

PROCESS FOR INITIATING RESEARCH AT CARLE FOUNDATION HOSPITAL

Carle Foundation Hospital is actively involved in many different types of research including nursing research, resident research, genomics, various models testing mechanism of actions and efficacy, clinical trials, imaging, medical informatics, aging, cancer and gastroenterology.

The goals of research at Carle Foundation Hospital are to advance the latest care and treatment, enhance disease prevention, and improve staff-provider performance, care delivery and outcomes.

All research projects involving Carle Foundation Hospital patients, nurses, residents, fellows physicians, hospitalists, other staff, facilities, and equipment, must undergo review by the Carle Scientific Review Committee and if deemed "human subject research", the studies will also need Carle Institutional Review Board approval. In addition, some research projects may require the development of contracts and/or access agreements.

If you are not sure whether an activity is quality improvement or human research, contact the Carle Institutional Review Board (Carle IRB) to do this determination for you. Please submit the [Human Subject Research Determination form](#).

If the Carle IRB determines that your activity is quality improvement, then your project does not need IRB approval. If the Carle IRB determines that your activity involves human research, then your project must be reviewed and approved by an IRB prior to initiation, under the requirements of the U.S. Department of Health and Human Services regulations at [45 CFR Part 46](#). We will assign your project to a Research Coordinator who can help you with the IRB submissions and other research related tasks. For more information on how to determine if an activity involves human research, you can visit the [Office for Human Subject Protections guidance documents](#).

You can also contact the Human Subject Protection Office at Carle Foundation Hospital (Phone): 217-383-4366 or (e-mail): irb@carle.com.

This document is intended to guide research investigators through the research project submission and review process.

The purposes of the reviews by Carle's Scientific Review Committee and Institutional Review Board are to:

- evaluate the value and scientific merit of a research project
- evaluate the feasibility and resource demands related to the conduct of the project
- protect the rights and welfare of research subjects
- assure compliance with federal and state regulations, and institutional policies governing human subject research

Documents required when submitting a research project for review

In order to submit a new research project to Carle's Scientific Review Committee and Institutional Review Board, certain documents will be required. All necessary applications, forms and templates can be found in the Carle investigator library at www.IRBNet.org.

1. **Research Study Protocol** including a study budget
2. **IRB Registration Form**
3. **IRB Application**- use one of the following applications:
 - Full & Expedited Review
 - Exempt from Regulations
 - CCOP Application Full & Expedited
 - Human Subject Research Determination
4. **Appendices** as required to supplement the Application and Registration Forms
5. **Preparatory to Research Form** (If protected health information is to be accessed in the development of the protocol, or to identify potential research subjects.)
6. **Informed Consent/Assent Form** (If waiver of documentation of consent is sought, these forms are not required.)
7. **HIPAA Authorization or Waiver Forms** (If protected health information will be used, obtained, or disclosed for research purposes.)
8. **Additional information relevant to the project** (such as recruitment advertisements and scripts, surveys or questionnaires, and data collection forms) must also be submitted together with the project package for review.
9. **Education Certificate** (demonstrating completion of training in the ethical conduct of human subject research, See Education Requirements).

You can print out a complete [submission checklist](#) for your convenience. Keep in mind that your specific research project might not need all the documents listed.

All documents should be submitted electronically via IRBNet.org. Each submitted document should have a version number and date, preferably placed in the footer.

Please note that submission deadlines can be found under [Deadlines](#).

How to Submit Your Research Project

I. Initial Discussion of Research Plan

Researchers are encouraged to make an initial email contact to the Research Office, Carle Foundational Hospital (CFH) to discuss their proposed project with the appropriate Research Coordinator below or with the Director (Anna Keck, 217-326-0387, Anna.Keck@carle.com)

1. University Faculty/ Translational Research - contact Barbara Hall, Barbara.Hall@carle.com (217-383-6199)
2. CFH Nursing Staff - contact Nancy Keith, Nancy.Keith@carle.com (217-326-4507)

3. CFH Physicians Initiated Research - contact Charletta Little, Charletta.Little@carle.com (217-326-0068)
4. Residents, Fellows, Residency Program Faculty and Medical Students - contact Pamela Talbott, Pamela.Talbott@carle.com (217-383-3617)
5. Industry Sponsored Projects Involving CFH - contact Rebecca Morgan-Boyd, Rebecca.Morgan-Boyd@carle.com (217-326-0144)
6. Carle Clinic Association (CCA) Physician, Nursing, and other Staff - contact Micki Suits, CCA Research Office, Micki.Suits@carle.com (217-326-0058)
7. Physicians not associated with CFH or CCA - contact Anna Keck, Anna.Keck@carle.com (217-326-0387)

If you do not know who to contact, contact Anna Keck (Anna.Keck@carle.com, 217-326-0387). She will assign a Research Coordinator to help guide the research team through the submission process.

