

# The Carle Foundation

## IRB Policy 1102

<b>Subject</b>	Recruitment Materials for Human Subject Research		
<b>Approval</b>	Apr 2008	<b>Review</b>	Apr 2010
<b>Purpose</b>	This policy informs the Carle Institutional Review Board (Carle IRB) reviewers of the standards established for the submission and review of recruitment materials, and informs the investigators of the expectations of the Carle IRB when reviewing recruitment materials.		

### Statement of Policy

1. Recruitment materials (e.g. advertisements, flyers, phone scripts, newspaper ads, radio and television announcements, bulletin board tear-offs, Internet postings, and posters) are part of the informed consent process and the subject selection process. As such, the Carle IRB must review and approve all recruitment materials prior to their use by an investigator.

### Specific Policy

1. When to Submit Recruitment Materials to the Carle IRB
  - a. Advertising for research subjects is considered part of the informed consent process. As such, recruitment materials must be submitted to the Carle IRB with the research protocol for initial review.
  - b. If the investigator decides at a later date to use recruitment materials or to change currently approved materials, the new/modified materials must be submitted to the Carle IRB for review as a modification to the research protocol.
2. Format and Use of Recruitment Materials
  - a. Recruitment materials are evaluated for visual impact (e.g. size, type face, size of print, graphics), context, and use. Materials should be submitted to the Carle IRB in their final format and be accompanied by a description of how the materials will be used (i.e. clinic staff will hand flyer to patients, advertisement will be published in local newspaper, flyers will be placed in the waiting room).
  - b. For recruitment materials that are to be recorded for broadcast, transcripts must be submitted for review and approval. The final recorded message may be approved via expedited procedure.
3. Content Restrictions
  - a. Recruitment material may not unduly influence potential subjects.
  - b. Recruitment material may not promise a cure or other benefits beyond what is set forth in the informed consent document and the research protocol.
  - c. If an investigational drug, device or service ("test article") is used in the research, this must be disclosed. No claims may be made (explicitly or implicitly) that the test article is safe or effective for the purposes under investigation, or that it is known to be equivalent or superior to any other drug, device or service.
  - d. Recruitment materials may not use the terms "new treatment," "new medication," or "new drug" without explaining that the test article is investigational, i.e. not approved by the FDA.
  - e. Recruitment materials may not promise "free medical treatment" without also disclosing if there may be costs to the subjects.
  - f. Recruitment materials may state that subjects will be compensated or reimbursed, but specific dollar amounts should not be a major feature of the advertisement.
4. Items that Must Be Included in Recruiting Materials
  - a. A description of the type of research (i.e. clinical trial) and purpose of the research. The word "research" must be included in this description.
  - b. Contact information for the person and/or office to contact for additional information.
  - c. The Carle IRB research study number.
  - d. The name of the institution responsible for the research.
5. Information that Must be Included in Recruiting Materials
  - a. The title of the research
  - b. The sponsor of the research
  - c. Where the research is being performed (specific location) (i.e. Carle Cancer Clinic).
  - d. In summary form, the criteria that will be used to determine eligibility for participation in the research.
  - e. A brief description of the time commitment and duration of the subjects' participation.
  - f. A brief description of the benefits of the research to the subjects, if any (e.g., smoking cessation).

## Specific Policy (cont.)

- g. The Principal Investigator's name and contact information.
  - h. The compensation/ reimbursement that may be provided.
6. Electronic Medical Records (EMR) use for identifying prospective study subjects: The EMR(s) may be used to help identify prospective patients for research studies.
- a. Upon approval of the study by the Carle IRB, the inclusion and exclusion criteria for the study will be programmed into the EMR.
  - b. During the course of providing medical care, the appropriate caregiver (provider or nurse depending on the nature of the study) will be notified electronically if the patient potentially could qualify for the study.
  - c. The caregiver may, at their medical or nursing discretion, discuss the opportunity to participate in the trial with the patient.
  - d. The patient's decision, on whether to receive further information or not, will be relayed to the research coordinator for that research study.
  - e. If the patient agrees to be contacted to receive more information on the study, the research coordinator will arrange a time to meet with the patient and begin the recruitment/consenting process.
  - f. If the patient does not wish to learn more about the study or declines to participate in the study, the research coordinator will update the patient's record so that future caregivers will not receive the notification as described above in (b).
7. The Carle IRB recommends that study protocols intending to use EMR will have the following, or similar, language inserted in the recruitment section of the protocols.
- "The EMR will be used to identify prospective patients for this study. Patients who could potentially qualify for this study will be identified and their physician or nurse will be notified. A member of the Carle Foundation Hospital workforce may ask a patient if he/she is interested in being contacted by study personnel to learn more about a research project and to possibly participate in the study. The patient's preferences will be relayed to the research coordinator who will either contact the patient if the patient is interested in participating, or indicate in the chart that the patient does not wish to participate."
8. What Does Not Require Carle IRB Review
- a. Medical society newsletters.
  - b. News stories (i.e. public service announcements).
  - c. Publicity intended for other audiences, such as financial page advertisements directed towards prospective investors.

## Related Links

[IRB Organization Policy 202 Duties of IRB Members](#)

[IRB Functions and Operation Policy 301 Research Submission Requirements](#)

## Electronic Approval On File

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