New HHS rule and NIH policy affecting clinical trials

DHHS and the NIH have released a new regulation and policy that affect registration and results reporting for clinical trials. The DHHS regulation, known as the Final Rule, describes requirements for registering and submitting summary results information for certain clinical trials to ClinicalTrials.gov. A complementary NIH policy applies to **all clinical trials** funded by NIH, regardless of whether they are subject to the Final Rule. Both the NIH policy and the Final Rule will take effect **January 18, 2017**.

Some changes that might affect your ongoing or new trials are:

- The Final Rule applies to most interventional studies of drug, biological and device products that are regulated by the FDA irrespective of product approval status.
  See policy for exceptions.
  - » Trials must be registered within 21 days of the first participant signing the consent form. As a reminder, ICMJE publication eligibility is dependent upon registry ***prior to*** enrollment of the first subject (other funding agencies have similar requirements).
  - » Results information for any applicable clinical trial must be submitted no later than one year after the primary completion date.
  - » The compliance date is 90 days after the effective date (01.18.17), meaning a responsible party has until that date to come into compliance with the requirements of the Rule.
- NIH's policy expands the requirement to ***all*** NIH-defined clinical trials[1] funded in whole or in part by NIH, regardless of study phase, type of intervention, or whether they are subject to the Final Rule.
  - » Policy applies to applicants for grants submitted on or after the effective date of January 18, 2017 that request support for a clinical initiated on or after the effective date.
  - » Applicants for NIH funding are required to submit a plan outlining how they will comply with the clinical trial information dissemination expectations of the policy.
  - » Clinical trials that use NIH-supported infrastructure, but receive no other NIH funds for the conduct of a specific clinical trial are not subject to the NIH Policy.
- Possible non-compliance consequences include:
  - » Suspension or termination of grant or contract funding, if required registration and results reporting cannot be verified
  - » Consideration of the non-compliance in future funding decisions
  - » Civil monetary penalties to the "responsible party" (PI) of up to $10,000/day

Here are some resources to help you better understand the changes:

- A summary of the Final Rule and NIH policy
- A table comparing and contrasting the Final Rule and NIH policy
- A summary table of changes to clinical trial registration and results information data elements resulting from the Final Rule
- Registration information for UNC investigators available on the Office of Clinical Trials website

If you have any questions about the new requirements or need help registering or reporting results for your clinical trial, please contact the following individuals:

- Marie Malikowski for Lineberger Cancer Comprehensive Center (LCCC) and oncology clinical trials
- Monica Coudurier for all other clinical trials (non-LCCC or oncology trials)

[1] Clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.