

The Carle Foundation

IRB Policy 413

Subject	"Exempt" Status Review of a Research Study			
Approval	Dec 2009	Review	Sep 2010	Revision
Purpose	To state the requirements for determination of "Exempt" status for research studies			

Statement of Policy

1. Carle Institutional Review Board (Carle IRB) requires that all human subjects research activities under its jurisdiction (activities at Carle Foundation Hospital (CFH) and its affiliate sites, use of CFH resources or CFH staff/ agents are under the Carle IRB jurisdiction) be reviewed to determine whether the research meets one or more of the exemption categories as defined by Federal regulations.
2. An "exempt" status determination for a research study shall be made by the Carle IRB Chairperson or his/her designee who is an IRB member.
3. Only the Carle IRB may determine which activities qualify for an exempt review involving CFH activities. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and therefore must contact the Office for Human Subject Protection at CFH (irb@carle.com or 217-383-4366 concerning the status of proposed research or changes in ongoing research.
4. "Exempt" status applies only for further IRB annual review. All studies must undergo reviews for modifications.

Definitions

Research – 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.

Human subject – a living individual about whom an investigator conducting research obtains

- Data through intervention or interaction with the individual or
- Identifiable private information

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 (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 for obtaining the information to constitute research involving human subjects.

Minimal risk – means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Policy

1. Investigators must submit their study protocol, the Exempt application, Investigator Agreement plus other study specific document to the Carle IRB via IRBNet.
2. In order to be granted "exempt" status, 45 CFR 46.101(b) requires that research activities in which the only involvement of human subjects will be in one or more of the following categories:
 - a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:
 - The human subjects are elected or appointed public officials or candidates for public office; or

Policy (cont.)

- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 - d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - e. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs;
 - Procedures for obtaining benefits or services under those programs;
 - Possible changes in or alternatives to those programs or procedures; or
 - Possible changes in methods or levels of payment for benefits or services under those programs.
 - f. Taste and food quality evaluation and consumer acceptance studies:
 - If wholesome foods without additives are consumed or
 - If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
3. Modifications: Changes to an exempt study may disqualify the research from exempt status. Therefore, any proposed change(s) to an exempt study must be submitted to the Carle IRB via IRBNet for review and approval prior to implementation.
4. All research that has been determined to be exempt may still be subject to other applicable policies of the Carle IRB. These include but are not limited to the adherence to the investigator's assurances, maintenance of all records relating to the study for at least three years (six years if Protected Health Information is involved) after completion of the study.
5. Types of research that **do not** qualify for exempt status include but are not limited to:
- a. Any research that includes prisoners, or
 - b. Children under certain situations, or
 - c. When the Carle IRB determines that the risks (such as physical, psychological, social or financial etc.) are greater than minimal and hence disqualify a study from being granted exempt status.

References

45 CFR 46.101(b) and Carle IRB Policies (<http://www.carleconnect.com/ResearchPolicies.shtml>)

Electronic Approval On File

*Approved by IRB Board Aug 2010

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