



CTN INVESTIGATOR TOOLBOX – AN ORIENTATION

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**CTN WEB SEMINAR SERIES:
A FORUM TO EXCHANGE RESEARCH KNOWLEDGE**

Produced by: CTN Training

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Learning Objectives

- Identify the location of the CTN Policies and Procedures, Bylaws, and the Investigator Toolbox.
- Describe the structure and some of the main tools and documents within each section of the Toolbox.
- Understand the ways in which the Toolbox can be used as a resource for those involved in developing, implementing and managing clinical trials.



Investigator Toolbox Development and Origin

- CTN Policies and Procedures Guide V6.0 – recently updated: <http://www.ctndsc2.com/>
 - Reminder - CTN studies must comply with all federal policies and the P&P provides highlights
- Current ByLaws: <http://www.ctndsc2.com/>
 - Inclusion of new definitions and new CTN structure
- Request for Applications (RFA) number: RFA-DA-15-008 (The NDAT CTN UG1):
<http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-15-008.html>

TPR Website – Investigator Toolbox Location

www.ctndsc2.com

CTN Clinical Trials Network Clinical Trial Reports



Home	Active Protocols ▾	Closed Protocols ▾	All Protocols Combined ▾	NIDA CTN ▾	CTN Documents ▾	Links ▾	Sitemap
					Research Staff Info Form		
					Policies and Procedures		
					By-Laws		
					Investigator Toolbox		

Welcome to the NIDA CTN Clinical Trials Report Website

The National Drug Abuse Treatment Clinical Trials Network, (CTN), established by the National Institute of Drug Abuse, has developed a comprehensive set of standardized Trial Progress Reports (TPR) to use as a management tool to effectively monitor trial progress within the CTN from the date of first randomization to final closeout and publication of main results. The content includes areas from all aspects of the clinical trials: enrollment, randomization, and follow-up.

For ongoing studies, the TPR is updated regularly (daily to monthly, depending on the report). On a monthly basis, the TPR is archived to allow review by study leadership. These reports, which are in PDF format, are found under the "Trial Progress Reports" link under "Active Protocols". Reports on Completed Studies are also provided and can be viewed by clicking on "All CTN Protocols".

Ongoing studies also require additional reports to assist the investigative teams in managing day-to-day operations. Protocol-specific data status reports are provided under the respective study title under "Data Status Reports" from the "Active Protocols" link.

Access to the reports on the web site is restricted. If you need access, please contact the NIDA DSC 2 help desk by either sending an email to nidadsc2help@emmes.com or by calling (888) 337-7071.

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Latest TPR Update: 03/21/2016 05:30:02



Investigator Toolbox Development and Origin

- The Toolbox provides elaboration and details on the CTN Policies & Procedures document sections.
- This website is dynamic, with new documents, updates, and resources added frequently.
- Suggestions from users are always welcome.



The Clinical Trials Network Investigator Toolbox

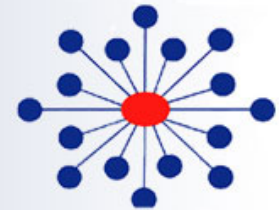
- The Clinical Trials Network (CTN) Investigator Toolbox is a resource designed to provide guidance to both new and experienced investigators that are conducting studies within the NIDA (National Institute on Drug Abuse) CTN.
- The Toolbox provides templates and examples for key documents and in-depth step-by-step guidance on the integral tasks associated with developing, implementing, and publishing a NIDA CTN clinical research study.



Investigator Toolbox Location

www.ctndsc2.com

CTN Clinical Trials Network Clinical Trial Reports



Home Active Protocols Closed Protocols All Protocols Combined NIDA CCTN CTN Documents Links Sitemap

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For ongoing studies, the TPR is updated regularly (daily to monthly, depending on the report). On a monthly basis, the TPR is archived to allow review by study leadership. These reports, which are in PDF format, are found under the "Trial Progress Reports" link under "Active Protocols". Reports on Completed Studies are also provided and can be viewed by clicking on "All CTN Protocols".

