

Monday, December 12, 2016

**1. The Department of HHS has new requirements for Clinical Trials compliance (effective 1/18/2017):**

HHS requires registration and results of applicable clinical trials into *clinicaltrials.gov* (FDAAA 801).

Applies to *all* clinical trials funded in whole or in part by NIH, regardless of study phase, type of intervention, or whether they are subject to the Final Rule. 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.

Clinical trial is 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.”

The Final Rule applies to “responsible parties” for “applicable clinical trials.” A responsible party is the sponsor of the clinical trial or a designated principal investigator.

**Significant fines of ~\$11,000/day may be levied for noncompliance.**

Costs can be included in the budget to cover costs of staff time, and perhaps other items related to data archiving. Some costs will be retrieved through indirect costs.

For more information, see:

<https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information>

**2. Notice of upcoming deadline from the Mentoring Academy:**

Annual individual development plans (IDPs) and mentor-mentee agreement forms are due January 15<sup>th</sup>. All assistant and associate step I professors are required to submit these forms to the Mentoring Academy at: HS-UC Davis Schools of Health Mentoring Academy - [hs-ucdavisshma@ucdavis.edu](mailto:hs-ucdavisshma@ucdavis.edu)

These forms should be reviewed by your mentoring team. Mentors may send an e-mail to the Academy to acknowledge they have read the form rather than using a physical signature. You can update last year's forms if there are only minor changes. Forms are at: <https://health.ucdavis.edu/ctsc/area/education/mentoring-academy/mentor-and-mentee-resources.html>

**3. Did you know? There are upcoming *Academic Personnel Training Classes*:**

**Academic Advancement Class**

December 15, 2016

CHT Building, Room 1341

11:30am-3:00pm