Policy Name: Research Record Retention	
Policy Owner: Research Activities and Compliance Committee	**Effective Date:** 01/30/2024
Approved By: System Performance Alignment & Innovation (SPAN)	**Last Reviewed Date:** 01/30/2024

1.0 Scope:

1.1 Applicable Entities:
This policy applies to:

- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals
- Texas Health Physicians Group
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities (except those listed in the Formulation and Adoption of System-Wide Policies and Procedures in Section 4.1.6 or in Section 4.1.7)

1.2 Applicable Departments:
This policy applies to all departments.

1.3 Applicable Personnel:
Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record.

2.0 Purpose:

2.1 To state the retention obligations of research records.

3.0 Policy Statements:

3.1 The Texas Health Retention policy should be used in conjunction with this policy as there may be a crossover between the record's requirements. In the event of a discrepancies in the timeframes between the policies the record must be kept for the greater time period.

3.2 The Human Research Protection Program Office (HRPPO) will retain all records (with or without participant enrollment) for six years after the closure or cancellation of research, which is sufficient to meet federal, state, and local regulations, sponsor requirements, and organizational policies.

3.2.1 Physical files may be sent to Texas Health long term storage or the files may be scanned and archived electronically.

3.3 The Principal Investigator shall retain research study files after the research is completed for no less than 3 years, but as long as required by law or as stated in the clinical trial agreement. The Principal Investigator will maintain the research records for the greater of the regulations that apply:

3.3.1 Office for Human Research Protections (OHRP) requirements requires research records to be retained for at least 3 years after the completion of the research.

3.3.2 Health Insurance Portability and Accountability Act (HIPAA) requirements require any research that involved collecting identifiable health information is subject to HIPAA regulations. As a result, records must be retained for a minimum of 6 years after each subject signed an authorization.

3.3.3 The Food and Drug Administration (FDA) requires drug studies conducted under an Investigational New Drug application (IND), two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

3.3.4 The FDA requires device studies conducted under an Investigational Device Exemption (IDE), two years after the latter of the following two dates

a. The date on which the investigation is terminated or completed, or

b. The date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

3.3.5 If the study is a sponsored study, you must ensure that you comply with any terms for record retention detailed in the contract with the sponsor

3.4 Protocols in which there was no subject enrollment, or no research was conducted are to be retained the same as protocols where research was conducted.

4.0 Policy Guidance:

4.1 Both Federal regulations and the Health Insurance Portability and Accountability Act (HIPAA) must be followed regarding research record retention. The research records are to be retained for the greater of the regulations that apply.

5.0 **Definitions:**

Not Applicable

6.0 **Responsible Parties:**

6.1 Texas Health Research Activities and Compliance Committee (RACC)
6.1.1 Has responsibility for the oversight and implementation of this policy.

7.0 **External References:**

7.1 45 CFR Part 46

7.2 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and 21 CFR Part 812.

8.0 **Related Documentation and/or Attachments:**

8.1 Human Research Protection - THR System Policy

8.2 Record Retention - THR System Policy

8.3 Research Compliance Program - THR System Policy

9.0 **Required Statements:**

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.