

# The Carle Foundation

## Research Policy 111

<b>Subject</b>	Definition of Human Subjects Research		
<b>Approval</b>	Nov 2010	<b>Review</b>	Jun 2011
		<b>Revision</b>	Jun 2011
<b>Purpose</b>	<p>To offer guidance on activities that would be defined as human subjects research, and ensure that any research activity conducted at The Carle Foundation is correctly identified as such. Other obligations, as described under other research policies and procedures, are triggered if human subjects research is being conducted.</p> <p>To assist in determining whether a proposed project should be classified as human subjects research. The investigator should contact the Research Department which can assist with determining whether the activity constitutes human subjects research.</p>		

### Statement of Policy

1. It is the responsibility of all staff to contact the Research Department regarding whether a proposed research activity constitutes human subjects research mandating Institutional Review Board (IRB) review and approval.
2. It is the responsibility of all staff to have a clear understanding of which activities are defined as human subjects' research. This is necessary to ensure that all such research is properly identified and submitted to the appropriate departments and designated IRB for review and approval.
3. All human subjects research conducted at The Carle Foundation must be submitted to an approved IRB for review. Approval must be received before any research activity is initiated. Failure to comply with this or any Carle policy can result in termination of research privileges; see IRB General Administration Policy 101 Compliance with Policies and Procedures Mandate.
4. The IRB of record is not intended to infringe on non-research activities, including the practice of medicine, quality improvement activities, case study educational activities, or other activities clearly falling outside the definition of research for IRB purposes. If the Principal Investigator is unsure whether a proposed activity constitutes research, he or she should contact the IRB and ask for assistance with this determination. The IRB of record has final authority in this determination.

### Definitions

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

**Engaged in Research** – In general, The Carle Foundation is considered engaged in human subjects research when its employees or agents for the **purpose of the research** project obtain:

1. Data about the subjects of the research through intervention or interaction with them;
2. Identifiable private information about the subjects of the research; or
3. The informed consent of human subjects for the research.

**Generalizable Knowledge** – New information that has relevance beyond the study population or program, information that is added to scientific literature, or knowledge that is systematically collected with methods that reduce bias (such as randomization and controls). A purpose of the study will be to inform individuals outside of the study population or program of the results.

**Human Subjects Research** – Research involving “human subjects” means any activity that either:

1. Meets the HHS definitions of “research” and “human subjects” (45 CFR 46.102 (d) and (f)); **or**
2. Meets the FDA definitions of “research” and “human subjects” (21 CFR 50.3, 21 CFR 56.102(e), and 21 CFR 812.3(p).

**Individually Identifiable Private Information** – Private information or specimens that can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. The identity of the subject about whom the private information pertains or may readily be ascertained by the investigator or associated with the information.

**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.

**Interaction** – Includes communication or interpersonal contact between investigator and subject.

**IRB Approval** – The determination of the IRB that the research/clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**Research Department** – All research at The Carle Foundation including, but not limited to, the Research Institute and the Cancer Research Office.

**Human Subject** – A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

## Definitions (cont.)

**Intervention** – Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to obtain the information to constitute research involving human subjects.

**Private Information** – Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**Research** – A systematic investigation, inquiry, or analysis designed to develop or contribute to generalizable knowledge that will primarily benefit those beyond the study participants. Research includes activities that aim to test a hypothesis, discover or collate facts, principles, or effects, reach new conclusions, or reexamine information by the critical study of a subject or by a course of scientific inquiry. Research also encompasses basic and applied product development, activities for which research funding is available from a Public Health Services component through a grant or cooperative arrangement, as well as any experiment that involves a test article and one or more human subjects.

**Innovative Medical Care** – The following are some of the characteristics of innovative medical care or non-validated practice, and absent any characteristics of research, would NOT constitute research:

- The intervention decision is based solely on the individual's condition and response to prior treatment.
- There has been prior "standard of care" treatment that has not been successful, or that is no longer efficacious in that individual, and an innovative treatment is tested only on that individual.

There is no systematic data collection, other than appropriate entries in an individual's medical record.

### Quality Improvement

- The Carle Foundation is committed to continually measuring and improving the quality of patient care and to the responsible conduct of research that ensures the protection of research subjects. Though these two important activities typically do not intersect, the distinction between quality improvement (QI) and research is not always clear and may change over time as QI programs evolve. Some quality improvement activities, though they are solely aimed at assessing an established program and using the feedback to improve the program, may be found to include a research purpose. For assistance in distinguishing between QI and research, contact the IRB and discuss your proposal before beginning the activity.
- The following QI activities that, absent any other characteristics of research, would likely NOT constitute research:
  - A QI activity will implement a proven practice that is expected to improve patient care, and collect patient or provider data on implementation of the practice for clinical, practical, or administrative purposes.
  - A QI activity is limited in its purpose to (a) delivering healthcare and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses.
- The following describes QI activities that include research aims, and WOULD constitute research for which IRB approval is required:
  - A QI activity aims to introduce an untested clinical intervention to not only improve the quality of care but establish scientific evidence on how well the intervention achieves its intended results.
  - A QI activity introduces risks or burdens beyond the standard of practice with the aim of making results generalizable beyond the local patient or provider population. A QI activity involves randomization among activities that are not all considered to be standard of care.
  - Regarding an intervention and the individual's response.

