MATRIX
Advancing R&D of Innovative
HIV Prevention Products for Women

MATRIX-003 CLINICAL CRF COMPLETION GUIDELINES

Protocol Name: MATRIX-003: Trial to Assess Acceptability and Safety of Two Placebo Intravaginal Ring (IVR) Designs, Version 1.0 approved 29 Jun 2023

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Version 1.0 Approved 18JAN2024

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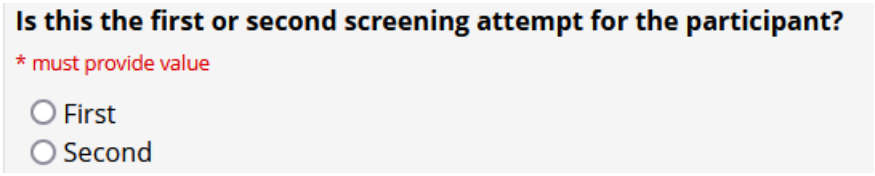
Guidelines for Direct Data Entry into REDCap utilizing eCRFs

Introduction: When entering data directly into REDCap, eCRFs are programmed to only show variables relevant to the specific visit. This includes skip patterns for subsequent questions that are only relevant if the leading question is answered in a manner that requires additional information. Leading questions typically follow a Yes/No (or normal vs abnormal) format. Site staff should familiarize themselves with the skip patterns on the eCRFs to ease data capture on occasions when they may need to use a paper CRF.

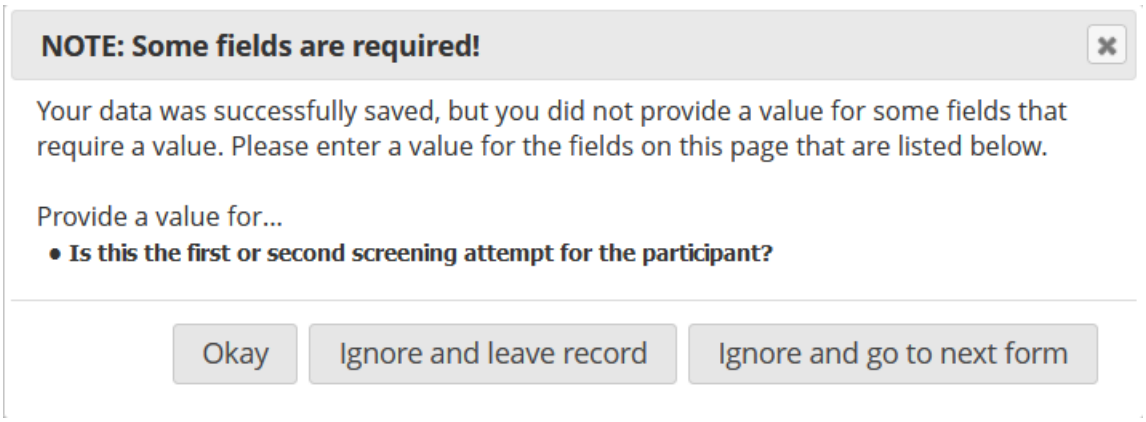
Forms that begin with "PRN" should be used only when needed.

Required Variables:

Many variables on the eCRFs include the *must provide value notation. Example shown below.



If the variable is not answered when the user saves the eCRF, an auto-generated system query pop-up alert (as shown below) will display on the screen. The eCRF will be saved despite the missing data, however you should make a note to return to the eCRF to enter the data once you have the information.



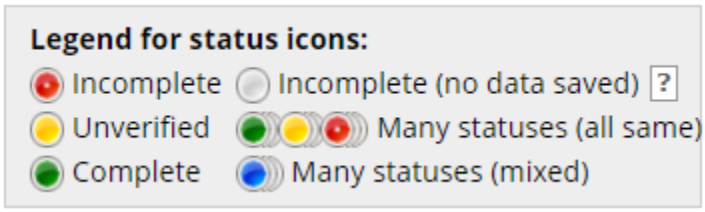
If the information is not available to be entered, use "Not Done" or 'ND" in places where, for example, a specimen was not collected. This will help minimize queries. The eCRFs include instructions for what to enter in situations where data is not available.

Data Entry/Corrections: After an eCRF has been completed, the user has the ability to save it with a status of "complete", a status of "incomplete" or a status of "unverified". Ultimately, the expectation is that eCRFs submitted will be in their "Complete" state, but at the time of data entry some data may

be missing or questionable, requiring verification. The RedCap eCRFs may be saved with a status that signals study staff that an eCRF requires additional attention before being finalized

It is required to mark the "Complete?" variable for every eCRF submitted in REDCap. Note that this is used to signal completeness on the Participant's dashboard; the variable is not included on paper CRFs.

When in the **Record Home Page**, users are able to view the status of all required eCRFs by noting the color of the eCRF icon. See legend for status icons:

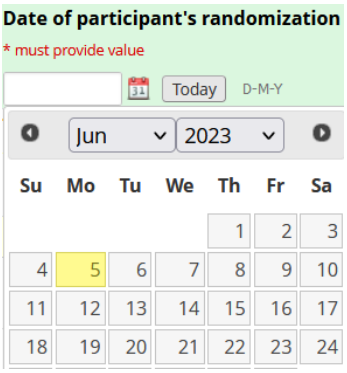


Once missing data are entered into empty fields, or unverified data are confirmed, the eCRF will need to be saved with a "Complete" status.

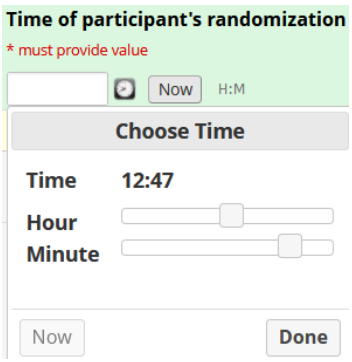
Any field within an eCRF may be updated/corrected by overwriting the incorrect data, then saving the eCRF again. An audit log is automatically maintained that notes which user made the correction. No other user action is necessary to affect a correction.

To back out of a correction i.e. maintain the eCRF as it was prior to unsaved correction(s), the user can select "Cancel". This will close the eCRF to editing and restore the eCRF to the state it was in prior to the editing session that was unsaved. Once saved, it will be impossible to restore eCRF to former versions.

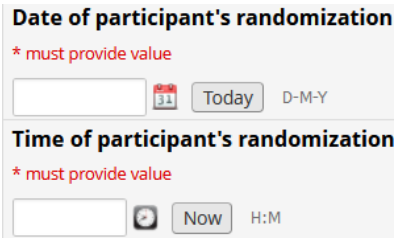
Date and Time fields: Date fields follow the format: DD-MM-YYYY, with the month depicted in its numeric form. For example, Christmas of 2021 would be recorded as “25-12-2021”. Date fields can be entered in either of two ways. They can be typed into the date field in the above described format, or a date can be selected from a calendar. To enter a date in this way, select the calendar icon that is situated next to date fields, and using arrows in the top portion of the calendar, advance to the desired month and year. Once a day is selected, the calendar will disappear and the selected full date will populate the date field. Verify that date entered is the intended date.



A few eCRFs contain time fields. The time field is entered through selection of hour and minutes from what resembles a Likert scale. To enter a time, click on the time icon. When time is properly selected by dragging Selection Cursors with your mouse, click on “Done” to populate field and cause the calendar to disappear.



If entering data in real time, use of the “today” (date) and “now” (time) button will automatically fill in the current date and time. Please note that the randomization time entered in REDCap should match the time on the paper randomization form.



REDCap Dashboard

Entering a New Screening Participant: A unique PTID (participant ID) is assigned to participants who have completed an informed consent. Login to RedCap and navigate to the **Record Status Dashboard.** Select the pre-assigned PTID number.

