Office of Research Compliance and Quality Assurance

Final Rule for Clinical Trials Registration and Results Information Submission 42 CFR § 11
(ClinicalTrials.gov)

Major changes affecting how researchers report the details of clinical trials on ClinicalTrials.gov will soon be effective. For example, researchers will now be required to submit results data for any ‘Applicable Clinical Trial,’ even for those products not approved by the FDA. And that’s just the tip of the iceberg.

Now is the time you should be asking how the changes will impact your study, such as:

- What information are we not collecting today that we will need to report tomorrow?
- Do the right people on our team have access to the required information for reporting?
- Are we using the right definitions for terms such as adverse events?
- Are we staying on top of deadlines for creating initial, interim and final reports?

To obtain more information, please sign up for an upcoming informational session at http://uresearch.miami.edu/regulatory-compliance-services/rcqa/clinical-trial-disclosure by clicking the link Final Rule Q & A session.

If you have any comments, questions, and/or concerns please contact Yolanda Davis at y.p.davis@med.Miami.edu.

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