

Policy Memorandum No. 30

Subject: Responsibility for Patient Follow-up

Departments Affected: All

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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.

2. If a patient is registered to more than one study from multiple institutions, the institution credited with the most recent registration is responsible for follow-up.
3. If an Affiliate/component institution ceases to be affiliated with the Group, it retains responsibility for the treatment and clinical management of all patients currently receiving treatment and active follow-up, and should provide necessary data forms and follow-up information. The LAPS or Member institution may, in some cases, be willing to assume responsibility for clinical follow-up once the patient is being seen annually (or less frequently) for study purposes.
4. If an institution changes status (e.g., from Affiliate to NCTN Member), the new affiliation is the responsible institution for follow-up.
5. If an investigator changes affiliation from one institution to another within the Group and the patient follows, the investigator takes with him or her responsibility for future follow-up of the patient.
6. If an investigator moves from one institution to another within the Group and the patient does not follow the investigator, or an investigator leaves the Group, follow-up responsibility should be transferred to another active investigator at the institution who knowingly accepts such responsibility. If the investigator does not transfer follow-up responsibility to another active investigator within the Group, the follow-up responsibility will fall to the institutional Principal Investigator. In the case of an Affiliate investigator, the Member institution may, in some cases, be willing to assume responsibility for clinical follow-up once the patient is being seen annually (or less frequently) for study purposes.
7. Notification of transfers of the follow-up responsibility for patients that were not registered through the Oncology Patient Enrollment Network (OPEN) must be made on-line using the Patient Transfer link on the web (www.swog.org) in the CRA Workbench. If the patient was registered through OPEN, the patient transfer will need to be initiated using the OPEN Transfer and Update Module (T&UM).

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8. If the transfer of follow-up responsibility is made to a new institution, verification of IRB oversight is required. The new institution must have current IRB approval of the protocol prior to accepting a transfer of a new patient that is currently on treatment. Transfer of a patient on long term follow-up may occur prior to IRB approval of the protocol as long as the new institution pursues approval prior to conducting any research activities involving the transfer patient(s). In this case, expedited review of the protocol for follow-up activities only is sufficient. Transfer patients must sign a new consent form and HIPAA authorization at the new institution.

It is our recommendation that accepting institutions receive a copy of the research record(s) from the transferring institution and time permitting, take measures to ensure all outstanding expectations and queries have been resolved prior to signing the transfer form. The transferring site must provide CRFs for resolution of this for any data obtained prior to the acceptance date.

9. If a patient withdraws consent after registration, the institution must determine with the patient whether 1) they no longer wish to be treated per protocol; 2) they no longer wish to be followed per protocol, or 3) *both*. Withdrawing consent to participate in a study does not necessarily mean the patient also withdraws consent to being followed. This distinction must be clearly noted on the Off Treatment Notice or Follow-Up form for pre-Rave studies. For patients enrolled on studies in Rave, the following institution must contact the SWOG Data Operations Center to request the Consent Withdrawal form is added to the chart for the institution to complete.
10. If SWOG has determined that a protocol no longer requires additional follow-up, the study will be added to the "List of Protocols with No Required Follow-Up" available on the CRA Workbench, under "Reports". Additional data will no longer be requested from these patients.
11. An institution may identify a patient as "lost to follow-up" if **all** of the following criteria are met:
- The last contact date for a patient has exceeded two years.
 - Since the last contact date, the institution can document at least three telephone attempts to contact the patient and/or a certified letter to the last known address has either been returned, or not answered.

To designate a patient as 'lost to follow-up', use the 'Add Event' tool on the Subject Summary page for studies using Rave. For pre-Rave trials, use the "Lost to Follow-Up" form, available on the CRA Workbench, under 'Tools of the Trade'.

NOTE: This policy applies only to studies coordinated by SWOG.