LONG TERM FOLLOW-UP

Long term follow-up begins when the protocol treatment is discontinued, treatment toxicities have resolved, and the response to therapy has been determined. The purpose of long term follow-up is to assure continued medical surveillance and allow meaningful end-results reporting. Study endpoints are dependent on having meaningful data on items such as recurrence, disease status, survival, long term adverse events or new malignancies.

It is the responsibility of the clinical research professional to design and coordinate an effective patient follow-up system. Database or spreadsheet computer programs are helpful in managing long term follow-up as data can be sorted by a number of different parameters such as last contact date, patient name, or physician to contact for follow-up information. Smaller sites can use a simple card file reminder system.

Most SWOG studies require follow-up data to be submitted every six months for the first two years then annually thereafter unless more stringently specified in the protocol. The Data Submission Schedule (Section 14 in the protocol) provides information on the frequency of data submission, the length of time follow-up data is required, and the forms to be used on the study. Some studies require many years of follow-up while some phase II studies may require follow-up for just a few years.

The CRA Workbench on the SWOG Web site (www.swog.org) offers useful reports, forms and tools to facilitate follow-up. The Expectation Report provides the date of last contact. The Off-Treatment Notice form is submitted when protocol treatment is discontinued. The Follow Up Form is utilized to submit follow-up data once protocol treatment is complete. If a patient completed protocol treatment without progressive disease, the CRA should submit a Follow Up Form upon learning that the patient has relapsed, recurred, or has progressive disease. The Follow Up Form is used to indicate a patient has a new primary or a long-term adverse event. Some protocols may have protocol specific forms related to progression of disease and follow-up. Always refer to the Study Calendar and Data Submission section of the protocol to determine the appropriate forms required for the study.

Closing Out Studies for Follow-up

Often sites feel that once all patients are off study or deceased they are able to close out the study at their site, however this is not the case in SWOG. Even if all queries have been addressed and expectations resolved, it is likely the study has not yet completed final analysis and/or the manuscript has not been written. It is common that additional findings will be found where the study chair or statistician requests clarification or additional data, therefore, the data coordinator will issue new queries. It is for this reason that sites must keep the protocol open at their institution until publication or once it has been added to the List of Studies with No Required Follow-Up report on the CRA Workbench.

Responsibility for Patient Follow-up

SWOG Policy Memorandum No. 30 defines responsibility for patient follow-up, procedures for transferring a patient to another institution, the criteria utilized to classify a patient as "lost to follow-up," and things to discuss with the patient if they wish to withdraw consent. It is important you be familiar with and use the most current policy to assure compliance with procedures and required documentation.

The following policies will be observed by all Group members in regard to follow-up of patients registered to studies coordinated by SWOG:

SWOG Policy Memorandum No. 30

Sources of Information for Follow-up

A number of sources may be utilized to obtain follow-up data. Always check the hospital or physician office record first. Referring physicians may be able to provide information or an updated address or telephone number. Some physicians may require a copy of the study consent to release information and some may not provide data at all. Some facilities may require an authorization for release of health information. The patient may be contacted directly if your facility policies permit it. If you utilize relatives and other non-hospital sources to locate the patient, extreme care must be taken not to violate patient confidentiality policies.

1. In-hospital sources:
   a. Medical record/Hospital information system
   b. Readmissions
   c. Clinics
   d. Outpatient departments
   e. Radiation therapy department
2. Current physicians (sample letter on page 8)
3. Referring physicians
4. Hospital cancer registries
5. Direct contact with patient
6. Relative or other follow-up contact
7. State population-based cancer registries or other central cancer registries
8. Home health agencies
9. Current telephone directories for entire state
10. City/county directory, cross-referenced by resident name and address (a copy may be in a hospital business office or development office, or in the library. Borrow these annual publications, as the costs are very high
11. County welfare department
12. Vital statistics office (local, county, state).
13. Religious affiliation
14. Present or former employer, (use caution; discrimination may cause a patient to lose his job)
15. Labor unions
16. State professional registries
17. Professional directories
18. Health insurance companies
19. Schools, alumni associations, etc.

20. American embassy of a particular country for Americans living abroad
21. Foreign country consulate or U.N. Mission
22. Social security administration (local or national). They will forward a letter if the social security number is known, but will not give out information as to the patient's whereabouts. If SSA verifies that benefits are being paid, you may report patient as alive.
23. Voter registrations records
24. Property tax records
25. City/county assessor (ownership of home)
26. U.S. Veterans Administration
27. Certified letters to be signed by the addressee only
28. Department of motor vehicles/Bureau of traffic safety
29. Jails and parole officers
30. Hospices
31. Nursing homes
32. Mailing list correction cards to the city postmaster
33. Forwarded mail information on a new address from the post office (write or preprint "FORWARD AND ADDRESS CORRECTION REQUESTED" on the envelope).
34. Social Security Death Index, for reporting deaths only. Failure to find death in SSDI does not allow you to report patient as alive.

Internet Sources

There are a number of search mechanisms on the Internet that can be utilized for locating patients. Sites like www.genealogybank.com provide links to the Social Security Death Index (SSDI). The SSDI allows searches based on name, Social Security number, etc. If a patient is found there, you will be provided with the date of death and, city and state of last residence. One must be careful in updating survival status based on Internet searches. Just because one patient is not listed in the SSDI does not mean they are alive. Additionally, the SSDI database is usually updated just twice a year. Some internet sites may require a fee or membership to access data.

