National Drug Abuse Treatment Clinical Trials Network

The Conduct of Follow-up and Offsite Assessments in the NIDA CTN:

A Toolkit for Investigators & Research Teams

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The Conduct of Follow-Up and Off-site Assessments in the NIDA CTN: A Toolkit for Investigators & Research Teams

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BACKGROUND

On September 27, 2011 the CTN Executive Committee (EC) discussed the need to attain high follow-up rates in CTN studies[1]. For some studies such activity may involve engaging study participants in locations other than the research site. The EC recommended formation of a Taskforce to examine suggested best practices for follow-up and off-site procedures, with the goal of compiling a toolkit that includes principles to follow, guidelines, and supporting materials.

The Taskforce prepared the following Toolkit, organized as follows:

- *The Conduct of Follow-up Assessments in the NIDA CTN: Principles to Follow.*
- *Follow-up in the Community- A Guide for CTN Investigators and Research Teams*, a guide for CTN investigators, includes items to consider during protocol development when planning for off-site follow-up activities, and a tool for research teams during study implementation.
- *Safety Precautions for CTN Field Staff* - Guide and checklist for staff working in the field.
- *Examples of Strategies Implemented to Facilitate Follow-up*- provides key ingredients/strategies used in two CTN trials
  - CTN 0032 HIV Rapid Testing and Counseling in Drug Abuse Treatment Programs in the U.S.
  - CTN 0044 Web-delivery of Evidence-Based, Psychosocial Treatment for Substance Use Disorders.

The Taskforce recognized that all studies are different and may require different strategies; however, this Toolkit may be used by investigators and research staff as a guide for general best practices, as well as preparation for CTN studies that include off-site or community follow-up. Above all, this Toolkit emphasizes the importance of proper preparation and planning in achieving meaningful follow-up rates.

[1] CTN strives to maintain high follow-up rates. For more information on follow-up rates, please review trial progress reports on www.ctndsc2.com

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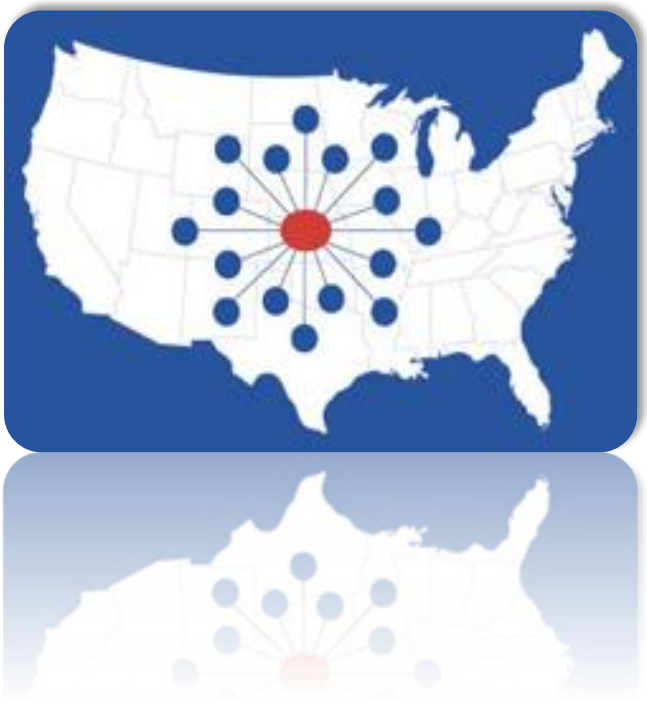
PRINCIPLES TO FOLLOW



- The NIDA CTN seeks to achieve the highest follow-up rates possible in all CTN studies.

- Staff and participant safety take the highest priority and should always be considered when planning for follow-up activities.

- All follow-up activities should be conducted in an ethical manner, and follow human subject protection regulations and good clinical research practices. Retention strategies should be part of the recruitment & retention plan that is submitted to the IRB for review and approval prior to implementation.

- CTN protocol teams should decide early in the planning process—well before the study starts---how any follow-up activity will be conducted, and should avoid mid-study changes. The LI should prepare recruitment & retention plan for submission submit to NIDA along with the protocol, for approval.

FOLLOW-UP IN THE COMMUNITY – A GUIDE FOR CTN INVESTIGATORS AND RESEARCH TEAMS

Prepared by Ingrid Usaga, Laurel Hall, Louise Haynes, Katharina Wiest, Liz Evans, and Valerie Robbins.

