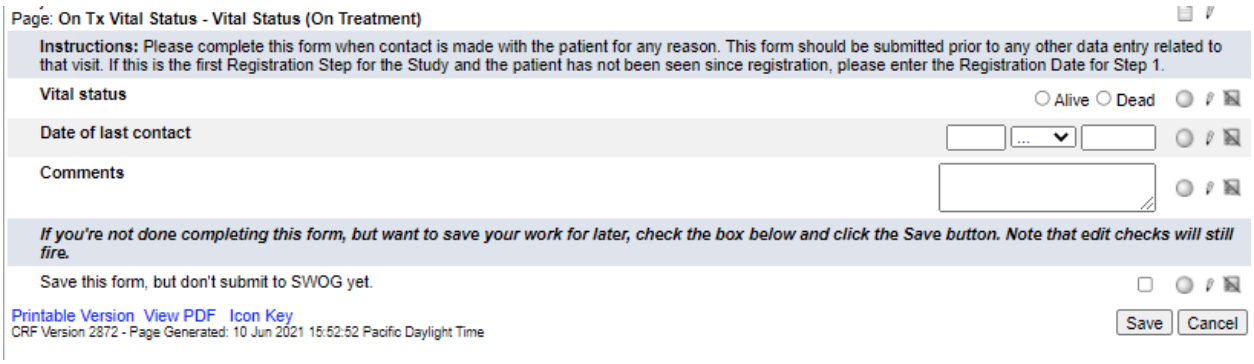
Version Date 12/15/2021

Vital Status

Fill out the Vital Status form any time you enter data, **PRIOR to submitting any other data**. Otherwise, you will get System queries on other forms. See protocol section 14 for required timepoints to complete it.



Page: **On Tx Vital Status - Vital Status (On Treatment)**

Instructions: Please complete this form when contact is made with the patient for any reason. This form should be submitted prior to any other data entry related to that visit. If this is the first Registration Step for the Study and the patient has not been seen since registration, please enter the Registration Date for Step 1.

Vital status ○ Alive ○ Dead

Date of last contact [ ] [...] [ ]

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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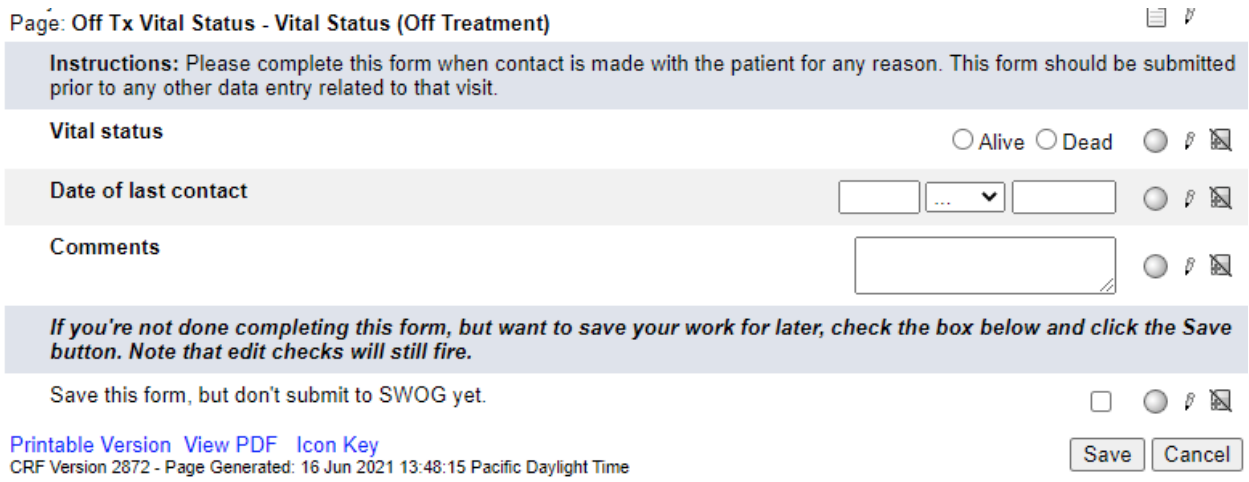
Save Cancel



Page: **Off Tx Vital Status - Vital Status (Off Treatment)**

Instructions: Please complete this form when contact is made with the patient for any reason. This form should be submitted prior to any other data entry related to that visit.