An empty Participant Dashboard will display on your screen:

PTID **TEST-1234**

Data Collection Instrument	V1 Screen	V2 Enroll (Stage 1, Day 0)	V3 (Stage 1, Day 7)	V4 (Stage 1, Day 14)	V5 (Stage 1, Day 28)	V6 (Stage 2, Day 0)	V7 (Stage 2, Day 7)	V8 (Stage 2, Day 14)	V9 (Stage 2, Day 28)	+ Add new Interim Visit	Ongoing Logs	Product Hold/Discontinuation
Establish PTID	●											
ICF Summary	○											
Demographic DEM Form	○											
Matrix-003 Randomization Assignment		○										
Baseline Medical And Menstrual History	○											
Screening Physical Exam And Vital Signs	○											
Pelvic Exam	○	○		○	○	○		○	○	○		
Hematology And Chemistry Results	○											
HIV, STI and Urine Test Results	○	○		○	○	○		○	○	○		
Updated Medical And Menstrual History		○	○	○	○	○	○	○	○	○		
Specimen Storage		○		○	○	○		○	○	○		
Baseline Behavioral BEH Form		○										
Baseline Acceptability BL Form		○										
Clinical Observations for Insertion COI Form		○				○						
Clinical Observations for Removal COR Form					○				○			
Post Insertion Acceptability FU1 Form		○				○						
Brief Acceptability FU2 Form			○				○					
Followup Behavioral And Acceptability FU3 Form				○				○				
Final Behavioral And Acceptability FU4 Form									○			
Visit Summary			○	○	○	○	○	○	○	○		
Concomitant Medications Log											○	
Preexisting Conditions Log											○	
Protocol Deviation Log											○	
Adverse Events Log											○	
Social Harms And Benefits Assessment Log											○	
Participant Disposition												○
Study Product Hold/Discontinuation Log												○
HIV Confirmatory												○
Pregnancy Report And Outcome												○
PRN Hematology And Chemistry Results		○		○	○	○		○	○	○		
PRN Symptom-directed Physical Exam		○		○	○	○		○	○	○		
PRN Missed Visit			○	○	○	○	○	○	○			
Delete all data on event:	×											

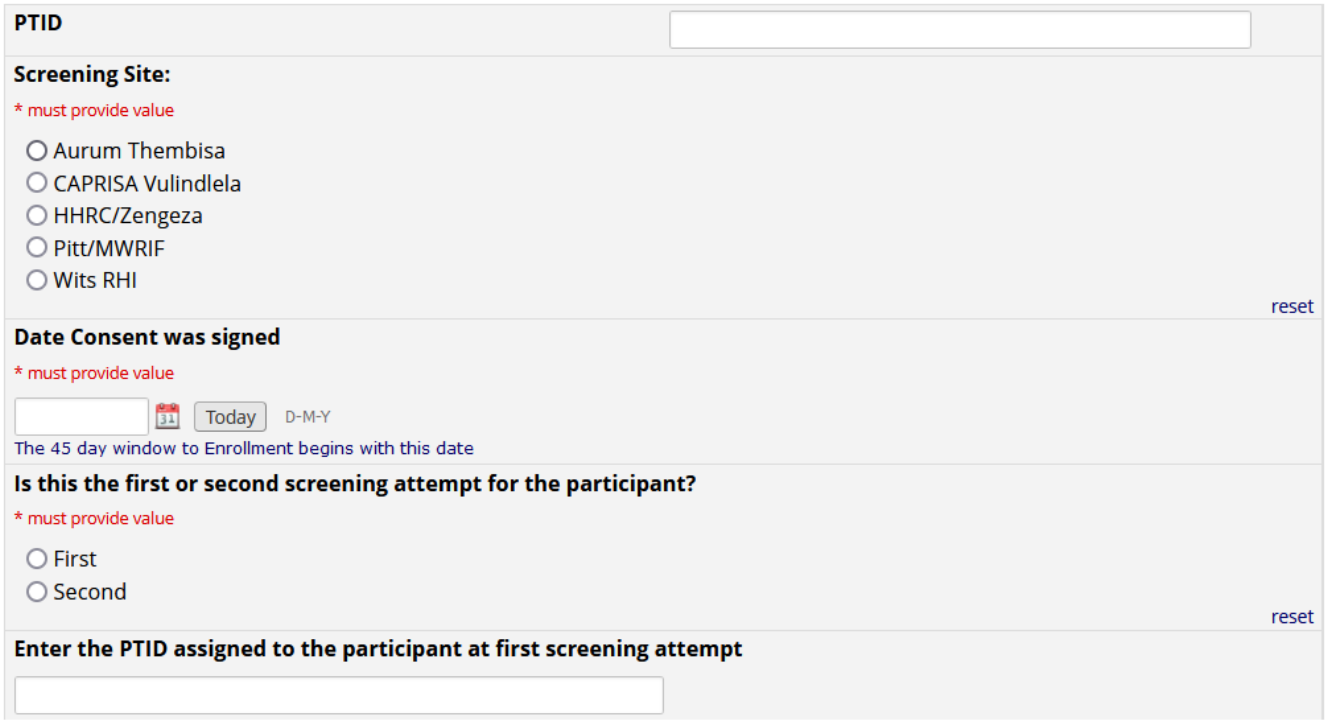
To begin entering data, click the bubble for the “Establish PTID” CRF in the top left corner of the grid.

Note for all Screening CRFs

If over the course of the 45 day Screening window, the participant needs to be re-examined or have samples collected again, a new instance of the relevant CRF can be added. This is done by clicking on the "+" button on the dashboard next to the CRF access bubble. Or clicking the "+ Add new" button below the existing instance of the CRF in the Repeating Instrument Section located under the PTID's dashboard. The option to add a new instance only becomes available after one instance is already entered. Additional explanation and visuals included in next section.

Establish PTID CRF

Choose the site at which this participant is screening, then document the date, and whether this is the first or second screening attempt for the participant. Sites are responsible for tracking this, as participants are only allowed per protocol to be screened twice for the study. If this is the second attempt, the previously used PTID should be entered for the "Enter the PTID assigned to the participant at first screening attempt" question. Then mark the form complete, and continue to the next eCRF.



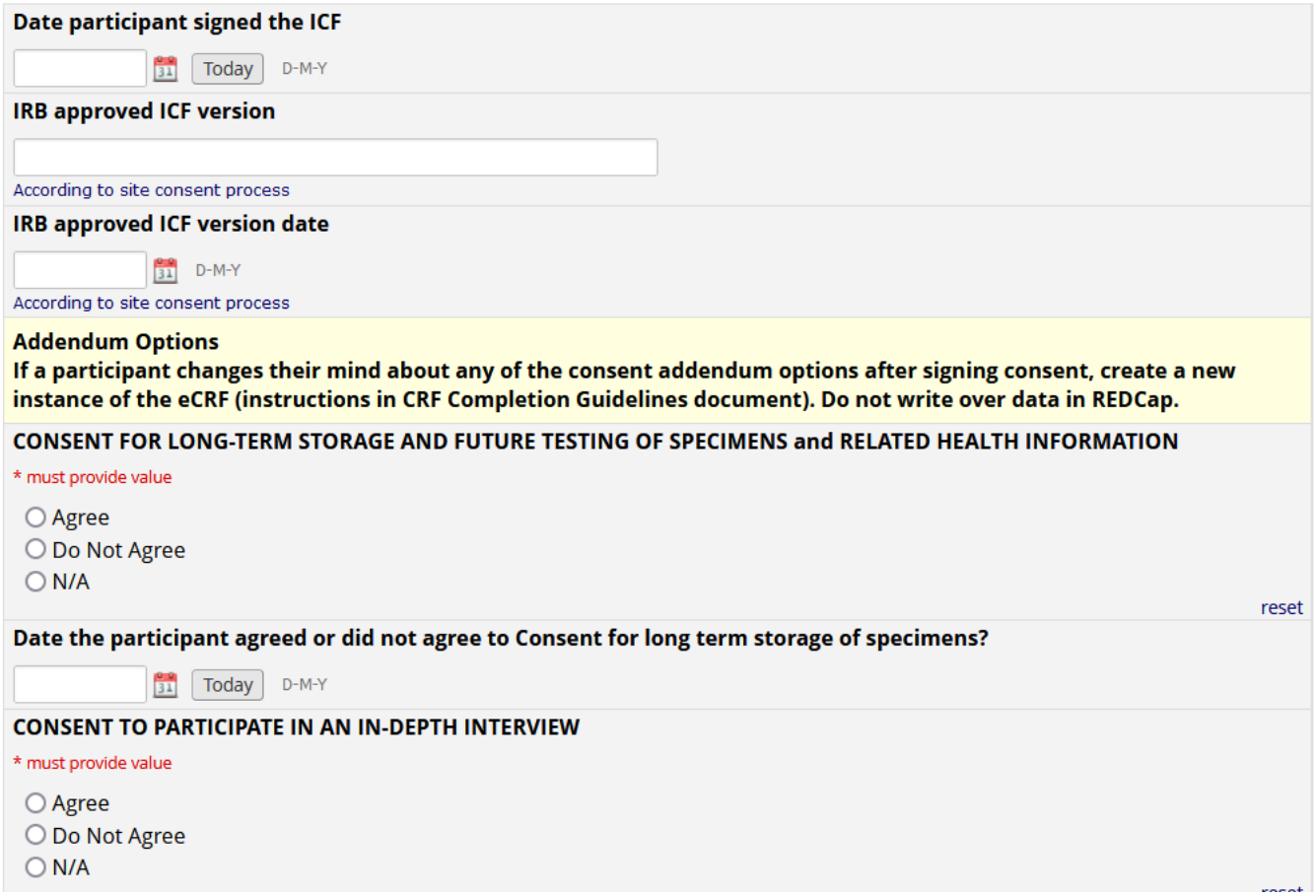
ICF Summary CRF

The ICF Summary CRF captures the ICF version/date and the consent addendum options that the participant agreed or did not agree to.

