

IRB Protocol: Multisite Outcomes Study in Adult Type 2 Diabetes

Version: 2.0 (Approved)

Population: Adults aged 18+ with Type 2 Diabetes (ICD-10: E11.*); Excludes pediatrics

Timeframe: January 1, 2019 through December 31, 2025

Sites: UAB-MainHospital; UAB-ClinicA

Approved Data Elements: encounter dates; labs (A1c, fasting glucose); medications (insulin, metformin, GLP

Identifiers: Direct identifiers are NOT approved for export; internal analysis may link via MRN in a secure enclave

HIPAA: IRB has approved a Waiver of Authorization for retrospective EHR review in a secure enclave

Sharing: External sharing limited to De-identified or Limited Dataset with DUA; no raw identifiers may leave enclave

Retention: Analysis workspace auto-deletes derived datasets after 24 months unless renewed

Notes: Expansion to new sites, pediatrics, or new identifiers requires IRB amendment