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Investigator Toolbox Sections



The screenshot shows a web browser window with the address bar displaying "http://www.ctndsc2.c..." and "CTNDSC2.COM". The main content area features a banner with the "CTN Investigator Toolbox" logo, which includes a magnifying glass over a cube with "CTN" and "TOOLBOX" text. The banner also displays "CLINICAL TRIALS NETWORK" and "Investigator Toolbox" in large, bold letters. Below the banner is a navigation bar with three tabs: "HOME", "DOCUMENTS", and "TPR".

HOME **DOCUMENTS** **TPR**

Welcome to the CTN 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 enigma of certain NIDA, CCC, and DSC functions.

The Investigator Toolbox link supports information found in the CTN Policies and Procedures and CTN By-Laws. While the Policies and Procedures and CTN By-Laws are the rules and regulations of the NIDA CTN, the Investigator Toolbox is designed to provide guidance to assist an Investigator from developing a Protocol concept to delivering the Final Study Report submission to NIDA and publication of study results.

Investigator Toolbox Sections



CTN Investigator Toolbox

CLINICAL TRIALS NETWORK

Investigator Toolbox

HOME DOCUMENTS TPR

PROTOCOL CONCEPT

PROTOCOL DEVELOPMENT

PRE-IMPLEMENTATION

IMPLEMENTATION

STUDY TERMINATION

Protocol concept to delivering the Final Study Report submission to NIDA and publication of study results.



Protocol Concept

- Protocol Concept Introduction
- Design and Analysis SIG input on early-phase trials in the CTN
- Research Development Committee (RDC)- CTN concept submission and review process and procedures

Concept Submission Procedures



Protocol Concept
CTN Investigator Toolbox Website

Research Development Committee CTN Concept Submission and Review Process and Procedures

General Guidelines for CTN Concepts

- The RDC reviews all CTN study concepts including those that are submitted investigators or special interest groups as investigator-initiated concepts and those that are in response to specific CTN requests for concepts.
- All CTN study concepts should be no more than 3 pages long (separate title page and references), with Arial 11 font and not less than 0.5" margins.
- Concepts proposing ancillary studies need to be accompanied by a letter/e-mail from the Lead Investigator(s) of the primary/parent protocol indicating that the ancillary concept has been reviewed and approved by the Lead Team.
- Concepts proposing ancillary genetics studies need to follow the specific guidelines developed jointly by the CCTN and the NIDA Genetics Consortium.
- CTN study concepts should be submitted to the RDC Chair, Dennis Donovan, ddonovan@u.washington.edu with a copy to the CCTN RDC Liaison (currently Dr. Geetha Subramaniam, subramaniamga@nida.nih.gov).
- Concepts are reviewed using current NIH categories (Overall Impact, Significance, Investigators, Innovation, Approach, and Environment). Consideration is also given to the Lead Node and participating Node/CTP budgets.
- http://grants.nih.gov/grants/peer_review_process.htm#scoring2
- Additionally, concepts are considered with respect to feasibility, stage of science and readiness for multisite trials, and suitability and potential sustainability of the interventions for use in community-based treatment programs (CTPs); involvement of CTP representatives in the concept development and study design is strongly encouraged.

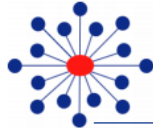


Protocol Development

- Protocol Template
- Management of Key Study Documents
- Protocol Review Board/DSMB
- Registering a CTN Study on [ClinicalTrials.gov](https://clinicaltrials.gov)
- Important Study Responsibilities
- Multicenter Trial Start Up and Timeline
 - Pre-Implementation Calculator
 - Protocol Timeline/Milestone Calculator



Important Study Responsibilities



Important Study Responsibilities
CTN Investigator Toolbox Website

Important Study Responsibilities

Study Lead Team (Lead Node, CCC, DSC, and NIDA CCTN) Responsibilities

- Overall study management and ensuring human subject protection.
- Oversight of all the research sites participating in the study.
- Meet regularly with the participating sites to review study performance and discuss overall timeline, recruitment, retention, training needs, summary of site visits, data issues, participant safety, preparation for and participation in DSMB review meetings, and review/oversight of other reports and study related activities.

