

**The Carle Foundation  
IRB Policy 702**

<b>Subject</b>	Waiver of Informed Consent or Waiver of Documentation of Informed Consent				
<b>Approval</b>	Dec 2006	<b>Review</b>	Jun 2009	<b>Revision</b>	Jun 2009
<b>Scope</b>	These policies and procedures apply to all research under the jurisdiction of the Carle IRB.				
<b>Purpose</b>	To provide guidance in granting Informed Consent Waiver or its documentation.				

**Statement of Policy**

1. The IRB recognizes that there may be exemptions to requirements for informed consent and/or documentation as follows:
  - a. **Waiver of Informed Consent.** In certain circumstances, the IRB may waive the requirement to obtain informed consent only if the Board finds that the research meets specific criteria that are in accord with the provisions of 45 CFR 46.116(c) and (d), 21 CFR 50.23 and 24.
  - b. **Alteration of Elements of Informed Consent.** The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (such as written documentation). 45 CFR 46.116(c) and 117(c).

**Specific Policies**

1. **Waiver of Informed Consent**
  - a. The IRB shall require that informed consent be obtained and documented prior to initiation of study procedures except in the following emergency situations:
    - **Research in Emergency Settings.** Obtaining informed consent shall be deemed feasible except in certain emergency situations where the Investigator has adequately documented the necessary exception under guidelines described in IRB Reviews Requiring Special Consideration Policy 502 Special Categories of Research.
    - **Review of Emergency Use of an Investigational Article.** Obtaining informed consent shall be deemed feasible except in certain emergency situations where the Investigator has adequately documented the necessary exception under guidelines described in IRB Reviews Requiring Special Consideration Policy 502 Special Categories of Research.
  - b. In other research, the IRB may only waive the requirement to obtain informed consent provided the Board finds and documents that the conditions listed at 45 CFR 46.116(c) and (d) are met.
2. **Alteration or Waiver of One or More Elements of Informed Consent**
  - a. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent if the provisions found at 45 CFR 46.116(c) and (d) apply.
3. **Waiver of Documentation of Informed Consent**
  - a. The IRB may waive documentation of informed consent for some or all subjects as follows:
    - The protocol demonstrates 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;  
**Note:** When the IRB waives the requirement for documentation under this condition, each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
    - 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.

**Reference**

45 CFR 46.116(c) and (d), 45 CFR 46.117(c), 21 CFR 50.23 and 24

**Approval On File**

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