



*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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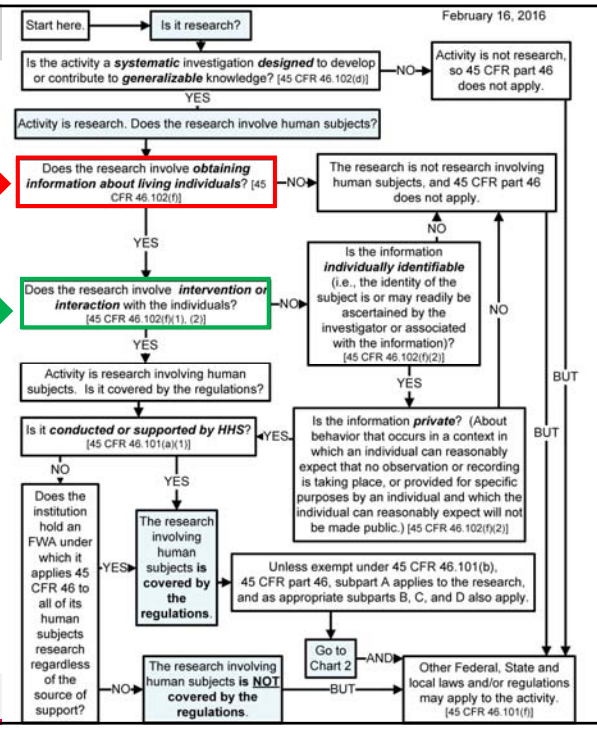
This training has been funded in whole or in part with federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN271201500065C.

- 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



# Human Subjects Research

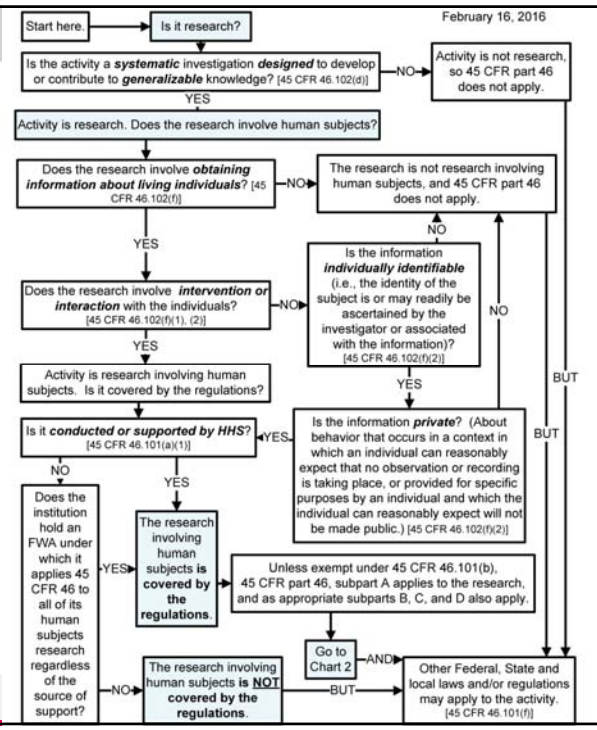
- Living Individuals
  - Information or biospecimen
- 
- Intervention or interaction



Ref: HHS.gov

# 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.”



Ref: HHS.gov

## 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.


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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.”

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## 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



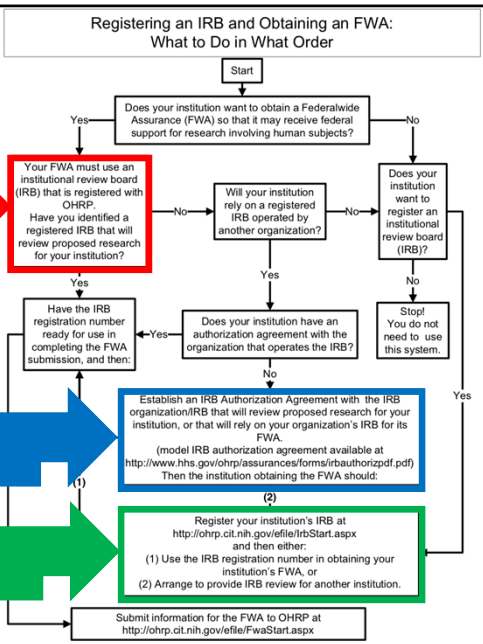
**So, what's the bottom line?**

## How to obtain an FWA—Assuring review of research

• Research is reviewed by an IRB

• External IRB identification / reliance

• IRB registration



Ref: HHS.gov



## 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
  - An Institution, not an IRB, obtains the FWA from OHRP
  - Signatory official and Human Protections Administrator
  - 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
  - Institution name
  - Human protections administrator
  - Signatory official
  - 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



