

**The Carle Foundation  
IRB Policy 701**

<b>Subject</b>	General Requirements and Documentation of Informed Consent				
<b>Approval</b>	Dec 2006	<b>Review</b>	Mar 2010	<b>Revision</b>	March 2010
<b>Purpose</b>	To provide guidance in obtaining and documenting Informed Consent applicable to all research under the jurisdiction of the Carle Institutional Review Board (Carle IRB).				

**Statement of Policy**

1. Except as described in Carle IRB 702 policy, no Investigator may involve a human being as a research subject unless and until the Investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Informed consent is an ongoing process. Unless documentation requirements are waived, the Carle IRB requires documentation of informed consent by use of a written informed consent form approved by the Carle IRB and signed and dated by the subject or the subject's legally authorized representative. No changes will be made in the information provided during the informed consent process, or to the informed consent document, without prior Carle IRB approval.

**Specific Policies**

1. **Principles of Informed Consent.** The purpose of informed consent is to assure that research subjects voluntarily agree to participate in research, after having been provided the information needed to make an informed and voluntary decision.

**Informed Consent Process**

- When research interventions include medical treatments, or when the research is intended to evaluate the efficacy of an intervention in diagnosis or treatment of disease, a physician who has been trained on the protocol shall provide to the potential subject the relevant medical information, including procedures/interventions which are experimental and alternative modes of diagnosis or treatment.
- When the subject of research or the research interventions are non-medical, but relate to areas of professional expertise, such as psychological research, an appropriately trained professional with expertise in the subject matter of the research will be responsible for describing the research, including procedures/interventions which are experimental and alternative means of managing the problem being studied.
- Within limits set by the investigator, study personnel may answer questions posed by the subject or the subject's representative. Once study personnel have provided information regarding the study, they may obtain and document consent following appropriate procedures.

2. **Required Elements of Informed Consent.** The following elements must be covered in the oral discussion regarding consent, and included in the written documentation of consent:
  - a. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. Where applicable, any ancillary studies should be noted and distinguished from the primary study.
  - b. A description of any reasonably foreseeable risks or discomforts to the subject.
  - c. A description of any benefits to the subject or to others that may reasonably be expected from the research.
  - d. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
  - e. A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA and other regulatory agencies may inspect the records.
  - f. For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, whether compensation for injury treatment will be provided, or where further information may be obtained.
  - g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
  - h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
  - i. Any compensation payable to study participants shall be clearly described in the informed consent, and shall not be so excessive as to be coercive.

## Specific Policies (cont.)

3. **Additional Elements.** When appropriate, one or more of the following elements of information shall also be provided to each subject:
- 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.
  - The approximate number of subjects involved in the study.
  - As applicable, an explanation that blood or other specimens obtained in the study may be retained and used for future research (separate consent should be designated).
  - The Carle Disclaimers.** The following provisions/statements must be included in each written informed consent, unless the IRB directs revisions:

### **What About Confidentiality?**

- We respect your right to keep your information private. We cannot promise complete confidentiality. People who may look at your information include the Investigator, research staff, members of the Institutional Review Board (a committee that oversees human subject protections at Carle Foundation Hospital), and representatives of the Sponsor of the research. Your information may also be seen by government employees, such as representatives of the FDA or the Office for Human Research Protections at the Department of Health and Human Services. Other officials, such as state health officials, may also need to see your information.
- To help assure quality in research, quality assurance and compliance employees of Carle Foundation Hospital [and the Investigator] may also have access to your information. Employees who work to assure quality and compliance protect the confidentiality of your information unless disclosure is required by law.
- We will keep records that include your information safe, and will put them in locked cabinets when they are not being used. If records that include your information are put on computers, we will use reasonable actions to keep those computers secure.
- Once your information is no longer traceable to you, we may share your information with other researchers.
- Your information will be combined with information about other people participating in the study to be analyzed. Your name will not be used when we publish results. Information from the study will be reported in a way that combines the results of many participants. If possible, we will replace identifiable information about you, such as your name or birth date, etc., with number codes that cannot be connected to you. Only research staff will have access to the key that connects the number code to your identifiable information.

