I. Purpose

The purpose of this policy is to provide guidelines in preparing, obtaining, documenting, and ensuring ongoing informed consent of individuals participating in human subjects research overseen by the Georgia Regents University Institutional Review Board. It is the Principal Investigator’s (PI) responsibility to ensure that informed consent is obtained for every participant in a research study before that participant begins any aspect of participation in the research unless the IRB has approved a waiver. {45 CFR 46.116, 38 CFR 16.116, and 21 CFR 50.20}

II. Definitions

a. **Assent** – Affirmative agreement to participate in research obtained from an individual who is not of legal age (18 years old) to give informed consent. Assent is obtained in conjunction with permission of the individual’s parents or legally authorized representative. Mere failure to object should not be construed as assent.

b. **Children** – According to the federal regulations, 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.” Under Georgia law, individuals under 18 years of age are considered children.

c. **Parental Permission/Consent** – The agreement of parent(s) or guardian(s) to the participation of their child or ward in research

d. **Legally Authorized Representative (LAR)** – Defined in the federal regulations as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to determine the participation in the research

e. **Witness** – A person who is independent of the research team and cannot be unfairly influenced by people involved with the research, who does not have a coercive relationship with the participant, who attends the informed consent process when the participant or the participant’s legally authorized representative is illiterate or legally blind. A witness is required when using a translated consent.

f. **Information Sheet** – A document that contains all the required elements of informed consent without a signature line. The act of participation is considered consent. Waiver of documentation of consent is required.
g. **Informed Consent** – An ongoing process by which a participant or his/her legal representative voluntarily confirms his/her willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the participant’s decision to participate.

h. **Oral Consent** – Process of obtaining informed consent without the use of a written document.

i. **Waiver of the Consent Process** – waiver of some or all required elements of informed consent for research that meets certain criteria and are not regulated by the FDA. The IRB will make the determination if the research meets criteria for granting the waiver.

j. **Waiver of Documentation of the Consent Process** – waiver of the requirement for the investigator to obtain a signed consent form from participants if the research meets certain criteria. The IRB will make the determination if the research meets criteria for granting the waiver and may require an information sheet be given to participants informing them of the research.

k. **Waiver of HIPAA Authorization** - waiver of research participants’ authorization for use/disclosure of protected health information about them for research purposes (ie: chart reviews). The IRB will make the determination if the research meets criteria for granting the waiver.

### III. Elements of Informed Consent

The elements of informed consent are mandated in the federal regulations in 45 CFR 46.116, 38 CFR 16.116, 21 CFR 50.25. The following elements must be included in the informed consent document/information letter:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant’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 participant;

3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
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4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any medical treatments or compensation 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 participants’ rights, and whom to contact in the event of a research-related injury to the participant; and

8. A statement that participation is voluntary and refusal to participate will not involve a penalty or loss of benefits to which the participant is otherwise entitled, that the participant may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled and that the participant will receive a copy of the signed informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each participant:

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

2. Anticipated circumstances under which the individual’s participation may be terminated by the investigator without regard to the participant’s consent;

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

4. The consequences of a participant’s decision to withdraw from the research and procedures for early and orderly termination of the participant’s participation;

5. A statement 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; and
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6. The approximate number of participants involved in the study.

IV. The consent form should provide research participants with information on how to contact the researchers or research staff in regards to concerns, complaints, questions, or request information about the research study. Standard Options for Consent

Informed consent is an ongoing process by which a participant, their parent or their legal representative voluntarily confirms willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the decision to participate. All research proposals involving human participants or the collection of private data linked to individuals, must address informed consent. The following options are available per federal regulations (OHRP and FDA) and GRU IRB policy.

A. Informed Consent with Signature

This is the default for all studies. The basic elements for informed consent are required for any participant enrolled in research unless some or all the elements are waived. Different consents may be required for different participant types such as parents, controls, prisoners, etc.

B. Information Sheet without Signature

The PI is responsible for submitting request for waiver of the documentation for informed consent to the IRB along with an information sheet/letter. The information sheet (or letter) should include elements for informed consent without a signature line for participants.

