ClinicalTrials.gov Reporting Decision Tree:
Apply Three Main Requirements (NIH, Law/Regulation, Publication)

Start

① NIH

NIH Dissemination Policy

Does the study receive NIH funding? — **No**

Yes

Was the funding application submitted on or after Jan 18, 2017 — **No**

Yes

Is the study NIH-defined clinical trial? — **No**

Yes

NIH policy applies Registration & Results Required

Not in scope of NIH dissemination policy

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② FDA — DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

Law (FDAAA) & Regulation (42 CFR 11)

Is the study an interventional clinical trial? — **No**

Yes

FDA-regulated clinical investigation of a drug, biologic, or device? — **No**

Yes

Is it conducted at ≥ 1 US site, or under an IND/IDE? — **No**

Yes

Is it other than phase 1 (drug/biologic) or device feasibility? — **No**

Yes

Applicable Clinical Trial (ACT) Registration & Results Required

Not required by law/ regulations

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③ ICMJE — INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Publication Policy

Do you plan to publish in Journal? — **No**

Yes

Is the study an interventional Clinical trial? — **No**

Yes

ICMJE Policy applies Registration (not results) is required

Not required by publishers

The 3 main requirements do not apply to your study, thus CT.gov reporting is optional. Other requirements may apply, check with sponsor.