Goal

- To provide guidance for CTN investigators planning follow-up activities during the protocol development phase of a study.
- To serve as a tool for research teams conducting follow-up activities during the protocol implementation phase.

Introduction

Importance of Follow-Up

- High participant retention is critical to support study validity, findings and conclusions.
- Establishing follow-up procedures and strategies early in the protocol development phase allows for proper planning for budgetary, staffing and training needs.
  - Follow-up activities will vary across protocols.
  - Preparing a retention plan before initial protocol implementation is essential.
  - Using multiple strategies within a protocol may work best because of individual participant or site differences.
  - Mid-study changes to follow-up procedures will need to be discussed and approved by NIDA prior to implementation.

Protocol Development

Factors to consider for follow-up activities:

- Budget:
  - Comprehensive, reasonable, and justifiable.
  - Identify/assess needs at the Node and site levels.
- Research staff:
  - Identify roles and responsibilities early with a clear description of expectations.
  - Select persons with adequate experience who consider themselves capable of conducting the tasks and responsibilities necessary for study procedures.
  - Outline safety procedures based on protocol needs, e.g. visits in specific locations away from the study site or during off hours.

- Training:
  - Devote more time and resources to site staff training in addition to the large protocol-specific training.
  - Plan for training and staff support to help maximize staff safety
  - Consider various methods of on-going training sessions, such as conference calls, webinars, etc.
  - Conduct periodic reminder discussions or "mini-training sessions" on the national site calls.
  - When study approaches the follow-up stage, increase number and detail of training sessions with applicable site staff to prepare them for this phase of the study.

Preparation for Study Implementation

Site Selection[2]

- Assess sites' ability and willingness to:
  - Conduct follow-up as described in study procedures.
  - Hire staff with adequate experience to conduct required follow-up procedures.
- Assess logistical needs:
  - Is there adequate space/equipment on-site to conduct follow-up activities?
  - Is transportation available for fieldwork and to transport participants to/from study visits?
  - Is equipment for fieldwork adequate?
- Assess site's follow-up staff:
  - Consider follow-up staff experience, personality.
  - Match outreach staff and participant characteristics.
  - Is staff able to accommodate flexible schedules for split shifts, weekend and "on-call" hours?
- Understand possible IRB issues for each potential site:
  - Is there prisoner representation on IRB to enable review of request for "prisoner certification" for participant follow-up within prisons and also for follow-up of study participants under house arrest?
  - What types of community locations are allowable for conducting follow-up activities (homes, restaurants, offices)?
  - Are the characteristics of off-campus sites suitable as research settings?

[2] Site responsibilities are shared between the local Node and the CTP(s) where the research is conducted. Assessment of sites must include support provided by all parties responsible for the site.

Training

- Consider webinar training on topics relating to follow-up and staff safety.
- Provide thorough study-specific training, including review of staff roles and responsibilities.
- Provide continuous training (conference calls, webinars, etc.) of local site staff by Lead Node on protocol, procedures and methods to improve rapport with participants, confidentiality, general safety precautions, good clinical practice, etc.

Budgeting

- Plan for follow-up related expenses as appropriate for each protocol and site, including staff, space, supplies and equipment, snacks for study participants with extended wait times or evening appointments, transportation (vehicle maintenance, mileage/gas, insurance, etc.).
- Anticipate and minimize possible changes/modifications to follow-up procedures. Example: Adding field visits after study start-up.
- Consider special site needs: extreme distances, specific language/ethnicity/gender characteristics of staff or participants.
- Prepare/update complete locator information throughout study.

Regulatory Requirements

- Ethical review of research by Institutional Review Boards (IRBs) and other internal review committees is necessary and in the best interest of participants and staff.
- Know/understand regulatory requirements and review processes before initiating a study:
    - Participant payment,
    - Re-contact efforts,
    - Vulnerable populations (prisoners, adolescents, elderly, etc),
    - Use of public sources/internet to locate participants (Facebook, MySpace, etc).
- Thoroughly discuss with Lead Team and local Node any necessary protocol changes and modifications, such as:
    - Conducting further follow-up with participants,
    - Addition/modification of forms (locator forms), advertisements or means of contact,
    - Contacting incarcerated participants.
- Remember that significant changes in follow-up procedures will require approval by IRB.

