

**The Carle Foundation  
Research Policy 106**

<b>Subject</b>	Electronic Signatures for IRBNet Users				
<b>Approval</b>	Jun 2008	<b>Review</b>	July 2010	<b>Revision</b>	July 2010
<b>Purpose</b>	To clarify who on a research team has the authority to electronically sign a research submission and the significance of electronic signatures on IRBNet.				

**Statement of Policy**

IRBNet allows the Principal Investigator (PI) or valid designee to submit research project packages to the Carle Scientific Review Committee and the Carle Institutional Review Board (Carle IRB) electronically, while at the same time affixing to the submission the PI's electronic signature.

An electronic signature process

1. Secures the user authentication (proof of claimed identity) at the time the signature is generated.
2. Affords the same legal weight associated with an original signature on a paper document.
3. Signifies acceptance and adherence to the Carle IRB Assurances.

**Carle IRB Assurances**

**I, the Principal Investigator, give the following assurances:**

1. I am familiar with the Carle IRB Guidelines. I will adhere to the policies and procedures explained therein, as well as other policies and procedures established by the Carle IRB.
2. I am aware of the legal, regulatory, and ethical requirements to protect human subjects, including without limitation, protection of their personal privacy and the privacy of all information identifying and/or relating to them, and agree to comply with all such human subject protections.
3. I am aware of the applicable Carle policies and contract provisions associated with this research that require me and other individuals working on this project to keep all research related activities and information confidential. This information may only be shared with those who have a business reason to know it. I have informed all individuals who will work on this research project of the confidentiality requirements and will inform all new individuals of the same.
4. I will not initiate recruitment of subjects prior to receiving notice of the Carle IRB's approval of the research project.
5. I will permit audits of the approved research by the Carle IRB and designated auditor(s), and understand that refusal to permit access to research-related documents will be grounds for suspension and possible termination of the Carle IRB's approval of the research.
6. If I wish to make changes to the protocol or any other project documents, I will submit the changes to Carle IRB for approval **prior to** initiating the changes.
7. If any unanticipated problems involving human subjects occur, I will **promptly** notify the office of Human Subjects Protection at Carle Foundation Hospital at (217) 383-4366.
8. If a research participant becomes incarcerated during the course of this project, I will **immediately** contact the Office of Human Subject Protection at Carle Foundation Hospital. Approval will be obtained before the research can continue with that participant.
9. Presentations and publications resulting from this research shall acknowledge Carle appropriately.

**Procedure**

1. Research project packages submitted via IRBNet to the Carle Scientific Review Committee and the Carle IRB will not receive final approval without a valid electronic signature.
2. A valid electronic signature can only be made by the PI or "on behalf of" the PI by a person designated by the PI to sign on their behalf.
3. The PI can designate a person to sign on their behalf by sending an email to the assigned Research Office Research Coordinator or to [Research@Carle.com](mailto:Research@Carle.com) stating that s/he designates one specific person to electronically sign (a) for one specific study or (b) for all of the PIs future studies until a notification is sent to [Research@Carle.com](mailto:Research@Carle.com). This person could be a co-I, a study coordinator (not part of the Foundation Research Office) or other research team member who has been granted "full" access to the submission package. One exception to this designation process is allowed when a PI signs and dates a printed front page of the new IRB Application. That signed page gets uploaded on IRBNet as part of the study package and then the assigned Research Office Research Coordinator electronically signs off on the study on the behalf of the PI.

<b>Procedure (cont.)</b>
4. Delegation of the authority to electronically sign the IRBNet submission package, does not absolve the PI to adherence of the Carle IRB assurances. Additionally, the PI remains the person ultimately responsible for the protection of the research subjects and regulatory compliance of the project.
<b>Approval on File</b>

Anna Keck, PhD  
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