

**The Carle Foundation
Corporate General Policy CF135**

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| Subject | Medical Research/Clinical Trials/Other Research Activities | | |
| Approval | Jul 2004 | Review | Feb 2010 |
| Purpose | To establish guidance for conducting Medical Research, Clinical Trials and/or any other research activities at or by Carle Foundation, Carle Foundation Hospital, or any Carle Foundation affiliated businesses (collectively "Carle" in this policy). | | |

Statement of Policy

- All medical research, clinical trials, and/or other research activities - (collectively called "Research" in this policy) conducted by or at Carle will be done in accordance with the Department of Health and Human Service's Protection of Human Subjects (45 CFR 46), Food and Drug Administration (FDA)'s Human Research regulations (21 CFR), Health Insurance Portability and Accountability Act and other requirements as applicable to the specific Research.
Research is defined as systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalize knowledge. Research includes:
 - The collection of data with the intent to report it in publications and/or publicly;
 - Any care where the choice of therapy is influenced by any consideration other than the direct welfare of the patient(s) (e.g. the selection between two (2) different accepted therapies according to a predetermined plan such as randomization).
 - Any use of drugs or devices that have not received FDA approval.
 Refer to these [Examples of Research and Non-Research Activities – CF135A](#) and IRB Policy 408 Research Defined for further definitions of Research.
- The Carle Scientific Review Committee must approve all Research in advance of any aspect of the Research being performed and if the Research involves human subject the Carle Institutional Review Board ("IRB") must also approve the Research. This includes Research conducted by physicians, staff/employees, residents, students, and/or external parties; and Research about or involving Carle patients, care of patients, and Carle Facilities and/or equipment.
- No Research activities will be allowed unless there is a connection to Carle (for example, Research is sponsored by Carle, Research is conducted by an employee in connection with a school project and has a Carle sponsor, Research is conducted by a medical student affiliated with Carle. Most Research requires the sponsorship of a Carle physician.)
- All Research conducted under Carle Foundation will be overseen by the Carle IRB and conducted in accordance with the Carle IRB Guidelines.
- Publications resulting from Research at Carle shall acknowledge Carle. Carle Sponsor(s) involved in the Research will be given publication credit.
- The Carle IRB has the authority to temporarily suspend or terminate Research, as it deems necessary.
- Further clarification of the Jurisdiction of the Carle IRB can be found in IRB Policy 203 Jurisdiction of the IRB.

Procedure

Prior to initiating any Research contact the Research Office (phone: 217-326-4508; research@carle.com) or visit www.carleconnect.com/ResearchInitiating.shtml for more information.
 Research or Research-related activity involving human subjects, contact the Human Subject Protection Office to obtain specific information about the submission process (phone: 217-383-4300; irb@carle.com) or visit www.carleconnect.com/irb.shtml for more information.

Related Links

- [Examples of Research and Non-Research Activities – CF135A](#)
- IRB Policy 203 Jurisdiction
- IRB Policy 408 Research Defined

Electronic Approval on File

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