
INTEROFFICE MEMORANDUM

TO: LSUHSC-NO FACULTY WANTING TO DO HUMAN SUBJECTS RESEARCH AT OCHSNER
FROM: IRB CHAIRS OF LSUHSC-NO AND OCHSNER
SUBJECT: IRB APPROVAL
DATE: SEPTEMBER 2009
CC:

CONTEXT FOR IRB APPROVAL

All human subjects research occurring at Ochsner requires IRB approval unless the Ochsner IRB Chair or designee has ruled it exempt research. LSUHSC-NO faculty wanting to do research at Ochsner are subject to two sets of rules: from LSUHSC-NO and from Ochsner. This memo is meant to explain how the process of obtaining IRB approval works in this situation where both sets of rules must be followed.

LSUHSC-NO requires all LSUHSC-NO faculty members doing human subjects research at Ochsner obtain LSUHSC-NO IRB approval. Ochsner requires that any human subject research at Ochsner where significant liability would be incurred by Ochsner (namely, drug, device, or radiation interventional studies), obtain Ochsner IRB approval. Therefore, LSUHSC-NO faculty doing research at Ochsner are required to obtain IRB approval from both IRBs. In non-interventional minimal risk studies it may be possible to have Ochsner recognize the LSUHSC-NO IRB approval. This memo will explain what you need to do to get approval.

The current rules about who has to get what IRB approvals are set up by senior executives and/or legal counsel for a variety of reasons, and the IRBs at LSUHSC-NO and Ochsner do not have the ability to make exceptions to the rules. However, we would like to make things as user friendly as possible within the framework we have.

DRUG/DEVICE/RADIATION INTERVENTIONAL STUDIES

In this situation LSUHSC-NO faculty members doing research at Ochsner will need two IRB approvals and two institutional approvals. For the IRB approvals, follow these steps:

1. Start with the "LSUHSC-NO faculty at Ochsner" templates, and submit these along with the IRB application to the LSUHSC-NO IRB for approval. The template has been worked out by the IRBs at both institutions to help speed the approval process.
2. Next, submit the LSUHSC-NO IRB approved consent form / HIPAA authorization along with study materials and the LSUHSC-NO IRB approval letter to the Ochsner IRB for Ochsner IRB approval of the study via the ERSA system.
3. If the study and consent form was approved as is by the Ochsner IRB, you now have all the IRB approvals you need to begin your research. Don't forget that IRB reports must go to BOTH the LSUHSC-NO and Ochsner IRB, and to do continuing reviews for both IRBs.

- a. If the Ochsner IRB required any minor changes to the consent form, then submit these to get LSUHSC-NO IRB expedited approval. In occasional cases there may be some back and forth between LSUHSC-NO and Ochsner expedited reviewers to get a final single consent form acceptable to both IRBs.

All human research studies for LSUHSC-NO faculty at Ochsner require institutional approvals from both LSUHSC-NO and Ochsner. For LSUHSC-NO, this approval will be provided in the grant/contract signed by an LSUHSC-NO Institutional Official. For Ochsner, this means submitting your study to the Ochsner's Office of Research Operations to review the budget, contract, liability, and billing legality issues. An Ochsner Institutional Official will sign the Ochsner site specific contract/grant.

Once you have both IRB approvals, and both institutional approvals, you can begin your research.

NON-INTERVENTIONAL STUDIES

LSUHSC-NO faculty doing non-interventional minimal risk studies at Ochsner (e.g., chart review or survey studies) must get LSUHSC-NO IRB approval. In this case Ochsner will accept the LSUHSC-NO IRB as the sole IRB for the study. The steps to obtain approval are:

1. Submit the study to the LSUHSC-NO IRB for approval.
2. Next, you would submit this study into Ochsner's ERSA system. The Ochsner IRB would issue a "facilitated acknowledgement" that allows the study to be tracked at Ochsner, but no Ochsner IRB approval is issued. This "facilitated acknowledgement" in ERSA gives Ochsner institutional approval to conduct the research unless there is a commercial sponsor.

Even minimal risk studies that involve an outside pharmaceutical or device company as sponsor must go through Ochsner's Office of Research Operations for approval so they can determine if there must be a contract.