Addresses and Telephone Numbers

www.anywho.com
www.whitepages.com
www.people.yahoo.com

Social Security Death Index Information

www.Ancestry.com (fee for service)
www.Rootsweb.com (fee for service)
www.genealogybank.com

Other Possible Internet Sources

Online obituary search
www.arrangeonline.com – National Obituary Archive
Online listing of funeral homes
Public Library web pages for links to other search sites.

Strategies to Use in Long Term Follow-up

Communication with your patient during the informed consent process, treatment, and after treatment is completed is extremely important in maintaining up to date follow-up. Develop a good relationship with your patients. Let patients know you will be contacting them on a periodic basis.

Contact patients if an appointment is canceled or missed. Communicate to the patient they are the most important part of our research and their participation is valued. Utilize the *Partnerships for Life* brochure to reinforce relationships and expectations. The brochure can be found on the CRA Workbench under "Tools of the Trade" and printed for local use.

Proactive efforts when a patient is placed on a study will facilitate the collection of long term follow-up data. You may obtain additional contact information for a patient to include other persons who generally know the whereabouts of the patient. This may include names, telephone numbers, addresses, and email addresses. A sample Research Participant Contact Information form is included on page 9. The form can be completed at the time the consent document is reviewed and updated during visits and follow-up contacts. Review this information with the patient/participant on an annual basis.

Maintain old addresses, telephone numbers, or other contact information. It may be helpful to go back to previous contacts. Document follow-up attempts in a notes section of your research record.

Appointment reminders are helpful, especially for prevention studies. When permitted, send birthday cards or other greeting cards to patients and participants.

Provide postage paid envelopes if you are asking for something to be returned. These may be printed or simply add a stamp to the return envelope. This is often helpful for patients and physician offices and helps assure the form is returned to the correct mailing address.

Utilize caution when using email or other social media to contact patients. Email is typically not a secure method for transmitting confidential information. Check your institutional or organizational policies for contacting patients and accessing information via social media sites to obtain follow-up information.

Patient Transfers

A patient transfer is initiated if a patient goes to another SWOG institution for treatment or follow-up, ex., a patient moves. To initiate a patient transfer for an enrollment that was conducted in OPEN, you must go to the CTSU website and access the Transfer and Update Module (T&UM). To initiate a patient transfer for an older enrollment that did not occur through OPEN, go to the CRA Workbench and select "Patient Transfer." Both the transferring and the accepting investigators must approve the transfer. Current IRB approval is required at the new institution. Refer to Policy Memorandum No. 30 for additional information on transfers.

Withdrawn Consent

Withdrawal of consent occurs when the patient refuses to participate further in the research study and does not wish for future medical information to be collected or used for the purpose of research. Unless a patient withdraws consent for all follow-up, patients must be followed as indicated in the protocol and SWOG Policy #30:

> If a patient withdraws consent after registration, the institution must determine with the patient whether 1) they no longer wish to be treated per protocol; 2) they no longer wish to be followed per protocol, or 3) both. Withdrawing consent to participate in a study does not necessarily mean the patient also withdraws consent to being followed. This distinction must be clearly documented in the research record and on the Off Treatment Notice or Follow-Up form.

Withdrawal of consent from all components of the research study or just the primary intervention must be documented via:

1. A letter from the patient.
2. A note in the research record by the investigator clearly reporting the patient's wishes for the study intervention (if on protocol treatment) and for study follow-up and participation.

When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed and remains subject to audit.

Data forms must be submitted, queries addressed, etc. for the timeframe prior to the time of withdrawal. If complete consent withdrawal status is established, all research activities involving the subject's participation in the study (direct intervention, collecting PHI from outside sources such as other departments accessible through the EMR, etc.) must be discontinued.

See the SWOG Regulatory Audit Guidance for additional information related to the consent process.

The Cancer Institute

1234 Molecular Road
Cure Cancer, CC 88888-5555

Date:
_____
_____
_____
_____

Dear Doctor:

We are seeking information on one of our patients, _____. This patient participated in one of our SWOG studies and we are in need of information pertaining to survival status. We would very much appreciate it if you will provide us with the following information at your earliest convenience. A postage paid envelope is enclosed for your convenience.

Date last seen: _____

- Patient is alive without disease: Yes _____ No _____
- Patient is alive with persistent disease: Yes _____ No _____
- Patient has developed a new malignancy: Yes _____ No _____
    - Date of new malignancy: _____
    - Site of new malignancy: _____

If patient has expired, please provide the following, if known:

- Date of death: _____
- Cause of death:_____
- Autopsy performed: Yes _____ No _____

Comments: _____

_____

Thank you in advance for your cooperation and assistance.

Sincerely,

Clinical Research Coordinator

Research Participant Contact Information

Name:_____

Address:_____

_____

Phone: Home:_____ Work:_____

Cell:_____ Pager:_____ Fax:_____

E-mail address:_____

Social Security Number:_____

Spouse: Name:_____

Phone: Home:_____ Work:_____

Local Physician:_____

Address:_____

_____

Phone:_____

Names, addresses and phone numbers of three people (other than spouse) who can reach participant. Include at least one from participant's hometown.

CONTACT #1	CONTACT #2	CONTACT #3
NAME :	NAME :	NAME :
Address:	Address:	Address:
Email address:	Email address:	Email address:
Home Phone:	Home Phone:	Home Phone:
Work Phone:	Work Phone:	Work Phone:
Relationship to Patient:	Relationship to Patient:	Relationship to Patient: