ClinicalTrials.gov and FDAAA for NIH Grantees

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Turning Discovery Into Health

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.

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Compliance Responsibilities

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

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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:**
  - **Disallowing costs,**
  - **Withholding of further awards, or**
  - **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.**

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Ensuring Compliance

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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 (US) & Center grants**

* Investigational New Drug/Investigational Device Exception

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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**

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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?**

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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**
  - **The Responsible Party has made all required submissions to ClinicalTrials.gov**
- **NIH certification of compliance with FDAAA applies to:**
  - **All grants supporting ACTs (even if only in part)**
  - **Grants where neither grantee nor PI is the RP of the ACT**

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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):**
  - **All SNAP and non-SNAP awards**
  - **Section 6.7 of RPPR Instruction Guide available at: http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf**

Unrelated to the FDA certification of compliance

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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:**
  - **NCT number/s**
  - **Brief Title/s**
  - **ID and contact info for the RP**
- **Under the heading, 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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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.

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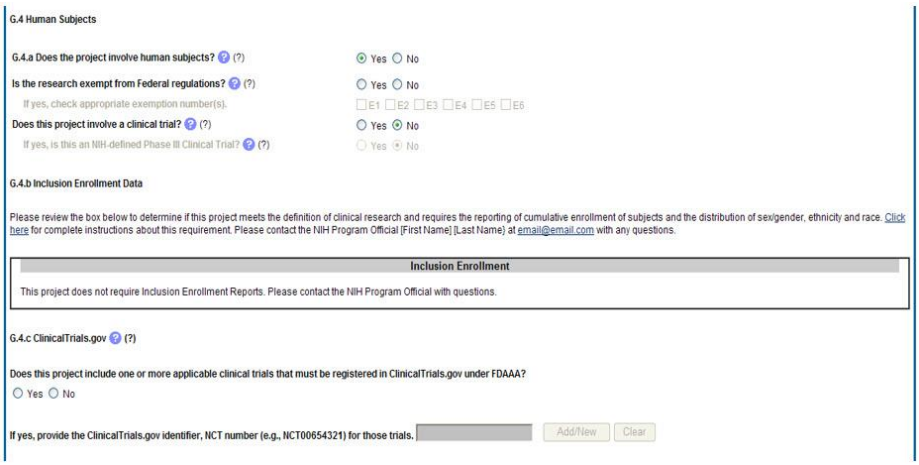
NIH Certification of Compliance: RPPR Screenshot



G.4 Human Subjects

G.4.a Does the project involve human subjects? (?) — Yes / No

Is the research exempt from Federal regulations? (?) — Yes / No

If yes, check appropriate exemption number(s). — E1 E2 E3 E4 E5 E6

Does this project involve a clinical trial? (?) — Yes / No

If yes, is this an NIH-defined Phase III Clinical Trial? (?) — Yes / No

G.4.b Inclusion Enrollment Data

Please review the box below to determine if this project meets the definition of clinical research and requires the reporting of cumulative enrollment of subjects and the distribution of sex/gender, ethnicity and race. Click here for complete instructions about this requirement. Please contact the NIH Program Official [First Name] [Last Name] at email@email.com with any questions.

Inclusion Enrollment

This project does not require Inclusion Enrollment Reports. Please contact the NIH Program Official with questions.

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. Add/New Clear

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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**

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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**

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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.

- **Draft policy requiring all NIH clinical trial grantees to register and report results published in NOT-OD-15-019 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html**

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

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Resources and Tips

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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**

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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**

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**
  - **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**

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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**
  - **Draft policy requiring all NIH clinical trial grantees to register and report results published in NOT-OD-15-019 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html**

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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**

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Thank You!

Questions?

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