EXEMPT RESEARCH. Some studies qualify for exempt research and therefore are exempt from further IRB review. If LSUHSC-NO has determined something is exempt research, then submit the study along with the LSUHSC-NO IRB exempt determination letter to the Ochsner ERSA system. The Ochsner IRB Chair or designee will review it to issue an Ochsner exempt ruling letter. Once you have the exempt ruling from both institutions, you can proceed, subject to whatever limitations are in the exempt approval letters.

HIPAA AUTHORIZATIONS

LSUHSC-NO requires a HIPAA authorization separate from the research informed consent. Ochsner allows this as an option, and also permits the HIPAA authorization to be contained within the consent form. LSUHSC-NO faculty members doing research at Ochsner should plan on a HIPAA authorization separate from the consent form.

The "covered entities" of LSUHSC-NO and Ochsner are required to have research subjects sign a HIPAA authorization. While it is OK to have the subject sign two HIPAA authorizations (one from LSUHSC-NO, one from Ochsner), we are working with legal and compliance offices at both institutions to approve a single HIPAA authorization that will cover both entities and make it simpler

for research subjects. Until this is completed, you should have both authorizations from LSUHSC-NO and from Ochsner signed.

WHO TO CONTACT AT LSUHSC-NO

The following people at LSUHSC-NO can be contacted for additional information.

- Kenneth E. Kratz, PhD, Director, LSUHSC-NO Office of Research Services and Chair, LSUHSC-NO IRB at kkratz@lsuhsc.edu or 568-4970
- Nicole Barron, Grants and Contracts Coordinator, LSUHSC-NO Office of Research Services at nbarro@lsuhsc.edu or 599-1533
- Charlene Walvoord, Coordinator, LSUHSC-NO IRB at cwalvo@lsuhsc.edu or 568-4060
- Linda Bernhard-Potter, Coordinator, LSUHSC-NO IRB at lbernh@lsuhsc.edu or 680-9070
- Sylvia Young, Coordinator, LSUHSC-NO IRB at syoun3@lsuhsc.edu or 568-3779
- LUSHSC-NO IRB <http://www.lsuhs.edu/no/administration/rs/irb/default.htm>

WHO TO CONTACT AT OCHSNER

The following people at Ochsner can be contacted for additional information.

- Ochsner IRB at irb@ochsner.org or 504-842-3535. IRB Administrator Karen Marie Sorapuru, CIP; IRB Specialist Arlene Becker, RN; IRB Special Services Coordinator, Robbie Bowman-Rush. These are your best contacts for how to use ERSA and how to proceed with a standard application. Staff listing is at <http://academics.ochsner.org/resstaff.aspx?menu=374>
- Ochsner IRB Chair at jbreault@ochsner.org or 504-842-3589 (T-W-T). This is your best contact at Ochsner for IRB issues for LSUHSC-NO Faculty doing research at Ochsner about IRB questions that do not fit into the situations described in this memo.
- Ochsner Research Operations, Director Anne Nicolay Anicolay@ochsner.org or 504-842-3562. Staff listing is at <http://academics.ochsner.org/resstaff.aspx?menu=376> . This is your best contact about grants/liability issues/budgets/contracts/sponsor relations.
- Ochsner Clinical Research Support, Director Lynn Thibodeaux lthibodeaux@ochsner.org 504-842-4685. Staff listing at <http://academics.ochsner.org/resstaff.aspx?menu=372> . If you are a CRC within Ochsner and need support or training, this is your best contact.
- Ochsner Vice-President of Academics jpiazza@ochsner.org or 504-842-2717. For interventional studies requesting an exception to needing Ochsner IRB approval due to special circumstances where liability is minimal, this would be the person who would have to issue the special exemption. An example might be an LSUHSC-NO faculty member moving his/her research to OMC-Kenner after all interventions are completed and subjects are in the follow-up only phase.

Relevant forms, such as LSUHSC-NO faculty at Ochsner templates for informed consent and HIPAA authorization, along with this memo, are posted in ERSA. Go to ersa.ochsner.org and before signing in, lick on the left column menu item called "Forms & Templates." Toggle down to the section called "LSUHSC-NO faculty at Ochsner."