During Study Implementation

Obtaining Locator Information

- Thoroughly complete locator information form at the intake interview and review at each follow-up visit.
- Explain the importance of the Locator Form and the need for extensive back-up contacts:
  - Identify back-up contacts and frequency of contact,
  - Explore methods of contacting back-ups,
  - Obtain back-up mailing addresses, cell and land line phone numbers (home and work).
- Explain confidentiality of locator information:
  - Review the level of information that study personnel may share with backup contacts.
- Collect all possible participant location information:
  - Mailing addresses, residence addresses, land and cell phone numbers ,
  - Alternate living situations are likely for participants such as with relatives, friends, hotels, shelters, correctional facilities, homelessness, treatment centers,
  - Record typical locations of daily activities: soup kitchens, stores, bars, known service workers at hangouts, places of worship,
  - Work locations.
- Supervisors should spot check completed Locator Forms and provide feedback to intake staff; retrain if necessary.

Use of Public Sources: Internet Searches

- Search for A.W.O.L. participants after exhausting Locator Form methods and after attempts to find participants in the field (outreach):
  - Web-based White Pages,
  - Social Networks (Facebook, Twitter, MySpace),
  - Criminal justice systems: incarceration, probation and parole records (expected release or transfer or court dates),
  - Vital statistics records/offices, death search,
  - Benefits/welfare sites,
  - Department of Motor Vehicles.
- Consider costs that may be associated with using search sites.

Field Visits: An Effective Method to Locate Hard-to-Reach Participants

- When conventional contact methods (telephone calls, mail/letters, contacting back-up contacts) do not yield results.
- For participants with unstable living arrangements and/or no regular contact with family, friends and social agencies.
- Outreach activities include:
  - Home visits to participants and their back-up contacts,
  - Door-knocking of neighbors of missing participants,
  - Regular field visits to community agencies that participants may frequent:
    - Homeless shelters, soup kitchens,
    - Treatment centers, public clinics, hospitals.
  - Regular field visits to popular hangouts.
    - Bring business cards, reminder cards to hand out to participants.
- Field visits/outreach also serve to:
  - Maintain study presence in the community,
  - Establish relationships with personnel at agencies that participants may frequent as well as with other members of the community,
- For participants who want to continue to be part of the study but are unable/unwilling to come to the research site for follow-up activities,
  - This is often a participant-initiated contact.

References

Coday M., Boutin-Foster C., Goldman Sher T., Tennant J., Greaney M.L., Saunders S.D., Somes G.W. (2005). Strategies for retaining study participants in behavioral intervention trials: retention experiences of the NIH Behavior Change Consortium. *Ann Behav Med.* 29 Suppl, 55-65.

Evans E., Murphy, D.A., Grella, C.E., Mouttapa, M., Hser, Y. (2008). Regulatory Issues Encountered when Conducting Longitudinal Substance Abuse Research. *J Drug Issues*. 38(4), 1003-1026

Horvath K.J., Nygaard K., Danilengo G.P., Goknur S., Oakes J.M., Rosser B.R.S. (2011). Strategies to Retain Participants in a Long-term HIV Prevention Randomized Controlled Trial: Lessons from the MINTS-II Study. *AIDS Behav*. [Epub ahead of print].

Burlew, K., Larios, S., Suarez-Morales, L., Holmes, B., Venner, K., Chavez, R. (2011). Increasing Ethnic Minority Participation in Substance Abuse Clinical Trials: Lessons Learned in the National Institute on Drug Abuse's Clinical Trials Network. *Cultural Diversity and Ethnic Minority Psychology*. 17(4), 345-356.

Scott C.K. (2004). A replicable model for achieving over 90% follow-up rates in longitudinal studies of substance abusers. *Drug Alcohol Depend*. 9;74(1), 21-36.

Sivaram S., Celentano D.D. (2003). Training outreach workers for AIDS prevention in rural India: is it sustainable? *Health Policy Plan*.18(4), 411-420.

Smith B.D, Kalayil E.J., Patel-Larson A., Chen B., Vaughan M. (2011). Retaining clients in an outcome monitoring evaluation study: HIV prevention efforts in community settings. *Evaluation and Program Planning*. 35(1), 16-24.

Villacortaa V., Kegelesb S., Galeac J., Kondac K.A., Cubaa J.P., Cáceres Palaciosa C.F., Coatesc T.J. (2007). Innovative approaches to cohort retention in a community-based HIV/STI prevention trial for socially marginalized Peruvian young adults. *Clin Trials*. 4(1), 32-41.

SAFETY PRECAUTIONS FOR CTN STAFF WORKING IN THE FIELD

Prepared by Katharina Wiest Ph.D.

