

The Carle Foundation

IRB Policy 408

Subject	Research Defined		
Approval	Dec 2006	Review	Jun 2009
Scope	This policy defines human subject research and distinguishes it from treatment, innovative care, quality improvement (QI), case study analysis, and other activities that are not research for IRB purposes.		
Purpose	To define human subject research.		

Statement of Policy

1. All human subject research conducted under the Carle Foundation Hospital Federal Wide Assurance must be submitted to the Carle IRB and approved in accordance with these policies before any research activity is initiated. (See IRB General Administration Policy 100, Overview, Introduction, & Statement of Authority and Purpose for Carle Foundation IRB Policies and IRB Organization Policy 203 Jurisdiction of the IRB). Failure to comply with this or any Carle IRB policy can result in termination of research privileges; see IRB General Administration Policy 101 Compliance with Policies and Procedures Mandate.
2. The IRB's oversight of research 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 investigator is unsure whether a proposed activity constitutes research, contact the IRB and ask for assistance with this determination. The IRB has final authority in this determination.

Specific Policies

1. **Definition of Human Subject [45 CFR 46.102]**
 - a. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - Data through intervention or interaction with the individual, or
 - Identifiable private information.
 - b. **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.
 - c. **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 (for example, 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 constitute research involving human subjects.
2. **Definition of Research [45 CFR 46.102]**
 - a. **Research** is defined in the Common Rule (45 CFR 46) as "a **systematic investigation**, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable** knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102].
 - b. **Intent to Publish** The intent to publish, or "generalize" the knowledge resulting from your activity, by itself, is not a sufficient criterion to characterize an activity as research. Conversely, you may be doing research though you have no intention of publishing the results. Consult the IRB for assistance in determining whether your proposed activity is research.
3. **FDA Definition of Research**
 - a. The FDA uses "research" and "clinical investigation" interchangeably and defines this as any experiment that (a) involves a test article and one or more human subjects and (b) that:
 - Is subject to requirements for prior submission to the FDA under section 505(i) or 520(i) of the Food, Drug, and Cosmetics Act (the Act); or
 - Is not subject to requirements for prior submission under the Act but the results of which will be submitted later, or held for inspection by the FDA as part of an application for a marketing or research permit.
4. **Characteristics of Research**
 - a. Each of the following is a characteristic of research activity. This is not an all-inclusive list.
 - The device, drug, biological product, or treatment intervention being used is not approved for use in the United States.

Specific Policies (cont.)

- The device, drug, biologic, or treatment intervention being used is approved for use in the United States, but the indication, formulation, dosage, or other aspect of its use is significantly different from what is approved.
- Interventions are based on randomization, “blinded” treatment protocols, or other experimental methods.
- Intervention decisions are based on any factor other than the standard of care for the person being treated.
- There was an intention, before beginning an intervention, to use systematically collected data on a series of individuals receiving similar treatments, or to compare one intervention against another course of action.
- Data sheets for research files are completed and kept separate from patient charts, for the purpose of a separate review and analysis of the outcomes.
- A decision is made to perform fewer or extra tests, a different frequency of tests, or otherwise not perform tests according to the standard of care, for the purpose of testing a hypothesis for broader application than the treatment of an individual patient’s condition.
- Innovative care is delivered consistently across a series of patients.
- Data is collected for submission to or inspection by the FDA in support of an FDA marketing permit for a food, including dietary supplements bearing nutrient content or health claims, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product for diagnosis or treatment.

5. Innovative Medical Care

- a. 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, regarding an intervention and the individual's response.

6. Characteristics of Quality Improvement

- a. Carle Foundation Hospital 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.
- b. 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.
- c. The following describes quality improvement 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.

7. Case Studies

- a. Carle Foundation Hospital 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 report, does not typically meet the definition of a “systematic investigation” and would not constitute research. This is more appropriately classified as an educational activity. Generally, the extension of this activity to a group of patients would still not constitute research, absent any other activity characteristic of research. However, introducing a statistical method for subgroup comparisons or to test for prognostic factors, for example, are characteristics of research for which IRB approval is required.

Specific Policies (cont.)
8. Assistance Regarding Proper Characterization
a. In areas that are not clear in regard to quality improvement programs, process improvement research, performance evaluations of approved treatments and procedures, the IRB shall be the final authority in decision making, and shall be directed in such a way as to maximize the requirements for human subject protection. If you are uncertain whether a proposed activity constitutes research, contact the IRB and ask for assistance. All human subjects' research must have IRB approval prior to the initiation of any research activity.
Reference
45 CFR 46, 21 CFR 56, and Carle IRB Policies
Approval On File

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