

# The Carle Foundation

## IRB Policy 402

<b>Subject</b>	Initial Review – Criteria for IRB Approval		
<b>Approval</b>	Dec 2006	<b>Review</b>	Apr 2011
		<b>Revision</b>	Apr 2011
<b>Scope</b>	This policy applies to all research submitted to the Carle IRB.		
<b>Purpose</b>	To state the criteria according to which the Carle IRB conducts initial review of research proposals.		

### Statement of Policy

1. All research studies under the jurisdiction of the Carle IRB intending to enroll human subjects must be reviewed and approved by the Carle IRB before study-related procedures can begin. The criteria by which the IRB reviews research studies are based on applicable HHS and FDA regulations, as well as the principles of justice, beneficence and autonomy as discussed in the Belmont Report. In addition, certain other criteria that are unique to The Carle Foundation's system may apply and must be met.

### Definitions

**Human Subjects Protection Office (HSP)** – Human Subjects Protection office at Carle, which supports the Carle IRB administratively.

**Institutional Review Board (IRB)** - Means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

**Principal Investigator** – The investigator/ researcher who is responsible for the conduct of a research study at an institutional site.

**The Carle Foundation** – Includes all legal entities part of The Carle Foundation such as Carle Foundation Hospital, Carle Physician Group, Mills Breast Cancer Institute, and Carle Cancer Center.

### Criteria for IRB Approval

1. **Minimal Criteria for Approval of Research** – In order for a research project to be approved, the Carle IRB must find that:
  - a. Risks to Subjects are Minimized
    - By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
  - b. Risk Assessment – Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
    - In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits that fall within the purview of its responsibility
  - c. Selection of Subjects is Equitable
    - In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons. ([IRB Reviews Requiring Special Consideration Carle IRB Policy 501 Vulnerable Populations](#)).
  - d. Unless waived by the IRB, 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 appropriate local, state and federal regulations.
  - e. Informed consent will be appropriately documented as required by local, state and federal regulations.
  - f. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
  - g. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

## Criteria for IRB Approval (cont.)

- h. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.
- i. Studies are reviewed at periods appropriate to the degree of risk research subject are exposed to due to their participation in the study, but at least annually.

### 2. IRB Review of Clinical Investigations Involving Drugs, Devices, and Biological Products

Research involving the use of drugs, devices, and/or biological products may only be implemented after the Carle IRB reviews and approves that research in accordance with the above criteria, as well as any applicable FDA regulations (including, but not limited to 21 CFR 50, 56) and Carle IRB Policy 409—Clinical Investigations Involving Drugs, Devices, and Biological Products.

### 3. IRB Review of Humanitarian Use Devices (HUD)

A Humanitarian Use Device (HUD) can be used only after the Carle IRB reviews and approves its use in accordance with the above criteria, as well as the FDA's 21 CFR 814 Subpart H and Carle IRB Policy 411—Humanitarian Use Device.

### 4. Other Criteria

- a. The IRB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the IRB at a convened meeting and follow Carle IRB Policy 408: Verification from Sources Other Than the Principal Investigator That No Material Changes Have Occurred to IRB-Approved Research. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

The criteria used to determine whether third-party verification is required may include:

- Investigators that conduct studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Investigators that conduct studies that involve large numbers of subjects, and
- Investigators selected at the discretion of the IRB.
- Projects that need third party verification from sources other than the Investigator that no material changes have occurred since previous IRB review is determined, will have such assessment performed as necessary.

- b. The IRB may require that the Investigator attend the IRB meeting.

### 5. Use of Consultants

The IRB Chairperson can request individuals with particular expertise in matters under review to provide information to the IRB relevant to consideration of the research in question.

### 6. Permitted IRB Actions

- a. The IRB may approve as submitted, require changes, table, or disapprove a research project. If the research project is approved, a letter will be sent to the Investigator indicating approval, and specifying the requirements for continuing review. Informed consent documents will be dated as of the date of IRB approval. All IRB actions will be communicated to the Investigators in writing.
- b. The IRB shall advise the Investigator of any changes or additional information required prior to approval. Changes or additional information shall be reviewed by the convened IRB, unless the change(s) requested are minor, in which case the Chairperson or an IRB member designated by the Chairperson may review submitted changes and approve them.
  - The IRB may decline to approve a research project. If the IRB declines to approve a study, the Principal Investigator must so advise the Sponsor, and any other IRBs which are currently exercising oversight, or whose approval of the project is sought. (IRB Review of Research Policy 406 Categories of Action)

## References

21 CFR 50

21 CFR 56

21 CFR 814 Subpart H

45 CFR 46.111

Carle IRB Policy 406: Categories of Action and Communication the Carle IRB's Decision to the Principal Investigator

Carle IRB Policy 408: Verification from Sources Other Than the Principal Investigator That No Material Changes Have Occurred to IRB-Approved Research

<b>References (cont.)</b>
Carle IRB Policy 409—Clinical Investigations Involving Drugs, Devices, and Biological Products Carle IRB Policy 411—Humanitarian Use Device Carle IRB Policy 501 Vulnerable Populations
<b>Electronic Approval on File</b>

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