

**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 SWOG and Institutional 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
  - Calendar Reminders – could be a bit overwhelming



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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.



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### 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



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### Follow-Up Notes

#### - Information to Document

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



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Every patient has the potential to be a lost patient.



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The best offense needs good defense.  
(Go Chiefs!)



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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




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### 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: \_\_\_\_\_




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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 a relationship with participant.
- Create a bond with the patient and assist them on the journey.
- Informed consent
- Treatment
- End of treatment
- Follow-up plan



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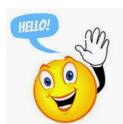
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### Keep in touch

- Birthday cards or notes
- Come see the patient at appointment check in or while they are waiting to see physician
- Appointment reminders
- Postage paid envelope



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### Foster good relationships

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



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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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**Example of Kansas Voter Registry Page**



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Internet resources

- [www.anywho.com](http://www.anywho.com)
- [www.whitepages.com](http://www.whitepages.com)
- [www.people.yahoo.com](http://www.people.yahoo.com)
- [www.switchboard.com](http://www.switchboard.com)
- [www.findagrave.com](http://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](http://www.legacy.com)
  - Online obituary search
- Ancestor Hunt ([www.ancestorhunt.com](http://www.ancestorhunt.com))
  - Obituary search
  - Newspapers by state
- [www.ancestry.com](http://www.ancestry.com)
- National obituary archive ([www.arrangeonline.com](http://www.arrangeonline.com))
  - Online listing of funeral homes

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Internet resources for Social Security Death Index

- [www.genealogybank.com/gbnk/ssdi](http://www.genealogybank.com/gbnk/ssdi)
- [www.RootsWeb.com](http://www.RootsWeb.com)
- [www.ancestry.com](http://www.ancestry.com)
- [www.worldvitalrecords.com](http://www.worldvitalrecords.com)
- [www.familysearch.org](http://www.familysearch.org)



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Policy #30:  
Responsibility for patient follow-up

- Login to SWOG member site ([www.swog.org](http://www.swog.org))
  - Policies and manuals
    - Policy 30



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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



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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

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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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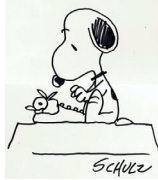
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### Lost to follow-up requirements

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




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### 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, address 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
- Please make sure the individual understands that they can still be followed on trial

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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

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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

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### 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



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### Follow-up data submission

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



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



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Questions?



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