Patient/Participant Long Term Follow-Up

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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 effects
  - Adverse events
  - New malignancies
  - Treatment-related malignancies

WHAT is long term follow-up?

During the course of the study:

- Protocol treatment – completed? Or discontinued?
- Treatment toxicities – resolved?
- Response to therapy?

LONG-TERM FOLLOW-UP:

- Beyond the active intervention phase

WHEN: Follow-up Intervals

- Every 6 months for first 2 years then annually
- Read the protocol carefully for length of follow-up
- Refer to specific protocol requirements, including **SWOG protocol section 14.0** Data Submission Schedule
- Patients on some older studies may be followed for life
- If in doubt…consult with SWOG

SWOG Policy Memorandum No. 30: "Responsibility for Patient Follow-Up"

Defines:

- Responsibility for patient follow up
- Procedures for transferring a patient to another institution
- Criteria to classify a patient as "lost to follow-up"
- Things to discuss with a patient if they wish to withdraw consent

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)

Sources for 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

Collect Demographic Information

- Patient
- Cell phone numbers and email address
- Relatives
- Referring or other physicians
- Insurance company

Info can be found in the patient chart or electronic health record

HOW: Tracking Follow-Up

- Track by date of last contact
- SWOG Expectation Report
- CTSU Data Quality Portal (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!

Participant Information

Name: _____
Address: _____
Phone: _____(Home) _____(Work) _____(Cell)
E-mail address: _____
Social security number: _____
Spouse – Name: _____
Phone: _____(Cell) _____(Work)
Primary care physician: _____
Address: _____
Phone: _____

- ✓ Completed at time of consent
- ✓ Reviewed annually
- ✓ Update at time of transitions and/or when the patient shares changes

Be Proactive

- Assume changes WILL happen
- Get to know your patients
- Confirm and update contact info during visits
- Review the timeline and plan for next follow-up
- Build in handoffs

Participant Information

- Names, addresses and phone numbers of more than one person (other than spouse/partner) who can reach participant.

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:

Communicate Regularly

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

Every patient counts…

Every patient has the potential to be "lost"

Foster good relationships

- Physician office personnel
- Navigators
- Genetic Counselors
- Health information personnel
- Oncology Data Specialists (Cancer registrars)

WHERE: Locating a "lost" participant

- Hospital EHR or computer system
- Hospital/Clinic Oncology Data Specialists (Cancer registrars)
- Family members

Keep in touch

- Appointment reminders
- Connect at clinic visits
- Birthday cards or notes
- Postage paid envelopes

Make it simple for them to reach you!

Additional Resources

- Department of Corrections
- Local library website – look for links on their web page
- Lexisnexis.com – links to legal and public records
  - Academic institutions or law schools may have a subscription
- Social Security Death Index (SSDI) – limited access
- Internet searches

Internet resources

- www.legacy.com - Online obituary search
- www.theancestorhunt.com
  - Obituary search
  - Newspapers by state
- www.whitepages.com
- www.findagrave.com
- www.yellowpages.com
- www.familysearch.org (need account)
- www.geneologybank.com/gbnk/ssdi (need account)
- www.ancestry.com (need account)
- www.RootsWeb.com (associated to ancestry.com)

Refer to Policy 30 for…

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

Policy 30: Responsibility For Patient Follow-up

Login to SWOG member site (www.swog.org)

- About → Policies & Procedures
- **Policy 30**

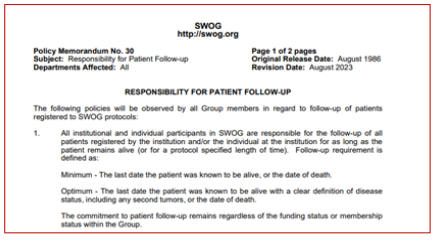
Policies can also be accessed from the CRA Workbench

- Resources → SWOG Policies
- **Policy 30**

Patient transfer

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

Policy 30: Responsibility For Patient Follow-up



SWOG
http://swog.org

Policy Memorandum No. 30
Subject: Responsibility for Patient Follow-up
Departments Affected: All

Page 1 of 2 pages
Original Release Date: August 1986
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RESPONSIBILITY FOR PATIENT FOLLOW-UP

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

1. 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). Follow-up requirement is defined as:

   Minimum - The last date the patient was known to be alive, or the date of death.

   Optimum - The last date the patient was known to be alive with a clear definition of disease status, including any second tumors, or the date of death.

