NCI Division of Cancer Prevention

Adherence and Retention Manual

(Template)

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Introduction and Acknowledgments

Retention is the effort of keeping the participant interested, participating, and committed to the study. Retention efforts are designed to promote adherence, and should begin with the initial interaction with a potential participant, not after randomization. As an on-going, dynamic process, promoting and routinely evaluating adherence and retention methods are vital to the success of the study.

This manual recommends strategies to keep participants interested in the study, with the goal being maximum adherence throughout the course of the trial. Because adherence begins with the first contact with the potential participant, the strategies and ideas that are discussed here are used for both potential and current participants.

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Promoting and Maintaining Adherence and Retention

The study site staff plays a key role because they have the most direct contact with participants. The quality of this interaction is crucial in bonding the participant to the trial.

Maintaining adherence and retention is a challenge for long-term prevention trials. It is important that the challenges of each trial are fully understood and that assumptions about how easy it may be to recruit and retain participants be made based on experience from other similar studies.

What Study Sites Can Provide

This trial cannot be done without the high quality of the professional staff at the study sites. Each site has its own unique attributes and contributions that they could add to this list:

- Access to their local media, business leaders, health care professionals, and advocates to assist in promoting the study as well as adherence and retention
- The ability to prepare their own adherence and recruitment materials based on their population needs or special circumstances.
- A comfortable setting for participant contacts, including parking and a sense of security
- Well-trained, friendly staff
- Sharing ideas with other compatible study sites to promote adherence and retention
- Frequent and routine monitoring of adherence and retention
- Enthusiasm and a positive attitude for conducting the study, following the protocol, and relaying your own enthusiasm and team approach to the participant

Identifying Factors That May Lead to Non-Adherence

Staff who have contact with study participants should become familiar with the "red flags" listed below that may be indicators of adherence problems. Most dropouts occur early. A watchful approach to those newly randomized is crucial. Be alert and be proactive.

Those lost due to adherence problems are frequently difficult to regain. Therefore, prevention and early treatment of reduced adherence is imperative. Use a team approach and communicate with each other! This helps with cross training and back-ups during times of staff vacations or turnover so there will be consistency for the participant.

Recognizing Changes in Previously Consistent Participant Behaviors

It may take a while for the participant to be on the study and have established patterns for you to be able to recognize changes in previously consistent behaviors. A potential or current adherence problem exists when a participant who has followed study protocols consistently no longer does so.

Listen carefully and do your best to address any participant concerns or problems. If possible, tailor trial requirements so that they will not be burdensome. Direct involvement of the Principal Investigator in adherence management activities may be particularly useful, especially if continued trial participation of the individual is threatened. The following are some signs or "red flags" of participant behavioral changes from previously consistent behavior:

- Missed visits
- Difficult to reach by phone or failing to return calls
- Rescheduling twice for a study site visit
- Unexplained change in adherence to study drugs/regimen

Changes in General Participant Behavior

The following is a list of general participant behavioral signs of current or potential adherence problems. To address adherence problems, gently and carefully probe reasons for the changes. Listen carefully to participant complaints and determine if the problem is related to study participation. Address concerns promptly. Often, participants may have had some life-altering event such as a relocation, major illness, accident, or death that affects them or a close family member.

Lost adherence is most commonly related to troublesome life circumstances. This may be a temporary situation that will resolve with time. You will need to use discretion to determine if it is appropriate to call in a few weeks or months to see how they are doing and feeling about their continued participation. Below are some of the red flags that may alert you to a changing attitude towards the study and your need to probe for the problem and resolution:

- Complaints about study site visits
- Impatience during study site visits
- Quiet, withdrawn during study site visits

- Unconcerned about adherence rate to study drug/agent
- Sarcastic remarks about study drugs

Medical Signs

The participant may have health issues that trigger adherence problems. If the participant becomes ill, talk to him about his illness. In some cases, the participant may feel that his illness is related to the study drug. If the participant expresses concern, discuss this with him and whether or not he should continue. The participant may feel more comfortable discussing the problem with his personal physician.

- Participant is hospitalized for any reason
- Participant experiences illness similar to "trial-related disease"

Change in Study Site Environment

If something about the study site environment changes, such as change in staff or location, it could trigger adherence problems. Let the participants know in advance about changes at the study site. Introduce them to new personnel. Listen to and address any concerns. Bond the participant to the study, not to a particular staff member.