Node Implementation Responsibilities

- Provide ongoing local help, quality assurance ("monitoring") and support throughout the planning, execution, and wrap-up for the trial.
- Responsible for study management and oversight at their participating site(s).

The Coordinating Centers (Clinical Coordinating Center [CCC] and Data and Statistics Center [DSC])

- Act as agents of NIDA by providing electronic data support, pharmacovigilance, regulatory monitoring/guidance and document collection, help desk support, clinical site monitoring (remotely and on site), obtain and distribute designated clinical study supplies (including study medication)/laboratory support and other study specific support as necessary, research staff with general and protocol specific training, and specialty assistance throughout the planning, execution, close out and reporting of trial activity.

Safety/Pharmacovigilance Responsibilities

- The study LI is responsible for distributing data safety monitoring plans, procedures, and training regarding proper assessment and reporting of adverse events in conjunction with the Pharmacovigilance team at Emmes.
- Each participating Node PI is responsible for the safety of study participants. Each RRTC/CTP for each study site must appoint an appropriate individual to assess, report to all necessary parties, and resolve adverse events.

CTN Protocol Timeline/Milestone Calculator

CTN00XX - title of protocol			Draft revision Oct 31 2013
	CTN Protocol Milestone	Expected Date Completed	Actual Date Completed
1			
2			
3	Protocol Development	Concept approved for protocol development	X'
4		Submit protocol to NIDA, including DSMP and informed consent	X' + 4 mo
5		Full protocol reviewed and approved by NIDA (8 months after concept approval)	X' + 8 mo
6		Budget finalized (8 months after concept approval)	X' + 8 mo
7	Trial Preparation	Protocol approved by NIDA for implementation	Y'
8		Site selection completed (3 months after protocol approved for implementation)	Y' + 3 mo
9		All data systems and databases in production (4 months after protocol approved for implementation)	Y' + 4 mo
10		Regulatory steps completed (includes IRB, IND, DEA, CoC, etc) 6 months after protocol approved for implementation	Y' + 6 mo
11		Training Completed (6 months after protocol approved for implementation)	Y' + 6 mo
12		First site endorsed (7 months after protocol approved for implementation)	Y' + 7 mo
13	Trial Conduct	First participant randomized (7 months after protocol approved for implementation)	Y' + 7 mo
14		Last participant randomized (based on sample size and randomization rate)	\$
15		Trial completed (last participant completes last follow-up) (based on sample size and randomization rate)	\$
16		Database locked (2 months after last follow-up)	\$
17	Data Management	Trial raw data submitted to Lead Investigator (2 weeks after database lock)	Z' + 2 weeks
18		Final Study Report submitted to NIDA (4 months after database lock)	Z' + 4 mo