Goal

Fieldwork is defined as any in-person contact with participants conducted outside of the research site. This section outlines a Code of Practice, identifies safety issues to consider in the design and conduct of CTN field research, and encourages procedures to reduce potential risk.

The most important rule to remember is: **Safety of research staff is always more important than any interview.**

Safety in CTN research is a shared responsibility among the Lead Team to adequately budget for the costs of training and implementation of procedures for researcher safety, the local Node to provide adequate resources as needed, and the researcher to comply with guidelines as appropriate to the trial.

Risk to the Researcher

While usually risk in fieldwork refers to the risk of physical threat or abuse, it is important to remember that personal risk also involves:

- Risk of psychological trauma resulting from something seen or heard,
- Risk of being in a compromising situation and,
- Increased exposure to everyday risks such as infectious illnesses, car accidents, theft/loss of property, etc.

Although the majority of this Code of Practice centers on protecting the researcher's physical safety, we must be mindful of the other risks and work to mitigate them.

Ways of Incorporating Guidelines into CTN Practice

CTN trials are conducted routinely at local CTPs, hospitals or other provider agencies. The local safety operating procedures of that agency should be identified and incorporated into any trial-specific safety SOPs. Failure to comply with local agency safety rules may have serious legal/insurance implications.

- Safety issues should be part of training sessions for each new CTN trial and tailored to the specific requirements of that trial, such as type of participants, location of fieldwork, etc.
  - The single most important technique to help field workers stay safe is to train them in de-escalation techniques.
  - Tense moments will occur. Depending on how a researcher responds, the situation can get either much worse or much better.
- All CTP research staff involved with a CTN trial must be trained in safety procedures for that specific trial.
- Safety policies and procedures should be evaluated on a regular basis by research teams.

- In addition to trial-specific safety training, CTP research staff should attend refresher training on general safety procedures, de-escalating techniques, and crisis prevention throughout their research career.

Safety Checklist for Field Visits

The following safety checklist is designed to be a framework and modified as needed based on the individual CTN protocol, procedures of the treatment agency, RRTC requirements, and state or local regulations. Safety to the researcher and to the participant is the primary focus. The components of this checklist were gathered from agencies practiced in field work, with special input from those routinely serving marginalized populations.

Research staff selected to conduct fieldwork should have adequate experience and training, and they should consider themselves capable of conducting the tasks and responsibilities necessary to carry out protocol procedures.

Prior to the off-site research visit:

1. Prepare and train staff according to local needs and circumstances:
   - **a)** Include expected dress code, e.g. dress to protect, avoid jewelry, etc.,
   - **b)** Include methods to improve rapport/diffuse situations with participants,
   - **c)** Review general safety precautions.
2. Research teams should engage in a thorough discussion to identify potential hazards:
   - **a)** Determine activities, individuals who will be in the home or site, and any specific alerts regarding the visit,
   - **b)** Use search engines (Google, Yahoo, etc) to identify the location of the closest police or fire department should the need arise to drive there for safety,
   - **c)** Establish a code word or phrase that indicates a problem. Determine an action plan (i.e. telephone call to supervisor) when the code word/phrase will be used.
3. Use HIPAA approved locked pouch for transporting records and participant compensation; only carry amount of money/gift card necessary to complete the visit.
4. Use the "buddy" system and work out who will summon emergency assistance, if needed.
5. Carry:
   - **a)** Identification (state driver's license, as well as agency ID badge and business cards),
   - **b)** Cell phone that is fully charged (do not use your personal cell phone, use research phone),

SAFETY PRECAUTIONS FOR CTN STAFF WORKING IN THE FIELD (cont'd)

c) Numbers of emergency contacts. Program into the cell phone the following numbers:

1. 911,
2. Supervisor cell number,
3. Main number for your primary facility.

6. Test the cell phone charge/batteries before heading into the field.

7. Use reliable transportation:

a) If driving, make sure tank is full and travel route is clearly identified,

b) Remove all valuables from vehicle,

c) If using public transportation, map out route and stops, know schedule ahead of time, and avoid remote areas or long walking distances.

8. If possible, confirm visit with participant before leaving.

9. Post the following information at your site, where it is clearly visible:

a) Time of departure,

b) Time of expected return/end of visit,

c) Location(s) of visit,

d) Cell phone number you are using,

e) List of intended participants,

f) If field visit is after normal work hours, arrange prior to departure who will be called/texted at end of visit,

g) If changes in schedule occur, such as expected time of return or field visit plans, NOTIFY designated contact.