The types of changes that are often upsetting to participants who have previously been adherent include:

- Reassignment to new clinic personnel for any procedures or tests
- Delays in the flow of study site visits
- Construction at the study site or adjacent parking areas

If possible, identify a primary staff member for each participant and use a constant caretaker model as much as possible. "Hand off" to another staff member openly and in the presence of the participant when a staff change is to be made. Let participants take some ownership in the change process.

Loss of Interest

If a participant states that he is losing interest or has already lost interest in the study, probe to see if you can clarify a specific reason. Sometimes it is because a co-worker or friend who was also on the study has recently stopped. Sometimes recent lifestyle changes or health issues create a temporary adherence problem. Listen carefully and don't coerce the participant into remaining. Restate his value to the study.

After speaking with the participant, if he still wants to stop, complete the appropriate forms for taking the participant off study. Ask him if you can call him in a few weeks or a month to see how he is doing. After a period of time and a friendly approach, his situation may have changed and he may be willing to go back on study. Do not coerce the participant; it is important to remember that his Informed Consent stated he could withdraw at any time for any reason.

In other prevention studies, when participants were re-contacted, some participants forgot what reason they gave for stopping the study drug and were willing to reactivate. When you call the participant back, do not remind him of his reason for discontinuing. Just inquire as to how he is doing and ask if his situation has changed and if he would like to come back to the study. Make his reactivation as convenient as possible.

Retention and Communications

Any time you promote retention, you are benefiting adherence. Helping a participant to feel comfortable, appreciated, informed, and valued at each contact may help the participant return for the next contact. Building trust is also important, especially in the minority populations. Below are several suggestions to help promote retention.

Participant-Staff Communication

Good written and verbal communication is essential to promote adherence and retention. There are many challenges when you are converting scientific language into lay terms, especially when English isn't the participant's first language. Here are some helpful suggestions:

- Familiarize yourself with lay terminology for scientific and medical terms by obtaining the free pamphlets available from the National Cancer Institute and the Cancer Information Services (for example, *Taking Part in Clinical Trials: Cancer Prevention Studies/What Participants Need to Know*, and *Spread the Word about Cancer: A Guide for Black Americans*.)
- Communicate in a personable, yet professional, manner. If you want the participants to be enthusiastic about the study, you must be perceived as supportive and enthusiastic about the study. This is as true for seeing the first participant of the day as for the last participant of the day.
- Use your full name and title when greeting a participant for the first time. Address the participant as "Mr." or " "Ms." If the individual gives you permission to use his or her first name or a nickname, make a note of this in the file for future reference.
- Listen carefully and address any concerns voiced by the participant. Use a tone of voice that is positive, sound interested and avoid being condescending. Speak audibly but do not speak so loud as to make the participant feel uncomfortable. Articulate each word and adjust your rate of speech if necessary.
- When appropriate, describe the purpose of the visit and what will happen during the time you are together. Always provide an opportunity for the participant to ask questions.
- Know the study well, don't "wing it." If the participant asks a question and you don't know the answer, admit it—credibility is crucial!
- Avoid using jargon or technical language.
- Give the participant your full attention. If possible, transfer your phone calls during visits.
- Always maintain a neutral position on the state of proof regarding the question and outcome being investigated in the trial. This is referred to as "equipoise" or balance.

Bonding Process

There are several factors that must be addressed when working to achieve optimal adherence. For instance, a comfortable setting will help make the participant want to return for visits and look forward to interaction with the staff.

Promoting a feeling of solidarity with both the staff and the other participants is the key to bonding the participant to the study. In long-term trials there is likely to be staff turnover. Thus, bonding the participant first to the study and second to the staff is important so the participant won't feel discouraged if a favorite staff member leaves or if he needs to transfer to another study site. Below are some strategies to develop and maintain bonding:

- Stress the importance of the participant's time and effort in working to prevent cancer.
- Promote a sense of belonging, of being a member of the study team. This requires an investigator, staff, and the participant to have a team.
- Provide a suggestion box. Encourage participants to put ideas in this box that would make them feel more comfortable with the study, the staff, or at the site.
- If possible, provide items with the study logo on them, such as mugs, magnets, or hats.
- Whenever possible, have the participant see the same staff member at each visit. However, if the participant is not relating well with one staff member, switch him or her to another.
- Send birthday and/or holiday cards to participants.

