



NEVER SAY LOST

3rd Edition

**A PRACTICAL GUIDE FOR MAINTAINING
PARTICIPANT FOLLOW-UP IN CLINICAL TRIALS**

**NATIONAL SURGICAL ADJUVANT BREAST AND BOWEL PROJECT
OPERATIONS CENTER
EAST COMMONS PROFESSIONAL BUILDING
FOUR ALLEGHENY CENTER – 5TH FLOOR
PITTSBURGH, PENNSYLVANIA 15212
412.330.4600
WWW.NSABP.PITT.EDU
WWW.BREASTCANCERPREVENTION.COM**

NSABP[®]
*National Surgical Adjuvant
Breast and Bowel Project*

TABLE OF CONTENTS

1	INTRODUCTION
2	THE IMPORTANCE OF ACCURATE CONTACT INFORMATION
4	IDENTIFICATION OF “AT RISK” STUDY PARTICIPANTS
5	THE 4 STEPS FOR PARTICIPANT FOLLOW-UP:
5	STEP 1: TELEPHONE COMMUNICATION
7	STEP 2: WRITTEN COMMUNICATION
8	STEP 3: HEALTH CARE POINTS OF SERVICES
10	STEP 4: COMMUNITY RESOURCES



INTRODUCTION

THE ULTIMATE SUCCESS OF ANY CLINICAL TRIAL DEPENDS UPON THE TIMELY SUBMISSION OF COMPLETE AND ACCURATE DATA. WITHOUT PERIODIC PARTICIPANT FOLLOW-UP, THE RELATIVE EFFECTIVENESS OF CLINICAL TRIALS COULD NEVER BE ASSESSED.

This booklet describes options to conduct follow-up and locate participants using multiple resources. **Users of this manual are encouraged to consider patient confidentiality and privacy issues while meeting the requirements of the study.**

Please consider the following:

- A consent form must be signed by the participant prior to taking part in the study. In consenting to the study, the participant may, unless done under separate documentation, also consent to the follow-up requirements of the study.
- Privacy boards and Institutional Review Boards (IRBs) provide structure to assure regulatory compliance and to protect human subjects. These boards can serve as a resource when questions arise regarding lost participants and confidentiality.
- The Code of Federal Regulations (CFR), International Code of Harmonization (ICH), and the Good Clinical Practice (GCP) guidelines state that the sponsor must ensure participant confidentiality.
- Public and state agencies may be used to find missing participants to insure that the health status of all randomized participants are known at the end of the trial. Recognize that public sources may differ among states and countries and the ability to access these sources will be locally mandated.

THE IMPORTANCE OF ACCURATE CONTACT INFORMATION

As part of the research record, research sites should maintain accurate addresses and telephone numbers for each participant, as well as for any family members or friends identified as primary contacts. This information is very important in the event that a participant misses any scheduled study visits as the study coordinator may need to follow-up with these individuals. Contact information should be verified and updated during each communication (i.e., participant visit or phone call) or whenever the participant notes a change; include the date when the change was made in the participant's research record.

To help minimize the chance that a participant will become lost to a study site, the study coordinator should try to obtain a:

- Participant's complete first, middle, and last name(s)
- Participant's home phone, daytime/work phone, cell phone, pager number, and e-mail address
- Participant's date of birth and US Social Security Number (SSN) or Canada's Social Insurance Number (SIN)
- Participant's passport or national identity card number, national insurance number, or other unique identifying numbers for sites in other countries
- Spouse's or significant other's complete first, middle, and last name(s)
- Complete names, addresses, and phone numbers of primary contacts (such as children, other relatives, neighbors, employer, pharmacy, and physicians)

Strive to develop a rapport with each participant prior to study enrollment. This will ensure open communication with the participant for the duration of the study. In addition, the study coordinator should:

- Ask the participant to tell his/her contacts that the study site has been given their name, the reasons why, and that they may be contacted in the future. These individuals will then be more cooperative should they ever need to be contacted.

- Make an effort to meet primary contacts and individuals who accompany participants to scheduled appointments. This will ensure recognition and cooperation should they need to be contacted later.

Suggestion: Consider giving business cards of the study coordinator and/or principal investigator to these individuals.