Vital status ○ Alive ○ Dead

Date of last contact [ ] [...] [ ]

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

Baseline Abnormalities Form

(please also refer to the SWOG CRA Manual for Oncology Research Professionals: General Forms and Guidelines, Chapter 16)

Page: **Baseline Abnormalities - Baseline**

Did the patient have any abnormalities or conditions present PRIOR to protocol treatment?

If Yes, using CTCAE 4.0 Grade definitions, please report them below

If day of Start Date is unknown, please write "UN" in the day field. If month of Start Date is unknown, please select "UNK" from the dropdown menu.

#	Verbatim term	CTCAE(4.0) adverse event term	CTCAE(4.0) grade	Serious	Start date
1	Vertigo	Vertigo	1	No	UN Jun 2014
2	Hot flashes	Hot flashes	1	No	UN UNK 2007
3	Hyperglycemia	Hyperglycemia	1	No	13 May 2019
4	Hypercalcemia	Hypercalcemia	1	No	13 May 2019

- Some studies use a Baseline Abnormalities Form to document existing conditions or continuing toxicities caused by prior treatment.
  - The collection of this form, if required, will be noted in Sections 14.0 and 18.0 of the protocol.

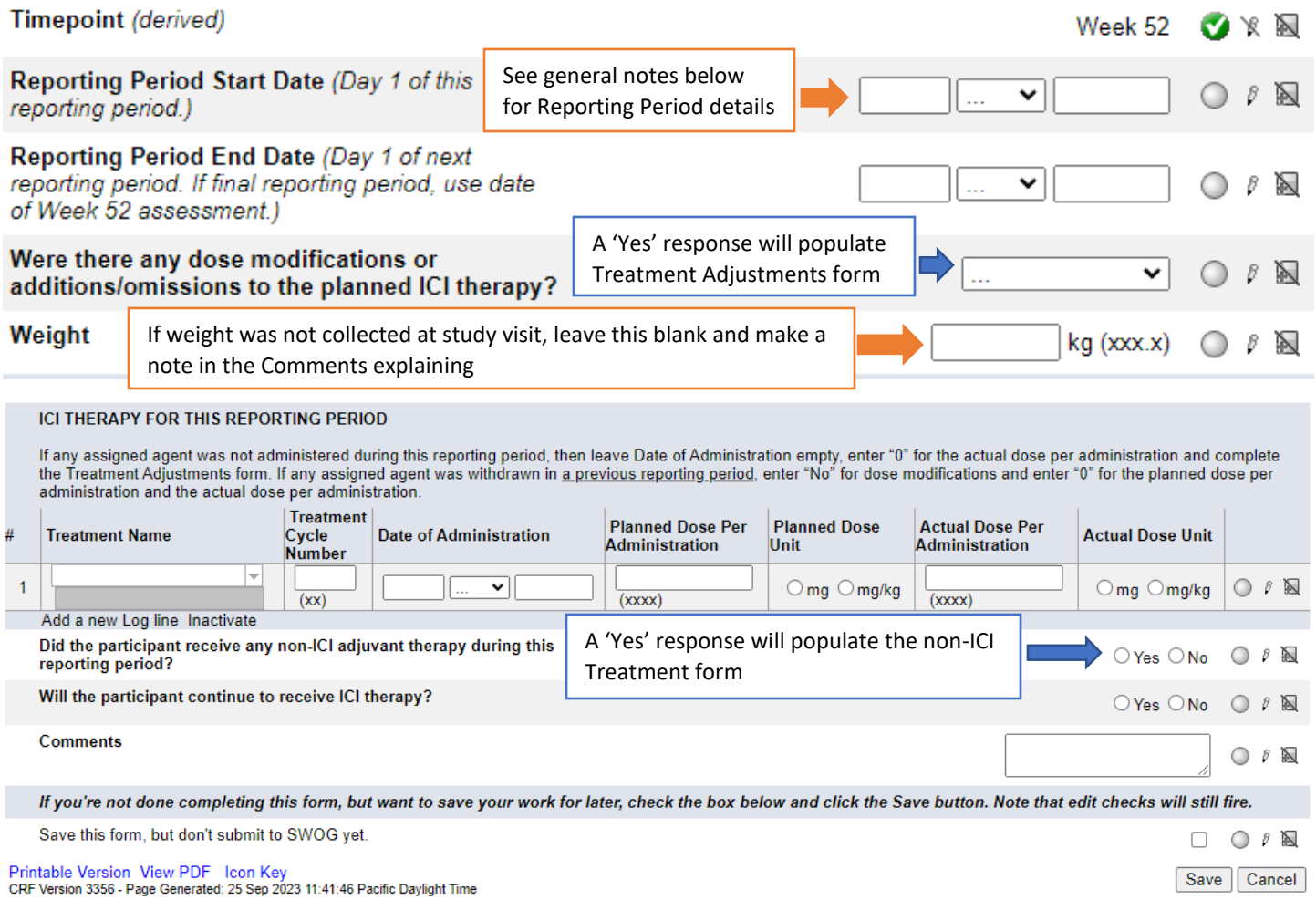
- A baseline abnormality is defined by CTEP as any abnormal assessment (e.g., physical finding, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up for which a CTCAE term exists.

