SWOG SDMC Update

Statistics and Data Management Center

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Withdrawn Consent - Policy

- SWOG Policy #30, Responsibility for Patient Follow-Up:
  - 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;
    3. or *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.

Withdrawn Consent - Process

- Dialogue should be patient initiated

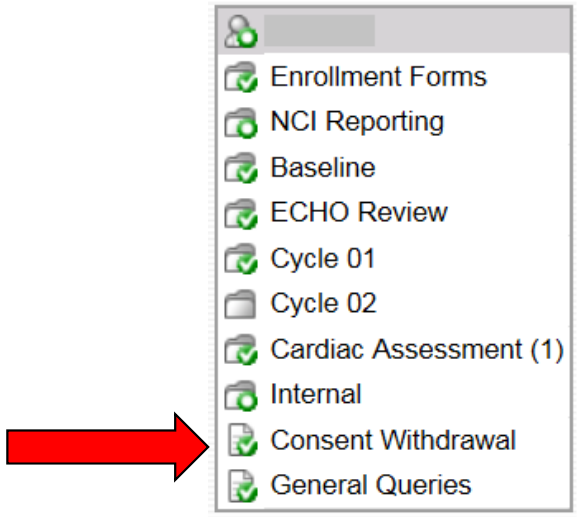
- Terminology – where there is ambiguity, ask for clarification
  - “Withdrawing consent”
  - “Refusing treatment”
  - “No longer wishes to be on study”

    ➢ Direct vs. indirect patient contact

- Pre-Rave Studies:
  - No specific “Withdrawn Consent Form” available
  - Document withdrawn consent in the Comments section of the Off Treatment Notice or a Follow-Up Form

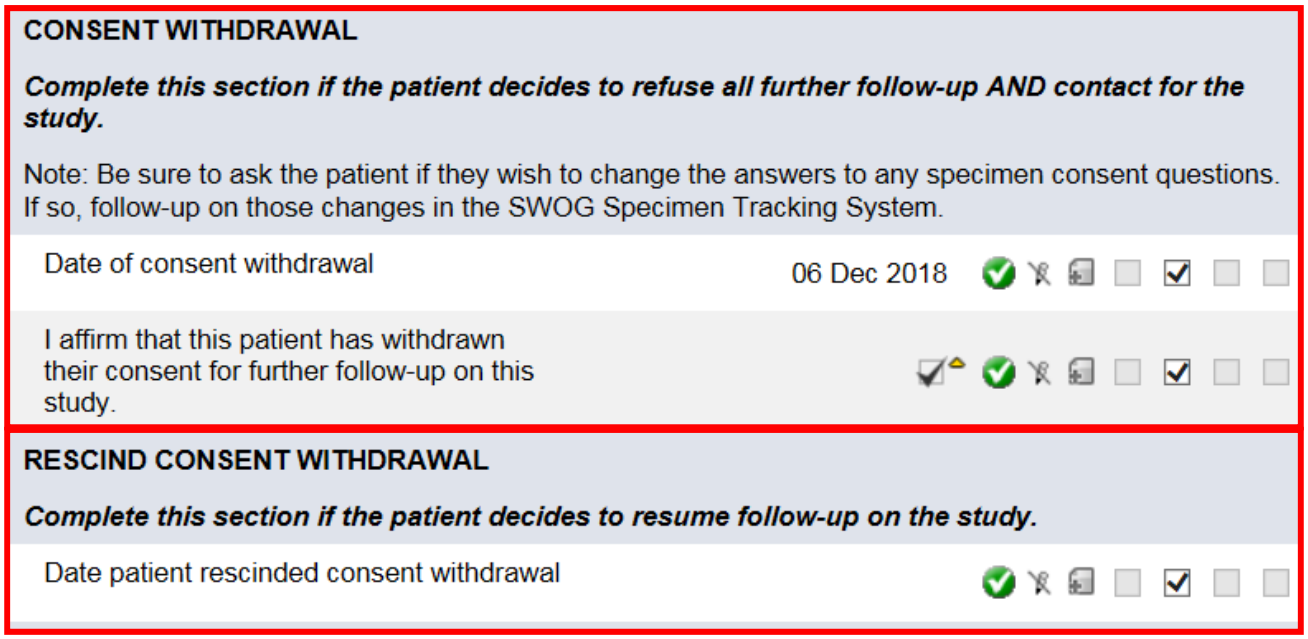
Withdrawn Consent - Process

- Rave Studies:
  - Call the SWOG Data Operations Center (206-652-2267)
  - Ask for the assigned Data Coordinator to request form



Withdrawn Consent - Process

- Rave Studies:
  - Fill out the form completely



CONSENT WITHDRAWAL

Complete this section if the patient decides to refuse all further follow-up AND contact for the study.

