Objectives for This Section

1. **Help you understand importance of compliance:**

2. **Help you understand how to comply:**
   - Taking the Responsible Party (RP) role for applicable clinical trials (ACTs) supported by NIH grants
   - NIH certification of compliance with FDAAA

3. **Help you avoid trouble spots:**
   - Resources to help you
   - Tips

*Note: NIH extramural grants only; not NIH research and development contracts.*
Compliance Responsibilities

• The relationship between NIH and its grantees is predicated on trust.
  o NIH and its recipient institutions share responsibility for compliance and oversight to ensure good stewardship of Federal funds.
  o Grantees are expected to properly administer sponsored activities and comply with applicable regulations and policies.

Compliance Responsibilities (cont’d)

• If a recipient fails to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions. This may include:
  o Disallowing costs,
  o Withholding of further awards, or
  o Wholly or partly suspending the grant (pending corrective action)
• NIH may also terminate the grant.
• See 45 CFR Parts 75.371 and 75.372 for more information.
Ensuring Compliance

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
  - **Note:**
    - Includes cooperative agreements (US) & Center grants

* Investigational New Drug/Investigational Device Exception
Criteria for PI as Responsible Party

• **Sponsor may designate the PI of the clinical trial as the Responsible Party provided they:**
  1. Are responsible for conducting the trial;
  2. Have access to and control over the data from the clinical trial;
  3. Have the right to publish the results of the trial; and
  4. Have the ability to meet all of the requirements for submitting information under the law.

• **PI must meet all criteria to be designated**

Designating the PI as Responsible Party (or Not)

• **Sponsor is not required to designate the PI as the RP**

• Carefully consider the implications of designating a PI as the Responsible Party
  - What is in the best interest of the Sponsor?
  - After the trial ends?
  - After the PI leaves?
Understanding the Requirement to Certify Compliance

• All Applicable Clinical Trials (ACTs) supported in whole or in part by an NIH grant must be in full compliance with FDAAA
  o The Responsible Party has made all required submissions to ClinicalTrials.gov

• NIH certification of compliance with FDAAA applies to:
  o All grants supporting ACTs (even if only in part)
  o Grants where neither grantee nor PI is the RP of the ACT

Certifying of Compliance to NIH

Competing awards (applications):
• SF 424: Part II, section 4.1.6
• PHS 398: Part II, section 4.1.6

Non-competing continuation progress reports:
• Research Performance Progress Report (RPPR):
  o All SNAP and non-SNAP awards

Unrelated to the FDA certification of compliance
NIH Certification of Compliance: Competing applications and PHS 2590

In the “Human Subjects” section:

• Add a heading entitled “ClinicalTrials.gov”

• Under the heading, registered trials provide:
  o NCT number/s
  o Brief Title/s
  o ID and contact info for the RP

• Under the heading, trials not yet registered (<21 days since enrollment of the first participant):
  o Include a clear statement that the project includes an ACT which will require registration in ClinicalTrials.gov.

NIH Certification of Compliance: RPPR

Section G. Special Reporting Requirements

G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?
  ○ Yes  ○ No

If yes, provide the ClinicalTrials.gov identifier, NCT number (e.g., NCT00654321) for those trials.
NIH Certification of Compliance: RPPR Screenshot

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
What if NIH has concerns about compliance?

- Extramural Program Official may generate a notification email:
  - PD/PI, Business Official, Responsible Part, NIH Grants Management

- FDAAA Issues Report from PRS (Protocol Registration System; NLM)
  - Missing FDAAA-required fields & results

- Work quickly to respond and remedy
  - Bring trial and grant into compliance

Registration and Results Reporting

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/](http://grants.nih.gov/ClinicalTrials_fdaaa/)
Resources and Tips

NIH OER Resources

“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
Tip: 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

Tip: Manage Risk Wisely

- Grantee Institutions as Sponsors
  - Do you have standard operating procedures?
  - 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
Tip: Understand FDAAA

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

Grants Information: Who to Contact

- Division of Grants Policy:
  - E-Mail: GrantsPolicy@mail.nih.gov
  - Phone: 301-435-0949

- Division of Grants Compliance & Oversight:
  - E-Mail: GrantsCompliance@mail.nih.gov
  - Phone: 301-435-0949
Thank You!

Questions?