NIH OFFICE OF EXTRAMURAL RESEARCH

FDAAA: NIH Extramural Grants Perspective

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Objectives for This Section

1. Help you understand <u>compliance</u>:
   - Responsible Party (RP) role for applicable clinical trials (ACTs) supported by NIH grants
   - NIH certification of compliance with FDAAA

2. Help you avoid <u>trouble spots</u>:
   - Resources to help you
   - Tips

<u>Note</u>: NIH extramural grants only; not NIH contracts.

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The NIH encourages registration and results reporting for all NIH-supported clinical trials, regardless of whether or not they are subject to FDAAA.

http://grants.nih.gov/ClinicalTrials_fdaaa/

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Responsible Party & NIH Grants

- Sponsor [only one per trial] is:
  - IND/IDE* holder; if none, then:
  - The Grantee Institution is generally considered to be the Sponsor
    - Grantee is the "initiator" of the trial, having submitted the funding proposal
      - http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf
  - Note:
    - Includes cooperative agreements & Center grants

* Investigational New Drug/Investigations Device Exemption

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Criteria for PI as Responsible Party

- Sponsor may designate the PI of the clinical trial as RP provided that she or he:
  1. Is responsible for conducting the trial;
  2. Has access to and control over the data from the clinical trial;
  3. Has the right to publish the results of the trial; and
  4. Has the ability to meet all of the requirements for submitting information under the law.
- PI must meet all criteria to be designated

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Designating the PI as RP (or Not)

- Sponsor is not required to designate the PI as the RP
- Carefully consider the implications of designating a PI as RP
  - What is in the best interest of the Sponsor?
  - After the trial ends?
  - After the PI leaves?

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Understanding Requirement to Certify Compliance

- All ACTs supported in whole or in part by an NIH grant must be in full compliance with FDAAA
  - The RP has made all required submissions to ClinicalTrials.gov
- NIH certification of compliance with FDAAA applies to:
  - All grants supporting ACTs (even if only supporting one aspect of trial)
  - Grants where neither grantee nor PI is the RP of the ACT

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Certifying of Compliance to NIH

Competing awards:

- SF 424: Part II, section 4.1.6
- PHS 398: Part II, section 4.1.6

Non-competing continuation progress report:

- PHS 2590: Section 2.2.6.D and section 4.6

Unrelated to the FDA certification of compliance

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Current NIH Certification of Compliance

"Human Subjects" section under heading entitled "ClinicalTrials.gov" :

- Registered trials provide:
  - NCT number/s
  - Brief Title/s
  - ID and contact info for the RP
- Trials not yet registered (<21 days since enrollment of the first participant):
  - Include a clear statement that the project includes an ACT which will require registration in ClinicalTrials.gov.

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Upcoming NIH Certification of Compliance

- Research Performance Progress Reports (RPPR)
  - Simplified NIH certification of compliance with FDAAA in Type 5s (non-competing progress reports)
  - In pilot; begin roll-out in 2013
  - Enter NIH Grant number (not application number) in NCT record!
- To learn more:

http://grants.nih.gov/grants/rppr/index.htm

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Record Retention for Clinical Trial Data

- Carefully consider requirements
- NIH Grantee Institution's responsibility
  - Minimum of 3 years after date of submission of final expenditures report to NIH
  - May be additional durations specified under CFR as well
- Requirements apart from those associated with NIH grants
  - State, other Agencies, etc.

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What if NIH has concerns about compliance?

- Extramural Program Official may generate a notification email:
  - PD/PI, Business Official
  - Responsible party
  - NIH Grants Management
- FDAAA Issues Report from PRS (Protocol Registration System; NLM)
- Work quickly to respond and remedy
  - Bring trial and grant into compliance

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Resources and Tips

NIH OER Resources to Help

"What NIH Grantees Need to Know about FDAAA"

http://grants.nih.gov/ClinicalTrials_fdaaa/

- Step-by-step guidance
- Flowcharts for ascertaining ACTs and RP
- "At-a-glance" requirements
- FAQs for NIH Grantees

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Tips: Take a Team Approach

- Be aware of your Institution's approach/SOP
- Work as a team to identify ACTs and RPs
  - Sponsored research office, PI, Counsel
  - Work across institutions
  - Take actions early to clarify roles and responsibilities
- NIH's role
  - Resources
  - Cannot make determinations or register/report results on behalf of Grantee or RP

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-147.html

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Tip: Manage Risk Wisely

- Grantee Institutions as Sponsors
  - SOP? Outreach to stakeholders?
  - Monitor compliance?
    - All ACTs belong in Institutional account
  - Use personnel appropriately to fulfill FDAAA
    - Not necessary to have a someone designated as RP in order for him/her to enter data
    - Multi-user access, including user from outside of Institution
  - Implement appropriate record retention

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Tips: Understand FDAAA

- Only the RP can register and report results
  - If trial is non-compliant, non-RP may not usurp RP's role
- Be attentive to rulemaking

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