



**Campus Institutional Review Board**  
University of Missouri-Columbia

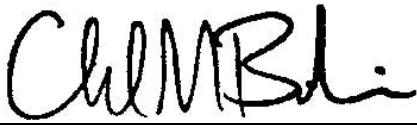
**Informed Consent Process**

Policy Number 2876.23

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Reviewed by: Campus IRB Membership


Effective Date: December 12, 2007

Approval Authority:

  
Signed \_\_\_\_\_  
IRB Chair

Date December 12, 2007

Institutional Approval:

  
Signed \_\_\_\_\_  
Associate Vice-Chancellor for Research

Date December 12, 2007

**1.0 Policy**

The Campus Institutional Review Board (Campus IRB) recognizes that Informed Consent is a process to assure that subjects are prospectively informed sufficiently enough to make a voluntary decision regarding participation in research. Legally effective consent shall be determined by governing State Law.

**2.0 Scope**

The guidelines for the Informed Consent process apply to all human subject research being conducted under the jurisdiction of the Campus IRB.

**3.0 Purpose**

Informed Consent forms are one of the cornerstones of ethical conduct of research involving humans. It is imperative that the Campus IRB ensure that all subject participants are *informed about* and *voluntarily consent* to research participation.

**4.0 Definitions.**

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**5.0 Standard Operating Procedure**

The investigator may involve a human being as a research subject only when he or she has obtained legally effective informed consent of the subject or the subject's legally authorized representative. Informed Consent assures that prospective human subjects receive the information necessary to help them understand the nature of the research to effectuate a process advocating respect for 1) prospective knowledge; and 2) voluntariness regarding the decision of whether or not to participate in the research. This policy provides guidelines for investigator(s) to obtain participant consent. The IRB reviewer must complete the applicable Informed Consent Checklists before approving a research project.

The Campus IRB does not review requests for a waiver of the requirement of consent for planned emergency research under the provisions of 45 CFR §46.116(f).

Informed Consent Process  
Policy Number 2876.23

All research involving human subjects must meet the requirements set forth in 45 CFR 46. The Campus IRB will review the proposed Informed Consent or Assent processes and application submissions in concert with the investigator's responses in compliance with the "Campus IRB Review Process" policy and may waive any aspect of the requirements set forth by these policies in compliance with the federal regulations.

1. In compliance with informed consent requirements set forth specifically in 45 CFR 46.116 and 45 CFR 46.117 of the Federal regulations, investigator(s) shall recognize that Informed Consent is:
  - a. A dynamic ongoing process that enables persons to voluntarily decide whether or not to participate as a research subject;
  - b. A fundamental mechanism to ensure the basic ethical principle of respect for persons is met through a provisional process of thoughtful consent for a voluntary act;
  - c. A procedure designed to educate the subject population in terms that they can understand;
  - d. A written form approved by the Campus IRB; and
  - e. A document signed by the subject or legal representative.
2. CATEGORIES OF CONSENT
  - a. Consent with documentation
    - i. Written Consent
    - ii. Online consent with secured signature
  - b. Consent without written documentation
  - c. Oral Consent
    - i. Oral Consent with written confirmation
    - ii. Oral Consent without written confirmation
3. Investigator(s) are prohibited from obtaining consent by any means other than with the Informed Consent document, or another means that was not prospective reviewed and approved by the Campus IRB.

## **I. THE INVESTIGATOR(S) RESPONSIBILITIES**

The Campus IRB review processes are conducted under the University of Missouri Columbia's Federalwide Assurance Agreement, which operates under the "Guiding Principles of the Belmont Report." The Campus IRB reviews all human subject research to assure its compliance with applicable regulations and guidelines. Research meeting the criteria for exempt is, by default, "exempt" from the regulatory requirements for informed consent. However, the basic ethical principle of Respect for Persons outlined in the Belmont Report compels investigators to obtain an individual's consent whenever possible. Permission may be obtained orally or in writing. If a written document is used, it should be based on the "Sample Informed Consent" Template available on the Campus IRB website (See Campus IRB website); however, it is not necessary to submit the form for review. Investigators completing the "Exempt Application" must describe how they will inform prospective participants about their participation in this research and obtain their voluntary permission. The researcher must also include the type of permission (written or oral) sought and who will obtain permission.