- The Adverse Event Code is the appropriate CTCAE code for a baseline abnormality.
  - The 'Other, Specify' options should only be used if there is not an appropriate adverse event term available.
  - While Pain is an acceptable CTCAEv4 term, Pain is also very generic. If this is the appropriate term to use, please specify site/type of pain in the Comments section at the bottom of the form.

- **The Baseline Abnormalities Form is not used as a place to record the patient's medical history, diagnosis and/or pre-existing condition. For example, prior tonsillectomy or ongoing diabetes should not be recorded.**

EXAMPLE Treatment Form for NCORP Studies:

Actual data entry fields may vary per study

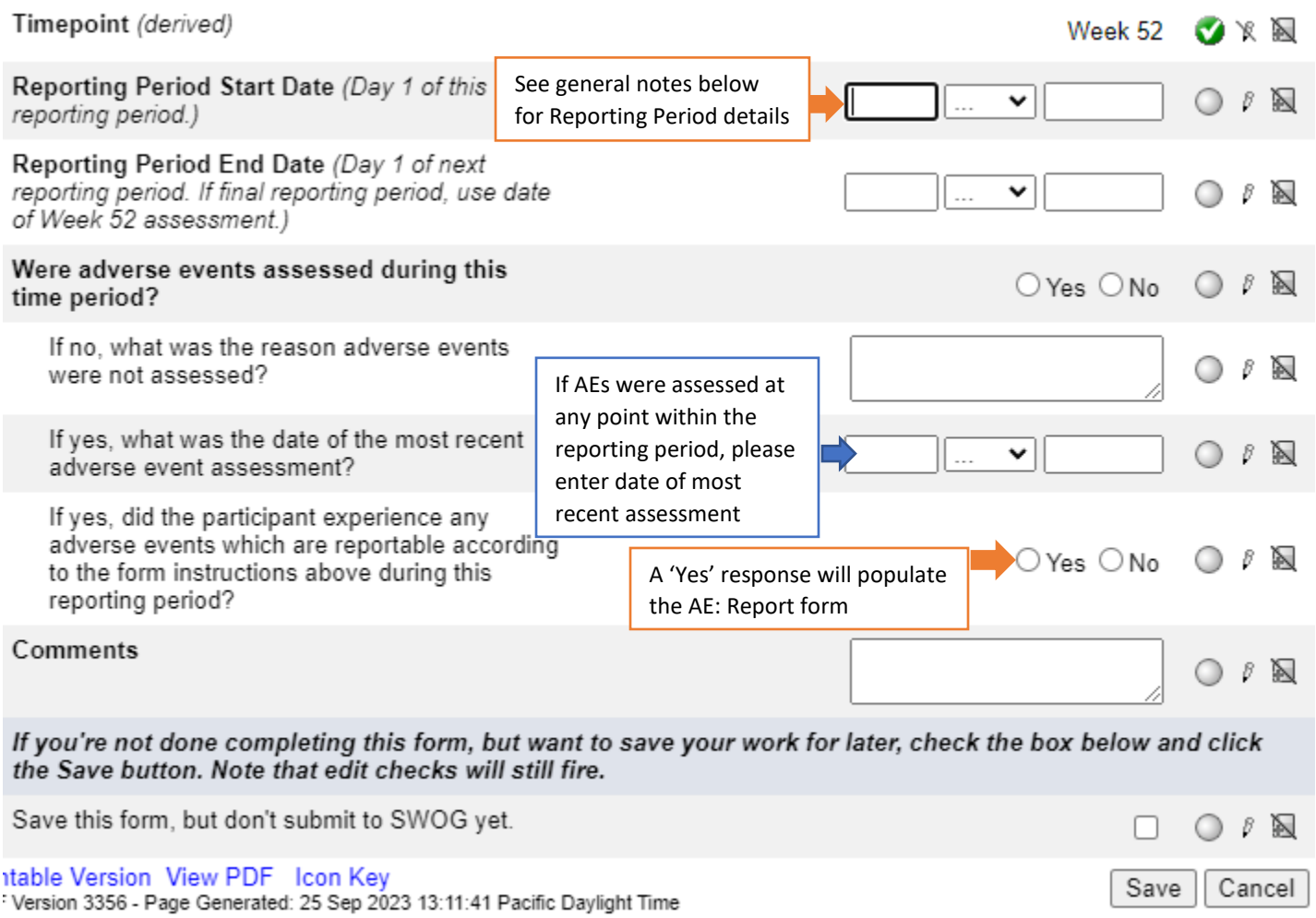


General Notes:

- The Reporting Period Start Date for the first study timepoint will generally be the date of registration, unless stated otherwise by the protocol or form instructions.
- The Reporting Period End Date will be the last date that data is collected for that study timepoint, which typically is the date of the study visit for that timepoint.
- The Reporting Period Start Date for subsequent timepoints should match the End Date of the previous timepoint.
    - For example: A participant is registered on 9/20/2023 and their first study visit (Week 4 timepoint) occurs on 10/18/2023
    - In this case, the Week 4 Reporting Period Start Date will be 9/20/2023
    - The Week 4 Reporting Period End Date will be 10/18/2023
    - The Reporting Period Start Date for the next timepoint will be 10/18/23
    - The Reporting Period End Date will be the date of the next study visit, this pattern repeats until the last timepoint
- The Planned Dose and Actual Dose fields have multiple unit options, for weight-based or fixed dosing.
- Additional treatments can be added to the table using the "Add a new Log line" link.

EXAMPLE Adverse Events Form for NCORP Studies:

Actual data entry fields may vary per study

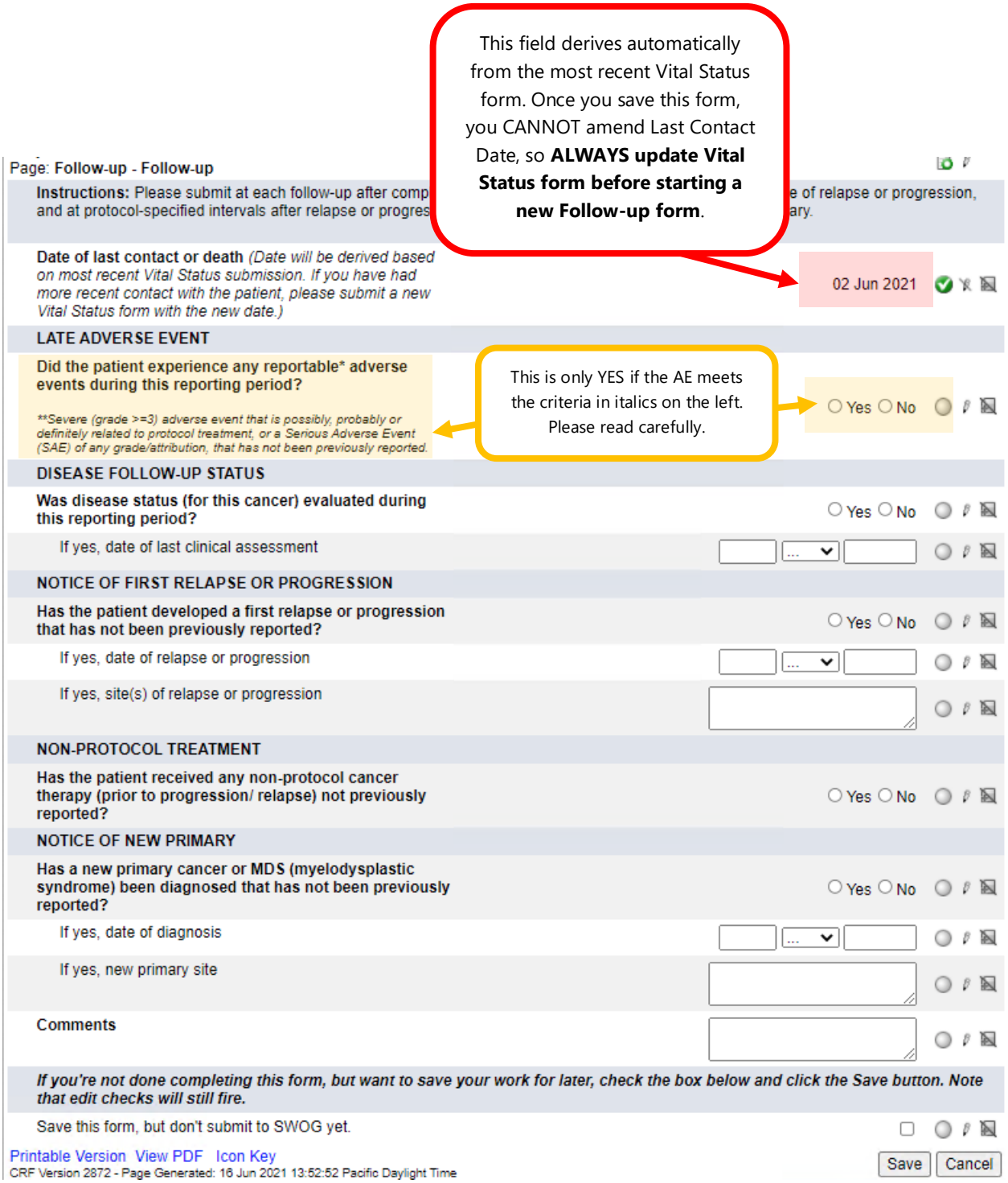


General Notes:

- The Reporting Period Start Date for the first study timepoint will generally be the date of registration, unless stated otherwise by the protocol or form instructions.
- The Reporting Period End Date will be the last date that data is collected for that study timepoint, which typically is the date of the study visit for that timepoint.
- The Reporting Period Start Date for subsequent timepoints should match the End Date of the previous timepoint.
    - For example: A participant is registered on 9/20/2023 and their first study visit (Week 4 timepoint) occurs on 10/18/2023
    - In this case, the Week 4 Reporting Period Start Date will be 9/20/2023
    - The Week 4 Reporting Period End Date will be 10/18/2023
    - The Reporting Period Start Date for the next timepoint will be 10/18/23
    - The Reporting Period End Date will be the date of the next study visit, this pattern repeats until the last timepoint
- AE reporting requirements may vary per study. Refer to the protocol and form instructions for study specific requirements.