C. Waiver or Alteration to Elements of Consent

The IRB is allowed to waive or alter the consent process by determining that the regulatory criteria for waivers or alterations of the consent process are met and that the research is not regulated by the FDA. The IRB documents its findings justifying the waiver or alteration of the consent process.

i. Waiver of Consent Process

Waiver of consent (which includes waiver of the informed consent process and waiver of the documentation of consent) is only granted in specific cases that meet the criteria found at 45 CFR 46.116(d). In order for the IRB to review a request for a waiver of the informed consent process, the investigator must clearly document in the protocol that the research complies with the following elements:
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1) The research involves no more than minimal risk to the subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practically be carried out without the waiver or alteration; and
4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Consent Process – Public Demonstration Project

For public demonstration projects, the following criteria must be met in order for the waiver of consent process (including waiver of parental permission) to be granted:

- The research is conducted by or subject to the approval of state or local government officials.
- The research or demonstration protocol is designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs.
  - Procedures for obtaining benefits or services under those programs.
  - Possible changes in or alternatives to those programs or procedures.
  - Possible changes in methods or levels of payment for benefits or services under those programs.
- The research cannot practicably be carried out without the waiver or alteration.
- The research is not FDA-regulated.

Waiver of the consent process is prohibited for studies that:

- Are FDA regulated
- Conducted or funded by the Department of Defense in which experimental subjects are used (See Research Regulated by Department of Defense)
- Involving non-viable neonates

Waiver of Consent Process – Permission is not a Reasonable Requirement
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For projects in which permission is not a reasonable requirement, the following criteria must be met in order for waiver of the consent process to be granted:

- The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants.
- An appropriate mechanism for protecting the children who will participate as participants in the research is substituted.
- The research is not FDA-regulated.

ii. Waiver of Documentation of Consent

The IRB is allowed to waive the requirement to document the consent process by determining that the regulatory criteria for waivers are met. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the research meets either of the following criteria:

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.

When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants. When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers requiring the researcher to provide participants with a written statement regarding the research. And documents the reason for waiving the requirement to obtain documentation of the consent process.
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This regulation does not involve waiver of the informed consent process. Rather, it involves waiver of the documentation of the informed consent process.

It also allows the investigator to ask the subject if they want documentation to link them with the research and if the subject does not want the documentation, then the requirement for documentation may be waived. When requesting waiver of written documentation of the consent process, the investigator must submit a written description of the information that would be provided to subjects.

Requests for waiver of consent and waiver of documentation of consent are reviewed on a case-by-case basis and are not to be viewed as an option for most research. These exceptions to the requirements are heavily scrutinized by the Committee to confirm that all requirements are met.

iii. Waiver of HIPAA Authorization

The HIPAA Privacy Rule which became effective on April 14, 2003, changed this standard of practice. The Privacy Rule has its own list of criteria that must be met in order to waive a subject's written authorization to use and disclose individually identifiable health information for research.

The following criteria found at 45 CFR § 164.512(i) (2) (ii) are similar, but not identical, to the criteria in the Common Rule.

1. The research involves no more than minimal risk to the privacy of the subjects and the protocol must include, at a minimum, the following elements:
   a) An adequate plan to protect identifiers from improper use and disclosure.
   b) An adequate plan to destroy the identifiers at the earliest opportunity. Identifiers can be maintained if there is a health or research justification or if retention is required by law. The investigator must document such justification.
   c) Adequate written assurances that the identifiable information will not be reused or disclosed except:
      i. As required by law
      ii. For authorized oversight of the research project


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iii. For other research for which the use or disclosure would be permitted

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

3. The research could not practicably be conducted without access to and use of this identifiable information.

The PI is responsible for requesting waiver of HIPAA authorization by submitting the protocol that addresses all three of the requirements outlined above. The PI must include all specific protected health information (PHI) to be collected and its source. The PI must assure that the protected information will not be reused or wrongly disclosed by the researcher. Practically, this item may be satisfied by the investigator stating that the information will only be used as described in the approved protocol, or in an amendment approved in writing by the IRB.

The IRB file is required to contain a “brief description” of the information to which access is requested. Therefore, a proper and clearly written protocol should fulfill this requirement.

