

	HUMAN SUBJECT PROTECTION EDUCATIONAL POLICIES AND RESOURCES			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	1.05	02.07.2020	5.1	03.25.2019

A. Investigator(s)

It is the policy of the LSUHSC-NO IRB that all LSUHSC-NO investigators desiring to engage in research using human subjects must familiarize themselves with all IRB policies and procedures and related federal regulations. Policies and Procedures are posted on the IRB website at <http://www.lsuhs.edu/administration/academic/ors/irb.aspx>. Any changes to these policies are distributed by e-mail to all employees. Investigators new to the Institution must meet with the IRB Chair, Vice-Chair or a staff member prior to submission of an IRB application. Investigators should maintain an on-going relationship with the IRB office staff to gain assistance in the preparation of applications and in following all IRB policies and procedures during the conduct of their studies. This will help assure that both investigators and the Institution remain in compliance with all state and federal regulations regarding research involving human subjects.

All employees involved in human subjects research must take advantage of the educational opportunities listed below.

- All investigators and their research team members submitting an initial or continuation application to the IRB must read the LSUHSC IRB “[Guidebook](#)” and the “[Belmont Report](#)”.
- In addition, they must complete appropriate (Biomedical or Social/Behavioral learner groups) Collaborative Institutional Training Initiative (CITI) <https://www.citiprogram.org/default.asp?language=english> modules as described in the Instructions for completing CITI training at http://www.lsuhs.edu/administration/academic/ors/docs/CITI_Instructions.pdf.
- In addition to training in human subjects protection, any investigative team conducting FDA-regulated research must complete the appropriate learner group for Good Clinical Practice (GCP) also available at <https://www.citiprogram.org/default.asp?language=english>.
- Continuing education of all investigators and their team members is required every three years. Appropriate refresher learner groups on the LSUHSC-NO CITI page are available for this purpose. Studies cannot be approved, amended or re-approved until all training requirements are met by all study team members.

B. Members

Members of the IRB have the important responsibility of protecting the many individuals in our community who volunteer to participate in this Institution's human subjects research programs. New Board members are expected to familiarize themselves completely with the IRB process in the manner described above for investigators. New members are asked to attend a number of scheduled IRB meetings to observe, and to contribute to, the discussion at the meeting prior to being assigned primary reviewer responsibility. New members should interact with the IRB Chair, Vice-Chair and IRB office staff regarding the requirements of, and for assistance with, reviews.

For the purposes of continuing education at each IRB meeting, an Educational Component is included in which issues of current interest related to human subjects protection are discussed. Related written materials are distributed as part of the Educational Component and a copy of the *Human Research*

Report is provided to each member at each meeting. Additional items of interest are distributed by email to all members.

All members are required to read the LSUHSC-NO Guidebook and the Belmont Report. They must complete the IRB Members learner group in the CITI program <https://www.citiprogram.org/default.asp?language=english> and maintain continuing education requirements of CITI courses every three years. Compliance is monitored by the IRB staff. Failure to comply with the requirements will result in termination of IRB membership.

C. IRB Staff

All IRB staff are required to read the LSUHSC-NO HRPP Guidebook, the OHRP Guidebook and the Belmont Report. They must complete all CITI learner modules at <https://www.citiprogram.org/default.asp?language=english>. They are carefully trained to understand all federal regulations related to human subjects protection and drug and device development. Continuing education occurs during attendance at all IRB meetings, by participating in the IRB Forum list-serve, by attending regional and national IRB conferences and workshops and completing continuing education modules offered by CITI. Compliance is monitored by the IRB Chair. Failure to comply with the requirements may result in personnel action taken by the Institution which can result in reassignment or include termination of employment.

D. Other Educational Opportunities

1. Lectures

Presentations by the IRB Chair, Vice-Chair and staff concerning IRB issues are made at departmental faculty meetings, business manager meetings, workshops, courses, and other academic settings to familiarize investigators and staff with the IRB process, human subjects protection, and with IRB policies and procedures. In addition, a number of IRB members lecture on IRB issues in ethics classes taught on campus.

2. Educational Meetings

On an unscheduled basis, the Institution sponsors, with other institutions and national organizations such as OHRP, locally-held meetings concerning IRB issues and human subjects protection, and invites consultants to present such issues to our employees. OHRP, PRIM&R, NCURA and AAMC have numerous national and regional meetings dealing with IRB issues, and announcements of these meetings are widely distributed. Our investigators and IRB members are encouraged to attend such meetings. The IRB Chair, Vice-Chair and staff regularly attend such meetings.

3. Resources

The educational materials mentioned are available from the IRB office to assist all investigators in familiarizing themselves with the history of human subjects protection, factors which necessitated the development of the IRB process, and regulations underlying IRB policies and procedures. Materials are also available in LSUHSC-NO libraries. The IRB library, housed in the IRB office, contains numerous videos and written materials on the history and operation of IRBs and human subjects protection. This includes Cynthia Dunn and Gary Chadwick's book entitled *Protecting Study Volunteers in Research* (Center Watch, Inc. Boston, MA 1999). Copies may also be purchased in the LSUHSC-NO campus bookstore. OHRP, FDA and other organizations and

institutions have educational materials concerning human subjects protection and IRB function available on their websites. Such information is electronically distributed to all employees.