

# Retention of Research Records

- FDA Investigational Drug Studies:
  - Clinical investigators must retain study records for a period of two years following the date a marketing application is approved for the drug/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.
  
- ❖ Review sponsor contract!



# Retention of Research Records

- FDA Investigational Device Studies:
  - Clinical investigators must retain study records for a period of two years after the latter of the following two dates:
    - The date on which the investigation is terminated or completed, *or*
    - 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.
- NIH Studies – three years after close of study or six years if PHI involved.

