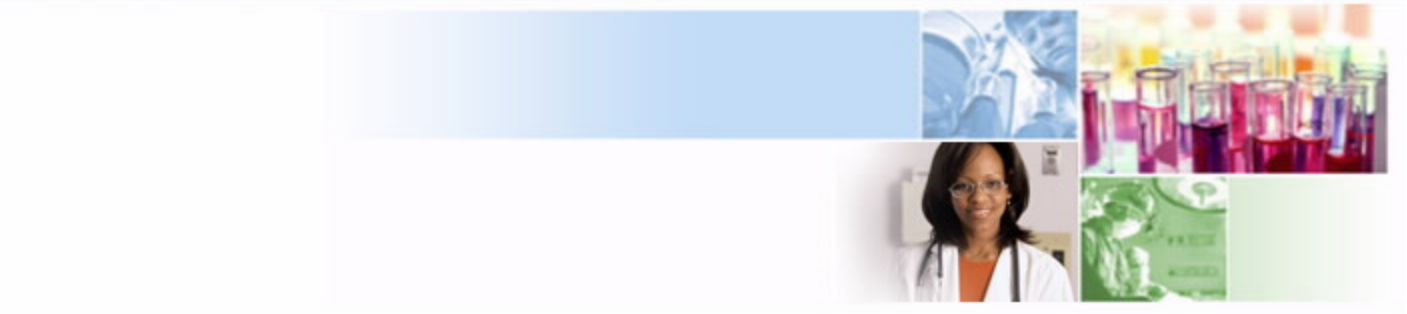

ClinicalTrials.gov and FDAAA for NIH Extramural Grants

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Objectives for This Section

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

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

Note: NIH extramural grants only; not NIH contracts.

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/

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

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

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?

Understanding the 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 in part)
  - 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:

- PHS 2590: Section 2.2.6.D and section 4.6
  - For non-Streamlined Non-competing Award Process (SNAP) awards
- Research Performance Progress Report (RPPR):
  - all SNAP awards
  - all F awards with start dates on or after July 1, 2013
  - Stay tuned for non-SNAP awards later in 2013.

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:
  - 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.

Section G. Special Reporting Requirements

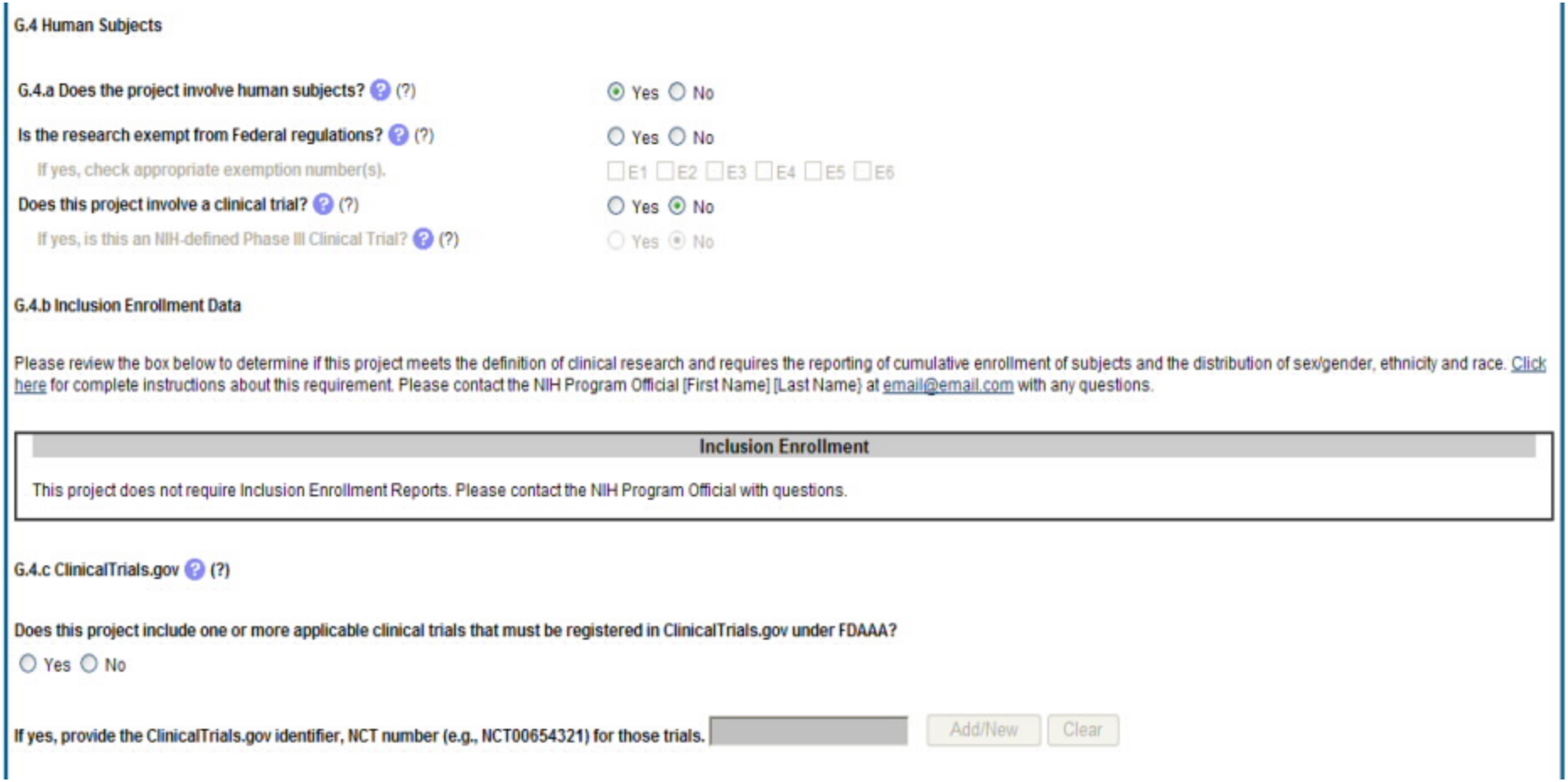
G.4.c ClinicalTrials.gov

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



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

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, RP, NIH Grants Mgmt
- 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

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

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

Tip: Manage Risk Wisely

- Grantee Institutions as Sponsors
  - SOP?
  - 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

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

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/