

Research at Carle : A Human Subject Protection Perspective

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Presentation Objectives

1. Develop an understanding of the research process at Carle Foundation Hospital.
2. Develop an understanding of the roles and responsibilities of the Human Subject Protection Office and the Institutional Review Board.
3. Develop an understanding of what resources are available for conducting human subject research, and where to find these resources.



Objective 1

Develop an understanding of the research process at Carle Foundation Hospital



Research Institute Goals:

- Increase quantity and quality of research studies conducted to enhance treatment and satisfaction of patients
- Develop a stronger research relationship with the University of Illinois at Urbana-Champaign
- Receive NIH and other Federal grants



Many different types of research

- Nursing research
- Resident research
- Genomics
- Various models testing mechanism of actions and efficacy
- Clinical trials
- Imaging
- Medical informatics
- Aging, Cancer and Gastroenterology



Research at Carle Foundation and Reviews Required

- All research projects involving Carle Foundation 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.





How to Submit Your Research Project

1. Initial Discussion of Research Plan

- Executive Director, Research Institute
Anna Keck, 217-326-0387, Anna.Keck@carle.com
- Medical Director, Research Institute
William Schuh, 217-326-1250, William.Schuh@carle.com
- Contact the appropriate Research Coordinator
(www.carleconnect.com/ResearchInitiating.shtml)
- Researchers in Residency Program visit Residency Program Research webpage
(www.carleconnect.com/ResearchFROResidency.shtml)



How to Submit Your Research Project

2. Joint Meeting of Researcher, Carle Staff, and Research Coordinator
 - The Principal Investigator (PI), Co-Investigators and key research personnel must register on IRBNet.org.
 - Online IRBNet training:
www.irbnetresources.org/training.html
Login name: carle Password: training01
 - All necessary applications, forms and templates can be found in the Carle investigator library at www.IRBNet.org.



How to Submit Your Research Project

Documents required at submission:

- Initial (Continuing or Modification) Review Application
- Research Protocol
- Recruitment Materials
- Questionnaires and Assessment Instruments
- Informed Consent Form
- Information Sheets
- HIPAA Documents
- Grant Applications



How to Submit Your Research Project

Cont. Documents required at submission:

- Financial and Conflicts of Interest Disclosure Statements
- Case Report Form Sample
- Other IRB approval (if involved)
- Evidence of education in human subject protection
- Outcomes of other reviews (audits, SRC)
- Carle Investigator Agreement
- IRB Registration Form
- Data Collection Forms



How to Submit Your Research Project

3. Upload study documents into a study platform in IRBNet.
4. PI or designee electronically signs the submission on IRBNet.
5. The PI or designee submits the complete research project package via IRBNet.
6. The Director or designee of the Research Office is notified via IRBNet of the submitted research project.



How to Submit Your Research Project

7. The Director or designee of Research Office assigns a Research Coordinator to the submitted research project.
8. The assigned Research Coordinator is notified via IRBNet of the submitted research project.
9. The assigned Research Coordinator reviews the package and communicates with the PI if needed.



How to Submit Your Research Project

10. The assigned Research Coordinator signs off on the research project package and submits it to the Scientific Review Committee .
11. The Chair/ designee of the Scientific Review Committee assigns reviewer(s) of the study submission.
12. The study submission is reviewed by the Scientific Review Committee who communicates with the PI if needed.



How to Submit Your Research Project

13. Scientific Review Committee approval = study submission is forwarded to the Carle Institutional Review Board (Carle IRB) via IRBNet.
14. IRB Chair/ designee determines level or review required for each study.
15. Human Subject Protection Office checks submission for completeness and communicates with the PI if needed.



How to Submit Your Research Project

- Study review and approval may be done by
 - the full committee,
 - the chair, or
 - the chair's designee,depending upon the nature and characteristic of the study and the applicable regulations.

To determine if your study qualifies for review other than by the full committee (exempt or expedited review) refer to the OHRP decision charts.

