IASIS HEALTHCARE	**POLICY TITLE**: Archiving Records
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.3.2 ☐ Addendum to Corporate Policy ☐ Form Available In I-REPP System
SECTION (as applicable): Clinical Research	**POLICY OWNER**: Tedd Adair, Vice President of Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	**FINAL APPROVAL DATE**: April 30, 2016

POLICY:

When archiving clinical trials records, to ensure that all study records are organized and stored according to regulatory and sponsor requirements after a trial is completed.

SCOPE:

This procedure applies to all clinical trials conducted at any IASIS facility.

DEFINITIONS:

Not Applicable

PROCEDURE:

After a clinical trial is completed, defined as successful submission of final reports to the IRB/IEC and final query resolution with the sponsor, the following procedures are followed:

- A storage place is selected for the regulatory binders and all subject data and documents.
- The documents are stored and maintained for one of the following time periods, whichever is longest:
    - Two years following the date a marketing application is approved for the drug for the indication for which it is being investigated
    - If no application is to be filed or if the marketing application is not approved for such indication, two years after the investigation is discontinued and FDA is notified
    - Three years after closure of the research study (i.e., the study is complete and is no longer being monitored by the IRB) or the time period required by the sponsor or other regulatory agency

- All informed consent documents shall be maintained for three years after study closure, or 6 years for forms containing authorization to use/disclose PHI
- The time period requested by the sponsor

Any transfer of responsibility for maintaining clinical trial records during the required time period as specified above will be clearly documented in writing.

Responsibility:

- The study coordinator is responsible for coordinating with the Principal Investigator/assigned party with regard to preparing the documents for storage and placing them in their storage place.
- The Principal Investigator/Study Coordinator/assigned party is responsible for ensuring that the trial documents are maintained for the time period specified above.
- The Principal Investigator/Study Coordinator/assigned party is responsible for ensuring that written documentation is filed detailing any transfer of responsibility between authorized parties for the retention of clinical trial records.

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration CFR Title 21 Part 58

Review/Revised Date:	Title:	Description of Change or Location of Change in Document:
04/30/2016	Tedd Adair, VP of Clinical Operations & CCO	Scheduled review; policy header update