Note: Be sure to ask the patient if they wish to change the answers to any specimen consent questions. If so, follow-up on those changes in the SWOG Specimen Tracking System.

Date of consent withdrawal	06 Dec 2018
I affirm that this patient has withdrawn their consent for further follow-up on this study.	

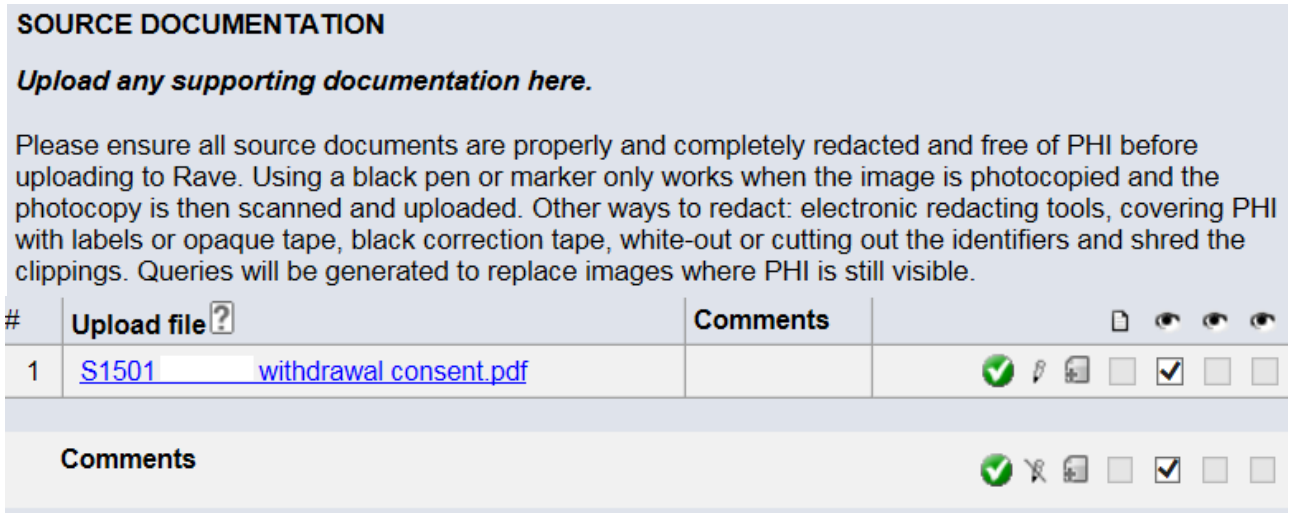
RESCIND CONSENT WITHDRAWAL

Complete this section if the patient decides to resume follow-up on the study.

Date patient rescinded consent withdrawal	

Withdrawn Consent - Process

- Rave Studies:
  - Source Documents – will be required



SOURCE DOCUMENTATION

Upload any supporting documentation here.

Please ensure all source documents are properly and completely redacted and free of PHI before uploading to Rave. Using a black pen or marker only works when the image is photocopied and the photocopy is then scanned and uploaded. Other ways to redact: electronic redacting tools, covering PHI with labels or opaque tape, black correction tape, white-out or cutting out the identifiers and shred the clippings. Queries will be generated to replace images where PHI is still visible.

#	Upload file	Comments
1	S1501 withdrawal consent.pdf	

Comments

Withdrawn Consent - Letters

- Form Letters or Checklists:
  - Dialogue should be **patient initiated**
    - Should not assume the patients intent
    - Non-compliance and failure to show for study visits does not necessarily mean they intend to withdraw their consent
  - Vet through Head CRA and/or site leadership
    - SWOG Auditors
    - SWOG Data Coordinators

  - Suggested Text:
    - *"Patient 123456 enrolled on SWOG S1605 contacted our site on 25-APR-2019 requesting to withdraw their consent. Further discussion clarified the patient wishes no further treatment and no further contact for follow-up."*

Withdrawn Consent - Examples

"Hello, I am responsible for conducting follow-up for study S1605 and have tried by phone on multiple occasions and couldn't reach you. I also have not received a call back and your scheduled doctor appointments were missed. I wanted to inform you that I am sending this letter to verify your consent to continue to be followed for this study. If there is no reply to this certified letter, your consent to be followed will be considered to have been withdrawn. If you would like to keep your consent current and to continue being followed, please contact me as soon as possible."