How to Submit Your Research Project

16. Review of study submission by the Carle IRB.
17. Criteria for approval
 - a. Risks to subjects are minimized.
 - b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
 - c. Selection of Subjects is Equitable.
 - d. Informed consent will be obtained and documented from each prospective subject or the subject's legally authorized representative



How to Submit Your Research Project

- e) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- f) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- g) Additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of vulnerable populations.



How to Submit Your Research Project

18. Actions by the Carle IRB

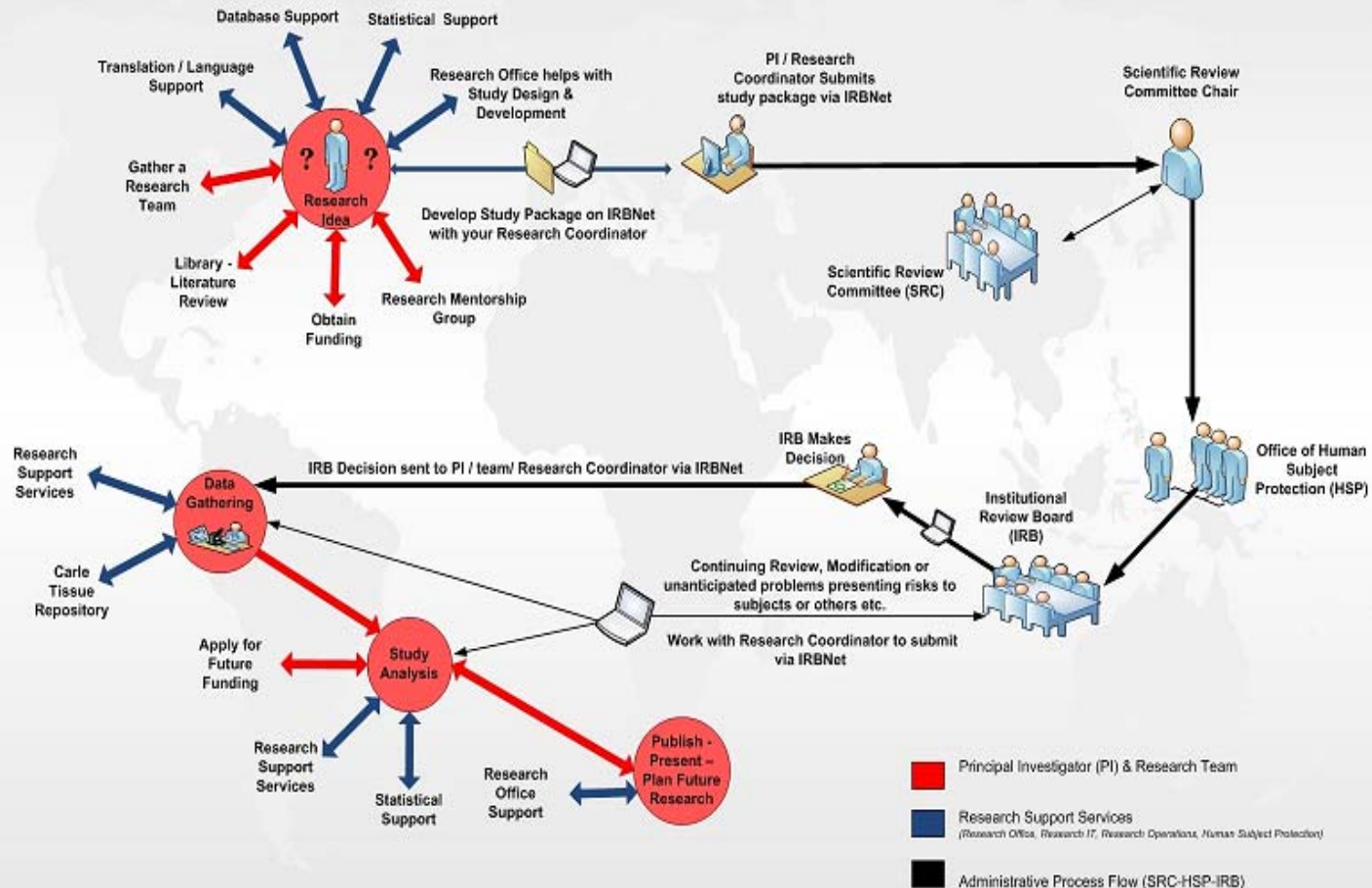
- a. Approved = study may begin
- b. Not approved = study does not meet criteria for approval.
- c. Tabled = PI makes modifications to the study and resubmits to the IRB for re-review.

