# RECORD-KEEPING BY INVESTIGATORS

| P & P | VERSION DATE | REPLACES P & P | PREVIOUS VERSION DATE |
|---|---|---|---|
| 5.02 | 02.07.2020 | 5.12 | 03.25.2019 |

Copies of all signed consent forms and associated HIPAA Authorization documents must be kept by the principal investigator and made accessible for review by the IRB. Files of all signed consent forms and associated HIPAA Authorization documents from research must be retained for a period of ten years following closure of the study.

For FDA-regulated studies, Case Report Forms and other related study documents must be retained for two years following when the termination or discontinuation of the investigational study (not merely an investigator's portion of a study) occurs or the records are no longer required for pursuit of marketing approval from the FDA.

Projects involving the intraocular lens have the following additional requirements: Files must be maintained for A.) A period of two years after the date on which the Food and Drug Administration approves the marketing of the intraocular lens for the purposes that were the subject of the study, and B.) A period of five years after the date on which the results of the study are submitted to the Food and Drug Administration in support of the marketing of the intraocular lens for the purpose that was the subject of the study. However, if any period is shorter than ten years from the close of the study, Louisiana state law requires that human research records be maintained for ten years following closure of the study. Furthermore, Louisiana state law requires that all patient records be maintained for 10 years after discharge unless related to a research project. In this case, the ten year rule following study closure applies.