Patient/Participant Long Term Follow-Up

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WHAT is long term follow-up?

LONG-TERM FOLLOW-UP:

- Beyond the active intervention phase

Begins:

- Protocol treatment completed
- Treatment toxicities/side effects resolved
- Response to therapy determined

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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
- Criteria 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?

- Continued medical surveillance and care
- Monitors for long-term effects
  - Adverse events
  - New malignancies
  - Treatment-related malignancies
- Helps capture accurate data
  - Disease recurrence and current status
  - Survival
- Meaningful end-results reporting

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Intent to Treat Analysis

- Follow-up requirements apply even if the participant:
  - Is later deemed ineligible after randomization
  - Doesn't receive the assigned treatment or study intervention
  - Intervention discontinued early

"Intention-to-treat analysis is a method for analyzing results in a prospective randomized study where all participants who are randomized are included in the statistical analysis and analyzed according to the group they were originally assigned, regardless of what treatment (if any) they received. This method allows the investigator (or consumer of the medical literature) to draw accurate (unbiased) conclusions regarding the effectiveness of an intervention. This method preserves the benefits of randomization, which cannot be assumed when using other methods of analysis."

(McCoy CE. Understanding the Intention-to-treat Principle in Randomized Controlled Trials. West J Emerg Med. 2017 Oct;18(6):1075-1078. doi: 10.5811/westjem.2017.8.35985. Epub 2017 Sep 18. PMID: 29085540; PMCID: PMC5654877)

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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

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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
- Second malignancy or secondary malignancy
- Long-term adverse events (AEs)

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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

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HOW: Tracking Follow-Up

- Set up and use Tools:
  - Database or spreadsheet
  - Clinical Trials Management System (CTMS)
  - Tickler systems
  - Calendar reminders
- SWOG Expectation Report
- CTSU Data Quality Portal (DQP)

Don't rely on memory!

Whatever your site uses to help you track and remember…works!

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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

Images: clipart-library.com

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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

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Participant Information

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

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Participant Information

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 :			
Address:			
Email address:			
Home Phone:			
Work Phone:			
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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Build relationships

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

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Keep in touch

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

Make it simple for them to reach you!

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Every patient counts…

Every patient has the potential to be "lost"

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WHERE: Locating a "lost" participant

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

Additional suggestions listed in the ORP Manual, Chapter 10

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Internet resources

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

Additional suggestions listed in the ORP Manual, Chapter 10

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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 ORP (CRA) Workbench

- Workbenches → ORP (CRA) Workbench → SWOG Policies
- **Policy 30**

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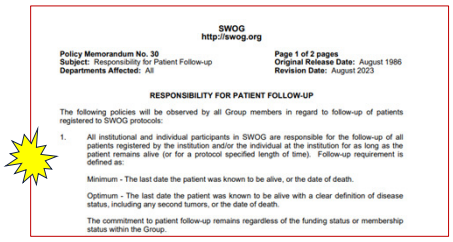
Policy 30: Responsibility For Patient Follow-up



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
Revision Date: August 2023

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.

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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

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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 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 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

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Consent Withdrawal

- Definitions are key!
- VERIFY with the patient:
  - No longer wish to be <u>treated</u> per protocol?
  - No longer wish to be <u>followed</u> 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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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!

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"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 Policy 30
  - Inform and discuss with your program leadership
  - Connect with the SWOG study coordinator
- Know local site policies
- Update your local files with status change

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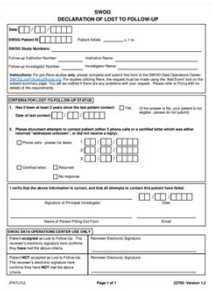
Declaration Of Lost To Follow-up

<u>To request the status for pre-Rave studies</u>:

- Locate the form on the ORP (CRA) Workbench:
  Patient Management (Non-Rave Studies) → Lost to Follow-up Form (Non-Rave Studies)
- Complete and submit form to SWOG Data Operations Center

<u>For studies utilizing Rave</u>:

- Use the 'Add Event' tool on the subject summary page to make the request



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DECLARATION OF LOST TO FOLLOW-UP