Upon arrival at the field visit area:

1. Drive by to make a visual observation of the site and determine that there are no safety/security concerns.

2. Park vehicle at least one house down from the location of visit. Back in and park the vehicle with no barriers to exiting.

3. After parking, make an additional visual check of surrounding area and look for potential hazards and routes of escape should the need arise.

SAFETY PRECAUTIONS FOR CTN STAFF WORKING IN THE FIELD (cont'd)

Prior to entering a location/beginning an interview:

Do not enter any location where you feel threatened or unsafe. Make this decision based upon your evaluation of the evidence on-hand.

1. While walking up to a location, complete another safety check of surroundings.
2. Knock, identify yourself and stand to the side of the door. If visit is at a public place such as a restaurant or park, scan the situation and walk up to the participant and identify yourself.
3. Remain to the side of the door.
4. Once the door is opened:
   - **a)** Identify yourself again,
   - **b)** Establish who is there and if additional people are present, assess impact on confidentiality and personal safety,
   - **c)** Identify two exit routes,
   - **d)** If there are any dogs/animals in the location, request dog/animal be secured.
5. Once inside the location:
   - **a)** Establish and maintain a clear path to the door for a quick exit should the need arise,
   - **b)** If possible, keep the door unlocked,
   - **c)** Maintain a "reactionary gap" between yourself and participant (out of the person's kicking distance),
   - **d)** Check the area for weapons or drug paraphernalia.
6. If at any time you do not feel safe, terminate the visit and exit the location.

At completion of interview:

1. Upon exiting location, complete another safety check of environment. Always be aware of surroundings.
2. Incidents of aggressive behavior such as pushing, threatening, or intimidation, with or without injury, should be reported to supervisor as soon as possible.
3. At completion of visit, notify supervisor or staff at primary site.

Follow-up:

Research staff should have weekly de-briefing sessions to review field work. In addition to highlighting positive experiences in the field, challenges, opportunities for improvement, and any psychological impact of events should be discussed.

Remember, safety of research staff is always more important than any interview.

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0032

Prepared by Laurel Hall, Recruitment and Retention Coordinator.

HIV Rapid Testing & Counseling in Drug Abuse Treatment Programs in the U.S. (CTN-0032)

This document recounts activities used by the CTN-0032 Study Team and is an example of flexibility and tailoring of processes to local needs. The procedures listed can be used as a guide and should not be viewed as prescriptive for all trials or all circumstances.

Number of participants randomized: 1,281

Number of participating sites: 12

Attendance at follow-up visits: 96%

Key ingredients for high follow-up rates in CTN-0032

- A centralized retention coordinator at the Lead Node helped create follow-up plans for hard-to-reach participants, keeping site teams on track.
- Frequent (monthly) contact with participants between study visits by phone AND mail
- Early preparation of participants for follow-up contacts.
    - Detailed explanation of follow-up activities during initial visit, including introduction to follow-up staff, when possible.
- Extensive participant location and identification information (See attached Locator Form).
    - All mailing addresses and land/cell phone numbers.
    - Physical description of locations/buildings (residence and hang-outs).
    - Email and/or social networking usernames and addresses.
    - Alternate living situations where likely to find participant (including relatives, friends, hotels, shelters, correctional facilities, homelessness, treatment centers).
    - Daily activities and hangout locations.
    - Typical locations of daily activities (soup kitchens, places of worship, stores, bars, known hangouts).
    - Information on public assistance received and sources.

Key ingredients for high follow-up rates in CTN-0032 (cont'd)

- Alternative names (street or nicknames, aliases) used by study participant.
- Occupation and work locations (legal and illicit).
- Identify individuals who can assist in locating participant, including local relatives, friends with phones/residences, social workers, parole officers, employers, and other contacts.
- Written consent from participant for study team to contact those listed on locator form to reveal whereabouts.
- Detailed physical description of participant, including visible piercings, tattoos and scars.
- Copy of ID or photo if possible.

- Outreach Team
  - Outreach staff went out into the community looking for participants if unable to reach them using contact numbers provided in Locator Form.
  - Detailed information gathered on the Locator Form was key in locating hard-to-reach participants.