Study Site Environment

The participant's comfort level while at the study site is of significant importance. It is important to make the participant as comfortable as possible by presenting yourself, the study site offices and waiting room as professional and accommodating. The participants should remember the sites as easy to find and comfortable.

The participant should be seen at the appointed time; delays could affect parking or arrangements to get home or back to work. Consider the following to promote a positive and comfortable environment for the participant:

- Post signs with directions to the study site office at appropriate areas of the building. Be sure the signs are easy to read, large and bold.
- Consider providing a suggestion box with blank paper and pencils.
- Provide daily newspapers and magazines related to health. Also provide magazines for women, young adults, and children who accompany participants to visits.
- Have a bulletin board with information specifically about the study such as the recruitment materials, facts about the study drug or information about general prostate health.
- Family members should be encouraged to accompany participants so consider providing toys, puzzles, and coloring books for young friends or relatives.
- Have extra recruitment materials available including participant fliers, brochures, and other related materials so the participant can share them with family and friends.
- Provide prevention and other health-related materials such as smoking cessation booklets, and breast and colon cancer screening information.

Whenever decorating the waiting room area for holidays, be careful to avoid showing denominational preference. Be aware of relevant cultural or minority issues in your study population. For example, you may want to have reading materials available in other languages or focused on specific minority groups.

Convenience and Accessibility

Consider accessibility and overall ease of participation. Some suggestions follow:

- Offer flexible scheduling to accommodate after work and evening or weekend visits.
- Have chairs with arms available to make getting in and out of chairs easy for those with arthritic conditions. People with knee or back problems often prefer to be in hard chairs, since they may have trouble getting out of soft chairs.
- Remind participants of upcoming appointments via postcards and/or telephone calls.
- Be cognizant of weather patterns when scheduling visits. Also be aware of participants who are "snowbirds" or seasonal residents, and schedule their visits accordingly.

The following suggestions are to assist with travel logistics:

- Make free parking available whenever possible. Consider paying travel expenses for those who express concerns about the cost of getting to the study site.
- Know the local transit routes that serve the study site so you can properly advise participants. Have bus or ferry schedules available, along with phone numbers for taxi services or buses. If possible, provide financial support for transportation and parking.
- Provide detailed maps with the study site phone number included. Be sure to make the map and directions easy to read by using large print.
- Facilitate access to the site as well as getting around once at the site for disabled and wheelchairbound participants.

Family Members' Involvement

Involvement of family members should be encouraged. Adherence and retention of minorities may depend on involvement of family and friends so be cognizant of ethnic issues relevant to the particular population you serve.

Other Suggested Retention Items and Activities

There are many methods to acknowledge a participant's time and dedication to the study. Some are as simple as having your Principal Investigator write a letter to the participant thanking them for their time and encouraging continued participation. Depending on your institution's policy, consider asking local vendors to donate money or items, or to partially assist with expenses for these items and activities.

Listed below are other possible ways to acknowledge participants, supportive family members, and recruitment sources. All materials should be reviewed by the IRB.

- Design Certificates of Appreciation to give at specific times during the study such as at the end of the study. Certificates could also be given to recruitment sources once recruitment is complete to encourage them to support the continued participation of their members, clients or patients. By recognizing the help of recruitment sources, you are also building a recruitment base for future prevention trials in your community.
- Design and provide study pins that participants can wear on hats and shirts, which promote the study and participants' pride in membership. As others ask them what the pin stands for, they can share information about the study and possibly recruit others.
- Order pocket calendars or Pocket Pals from catalogues. Often when ordered in large quantities, these can be purchased at reduced cost. You can mark their study site visits on the calendar and consider sending the calendar as thanks for their continued participation.
- Provide non-childproof caps for the study drug bottles if participants indicate they have trouble getting the caps off the bottles.
- Consider sending non-denominational birthday, sympathy, congratulations, holiday cards or a holiday letter from the staff.
- Consider providing them with pencils or pens with the study logo, to promote their pride in the study.
- Send hand-written personal notes of thanks or encouragement.
- Obtain coupons from local businesses such as golf stores, hardware stores, sporting goods shops, nurseries, video stores, restaurants and coffee shops that can be used to acknowledge good adherence.

Here are a few ideas for adherence and retention logo items:

- Key chains
- Magnets
- Post-it notes
- Ice scrapers
- Bottle openers
- Business card holders
- Sun visors
- T-shirts
- Appointment books
- Cup holders
- Hats
- Tape measures
- Golf balls