Pre-Implementation

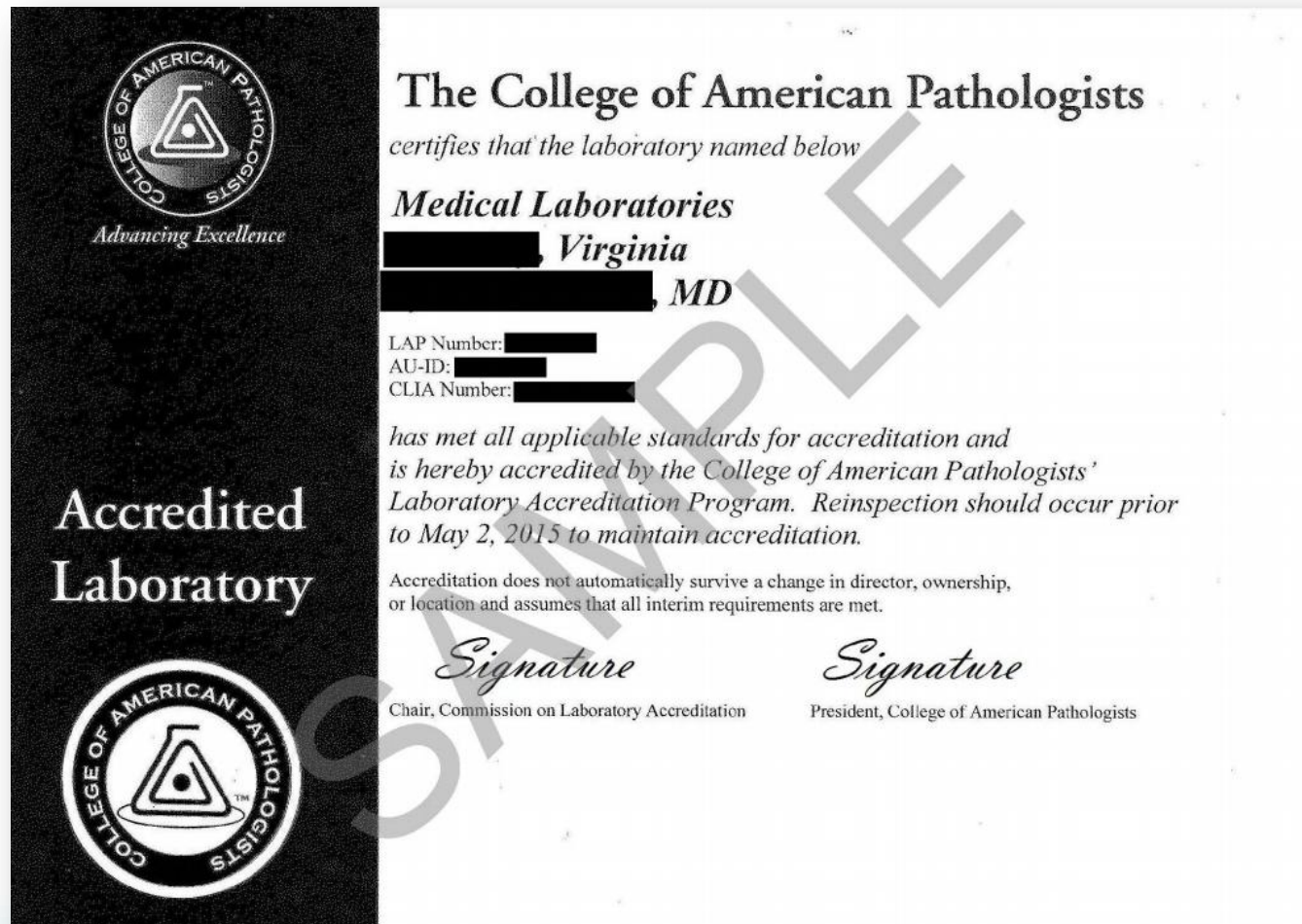
- Training
- Site Selection
- Regulatory
 - Forms- samples, instructions, templates
 - Certificate of Confidentiality (CoC)
 - CTN Regulatory Binder requirements
 - CTN Guidelines for Defining IRB Involvement
- Assessments

CLIA document (example)

