized representative. The investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document accompanied by translation of the English consent form, as discussed above in section 7.3.I.C.

IV. Broad Consent

A. Beginning in January 2019, federal regulations allow the use of broad consent for the storage, maintenance and research use of identifiable information and biospecimens that have been collected for non-research purposes. The research is eligible for exempt review under exemption categories 7 and 8 discussed in SOP 2.5.

B. KUMC is not implementing the broad consent provisions at this time. In the future, this aspect of the Revised Common Rule may be implemented, if capacity to meet technical and regulatory requirements is confirmed.

7.4 Modifications of the Informed Consent Process

I. Documentation of Informed Consent by Electronic Means

A. Federal regulations clarify that the requirement to obtain written consent includes the option to document consent by electronic means. Use of electronic formats for consent must be described in the IRB submission and receive prior IRB approval. The IRB has the final authority to determine whether or not electronic means are approvable for a particular study.

B. The following issues are considered in reviewing a request to obtain electronic consent:

1. The investigator must demonstrate adequate security protections in the proposed hardware and software.
2. Subjects must be offered the opportunity to discuss the research and have their questions answered. Preference is given to direct interpersonal communication. If the research design does not support direct communications, then the potential subjects must be provided with clear instructions about contacting individuals who are knowledgeable about the study and readily available to answer questions.

3. Unless the IRB waives the requirement for a signed consent document, the consent process must include a mechanism for the subject to electronically sign the consent. Preference is given to the use of a stylus or on-screen finger signature.

4. Subjects must be provided with a signed copy of their consent form. The signed copy can be provided through a print-out at the time of the consent conversation. Alternatively, it could be provided through an automatically-generated PDF document or mailed through U.S. mail. Providing a signed copy of the consent by email requires secure email functionality for the sender and recipient.

5. The copy of the consent form provided to the subject must include all materials viewed by the subject, including graphics and visual aids used in the informed consent process. If the electronic consent form uses hyperlinks, the information in the hyperlinks should be included in the copy provided to the subject.

6. An FDA-regulated study cannot be approved for an electronic signature process unless the electronic system housing the consent documents and process are confirmed to comply with FDA regulations at 21 CFR Part 11.

II. Waiver of Documentation of Consent

A. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

   1. That the only record linking the subject and the research would be the consent document, the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not subject to FDA regulations. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

   2. That 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.

B. For cases in which the documentation (signature) is waived, the investigator must submit to IRB a description of the information that will be communicated to the subject. Whenever feasible, the investigator will provide subjects with a written summary about the research. The written summary should contain at least the basic consent elements.

C. When the IRB approves a waiver of the requirement to document consent, the IRB file or meeting minutes document the protocol-specific reasons justifying each criterion

III. Waiver or Alteration of Consent

A. The IRB may approve a consent procedure that does not include, or which alters, some of the informed consent elements in section 7.3.II above or waive the requirements to obtain informed consent provided that the IRB finds and documents that:

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

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

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

4. The waiver or alternation will not adversely affect the rights and welfare of subjects;

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

6. The research is not subject to FDA regulations.

B. To be considered for such a waiver, the principal investigator must address each of the above criteria, including a justification of its applicability to the proposed research and subject population for whom the waiver is being requested.

C. The IRB find and documents these criteria in the file or in the meeting minutes.

D. In addition to considering a waiver of consent for the study as a whole, the IRB may consider a waiver of consent for recruitment activities. When informed consent is planned but identifiable private information must be accessed prior to consent in order to identify potential subjects, a waiver of consent is necessary. Access to identifiable data for screening purposes is considered minimal risk; subjects’ rights and welfare can be protected by confirming appropriate security measures and training of study personnel; the recruitment activity could not practicably be carried out if prior informed consent for recruitment was required; and subjects will be provided with pertinent information if they are eligible for the study. If these conditions are confirmed during IRB review, the IRB routinely grants a waiver of consent for the recruitment activities.

IV. Waiver of Parental or Legal Guardian Permission

A. The IRB may waive permission by the parent or legal guardian if it determines the research meets the waiver of consent criteria described in item 2.A. above.

B. In addition to the standard criteria for waiver of consent in all studies, federal regulations provide an additional mechanism by which parental permission may be waived. If the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or legally authorized representative permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), it may waive the consent requirements described above, provided that:

1. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and

2. The waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

3. The research is not subject to FDA regulations.

V. Exception to Consent for Activities Related to Screening, Recruiting or Determining Eligibility

A. Investigators are provided with an exception to the informed consent requirements to obtain identifiable information or stored identifiable biospecimens for the purposes of screening, recruiting or determining eligibility for the research.

B. The following considerations apply:

1. The activities may begin only after the study has IRB-approval.
2. Investigators may obtain information directly from the prospective subject or their legally authorized representative. Alternatively, investigators may obtain identifiable private information or identifiable biospecimens by accessing existing records or stored biospecimens.

3. Identifiable information or specimens must be limited to the minimum necessary to accomplish the purpose.

4. Permission from the potential subject or legally authorized representative may be obtained orally or through written communication. The permission does not need to include formal informed consent elements.

5. Alternatively, the investigator may obtain identifiable private information or identifiable biospecimens by accessing existing records or stored biospecimens.

6. Data must be recorded and stored under adequate privacy and security safeguards, with access limited to approved study team members.

7. When the information or specimens is subject to the HIPAA Privacy Rule, additional requirements apply as discussed in SOP 8.2.