Regulatory guidelines for exempt and full board review permit the Investigator to involve a human being as a research subject once legally effective informed consent has been obtained from the subject or the subject's legally authorized representative. The investigator must submit the Informed Consent documents in compliance with the "Informed Consent" and "Privacy and Confidentiality" policies, or has been granted a waiver of such requirements by the Campus IRB.

All research activities involving vulnerable subjects must comply with the Campus IRB "Recruitment Process" and "Recruitment of Vulnerable Subjects" policies.

**A. CIRCUMSTANCE FOR OBTAINING CONSENT**

The Campus IRB requires documentation of informed consent by use of a written informed consent form approved by the IRB, signed and dated by the subject, or the subject's legally authorized representative.

1. The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate
  - a. How much time will be devoted to the consent discussion?
  - b. How much time will be allowed for a decision?
2. The circumstances of consent minimize the possibility of coercion or undue influence
  - a. Is there a power differential?
  - b. Are there communication issues?
  - c. Are there issues regarding the capacity to make a decision?
  - d. Are there excessive motivating factors?
  - e. Is the recruitment process acceptable?
  - f. Are advertisements acceptable?
  - g. Are payment arrangements acceptable?

**B. LEGALLY AUTHORIZED REPRESENTATIVE**

The Campus IRB requires the investigator to obtain the legally effective informed consent of either the participant or the participant's legally authorized representative to conduct human subject research. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

**Definition of LEGALLY AUTHORIZED REPRESENTATIVE According to the Federal Regulations (45 CFR 46.102)**

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.

1. Which individuals meet the DHHS definition of "legally authorized representative" when research was conducted in Missouri?

When a potential adult subject is unable to consent to research, the investigator must obtain the permission of one of the following legally authorized representatives:

- a. The potential adult subject's legal (court-appointed) guardian.
- b. An individual authorized under the potential adult subject's Durable Power of Attorney to provide consent for the research proposed.
- c. If the potential adult subject is being treated by a teaching hospital for an accredited medical school and the research is of an experimental treatment, test or drug, then consent may be obtained from a legal (court-appointed) guardian, attorney-in-fact, or a family member in the following order of priority:
  - i. Spouse, unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or is overseas;
  - ii. Adult child;
  - iii. Parent;
  - iv. Brother or sister;
  - v. Relative by blood or marriage.

Informed Consent Process  
Policy Number 2876.23

2. Areas in which federal and state law differ.

In determining applicability of the regulations, the Campus IRB will take into consideration the subject's capacity to consent to treatments or procedures involved in the proposed research, under the applicable law of the jurisdiction in which the research will be conducted. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU's General Counsel's office to determine if the proposed procedures/treatments are compliant with the laws within the specific jurisdiction.

If the research is to take place outside of Missouri and is anticipated to involve adults unable to consent for themselves, the Principle Investigator will supply the IRB with documentation (such as relevant statutes, regulations, Attorney General's or other legal opinions by practicing attorneys from the jurisdiction) regarding who is legally authorized to provide consent under applicable law of the specific jurisdiction. The Campus IRB may consult with Legal Counsel for review and a determination as to whether the proposed method would provide legally effective consent under applicable law.

**C. GUARDIAN**

In determining who other than parent may consent on behalf of a child to their participation in research, the Campus IRB will take into consideration who under the applicable law of the jurisdiction in which the research will be conducted meets the DHHS definition of a "guardian."

Federal regulations define "guardian" as an individual who under the applicable law of the jurisdiction in which the research will be conducted, is authorized to consent to general medical care..." on behalf of the child [§46.402(d)]. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU General Counsel's office to determine the who is authorized to consent to general medical care on behalf of the child within the specific jurisdiction

**1. PROCESS TO DETERMINE WHICH INDIVIDUALS MEET THE DHHS DEFINITION OF "GUARDIAN."**

Step 1 The Reviewer must comply with the 2876.20 Campus IRB Review Process Policy

Step 2 The Reviewer must comply with the 2876.23 Informed Consent Process Policy

Step 3 The IRB will consult with Legal Counsel to determine if the proposed consent process is legally effective under applicable Missouri law.

Step 4 The Reviewer must complete the applicable Checklist(s):

1. "Research Involving Children"
2. "Research Involving Children as Wards"
3. "Parent or Guardian Permission"

**II. APPLICABILITY OF STATE, FEDERAL AND LOCAL LAWS**

In determining applicability of the regulations, the Campus IRB will take into consideration the subject's capacity to consent to treatments or procedures involved in the proposed research, under the applicable law of the jurisdiction in which the research will be conducted. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU's General Counsel's office to determine if the proposed procedures/treatments are compliant with the laws within the specific jurisdiction.