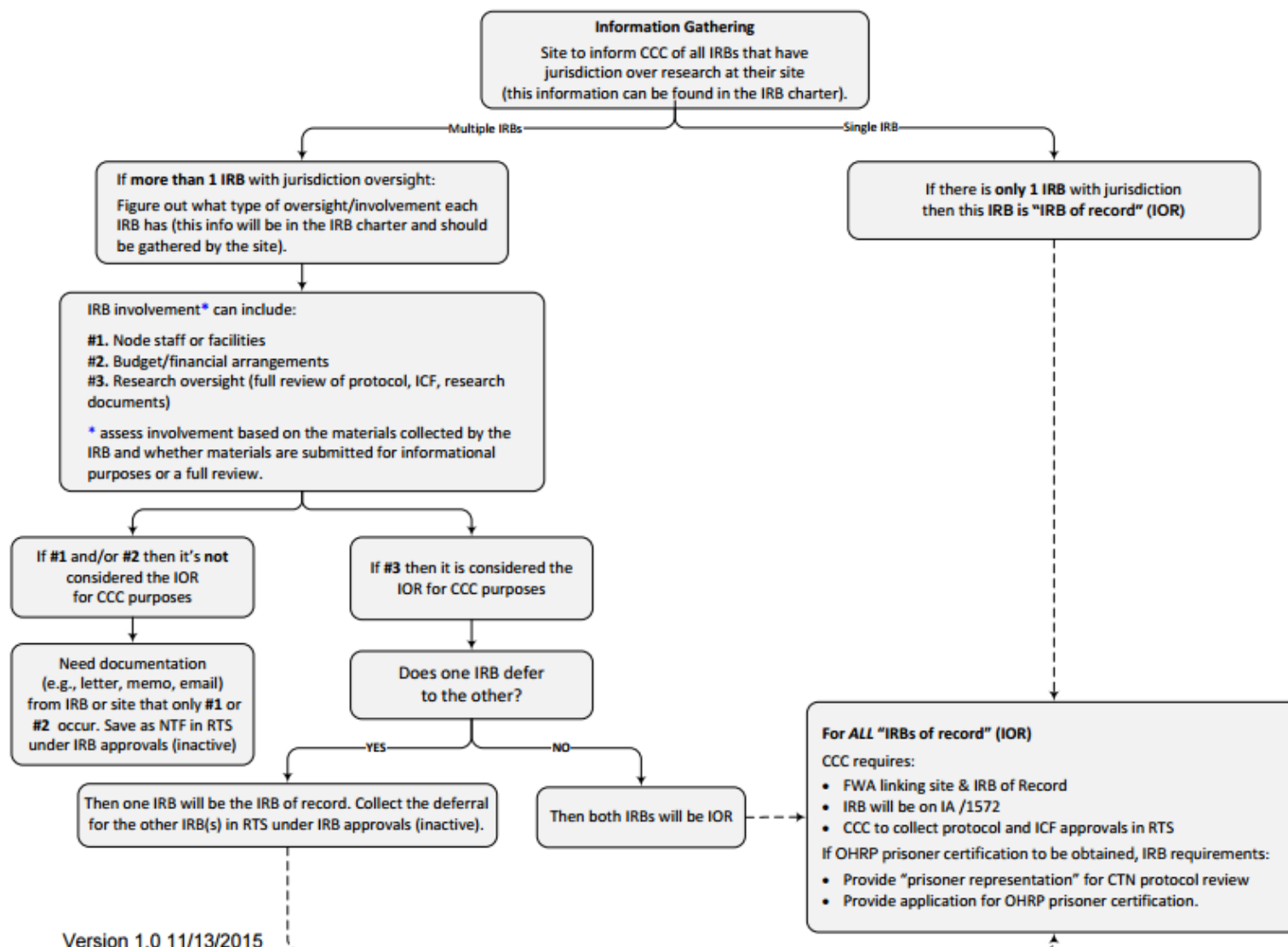
CENTERS FOR MEDICARE & MEDICAID SERVICES CLINICAL LABORATORY IMPROVEMENT AMENDMENTS CERTIFICATE OF ACCREDITATION	
LABORATORY NAME AND ADDRESS LABORATORIES 123 MAIN STREET NEW CITY, IA 025321	CLIA ID NUMBER [REDACTED]
LABORATORY DIRECTOR [REDACTED]	EFFECTIVE DATE 03/15/2015 EXPIRATION DATE 03/14/2017
Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures. This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.	
 CENTERS FOR MEDICARE & MEDICAID SERVICES	Karen W. Dyer, Acting Director Division of Laboratory Services Survey and Certification Group Center for Clinical Standards and Quality