- Areas of concern:
  - Dialogue was not patient initiated
  - Site assumed the intent
  - Letter somewhat encourages withdrawn consent

Withdrawn Consent - Examples

To whom it may concern:

I, _____ withdraw my consent to be enrolled in the Sxxxx clinical trial. This should be effective as of _____. I also withdraw my consent to be followed by the study.

Participant Signature: _____
Physician Signature: _____

- Areas of concern:
  - Not clear if dialogue was patient initiated
  - Suggest additional text at the top to clarify the patient reached out making the request and the date that contact occurred

Withdrawn Consent - Examples

Clinical research note for patient 123456 on Sxxxx, 25-APR-2019

Consent withdrawal: Patient wishes to withdraw consent for study participation due to too much time commitment and travel involved for clinic visits.

Patient has declined further direct and indirect study contact for follow-up. Patient has declined use of blood and tissue collected during trial participation for future research. Patient has declined future study scans.

- No areas of concern
  - Patient initiated
  - Documentation is clear

Lost to Follow-Up – Policy

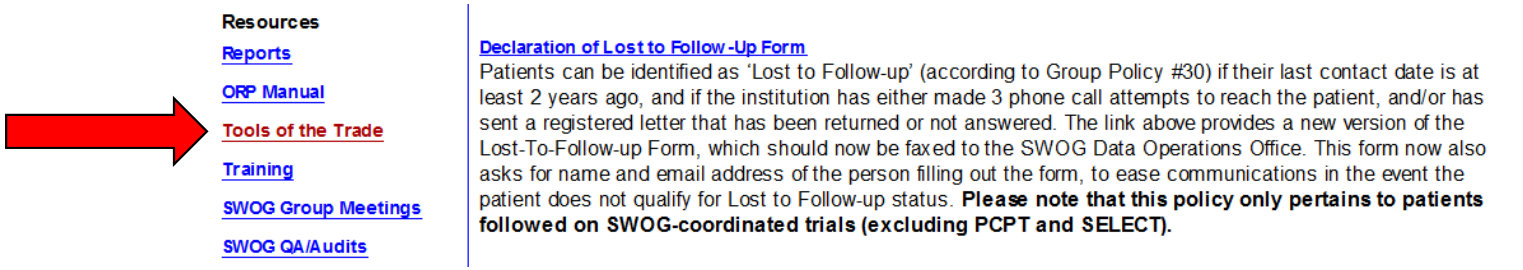
- SWOG Policy #30, Responsibility for Patient Follow-Up:
  - An institution may identify a patient as “lost to follow-up” if **all** of the following criteria are met:

    a) The last contact date for a patient has exceeded two years.

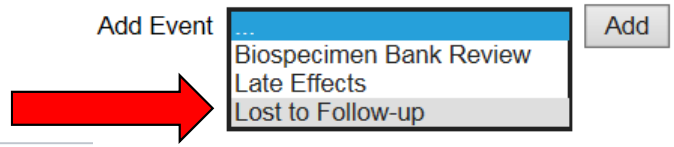
    a) Since the last contact date, the institution can document at least three telephone attempts to contact the patient and/or a certified letter to the last known address has either been returned, or not answered.

Lost to Follow-Up – Process

- Pre-Rave Studies:
  - Fill out the “Lost to Follow-Up Form” available on the CRA Workbench under ‘Tools of the Trade’.



- Rave Studies:
  - Utilize the ‘Add Event’ tool on the Subject Summary page in Rave to add the “Lost to Follow-Up Form”, then complete.



Upcoming Initiatives

- Uploaded Source Documents
  - Required
- Form Instructions
  - Process amended for clarity
- Data Coordinator Contact and Form Review
  - Increased dialogue, continued education
- SWOG Report of Studies
  - Now includes the number of patients that have withdrawn consent and reported as lost in each study. SDMC will monitor by site.

Consent and Follow-Up – Questions

- SWOG Auditors, Operations Office: 210-614-8808
  - Elaine Armstrong: earmstrong@swog.org

- SWOG Data Operations Center: 206-652-2267

breastquestion@crab.org
cancercontrolquestion@crab.org
giquestion@crab.org
guquestion@crab.org
leukemiaquestion@crab.org
lungquestion@crab.org
lymphomaquestion@crab.org
melanomaquestion@crab.org
myelomaquestion@crab.org
raretumors@crab.org

SDMC Updates – CRA WB

Expectation and IPR Reports

Query Reports

Ineligible Patients Report

Serious Adverse Events (SAE) for a Given Study

Study-wide Unblinding Report

List of Applicable Protocols for S9808 - Long Term Follow-Up Protocol

List of Protocols with No Required Follow-Up

Accrual Reports

S0820 (PACES) Potential Patients

For SWOG-credited Registrations

SWOG-credited Registrations for a Given Date Range

Accrual for SWOG-credited Registrations by Race and Sex

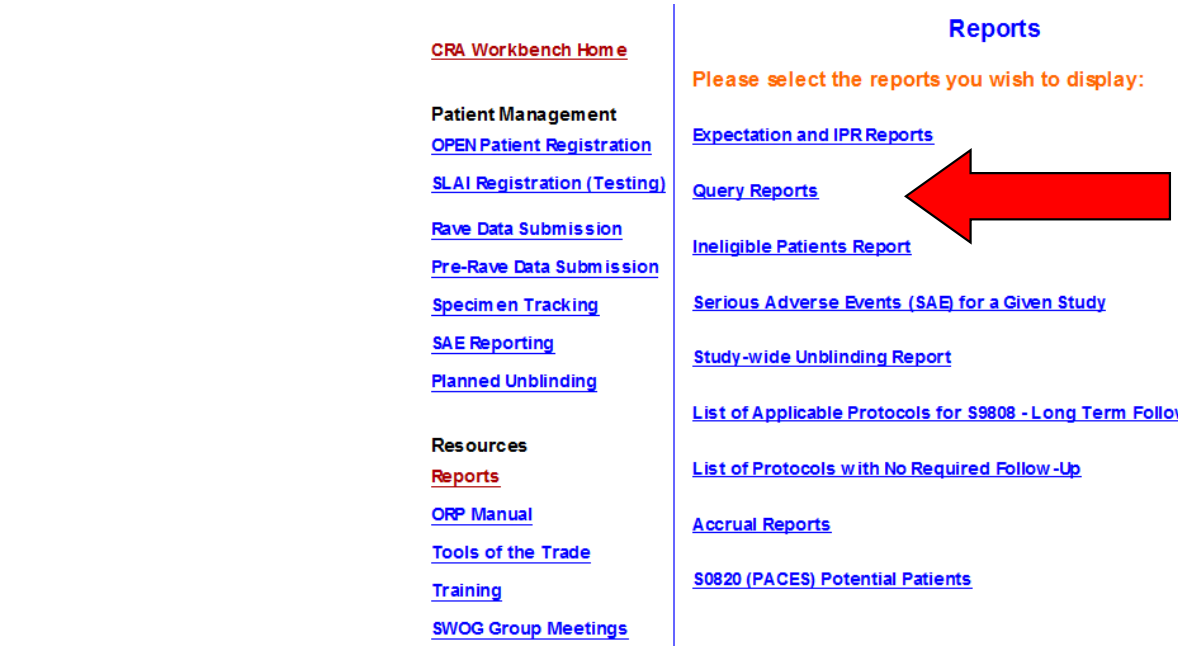
SWOG Patients in Follow-up

Approved SWOG Bone Marrow Transplant Facilities

- Reports
  - Links Reorganized
    - Site Management Reports
    - Accrual Reports
    - Study Management
    - SWOG Facilities
  - Current Expectation Report: Add Treating Institution NCI Code to be consistent with the monthly report
  - New Reports: Withdrawn Consent and Lost to Follow-Up
- Download to Excel
  - Ineligible Patients Report
  - SWOG-Credited Registrations

SDMC Updates – Query Report

- Where is it located?
- How often is it accessed?
- How is it managed?



SDMC Updates – Legacy Studies

- Studies activated prior to Medidata Rave
  - Many closed, but still open to follow-up

- Subset of forms in Rave (no longer available in CRA WB)
  - Follow-Up Form
  - Notice of Death
  - Consent Withdrawal
  - Lost to Follow-Up
  - Late Effects

- Studies affected
  - S1011 – *Released*
  - S0221 – *Planned for May*
  - No others

SDMC Updates – ORP GM Travel

- Continued travel opportunities!
  - We were able to provide travel for up to 10 ORP members for both meetings in 2019
  - Watch for applications available this summer for the Chicago meeting

THE HOPE FOUNDATION FOR CANCER RESEARCH

Please Welcome,

Phyllis Goodman

SWOG Managing Statistician

Data Quality Tools:
SWOG Reports & CTSU Data Quality Portal