

Retention of Records for the New IDEAS Study

FOR ACR STUDIES INCLUDING NEW IDEAS:

FDA and ACR regulations require that all records related to human subject research be retained by the institution and Investigator for at least 2 years after the completion of the research. Records should be kept in either printed or electronic form and be readily accessible for inspection at reasonable times [21.CFR.312.62(c)]. ACR requires that each institution and investigator associated with the New IDEAS retain all records to meet the DHHS requirements.

All sites participating in New IDEAS are required to use Advarra Inc. as the IRB of record. Advarra will maintain all records of studies on their CIRB site for 3 years after the closure of a study as lined out by their Handbook and per 45 CFR 46.115(b">46.115(b">46.115(b") DHHS guidance.

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