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

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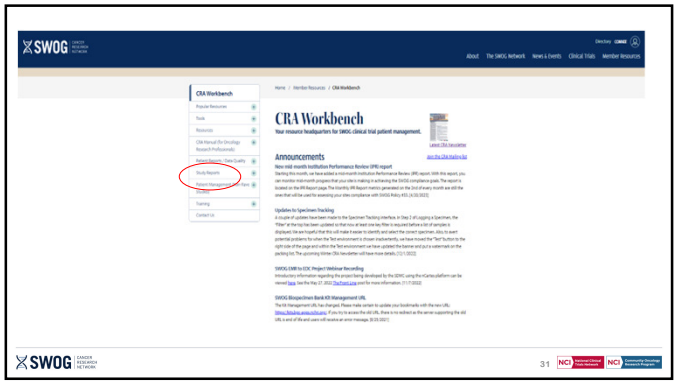
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CRA Workbench
CRA Workbench
Your resource headquarters for SWOG clinical trial patient management.
Announcements
SWOG
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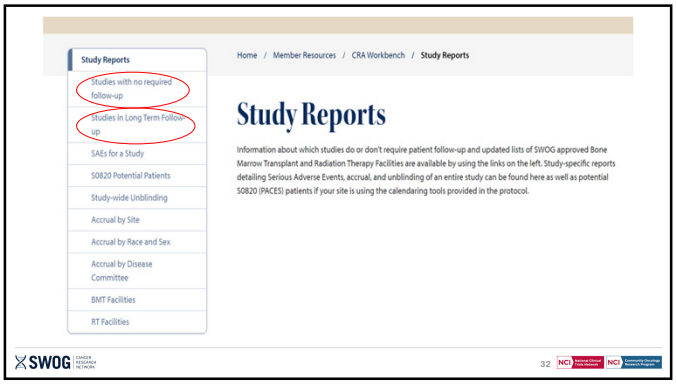
Study Reports
Studies with no required follow-up
Studies in Long Term Follow-up
SAEs for a Study
S0820 Potential Patients
Study-wide Unblinding
Accrual by Site
Accrual by Race and Sex
Accrual by Disease Committee
BMT Facilities
RT Facilities
Home / Member Resources / CRA Workbench / Study Reports
Study Reports
Information about which studies do or don't require patient follow-up and updated lists of SWOG approved Bone Marrow Transplant and Radiation Therapy Facilities are available by using the links on the left. Study-specific reports detailing Serious Adverse Events, accrual, and unblinding of an entire study can be found here as well as potential S0820 (PACES) patients if your site is using the calendaring tools provided in the protocol.
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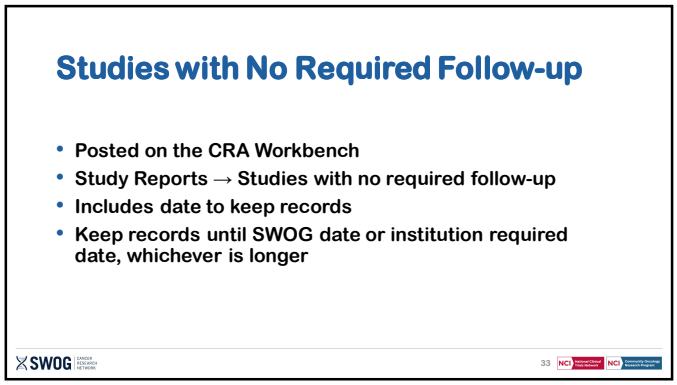
Studies with No Required Follow-up
Posted on the CRA Workbench
Study Reports → Studies with no required follow-up
Includes date to keep records
Keep records until SWOG date or institution required date, whichever is longer
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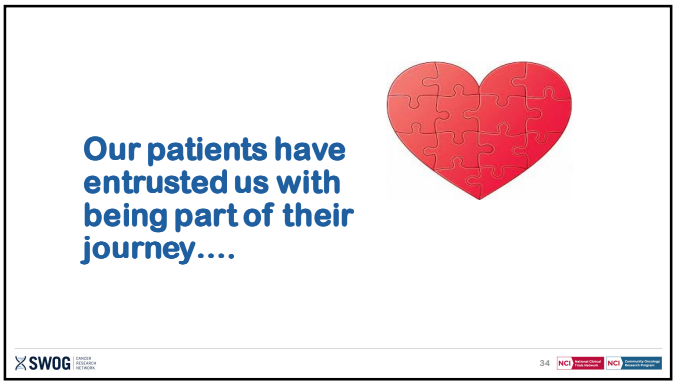
Our patients have entrusted us with being part of their journey….
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QUESTIONS?
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