

Your Mission: Follow Ups

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The Rule

- 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 a 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.

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What is long term follow up?

- Protocol treatment discontinued
- Treatment toxicities resolved
- Response to therapy has been determined
- May vary if an observational study

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Purpose of long-term follow up

- Assure continued medical surveillance
- Allow meaningful end-results reporting
- Accurate survival data
- Disease recurrence
- Disease status
- Survival
- Monitor for long – term adverse events and treatment – related malignancies
- New Malignancies

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Tracking Follow Up

- Track by date of last contact
- Use of the Expectation Report
- Database or spreadsheet
- CTSU Queries/Tracking
- Ideas for an effective patient follow-up system:
 - Tickler system
 - Database
 - Spreadsheet – could be sorted by patient name, physician, disease or trial

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Follow – Up Interval

- Every 6 months for first 2 years
- Annually after 2 years
- Refer to specific protocol requirements – SWOG protocol section 14.0 Data Submission Schedule

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Follow Until Death???

- Patients on some older studies may be followed until death or the protocol may not define the follow-up period.
- Read the protocol carefully for length of follow-up.



Priority for Follow-up

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





**Follow-up Notes
- Information to Document**

- Date of last contact
- Vital and cancer status, progression/recurrence
- Subsequent treatment
- New malignancy/MDS
- Long-term adverse events (AE's)

Every patient has the potential to be a lost patient



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The best offense needs good defense.



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Collect demographic information from chart



- Patient
- Referring or other physicians
- Relatives
- Insurance company
- Cell phone numbers and e-mail address
- Twitter handle (@NCORPRN)

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Resources

- Participant contact information sheet
 - Complete at consent
 - Review each year
- Use Partnership for Life brochure

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.


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 a relationship with participant
 Create a bond with the patient and assist them on the journey


1. Informed consent
2. Treatment
3. End of treatment
4. Follow up plan



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Keep in touch

- Birthday cards or notes
- Come see the patient at appointment check in
- Appointment reminders
- Postage paid envelope



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Foster good relationships

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





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**IF THESE METHODS FAIL:
BECOME A
DETECTIVE!**





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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 EMR systems
- 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
- Lexisnexis.com – links to legal and public records
 - Academic institutions or law schools may have a subscription



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



Internet resources for
Social security death index

- www.genealogybank.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



Policy #30 – Follow-up

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



Patient transfer

- Patient goes to another institution***
- Transferring & accepting investigators must approve transfer
- Complete patient transfer (Link on CRA Workbench) see info here for non-SWOG transfer



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

Lost to follow-up requirements

- Document ≥ 2 years since last contact
- Document contact attempts
 - Must attempt to reach patient at *least* 3 times
 - DOCUMENT!
 - DOCUMENT!
 - DOCUMENT!

Declaration of lost to follow-up

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: / /

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Lost to follow-up form

Location:

- CRA Workbench
 - Tools of the Trade
 - "Declaration of lost to follow-up" form
- SWOG coordinated studies only

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Study withdrawal of consent

- Patient withdraws consent for treatment only
 - Continue with follow-up
- Patient withdraws consent to be contacted/followed
 - Cannot continue with follow-up
- Both

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**Withdrawal of consent –
Specimens/future research**

- Patient withdraws consent to maintain specimens for research
 - Determine if specimen is destroyed or returned
- Patient withdraws consent to be contacted for future research



SWOG 9808

- Relieve burden for continuing review
- IRB approval required
- Studies are closed to patient registration
- No patients receiving protocol treatment
- List on CRA Workbench - Reports



No follow-up required

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







Follow-up data submission

- CRA Workbench
 - Data submission
 - Follow-up form & Notice of death
- Medidata Rave
 - Follow-up questions
 - Notice of death questions

With careful planning, you can help minimize the number of patients you lose.

Questions?