From section 4 SSP Informed Consent: Informed consent is a dynamic process that should continue throughout the duration of study to ensure participant understanding of protocol requirements. Site staff should review protocol requirements and processes at study visits/contacts as applicable and as deemed necessary. Study participants are free to withdraw consent at any time during participation.

This CRF is repeatable. The ICF Summary CRF is to be updated anytime there is a new ICF version. Also, participants may change their minds about consent during the 45 day screening process OR even after they have been enrolled/randomized. Changes to the ICF version or the addendums the participant agreed to will necessitate a new entry of the ICF Summary CRF. The previously recorded data should NOT be written over.

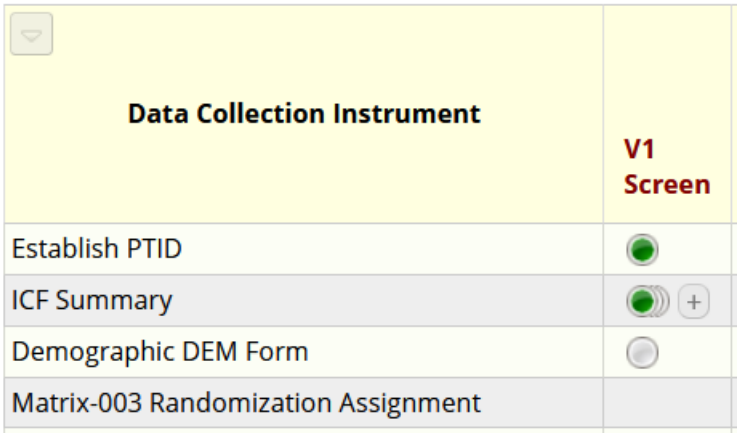
Below is a section of the ICF Summary CRF as it appears in REDCap:



How to add an updated instance of the ICF Summary:

If there are changes to be recorded for a participant on the ICF Summary, a new instance of the CRF must be created. This is done by clicking the "+" button on the dashboard next to the CRF access bubble:

The dashboard example shown below indicates that the PTID already has multiple ICF Summary CRF instances entered (the access bubble has a 3-dimensional effect).

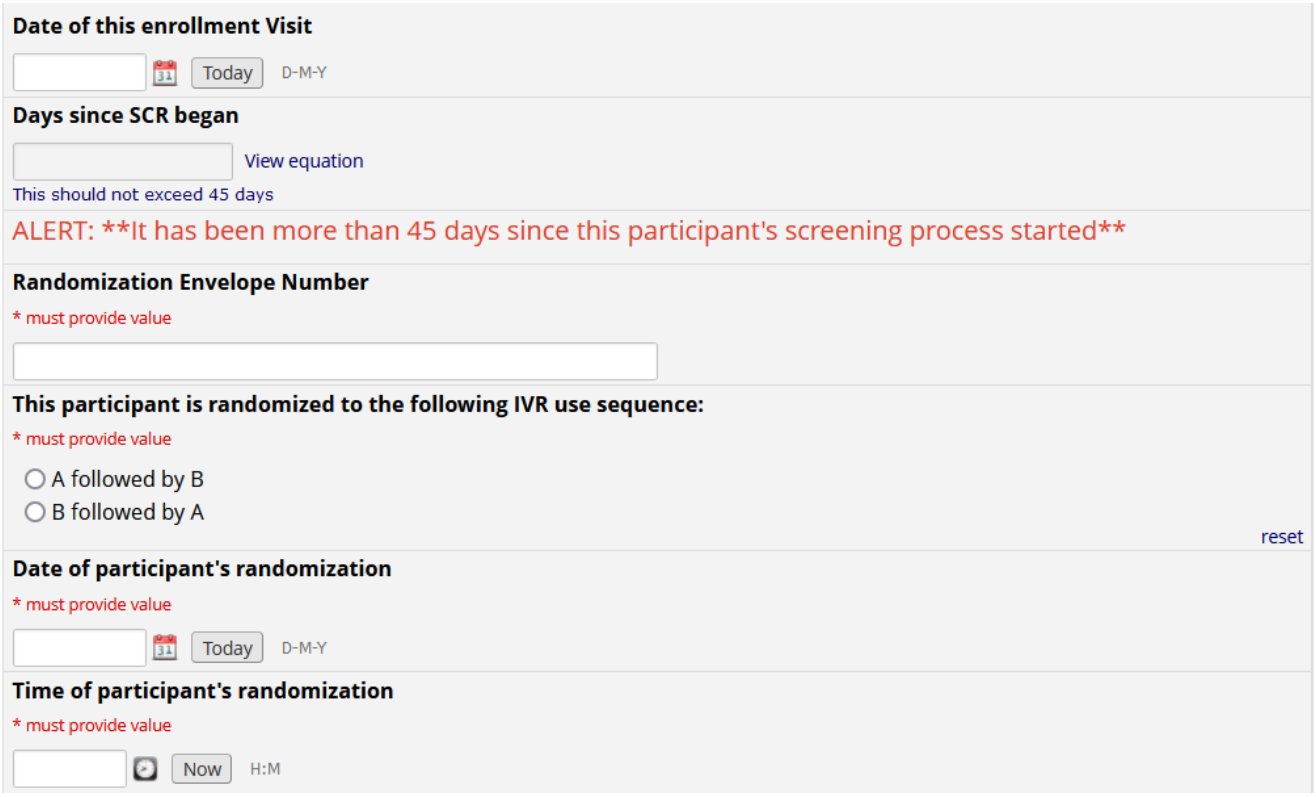


Alternately, you may use the "Repeating instruments" section below the PTID's dashboard. Clicking the "+ Add new" button below the existing ICF Summary CRF(s) will activate another instance of the ICF Summary to be entered.