154 Certs2_021715

CAP document (example)



NIDA CCC Guidelines for Defining IRB Involvement and Required Documentation in CTN Trials





Implementation

- CTN Follow-up and Offsite Assessments
- Site Initiation Preparation and Endorsement

Site Initiation Preparation and Endorsement

Site Initiation Preparation and Endorsement
CTN Investigator Toolbox Website

Site Readiness Checklist

Node Name: _____

CTP Name: _____

Completed by: _____

Date Submitted: _____ (date format: mm/dd/yyyy)

Regulatory Documents

Activity/Task	Completed?	Date mm/dd/yyyy	Comments
Funding secured (budget and necessary contracts in place)	☐		
IRB/IEC application prepared and submitted to IRB/IEC as required (state IRB name/s in Comments Box).	☐		
IRB/IEC study approval/s	☐		
Regulatory Binder/Files are completely assembled and on-site (in the section below indicate as documents are filed and submitted, as required).	☐		
Supply of IRB-approved consents, quizzes, HIPAA Authorizations, and other IRB-required documents duplicated and on-hand	☐		

Name of Document	Binder Tab Number	Submitted to the CCC via	Emailed to the Lead Node	Completed?	Date mm/dd/yyyy	Comments
Copy of the IRB Approved Protocols - Version 4.0 (parent protocol) and 4.0-G (genetics protocol) on file	2.1	N/R		☐		
Main Study Protocol v4.0 Signature Page	2.2	RTS	Required ☐	☐		

Site Initiation Preparation and Endorsement

CTN-POL-019
Version 4.0

**AUTHORIZATION FOR PROTOCOL
INITIATION (Endorsement)**

Date Approved:
April 2001

Approved by:
NIDA CCTN

Date Revised: September 20, 2010; Revised by: NIDA CCTN

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Attachment A

Protocol Initiation Endorsement 

Protocol #/Name: _____

CTP Code/Name: _____

Node Code/Name: _____

CCC Principal Investigator

As the CCC Principal Investigator (or designee), I confirm that the CTP named above has completed all the required elements identified on the initiation site visit for this protocol/study plan and recommend they be authorized to start the study at this site.

Signature of CCC PI or Designee _____ Date _____

Name _____

DSC Principal Investigator

As the DSC Principal Investigator (or designee), I confirm that the CTP named above has completed all the required data system training and other data related requirements for this protocol/study plan and recommend they be authorized to start the study at this site.

Signature of DSC PI or Designee _____ Date _____

Name _____

Node Principal Investigator

As the Node Principal Investigator (or designee), I confirm that the CTP named above has completed all the required elements for this protocol/study plan and authorize to start the study at this site.

Signature of Node PI or Designee _____ Date _____

Name _____

Lead Investigator

As the Lead Investigator (or designee) for the protocol/study plan named above, I authorize study initiation at this CTP.

Signature of LI or Designee _____ Date _____

Name _____

NIDA CCTN

As NIDA CCTN representative, I authorize study initiation at this CTP.

Signature _____ Date _____

Name _____

16 Version 1.0 09/15/2015



Study Termination

Final Study Report Preparation

Final Study Report Preparation

Introduction and Purpose

Lead investigators will submit a final study report to NIDA CCTN within four months of database lock.

In general, the Final Study Report should include sufficient detail to allow an understanding of the study, but will focus on the data collected in the study, utilizing the planned analysis described in the protocol and Statistical Analysis plan to address the primary outcome analyses. While the data tables may generate additional length, it is expected that the text portion of the Final Study Report will be approximately 20 pages. The following sections should be included.