If the research is to take place outside of Missouri and will involve subjects unable to consent for themselves, the Principle Investigator will supply the IRB with documentation (such as relevant

Informed Consent Process  
Policy Number 2876.23

statutes, regulations, Attorney General's or other legal opinions by practicing attorneys from the jurisdiction) regarding who is legally authorized to provide consent on behalf of the subject under the applicable law of the specific jurisdiction. The Campus IRB may consult with Legal Counsel for review and a determination as to whether the proposed method would provide legally effective consent under applicable law.

### III. ELEMENTS OF CONSENT

A. The Informed Consent document must include the following BASIC ELEMENTS:

- 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;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation is provided;
- An explanation as to whether any medical treatments are available if injury occurs and, a detailed description defining the treatment; and/or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research methodology;
- An explanation of whom to contact for answers to questions about the subjects' rights;
- Directions regarding whom to contact in the event of a research-related injury to the subject; and
- 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.

B. ADDITIONAL ELEMENTS that may be required the Informed Consent document:

- 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;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator, without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research; and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research, (which may relate to the subject's willingness to continue participation), will be provided to the subject; and
- The approximate number of subjects involved in the study.

#### **IV. ADDITIONAL ELEMENTS OF CONSENT DISCLOSURE**

- The consent process will disclose that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable OR the risk profile of all research-related interventions is well known and the research involves no investigational drugs or devices
- There are no anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent; OR
- The consent process will disclose anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- There are no costs to the participant that may result from participation in the research; OR the consent process will disclose additional costs to the participant that may result from participation in the research
- There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research; OR
  - The consent process will disclose the consequences of a participant's decision to withdraw from the research
  - The consent process will disclose procedures for orderly termination of participation by the participant
- Significant new findings during the course of the research which may relate to the participant's willingness to continue participation are unlikely OR the consent process will disclose that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant
- The approximate number of participants involved in the study (locally and in total) is not important to a decision to take part in the research; OR the consent process will disclose the approximate number of participants (locally or in total) involved in the study

#### **V. ADDITIONAL CONSIDERATIONS REGARDING THE INFORMED CONSENT PROCESS**

##### **A. BENEFICIAL**

The benefits to the subject or society must outweigh the risks of participation in the research. All activities must comply with the "Assessing the Level of Risk" policy. See policy. No information can be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents.

- Is the information factual? (E.g., the policy, plan, expectation, or law)
- Does the information avoid stating an outcome? (E.g., something will or will not happen).

##### **B. CONFIDENTIALITY**

The investigator must address to what extent, if any, to which confidentiality of records identifying the participant will be maintained.

- All investigators or key personnel activities must comply with Campus IRB "Privacy and Confidentiality" policies when.
- All activities must comply with governing State, Federal and Local Laws.

##### **C. RESEARCH RELATED INJURY**

The subject has a right to make an informed decision about whether to participate in the proposed research activities. The investigator should address the following to assure the subject understands the risk posed by participation and the process for if a research related injury occurs:

The consent process should disclose if:

- there is a plan to make medical treatments available should injury occur
- compensation is available if injury occurs.

Informed Consent Process  
Policy Number 2876.23

- there is an explanation describing what the compensation is AND where further information may be obtained regarding that compensation
- there is an explanation describing what that the medical treatments involve
- there is an explanation describing where further information may be obtained regarding those medical treatments
- the consent process will disclose whether any medical treatments are available if injury occurs
- there is an opportunity to obtain answers to pertinent questions about the research or the participant's rights
- there is an opportunity to voice concerns or complaints about the research

**D. CONTACT INFORMATION**

The subject has the right to:

1. Obtain answers to questions about the research or their rights as a research participant
2. To voice concerns about the research
3. To voice complaints about the research
4. In the event that the research staff could not be reached or the participant wanted to talk to someone other than the research staff, there is someone to voice concerns or complaints about

**E. PARTICIPATION RIGHTS**

The subject has the following rights of participation in human subject research:

1. Participation is voluntary
2. Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
3. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
4. The Consent Form must not include exculpatory language through which the participant or the representative released or appeared to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**F. LANGUAGE**

**1. STYLE**

The language of the consent document should be in the second person style so the consent form conveys a dialogue with information being provided and that there is a choice to be made by the subject rather than presumption of the subject's consent with the use of the first person style.

