Allowable costs on NIH supported clinical trials under FDAAA

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Policy, Compliance, NIH, Clinical Trials

U.S. Public Law 110-85, the Food and Drug Administration Amendments Act of 2007 (FDAAA), requires the registration of clinical trials in ClinicalTrials.gov. The new law expanded the scope of trials that must be registered. NIH encourages registration of all clinical trials whether required under the law or not.

For applicable clinical trials, the costs (including staff time) of registration and results reporting (including summary adverse even information) in ClinicalTrials.gov to maintain FDAAA compliance are allowable as direct charges to NIH supported grants. These responsibilities should be included in the effort and role description of clinical project staff that are maintaining and submitting data under FDAAA requirements. While it is expected that these costs will be covered by the funds provided with the grant, administrative supplements will be considered.

Trials considered to be ?applicable clinical trials? under the statute are subject to FDAAA. Applicable clinical trials generally include:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 ___-investigations, of a product ____subject to FDA regulation; and
- Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and ___-pediatric post-market ____surveillance.

Thus applicable clinical trials generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S., involves a drug, biologic, or device that is manufactured in the U.S. (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).

More information may be obtained at the sites listed below.

NIH guidance relating to ClinicalTrials.gov and FDAAA can be found at:
University guidance relating to ClinicalTrials.gov

Policies and Guidelines

Specific information relating to the FDAAA can be found at:
If you have questions, please contact Joyce Abe, Proposal Team Manager at 415-476-2977 or info@somthing.edu.

Related FAQs
What is the status of my award?
Where are the forms I need?

Where can I find new sources of funding?