### Investigator Toolbox

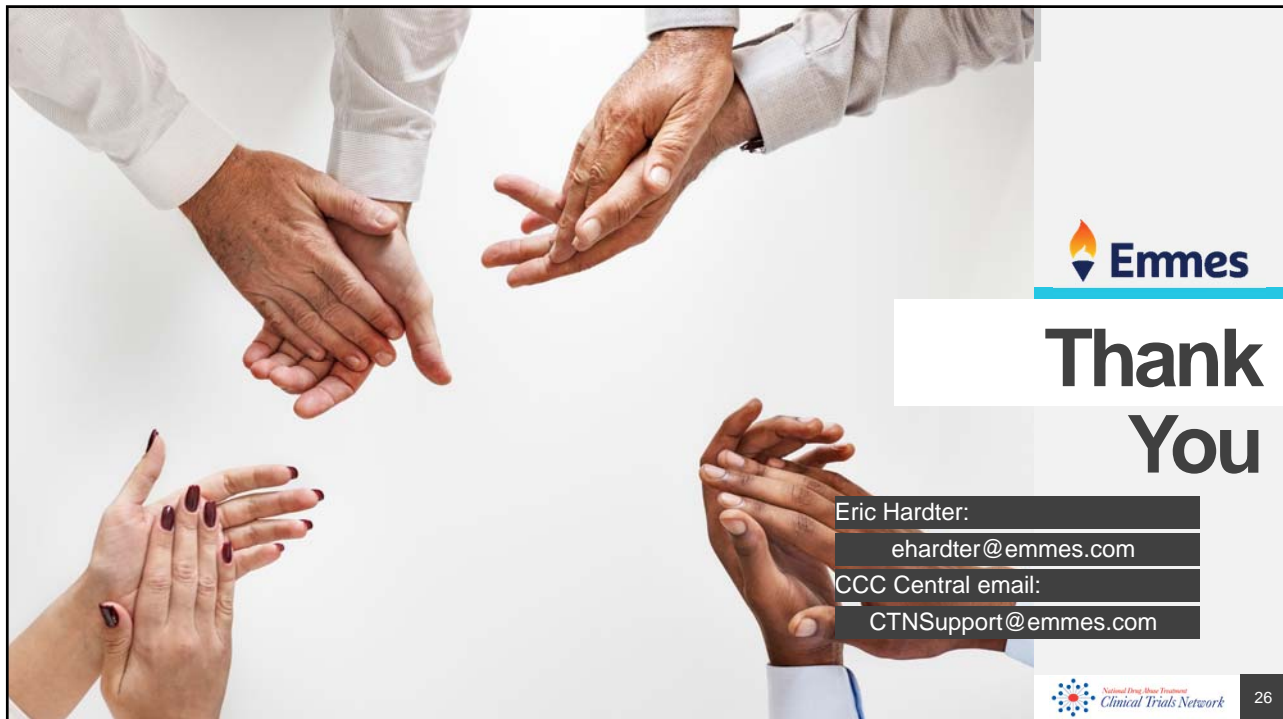
The Clinical Trials Network (CTN) Investigator Toolbox is a resource to both new and experienced investigators that are conducting studies within the NIDA (National Institute on Drug Abuse) CTN. The Toolbox provides templates for key documents and in-depth step-by-step guidance on the integral tasks associated with developing, implementing, and publishing a NIDA CTN clinical research study. This guidance was created to provide a compilation of important documents (e.g., Protocol template, Study timeline and Endorsement form), layout the important tasks of the Lead Investigator and their team with the Center for the Clinical Trial Network (CCTN) and Coordinating Centers (CCC and DSC) and decrease the onerous of certain NIDA, CCC, and DSC functions.

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

<p><b>Protocol Concept</b></p> <ul style="list-style-type: none"> <li>&gt; Design and Analysis SIG Input on Early-Phase Trials <span style="float: right;">Edit</span></li> <li>&gt; Protocol Concept Introduction <span style="float: right;">Edit</span></li> <li>&gt; Research Development Committee <span style="float: right;">Edit</span></li> </ul> <p>Includes: Protocol Concept</p>	<p><b>Protocol Development</b></p> <ul style="list-style-type: none"> <li>&gt; Addressing Sex as a Biological Variable in the CTN <span style="float: right;">Edit</span></li> <li>&gt; CTN Protocol Template, v2.0 <span style="float: right;">Edit</span></li> <li>&gt; Data and Safety Monitoring Board (DSMB) Overview <span style="float: right;">Edit</span></li> <li>&gt; Management of Key Study Documents <span style="float: right;">Edit</span></li> <li>&gt; Registering CTN Studies on the ClinicalTrials.gov Website <span style="float: right;">Edit</span></li> <li>&gt; Study Responsibilities <span style="float: right;">Edit</span></li> <li>&gt; Trial Start-Up Timelines and Calculators <span style="float: right;">Edit</span></li> </ul> <p>Includes: Protocol Development</p>
<p><b>Pre-Implementation</b></p> <ul style="list-style-type: none"> <li>&gt; Site Selection Plan <span style="float: right;">Edit</span></li> <li>&gt; Assessments <span style="float: right;">Edit</span></li> <li>&gt; Regulatory                     <ul style="list-style-type: none"> <li>&gt; Certificate of Confidentiality (CoC) <span style="float: right;">Edit</span></li> <li>&gt; Federalwide Assurance (FWA) <span style="float: right;">Edit</span></li> <li>&gt; Financial Disclosure Tracking Form <span style="float: right;">Edit</span></li> <li>&gt; How to Complete Form FDA 1572 <span style="float: right;">Edit</span></li> <li>&gt; How to Complete the Investigator Agreement Form <span style="float: right;">Edit</span></li> <li>&gt; Link to Form FDA 1571: Investigational New Drug Application and Instructions <span style="float: right;">Edit</span></li> </ul> </li> </ul> <p>Includes: Pre-Implementation, Investigator Toolbox Pre-Implementation</p>	<p><b>Implementation and Study Closeout</b></p> <ul style="list-style-type: none"> <li>&gt; Study Closeout <span style="float: right;">Edit</span></li> <li>&gt; Study Implementation <span style="float: right;">Edit</span></li> </ul> <p>Includes: Study Termination, Implementation</p>

## References


- HHS/OHRP Website
  - FWA Guidance (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/fwa-protection-of-human-subject/index.html>)
  - FWA FAQs (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/assurance-process-faq/index.html>)
  - HHS Forms (<https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwafwas/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](mailto:CTNSupport@emmes.com)





# Thank You

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