**2. COMPREHENSIBLE**

The information provided in the informed consent documents must be in language understandable to the subject. The informed consent document should not include complex language that would not be understandable to all subjects. Technical and scientific terms should be adequately explained using common or lay terminology.

The investigator should ask the following questions to assure the subject comprehends the information given to obtain permission for participation:

- What is the native language that the participants or representatives speak?
- Can the research team communicate in understandable language to the participants or representatives?

Informed Consent Process  
Policy Number 2876.23

- Will written information be in the language understandable to the participants or representatives?
- Is there a translator available for oral or written interpretation of the consent process?
- Provide a copy of the Consent Form to the participant and/or legal representative;
- Seek consent only if the potential subject has the mental and legal capacity to give consent; if not, consent must be obtained by a legal representative;
- Obtain parental or legally authorized permission for minor participants;
- Provide sufficient opportunity to the potential subject or legal representative to consider whether or not to participate;
- Ensure that the possibility of coercion or undue influence is absent;
- Enhance each subject's comprehension of the information; and
- Utilize a consent form appropriate to the age level.
- Provide the subject with a sufficient amount of waiting time between informing the prospective participant about the research and obtaining consent, to encourage optimal comprehension and avoid undue influence.
- Information must be provided in a language understandable to the participant or the legal representative, and without language barriers that haven't been managed.

### **3. EXCULPATORY LANGUAGE**

Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights or releases or appears to release the Investigator, the Sponsor, or The University of Missouri-Columbia from liability for negligence.

### **G. PARTICIPANT QUESTION, CONCERNS, OR COMPLAINTS:**

The Informed Consent process should document procedures implemented to provide the subject with an opportunity to ask questions and voice concerns or complaints to the investigator.

- The Informed Consent process **MUST** provide prospective participants with contact information for a research team in the event they want to ask questions and voice concerns or complaints to the investigator
- The Informed Consent process **MUST** provide prospective participants with contact information for the Campus IRB, as a person independent of the research team, in the event the research staff can't be reached; or the participant wishes to speak with someone other than the research team about question/concern/or complaints about the research team.
- If the PI hosts a website, it should contain this information also.

### **H. COMPENSATION**

Payment or compensation to research participants should not be considered a benefit, but a recruitment incentive. The compensation should not be such that it would be considered coercive or unduly influence subjects to enroll into a study or stay in a study. All information concerning the compensation, including the amount and schedule of payments should be included in the consent document. The compensation should not be contingent upon completion of the study, but should be prorated.

If compensation is class extra-credit, an alternative means of obtaining credit must be made available to the students who wish not to volunteer as a research subject. The alternative means of obtaining credit needs to be comparable in time and effort.

## I. CONFLICTS OF INTEREST

Researchers must comply with the Campus IRB “Conflict of Interest” Policy when conducting human subject research activities.

### WHEN FINANCIAL DISCLOSURES ARE REQUIRED DURING THE CONSENT PROCESS

The Campus IRB must require the disclosure of the following financial interests of investigators and other persons responsible for the design conduct, or reporting of research, and their spouses and dependent children in the Informed Consent Processes:

- Any ownership interest, stock options, or other financial interest related to the research unless it met four tests:
  - Less than \$10,000 when aggregated for immediate family member.
  - Publicly traded on a stock exchange.
  - Value would not be affected by the outcome of the research.
  - Less than 5% interest in any one single entity.
- Any compensation related to the research unless it met two tests:
  - Less than \$10,000 in the past year when aggregated for immediate family.
  - Value would not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.

## VI. THE SHORT FORM: WRITTEN CONSENT

The investigator may propose a short form written consent document, but must meet the following requirements for IRB approval:

- The Investigator(s) shall issue assurance that the elements of informed consent required by 45 CFR 46.116 will be presented “orally” to the subject or the subject’s legally authorized representative.
- There shall be a witness to the oral Consent delivery process.
- The investigator(s) shall provide the Campus IRB with a written summary of what is to be said to the subject or the legal representative.
- The subject or legal representative only has to sign the short form itself.
- The witness shall sign both 1) the short form; and 2) a copy of the summary;
- The person actually obtaining consent shall sign a copy of the summary.
- The subject or legal representative shall be given a copy of the summary, in addition to a copy of the short form.

