### www.ClinicalTrials.gov Policies and Changes

<table>
<thead>
<tr>
<th>What trials need to be registered?</th>
<th>All Applicable Clinical Trials (Phase II-IV Drug, Biologic, and most Device Trials)</th>
<th>All NIH funded Clinical Trials measuring a health-related biomedical or behavioral outcome of any intervention</th>
<th>All trials aiming to publish, measuring a biomedical or health outcome of any intervention, including pharmacokinetics</th>
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#### What information is needed for registration?
- Study Design
- IND information
- Inclusion and Exclusion Criteria
- Primary and Secondary Outcome Measures must be expressed as specific, measurable units
- Prior to enrollment (to protect ability to publish)
- (Statute and regulation give 21 day grace period)

#### What Maintenance Updates are Required
- Recruitment status
- Other substantive changes to protocol
- Updates are required for recruitment status and other substantive changes to protocol and every 12 months
- 2-10 hours over study life

#### What information is required for results reporting?
- Results for primary and secondary outcome measures must be reported in numeric tables for all Applicable Clinical Trials and all NIH funded trials:
  - Participant flow
  - Demographic and baseline characteristics
  - Outcomes and statistical analysis
  - Adverse Event information
  - All cause mortality
  - Final protocol and SAP
  - Administrative information
  - Additional results information for device trials of unapproved devices
- Results must be reported within 12 months from the primary completion date (last data collection for primary outcome measure)
- 40+ hours to report results

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All NIH funded and Applicable Clinical trials completing in 2017 or later, as well as any others that report results, must upload Protocol and Statistical Analysis Plans to face the public, so protocols need to cohere precisely with ClinicalTrials.gov submissions.

Under 42 CFR 11, all outcomes not explicitly identified as “other” or “exploratory” are considered secondary or primary and must report results in numeric tables.

**How can the CTSUs, Office of Regulatory Affairs, and MICHR help?**
- Office of Regulatory Affairs offers training monthly
- CTSUs facilitate study team partnerships with MICHR & Regulatory Affairs, who can assist with reporting consultations