The initial contact with the Research Office should be made early in the research project development process to assure coordination of efforts and to maximize support in the submission process. At a minimum, the Research Office should be contacted at least 1 month before the submission deadline for the Scientific Review Committee meeting at which the investigator seeks to have the research reviewed. Our Research Coordinators can assist investigators in development of the research project submission, preparing responses to the reviewers, and otherwise provide support throughout the life of a project.

II. Interface with Carle Clinic Association Research Department

If the project involves Carle Clinic Association (CCA) physicians, the Research Office will contact the CCA research office to identify a CCA collaborating physician or, when a collaborating physician has already been identified, to notify the CCA research office of the identified physician's interest.

III. Joint Meeting of Researcher, Carle Professional Staff, and Research Coordinator

It is recommended that at least one joint meeting be held that includes all involved parties for the purpose of finalizing a plan for the development of the research project, project documents, implementation, budget, etc.

IV. Research Project Submission Process

1. The Principal Investigator, Co-Investigators and key research personnel must register on IRBNet.org.
2. The Principal Investigator or designee develops the research project documents and imports them into a study platform on www.IRBNet.org. A [Submission Checklist](#) is available. At that time, the IRB Registration Form is also completed online. If you are associated with a Residency Program at Carle, there is additional information about conducting research to review on the [Residency Program Research](#) webpage.
3. Once the Registration Form is finalized and complete, the Principal Investigator or designee electronically signs the project submission package on IRBNet. Please be familiar with the [electronic signature policy](#) since the submission will not be reviewed unless it has been electronically signed by the appropriate person.

4. The Principal Investigator or designee submits the complete research project package online via IRBNet.
5. The Director or designee of the Research Office is notified via IRBNet of the submitted research project.
6. The Director or designee of Research Office assigns a Research Coordinator to the submitted research project. (if this has not already been done)
7. The assigned Research Coordinator is notified via IRBNet of the submitted research project.
8. The assigned Research Coordinator reviews the package and communicates with the Principal investigator if needed.
9. The assigned Research Coordinator signs off on the research project package and submits it to the Scientific Review Committee.
10. The Chair of the Scientific Review Committee or a designee assigns reviewer(s) of the new research project package.
11. The new research project package is reviewed by the Scientific Review Committee. The committee communicates with the Principal Investigator if needed.
12. If the Scientific Review Committee approves the research project package, it will be electronically forwarded to the Carle Institutional Review Board. The Principal Investigator will be notified via email by the Scientific Review Committee of the status of the research project package i.e. whether it was approved and submitted to IRB for review, needs revision, or not accepted.
13. The new research project package is reviewed by the Carle Institutional Review Board. The Institutional Review Board communicates with the Principal Investigator if needed.
14. Carle Institutional Review Board approval is needed before the research project can begin recruitment or any other project related activities that involve research subjects.

It is the responsibility of the Principal Investigator to ensure that all necessary approvals have been obtained before the research project begins.

If you have any questions regarding the submission of a research project or need assistance in completing your paperwork, please contact the Research Office using the contact information provided above.

Certain research studies may be eligible for an "expedited" review or be "exempt" from further review under Federal regulations. You may contact a member of the Research Office to learn more about eligibility for "expedited" review and "exempt" research, and for assistance with the submission processes. Alternatively, you can review the following Office for Human Research Protections (OHRP) online guidance which can help with making regulatory determinations:

1. [Does the research qualify for an Exempt determination?](#)
2. [Can the research receive Expedited review?](#)

V. Research Projects Involving Universities and Other Institution may need additional Institutional Review Board Approvals

When institutions in addition to Carle are engaged in the research, and the research is federally funded, the Investigator must obtain approval from Carle's Institutional Review Board as well as the Institutional Review Board representing each additional institution engaged in the research prior to initiation of the research project. A copy of the non-Carle Institutional Review Board approval(s) must be submitted to the Carle Institutional Review Board. If the research is not federally funded and an engaged institution does not have an IRB, a letter of cooperation may suffice. This will be determined on a case-by-case basis.

