



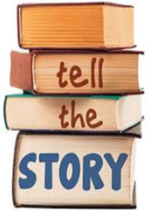
Your Mission: Patient/Participant Long Term Follow-Up

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WHAT is long term follow-up?



Answering questions:

- Protocol treatment – completed?
- Protocol treatment – discontinued?
- Treatment toxicities – resolved?
- Response to therapy?
- Beyond the active intervention phase?
- May vary if an observational study







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SWOG Policy Memorandum No. 30 “Responsibility for Patient Follow-Up”

Defines responsibility for:

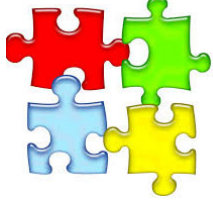
- patient follow up
- procedures for transferring a patient to another institution
- the criteria utilized to classify a patient as “lost to follow-up”
- things to discuss with a patient if they wish to withdraw consent

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WHY Do Long-Term Follow-Up?

- Assures continued medical surveillance
- Allows meaningful end-results reporting
- Helps capture accurate data
 - Disease recurrence
 - Disease status
 - Survival
- Monitors for long-term
 - Adverse events
 - Treatment-related malignancies
 - New malignancies




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Follow-Up Intervals: The WHEN


- Every 6 months for first 2 years
- Annually after 2 years
- Refer to specific protocol requirements – **SWOG protocol section 14.0** Data Submission Schedule
- Read the protocol carefully for length of follow-up
- Patients on some older studies may be followed until death
- If not defined or in doubt...go with the most conservative option and verify with SWOG



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The HOW: Tracking Follow-Up

- Track by date of last contact
- Use the Expectation Report
- CTSU Queries/Tracking -- DQP
- Set up and use Tools:
 - Tickler systems
 - Calendar reminders
 - Database or spreadsheet
 - Clinical Trials Management System (CTMS)




Whatever works at your site to help you track and remember...works!

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Follow-Up Documentation



- Date of last contact - Vital status
- Date of last clinical assessment or disease assessment
- Progression/recurrence
- Subsequent treatment
- New malignancy/MDS
- Long-term adverse events (AEs)



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Priority Sources of Follow-Up Information

- Hospital record and/or treating physician's record
- Referring physician's office
- Family physician's office
- Call or send letter to patient



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Every patient counts...
Every patient has the potential to be "lost"



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Be Proactive

- It starts at the beginning
- Assume changes WILL happen
- Get to know your patients and their journey
- Confirm and update contact info at every visit
- Verify the plan and timeline for next follow-up
- Build in handoffs



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Collect Demographic Information

Can be found in the patient chart or electronic health record

- Patient
- Referring or other physicians
- Relatives
- Insurance company
- Cell phone numbers and e-mail address
- Put together a Participant Information Sheet

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Participant Information Sheet

- Complete at time of consent
- Review each year
- Update at time of transitions &/or when patient shares changes

• Name: _____

• Address: _____

• Phone: _____ (Home) _____ (Work) _____ (Cell)

• E-mail address: _____

• Social security number: _____

• Spouse – Name: _____

• Phone: _____ (Cell) _____ (Work)

• Primary care physician: _____

• Address: _____

• Phone: _____


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Participant Information Sheet

- 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:
Phone (cell):	Phone (cell):	Phone (cell):
Phone (work):	Phone (work):	Phone (work):
Relationship to patient:	Relationship to patient:	Relationship to patient:


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Communicate Regularly

- Communication is key to building relationships
- Be part of the journey
 - Informed consent
 - Treatment
 - End of treatment
 - Follow-up plan
 - Key timepoints




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Foster good relationships


- Physician office personnel
- Health information personnel
- Hospital cancer registrar
- Navigators
- Genetic Counselors



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Keep in touch

- Build a bond with your patient(s)
- Stop by to see the patient at appointment check-in or while they are waiting to see physician
- Birthday cards or notes
- Appointment reminders
- Postage paid envelopes
- Make it simple for them to reach you






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Tips for finding a “lost” participant

- Hospital EHR or computer system
- Social media
- Voter registration
- Hospital cancer registries
- Family members
- State cancer registries
- Internet searches





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Internet resources



- www.anywho.com
- www.whitepages.com
- www.people.yahoo.com
- www.switchboard.com
- www.findagrave.com

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Other internet sources



- Local library – look for links on their web page
- Social Security Death Index (SSDI)
- Department of Corrections
- Send a letter to physician office or tertiary referral hospital center
- Lexisnexis.com – links to legal and public records
 - Academic institutions or law schools may have a subscription

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Other internet sources



- www.legacy.com
 - Online obituary search
- Ancestor Hunt (www.ancestorhunt.com)
 - Obituary search
 - Newspapers by state
- www.ancestry.com
- National obituary archive (www.arrangeonline.com)
 - Online listing of funeral homes

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Internet resources for Social Security Death Index

- www.genealogybank.com/gbnk/ssdi
- www.RootsWeb.com
- www.ancestry.com
- www.worldvitalrecords.com
- www.familysearch.org

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**Policy #30:
Responsibility For Patient Follow-up**



- Login to SWOG member site (www.swog.org) /
 - Policies and manuals /
 - Policy 30
- You can also access policies from the CRA Workbench

“All institutional and individual participants in SWOG are responsible for the follow-up of all patients registered by the institution and /or the individual at the institution for as long as the patient remains alive (or for a protocol specified length of time). The commitment to patient follow-up remains regardless of the funding status or membership status within the group.”