Demographic (DEM) Form – refer to Behavioral CCG document for DEM Form

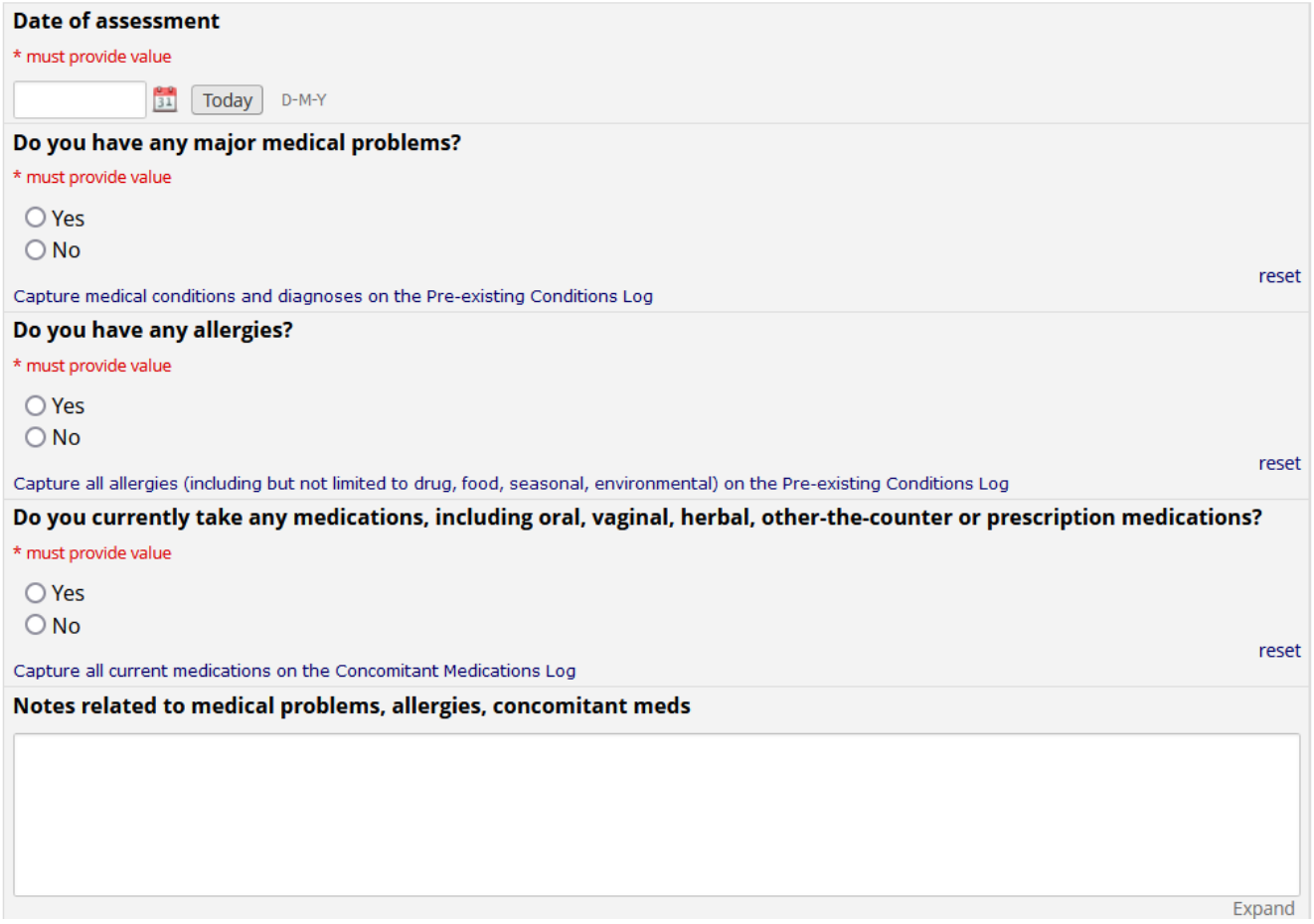
Matrix-003 Randomization Assignment CRF

The Randomization Assignment CRF in REDCap will alert you as the user if the participant has surpassed the 45 day window period for enrolling. All variables on this CRF must be completed for the participant to be considered randomized and enrolled. Be sure that the randomization time entered in REDCap matches the time on the paper randomization form.

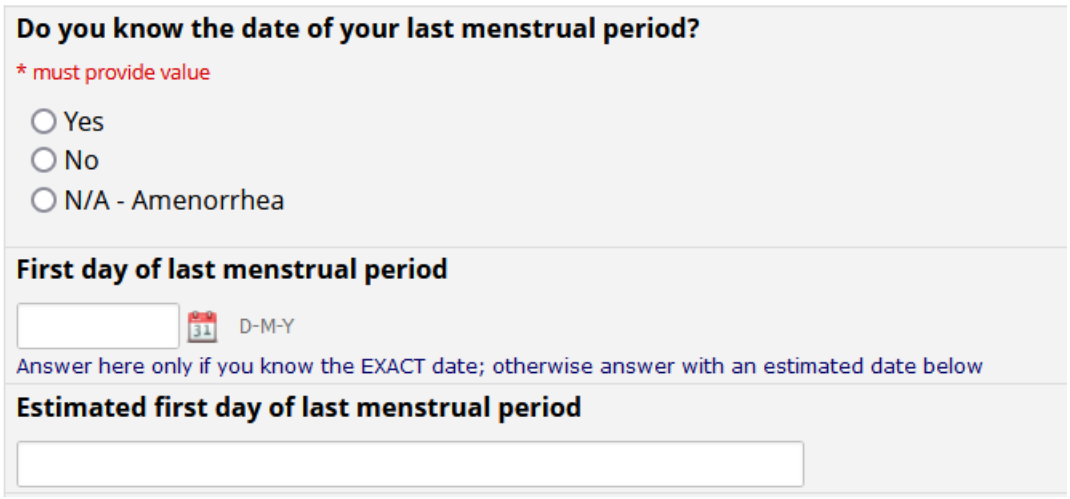


Baseline Medical and Menstrual History CRF

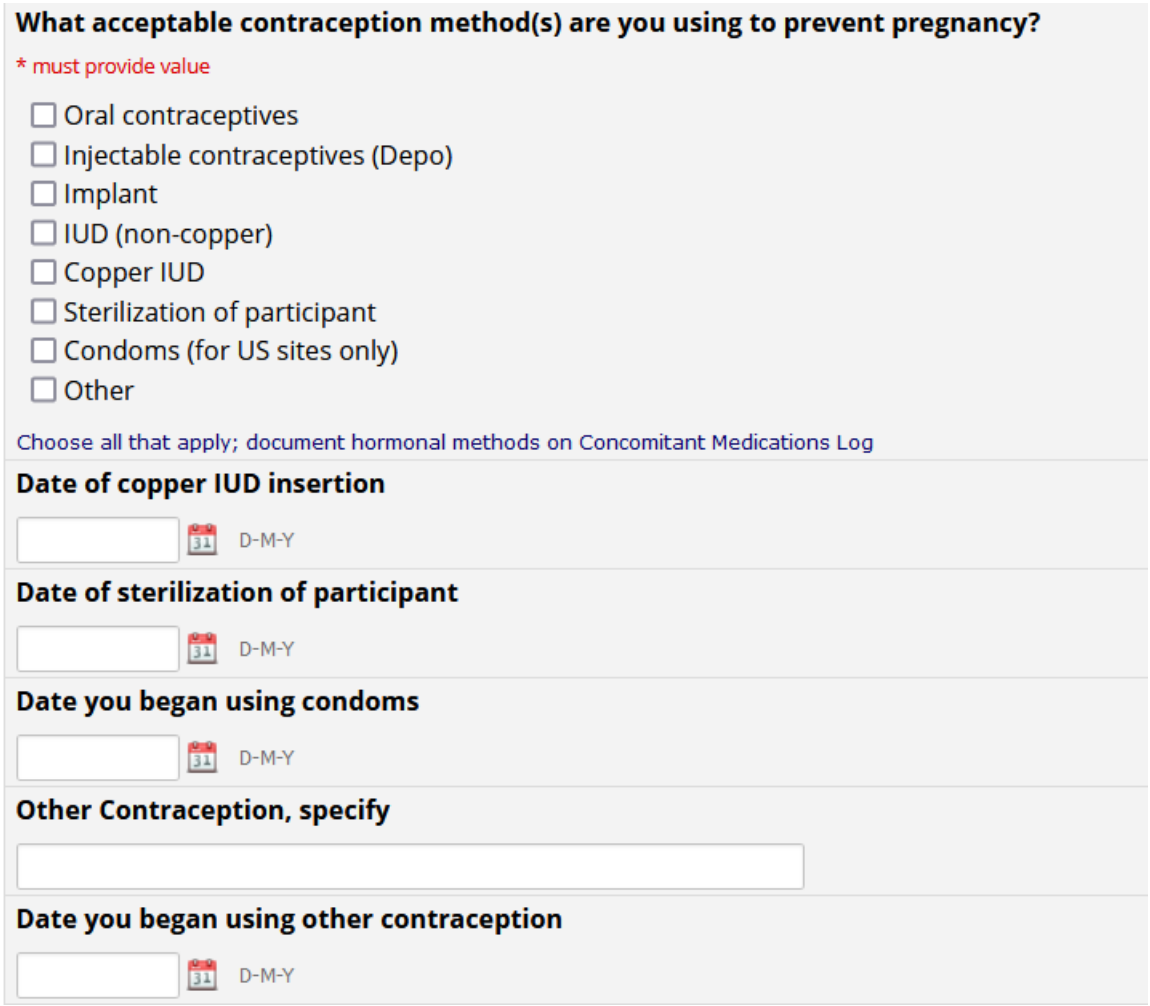
This CRF establishes a baseline for existing medical conditions, allergies, current Rx and OTC medications; as well as capturing family planning methods currently being used by the PTID. Most of the questions are Yes/No answer format, with notes reminding staff to document conditions and medications on the appropriate logs.



Participants will be asked if they know the date of their last period, and then asked to provide the date. Even if the participant has not had a period in months or even years, if they know the date, it should be entered. If the participant recalls their last period was “sometime in June of 2021” enter 15-6-2021 (as a default, if the participant cannot remember the exact date, using the 15th of the month is acceptable). There is a place to answer exact date, and a separate place if entering an estimated date



In the family planning section, all of the acceptable methods the participant is currently using should be marked. If a non-hormonal method of birth control is marked, REDCap will ask for the start date of that method, as shown in the example below:



An assessment of vaginal and urinary symptoms is done, and all symptoms that apply are to be marked. If “other” is marked, a text box to specify the other symptoms will appear in REDCap. If “other” is not marked, the text box will not appear in REDCap:

Are you currently experiencing any vaginal symptoms or concerns?

