The written procedures and guidelines of the IRB are maintained in the “LSU Health Sciences Center-New Orleans Human Research Protection Program Institutional Review Board Policies and Procedures Guidebook” at <http://www.lsuhsc.edu/administration/academic/ors/irb.aspx>.

The IRB maintains an electronic and a written file for each pending and approved protocol. Combined materials contained in these files comprise the official Protocol File for a study. Written documentation of communication between the investigator and the IRB are maintained in this Protocol File. All correspondence, regardless of the source, including all correspondence between the investigator and the IRB, is maintained in the Protocol File. In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records include copies of the Investigator brochure, if any; scientific evaluations, when provided by an entity other than the IRB; recruitment materials; consent documents; progress reports submitted by researchers; reports of injuries to participants; records of continuing review activities; data and safety monitoring reports, if any; modifications to previously-approved research; unanticipated problems involving risks to participants or others; documentation of non-compliance; significant new findings; records for initial and continuing review of research by the expedited procedure, which include the justification for using the expedited procedure, actions taken by the reviewer, and any findings required by laws, regulations, codes, and guidance to be documented; the justification for exempt determinations.

These documents create a complete record of a protocol and its activity. Note that all correspondence between the investigator and the FDA and/or OHRP must be copied to the IRB and will be maintained in the IRB protocol files.

IRB records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

In compliance with Louisiana State Law, protocol files are maintained for ten years following closure of the study, at which time the files are destroyed. If a protocol is cancelled without participant enrollment, IRB records are maintained for at least three years after cancellation

Any pending study is administratively rescinded and destroyed if communications are not received from the principal investigator within a two-month period following a request for information. A new application must then be submitted if further consideration is desired of the Board.

All actions of the Board are documented in the minutes of each convened meeting as required by the current policies and Federal regulations at 45CFR46.115(a)(2) and 21CFR56.115(a)(2). IRB minutes document actions taken by the IRB; separate deliberations for each action; votes for each protocol as numbers for, against, or abstaining; attendance at the meeting; when an alternate member replaces a primary member; the basis for requiring changes in research; the basis for disapproving research; a written summary of the discussion of controverted issues and their resolution; for initial and continuing review, the approval period; the names of IRB or EC members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence; required determinations and protocol-specific findings justifying determinations for a waiver or alteration of the consent process, research involving pregnant women, fetuses, and neonates, prisoners, children, or participants with diminished capacity.

Minutes are prepared by the staff and reviewed by the Chair or designee for completeness prior to presentation to the Board for review and approval. Board-approved versions of the minutes are maintained in the office of the HRPP, and electronically on the server. Documentation of actions taken by the Chair through expedited procedures are attached to and made a part of the minutes.

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| **Version Number** | **Version Date** | **Summary of Changes** |
| 2.1 | 11.19.2020 | Re-numbered policy due to consolidation of other policies |
| 2.0 | 2.07.2020 | Separated section in Guidebook into multiple online policies |
| 1.0 | 3.35.2019 | N/A |