- Note the participant's place of employment and insurance company.
- Note the participant's professional organization affiliations (i.e., bar associations, beauty salon certifications, etc.).
- Maintain a current list of the participant's health care providers, especially their primary care provider(s), include addresses, phone numbers, and obtain releases from them to assist in future information gathering. Document all updates.
- Be aware that some health care facilities may present barriers to the obtainment of information, such as:
 - **Military Facilities**
 - Military personnel are allowed to keep their medical records. The study coordinator should consider requesting a copy of these records to maintain on file.
 - Because military personnel are transferred frequently, it may help to know where records are archived should you ever need to locate the participant.
 - Obtain the names of relatives who are not in the armed services and who have a relatively permanent address (primary contact persons in the armed services may also move frequently and be difficult to locate).
 - Should a participant divorce, spousal benefits may be cut off and complicate follow-up because the spouse may no longer have access to armed services institutions. Updating the participant's records, therefore, is essential.

IDENTIFICATION OF “AT RISK” STUDY PARTICIPANTS

Be aware that some study participants are more “at risk” for being lost to study follow-up. The study coordinator should attempt to identify these individuals early and plan a strategy in an effort to minimize losing them. Suggested strategies include more frequent contacts, calling to remind participants in advance of scheduled appointments, and addressing transportation and/or scheduling needs. Remember to update their address and telephone numbers frequently as well as those of their primary contacts.

Participants of concern may include:

- Participants with no fixed addresses or who move frequently.
- Participants who travel often for business or recreation.
- Participants whose first language is different than the study coordinator’s.
 - Have an interpreter take the required information.
- Participants with common-law partners or who divorce and/or remarry during the study.
- Participants experiencing employment or financial issues.
- Participants who elect to receive health care from another physician or facility during the study.
 - Ask those participants for the name of the new physician or facility.

THE 4 STEPS FOR PARTICIPANT FOLLOW-UP

If a participant does not keep a scheduled study contact, and the study site suspects that future contacts will also be missed, the site may wish to take the following steps to reach the participant. Document in the research record **all attempts**, even if unsuccessful, to reach the participant. This will aid in organizing efforts to locate the participant and prevent re-approaching unsuccessful contacts. The study site may consider developing a written protocol or policy to address locating lost participants.

STEP 1 TELEPHONE COMMUNICATION

Try to reach the participant by telephone at least three times. Although obtaining information by telephone must be done with care, it is a critical step in locating a lost participant.

If the study site is unsuccessful in reaching the participant, contact the participant’s primary contacts (i.e., relatives, friends, primary care provider and/or other referring physician). If necessary, a message could be left with the participant’s employer requesting a return call. To maintain confidentiality, the message should remain generic and should reference an individual (i.e., study coordinator’s name), as opposed to a program/clinical trial, physical condition (i.e., cancer), or doctor’s office.

THE PARTICIPANT

If the participant is contacted directly, explain the purpose for the call.

- Establish rapport by explaining that the study site is responsible for calling all participants who have missed a follow-up appointment. Express interest and concern in how the participant is doing. State the primary reason for the call is to determine the participant’s health.
- Remind the participant of the importance of completing follow-up contacts, whether they are face-to-face or via phone.
- Try to set up the next contact at the participant’s convenience.
- Provide the study coordinator’s name, telephone number, and any other pertinent contact information (i.e., pager number or e-mail address) and ask that the participant call if they cannot make the next appointment.

- If the participant does not want to continue with the study visits, ask permission to keep in touch periodically to check any changes in the participant's health status. Use the opportunity to review the follow-up requirements stated in the consent form.
- If the participant does not want to return to the study, ask if there is anything the study staff can do to make staying in the study easier. Explain that it isn't necessary to continue the assigned study therapy to remain an active and contributing member of the study. Also state that the study staff would still like to maintain contact to monitor the participant's medical care. And in most cases, remind the participant that rejoining the study in the future is an option. Request that any unused drug and/or empty drug bottles (or other study components) be returned to the study site.
- If the participant is adamant and does not want any further study contact, ask for a written letter withdrawing the participant's consent. Request that any unused drug and/or empty drug bottles (or other study components) be returned to the study site.

