Consent Withdrawal

This form can only be populated by the SWOG Data Coordinators. If the patient has withdrawn all consent, **including** consent for follow-up and survival follow-up, please email the data coordinators via the email address listed on the SWOG Protocol Contact Information Page (near the beginning of the protocol document).

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CONSENT WITHDRAWAL

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

Obtain clarification if the participant does not explicitly state why they do not want to be contacted. Ask if they would consider indirect contact gleaned from medical record review in lieu of direct follow-up such as a phone call in order to continue reporting survival data. Date is in **DD MON YYYY** format.

Date of consent withdrawal

I affirm that this patient has withdrawn their consent for further follow-up on this study.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Date patient rescinded consent withdrawal

SOURCE DOCUMENTATION

Source documentation is <u>required</u> to support the consent withdrawal.

Please ensure all source documents are properly and completely … sing a black pen or marker only works when the image is photocopied ar… er ways to redact: electronic redacting tools, covering PHI with labels … utting out the identifiers and shred the clippings. Queries will be generat…

Please also ensure that file names on uploaded documents a… c.) and does not have the participant's name in it.

DO NOT enter a date here unless the patient changes their mind and wants to be followed after all. A date here means that we ARE following the patient.

#	Upload file	Comments
1	Choose File No file chosen	

Add a new Log line Inactivate

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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Save Cancel

NOTE:

If the patient withdraws consent after registration, then the institution must determine with the research participant whether:

1) The participant no longer wishes to be treated per protocol;
2) The participant no longer wishes to be followed per protocol, or
3) The participant (both) no longer wishes to be treated nor wishes to be followed per protocol.

The participant may be willing to allow the investigator to continue other research activities (e.g., follow-up assessments, specimen collection, questionnaires, survival status, etc.). The distinction must be documented in the research record and on the Off-Treatment Notice or Follow-Up Form, as appropriate to the participant's indication.

See also: SWOG Best Practices document, accessible from: https://www.swog.org/clinical-trials/protocol-workbench and SWOG Policy #30, accessible from: https://www.swog.org/about/policies-procedures.