## VII. THE CONTINUING REVIEW PROCESS

A copy of the *approved* CURRENT Informed Consent document must be submitted as an attachment with the Continuing Review Report, if the investigator intends to keep the project open and collect further data. The IRB will review the proposed Informed Consent and Assent methods in concert with the investigator’s responses

A copy of the consent form is NOT required for activities where there is no active data collection, interaction with subjects, and the only activities remaining involve data analysis.

## **VIII. CONSENT BY MAIL, TELEPHONE, AND INTERNET SURVEYS**

When 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 for the following may be considered:

1. The IRB may approve consents sent by mail in one of two ways:
  - a. The investigator mails the consent document along with a letter requesting participation. The subject signs the consent and returns it with the survey. If the study is anonymous, the consent form is separated immediately upon the opening the package.
  - b. The Investigator sends an Informed Consent Document to the subject which includes a statement that by returning the completed survey, the subject is providing and documenting his/her consent.
2. The IRB may approve telephone consent for survey research. The Investigator must use a script when obtaining consent by telephone (The Investigator must include the script in their IRB submission). The script must contain a comprehensive, succinct, description of the study and include the relevant elements of informed consent in narrative form. (All possible efforts should be made to mail the informed consent document in advance to the subject). The interviewer solicits any questions the potential subject may have and answers them. The Investigator needs to document that the script was read, the individual was offered the opportunity to answer questions and whether the subject agreed to or declined participation in the study. If an Investigator is taping phone conversations with the subject, the interviewer must immediately inform the subject that they are being taped.
3. For anonymous internet-based surveys, it is sometimes appropriate to modify the informed consent process. Subjects would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey and/or clicking on an "I agree" or "I do not agree" button on the website.
4. E-mail Informed Consent: If the IRB determines that some sort of documented consent is required, the IRB may approve a consent sent via e-mail. The consent form is sent e-mail to subjects who then type their name and date into the spaces provided on the consent form, and return it to the researcher via e-mail.

### **USE OF FACSIMILE OR MAIL TO DOCUMENT CONSENT**

The IRB may approve a process that allows the informed consent document to be delivered by mail or facsimile to the potential subject or the potential subject's legally authorized representative and to conduct the consent interview by telephone when the subject or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

## **IX. WAIVER OF THE INFORMED CONSENT PROCESS**

An 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 and the principal risk would be potential harm resulting from a breach of confidentiality. 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.

Informed Consent Process  
Policy Number 2876.23

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

**A. PROCESS TO REQUEST WAIVER**

An Investigator(s) may request that the Campus IRB waive certain requirements of the informed consent process when:

- a. The research involves no more than minimal risk to the subjects, and waiver will not increase the risk; AND
- b. The waiver or alteration will not adversely affect the rights and welfare of the subjects; AND
- c. The research could not practicably be carried out without the waiver or alteration (there is no reasonable alternative, without the waiver); AND
- d. The subject will be given the opportunity to be debriefed immediately after participation.
- e. The investigator must provide the IRB a written description of the information that would be provided to participants.

**X. ADDITIONAL IRB CONSIDERATIONS FOR WAIVER OR ALTERATION OF THE CONSENT PROCESS**

1. The research presents no more than minimal risk of harm to participants
2. The research was to be conducted by or subject to the approval of state or local government officials
3. The research or demonstration project was designed to study, evaluate, or otherwise examine a 1) Public benefit or service program; 2) procedure for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures or possible changes in methods or levels of payment for benefits or services under those programs
4. The research could not practicably be carried out without the waiver or alteration
5. The investigator should consider providing participants with a written statement regarding the research
6. The IRB must document protocol-specific justification for waiver according to the "Record Keeping Process" policy and when applicable, the "Minutes" policy.

**XI. DOCUMENTATION**

**A. INVESTIGATOR DOCUMENTATION**

In order to approve human subject research, Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. Section 46.117 provides:

§46.117 Documentation of informed consent.

(1) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(2) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

- (a) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

Informed Consent Process  
Policy Number 2876.23

(b) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (i) That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (ii) 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. (Approved by the Office of Management and Budget under Control Number 0990-0260.) [56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

The Investigator must give either the participant or the legal representative adequate opportunity to read the consent document before it is sign, and document this process for the record. A copy of the consent document must be given to the signer and documented in the investigator's records.