19. Carle IRB approval is required before any human subject research activity may occur.

Research Process



*We will be a world class innovator
providing exceptional patient care and research*





Objective 2

Develop an understanding of the roles and responsibilities of the Human Subject Protection Office and the Institutional Review Board.



Responsibilities of the Scientific Review Committee

Research Policy 104

- Evaluate all new research proposal packages for scientific quality and merit including, but not limited to, experimental design, statistical analysis, number of subjects, frequency of these subjects, and potential scientific impact.
- Evaluate for the utilization of Carle Foundation resources and services.
- Evaluate if the proposals are within the priority research areas.
- Evaluate the potential long-term beneficial impacts of proposals on patient care.
- Evaluate ongoing research studies at least annually.



Human Subject Protection Office Mission

- Facilitate ethical and regulatory compliant research
- Protect the rights and welfare of research subjects
- Assure compliance with federal regulations, state regulations, and institutional policies governing human subject research



Human Subject Protection Office Goals

- Work cooperatively with investigators to protect the rights and welfare of research subjects and their communities.
- Provide timely review of study submissions and communicate to investigators within 48 hours of an IRB determination.
- Make available to investigators systems and processes that improve research collaborations and streamline communication with reviewing bodies.
- Provide educational offerings that allow investigators and their research teams to stay current in research ethics and regulatory changes.
- Enhance community awareness of the Carle research enterprise and the opportunities to participate.



Responsibilities of the Carle IRB

The primary responsibility of the IRB is to protect the rights and welfare of the research subjects and their community, and ensure compliance with human subject protection regulations and institutional policies.



Responsibilities of the Carle IRB

- Carle IRB policies reflect the overarching commitment of Carle Foundation Hospital to provide protection for all human subjects involved in research conducted under the supervision of the Carle IRB.
- These policies are the framework upon which research reviewed by the Carle IRB is conducted.
- All members of the research enterprise under the jurisdiction of the Carle IRB are expected to read, understand and comply with these policies.



Responsibilities of the Carle IRB

- Meet the regulatory requirements
- Provide guidance
- Enforce compliance
- Help apply the ethical principles in the conduct of research
- Help develop forms, checklists, SOPs, etc



Policies & Procedures

- Research Institute Policies:
www.carleconnect.com/ResearchPolicies.shtml
- Carle IRB Policies:
[www.carleconnect.com/ResearchPolicies.shtml](http://www.carleconnect.com/ResearchPolicies.shtml#IRB)
[#IRB](#)



Carle IRB policies are based on

1. 45 CFR 46
(www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)
2. The Belmont Report
3. (<http://ohsr.od.nih.gov/guidelines/belmont.html>)
4. WMA-Declaration of Helsinki
(www.wma.net/e/ethicsunit/helsinki.htm)
5. Good Clinical Practices
6. Institutional Guidelines



Topics addressed by the Carle IRB policies

- Education and training
- Study submission requirements
- Criteria for Review and approval
- Reporting and documentations
- IRB and GCP compliance



Jurisdiction of the Carle IRB

1. Carle Foundation
2. Carle Affiliate Sites
3. IRB Authorizations with outside entities (for each study)



Carle Investigator Agreement

- Required with every new research project submission
- Purpose: Proactively enable investigators to be compliant with applicable regulations and policies



Carle Investigator Agreement Key Points

- Research activities and modifications to such activities have prior IRB approvals
- PIs and key research personnel have human subject education
- Submission of required documents for initial, continuing reviews and project closures are filed appropriately
- Reporting requirements are fulfilled appropriately
- Agreements and cooperation with Carle IRB
- Reporting of audits and accessibility granted to monitors/auditors
- Streamline research compliance within the Institution and facilitate obligations to sponsors
- Proper maintenance of documents



Research Policy 102: Education Requirements for Investigators and Key Personnel

All Investigators and their key research personnel must complete requirements in human subject protection training before initiating their involvement in human subject research.



