0540 Human Subjects Research Records

Description: Records that contain required documentation of human research subjects.

Examples: Board review records, consent forms, HIPAA authorizations, protocols, proposals, report of injuries, scientific evaluations, statements of significant new findings, progress reports, and related correspondence.

Retention Period: Retain for 5 years after grant completion and closing (unless a longer period is specified by the granting agency), and then securely destroy.

Authority: 21 C.F.R. § 50, 56.115; 45 C.F.R. § 46-115