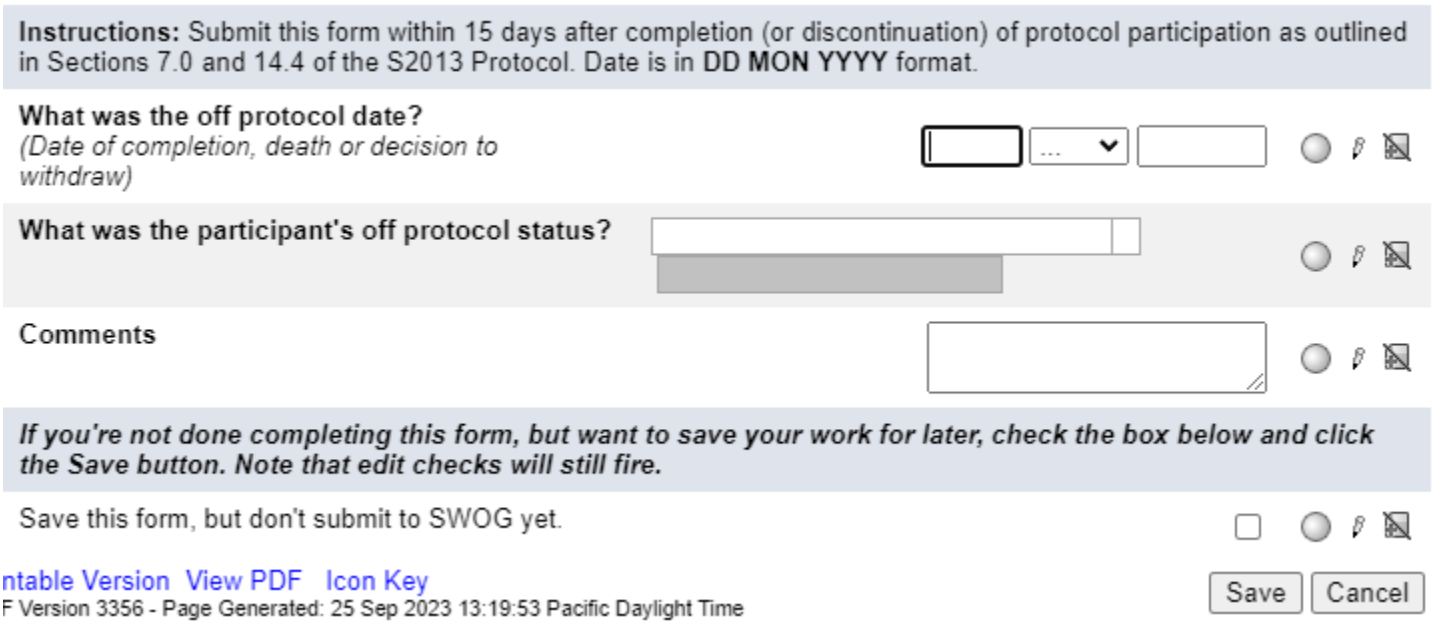
Follow-up Form

DO NOT MAKE ANY ENTRIES ON THE FOLLOW-UP FORM UNTIL YOU HAVE UPDATED THE VITAL STATUS FORM.



EXAMPLE Off Protocol Form for NCORP Studies:

Actual data entry fields may vary per study



Instructions: Submit this form within 15 days after completion (or discontinuation) of protocol participation as outlined in Sections 7.0 and 14.4 of the S2013 Protocol. Date is in **DD MON YYYY** format.

What was the off protocol date?
(Date of completion, death or decision to withdraw)

What was the participant's off protocol status?