Research Policy 102: Education Requirements for Investigators and Key Personnel

■ Initial Education

- The initial educational requirement should be met by registering as a Carle Foundation Hospital affiliate and completing the basic bio-medical CITI initial training module plus one elective at www.citiprogram.org.



Research Policy 102: Education Requirements for Investigators and Key Personnel

- Continuing education
 - Required every 2 years
 - Documentation of external education should be submitted to the Carle IRB at IRB@Carle.com



Ongoing Oversight

- Oversight includes review of, but may not be limited to, the following activities:
 - Site Visits and Third-Party Verification
 - Collection and Review of Data
 - Serious and Unexpected Adverse Events
 - Amendments
 - Significant New Findings
 - Revised protocols and informed consent documents
 - Reports from Employees, Staff and Faculty
 - Noncompliance
 - Unanticipated Problems
 - Internal and External Audits



Quality Improvement vs Research

- Unsure? Contact the Carle IRB to assist with this determination.
- Submit the Human Subject Research Determination form
(www.carleconnect.com/ResearchInitiating.shtml)
- If activity is quality improvement = project does not need IRB approval.
- If activity involves human research = project must be reviewed and approved by an IRB prior to initiation.



Quality Improvement vs Research

- For more information on how to determine if an activity involves human research, visit the Office for Human Subject Protections guidance documents at www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm
- You can also contact the Human Subject Protection Office at Carle Foundation Hospital (Phone): 217-383-4366 or (e-mail): irb@carle.com

Dates to Remember

- Deadlines for upcoming 2009 IRB meetings are provided on the Deadlines webpage at <http://www.carleconnect.com/ResearchDeadlines.shtml>

Objective 3

Develop an understanding of what resources are available for conducting human subject research, and where to find these resources.



Research Mentorship Group

Mission: To help create and maintain a dialogue of research amongst all healthcare professionals at Carle and support research productivity by promoting the idea that high quality clinical research can be done appropriately by any interested individual or group.



Research Mentorship Group

They can:

- Guide your imagination
- Discuss the design
- Assign an expert to further develop the project
- Transform ideas into research projects



Research Mentorship Group

Research Mentorship Group composed of experts in:

- Qualitative Research
- Survey Research
- Retrospective Research
- Basics of Research
- Case Studies
- Population Based Research
- Quantitative Research
- Prospective Research
- Cohort Research



Research Mentorship Group

Co-Chairs

- Bharat Gopal, MD, FAAFP
- John A. Aucar, MD, MSHI, FACS

**Any questions, contact Charletta Little, Research Coordinator, at
(217) 326-0068.**



Carle Tissue Repository (CTR)

- There are two separate IRB approvals involved for each project that uses tissue repository materials:
 1. The first IRB approval is needed for the CTR to collect tissues and maintain a clinical database. This is received by the Carle Tissue Repository.
 2. The second approval is needed for each research protocol which will use CTR resources. This is submitted by each researcher.



Carle Tissue Repository (CTR)

- Research Institute
 - Carle Tissue Repository
Phone: (217) 326-4513
Fax: (217) 326-4523



Resource list

- CONSENTING
- CONTRACTS
- DATABASE SUPPORT
- EDUCATIONAL SEMINARS
- FORMATTING AND SUBMISSION OF PROTOCOLS
- RESEARCH ARTICLES
- GME SCHOLARLY ACTIVITY TRACKING
- GRANT OPPORTUNITY IDENTIFICATION
- GRANT SUBMISSION
- LUNCH 'N' LEARN SERIES
- PHI REVIEW/SCIENTIFIC MERIT REVIEW
- POSTER PRINTING
- RESEARCH BILLING
- RESEARCH PRESENTATION EDITING
- RESEARCH REGULATIONS
- STATISTICAL SUPPORT
- STUDY DESIGN AND PROTOCOL DEVELOPMENT
- STUDY PACKAGE DEVELOPMENT FOR IRBNET
- TISSUE TRANSFER
- TRANSLATION/LANGUAGE SUPPORT