### **What Are the Costs?**

- Taking part in this study may lead to added costs to your or your insurance company. Please ask about any expected added costs or insurance problems.
- In the case of injury or illness resulting from this study, emergency medical treatment is available. It will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury or other problems.
- You or your insurance company will be charged for continuing medical care and/or hospitalization.
- You will receive no payment for taking part in this study.  
*[If appropriate:]*
- If, during the study, the **STUDY DRUG** becomes commercially available, you may have to pay for the amount of drug needed to complete the study.

### **What Are My Rights as a Participant?**

- Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.
- You will be informed about new information that may affect your health, welfare, or willingness to stay in this study.
- There are no plans at this time by Carle Foundation Hospital, the Investigator, or any Sponsor of this study to compensate you if the research results in the development of any drug, device or other article which can be

## Specific Policies (cont.)

sold, even if your blood or tissues were the basis of the discovery, or if the discovery would not have been made if you had not agreed to participate in the study.

### Who Do I Call If I Have Questions Or Problems?

- For questions about the study or a research-related injury, contact the researcher **NAME(S)** at **TELEPHONE NUMBER**.
  - For questions about your rights as a research participant, contact the Carle Institutional Review Board (a group of people who review the research to protect your rights) at 217/383-4366.
- i. **Other Other Requirements.** Additional informed consent requirements may apply, such as ethical requirements of professional societies. Informed consent must comply with all applicable legal and ethical requirements.
  - j. **Signature Line for a Witness.** The signature of a witness is not required for a full consent when the subject is alert and oriented. A witness is recommended if a subject has demonstrated or demonstrates a potential for confusion, is ill, or disoriented. If present the witness signature line must include an explanation of the capacity of the witness (witness to entire consent process; witness to signature).
4. **Documentation of Consent.** All consent to participate in research studies conducted at Carle Foundation Hospital must be documented, unless the Carle IRB waives documentation. The Investigator may only use the consent form currently approved for that study by the Carle IRB. The Carle IRB may approve the use of a full written consent form, or a short form:
- a. A written consent document that embodies the elements of informed consent described in 21 CFR 50.25 and 45 CFR 46.116(a). This form may be read to the subject or the subject's legally authorized representative, but, in any event, the Investigator shall give the subject (or legal authorized representative) adequate opportunity to read it before it is signed. The subject or legal authorized representative must also be given a copy of the signed and dated form. When the Investigator has reason to believe that a written consent form in English will not be understood by the subject (or legal authorized representative), either because English is not the subject's first language or for other reasons, the Investigator shall make available to the subject (or legal authorized representative) a written consent form in a language understandable by the subject or legal authorized representative, as the case may be. The translated informed consent form must be prepared by a qualified translator and approved by the Carle IRB. A certification of the translation process by the qualified translator must be submitted to the Carle IRB with the translated document.
  - b. A "short form" written consent document stating that the elements of informed consent as required above may be approved by the Carle IRB. When the short form consent document has been authorized, the subject (or legal authorized representative) must be told orally all of the information necessary for informed consent, as described above. A witness must observe the oral presentation. The Carle IRB must approve the short form consent and a written summary of what is to be said to the subject (or legal authorized representative). The Carle IRB may authorize the use of the full informed consent form approved for the study as the written summary. The subject (or legal authorized representative) signs only the short form itself. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject (or legal authorized representative) in addition to a copy of the short form. In the event the subject (or legal authorized representative) is not fluent in English, the person obtaining consent should be assisted by a translator who is fluent both in English and in the language spoken by the subject (or legal authorized representative). The translator may sign as the witness.
  - c. Except in unusual circumstances, the Investigator should not rely on a family member to provide translation services. A professional translator who is skilled in translating medical information should be used. If the data is expected to be submitted to the FDA, the Sponsor should provide an Affidavit of Accuracy with the translated consent form.
  - d. A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If the person (1) retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document attesting to the subject's voluntary consent. A video tape recording of the consent interview is recommended.
5. **Other Requirements**
- a. **Second Person.** The use of "I understand" and other first-person language may be viewed as suggestive or coercive. The language of the consent document should be in the second person style so the consent form provides information in an educational manner. There should be a choice made by the subject rather than presumption of the subject's consent, which can be suggested with the use of the first person style.