RELATIVES AND FRIENDS

If family members or friends are contacted, there are several guidelines the study coordinator should follow:

- Calmly and briefly:
 - Identify yourself and the study site
 - Share that the participant listed them as a contact and gave you permission to call
 - State that your purpose for calling is that you have been unsuccessful in reaching the participant
 - Express interest in how the participant has been doing since your last contact
 - Ask the contact for an updated telephone number and/or address for the participant.
- Alternatively, if the contact does not wish to provide you with any information, ask that your name and telephone number be given to the participant with a message to call.

PRIMARY CARE PROVIDER OR REFERRING PHYSICIAN

If the primary care provider or another physician is contacted, explain the participant's enrollment in the study and that as the study coordinator, you are obligated to locate all participants enrolled in the clinical research.

- Confirm the most recent participant address and phone number on file. If different, ask the office for any updated information or if they can contact the participant and leave a message to call you.
- Ask for the last date of contact with the participant. Request a copy of the progress notes or provide the office with a worksheet to fill out and sign regarding the participant's current or last known health status.

EMPLOYER

Should the participant's place of employment be contacted, simply state that you would like to leave a message to have the participant return your call. The study coordinator should use his/her discretion in stating that the call is from a medical facility or physician's office.

If attempts to reach the participant by telephone are unsuccessful, continue to STEP 2.

STEP 2 WRITTEN COMMUNICATION

Try to reach the participant in writing at least three times. If unsuccessful in reaching the participant, you may also write to the primary contacts as provided by the participant upon entry into the study. It is important to keep a copy of written communications sent to participants and/or their contacts in their research record.

- Prepare a letter from the study coordinator to notify the participant that other attempts to reach them have been unsuccessful. Enclose a business card with contact information and ask the participant to call. In addition, include a self-addressed, stamped, prepaid envelope and a worksheet for the participant to complete with updated contact information and basic health status.

- If there is no response, send a second letter via *Certified Mail* with a *Return Receipt* that requires a signature from the participant. Remember to put the return receipt in the participant's research record when it returns from the post office.
- If there is no response, a third letter could be sent from the principal investigator reinforcing the participant's importance to the study. This letter should also include study follow-up options such as: on-study and off-protocol therapy, reactivation of therapy, or a total consent withdrawal. Stress that study participation is voluntary, but that it is imperative the study site have verification of a decision in writing.

OTHER FORMS OF WRITTEN COMMUNICATION

- *Send a letter* to primary contacts (i.e., friends, relatives, or other individuals identified by the participant). File copies in the participant's research record to serve as a source document.

SUGGESTION: E-mail or copies of e-mail are another form of source documentation. Print a copy of the e-mail communication and sign and date it in ink prior to filing in the participant's research record.

If attempts to reach the participant by telephone and written communication are unsuccessful, continue to STEP 3.

STEP 3 HEALTH CARE POINTS OF SERVICES

Resources may include hospitals, mammogram centers, outpatient clinics and physician offices. Due to the US Health Insurance Portability and Accountability Act (HIPAA) and other privacy regulations, it is important to have the following materials available when requesting data:

- 1- participant study consent form;
- 2- a current release of information signed by the participant; and
- 3- a letter from your principal investigator and/or study coordinator requesting information.

Institutions may have additional requirements to allow for information sharing. Consult the local privacy board and institution officials. To ensure participant confidentiality, some contacted facilities may prefer the use of initials and/or study identification number.

Consider all points of health care services as potential sources of information regarding the participant (i.e., mammography centers, specialty physicians, and outpatient clinics).

HOSPITALS CAN BE A USEFUL RESOURCE FOR LOCATING MISSING PARTICIPANTS

- The hospital chart/patient notes/medical records will contain the participant's most recent information, including: home address, telephone number, place of employment, spouse's name, and an emergency contact's name. In addition, a participant's insurance company can be enlisted to provide survival status. Or, if the participant has indicated a religious affiliation, you can contact area clergy for help.
- Check the schedules in the surgery, medical, cardiology, cardiac catheterization, and other hospital outpatient clinics where the participant may have had a recent appointment.
- In most facilities, copies of participant records are sent to the attending physician, the referring physician, and consultants. These individuals may be able to provide information about the participant.
- The medical records department of the hospital in which the participant was originally treated can confirm a readmission.
- The medical records department will normally record all requests for patient information from other hospitals, physicians, insurance companies, as well as local (county, state or province) social security departments and the vital statistics departments. If a request was made, contact that organization to determine the participant's location or survival status.