* must provide value

- ○ Yes
- ○ No

Mark all vaginal symptoms that apply

- ☐ Itching or irritation
- ☐ Abnormal discharge (different than fluctuations in discharge with participant's menstrual cycle or contraception)
- ☐ Abnormal odor (outside of normal)
- ☐ Discomfort or Pain
- ☐ Unexpected vaginal bleeding
- ☐ Other

Other vaginal symptom(s), specify

Are you currently experiencing any urinary symptoms or concerns?

* must provide value

- ○ Yes
- ○ No

Mark all urinary symptoms that apply

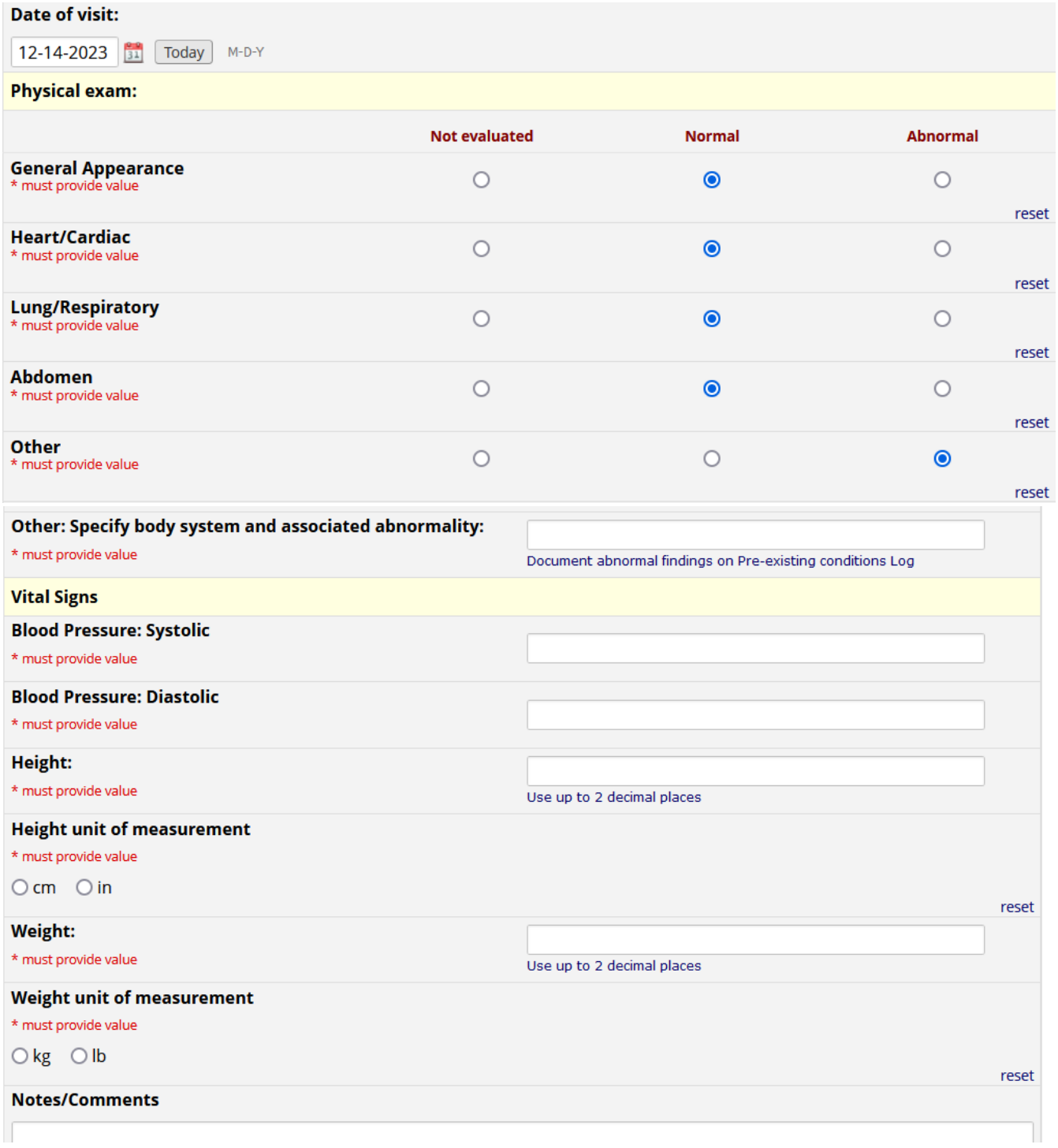
- ☐ Burning with urination
- ☐ Frequency (urinating more than normal and not explained for instance by increased water intake)
- ☐ Urgency (feeling the urge or need to urinate but not being able to go)
- ☐ Other

Other urinary symptom(s), specify

Note: This CRF (Baseline Medical and Menstrual History) references utilizing The Pre-existing Conditions Log and the Concomitant Medications Log, which are Ongoing Logs to be reviewed at every in-clinic visit.

Screening Physical Exam and vital signs CRF (PRN Symptom-directed physical exam)

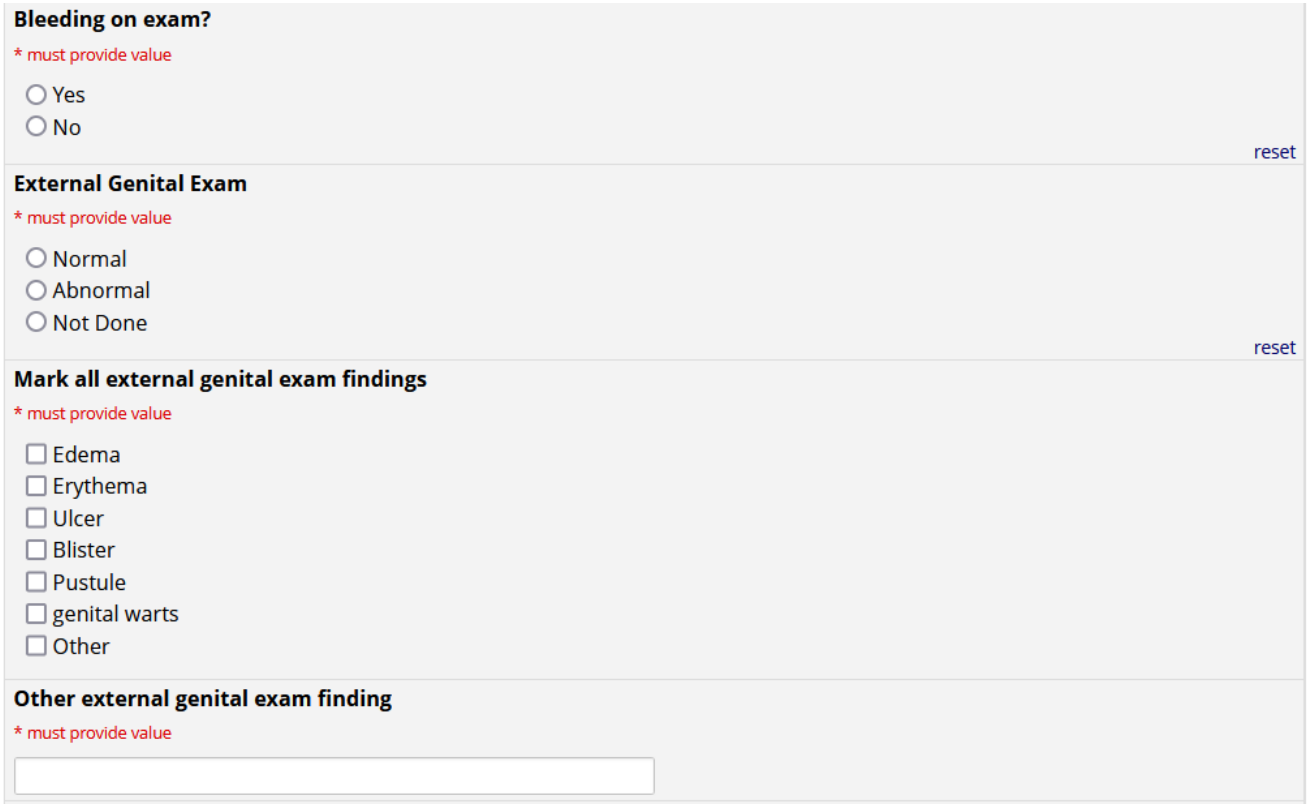
A physical examination is required at Screening (all variables require an answer). If "Abnormal" is marked for any of the specific body systems, an additional data entry box will appear to document the abnormality (shown below for "Other"). Indicate unit of measurement for height and weight.
The PRN Symptom-directed physical exam is available at all in clinic visits, though not required.