## Specific Policies (cont.)

- b. **Language Should Be Simple.** The information provided in the informed consent documents must be in a language and at a level 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. Software or other analytical methods shall be used to evaluate the complexity of the language in the informed consent when appropriate. All reasonable efforts will be made to keep the explanatory language at an eighth grade reading level. However, it is recognized that the inclusion of names of investigators, pharmaceutical companies, position titles, drug names, titles of protocols, etc. may be deemed necessary in the consent form. If that is the case, that information may be included without further consideration to the grade level of those sections. In addition, the use of standard language approved by the Carle IRB regarding confidentiality, financial considerations, participant rights, and contact information, is permitted without further consideration of the grade level of that language.
  - c. **Translation Requirements.** When studies involve non-English speaking subjects, it is the Principal Investigator's responsibility to ensure that the subjects are provided with consent form (short or long version as deemed appropriate by the Carle IRB), information sheets and study summary translated in a language understandable to the subject or his/her legally authorized representative. The Carle IRB will also determine if other documents (e.g. recruitment flyers etc.) need to be translated. All such translated documents and their original English versions must be approved by the Carle IRB before being used in the study. The translated versions after consenting are signed by the subject. The English versions are signed by the person administering the consent and both translated and English versions of documents are signed by the interpreter present during consenting.
    - *Note: Carle Foundation Hospital) Case Management (Phone: 217-383-3092) can assist in translation services and or will assist in working with a translation service contracted by Carle Foundation Hospital.*
  - d. **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 Carle Foundation Hospital from liability.
  - e. **FDA-Regulated Test Articles.** For all research involving test articles regulated by the FDA, informed consent documents must include a statement that the study involves a test article that has not been approved by the FDA, and that the purpose of the study includes evaluation of both the safety and the potential effectiveness of the test article. The consent form must also include a statement that the FDA may have access to the subject's medical records for the purposes of study review, evaluation and oversight.
  - f. **Competency.** In the case of research involving subjects who may be cognitively impaired, the investigator must propose adequate procedures for evaluating the mental status of prospective subjects to determine whether they are capable of consenting. IRB Reviews Requiring Special Consideration Policy 501 Vulnerable Populations addresses research involving cognitively impaired individuals.
6. **Documentation of Informed Consent.** Each subject or his/her legally authorized representative must sign and date a copy of the current Carle IRB-approved consent form prior to enrollment or any participation in any phase of the study, or otherwise indicate consent as described in this Policy, unless the requirement is waived by the Carle IRB. The subject must also be given a copy of the signed and dated document. The IRB may approve procedures for documentation of informed consent that involve (a) a written consent form signed by the subject; (b) a short form written consent form with oral presentation; or (c) in limited circumstances, waiver of signed written consent form. Each of these three options is described in detail below. It is the responsibility of the IRB to determine which of the procedures described below is appropriate for documenting informed consent in protocols that it reviews. Generally, the Carle IRB expects that a written consent form will be signed by the participant or the participant's legal representative.
- a. Written consent form signed by subject or legally authorized representative. In most circumstances, the Carle IRB should require that informed consent is documented by the use of a written consent form approved by the Carle IRB and signed by the subject or the subject's legally authorized representative. The Investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document must be given to the person signing the form.
  - b. The written informed consent document should embody, in a language and at a reading level understandable to the subject, all the elements necessary for legally effective informed consent (see above).
  - c. Subjects who do not understand English should be presented with an informed consent document written in a language understandable to them.
  - d. The signature of a witness is not required for a full consent when the subject is alert and oriented. A witness is recommended if a subject has demonstrated or demonstrates a potential for confusion, is ill, or disoriented. If present, the witness signature line must include a description of what is being witnessed. Examples of the description may include, but are not limited to: a statement that the witness is observing the entire consent process, or a statement that the witness is only observing the study participant's signing of the informed consent.