Participating Nodes and Sites CTN0032

Node	Site
Florida Node Alliance (Lead)	Daymark Recovery Services
Appalachian Tri-State Node	Addiction Medicine Services
Mid-Atlantic Node	Chesterfield Community Service Board Substance Abuse Service Glenwood Life Counseling Center
New England Consortium (formerly New England)	Midwestern Connecticut Council on Alcoholism Wheeler Clinic, Inc.
Ohio Valley Node	Gibson Recovery Center
Southern Consortium	Lexington-Richland Alcohol and Drug Abuse Council Morris Village Alcohol and Drug Treatment Center (LRADAC)
Southwest Node	The Life Link
Western States Node (formerly California/Arizona) (formerly Oregon/Hawaii)	CODA, Inc. La Frontera Center

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0032 (cont'd)

HIV Rapid Testing and Counseling

CTN 0032

Prepared by Laurel Hall, Recruitment and Retention Coordinator.

CTN-0032 Locator Information Form

CONFIDENTIAL

NOTE TO STAFF: Get as much tracking information as possible, but if participants don't want to share certain pieces of data, that is fine. Update the locator form at the 1-month follow-up visit and fill in missing information if the participant is willing.

Today's Date: _____ / _____ / _____ **Staff Initials:** _____
month day year

CTP Program Recruited from: _____

Since the study will last about 6 months, I'm going to ask you for contact information about you and some people you don't live with who could help us get in touch with you if you move or relocate. All of this information will be kept confidential.

Participant's Name _____
(first, middle, last)

Nicknames/ Other Names Used _____

Street Address _____

City _____ State_____ Zip_____

Can we send you information at this address? ☐ **No** ☐ **Yes**

Day Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

Evening Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

Other Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

IMPORTANT: What is the best way to leave you reminders about follow-up visits?

☐ **Phone** (which one _____)
☐ **Mail**
☐ **Note at clinic** (which one _____)
☐ **E-mail address:** _____
☐ **Other** (Describe _____)

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0032 (cont'd)

HIV Rapid Testing and Counseling

CTN 0032

Contact Information

Interviewer: *Try to get at least 2 (or more if possible) contacts living outside of the household (e.g., the address given above)*

MAIN CONTACT (#1):

Name _____

Relationship _____

Street Address _____

City _____ State _____ Zip _____

Can we send you information at this address? ☐ No ☐ Yes (Code name: _____)

Day Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

Evening Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

CONTACT (#2):

Name _____

Relationship _____

Street Address _____

City _____ State _____ Zip _____

Can we send you information at this address? ☐ No ☐ Yes (Code name: _____)

Day Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

Evening Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

CONTACT (#3):

Name _____

Relationship _____

Street Address _____

City _____ State _____ Zip _____

Can we send you information at this address? ☐ No ☐ Yes (Code name: _____)

Day Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

Evening Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0032 (cont'd)

HIV Rapid Testing and Counseling

CTN 0032

Employer_____

Work Address _____

City_____State_____Zip_____

Work Phone ( ) _____

Can we send you information at this address? ☐ No ☐ Yes (Code name: _____)

Work Phone: ( ) _____
Would you prefer we say: ___ CTP Name ___ Staff Name
Instruction / comments: _____

OTHER WAYS TO CONTACT PARTICIPANT:

Are there other ways we can get in contact with you? Probe for:

Is there a neighborhood park, cafe, bar where we could look for you?

How about coming by your house or apartment and leaving a message?

Any other ideas?

OTHER INFORMATION:

These next questions are voluntary. Like I mentioned before, it is very important that we be able to follow up with you during the study to remind you of study visits. Many times people move and although they want to participate in the study, they cannot be found. This information will help us to find you for follow up. I realize that I am asking for some sensitive information; however, I assure you that this information will be confidential. Any of this information you want to give us would be greatly appreciated.

1. Do you have a driver's license or ID? [ ] No [ ] Yes: State: ____ # _____

2. Are you a Veteran?

[ ] No [ ] Yes: Case No. (VA File No.)?_____ [ ] Don't know the number

3. Do you have a Medicare or Medicaid No.?

[ ] No [ ] Yes: MA# _____ [ ] Don't know the number

4. Where do you go for medical care?

5. Do you have a car?

[ ] No [ ] Yes: State: _____ License plate # _____ [ ] Don't know the number

6. Where do you "hang out," or where can you usually be found when not at work or at home?

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0032 (cont'd)

HIV Rapid Testing and Counseling

CTN 0032

INCOME RESOURCES: (Include past and present)

Check all that apply: (Note: Include anticipated resources under additional information)

Aid to Families with Dependent Children	☐
Unemployment	☐
General Assistance	☐
State Disability Insurance	☐
Food Stamps	☐
Supplemental Security Income/ Social Security	☐
Women, Infants and Children	☐
Disability	☐

ADDITIONAL INFORMATION:

_____

_____

_____

OTHER IDENTIFYING INFORMATION:

_____ Place of Birth

_____ Date of Birth (month/day/year)

_____ Social Security Number

_____ Your Maiden Name (If Applicable)

_____ Mother's Maiden Name

Interviewer's notes:

_____

_____

_____

Interviewer:

The next page is the Authorization for release of information. It is very important that the participant know that: 1) all we get from agencies is their address and phone number, and 2) no other information will be exchanged (i.e., HIV status, etc.).

