

The Carle Foundation

IRB Policy 100

Subject	Overview, Introduction, & Statement of Authority and Purpose for Carle Foundation IRB Policies				
Approval	Feb 2009	Review	Jun 2009	Revision	Jun 2009
Purpose	To give a general overview, Introduction, & Statement of Authority and Purpose for the Carle Foundation Hospital IRB governing board.				

Overview

1. Carle Foundation Hospital ("CFH") is committed to ensuring an institutional culture where research is conducted in an ethical and scientifically rigorous manner and where safeguards to subjects who participate in clinical studies are of paramount importance. Ensuring an institutional culture of research excellence begins with the establishment of a strong and dynamic Institutional Review Board with committed members who are well-trained in regulatory requirements, ethical conduct and sound implementation of research and have the support and resources necessary to effectively review and oversee proposed human subject research. In furtherance of this institutional commitment, Carle Foundation Hospital has created its Institutional Review Board.
2. The mission of Carle Foundation Hospital Institutional Review Board ("IRB" or the "Carle IRB") is to ensure that all human subject research which is conducted under the oversight of the IRB is conducted in accordance with applicable law and regulations, as well as research ethics. The rights of individuals who are participants or potential participants will be protected by the Carle IRB through the thoughtful consideration of research risks and benefits, including scientific merit; by ensuring appropriate informed consent is obtained from each participant (or the legal representative) in a process which is ongoing, voluntary and non-coercive; by requiring appropriate training of IRB members, Investigators and research staff; and by monitoring and re-reviewing research at appropriate intervals, based on the risks posed. Research conducted at Carle Foundation Hospital must meet the ethical standards of respect for persons, beneficence, and justice.
3. Regulations require that IRBs have written policies and procedures and that IRB oversight of research is carried out as described in those policies and procedures documents. These Standard Operating Policies and Procedures (SOPs) are written to enable Carle IRB to maintain a system of compliance. These SOPs reflect not only the laws and regulations, but also the underlying ethical principles that are the basis of the IRB's mandate. Finally, these policies also reflect our overarching commitment to provide protection for all the human subjects involved in research at this and affiliated facilities. The forms, checklists, and other documents that are part of the SOPs are included in order to assure that the procedures are integrated into the daily activities of not only IRB members and staff, but also into the activities of each research team.

Introduction

1. Federal regulations require review and oversight of federally sponsored research by a body committed to protecting human research subjects – the Institutional Review Board. These regulations also require the IRB to have written policies and procedures which describe the operation of the IRB, and which permit the IRB to ensure compliance with laws and regulations, as well as the underlying ethical principles that are the basis of the IRB's mandate. These policies also reflect the overarching commitment of Carle Foundation Hospital and its affiliated organizations to provide protection for all human subjects involved in research conducted under the supervision of the Carle IRB.
2. The ethically responsible researcher is expected to carry the dual burden of advancing existing or generating new knowledge that can improve the human condition and, at the same time, of recognizing the absolute imperative to treat human research subjects with the utmost care and respect. In no event can the anticipated outcomes of research be used to excuse the unethical treatment of study participants.
3. The responsibility imposed on researchers is shared with others. All those involved in the conduct of research are responsible for ensuring compliance with legal and ethical mandates.
4. This responsibility also falls to the men and women who sit on Institutional Review Boards. They are expected to act as custodians of the research, to manage the research enterprise to enable the advancement of science, and have as their overriding concern the protection of the human subjects of the research.
5. These Standard Operating Policies and Procedures (SOPs) apply to all of the day-to-day operations of the IRB. The SOPs apply to each member who serves on the IRB, each individual who supports the IRB and all others who must comply with its decisions and its requirements (for example, Investigators, research managers/coordinators, research nurses, support staff, etc.).
6. The forms, checklists, and other documents that are part of the SOPs are included in order to assure that the procedures are integrated into the daily activities of not only IRB members and staff, but into the activities of the research team as well. These SOPs will be reviewed periodically to ensure that they are current, that new legislation, regulations or ethical standards are reflected and that daily activities are being performed as described in the SOPs.

Introduction (cont.)

7. These policies are based on current regulations, ethical principles, and guidelines for the protection of the human subjects of biomedical and behavioral research. The policies state what this institution requires for the ethical conduct of clinical research. The procedures detail how these policies are carried out.
8. These policies and procedures are the framework upon which research reviewed by the Carle IRB is conducted. Therefore, all members of the research enterprise under the jurisdiction of the Carle IRB are expected to read, understand, and comply with them. Each individual who engages in or supports research at Carle Foundation Hospital must be committed to conducting sound, effective and ethical research

Statement of Authority and Purpose

1. Governing Principles

- a. The Carle IRB is guided by the same ethical principles as are applied to all federally-supported research in the United States involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report"). These principles are defined in the Belmont Report (Appendix A) as follows:
 - **Respect for Persons** -- Respect for persons includes two ethical convictions: that individuals capable of autonomy should have the right to agree, freely and without coercion, to participate or not participate in research; and that persons with diminished autonomy are entitled to protection. The expression of the ethical principle of Respect for Persons is seen most clearly in requirements for a legally effective informed consent, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.
 - **Beneficence** -- The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the research to go forward; benefits have been maximized and risks have been minimized, to the extent possible.
 - **Justice** -- The selection of subjects is equitable. To the extent possible, subjects are representative of the group that will benefit from the research. Those subjects, who are particularly vulnerable, such as children, pregnant women and fetuses, and prisoners, are provided special protections

2. Authority

- a. The Carle IRB is established and empowered by the executive management of Carle Foundation Hospital and by the Institution's Federal Wide Assurance (Appendix B) with the federal Office for Human Research Protections ("OHRP"). All IRBs at Carle Foundation Hospital ("CFH") subscribe to the same underlying principles and authorities, and all are subject to these SOPs.
- b. Carle's IRBs have been established to review all human subject biomedical and behavioral research which involves funds, assets, employees, students, patients, or otherwise has a significant connection with Carle Foundation Hospital, the Carle Foundation, or any affiliate or subsidiary of either. All research involving human subjects, and all other activities which even in part involve such research, regardless of funding or sponsorship, are subject to IRB review and oversight and these SOPs, unless the only involvement of humans as subjects is in one or more of the categories exempted or waived under 45 CFR §§ 46.101(b)(1-6) or 101(i).
- c. Carle IRB review and approval is required if:
 - The research is sponsored, in whole or in part, by Carle Foundation, Carle Foundation Hospital, or any entity with a prior IRB Affiliation Agreement with the Carle IRB, regardless of whether the research is conducted at Carle Foundation Hospital or at another institution;
 - The research is conducted by or under the direction of any employee, faculty, staff, student or agent of CFH;
 - The research is conducted by and/or at other institutions or organizations and that institution/organization has requested Carle IRB review, approval and oversight of the Research and the Carle IRB has accepted the request;
 - The research is being conducted by Carle Clinic Association (CCA) and the Carle IRB is the IRB of record for CCA;
 - The research is conducted by or under the direction of any employee, faculty, staff, student or agent of CFH using any property or facility of CFH; and/or the research involves the use of nonpublic information (including patient information) of Carle Foundation, Carle Foundation Hospital, or any affiliate or subsidiary of either of them, including use of such information to identify or contact potential research subjects;
 - CFH information, including identifiable patient information, is provided to an Investigator or used to identify possible study subjects;
 - CFH serves as a collating center or statistical center for analysis or retention of data gathered by other study sites; and/or
 - The research is conducted on individuals who have a relationship with CFH, and the research otherwise has a connection to CFH.

Statement of Authority and Purpose (cont.)

- d. In the context of research, a person is acting as an agent of CFH if that person is being compensated by CFH for the performance of research activities or is under contract with CFH to provide such services.
- e. The Carle IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. Specifically:
 - The IRB may reject, modify or approve research based solely upon consideration of human subject protection aspects;
 - The IRB reviews, and has the authority to approve, require modification in, reject, suspend, or terminate all research activities that fall within its jurisdiction;
 - The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators, auditing the conduct of the study, observing the informed consent process, and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects; and
 - The IRB may place restrictions on a study or on an Investigator.
- f. If federal funding for a study is sought, the application for funding and the protocol must be reviewed by the IRB. Under current regulations, the IRB review can be requested once the application is identified as fundable by the applicable federal agency. The protocol and grant application must be reviewed and approved by the IRB prior to release of any grant funds. In some cases, additional laws, regulations or other requirements, including grant requirements, will apply to research. Examples are research studies funded by the Department of Energy, the Veterans Administration, or the Bureau of Prisons. Similarly, in some cases state law imposes additional requirements. Compliance with all applicable laws and regulations is required.

3. Relationship of IRB to Other Administrative Entities

- a. The IRB also has a relationship to other CFH research review committees, such as the Scientific Review Committee. The IRB functions independently of, but in coordination with, those other committees. Projects may require administrative approval in addition to IRB approval, and research that has been reviewed and approved by the IRB may be subject to administrative review and approval or disapproval by institutional officials or other committees. However, those officials or committees may not approve research if it has been disapproved by the Carle IRB. The Investigator is responsible for ensuring all necessary approvals have been received prior to beginning the project.
- b. Other areas of CFH with responsibility over some aspects of research include executive and administrative leadership, quality assurance, compliance, contracting, training, human resources and contract management. A data safety monitoring board (DSMB) may be used, at the request of the IRB. When appropriate, legal guidance is obtained. As areas of expertise are identified, the IRB may seek guidance from individuals with such expertise to best assure human subject protection.

4. Responsibility

- a. Activities Subject to IRB Review
 - All human subjects research (as defined in IRB Review of Research Policy 408 Research Defined), and all other activities, which even in part involve such research, regardless of sponsorship, must be submitted to the CFH IRB(s) and approved in accordance with these policies before any research activity is initiated (see also, IRB Organization Policy 203 Jurisdiction of the IRB).
 - No intervention or interaction with human subjects in research, including recruitment, identification of possible subjects or other activities preparatory to research which require access to personal information, may begin at CFH or using CFH staff or assets until Carle IRB has reviewed and approved the research protocol. Specific determinations as to the definition of "research" or "human subjects," and their implications for the jurisdiction of the IRB under Carle Foundation Hospital policies are determined by the IRB (see IRB Review of Research Policy 408 Research Defined). If you are unsure of whether a given activity constitutes human subject research, obtain guidance from the IRB prior to engaging in the activity. The IRB retains final authority over the determination of what constitutes research for which IRB approval is required.
 - The IRB's purpose and responsibility is to protect the rights and welfare of human subjects. The Carle IRB reviews and oversees human subject research to ensure that it meets well established ethical principles and that it complies with federal regulations at 45 CFR Part 46 and 21 CFR Parts 50 and 56, that pertain to human subject protection, as well as any other pertinent regulations and guidelines, such as the Good Clinical Practice (GCP) Guideline (E6) of the International Conference on Harmonization (ICH).
 - According to federal regulations, the activities that require IRB review include any human research activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual. Specific activities that require IRB review include, but are not necessarily limited to the following:

Statement of Authority and Purpose (cont.)

