

CTN WEB SEMINAR SERIES: A FORUM TO EXCHANGE RESEARCH KNOWLEDGE



National Drug Abuse Treatment
Clinical Trials Network



Utilizing a Robust and Comprehensive Locator Form as a Retention Tool in Clinical Trials

Phoebe Gauthier, MA, MPH
Dartmouth College
Northeast Node

Dagmar Salazar, MS
Clinical Coordinating Center
at The Emmes Corporation

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Retention Statistic

Number of participants that can be lost to follow-up without mistrusting the results:

< 5% loss leads to little bias

> 20% poses serious threats to validity

Sackett D L, Richardson W S, Rosenberg W, New York: Churchill Livingstone; 1997.



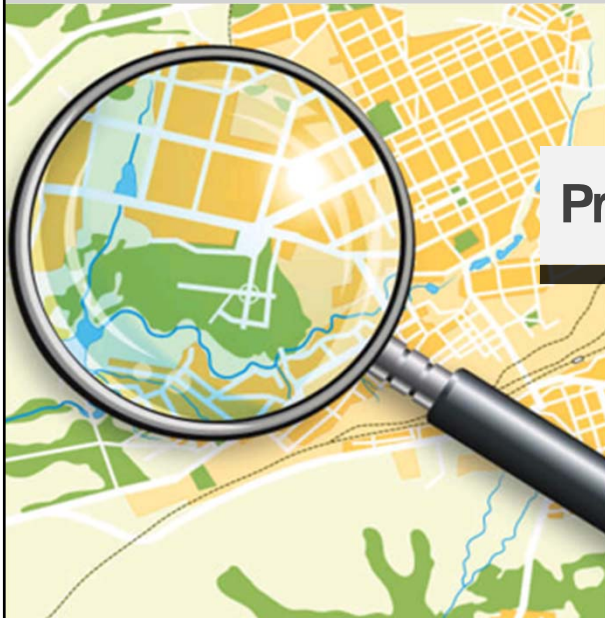
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Minimize the number of participants lost to follow-up to maintain the integrity of the study

How can the Locator Form help?



Retention Goal



Presentation Outline

- Locator Form
 - Information to collect
 - Collection methods
 - Data entry
 - Best practices
- Conclusion

Locator Form

Data collection forms; used for participant contact / visit reminders

Participant's Contact Information

Locator Information Form

Participant ID: _____
 Segment: _____
 Visit number: _____

IRB Instruction: Fill out as much tracking information as possible. Participant may withhold certain pieces of data he or she chooses not to share.

Information collected on this form will be used to reach you when it is time for your follow-up interviews. The information you provide will be kept in a separate place from your answers to any questions you have provided. It will only be used to locate you during the study and will not be given to anyone else. If we need to reach any of your contacts, they will not be told anything except that you have been asked to take part in a survey. May we have the following information and your permission to use the information to try to find you in case we lose touch?

Date form completed or updated: (mm/dd/yyyy)

PARTICIPANT INFORMATION

Participant's Full Legal Name:

First:
 Middle:
 Last:

Information on Additional Contacts

LOCATOR INFORMATION

We would also like to have the names of 2 or 3 people who might be able to help us locate you if we lose touch with you. Please include at least one person who does not live with you.

These should be:

- People with whom you are likely to keep in touch and who would know how to contact you.
- People who are likely to have the same address and telephone number for the next few months.

These people need not be told anything about the nature of the Project Health study in which you are participating. We would contact them only if we are unable to locate you. In each case, you can indicate whether or not it is okay for the person to know about the Project Health study in which you are participating.

Person #1:

For this first contact we would like to know who is the one person that you would turn to if you were in trouble.

First name: Last name:

Relationship to participant:

Number and street address:

City or town: State: Zip code:

Phone 1 number: Ext: Area: Type:

Phone 2 number: Ext: Area: Type:

Phone 3 number: Ext: Area: Type:

Best times to call:

E-mail address (e.g., xyz@abc.net):



What information is collected?

- Standard Participant Information
 - Full Name (First, Middle, Last)
 - Home Address
 - Phone number

What information is collected?