- The facility's billing office may be able to confirm the most recent contact with the participant. If a long-term billing agreement is in force, you may be able to determine the participant's current address and/or telephone number.
- The hospital pharmacy can be another source if the participant has recently obtained a prescription.
- Local health clinics affiliated with the hospital that the participant may have recently visited for medical reasons unrelated to the study may also be a good resource.
- Additionally, contact tumor registries in institutions where the participant may have been seen (for any reason). Document which institution maintains follow-up records for future contacts.
- And if all else fails, the principal investigator may want to make a formal request for information from the medical record's administrator, the physician in charge of the medical records department, the physician treating the participant, the hospital administrator, the hospital's chief executive officer, etc.

If all attempts to reach the participant to this point are unsuccessful, continue to STEP 4.

STEP 4 COMMUNITY RESOURCES

Community resources may be used to locate missing participants. However, be aware that the ability to use these resources will be governed by local regulations on privacy and access to information. Maintain confidentiality, observe the relevant aspects of the Privacy Rule, and comply with all local guidelines of the study site's Privacy Officer/Board when trying to locate participants through outside parties.

- **Internet search engines/Web sites** – May be useful in obtaining recent addresses and phone numbers. *NOTE: Some internet Web sites may charge a fee to access information.*
- **City directories** – Many public libraries can help find directories that list the most recent addresses and phone numbers of city residents. The criss-cross directory that lists by addresses can also be utilized.

- **Telephone Directory Assistance** – Study coordinators may obtain participant telephone numbers using **local directory assistance (or 411 service)** that provides telephone number information in the telephone company's local service area or **long distance directory assistance** by dialing 1 + area code + 555-1212 for a number outside a local telephone company's calling area.
- **Voter registration/Electoral registers** – Many countries keep a file on all registered voters. On request, you may find out whether the participant has voted recently and the most recent address. State/Province laws apply.
- **Newspaper obituary columns** – Local newspapers usually publish the names of deceased local residents.
- **Vital Statistics Department/Registry of Births, Deaths, and Marriages (state/province), the Office of the Registrar General of Canada (for each province), or the US Social Security Administration's Death Index** – An applicant can request a search for a death certificate, if the study participant is thought to have died. *NOTE: This information can be accessed in writing, in person at a local office, or via these agencies' Web sites. There is a fee to obtain this information.*

Secondary Suggestions (if appropriate in your area):

- **Public utilities** – Contacting the local public utility offices, including gas, electric, phone, water, garbage, cable TV, etc., may provide a current address.
- **Public agencies** – The participant's employment history may identify a union or professional organization.
- **Post office** – May provide a current address.
- **Community centers/Social organizations** – If you know of the participant's involvement in a local group or organization (i.e., senior center), call or visit it to determine any recent participation.
- **Church/Temple** – Often know of any recent hospitalizations or deaths associated with their parishioners and may provide this information upon request.
- **Local pharmacy** – May have recent records of the participant.

NOTES

ACKNOWLEDGEMENT

IN 1979, MARJORIE MACLACHLAN, FORMERLY OF THE NSABP, PUBLISHED THE FIRST NEVER SAY LOST IN AN EFFORT TO PROVIDE GUIDELINES AIMED AT MAINTAINING GOOD LONG TERM PARTICIPANT FOLLOW-UP IN CLINICAL TRIALS. A SECOND EDITION OF THIS BOOKLET WAS UPDATED IN 1988 BY WALTER CRONIN OF THE NSABP BIOSTATISTICAL CENTER. THIS THIRD EDITION OF NEVER SAY LOST REMAINS DEDICATED TO MARJORIE AND WALTER FOR THEIR PIONEERING SPIRIT AND WORK IN THE FIELD OF CLINICAL TRIAL COMPLIANCE THAT HAS WITHSTOOD THE TEST OF TIME.

– THE 2004 STAR COORDINATOR
COMMITTEE AND STAFF OF THE NSABP