1. Descriptive Information

- CTN number and CTN title of the protocol. Version number and date of the last protocol
- The name, node, and mailing address of the lead investigator and each co-investigator
- The specific community treatment programs or sites where the study was performed
- Dates for enrollment of the first participant and final evaluations of the last participant
- Date of the Final Study Report, along with signature
- Brief executive summary of the goals and results presented

2. Rationale and Aims of the Study (short description from the protocol)

3. Clinical Trial Design (short description from the protocol)

4. Statistical Analysis

- Primary analysis only, per the original protocol and a statement of the conclusions drawn from this analysis.
- Primary outcome analyses may include sensitivity of the primary outcome to missing data and investigation of site effects and interactions, consistent with the primary analysis approach defined in the protocol and/or statistical analysis plan.
- Primary analysis by sex/gender and race/ethnicity per NIH Policies.
- Results from any interim analysis, and any modifications made.



Investigator Toolbox Next Steps

- Add more materials and examples.
- Obtain feedback on existing content and ideas for new tools, documents, and materials – direct comments to the Toolbox support team at:



CTNtoolbox@emmes.com

- Share materials developed by others (e.g., site tools that may be relevant for other study sites).
- Alternatively, contact Dee Blumberg directly at dblumberg@emmes.com.



Questions / Comments



*Alternatively, questions can be directed to the presenter(s)
by sending an email to CTNtraining@emmes.com.*

<http://ctndisseminationalibrary.org/ctntraining.htm>

A recording of this presentation will be available electronically.

National Drug Abuse Treatment
Clinical Trials Network • Dissemination Library

Main • What's New • Search • Implementation • Training • Resources & Policies • About • Site Map

The **CTN DISSEMINATION LIBRARY** is a digital repository of resources created by and about NIDA's [National Drug Abuse Treatment Clinical Trials Network \(CTN\)](#). It provides CTN members and the public with a single point of access to research findings and other materials that are approved for dissemination throughout the CTN and to the larger community of providers, researchers and policy-makers.



Browse the Library

- Journal Articles
- Primary Outcomes Articles
- Blending Initiative/Products
- Presentations
- Manuals / Reports
- Workshops, Webinars, & Videos
- View All Items (Newest First)
- CTN Bulletin



Search the Library

Tip: for authors, search last name first.

- Advanced Search
- Need help? Ask a Librarian!



Conferences & Trainings

- National/International Conferences



Provider CEU Opportunities

- Neuroscience of Impulsivity & Addictive Disorders Webinar
- Helping Clinicians Become Proficient in Motivational Interviewing

Earn More CEU: See [Training](#).



About the CTN

- Protocols (Studies) in the CTN
- CTN Nodes & Community Treatment Programs (CTPs)
- CTN International Activities *new!*
- NIDA's CTN web site
- ATTC's Blending Product site
- NIDA Data Share
- CTN Directory (2014)



New in the Library RSS



Lessons Learned for Follow-up Phone Booster Counseling Calls with Substance Abusing Emergency Department Patients by Donovan, Hatch-Maillette, Phares, et al. *J Subst Abuse Treat* 2014 (in press).



Client and Provider Views on Access to Care for Substance-Using American Indians: Perspectives from a Northern Plains Urban Clinic by Kropp, Lilleskov, Richards, et al. *Am Indian Alsk Native Ment Health Res* 2014;21(2):43-65.



Blending Initiative Motivational Interviewing CME/CE & Patient Simulation *NEW!*

The newest **NIDA/SAMHSA-ATTC Blending Team Product** has just been released. It combines a CME course and interactive online Patient Simulation to provide practical guidance for physicians, nurses, and other practitioners in effective MI techniques. [Check it out!](#)



"What's New?" Library Blog



Next Topic...

**CTN-0044 WEB-TX: A
Review of the Primary
and Secondary
Outcomes**

**Wednesday, May 25, 2016
at 1:00 pm ET**



**THANK YOU FOR YOUR
PARTICIPATION**