



GUIDANCE: Research File Scanning		
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As an overarching matter, OHRP issued guidance in 2016 regarding using an electronic system for research records and storing records electronically. Both OHRP and the FDA permit electronic storage as long as the system is secure, the data is accurately captured (if scanned), and it is kept confidential and with appropriate restricted access.

Electronic Storage Best Practices:

- **Index the documents for ease of retrieval**
- **Certify the electronic copies which should include a review of each page to confirm that all pages are present and legible**
- **Complete certification statement and maintain in study files**
- **Use appropriate security measures to protect files from unauthorized access**

The person creating the electronic files can be the person to certify the copies as long as they document that they certified the files.

The person completing the certification form is certifying that they have done ALL of the following:

- **Reviewed all pages of the scanned document and confirmed that they are EXACT copies of the originals.**
- **Confirmed that each scanned page is legible and facing in the appropriate direction.**
- **Confirmed that each scanned consent is bookmarked and named appropriately.**
- **Confirmed that the scanned document is password protected and saved in a secure location.**

If an external company is being used, the Agreement with the scanning firm should incorporate all of the certification requirements as a material requirement of the Agreement IF we are relying on the company for certification.

Lastly, for industry sponsored projects, the study team should confirm with the company that is allowable to store the files electronically. This is important in the event that there is anything in the agreement to the contrary.