Records Retention

Research records are identified in the University of Arizona Common Records Retention and Disposition Schedule. A record generally is defined as information in any format associated with a research project.

**IRB record**
IRB records are retained for at least six (6) years following completion of the research, which is the longer of the time requirements by the Common Rule, FDA, and HIPAA regulations.

This applies to all research studies, whether or not participants were enrolled. Sponsored grants and contracts may require additional periods for record retention.

**Investigator records**
Research records should be maintained for whichever of the following time periods is the longest:

a) The length of time required by law; or  
b) As long as the sponsor requires (for sponsored research); or  
c) 6 years after the completion of the research; or  
d) If the research involves children, 6 years after the youngest child in the research reaches the ages of majority (In Arizona the age of majority is 18 years old).

For accessibility purposes (such as audit), original, signed consent forms must be kept in a secure location on University of Arizona property. Store research records as described in the IRB approved project. If desired, the investigator may archive these records with [UA Records Management and Archives (RMA)](https://research.arizona.edu/records-management/archives).

**FDA regulated research**
In accordance with FDA requirements, an investigator shall retain records required to be maintained under FDA for a period of two (2) years following the date a marketing application is approved for the drug or device for the indication for which it is being investigated. The sponsor is responsible for notifying the investigator in advance if a marketing application is planned. If no application is to be filed or if the application is not approved for such indication, records must be retained until two (2) years after the investigation is discontinued and the FDA is notified.

**Imaging of records**
The question most often asked is "Can I scan the signed consents and then destroy the originals?" The answer is yes, but you must meet state standards for imaging. State statute requires that any unit of a State Agency must seek State approval for the imaging program PRIOR to purchasing any hardware or software for the project. If no software will be purchased, the request to scan and store still must be made.

The request for imaging form can be found on the website for the State of Arizona - Records Management. The request must be submitted through RMA at the University of Arizona.
addition, records retention requirement may exist if the sponsor requires a one year (or other) hold on the hard-copy for audit purposes. RMA can guide the unit through the process.