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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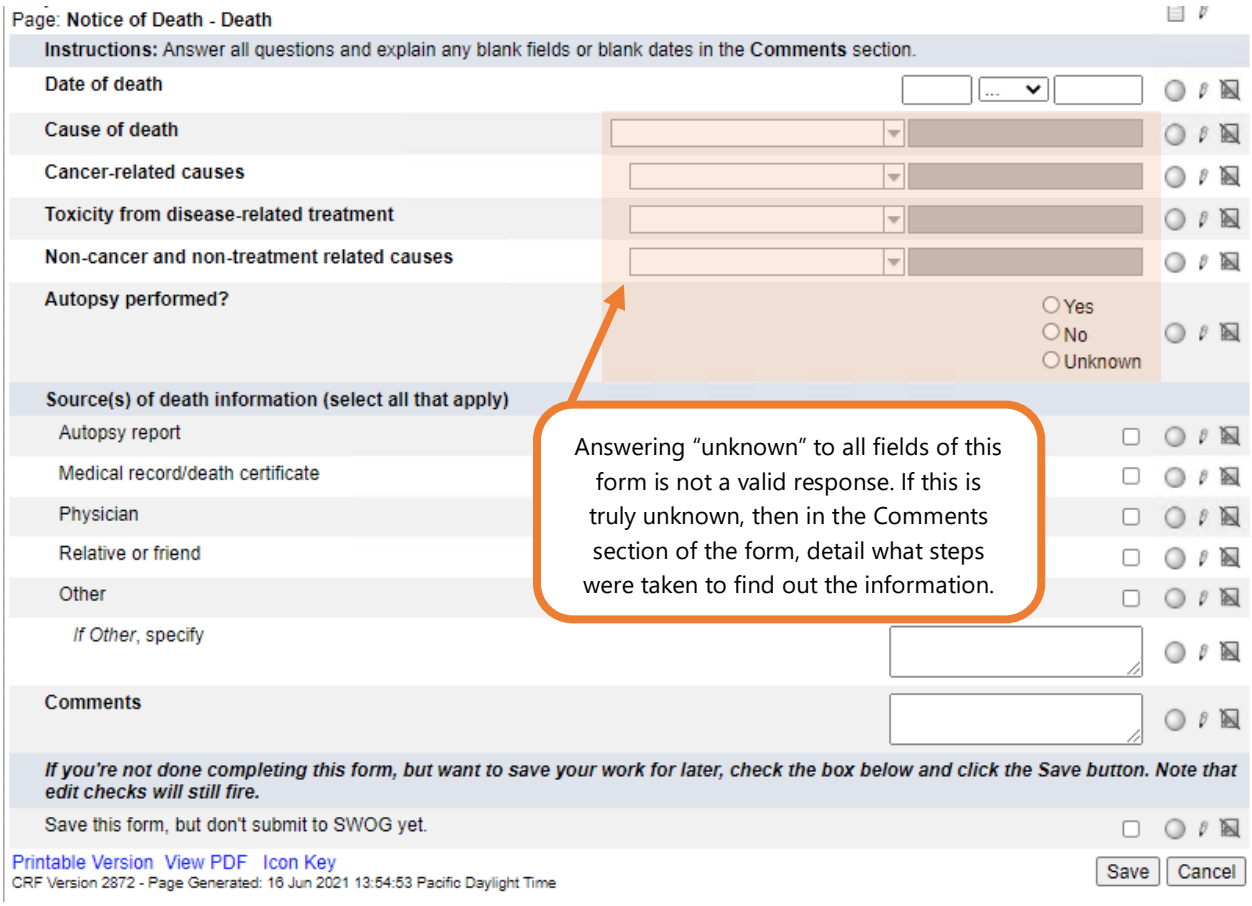
Save Cancel

General Notes:

- The Off Protocol Notice form should be submitted whenever a participant meets the criteria for removal from protocol participation detailed in the protocol.
    - Treatment changes (discontinuation, new therapy, etc.) or disease changes (progression, relapse, etc.) may or may not require Off Protocol Notice submission. Confirm with the protocol before submitting the Off Protocol Notice form.
- Some studies may also require an Off Treatment/Intervention Notice form be submitted when specific criteria are met
- In the event of a participant death, the Off Protocol Notice may need to be submitted in addition to the Notice of Death form.
- If the Off Protocol Notice is being submitted due to consent withdrawal, make sure to confirm with the participant that they wish to withdraw from all follow-up, including direct and indirect follow-up. If confirmed, please enter a comment noting that participant is withdrawing from all follow-up.