## Specific Policies (contd)

7. **Oral Presentation Using Short Form.** As an alternative to standard written informed consent documents, oral presentation of informed consent information may be used.
- In such cases, the subject must be provided with both:
    - A short form written informed consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative; and
    - A written summary of the information that is presented orally.
  - A witness to the oral presentation is required. The witness must sign both the short form written informed consent document and a copy of the written summary.
  - The subject or the legally authorized representative must sign the short form written consent document.
  - The person obtaining consent (e.g., the Investigator) must sign a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.
  - Subjects who do not speak English: Where informed consent is documented using this short-form procedure for non-English speaking subjects, the written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written informed consent document should be in a language understandable to the subject; (ii) the Carle IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.
  - The IRB must receive all foreign language versions of the short form document as a condition for approval.
8. **Observation and Monitoring of the Informed Consent Process.** The Carle IRB may determine at any time that it wishes to observe the consent process. For example, at the time of initial protocol review, the Board may determine that although the risk/benefit determination allows for consenting of potentially cognitively impaired adults, additional safeguards may be instituted to protect the rights and welfare of subjects. In this situation, the Carle IRB may delegate the administration or observation of the consent process to a qualified third party. Studies involving subjects who are decisionally impaired may take place over extended periods. The Carle IRB should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The Carle IRB may require that Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the Carle IRB should consider whether, and when, it should require a reassessment of the subject's decision-making capacity.
9. **Waiver of Informed Consent or Waiver of Documentation of Consent.** See IRB Informed Consent Policy 702 Waiver of Informed Consent or Waiver of Documentation of Consent.
10. **Special Approaches to Documentation of Consent**
- Use of Facsimile or Mail to Document Informed Consent.** The Carle 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.
  - Consent by Mail: 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, the Carle IRB may approve consents sent by mail in one of two ways:
    - The Investigator mails the consent document along with the survey. The subject signs the consent and returns it with their survey. If the study is to be anonymous, the consent form is mailed back separately, or is separated from the data immediately upon the opening the package.
    - The Investigator sends a letter requesting participation along with the survey to the subject. The letter should include a statement that by returning the completed survey, the subject is providing consent.
  - Telephone Consent.** The Carle IRB may approve telephone consent for survey research. The Investigator must use a script approved by the Carle IRB when obtaining consent by telephone. 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 or fax the informed consent document in advance to the subject). The interviewer solicits any questions about the research the potential subject may have and answers them. The Investigator needs to document that the script was read, that the individual was offered the opportunity to ask questions, and whether the subject agreed or declined to participate in the study. If an Investigator is taping his/her phone conversations with the subject, the interviewer must immediately inform the subject that they are being recorded.

**Specific Policies (contd)**

- d. **Internet Surveys.** For anonymous Internet-based surveys, it is sometimes appropriate to use implied informed consent. 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.
- e. **E-mail Informed Consent.** If the Carle 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 via 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.
- f. Any use of alternative forms of informed consent must be carefully structured to provide security and confidentiality to study participants. It is not anticipated that any of these alternative forms of consent will be used if the Investigator interacts in person with the research participant.

**Reference**

21 CFR 50, 45 CFR 46.116(c) and (d), 45 CFR 46.116, and 45 CFR 46.117  
"Guidance for Writing Informed Consent Documents" ([ohsr.od.nih.gov/info/sheet6.html](http://ohsr.od.nih.gov/info/sheet6.html))  
Carle Foundation Hospital Policy 115- Foreign Language Interpreters

**Electronic Approval On File**

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