University of Illinois at Urbana-Champaign (UIUC) Institutional Review Board Process: The process of completing the UIUC Institutional Review Board application and obtaining UIUC approvals* may be undertaken simultaneously with seeking Carle approvals after the initial discussions and/or meetings have occurred and the support of both institutions has been expressed. Details regarding the UIUC Institutional Review Board process can be found at <http://www.irb.uiuc.edu>. A copy of the UIUC Institutional Review Board approval letter must be forwarded to the Carle Institutional Review Board.

*If the research project involves handling or use of human tissues or other biohazardous materials, it must be registered with UIUC's Institutional Biosafety Committee and if it involves radiation it must be registered with UIUC's Radiation Safety. Information regarding the registration processes can be found at <http://www.drs.uiuc.edu/index.aspx>.

University of Illinois Institutional Review Board Deadlines: The deadlines for submission of new projects to UIUC Institutional Review Board are available on the web at: <http://irb.illinois.edu/?q=board-calendar.asp>

VI. Project Agreements

In addition to Institutional Review Board approval, a formal Collaborative Research Agreement (CRA) between Carle Foundation Hospital and collaborating universities/institutions may be required prior to initiating a research project.

A Data Use Agreement and, if limited data set, a Business Associate Agreement will be required when the project involves a transfer of tissues or bio-specimens from Carle Foundation Hospital Tissue Repository to any other entity or to an employee of any other entity.

A Research Affiliate Agreement will be required if the researcher or student is affiliated with an institution who has 3 or more research projects initiated with Carle Foundation Hospital.

Carle Research Coordinators will assist investigators in determining the need for formal research agreements, and will initiate requests for the development of specific agreements between Carle and another entity. Master templates have been established between Carle Foundation Hospital and UIUC to facilitate this process.

VII. Carle Research Affiliate Status

All external researchers and research staff who are not a part of the Carle workforce, are required to become Carle Research Affiliates before starting the research project if part of the research project is conducted on Carle's premises and if the non-Carle investigators will be present on Carle premises. In some cases, a research affiliate contract may be required, as well. A research coordinator will be able to assist you. See link "How to Become a Carle Research Affiliate".

VIII. Funding Requests from Carle Foundation Hospital:

Funding for research may be obtained from Carle Foundation Hospital for select priority research studies. Researchers may request funds to support a proposed research project by submitting a proposal with a detailed budget request and budget justification to Anna Keck (Anna.Keck@carle.com). The proposal will be reviewed by the Carle Foundation Hospital Funding Committee. Researchers will receive written feedback following this committee's review.

IX. Ongoing Review

After Institutional Review Board approval has been received, and all necessary agreements are in place, the research project may be initiated. The Scientific Review Committee and Institutional Review Board have ongoing oversight for the research project until it is completed, including data security and analysis.

Throughout the life of a research project, it is monitored for compliance with the approved processes and Institutional Review Board requirements, and the timely reporting of unanticipated problems involving risks to subjects or others. As such, before any changes are made to the research project, they must be submitted to the Institutional Review Board for review and approval. This includes both minor and substantive changes. The only exception is when a change is required to prevent imminent harm to a research participant. Such deviations must be reported immediately to the Institutional Review Board. All changes to a research project and ongoing reviews will be reviewed by the Scientific Review Committee.

Continuing Reviews are required by the Institutional Review Board prior to the expiration of the current Institutional Review Board approval date, and at intervals not exceeding 365 days. The Human Subject Protection sends notice of continuing review to the Principal Investigator. However, this is a courtesy. The investigator should maintain a project calendar and not rely on the reminder. Review forms should be submitted to the Carle Institutional Review Board via IRBNet in sufficient time to allow for re-approval before the current Institutional Review Board approval expires.

Modification requests and other required reporting forms are available in the Carle Investigator library on IRBNet.org.

Additionally, all studies receiving financial support from the Carle Foundation Hospital are monitored for their use of funds as compared to the approved budget. These reviews assure fiscal responsibility and assist in successful project implementation.

- [Semi-Annual Research Report](#): All Principal Investigators who have research projects funded in part by Carle Foundation Hospital must submit a report to Anna Keck (Anna.Keck@Carle.com), Director of Research Office, every 6 months to allow us to monitor the progress of the research and use of project funds.
- [Final Research Report](#): All Principal Investigators who have research projects funded in part by Carle Foundation Hospital must submit a Final Research Report to Anna Keck (Anna.Keck@carle.com), Director of Research Office, no later than 2 months after closing the study with the Carle Institutional Review Board.