**D. Short Form with Oral Translation**

Refer to IRB Policy: Short Form Consent.

**E. Assent**

Studies that involve children aged seven to seventeen must include a separate children’s assent document (CAD) for the children to sign unless waived. This is a simplified version of the consent that is written at a level that the youngest subject can understand. If possible, children under 7 years old should give verbal agreement. It may be appropriate to have more than one CAD for different age levels (i.e., 7-12 and 13-17 years of age). Parental consent may be required.

**F. Parental/Guardian**

The PI must address parental permission when enrolling participants under the age of 18. Parents or legal guardians with parental rights must provide consent for the child unless waived or the child is legally emancipated. The options for consent include an informed consent document with signature
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line(s), information sheet, or partial/complete waiver. Signatures of one or both parents may be required. See Children/Pediatric Research Policy.

V. IRB Review

The IRB determines that:

- The circumstances of the consent process minimize the possibility of coercion or undue influence.
- The information being communicated to the participant or the representative during the consent process will not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant’s legal rights.
- The information being communicated to the participant or the legally authorized representative during the consent process will not include exculpatory language through which the participant or the legally authorized representative releases or appears to release the researcher, the sponsor, the organization or its agents from liability for negligence.
- The required disclosures will be provided to each participant or a legally authorized representative in accordance with legal and regulatory requirements.
- Whether additional disclosures are required for inclusion in the consent process.
- The consent process will be documented according to legal and regulatory requirements.

The IRB determines that the following disclosures are included:

- The alternative procedures or treatment that might be available to the participant, and their important potential benefits and risks.
- That the monitor, the auditor, the IRB, and the regulatory authority will be granted direct access to the participant’s original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the participant or the participant’s legally acceptable representative is authorizing such access.
- The approval of the IRB.
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When participants withdraw from a clinical trial, IRB determines for FDA regulated studies:

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

- The researcher must obtain the participant’s consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.

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

VI. Obtaining and Documenting Consent

A. Personnel Who Can Obtain Consent

An investigator must be approved by the IRB and delegated by the PI in order to obtain consent. Regardless of the professional education of the individual, it is critical that the role and activities of all investigators involved in clinical research studies be defined. The rationale for the following recommendations is based upon the fact that non-physician investigators play a critical role in the initiation of a study and answering subject’s questions in non-medical terms. A higher level of specialty expertise would be expected if the protocol involves decision-making about alternative treatment, particularly if an experimental drug/device is involved than if the study involves more common and/or standard treatments. The PI should indicate which study personnel are obtaining consent in the IRB application at initial submission or at an amendment.

B. Informed Consent Document (ICD)/Children’s Assent Document (CAD)
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For all research that does not involve the VA, the GRU IRB consent/assent templates must be used. If participants include subjects from vulnerable populations, then the appropriate GRU IRB policies should also be followed (i.e., Children, Prisoners, etc.). The consent form VA 10-1086 must be used for VA research. If the research study is sponsored, a copy of the draft should be submitted for sponsor to review prior to submitting to the IRB.

The ICD must be written in a language that the participant and/or legal representative can be expected to understand. The readability of the informed consent document should be written at an eighth grade reading level or lower depending on the targeted population. In general, the document should be written in first or second person avoiding coercive statements such as “you must” or “you will have to”. If the ICD is being used as a parental consent, be sure to state “your child” or “he/she” avoiding excessive use. Language should be as simple and direct as possible without removing key information regarding the study. The CAD should be written at a second grade reading level. First person is strongly preferred for CADs as the child may perceive a CAD written in the second person as a demand. This is a simplified version of the consent written at a level that the youngest subject can understand. If research subjects are minors, but in the age range from 16-18, and the standard consent for the parents’ signature is written at a level they can understand, it may be acceptable to use the single document with both child and parent signing the ICD. The IRB will determine if this is acceptable.

Once the informed consent/assent document is approved by the GRU IRB, an approval stamp is applied in the header to the last page of the document. The stamp includes the IRB number (including the package number), approval date, and expiration date as established by the IRB. The informed consent document expires when the protocol approval period expires at midnight on the date of expiration. If the consent document is amended during the protocol approval period, the consent document will reflect the approval date of the amendment.

