CTN WEB SEMINAR SERIES: A FORUM TO EXCHANGE RESEARCH KNOWLEDGE

National Drug Abuse Treatment Clinical Trials Network

Federalwide Assurances in the National Drug Abuse Treatment Clinical Trials Network (CTN)—An Overview

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- Human Subjects Research and Good Clinical Practice
- What is FWA?
  - Regulatory background for an FWA
  - FWA tenets
- Obtainment of FWA
  - Key stakeholders
- Updating an FWA
- FWA Exemptions
- Unique Circumstances
- NIDA CTN Roles and Responsibilities
- Resources

Discussion Overview

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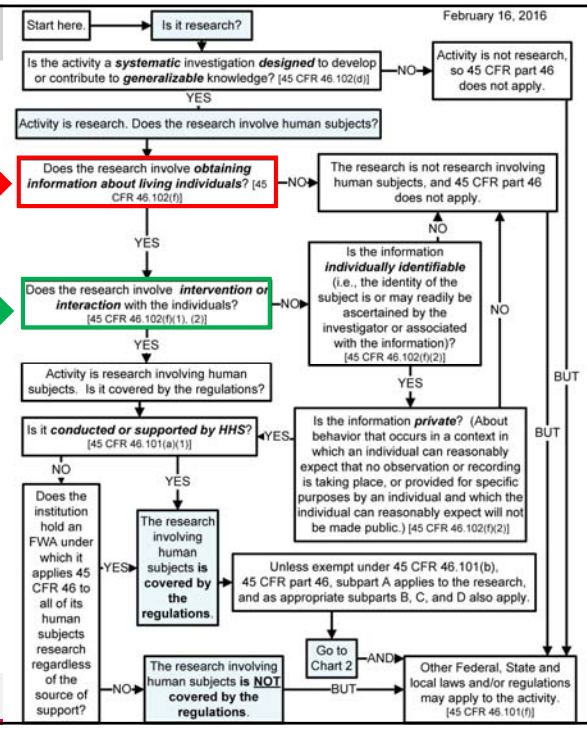
Human Subjects Research

- **Living Individuals**
- **Information or biospecimen**
- **Intervention or interaction**



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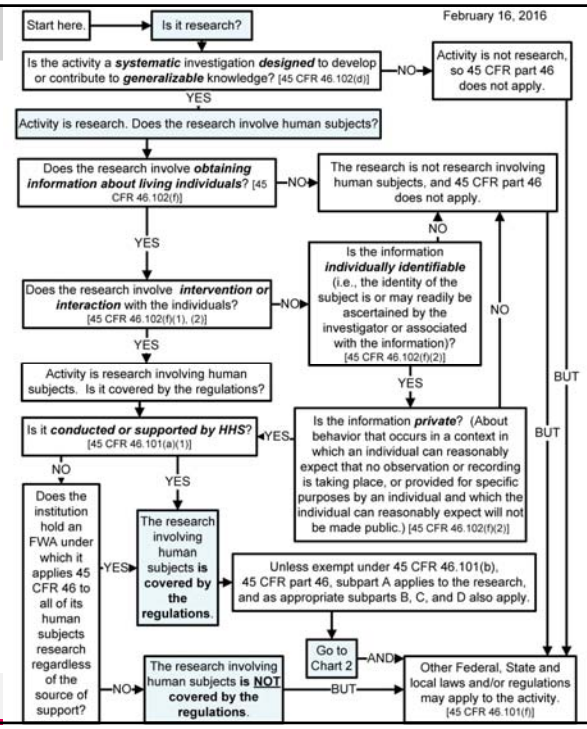
Good Clinical Practice

"A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that **provides assurance…that the rights, integrity, and confidentiality of trial subjects are protected**."