HIV Rapid Testing and Counseling

CTN 0032

AUTHORIZATION FOR RELEASE OF INFORMATION

By my signature below, I _____ do hereby authorize each
(Print: first, middle, last)

of the agencies listed below to provide only my current address and phone number to the study research team at (Name of CTP). No other records about me may be provided to the study research team.

The agencies included in this release of information are as follows:

> Veteran's Administration, unemployment agency, SSI (Supplemental Security Income), SSA (Social Security Assistance), state disability insurance, Medicare, Medicaid, Department of Motor Vehicles, probation offices, other social services, (e.g., food stamps, vocational rehabilitation), shelters, alcohol and drug treatment facilities, medical providers.

I understand that the study research team will request this information from the agencies if other attempts to locate me have failed. The information will be used for the purpose of contacting me for a follow-up interview for the study.

This authorization will cover three (3) years and I understand that it can be revoked (cancelled) by me in writing at anytime between now and then. This form was read by me (or to me) before I signed it.

Agencies NOT to be contacted: _____

_____	_____
Participant's Signature	Witness Signature
_____	_____
Date	Date

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0044

Prepared by Eva Turrigiano, Lead Team Project Coordinator.

Web-Delivery of Evidence-Based, Psychosocial Treatment for Substance Use Disorders (CTN-0044)

This document recounts activities used by the Study Team in CTN 0044, and is an example of flexibility and tailoring of processes to local needs. The procedures listed should not be viewed as prescriptive for all trials or all circumstances. Procedures for follow-up were planned in advance and included in the original MOP; the Study Team laid out a hierarchical approach, with decision points and next steps clearly identified.

Number of participants randomized: 507

Number of participating sites: 10

Attendance at follow-up visits: 90%

Informed Consent

- The Consent Form explained that study staff would use multiple forms of contact and listed the various ways including spontaneous off site visits.

Locator Form

- Extensive participant location and possible contact information collected including:
  - All relevant addresses.
  - Land and cell phone numbers.
  - Email.
  - Names, addresses and phone numbers of at least two people who knew how to contact participant.
  - List of places were the participant would hang out.
  - Driver's license ID.
  - Social Security number.
  - Employment address and phone number.
  - Facebook information (if applicable).

- Locator form was verified and updated at every study visit.

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0044 (cont'd)

Maintaining Contact

- Study staff called, texted and/or emailed participants to remind them of study visits on a regular basis.
- Three of our 10 sites sought and received approval to use social media (i.e. Facebook) and sent out private messages to participants reminding them of study visits.
- Staff sent birthday and holiday cards to participants to maintain contact.
- Some staff sent out calendars with future study visits labeled to help participants remember their study appointments.
- Sites provided money for public transportation or taxi for participants who had difficulty getting to the clinic on their own. Staff at two sites would occasionally pick up participants and drive them to the study site[3].
- Study staff offered flexible appointment scheduling to accommodate participant schedules (i.e. early and late appointments if needed).

Tracking

- After multiple attempts at contacting the participants produced no results, staff went into the community looking for participants using the information gathered on the locator form. Study staff or a part-time "tracker" (at some locations) performed off-site visits.
- Some sites used online public databases to find participants.
- Sites mailed certified letters to participants' listed addresses along with consistent phone calls, texts and/or emails[4].
- Three of 10 sites used Facebook[5] to contact participants via private messages.
- Sites held weekly meetings with trackers, study staff and RRTC staff to discuss hard-to-reach participants and strategies to locate them.
- Sites participated in monthly Research Staff conference calls with the Lead Team and other participating sites, and discussed tracking and retention strategies. The Lead Team encouraged sites to bring up difficult cases for discussion and consultation.

[3] These procedures depended on local/site-specific circumstances, and were NOT recommended across the trial.

[4] Texting seemed to be the most successful way to reach participants. Both study staff and participants were comfortable using text to maintain contact.

