Growing Biomedical Research: Collaboration Between Carle and University of Illinois

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Overview

- Memorandum of Understanding
- Stephens Family Clinical Research Institute (SFCRI)
- UIUC IRB & Carle IRB submission process
- Including Carle in your research project
- Submission process-flow
- Post-Determination
- HIPAA/Privacy Board Considerations
- Improvements
Memorandum of Understanding

• **January 2014:** Officials at UIUC and Carle signed a Memorandum of Understanding (MOU) for IRB review, allowing (not mandating) one IRB to rely on the other for review and continuing oversight of its human subjects research.

• **February 2017:** Any projects in which neither institution had deferred oversight were identified and reviewed by both IRB offices. Determinations were made as to which IRB would maintain oversight and which IRB would defer oversight.
Stephens Family Clinical Research Institute (SFCRI) Supports All Research at Carle

STEPHENS FAMILY CLINICAL RESEARCH INSTITUTE (SFCRI) AT CARLE

- Research Development/Study Design
- Clinical Coordination
- Finance
- Regulatory
- Institutional Review Board
Carle gives priority to collaborative research between Carle clinicians and UIUC faculty.

If you would like to find a Carle collaborator, please contact IHSI.
How do I include Carle in my research project?

INVESTIGATORS MUST FIRST RECEIVE SUPPORT FROM SFCRI

To initiate the process, please complete a Research Project Intake Form:
https://redcap.carle.org/REDCap/surveys/?s=X4YKYK77LF
How do I include Carle in my research project?

**NEW PROJECT**
- Submit Research Project Intake Form
- SFCRI Determines Resource Availability

**EXISTING PROJECT**
- Submit Research Project Intake Form
- SFCRI Determines Resource Availability
If SFCRI has resources for your project, they will assist with:

- CLINICAL COORDINATION
- FINANCE
- REGULATORY
**UIUC IRB & Carle IRB Submission Process**

**UIUC IRB**
- Investigator submits directly to UIUC IRB via email.

**Carle IRB**
- Investigator receives support & assistance from SFCRI.
- SFCRI regulatory submits to Carle IRB on your behalf via IRBNet.
Preliminary oversight designation is assigned:

BOTH IRB OFFICES REVIEW:

- RESEARCH LOCATIONS
- STUDY PROCEDURES
- RISKS
After preliminary oversight designation is assigned:

**UIUC OVERSIGHT**
- UIUC IRB completes a thorough & comprehensive review of all study documents
- CARLE IRB completes a limited review

**UIUC OVERSIGHT WITH CARLE IRB SERVING AS PRIVACY BOARD**
- UIUC IRB completes a thorough & comprehensive review of all study documents
- CARLE IRB completes a thorough review of the recruitment procedures & HIPAA documents
- Limited review of all other study documents

**CARLE OVERSIGHT**
- CARLE IRB completes a thorough & comprehensive review of all study documents
- UIUC IRB completes a limited review
A Determination Has Been Made. Now What?

Prior to initiating a research project, investigators must receive:

- An \textit{approval} letter from the IRB of oversight, \textbf{AND}
- A \textit{deferral} letter from the IRB that has deferred oversight
If Carle IRB Has Oversight of Your Project:

**WHICH IRB DO I SUBMIT TO?**

CARLE IRB

**WHO ASSISTS ME WITH THIS PROCESS?**

SFCRI COORDINATORS & REGULATORY
If UIUC IRB Has Oversight of Your Project:

WHICH IRB DO I SUBMIT TO?

UIUC IRB*

WHO ASSISTS ME WITH THIS PROCESS?

UIUC IRB*

* If Carle IRB is serving as the Privacy Board, you may need to submit to Carle IRB, as well. See next slide.
HIPAA/Privacy Board Considerations:

If an investigator intends to utilize SFCRI/Carle for recruitment services and requests that SFCRI/Carle staff:

- Generate a list of potential subjects from the electronic medical record (EMR)
- Review EMR for inclusion/exclusion criteria
- Access clinical schedules to identify potential subjects, or
- Access and collect data/specimens

Project will require a Waiver/Alteration of HIPAA Authorization which must be granted by Carle IRB as a HIPAA Privacy Board.

This means that even if UIUC IRB has oversight, Carle IRB will still be involved as the Privacy Board in order to grant the waiver/alteration and review any future changes related to the waiver/alteration.
Human Subjects Research Conference

Improvements to facilitate better communication & foster more collaboration.

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<th>IMPLEMENTED</th>
<th>IN PROGRESS</th>
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<tr>
<td>• Referring investigators to complete SFCRI Research Project Intake Form</td>
<td>• Updating information on websites about UIUC/Carle submission processes</td>
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<td>• Accepting applications/forms from either institution</td>
<td>• Updating UIUC forms to ask more directed questions about UIUC/Carle collaboration</td>
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<td>• Granting IRBNet access to UIUC IRB staff</td>
<td>• Developing submission process flowcharts</td>
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<td>• Combining IRB pre-review requests/questions, when appropriate</td>
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<td>• Using a web application to provide real-time updates to IRB staff</td>
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<td>• Recurring bi-weekly HSR Manager meetings</td>
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Conclusion

We recognize this is a complex and oftentimes confusing process.

We are working together to simplify and clarify the process.

We appreciate your feedback and patience.