CHANGES TO NIH-FUNDED RESEARCH

RICRO would like researchers to be aware of some important changes associated with NIH-funded research. If you have been funded by NIH or will be submitting to NIH, please read below for a summary of the changes that will impact you.

NIH has EXPANDED their definition of a clinical trial: 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. - See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html

Who is impacted? “All NIH-funded awardees and investigators conducting clinical trials, funding in whole or in part by NIH, regardless of study phase, type of intervention or whether they are subject to the FDAAA registration and results-submission requirements,”
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html.) Some of you may have experienced NIH feedback!!

You already have NIH funds, and will be submitting a competing renewal? If you intend to submit a competing renewal to NIH, this new definition will be a new requirement for you.

Not yet funded, but will be submitting a new grant to NIH? If you be submitting a new grant to NIH, be aware that this new definition will apply to your research.

Why is this different from FDA and FDAAA (clinicaltrials.gov)? NIH’s definition includes Phase I and all intervention types (health-related behavioral, included) so the trials may not include a drug or device, but nutritional or health-related behavioral interventions.

Why the proposed NIH changes? NIH would like to have more “dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov,” (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html.)

What does this mean if you meet the new definition?

- You will need to register your trial in ClinicalTrials.gov per requirement of effective NIH proposed rule and have summary results (adverse events, etc.) reported to ClinicalTrials.gov. Contact Cat Bens, CSU Clinicaltrials.gov administrator, (cat.bens@colostate.edu or 491-5445) for a ClinicalTrial.gov account.

- You will need to add the ClinicalTrials.gov required language to your consent as follows (note this language is not subject to editing): “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

- You will need to develop a monitoring plan for your clinical trial (Data Safety Monitoring Plans): More information can be found http://grants.nih.gov/grants/policy/hs/data_safety.htm.
Are You a Member of CCTSI??

- They have resources to help you with maneuvering through these new regulatory requirements
- They have training for clinical trial investigator responsibilities

Need more assistance? Contact the RICRO Biomedical Coordinator, Tammy Felton-Noyle, at 970/491-1655 or RICRO_IRB@mail.colostate.edu.