   The commitment to patient follow-up remains regardless of the funding status or membership status within the Group.

Patient Transfer: Transferring Institution 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)

Patient transfer: Accepting Institution Responsibilities

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

"Lost To Follow-up" – Requirements

- Has it been >2 years since last patient contact?
- Must attempt to reach patient at least 3 times
- Document contact attempts
  - DOCUMENT!
  - DOCUMENT!
  - DOCUMENT!
- Before finalizing this status:
  - Review and re-review the policy
  - Inform and discuss with your program leadership
  - Connect with the SWOG study coordinator
- Know local site policies
- Update your local files with status change

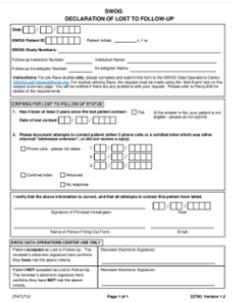
Consent Withdrawal

- 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

Declaration Of Lost To Follow-up

Form can be found on the CRA Workbench

Patient Management (Non-Rave Studies)

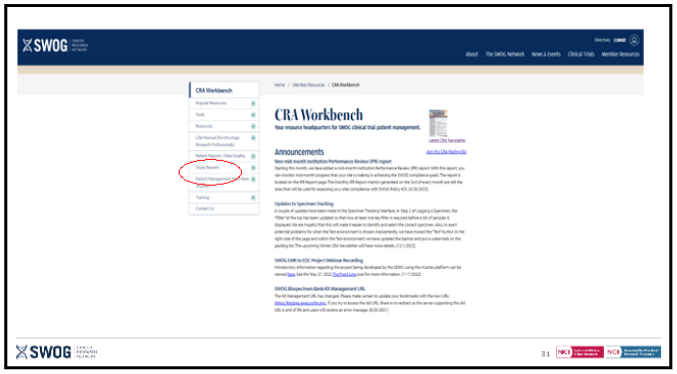


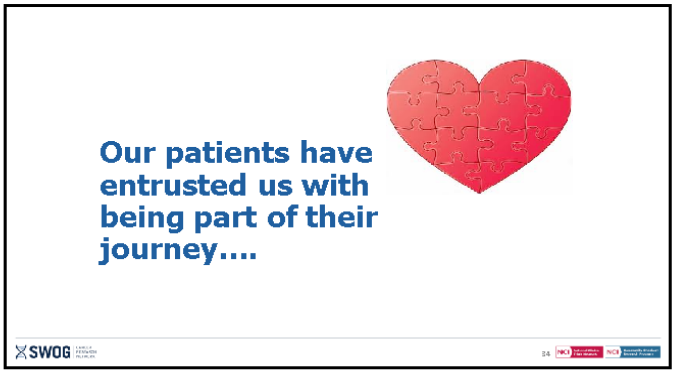
Consent withdrawal

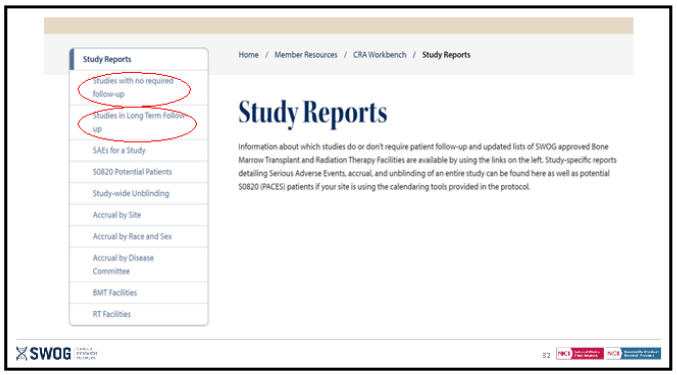
- Before finalizing this status:
  - Review and re-review Policy 30
  - Inform and discuss with your program leadership
- Know and understand the implications of using this designation. For example:
  - Patient withdraws consent to maintain specimens for research
  - Patient withdraws consent to be contacted for future research
- Inform SWOG
  - Connect with the study coordinator to verify form to use (e.g.: Rave vs non-Rave studies)
- DOCUMENT!

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 an individual study continuing review)
- List of studies under S9808 can be accessed on CRA Workbench:
  Study Reports → Studies in Long Term Follow-up







Studies with No Required Follow-up

- Posted on the CRA Workbench
- Study Reports → Studies with no required follow-up
- Includes date to keep records
- Keep records until SWOG date or institution required date, whichever is longer