- Clinical investigations, and any experiment that involves a test article and one or more human subjects, and that meets the requirements for prior submission to the Food and Drug Administration (FDA) under relevant investigational drug or medical device provisions of the Food, Drug, and Cosmetics Act, or experiments that need not meet the requirements for prior submission to the FDA, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
 - Collection of data about one or more of standard procedures or treatments for publication, dissemination or generalization of knowledge gained.
 - A patient's care or assignment to intervention is altered for research purposes in any way (*i.e.*, treatment or other interventions are selected on a basis other than purely based on patient condition).
 - A diagnostic procedure for research purposes is added to a standard treatment.
 - Systematic investigation involving innovative procedures or treatments. For example, if a physician plans to collect information about the innovation for scientific purposes or to repeat the innovation in other patients in order to compare it to standard treatment, it is considered research.
 - Emergency use of an investigational drug or medical device. Note that when emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject, and data generated from such care cannot be included in any report of a research activity.
 - Human cell or tissue (including blood) research that uses newly collected tissue or blood.
 - Human cell or tissue research that involves repositories that collect, store, and distribute human tissue materials for research purposes. However, human cell or tissue repositories activities **do not require** IRB review if material submitted to the repository satisfies both of the following conditions: (i) The material, in its entirety, was collected for purposes other than submission to the repository (*e.g.*, the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no "extra" material collected for submission to the repository); and (ii) The material is submitted to the repository without any identifiable private data or information, *i.e.*, no codes or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained. In accordance with HIPAA and the CFH HIPAA Policies, the requirements imposed by HIPAA do not apply to de-identified information.
 - Investigator-initiated research, where an Investigator both initiates and conducts, alone or with others, a clinical trial. In the case of Investigator-initiated studies, it is the Investigator's responsibility to keep IRB informed of unanticipated non-serious research related events and unanticipated serious adverse events and other unexpected findings that affect the risk/benefit assessment of the research, even if the event occurred at a location for which the Institution's IRB is not the IRB of record.
 - Student-conducted research, which includes all activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree, must be reviewed by the IRB. These activities include: (i) All master's theses and doctoral dissertations that involve human subjects; and (ii) All projects that involve human subjects and for which findings may be published or otherwise disseminated.
- Federal regulations exempt some research from IRB review, even though the research involves human subjects. In furtherance of the IRB's mission, the IRB strongly encourages review of research which is exempt from IRB review per 45 CFR 46 §§ 101(b)(1-6) or 101(i) but involves human subjects or materials, in order to ensure that the subjects are appropriately protected.
- b. Failure to Submit a Project for IRB Review.
- The implications of engaging in activities that qualify as research subject to IRB review without first obtaining such review are serious. Results from such studies may not be published unless IRB approval was obtained prior to collecting the data. To do so is violation of CFH policy. It is also against CFH policy to use those data to satisfy thesis or dissertation requirements. If an Investigator begins a project and later finds that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the Investigator should submit a proposal to the IRB for review as soon as possible. If the IRB does not approve the research, data collected cannot be used as part of a thesis or dissertation, and the results of the research cannot be published. Furthermore, the FDA may reject such data if it is submitted in support of a marketing application. The IRB will adhere to the requirements set forth by the federal government in 45 CFR 46, 21 CFR 56, and all other applicable federal and state laws or regulations regarding the reporting of Investigators who engage in research without first obtaining IRB approval. **Investigators who engage in research without first obtaining IRB approval will be reported to the Office for Human Research Protections as required by law and regulation.**

Statement of Authority and Purpose (cont.)

c. Assurance of Independence.

- Carle Institutional Review Board (IRB) has the mandate to act as an independent entity within the corporate structure of Carle Foundation Hospital. The Institutional Official (IO) has established and maintains a federal wide assurance (FWA) between Carle Foundation Hospital (CFH) and the United States Department of Health and Human Services (HHS), through its Office for Human Research Protections (OHRP). In that assurance, CFH pledges to comply with federal regulations for all federally supported research. The IO, on behalf of CFH, is authorized to establish and has established an Institutional Review Board (IRB) to assist in complying with applicable laws, regulations and CFH policy in the review, approval and monitoring of human research. The IRB office is responsible for the day-to-day operation of the IRB. The office functions in coordination with CFH officials and other review committees but at all times maintains its independence to appropriately review, approve and monitor human research. It is the responsibility of the IO to maintain and enforce the independent nature of the relationship between the Carle Institutional Review Board and Carle Foundation Hospital.

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