LSU Health NEW ORLEANS
Human Research Protection Program

FEDERAL, STATE, AND UNIVERSITY REGULATIONS RELATED TO THE IRB

P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
1.01	02.12.2020	1.01	02.05.2020

The LSUHSC-NO Human Research Protection Program (HRPP) is guided by ethical principles established by the World Medical Association, and its adoption of the Declaration of Helsinki, and the Belmont Report. These principles are implemented in consonance with applicable university, state and federal laws and regulations. Review by the LSUHSC-NO IRB is required for all research and related activities involving human beings and/or information and tissue from human beings conducted by investigators with an appointment (hereafter referred to as employee) at LSUHSC-NO.

The LSUHSC-NO IRB is registered with OHRP, as required by Federal Regulations, and is designated a Federalwide Assurance Number to conduct reviews involving human subjects research. If additional registrations are required by different regulatory agencies or if a new IRB is formed, a submission will be initiated through the appropriate agency system by a member of the HRPP staff.

As appropriate, LSUHSC-NO conducts its research and Institutional Review Board (IRB) oversight in compliance with the following federal regulations:

- The Code of Federal Regulations related to the Office for Human Research Protections (OHRP) authority (45 CFR 46, Subparts A-D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- The Federalwide Assurance with OHRP that LSUHSC-NO has adopted can be viewed at the OHRP website at http://www.hhs.gov/ohrp/. Note that while LSUHSC-NO has chosen not to formally extend the Common Rule to all of its human subjects research through its Federalwide Assurance (FWA), LSUHSC-NO adheres to the ethical principles established by the Belmont Report and their application as expounded in the Common Rule. This approach applies to all human subjects research conducted by this institution independent of the sponsorship of the project.
- Other federal agency Code of Federal Regulations (CFRs) incorporating the Common Rule or in addition to the Common Rule.
- The Code of Federal Regulations related to the Food and Drug Administration (FDA) http://www.fda.gov authority (Title 21 CFR Parts 50, 56, 312, 600 and 812.66) http://www.gpoaccess.gov/cfr/index.html.

As applicable, the Institution and IRB comply with the International Conference on Harmonization (ICH) "Guidance for Industry—E6 Good Clinical Practice: Consolidated Guideline." Generally this applies to FDA-regulated studies where data are submitted to the regulatory agency. When following ICH-GCP (E6), clinical trials are conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with good clinical practice and the applicable regulatory requirements.

Approval of any submission to the IRB is contingent upon meeting all of the requirements of LSUHSC-NO's Human Research Protection Program (HRPP) policies detailed in this Guide, of 45 CFR 46 (Subparts A-D) for all federally-funded research, and 21 CFR 50, 56, 312, 600 and 812, including all operative Subparts, for FDA-regulated research. All other human subjects studies not OHRP- or FDA-regulated must adhere to the policies set forth in the current document. Submissions must also comply with all

state and local requirements and laws. The HRPP looks to the LSUHSC-NO Senior Staff Attorney for advice on legal issues and to help resolve any conflicts between federal, state, and local laws.

It is the policy of LSUHSC-NO that all activities or investigations involving human beings and/or information or tissue collected from human beings must be presented to the IRB for a determination whether:

1. The activity is human subjects research,
2. The human subjects research activity can be given Exempt status under the regulations, or
3. The human subjects research activity must have IRB review, approval, and continued oversight.

These determinations are made, as described in the following sections, by the Chair or his/her designee. As part of these considerations and based upon guidance provided by OHRP at (http://www.hhs.gov/ohrp/policy/engage08.html) and the definition of human subjects research provided in the next section, the Chair and/or designee makes a determination whether the investigator and institution are engaged in human subjects research. Requests for a determination should be made following the instructions provided at https://www.lsuhsc.edu/administration/academic/ors/is_it_hsr.aspx.