#### **B. CAMPUS IRB DOCUMENTATION**

When approving research that involves children, the Campus IRB minutes will document the Committee's justifications and findings regarding the determinations stated in Subpart D of 45 CFR 46 or the Committee's agreement with the findings and justifications as proposed. In the case of expedited research, these determinations will be documented in eIRB under the screening tool in the "Comments" section of the file in compliance with the "Minutes" policy and the "Reviewer Checklist". All individuals authorized to access eIRB may review the comments under their user name and password ID. All members receive a copy of the minutes electronically. A copy of all approved IRB Minutes are provided to institutional officials in accordance with the "Reporting" policy to meet the requirements for notification to the organization of IRB findings/actions.

## **XII. MANDATORY REPORTING**

Investigators conducting research under the jurisdiction of the Campus IRB must comply with the (3) tenets of the Belmont Report (beneficence, respect and justice) in protecting human subject participants. The investigator must assure compliance with the Reporting laws of the jurisdiction in which the research will be taking place.

### **A. RESEARCH CONDUCTED IN MISSOURI**

Informed Consent Process  
Policy Number 2876.23

Investigators conducting research in Missouri must comply with the laws of the State of Missouri regarding Mandatory Reporting requirements of Section 210.115.1 (Child Abuse Reporting Statute) of Missouri Revised Statutes.

1. Section 210.115.1 (Child Abuse Reporting Statute) of Missouri Revised Statutes provides that:  
provides that:

“For any research taking place in Missouri in which a mandatory reporter under Section 210.115.1, may obtain reasonable cause to suspect that a child has been or may be subjected to abuse or neglect or observes a child being subjected to conditions or circumstances which would reasonably result in abuse or neglect, that person shall immediately report or cause a report to be made to the division in accordance with the provisions of sections 210.109 to 210.183. As used in this section, the term “abuse” is not limited to abuse inflicted by a person responsible for the child’s care, custody and control as specified in section 210.110, but shall also include abuse inflicted by any other person.”

2. Investigators shall assure that the Consent form includes a statement indicating any reporting limitations on confidentiality.

**B. RESEARCH CONDUCTED OUTSIDE OF MISSOURI**

If the research is to take place outside of Missouri the Principle Investigator will supply the IRB with documentation (such as relevant statutes, regulations, Attorney General’s or other legal opinions by practicing attorneys from the jurisdiction) regarding any mandatory reporting requirements. The Campus IRB may consult with Legal Counsel for review and a determination as to whether the proposed method would provide legally effective consent under applicable law.

**XIII. INFORMED CONSENT PROCESSES FOR SUBJECT SPECIAL PROTECTIONS**

All research activities involving human subjects must comply with the “Informed Consent” policy. The Campus IRB recognizes the following as vulnerable subjects for human subject research purposes. Investigators must comply with the “Recruitment Process” and “Recruitment of Vulnerable Subject Populations” policies if the research will involve any of the following vulnerable subject categories:

**VULNERABLE SUBJECT CATEGORIES:**

- Pregnant Women
- Fetuses and Human In Vitro Fertilization
- Prisoners
- Children
- Cognitively Impaired Persons
- Students, Employees and Normal Volunteers
- Low-Income Persons
- Minorities
- Elderly Persons
- International Persons

**A. PREGNANT WOMEN, FETUSES OR NEONATES**

If research involves pregnant women, fetuses or neonates, the investigator and IRB must assure additional protections are provided as set forth in Subpart B. See “Recruitment of Vulnerable Subject Populations” policy.

**B. CHILDREN**

Section 46.402 of the federal regulations, provides that Subpart D applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services. Section 46.402 of the federal regulations, provides that Subpart D applies to

Informed Consent Process  
Policy Number 2876.23

all research involving children as subjects, conducted or supported by the Department of Health and Human Services. See “Recruitment of Vulnerable Subject Populations” policy for specific guidelines involving the children.

Federal regulations define *Children* as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”

The Campus IRB will ensure that all research involving children complies with the additional safeguards and requirements set forth in Subpart D of 45 CFR 46 . Research involving children will only be approved when the applicable conditions outlined in 45 CFR 46.404 – 406 have been met.

1. Which individuals may consent on behalf of a subject meeting the DHHS definition of “child” when research was conducted in Missouri?

The Campus IRB recognizes that a “child” is any subject who has not attained the legal age for consent to treatments or procedures involved in research. It is the policy of the Campus IRB, in accordance with Missouri law, that for subjects under 18 years of age, their parents, legal guardians, or the legally authorized representatives who may consent on behalf of a child.

