IRB AUTHORITY

SECTION	EFFECTIVE DATE	REPLACES POLICY	REPLACES SECTION
P&P 2.01	11.29.2021	02.06.2020	3.1

The Board is designated as the Institutional Review Board (IRB) and is responsible for reviewing all research projects involving the use of human subjects to determine that (a) the risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained, as to warrant a decision to allow the subject to accept those risks; (b) the rights and welfare of the subject are adequately protected; and, (c) legally effective informed consent is obtained by adequate and appropriate methods. As defined by federal regulations, IRB authority extends to any study using live human subjects, or data, or tissue collected from live humans. It is also institutional policy that if a subject passes away while still enrolled in a study, and the study team wants to continue to use or collect that subject's data, then the subject's LAR or next of kin must be consented.

LSUHSC-NO grants the IRB the authority to:

- approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization;
- suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants;
- observe, or have a third party observe, the consent process and the conduct of the research.

The Health Sciences Center administration may not approve research which has not been reviewed and approved by the IRB.

The IRB interacts directly with the departmental heads and center directors of the schools within the Health Sciences Center to assure department/center review of protocols. The IRB Staff will assign the Department Head as an Ancillary Reviewer in the Kuali System upon receipt of an initial application. The initial application will not receive IRB approval until the Department Head has approved their ancillary review. The departmental head or center director's approval verifies that:

- the principal investigator has permission to conduct the study if approved,
- the IRB application, protocol, and related documents have been reviewed and are recommended for submission to the IRB,
- the principal investigator has the expertise to conduct the study, and
- the principal investigator is an employee in good standing at LSUHSC-NO.

The Board reviews all human research studies in which LSUHSC-NO employees and students are involved, regardless of location. For example, if studies are to be performed at other institutions, all LSUHSC-NO employees must apply to the LSUHSC-NO IRB even if their participation is limited to that of co-investigator or other roles. Approval by the LSUHSC-NO IRB for its employees does not extend to individuals on the project who are not LSUHSC-NO employees unless a reliance arrangement is in place. If a reliance arrangement is not in place, those individuals must seek IRB review from the IRB of their home institution(s) or their designee. LSUHSC-NO IRB is the IRB of record for all of its employees (both full and part-time). Prior to initiation, any human subjects research conducted by Gratis faculty in LSUHSC-NO facilities or through an award made to or contract with the Institution must also be evaluated and approved by the LSUHSC-NO IRB.

Student-conducted (student, fellow, resident, and others in training without a faculty appointment) research must be supervised by an LSUHSC-NO faculty mentor. The IRB application must be submitted by

that mentor, who will assume the role and responsibilities of principal investigator. The approval is given to the principal investigator (faculty mentor).

Research potentially considered to be Exempt under federal regulations must also be submitted for review and approval by the IRB. Exempt research must be evaluated by the IRB as to its fulfillment of the ethical standards to which this Institution adheres:

- the research must hold out no more than minimal risk to participants;
- selection of participants must be equitable;
- if there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data; and
- there are adequate provisions to maintain the privacy interests of participants.

If there are interactions with participants, the IRB will determine whether there should be a consent process that will disclose information such as:

- the activity involves research;
- a description of the procedures;
- participation is voluntary and may be discontinued at any time;
- whether participation is anonymous;
- and the name and contact information for the researcher.

The Board has the authority to require progress reports from e investigators for all studies including those classified as Exempt. This requirement is fulfilled when the investigator submits an Annual Report or Triennial Status Report depending on the classification of the research. The Board may take any other action it deems appropriate to oversee the conduct of any study. Although studies classified as Exempt under these policies have less stringent oversight requirements, they still must meet the ethical principles of the Belmont Report. Therefore, the IRB may require that subjects give some form of informed consent prior to participation. Such decisions are predicated on the nature of the study and factors related to risk and confidentiality.

Research applications involving prisoners cannot be classified as Exempt studies. Most new applications received by the LSUHSC-NO IRB involving prisoners are reviewed at a convened meeting of the IRB This includes research involving interaction with prisoners, as well as research that does not involve interaction with prisoners. For studies that only involve review of prisoner medical charts, a Board Member who is a Prisoner Representative may review the application using the Expedited procedure.

While approval of an IRB application is given in the principal investigator's name, it should be understood that all study personnel have a responsibility to ensure that all IRB policies and procedures are adhered to during the conduct of the study.

To assure compliance with all policies and regulations, the Board has been granted the authority by the institution to conduct audits of all study-related documents. In addition, the IRB, following a thorough investigation, may impose a corrective action plan that must be completed by all study team members. The Board may also take actions against any or all study personnel including warning, reprimand, censure, or suspension and prohibition from conducting human subjects research at LSUHSC-NO and its facilities.

All substantial, non-administrative changes to policies and procedures governing the IRB must be reviewed and discussed at a convened meeting. Such changes to policies require a vote by a majority of the Board members present, based on quorum.

The IRB interacts with all governmental agencies through the Vice-Chancellor for Academic Affairs.