Carle IRB Policy 701: Informed Consent General Requirements and Documentation

- Informed Consent is an ongoing process
- It is a privilege, not a right, to use Human subjects in research
- Unless documentation requirements are waived, the Carle IRB requires documentation of informed consent by use of a written informed consent form approved by the Carle IRB and signed and dated by the subject or the subject's legally authorized representative.
- No changes will be made in the information provided during the informed consent process, or to the informed consent document, without prior Carle IRB approval.



Carle IRB Policy 701: Informed Consent General Requirements and Documentation

- Informed consent ensures that research subjects voluntarily agree to participate in research, after having been provided the information needed to make an informed and voluntary decision.
- Who should conduct the consent process?



Carle IRB Policy 701: Informed Consent General Requirements and Documentation

- Required elements:
 - A statement that the study involves research, the purposes of the research, the expected duration of the subject's participation, a description of the procedures, and identification of any experimental procedures. A description of any reasonably foreseeable risks or discomforts to the subject.
 - A description of any benefits to the subject or to others that may reasonably be expected from the research.
 - A disclosure of appropriate alternative procedures or courses of treatment.



Carle IRB Policy 701: Informed Consent General Requirements and Documentation

- Required Elements cont.
 - A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained.
 - For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs.
 - Whom to contact for answers to questions about the research and research subjects' rights.



Carle IRB Policy 701: Informed Consent General Requirements and Documentation

- Required Elements cont.
 - Whom to contact in the event of a research-related injury.
 - A statement that participation is voluntary
 - Refusal to participate will involve no penalty or loss of benefits.
 - May discontinue participation at any time without penalty or loss of benefits.
 - Type and amount of compensation for participation.



Carle IRB Policy 701: Informed Consent General Requirements and Documentation

- Types of waivers
 - Waiver of one or more elements
 - Waiver of documentation of Informed Consent
 - Appropriate disclaimers

21 CFR 50, 45 CFR 46.116(c) and (d), 45 CFR 46.116, and 45 CFR 46.117

Guidance for Writing Informed Consent Documents
(ohsr.od.nih.gov/info/sheet6.html)



Does my research need IRB review?

According to federal regulations, the activities that require IRB review include any human research activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual.



Does my research need IRB review?

- The implications of engaging in activities that qualify as human subject research without first obtaining IRB review and approval are serious.
- Study review and approval may be done by the full committee, the chair, or the chair's designee.



HIPAA Forms

To be compliant with HIPAA regulations, most submissions will require an accompanying HIPAA document.



IRB 801: Unanticipated Problems and Other Events Requiring Prompt Reporting

- Unanticipated problems involving risks to subjects or others
 - Includes any incident, experience or outcome that meets all of the following criteria:
 - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents; and (b) the characteristics of the subject population being studied;



IRB 801: Unanticipated Problems and Other Events Requiring Prompt Reporting

- Non compliance
- Related or possibly related to participation in the research
- Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.



IRB 801: Unanticipated Problems and Other Events Requiring Prompt Reporting

- **Adverse Events**
- **Serious Adverse Events**
- **Internal**
 - **Events occurring at sites where the Carle IRB has oversight responsibility for the research**
- **External**
 - **Events occurring at sites in the clinical study where the Carle IRB has no oversight responsibilities**
- **Protocol Violations (accidental, unintentional or intentional deviation from the IRB approved protocol)**
- **Other reporting obligations: Sponsor, HHS and FDA**



Conclusion

It is our earnest desire to enhance
the research enterprise
at the Carle Foundation Hospital
while helping you do it right!



Contact Information

Human Subject Protection

(217) 383-4366

IRB@carle.com



Thank you!