

The Carle Foundation

IRB Policy 103

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| Subject | Training and Education | | |
| Approval | Dec 2006 | Review | Sep 2010 |
| Revision | Jun 2009 | | |
| Scope | These policies apply to all IRB members and staff. | | |
| Purpose | To ensure appropriate education and training for IRB members and HSP staff. | | |

Statement of Policy

1. All IRB members and staff will be apprised of Carle Foundation Hospital's organizational structure with emphasis on the independent nature of the relationship between the IRB and Carle Foundation Hospital. The actions of the Board relating to their responsibilities to protect human subjects of research will not be measured or evaluated in terms of institutional financial goals.
2. Training of IRB staff and members is critical if the IRB is to fulfill its mandate to protect the rights, safety and welfare of research subjects in a consistent manner throughout the Carle Foundation Hospital research community.
3. IRB members, staff and others charged with responsibility for reviewing, approving, and overseeing human subject research shall receive detailed training in the state and federal laws, regulations, guidelines, ethics, standards and policies applicable to the protection of research subjects and human subject research in general.

Specific Policies

1. IRB Member Training
 - a. All IRB members shall receive an in-person orientation (for new members upon initial appointment), receive a copy of the Carle IRB policies, and receive training, at a minimum, on the following topics:
 - Carle IRB Policies
 - OHRP principles, standards, regulations, etc.
 - NIH/Federal Grants
 - Conflicts of Interest
 - Scientific Misconduct
 - Interface of HIPAA, state law and research
 - Ethics and standards associated with research (Belmont Report, Nuremberg Code, Declaration of Helsinki)
 - Vulnerable populations
 - Federal laws and regulations governing research (45 CFR 46; 21 CFR 50; 21 CFR 56)
 - IRB Member Handbook, "Institutional Review Board" – by Robert J. Amdur and Elizabeth A. Bankert
 - b. The IRB Chair (or designee) shall establish the educational and training programs and schedules for IRB members who review biomedical and behavioral research involving human subjects at this institution and who perform related administrative duties. Member attendance and participation in training courses shall be documented and such documentation shall be maintained by the Office of the IRB. No IRB member may be allowed to vote in an IRB meeting until he or she has completed all the initial required training.
 - c. Members of the IRB will participate in initial and continuing training in areas germane to their responsibilities.
 - d. The Chairperson will receive additional training in areas germane to his or her additional responsibilities.
 - e. All IRB Members shall complete training upon initial appointment to the IRB and shall receive ongoing training and additional resources on a bi-annual basis and as needed per the discretion of the Chairperson of the IRB.
 - f. IRB members will be encouraged to attend workshops and other educational opportunities focused on IRB functions. The IRB Members shall participate in effective educational activities regarding the roles and responsibilities of the IRB, focusing in part on ethical principles, standards and recent developments. The Carle Foundation Hospital will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.
2. IRB Staff Training
 - a. All IRB staff shall receive an in-person orientation (for new staff), receive a copy of the Carle IRB policies and procedures, and receive training, at a minimum, on the following topics:
 - IRB Policies
 - Interface of HIPAA, state law and research
 - Conflicts of Interest
 - Scientific Misconduct
 - OHRP principles, standards, regulations, etc.

Specific Policies (cont.)

- NIH/Federal Grants
 - Ethics and standards associated with research (Belmont Report, Nuremberg Code, Declaration of Helsinki)
 - Federal laws and regulations governing research (45 CFR 46; 21 CFR 50; 21 CFR 56)
- b. The IRB Chair (or designee) shall establish the educational and training programs and schedules for IRB staff. Staff attendance and participation in training courses shall be documented and such documentation shall be maintained by the Office of the IRB. No IRB staff may be allowed to perform any administrative or other duties until he or she has completed all the training necessary to permit performance of duties in accordance with the laws and these policies.
- c. All IRB staff shall complete training upon initial hire/appointment to the IRB staff and shall receive ongoing training and additional resources on a bi-annual basis and as needed per the discretion of the Chairperson of the IRB or the Medical Director of Research.
3. Documentation
- a. Training and continuing education shall be documented and added to the records of the IRB as described in these policies and procedures.
- b. All IRB members, IRB Chair, Institutional Officials and IRB staff are required to complete CITI training once every two years, and such training will be documented. In addition, they will be encouraged to attend seminars, conferences and training at local and national levels.

Reference

45 CFR 46 and Carle IRB Policies

Collaborative Institutional Training Initiative at www.citiprogram.org.

Public Responsibilities in Medicine and Research at www.primr.org.

IRB Member Handbook, "Institutional Review Board"- by Robert J. Amdur and Elizabeth A. Bankert (Second edition, 2007, Jones and Bartlett Publishers)

Approval On File

*Approved by IRB Board Aug 2010

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