Changes to the ICD/CAD

Any modification (e.g., administrative changes, typographical error corrections, clarification issues, etc.) of an IRB approved informed consent document without prior IRB approval is not permitted. The informed consent document must be used in the manner in which it is approved by the IRB. If a change to the informed consent document is
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required then this document must be submitted as an amendment or informed consent document addendum to the IRB for approval before it can be used.

C. Process for Obtaining and Documenting Consent/Assent

i. Standard Consent

Informed consent is more than just a signature on an ICD/CAD but rather an ongoing information sharing process. Consent is to be obtained from the subject or his/her legally authorized representative in circumstances that encourage and preserve the subject's free choice to participate; and the investigator communicates in language that is understandable to the subject.

Once a potential participant indicates an interest in joining a research study, the following must occur:

1. The discussion of the ICD/CAD should occur in a private location prior to the initiation of any study-related procedures.

2. The prospective participant must be legally and individually competent to give informed consent. For incompetent participants, a legally authorized representative, whose primary interest is in the subject’s welfare may provide informed consent for the participant. The guidelines are defined in Code 31-9-2 of the Official Code of Georgia and in VHA 1200.5 as appropriate to the site of study conduct.

3. Using the most current IRB approved ICD/CAD, details are to be presented by the consenting investigator who has been approved by the IRB to consent. The consenting investigator should be knowledgeable about both the study and the IRB requirements of informed consent process. If a witness is required for the study, they must be present during the entire informed consent process.

4. Adequate information is given concerning the research via the IRB approved informed consent document in a language that is as non-technical as possible.
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5. Ample time and opportunity are provided for the potential participant or his/her LAR to inquire about the details of the research project and to decide whether or not to participate in the research, as well as to consider other available options, if applicable. It is acceptable for the participant to take a copy of the informed consent document home to discuss with family/friends if needed.

6. Potential participants or his/her LAR have asked questions and received answers to their satisfaction.

7. It is ensured, to every degree possible, that the potential participant has comprehended the information provided about the research. Ask the participant questions about the study that requires more than a yes/no answer.

8. The potential participant or his/her LAR voluntary consent is obtained by way of a signature on the informed consent document or as otherwise authorized. The participant (LAR/witness, if applicable) and consenting investigator must sign, date, and time in their own handwriting using blue or black ink. The consenting investigator should review the ICD/CAD to ensure that all items have been addressed prior to signing (ie: participant initials

9. Documentation should be provided to the participant about the research that the participant can refer to later. This includes a copy of the informed consent document, calendars, instructions, etc. Note that all materials provided to participants require IRB approval.

10. The original signed ICD/CAD is filed with the other participant related documents in a secure location by the PI.

11. If the participant is a patient of Georgia Regents Medical Center (GRMC), a copy of the ICD/CAD must be placed in the participant’s medical record. The Joint Commission on Accreditation of Healthcare Organizations [TJC; previously known as The Joint Committee on Accreditation of Healthcare Organizations (JCAHO)] requires the information to be placed in the subject’s medical record.
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12. A copy of the signed ICD/CAD must be forwarded GRMC Clinical Research Pharmacy, for their records prior to dispensing drug if using the pharmacy to dispense drug.

13. Document that the informed consent process has occurred. This may be done in the research record via an enrollment note, a narrative note in the medical record, or an entry onto a research worksheet kept in each participant’s research file. The note should be signed and dated by the consenting investigator to verify that the process is correctly documented. If the participant is a patient of GRMC, the enrollment note must be placed in their medical record.

14. Enter the participant’s information into a participant enrollment log.

If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written consent document and any other written information to be provided to participants, is read and explained to the participant or the participant’s legally acceptable representative, and after the participant or the participant’s legally acceptable representative has orally consented to the participant’s participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document. By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant’s legally acceptable representative, and that consent was freely given by the participant or the participant’s legally acceptable representative.

ii. Process for Remote Consent

1. Send the IRB approved informed consent document (ICD) to the site via facsimile or scanned email attachment. The subject must have possession of the IRB approved ICD before the informed consent process is initiated. If duplicating facilities are not available, send multiple documents to ensure
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that the subject retains a copy.