VI. Waiver of Consent for Planned Emergency Research Subject to FDA Regulation

A. The IRB may approve a study without requiring informed consent from all research subjects if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

1. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

2. Obtaining informed consent is not feasible because:
   a. The subjects will not be able to give their informed consent as a result of their medical condition;
   b. The intervention under investigation must be administered before consent from the subjects’ legally authorized representatives is feasible; and
   c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

3. Participation in the research holds out the prospect of direct benefit to the subjects because:
   a. Subjects are facing a life-threatening situation that necessitates intervention;
   b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
   c. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

4. The clinical investigation could not practicably be carried out without the waiver.
5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with standard informed consent procedures. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with item 7(e) below.

7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
   a. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
   b. Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;
   c. Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
   d. Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and
   e. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

B. The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject...
dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

C. Protocols involving an exception to the informed consent requirement must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists.

D. If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under item A of this SOP or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRBs that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

VII. Waiver of Consent for Planned Emergency Research That Is Not Subject to FDA Regulation

A. The IRB may approve a study without requiring informed consent from all research subjects if the IRB finds and documents each of the following:

1. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

2. Obtaining informed consent is not feasible because:
   a. The subjects will not be able to give their informed consent as a result of their medical condition;
   b. The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
   c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

3. Participation in the research holds out the prospect of direct benefit to the subjects because:
   a. Subjects are facing a life-threatening situation that necessitates intervention;
   b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
   c. Risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

4. The research could not practicably be carried out without the waiver.

5. The proposed research protocol defines the length of the potential therapeutic window based on
scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with standard informed consent procedures. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research consistent with item 7(e) below.

7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:

a. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn;

b. Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the investigation and its risks and expected benefits;

c. Public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;

d. Establishment of an independent data monitoring committee to exercise oversight of the research; and

e. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

B. The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the research is to be provided...
to the subject's legally authorized representative or family member, if feasible.

C. For the purposes of this waiver "family member" means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

7.5 Surrogate Consent

I. Federal regulations require informed consent to be provided by the individual or by their legally authorized representative. For research conducted by KUMC, the legally authorized representative is defined by state law governing surrogate decision-makers for research. Effective July 1, 2004, Kansas law defined the group of individuals who may act as surrogate decision-makers for participation in clinical research. The law applies to decisions made on behalf of adults or emancipated minors who are incapable of giving informed consent for a research protocol. The State of Missouri has enacted a similar law. Detailed requirements for the use of surrogate decision-makers in research are discussed in SOP 9.5.

II. KUMC researchers who are conducting clinical trials that may involve incapacitated persons must use a consent form that has been specifically designed for such purpose. The consent form must be reviewed and approved by the IRB prior to its use.

III. KUMC researchers who conduct research in states other than Kansas or Missouri are responsible to know applicable state laws about the inclusion of persons with impaired decision-making capacity.

7.6 Observation of Informed Consent Process

I. Under federal regulation, the IRB may exercise its prerogative to observe the informed consent process.

II. Protocols may be chosen for observation of the informed consent process by one of the following methods:

   A. At the request of the IRB;

   B. As a result of a known or suspected problem;

   C. As part of a randomly selected monitoring visit;

   D. At any time the study is enrolling participants. The level of risk or complexity may dictate the implementation of this process.

III. Once a protocol is identified, the designated observer will notify the investigator and research staff of the planned informed consent review visit and explain the procedures surrounding the observation. The investigator will be requested to inform the observer when a prospective participant is scheduled for a visit in which the informed consent will be presented. The observer will attend at this time if scheduling permits.

IV. Before the informed consent process is implemented, verbal permission to be present for the informed consent discussion will be secured from the participant. The observer will introduce him/herself to the participant and give an explanation for presence and assurance that confidentiality will be maintained.

V. The observer will document his/her observations of the informed consent process. At the conclusion of the informed consent process, the observer will interview the participant regarding their understanding of the consent.

VI. A post-approval monitor may also interview a participant after starting the study if no further enrollment into the study is planned. This interview may be done in person or by phone. The monitor will again obtain the participant's (or participant's legal representative) verbal permission to proceed with the interview.
VII. At the conclusion of the observation visit, phone interview, or in person interview, the monitor will include a report of informed consent process. This will be sent to the IRB Administrator and the Chair of the IRB as well as the principal investigator of the study.

7.7 Retention of Consent Forms

I. The original of the signed consent form must be kept on file by the investigator and is subject to recall and review by the IRB at any time.

II. Consent forms, and all other study documentation, must be retained in accordance with the KUMC Research Records Retention Policy. This policy states, in part, that research records are to be retained by the investigator for a minimum of seven (7) years unless a longer retention period is specified by the sponsor, funding source, or regulation. Research records involving pediatric subjects must be retained for a minimum of 25 years after completion or termination of the study.

References:

45CFR 46.111
21 CFR 56.111
45 CFR 46.116
21 CFR 50.25
45 CFR 46.117
21 CFR 50.27
45 CFR 46.115
21 CFR 56.115

Approved By:
Vice Chancellor for Administration

Attachments:

Approval Signatures

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<tr>
<th>Approver</th>
<th>Date</th>
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<tr>
<td>Steffani Webb: Vice Chancellor for Administration</td>
<td>12/10/2019</td>
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<tr>
<td>Lisa Hoebelheinrich: Chief Compliance Officer</td>
<td>12/10/2019</td>
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<td>Annie Fors: QA Director</td>
<td>12/3/2019</td>
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<td>Karen Blackwell: Director HRPP</td>
<td>11/26/2019</td>
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<td>Kyle Stephens: Assistant Director</td>
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Applicability

KU Medical Center, KU SoM Wichita