

IRB jurisdiction

All research studies that will be conducted in part or in whole at Carle Foundation Hospital (CFH), that are supported by CFH, or in which CFH is engaged must receive Carle IRB review and approval before the research is initiated.

In clinical trials that involve both CFH and the Carle Clinic Association, Western IRB may be the reviewing IRB. However, these studies must first pass through the Carle IRB. In limited circumstances, CFH may be the IRB of record for another institution. If you have questions concerning multiple IRBs reviewing a study, please contact the Human Subject Protection Director (above).

Initial study submissions

The following documents are required for submission to Carle IRB:

- Investigator and key research personnel education in human subject protection (The IRB application provides summary information about the study for the Carle IRB. Forms and additional guidance for submission are available in the investigator library for Carle Foundation Hospital at [IRBNet](#).)
- [Research protocol](#)
- Data collection forms
- Recruitment materials
- Informed consent*
- HIPAA forms* (if applicable)
- Additional information relevant to the study (such as an Screening Forms, Assent form for children, and Subject Information Sheets)

*If your submission to the IRB is a "paper submission" (not made through IRBNet), all consent and HIPAA forms must also be sent electronically to the IRB staff at IRB@Carle.com.

Note:

All supporting documents accompanying an IRB submission (such as consent forms, recruitment materials, data collection forms, etc.) must be identified with a version number or version date.

Carle Research Coordinators will assist in submission of required IRB documents to the Carle IRB.

IRBNet

Carle is transferring to [IRBNet](#), an online study management and submission system. IRBNet provides a user-friendly, secure, electronic protocol management and on-line submissions system. Through IRBNet, you can submit to and receive approval letters from the Carle IRB from any location at any time. After June 6, 2008, all IRB submissions must come through IRBNet. Paper submissions will be discontinued at that time.

You can submit to the Carle IRB using IRBNet by signing up for an account with [IRBNet](#). The investigator and all key research personnel on the study must have accounts with IRBNet. The use of IRBNet is provided to investigators without charge.

Online training is available for you and your staff on how to use IRBNet:

<http://www.irbnetresources.org/training.html>

Login name: carle

Password: training01

[IRBNet job aid](#) - Click here to access the job aid to assist you with navigating IRBNet.

IRBNet frequently asked questions

Under development

IRB Forms

In IRBNet, when you indicate that you will be working with Carle, the Carle investigator library will be made available to you. In that library you will find the Carle IRB forms, templates, and instructions. The IRB application itself is a “smart form” that is searchable and populates the IRB database. All other forms are forms that can be completed by downloading them to your computer, completing the forms, then uploading and attaching the completed form to the IRB submission system.

IRB forms can also be accessed outside the IRBNet system, and are available on the [Forms & Templates](#) page.

HIPAA Forms

To be compliant with HIPAA regulations, most submissions will require accompanying HIPAA document. Investigators are strongly encouraged to read through the [instructions](#) and consult with a research coordinator before choosing which form(s) to complete and submit.

All supporting documents accompanying an IRB submission (such as consent forms, recruitment materials, data collection forms, etc.) must be identified with a version number or version date.