2. Which individuals meet the DHHS definition of “child” when research is conducted in other jurisdictions?

If the research is to take place outside of Missouri and is anticipated to involve persons who have not attained the legal age for consent to treatments or procedures under the applicable law in which the research will be conducted, the Campus IRB may consult with Legal Counsel to determine if consent is legally effective. The Principal Investigator will supply the IRB with documentation (such as relevant statutes, regulations, Attorneys General or other legal opinions by practicing attorneys from the research site jurisdiction) regarding how legally effective consent will be obtained. The Campus IRB will consult with Legal Counsel for review and a determination as to whether the proposed method would provide legally effective consent for the “child” under applicable law in the jurisdiction of the research site.

3. In determining who other than parent may consent on behalf of a child to their participation in research, the Campus IRB will take into consideration who under the applicable law of the jurisdiction in which the research will be conducted meets the DHHS definition of a “guardian.” A guardian is an individual who under the applicable law of the jurisdiction in which the research will be conducted is authorized to consent to general medical care on behalf of the child. In instances where research will take place in jurisdictions outside of Missouri (including other states and other nations), the Campus IRB will consult with MU General Counsel to determine the who is authorized to consent to general medical care on behalf of the child within the specific jurisdiction.

4. Additional Information

Enrolling children into research studies presents especially difficult considerations for the IRB’s. The IRB shall determine that the following factors are present to make a case for research in children:

- a. Children differ markedly from adults, and therefore, cannot substitute as alternatives to testing in children.

Informed Consent Process  
Policy Number 2876.23

- b. Lack of appropriate research in children will increase their risk of harm from exposure to practices and treatments untested in this population. In addition, new therapies could not be developed for medical conditions specifically affecting children.
  - c. Research in children requires that the IRB carefully consider consent, beneficence, and justice.
    - i. The determination of risk (possible harms) and possible benefit to the child is at the core of the concept of beneficence when considering research in a pediatric population.
    - ii. The IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has the authority to approve the study.
5. Research that is not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children will be sent to the Secretary of HHS for review. The Secretary will determine the approvability of the research based on the conditions stated in 45 CFR 46.407 (a-b).

6. PROCESS FOR DETERMINATION OF RISK IN CHILDREN:

When reviewing research conducted on children, risk is defined in terms of minimal and greater than minimal risk, and may only be approved by the IRB's as follows:

<b>Risk determination</b>	<b>Benefit assessment</b>	<b>IRB's action</b>
Minimal	With or without direct benefit	Approvable *
Greater than minimal risk*	Potential benefit to child	Approvable *
Greater than minimal risk *	No direct benefit to individual offers general knowledge about the child's condition or disorder	Approvable case-by-case*
Greater than minimal risk**	No direct benefit to child offers potential to, "understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects"	Not approvable**

\* Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances.  
 \* Respect for persons require oral communication with children younger than age 7 about the research and what they will experience to the extent of their development permits.  
 \*\**Special Note:* Approval to proceed with this category of research must be made by the Secretary of the HHS with input from selected experts, and following opportunity for public review and comment.

- Children may be subjects of research only if informed consent is obtained from the parents, legal guardian or legal representative. Children over the age of 7 must agree to participate in the

Informed Consent Process  
Policy Number 2876.23

research and provide assent. When appropriate the researcher and child will sign the form in accordance with the “Child Assent” section of this policy.

- The Campus IRB notes that the “No Child Left Behind Act of 2001” identified 8 categories of protected information for survey, questionnaires, interview materials, or other testing instruments responses:
  1. Political affiliations of student or student’s parents;
  2. Mental or psychological problems of student or student’s family;
  3. Sex behavior or attitudes;
  4. Illegal, anti-social, self-incriminating or demeaning behavior;
  5. Critical appraisals of others with whom students have close family relationships;
  6. Legally recognized privileged or analogous relationships;
  7. Religious practices, affiliations or beliefs of student or student’s parents; and
  8. Income.

NOTE: The Campus IRB mandates that research involving any of the eight identified categories requires Written Parental Informed Consent prior to participation of a child.

#### 7. CHILD ASSENT

Assent is defined as the child’s affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent. In determining whether subjects are capable of assenting, the Investigator and the Campus IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the Campus IRB deems appropriate.

If research involves children as participants, the investigator and Campus IRB must assure additional protections are provided as set forth in Subpart D for the permission of parents or guardians and in compliance with this policy.

