

**The Carle Foundation
IRB Policy 105**

Subject	Signatory Authority		
Approval	Dec 2006	Review	Jun 2009
Purpose	This policy establishes who has authority to sign documents on behalf of the Carle IRB.		

Statement of Policy

1. This policy describes signature authority for matters related to the Carle IRB for Institutional Officials, IRB Members and HSPP staff. The Chairperson(s) of the Carle IRB is authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as subjects. Certain documents may be signed by staff of the Human Subject Protection Program (HSPP) which supports the IRB. Policies must be signed by the Medical Director of Research and the Director of the HSPP, while procedures are to be signed by the Director of the HSPP or his/her designee. In all cases, individuals must sign their own name and no other and indicate their title under their signature.

Specific Policies

1. Authorization for Signatory Authority
 - a. Authorization to sign documents not described in this policy may be made in writing by the Chairperson(s) of the Carle Institutional Review Board (or designee) or the Director of the HSPP. **Any delegation of signature authority must be consistent with law and principles of good governance.**
2. Results of Reviews, Actions and Decisions
 - a. The results of reviews and actions taken by the IRB, either by the full IRB or by expedited review, that grant or appear to grant initial or continuing approval of research may only be signed by the Chairperson of the IRB, or as delegated by the Chairperson to a Member of the IRB. Likewise, letters of disapproval, suspension and/or termination may only be signed by the Chairperson of the IRB, or as delegated by the Chairperson to a Member of the IRB.
3. Exempt and Not-Human-Subject-Research Determinations
 - a. Determinations that studies do not fall under the jurisdiction of the Carle IRB may be signed by the Chairperson of the IRB, or as delegated by the Chairperson to a Member of the IRB or the Director of the HSPP.
4. Routine Internal Correspondence
 - a. Any action, letters, memos or emails between the IRB, and/or members of the staff of the Carle Foundation Hospital that provide information concerning research protocols that have been submitted to the IRB or that are under the jurisdiction of the IRB, and which do not imply or appear to imply approval of the research, may be signed by HSPP staff in keeping with their job descriptions. This includes reminders for continuing review, expiration notices, requests for clarification, and other administrative matters.
5. Correspondence with External Agencies
 - a. Any letters, memos or emails sent to agencies of the federal or state government, funding agencies (whether private or public) or their agents will be signed by the Institutional Official, Medical Director of Research, IRB Chairperson, or Director of the HSPP as appropriate. Any reply to an inquiry or investigation by an external agency will be signed by the Institutional Official, Medical Director of Research, Director of the HSPP, IRB Chairperson, or the Chief Compliance Officer.
6. Decisions Made by Chairperson
 - a. Any letters, memos or email sent representing the decision or opinions of the Chairperson of the IRB or his/her respective designees, as long as such correspondence does not imply review and approval, disapproval, suspension, or termination of research projects, may be signed by IRB staff who have been designated that authority in writing. Current delegation authority must be provided for any non-routine correspondence.
7. Operating Policies
 - a. All policies shall be signed by the Director of the HSPP and the Medical Director of Research. All procedures supporting these policies shall be signed by the Director of the HSPP or designee.

Reference

45 CFR 46 and Carle IRB Policies

Approval On File

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