Notice of Death



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).

Page: **Consent Withdrawal - Consent Withdrawal**

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.

Referral Date: Click or tap to enter a date. *Referring MD:* MD Initials

Patient Information and Work-Up Documentation Sheet

Name: Pt name *Clinic #:* Pt MRN. *Date of Birth:* Click or tap here to enter text.
Protocol: Protocol # *Cancer Type:* Cancer type. *CRA:* CRA initials

Study Specific Tests:

Required Tests (protocol version date: 11/6/18)	*Date Completed*	*Expiration Date*	*Protocol Guidelines*

Follow Disease By:

CT CXR MRI BONE SCAN PET OTHER

Prior Treatment:

*Type of treatment and dates:*_____
_____
_____

Date of last Chemotherapy: _____ *Washout required?* _____
Date of last Radiation Therapy: _____ *Washout required?* _____

Protocol Specifics:

Surgical Guidelines/Wait time: _____
*Treatment Must Start By:*_____
Central Pathology Review Needed?: ____
Teach Date: _____ *By Whom:*_____ *Consent/HIPAA Date:* _____
*Ancillary/CC/CCDR Study Available?:*_____ *DCP001?:* ___
Notified Pharmacy of work-up: ____ *Provided Agents(s) on site?:* _____
Notified RN Clinician & Financial Services: ____ *QOLs Available:* _____ *Kits Available?:* _____
In CTMS: ___

Example from Samantha Wright, Carle Cancer Center – SWOG Fall 2023 NCORP Research Base Clinical Trials Workshop Breakout Session

IMPORTANT! CONFIDENTIAL PATIENT INFORMATION!

Name _____ CL# _____ CRA _____ DATE _____

Protocol _____ Arm _____ Current Cycle # ____ MD _____

Reported toxicities for Cycle # _____

***relationship to study drug: 1=not related, 2= unlikely, 3=possible, 4= probable, 5= definite**

Toxicity	Grade	*Relationship to Neulasta	Comments
Nausea	0 1 2 3 4	1 2 3 4 5	
Vomiting	0 1 2 3 4	1 2 3 4 5	
Diarrhea	0 1 2 3 4	1 2 3 4 5	
Constipation	0 1 2 3 4	1 2 3 4 5	
Alopecia	0 1 2 3 4	1 2 3 4 5	
Mucositis	0 1 2 3 4	1 2 3 4 5	
Skin	0 1 2 3 4	1 2 3 4 5	
Neuro	0 1 2 3 4	1 2 3 4 5	
Fever/Infection	0 1 2 3 4	1 2 3 4 5	
Fatigue	0 1 2 3 4	1 2 3 4 5	
Dyspnea	0 1 2 3 4	1 2 3 4 5	
Arthralgia	0 1 2 3 4	1 2 3 4 5	
Bone Pain	0 1 2 3 4	1 2 3 4 5	
Myositis	0 1 2 3 4	1 2 3 4 5	
Myalgia	0 1 2 3 4	1 2 3 4 5	
	0 1 2 3 4	1 2 3 4 5	
	0 1 2 3 4	1 2 3 4 5	

Hematology Nadirs:

ANC _____ Date _____Grade_____Attribution_____ PS= _____

WBC _____ Date _____Grade_____Attribution_____ DZ Status= _____

PLTS _____ Date _____ Grade_____Attribution_____ Weight= _____

HGB _____Date_____ Grade_____Attribution_____

Next Visit: _____

Other notes and dose modification recommendations:

_____

_____

_____

_____

I agree with the above toxicities. _____ Date: _____

(Physician signature)

RETURN TO: CANCER CENTER RESEARCH (CCON)/CRA and Phone number