# LSU Residency Research Policy

This policy serves as a guide to medical residents from Louisiana Health Sciences Center, New Orleans (LSUHSC-NO), regarding their requirements as study investigators at Woman's. Research conducted by LSUHSC-NO residents at Woman's is considered multi-site research.

**Definitions:**

Multi-site research (cooperative research) – When the same protocol is being conducted at multiple locations (NIH definition) and/or when a single project involves more than one institution (45CFR46 definition).

Reviewing IRB (single IRB of record) – The IRB that will provide review for all or most sites participating in a multi-site study.

Relying Institution – the institution that has assigned an external Institutional Review Board (IRB) to serve as the Reviewing IRB under an IRB Authorization Agreement. Note the use of relying *institution* and not relying *IRB*, as the reliance agreement is between institutions.

## Resident requirements

Any resident involved in a research study at Woman's should complete the following requirements prior to consenting participants for a research study:

- CITI training in human subjects research through LSUHSC-NO or Woman's found online at citiprogram.org
- In-person orientation with the Human Protections Administrator (HPA) about conducting research with human subjects at Woman's

## Submission of a research proposal

The following materials should be submitted to the Woman's Hospital Research Center (WHRC):

- Initial study application form, protocol, informed consent form, initial study submission form, and associated study documents for to Research and Development (R&D) Committee and Institutional Review Board (IRB) review
- Participant eligibility screening form to use for participant enrollment
- Submission of a list of all residents who will conduct the research and consent participants

Only those residents who are listed as a co-investigator on the research protocol and who have completed CITI training may conduct research and consent participants. All consent forms used for resident research should include a signature line for the Principal Investigator.

All resident studies that require consenting of participants will be audited at least annually by the Human Protections Administrator, or by the IRB audit committee, at the discretion of the IRB Chair.
Once approved by the IRB, continuing review may need to be conducted more frequently than annually, as determined by the IRB reviewers.

## For exempt studies:

LSUHSC-NO may rely on Woman's IRB for review and continuing oversight of human subjects research described as follows: any study conducted at Woman's involving LSUHSC-NO faculty or trainees where Woman's IRB either (i) determines the study is not humans subjects research or (ii) determines the study to be exempt under applicable federal regulations. Residents should submit any research proposals anticipated to qualify as exempt to the WHRC for review.

## For non-exempt studies with a Woman's employee as the Principal Investigator:

For non-exempt research conducted at Woman's with a Woman's employee listed as the Principal Investigator, Woman's IRB will be the IRB of record. The research proposal should be submitted to WHRC for R&D and IRB review. The study will be managed using IRB Exchange (IREx). Woman's will use the SMART IRB Standard Operating Procedures (available online) for delineation of responsibilities for the relying institution (LSUHSC-NO) and the reviewing IRB (Woman's).

## For non-exempt studies with an LSU employee as the Principal Investigator:

LSUHSC-NO's IRB will be the IRB of record and Woman's will be the relying institution. Submissions should be sent to LSUHSC-NO and will be managed through IREx with Woman's relying on LSUHSC-NO for review and oversight of the research.

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