- There can be no evidence that some or all of the children is so limited that they cannot reasonably be consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that was important to the health or well-being of the children and was available only in the context of the research.
- If participants lack the ability to consent, the investigator must implement a plan to assure the assessment of the capacity to consent was adequate; and if “assent” is required and adequate.

#### PROCESS TO DETERMINE WHICH CHILDREN ARE CAPABLE OF PROVIDING ASSENT

The Campus IRB must make a determination of which children are capable of providing assent in accordance with the “Application Submission Process”, “CIRB Review Process”, “Recruitment Process”, “Assessing the Level of Risk”, “Assessing Scientific Merit” and “Board Member Procedures” policies

##### Requirements for Assent from children

- a. In accordance with 45 CFR 46.408(a) (the Campus IRB does not have jurisdiction over FDA regulated activities), the Campus IRB must determine that adequate provisions have been made for soliciting the Assent of children when in the judgment of the CIRB the minors are capable of providing Assent. Assent is typically required for children ages seven and older, but may be appropriate for younger children depending on their aptitude and cognitive ability.
- b. The CIRB may determine that Assent is not a necessary condition for approval of the research if:

Informed Consent Process  
Policy Number 2876.23

- i. The capability of some or all of the children is so limited that they cannot reasonably be consulted (When determining capacity to consent, the CIRB will take into account the age, maturity, and psychological state of the minor. This judgment may be made for all children involved in the research or for each child, as the CIRB deems appropriate); OR
  - ii. That the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well being of the children and is available only in the context of the research; or
  - iii. The research meets the required criteria for waiver of consent provided in 45 CFR 46.116(d)(1-4). The Campus IRB does not have jurisdiction over FDA regulated activities.
- c. When the IRB determines that assent is required, the investigator and the child (when appropriate) will sign the consent form to document that the participant has been given a verbal explanation of the proposed research in a language that is appropriate to the child's age, experience, maturity, and condition. The Campus IRB may require that the investigator develop a separate assent form. Such instances will be documented in the meeting minutes. When it is inappropriate to obtain the signature of the child (due to age or ability) either on the consent form or the separate assent form, the Campus IRB requires that the document be signed by the investigator and the parent(s).

Requirements for permission of each child's parent(s) or legally authorized representative

- a. In accordance with 45 CFR 46.408(b) the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent(s) or guardian.
- b. Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a)(1-8) and any additional elements the IRB deems necessary.
- c. The Campus IRB may find that the permission of one parent is sufficient for research to be conducted under the regulations. The determination of whether consent must be obtained from one or both parents will be documented in the meeting minutes or, in the case of expedited research, in the "Comments" and the reviewer checklist.

Waiver of Consent:

The Campus IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

- The research meets the provisions for waiver in 45 CFR 46.116(d)(1-4) or
- In accordance with 45 CFR 46.408(c): The IRB determines that the research is designed for conditions or a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and that 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.
- Permission from parents or legal guardians must be documented in accordance with 45 CFR 46.117.

Research involving children who are WARDS OF THE STATE or any other agency, institution, or entity

- a. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 only if such research is:
  1. Related to their status as wards; or

Informed Consent Process  
Policy Number 2876.23

2. Conducted in school, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.
- b. If the research meets the criteria above, the Campus IRB requires appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one minor. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the minor for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

**C. PRISONERS**

1. If research involves prisoners, the investigator and IRB must assure additional protections comply with the provisions set forth in Subpart C. See "Recruitment of Vulnerable Subject Populations" policy for specific guidelines involving prisoners.
2. If prisoners are participants, the investigator must assure that the subject is literate; if literate, the language of all documents must not exceed the 6<sup>th</sup> grade reading level.
3. If prisoners are participants, the investigator must assure that the subject is literate; if the subject is illiterate the investigator must have measures for an oral translator to communicate information regarding the project and all correspondence and the individual must have no direct involvement with the prisoner.

**D. COGNITIVELY IMPAIRED**

See "Recruitment of Vulnerable Subject Populations" policy for specific guidelines involving the cognitively impaired.

**E. OTHER CATEGORIES OF VULNERABLE SUBJECT POPULATIONS**

Although federal regulations list specific subject categories requiring special protections, other vulnerable groups may include subjects in certain circumstances or activities. The Campus IRB will determine if special protections for these groups are appropriate on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies, state and federal law. See "Recruitment of Vulnerable Subject Populations" policy for specific guidelines involving individuals who may be vulnerable subjects in certain circumstances or activities.

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