[5] Privacy settings allowed staff to communicate on Facebook while maintaining confidentiality. For example, one site created a profile and told clients their user name. This site "friended" participants, but friends could not see other friends

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0044 (cont'd)

Off-Site Visits[6]

- Research staff would first try to contact the participant by phone (or email, text, letter), or contact other individuals listed on the locator form, to schedule a research visit at the treatment program. The method of communication differed depending on participant preferences and locator information. Research staff would use more than one method simultaneously to locate hard-to-reach participants.
- Staff would attempt an off-site visit if a participant missed two scheduled research visits in a row (if research staff were in verbal contact with participants, they would offer to conduct an off-site visit).
- Staff would attempt an off-site visit if they had been unable to make contact with a participant after three or more attempts.
- Staff would attempt an off-site visit if they made contact with the participant but s/he was unable or unwilling to come to the treatment program.
- Staff made off-site visits at least one week prior to the end of the assessment window, to allow for multiple off-site attempts as necessary. As informed consent allowed, the off-site visit could be spontaneous.
- Study staff conducted off-site at public places, including local coffee shops, libraries, parks, halfway houses. Staff first ensured that confidentiality would be protected and the location was safe before proceeding with the interview.
- Study staff conducted visits at participants' homes when it was deemed safe for study staff and confidentiality could be maintained.
- Staff attempted to obtain urine drug screens and alcohol breathalyzers only in private settings where the participant's confidentiality could be assured.

Staff made arrangements to conduct phone interviews with participants who could not be seen in person. Assessments were mailed to participants prior to phone interviews. Research staff obtained permission from participants and verified addresses prior to mailing assessments

Prison Interviews

- About half of our sites received approval to conduct interviews in prison. Those sites worked closely with their local prison systems to get in touch with/conduct study visits with incarcerated participants and to ensure study participant confidentiality with regard to assessments and materials going into and out of the prison.

Tips for research staff for conducting an off-site visit

- Read the participant's clinic chart and research progress notes to determine if there is any information that might be helpful or required to follow up (e.g., adverse events)
- When at all possible, have two staff members conduct an off-site visit together, especially if it is possible to collect a urine drug screen. If conducting an off-site visit alone, let other staff members know when and where you are conducting the visit.
- Prepare an off-site visit kit that is easy to transport (e.g., file box or rolling briefcase). This kit can contain paper assessments, office supplies, UDS and ALB collection supplies participant's contact information, compensation/gift cards.

[6] An off-site visit is any visit conduct away from the clinic location.

STRATEGIES IMPLEMENTED TO FACILITATE FOLLOW-UP IN CTN-0044 (cont'd)

- Only bring what is needed for the visit and leave unnecessary laptops, supplies and extra gift cards at the treatment program.
- Be mindful of where you park your car.
- Never leave valuables in plain sight within your vehicle.
- Even though you may have developed a good rapport with a participant, drug/alcohol relapse or worsening of psychiatric symptoms may change a participant's personality or demeanour. Research staff should always be aware of surroundings and should not attempt an interview if they feel uncomfortable doing so.
- If you do not feel comfortable or safe in your surroundings leave immediately and call someone.
- Attempt urine drug screens or alcohol breathalyzers only in a private setting where the participant's confidentiality can be assured. Do not conduct UDS/ALB in public settings (e.g., restaurants, libraries, etc.).
- Always carry a well-charged cell phone and share your cell number with other members of your research team. Stay in close contact with other staff members when conducting an off-site visit (call someone when you arrive and when you leave).
- Bring the participant's phone number with you and call them if you are at their front door and they are not answering or if you are unsure of your surroundings.

CTN-0044 PARTICIPATING NODES AND SITES

Node	Site
Greater New York Node (Lead Node)	North Shore - Long Island Jewish Health Systems
Florida Node Alliance	The Center for Drug-Free Living (CFDFL)
Mid-Atlantic Node	HARBEL Prevention and Recovery Center
New England Consortium	Midwestern Connecticut Council on Alcoholism SSTAR of Massachusetts (Stanley Street Treatment & Resources, Inc.)
Ohio Valley Node	Midtown Community Mental Health Center (under Health & Hospital Corporation of Marion County)
Pacific Northwest Node	Evergreen Manor
Pacific Region Node	Hina Mauka Kaneohe Rehabilitation Services
Texas Node	Homeward Bound, Inc.
Western States Node	Willamette Family Treatment Services