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

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 utilized to classify a patient as “lost to follow-up”
- Things to discuss with a patient if they wish to withdraw consent
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

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

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!
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)

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

Every patient counts...
Every patient has the potential to be “lost”
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

Collect Demographic Information

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

Participant Information Sheet

- Name: __________________________
- Address: _______________________
- Phone: ___________ [Home] _________ [Work] _________ [Cell]
- E-mail address: __________________________
- Social security number: __________________________
- Spouse – Name: __________________________
- Phone: __________________ [Cell] _________ [Work]
- Primary care physician: __________________________
- Address: __________________________
- Phone: __________________________
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.

<table>
<thead>
<tr>
<th>Contact #1</th>
<th>Contact #2</th>
<th>Contact #3</th>
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<tbody>
<tr>
<td>NAME:</td>
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<td>Relationship to patient:</td>
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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

Foster good relationships

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

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

Internet resources

- www.anywho.com
- www.whitepages.com
- www.people.yahoo.com
- www.switchboard.com
- www.findagrave.com
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.geneologybank.com/gbnk/ssdi
- www.RootsWeb.com
- www.ancestry.com
- www.worldvitalrecords.com
- www.familysearch.org
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.”

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!**

Patient transfer

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

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

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
Consent withdrawal

- Before finalizing this status:
  - Review and re-review the policy
  - 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!

“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

Declaration Of Lost To Follow-up

Look for the form on the CRA Workbench / Patient Management (Non-Rave Studies)
Declaration Of Lost To Follow-up

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

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
Our patients have entrusted us with being part of their journey....
Questions?