**Case Studies** - Carle Hospital, part of The Carle Foundation, is a teaching hospital that uses case studies in a variety of ways for non-research purposes. The organization of information from a patient's medical record, for a single case study, does not typically meet the definition of a "systematic investigation" and would not constitute research. This is more appropriately classified as an educational activity. Two or more case studies constitute research and therefore need IRB approval prior to implementation.

## Procedures

1. Determine if the proposed activity is research by answering questions a and b below.
  - a. **Are you planning to engage in a scientific, systematic investigation or study?**

**Yes:** Activities which would suggest you will be conducting a scientific, systematic investigation would include identifying the problem, investigating and examining the problem, developing and testing a hypothesis, or analyzing results learned, and formulating a conclusion.

**No:** Examples of activities which would **NOT** be considered a systematic investigation or study include asking company officers to collect data about company facts (such as the number of employees, data collected on institutional practices which does not affect any person) or reviewing results from a published study without independently testing the results stated within the study.
  - b. **Who will benefit from the study, or will the study contribute to the “generalizable knowledge” as defined below?**

**Yes:** Examples of studies intended to be used for “generalizable knowledge” include information which will be published in a medical journal, or disseminated outside The Carle Foundation, results of a study are to be printed in a newspaper, placed on the internet, or published in some other media form, or quality improvement projects where the data derived from the project is intended to improve or alter the quality of care or the efficiency of an institutional practice.

**No:** Examples of studies which are **NOT** “generalizable knowledge” include data collection for administrative or interdepartmental purposes not meant to be generalizable knowledge or results from a study are to be used for internal quality improvement, and not be shared outside The Carle Foundation.
2. If you answered yes to questions a and b then you are probably engaged in research. Please fill out and submit the Human Subject Research Determination form (available on IRBNet.org for Carle affiliated users) to the Carle IRB for a final determination. If you answered no to either question your project is probably not research and no action is required.
3. If you know that the proposed research involves human subjects (see questions a and b below for guidance), contact the Research Department to obtain assistance in submitting your study to the Carle IRB for full or expedited review and approval. *(If you submit the study to the Carle IRB, the Human Subject Research Determination form doesn't need to be submitted.)*
  - a. **Will your activity involve intervention or interaction with “human subjects”?**

**Yes:** Examples of intervening or interacting with human subjects include performing invasive or non-invasive procedures such as drawing blood, collecting biological samples, or administering other procedures for the purpose of research, studies in which a substance or stimulus is administered to a subject, or responses or states are measured or studies that involve changes in the subject's physical or psychological state or environment, or changes in diet.

**No:** Examples of activities which do not involve intervening or interacting with human subjects include collecting publicly available data, such as census information, labor statistics, and so forth, activities including cadavers, autopsy material or bio-specimens from deceased individuals, *(some research in this category, such as genetic studies providing private or medical information about living relatives, may qualify)*, or studies where there is no communication between the investigator and any living subject.
  - b. **Will the information collected from the human subjects be *identifiable*, or will the identity of the subjects be readily ascertained by the investigator or associated with the information?**

**Yes:** Examples of individually identifiable information include interviews, surveys, tests, inquiries, and observations designed to elicit or obtain nonpublic information. Studies using private information that can be readily linked to individuals, even if the information was not collected specifically for the study in question or information elicited from an individual that the individual can reasonably expect not to be made public.

**No:** Examples which would **NOT** include individually identifiable information include information gathering anonymous interviews (through interviews, surveys, etc.).

**Assistance Regarding Proper Characterization of the Activity** - In areas that are not clear in regard to QI programs, process improvement research, performance evaluations of approved treatments and procedures, the Carle IRB or designated outside IRB shall be the final authority in decision making, and shall be directed in such a way as to maximize the requirements for human subjects protection. If you are uncertain whether a proposed activity constitutes research, contact the Carle IRB and ask for assistance. All human subjects' research must have IRB approval prior to the initiation of any research activity.

## Related Links

IRB General Administration Policy 101

**References**

45 CFR 46

21 CFR 50, 56

ORHP's Human Subject Decision Chart: [www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm).

**Electronic Approval on File**

Supersedes CCA policy 5311 and Carle IRB 408. No similar policy was in effect for CFH.

Melissa Phillips, RN  
Director of Cancer Center

Anna Keck, PhD  
Executive Director of the Research Institute

Charles E. Sanders, Jr., MD  
Vice President of Research and Chief Academic Officer

R. Bruce Wellman, MD  
CEO of Carle Physician Group  
Institutional Official