2. Subject and/or subject’s legally authorized representative (LAR) such as a parent/guardian or other reads and receives explanation of the ICD and the study over the telephone line. The potential for loss of confidentiality must be addressed if using a cellular phone.

3. Document that the informed consent process has occurred. This may be done in the research record via an enrollment note, a narrative note in the medical record, or an entry onto a research worksheet kept in each participant’s research file. The note should be signed and dated by the consenting investigator to verify that the process is correctly documented. If the participant is a patient of GRMC, the enrollment note must be placed in their medical record.

4. Enter the participant’s information into a participant enrollment log.

5. The signed ICD(s) should be sent to PI by facsimile or scanned and sent by email. The original signed and dated ICD must be sent to the PI by mail.

6. Upon receipt, the person obtaining consent signs both copies. A copy of the ICD, signed by the investigator authorized to obtain consent, is sent to the subject with a self-addressed, stamped receipt acknowledgement card for the subject to return to the PI. The study may proceed upon receipt of the (faxed or scanned email copy, when applicable) consent.

7. If the participant is a patient of Georgia Regents Medical Center (GRMC), a copy of the ICD/CAD must be placed in the participant’s medical record. The Joint Commission on Accreditation of Healthcare Organizations [TJC; previously known as The Joint Committee on Accreditation of Healthcare Organizations (JCAHO)] requires the information to be placed in the subject’s medical record.

8. A copy of the signed ICD/CAD must be forwarded GRMC Clinical Research Pharmacy, for their records prior to dispensing drug if using the pharmacy to dispense drug.
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ii. Continuing Consent Process and Documentation

The consent process should take place at each protocol visit to ensure that the subject is aware of the research and that they want to continue to participate. This is a verbal confirmation of continuation of consent. Continuing consent should be documented in the research chart and medical record via a research note. If the participant is a patient of GRMC, a copy of this note should be placed in the participant’s medical record.

iii. Re-Consent of Subjects

Once a subject has enrolled in a study by signing the IRB-approved consent document, there are circumstances when researchers are required to re-consent them:

- Protocol amendments that affect the risk/benefit ratio (ie: investigational drug found to cause liver failure that was not known at the time the participant consented)
- Additional research procedures/tests added (ie: additional blood draw)
- The IRB or sponsor/funding agency specifically requests re-consent of subjects
- A minor enrolled in a study reaches the age of legal majority
- Any other circumstance that may affect the participant’s willingness to continue in the study

If re-consent is required, the site must have a new version of the consent document and/or children’s assent document approved by the IRB before the subjects are re-consented. When re-consent occurs, the site must document the reason why the re-consent was required in the subject’s record via a research note.

iv. Remote Consent

IRB approval for obtaining informed consent from a remote site is considered on a case-by-case basis. Only those studies that qualify for, and obtain prior written IRB approval for remote informed consent, are eligible for this policy.
v. Illiterate Subjects

If a written informed consent document [21 CFR 50(b) (1)] is used, then the PI or authorized Sub-I to obtain informed consent reads the consent to the subject in the presence of an identified witness (with the subject).

Non-English Speakers

Individuals may not be excluded from a study based on their inability to speak, read, or write English. Justifications for exclusion of non-English speakers must be included in the IRB application. Subjects who do not speak English must have all written documents written in their native language (21CFR 50.20) to include an IRB approved consent documented translated into the subject’s language by a certified translator (certification documentation is required). The subject must be given a copy of the translated ICD. An interpreter in the subject’s native language must assist with the discussion. Please note: ad hoc translation may not replace the written document. There are provisions for use of Short Form Consent in certain circumstances (see IRB Policy: Short Form Consent).

VI. IRB Policies with Additional Informed Consent Requirements

The following policies list specific information that is required for consenting subjects. Please refer for any additional items that may be applicable.

- Research Regulated by the Department of Justice
- Research Regulated by the Department of Defense
- Human Subjects Research Conducted at the Charlie Norwood VA Medical Center
- Research Conducted in Public School Setting
- Pediatric Research
- Cognitively Impaired
- Illiterate Subjects
- Pregnant Women
- Research Involving Prisoners
- Diminished Capacity
- Emergency Use