Detailed Participant Information

- Medical Record Number, Nickname(s)
- Most Frequented Locations for sleeping, eating, socializing, etc.
- Preferred Contact Method
 - Best times to call
 - Best method for contact



What information is collected?

Additional Contacts

- Additional locators
- Social Media Contact (i.e., Facebook, twitter)

Is it OK for this person to know about the research?

Does the person speak and understand English?





Techniques for Completion

- **Prepare for the collection of information**
 - Build trust, be honest
 - Gather cues from other assessments



Techniques for Completion

- **Collect and Confirm**
 - Probe for multiple contacts
 - Verify information received

Data Entry

Locator eCRF

An electronic collection form (eCRF) within data entry system facilitates incorporation of checks/flags



Data Entry

Participant's Contact Information:

Person #1: _____
Please contact us if you would like to know who is the one person that you would turn to if you were in trouble.
First name: _____

Phone 1 number: (301)523-4567 Ext: xx

Error Message
This phone number has already been entered for the participant. Please enter an additional phone number.

Phone 1 number: (301)523-4567 Ext: xxxxxx Type: Home phone

e: 20852

Locator eCRF - Data Entry

Person #1:

For this first contact we would like to know who is the one person that you would turn to if you were in trouble.

First name: Sue Last name: Smith
 Relationship to participant: Friend
 Number and street address: 4568 Street
 City or town: State: Zip code: xxxxxx
 Phone number: (xxx) xxx-xxxx Ext: xxxxxx Type:
 Last name: Smith
 State: Zip code: xxxxxx
 Ext: xxxxxx Type:
 Phone 1 number: (xxx) xxx-xxxx

Error Message

Two additional contact numbers must be provided for this participant to meet study eligibility criteria. Please add either a locator or an additional participant phone number. If participant is unable to provide this information, please submit the Study Completion and Protocol Deviation forms.

Cancel OK

Best Practices with the Locator Form

Complete the form interview-style – have a conversation with the participant

Confirm information before the participant leaves the research visit

Utilize contact information immediately



Trust, but Verify

Locator Form

Participant's Contact Information

Locator Information Form

Participant ID: _____
 Segment: _____
 Visit number: _____

IRB Instruction: Fill out as much tracking information as possible. Participant may withhold contact for or site chooses not to share.
 Information collected on this form will be used to reach you when it is time for your follow-up. Information you provide will be kept in a separate place from your answers to any questions provided. It will only be used to locate you during the study and will not be given to or reach any of your contacts. They will not be told anything except that you have been surveyed. May we have the following information and your permission to use the information we have located?

Date form completed or updated: (mm/dd/yyyy)

PARTICIPANT INFORMATION

Participant's Full Legal Name:

First:
 Middle:
 Last:

Information on Additional Contacts

LOCATOR INFORMATION

We would also like to have the names of 2 or 4 people who might be able to help us locate you if we lose touch with you. Please include at least one person who does not live with you.
 These should be:
 People with whom you are likely to keep in touch and who would know how to contact you.
 People who are likely to have the same address and telephone numbers for the next few months.
 We would contact them only if we are unable to locate you. In each case, you can indicate whether or not it is okay for the person to know about the study.

Last name

State Zip code

E-mail address (e.g., xyz@com)

Update

Conclusion

- Many barriers to retention
- While no universal acceptable follow-up rate...
 - The Locator can greatly assist with minimizing the number of participants lost to follow-up
 - Locator Techniques
- Collect, verify, utilize
 - Collect complete and accurate locator information
 - Ensure the form is regularly-updated throughout participation in the study.
 - Leverage data capture system to collect Locator and incorporate checks/flags

Contact us...

- **Phoebe Gauthier, MA, MPH**
Research Scientist
Dartmouth College
Northeast Node
Phoebe.R.Gauthier@Dartmouth.edu
- **Dagmar Salazar, MS**
Protocol Specialist
NDAT CTN Clinical Coordinating
Center at The Emmes Corp
dsalazar@emmes.com

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