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Reference Policy #30 when changes occur...

- Change in institutional status
- Change in investigator status
- Patient moves from one SWOG institution to another
- Consent withdrawal
- Lost to follow-up requirements



DEFINITIONS MATTER!

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Patient transfer


- Patient goes to another institution
- Transferring & accepting investigators must approve transfer
- Be sure you work with your program leadership

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**Patient Transfer:
Transferring Institution's Responsibilities**


- Contact new site for transfer
- Initiate patient transfer form online
- Resolve ALL expectations and queries
- Provide accepting institution with copy of research record and case report forms (CRFs)

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**Patient transfer:
Accepting institution's responsibilities**


- Complete patient transfer form
- Obtain IRB approval prior to conducting study activities
- Patient signs new consent form and HIPAA authorization at accepting institution


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Consent Withdrawal

- **Definitions are key!**
- VERIFY with the patient:
 - No longer wish to be treated per protocol?
 - No longer wish to be followed per protocol?
 - Both?
- *Withdrawing consent to participate in a study does not necessarily mean the patient also withdraws consent to being followed.*
- Please make sure the individual understands that they can still be followed on trial



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Declaration Of Lost To Follow-up

Look for the form on the
CRA Workbench /
Patient Management
(Non-Rave Studies)

CRITERIA FOR LOST-TO-FOLLOW-UP STATUS

1. Has it been at least 2 years since the last patient contact: Yes *(if the answer is No, your patient is not eligible - please do not submit)*
 Date of last contact: / /

2. Please document attempts to contact patient (either 3 phone calls or a certified letter which was either returned "addressee unknown", or did not receive a reply):

Phone calls - please list dates: 1: / /
 2: / /
 3: / /

Certified letter: Returned
 No response

I verify that the above information is correct, and that all attempts to contact this patient have failed.
 Signature of Principal Investigator: _____ Date: / /

SWOG S9808 Long Term Follow-Up Protocol

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SWOG S9808 Long Term Follow-Up Protocol

- Objective -- Relieve burden for local IRBs doing continuing review (CR) for studies:
 - Closed to patient registration
 - On which no patients are receiving protocol treatment
 - Patients are still alive and being followed
- Local IRB
 - Approval required for protocol S9808
 - Reviews a report annually for the LFTU Protocol (vs individual study CRs)
- List of studies under S9808 on CRA Workbench / Reports / Study Management

SWOG S9808 Long Term Follow-Up Protocol

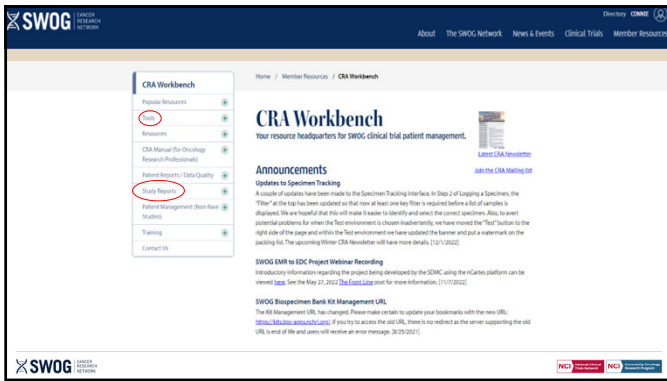
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List of No Follow-up Required Studies

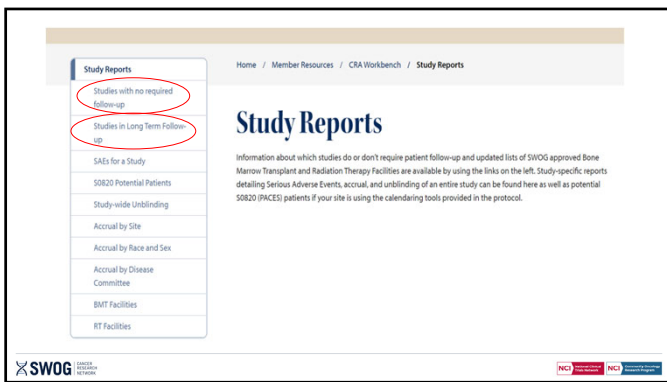
- Posted on the CRA Workbench / Reports
- Follow-up no longer required
- Includes date to keep records
- Keep until SWOG date or institution required date – whichever is longer

SWOG S9808 Long Term Follow-Up Protocol

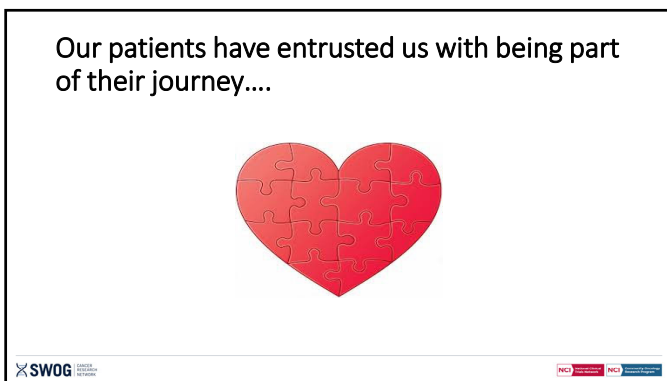
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Questions?



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