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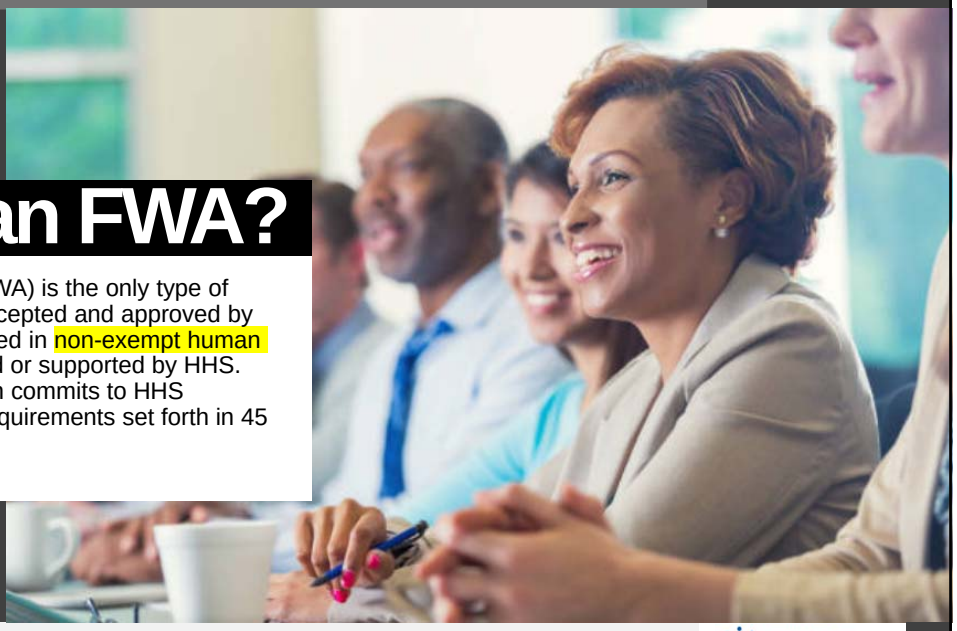

What is an FWA?

Federalwide Assurances (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR 46.

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Regulatory Background

45 CFR 46: Protection of Human Subjects (Common Rule)

- IRBs, Informed Consent, Vulnerable Populations, etc.

Regulatory Background *(continued)*

45 CFR 46.103(a)

- "Each institution engaged in research that is covered by this policy…and that is conducted or supported by a Federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy."

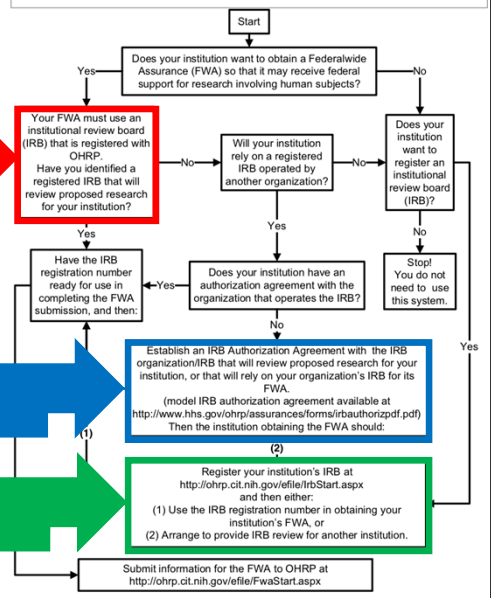
FWA Tenets

Statement of ethical principles	"Guided by a statement of principles…for protecting the rights and welfare of human subjects of research."
Applicability statement	FWA application for non-exempt studies
Assurance of compliance	Common Rule adherence
"Federalwide"	Common Rule adoption

So, what's the bottom line?

How to obtain an FWA—Assuring review of research

- **Research is reviewed by an IRB**
- **External IRB identification / reliance**
- **IRB registration**



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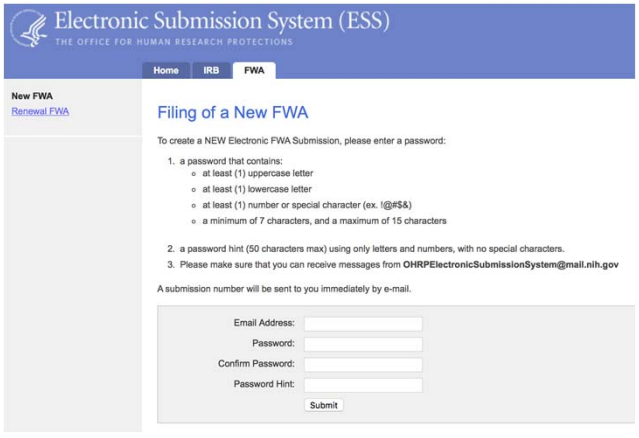
How to obtain an FWA—Registration

- Electronic submission to OHRP
- FWA application contents
  1. Name and address of institution
  2. Institutional components name and address
  3. Statement of principles
  4. Applicability
  5. Assurance of compliance
  6. Designation of IRBs (internal vs external)
  7. Human Protections Administrator
  8. Signatory Official



Key FWA Stakeholders

- The institution
  - o An Institution, not an IRB, obtains the FWA from OHRP
  - o Signatory official and Human Protections Administrator
  - o Employees/agents of the institution
- The IRB(s)
- The HHS/OHRP (and other Common Rule adopters)
- The clinical trial participants

Updating an FWA

- Five-year coverage
- Updated for major changes
  - o Institution name
  - o Human protections administrator
  - o Signatory official
  - o 90 days
- Updates to designated IRBs

FWA Exemptions Examples

- Educational settings
- Tests, surveys, interviews*
- Benign behavioral interventions*
- Secondary research
- Taste/food evaluation

**inadvertent disclosure*

Unique Circumstances

International sites

- "Funding versus location"
- Different FWA terms of assurance?

Outside investigators

- Collaborating independent investigator
- Collaborating institutional investigator
- Individual Investigator Agreement (IIA)

Reliance on an external IRB or Single IRB

- IRB Authorization Agreement (IAA)/Reliance Agreement

NDAT CTN Expectations

Lead Node/Principal Investigators (PIs) are responsible for ensuring that:

- ✓ Collaborating institutions must hold an FWA or are under the Lead Node's Institutional FWA
- ✓ If an external IRB will be used, a written agreement is in place establishing commitment of that IRB to adhere to requirements of the institution's FWA

Research site staff and Lead Node staff are expected to:

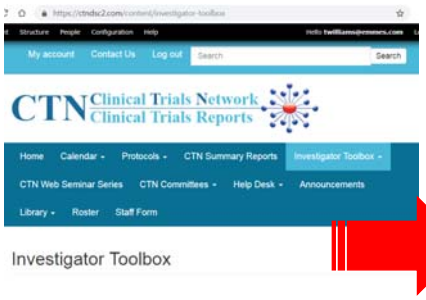
- ✓ Check periodically (at least annually) their FWA to ensure that it is still active
- ✓ Notify the Clinical Coordinating Center (CCC) if there are any changes to their FWA status or FWA expiration date

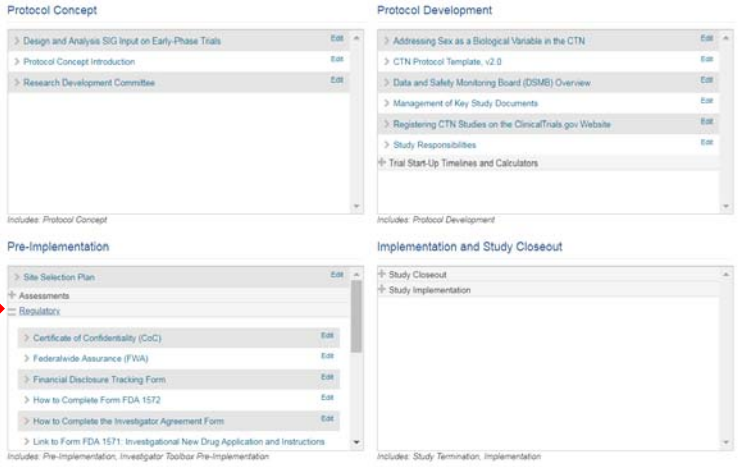
Documentation

- ✓ Maintain accurate and current study documentation of IRB FWAs, reviews, comments, and approvals

CTN Investigator Toolbox

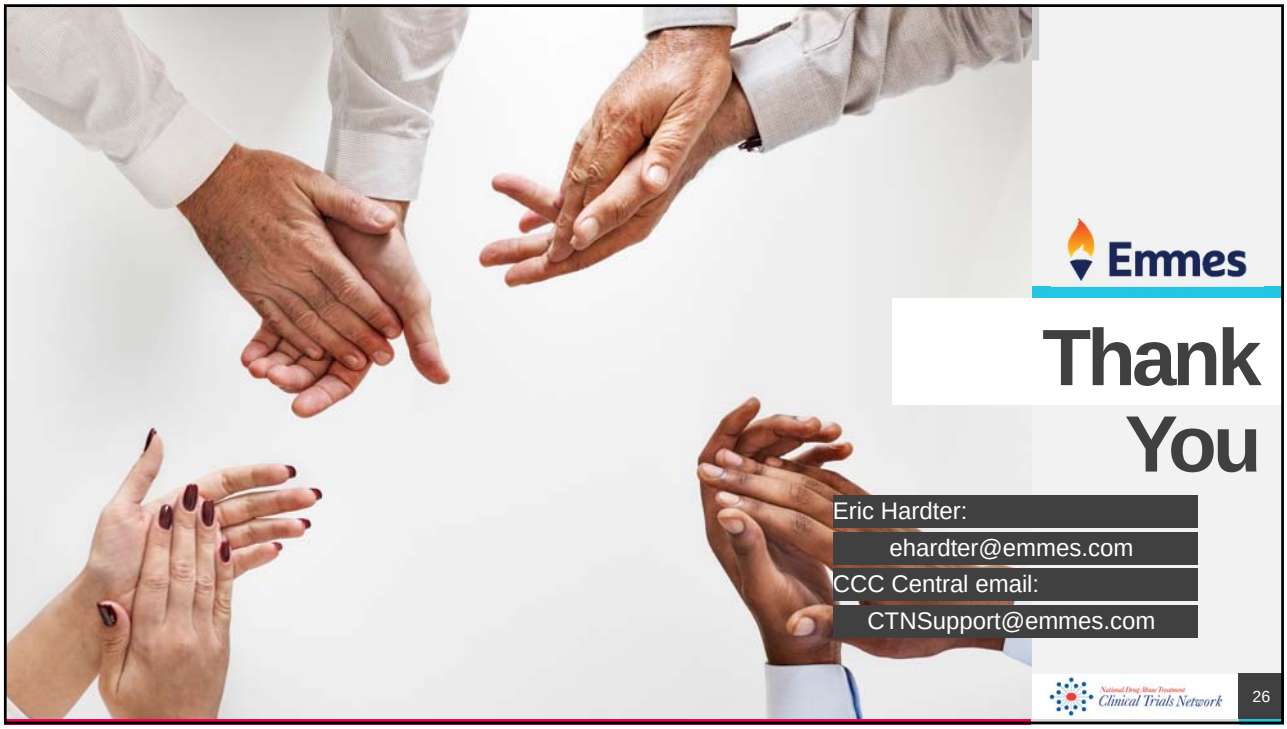
https://ctndsc2.com/content/investigator-toolbox





References

- HHS/OHRP Website
  - FWA Guidance (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html)
  - FWA FAQs (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/assurance-process-faq/index.html)
  - HHS Forms (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html)
- 45 CFR 46 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)
- FWA/IRB Status (https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc)
- NDAT Clinical Coordinating Center at CTNSupport@emmes.com



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Thank You

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