Pelvic Exam CRF

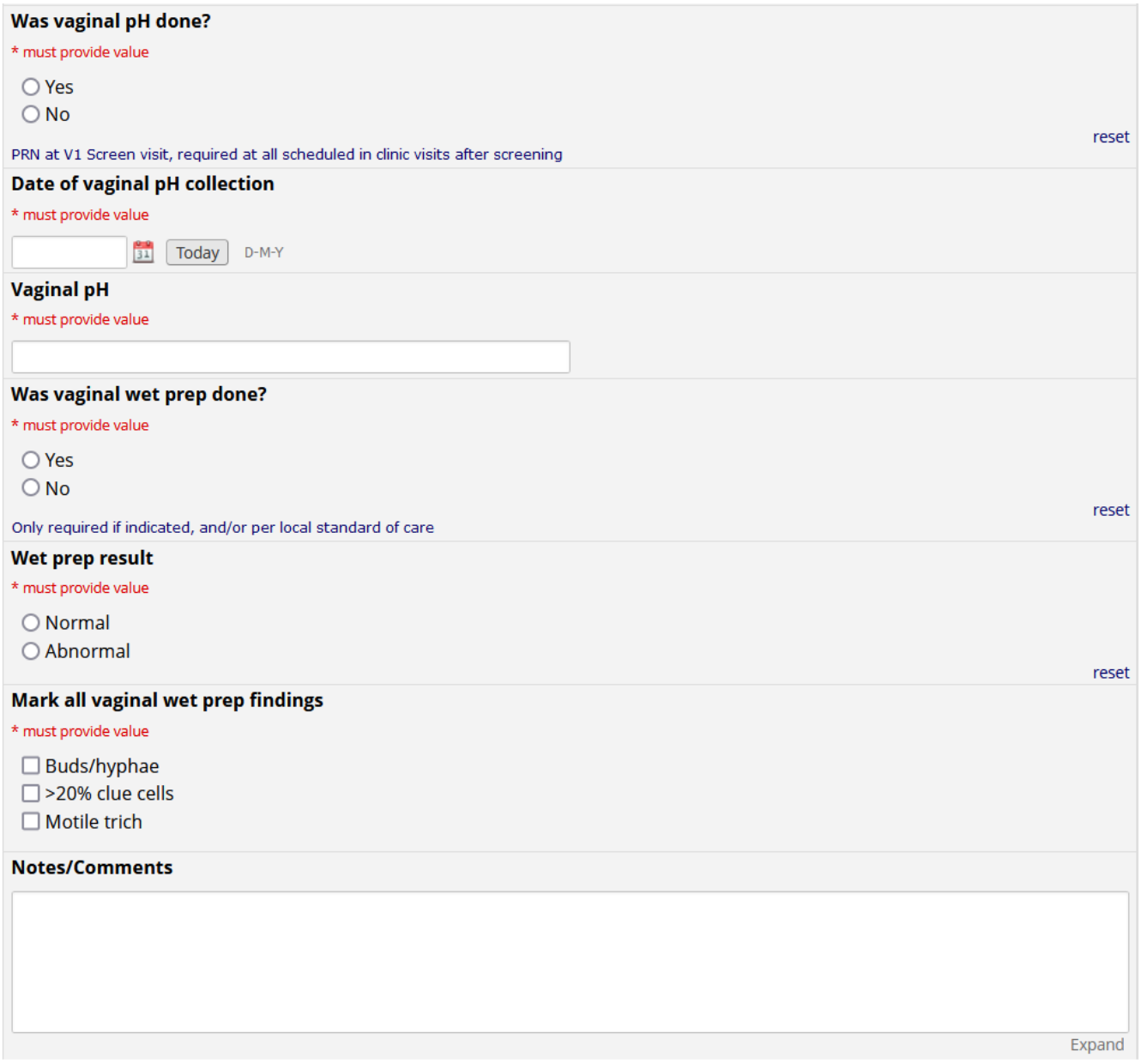
Intravaginal Ring placement should be confirmed at all in person visits after screening. This question will not appear in REDCap when completing the eCRF, and there are clear directions on the paper CRF to skip it during screening.

The CRF continues with the standard pelvic exam



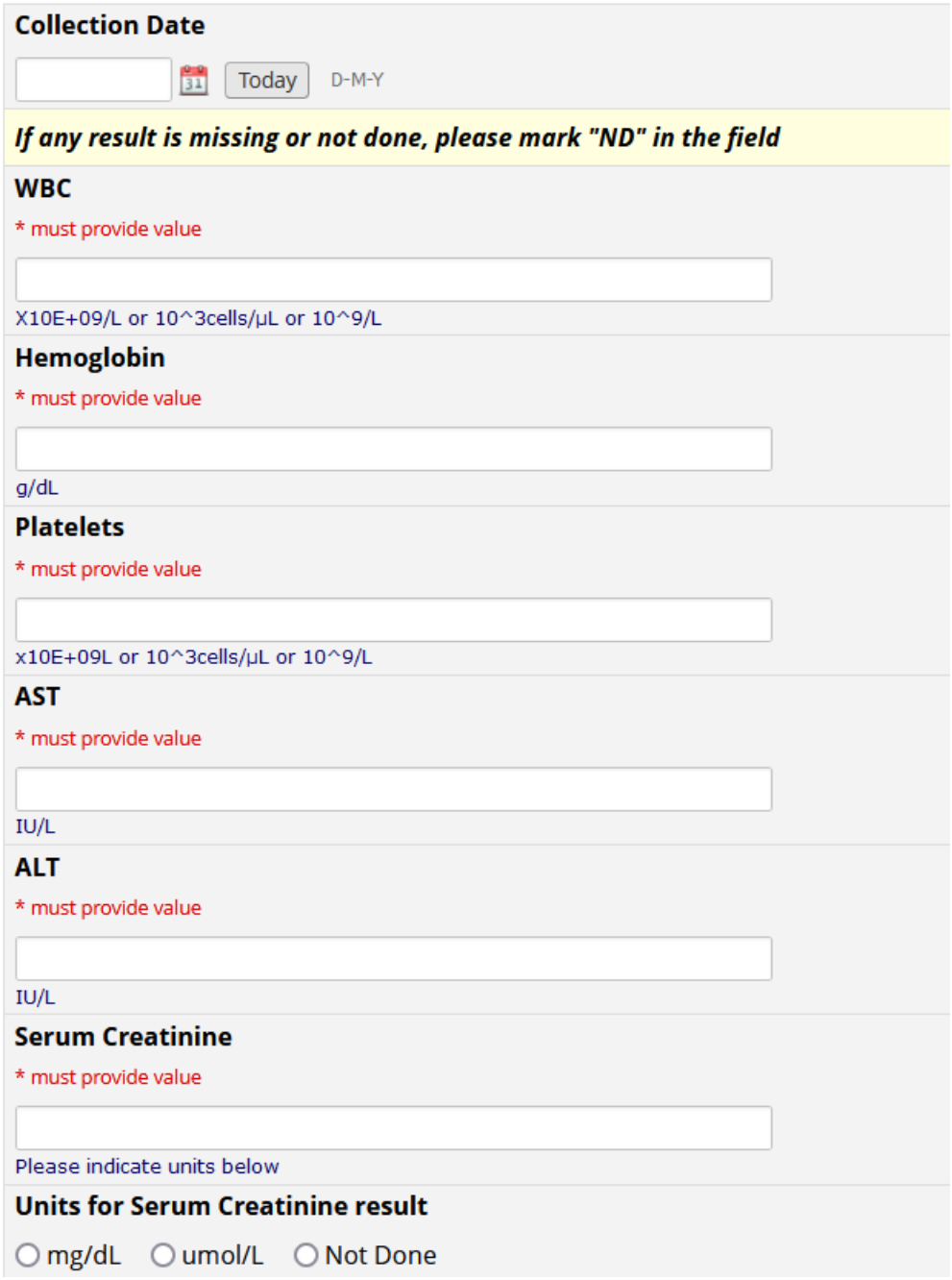
If “Abnormal” is marked for any section of the pelvic exam, another question will ask the user to mark all of the findings. If “other” is then chosen, a text box will populate asking you to indicate the finding:

Vaginal pH and wet prep are available at screening if indicated, though neither are required. Vaginal pH is required at all in clinic visits after screening. If “yes” is marked indicating that vaginal pH was done, then additional data will need to be entered (date of vaginal pH collection and vaginal pH value). Similarly, if “yes” is marked indicating vaginal wet prep was done, questions will populate to document the wet prep result. If “abnormal” is noted, you are then asked for a more detailed description of findings:



Hematology and Chemistry Results CRF (and PRN Hematology and Chemistry Results)

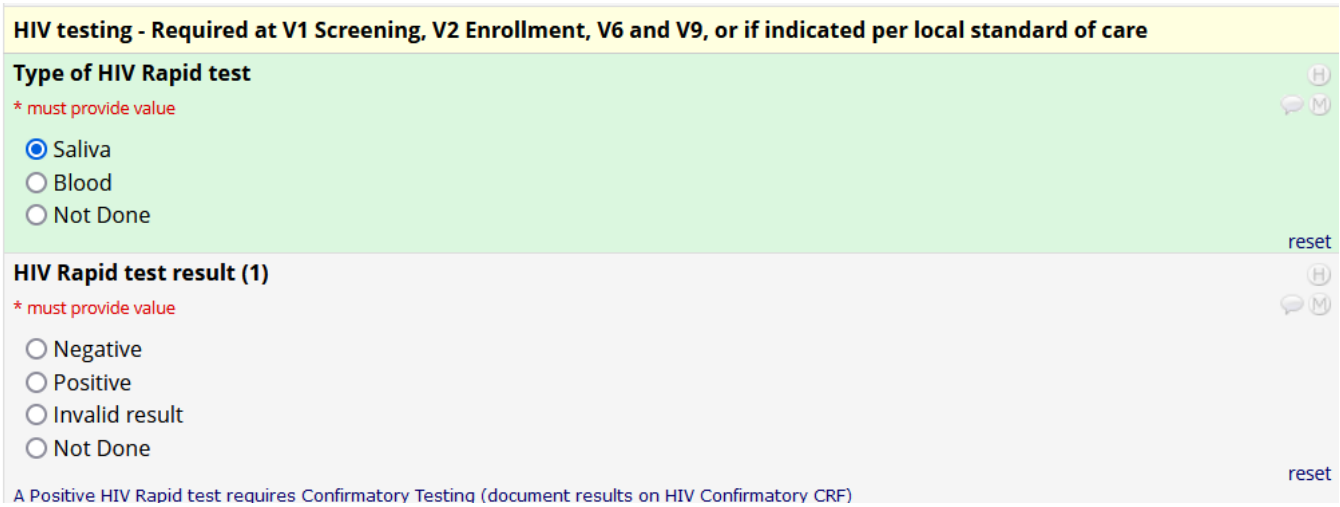
This CRF is required for V1 screening. Units for results are listed in the different measurements used by sites. Creatinine requires a unit to be marked. The **PRN Hematology and Chemistry Results CRF** is linked with all other in clinic visits but should only be used if necessary.



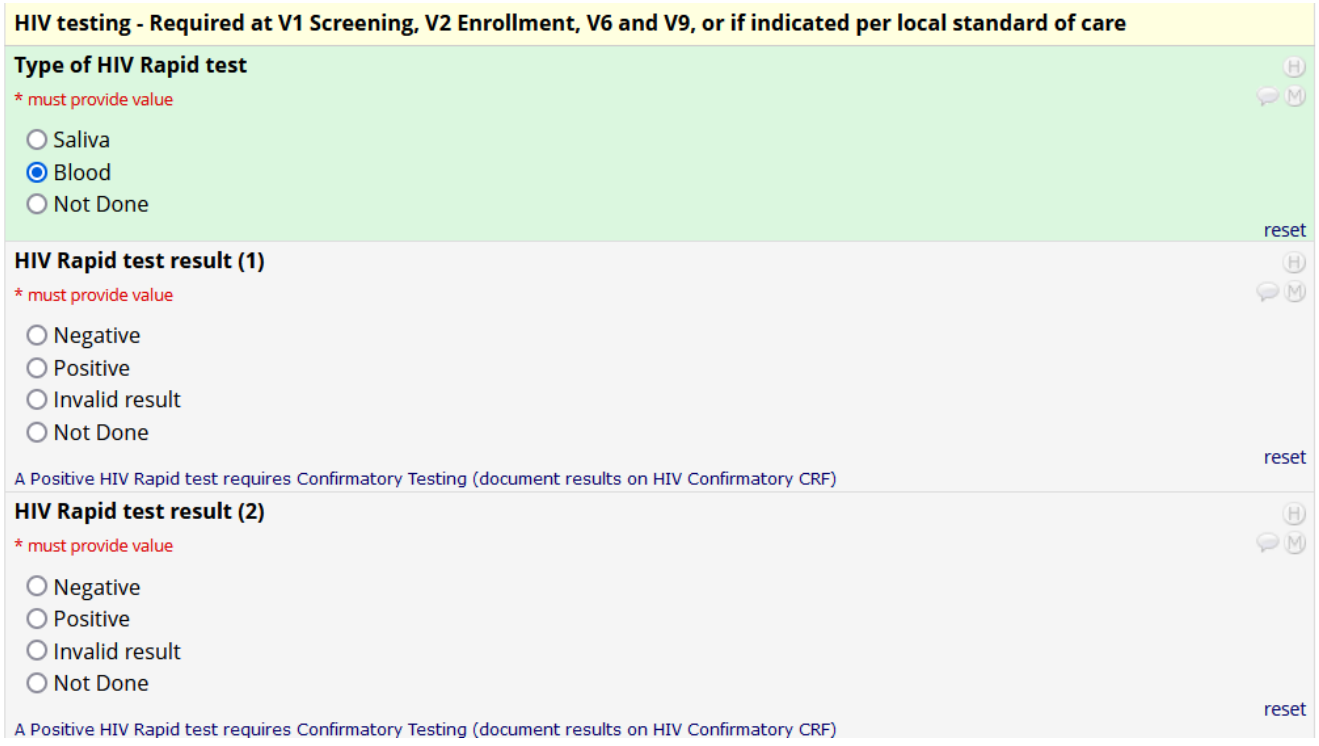
HIV, STI and Urine Test Results CRF

An HIV test is required at V1, V2, V6 and V9. For sites that have CLIA certification for saliva testing, there is one place to document a rapid test result. If a blood test is collected, there are two places to capture results. Both options are shown below as they appear on the CRF during data entry.

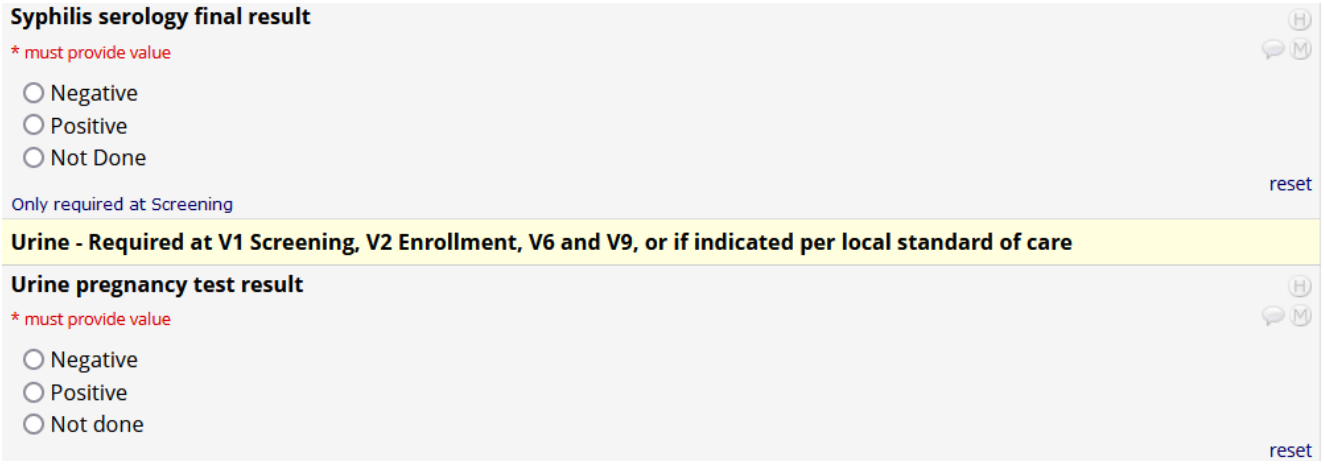
If “Saliva” is selected:



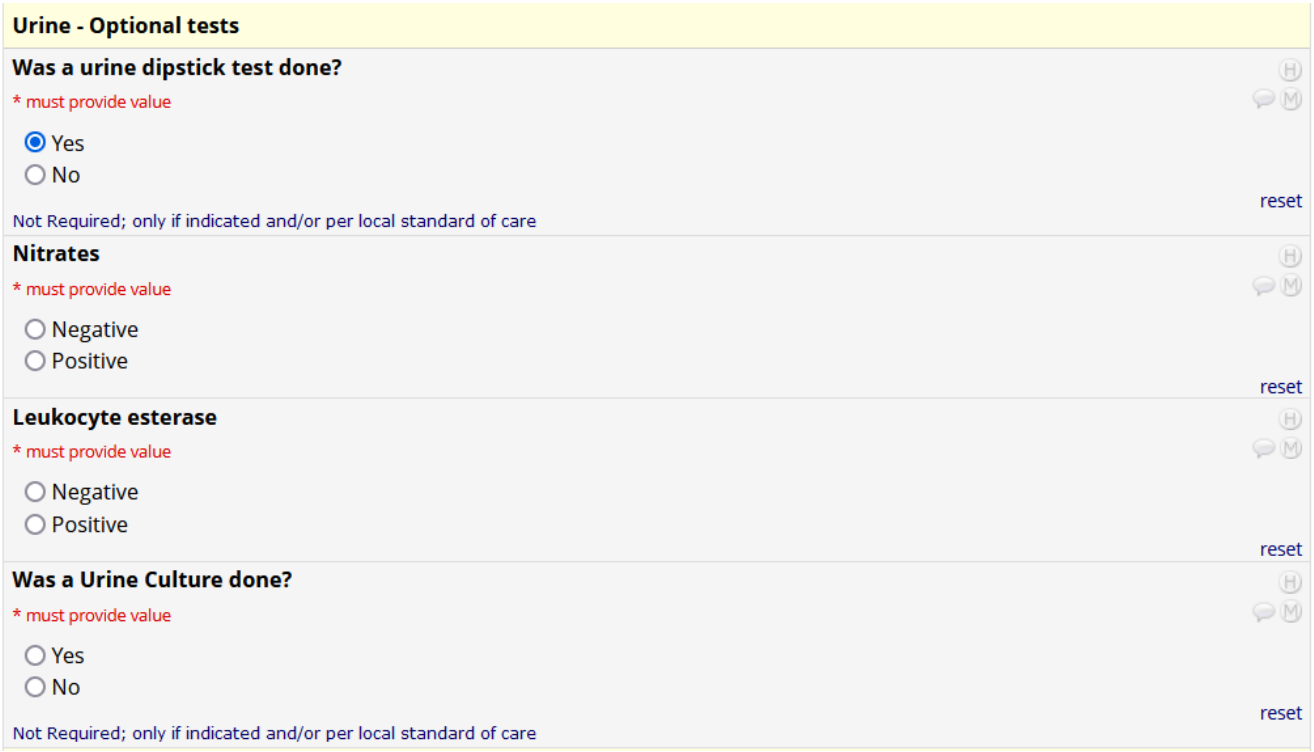
If “Blood” is selected:



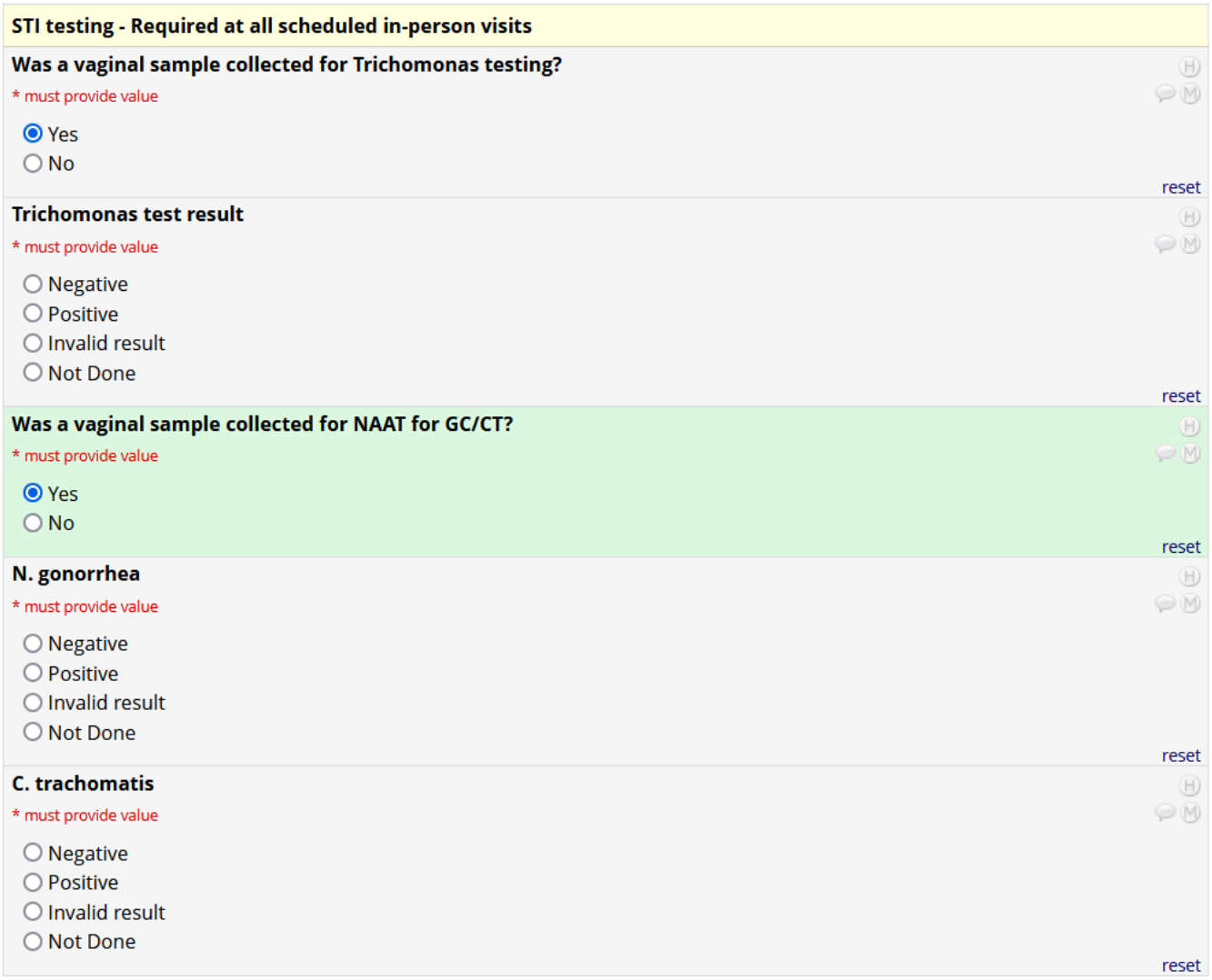
As indicated on the eCRF, Syphilis serology is only required at screening; whereas urine pregnancy testing is required at V1, V2, V6 and V9.



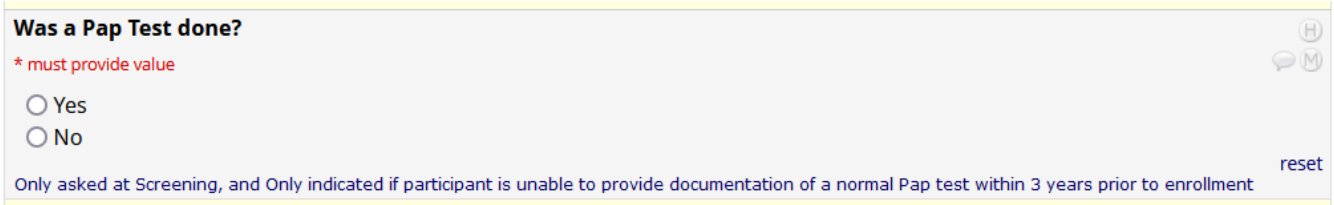
Additional urine tests may be collected but are not required. This includes urine dipstick and urine culture. Note that there is not a field to capture the urine culture result in REDCap. Relevant results should be captured as Adverse Events.



STI testing is only required at V1 Screening, but available if indicated at all in-clinic visits.

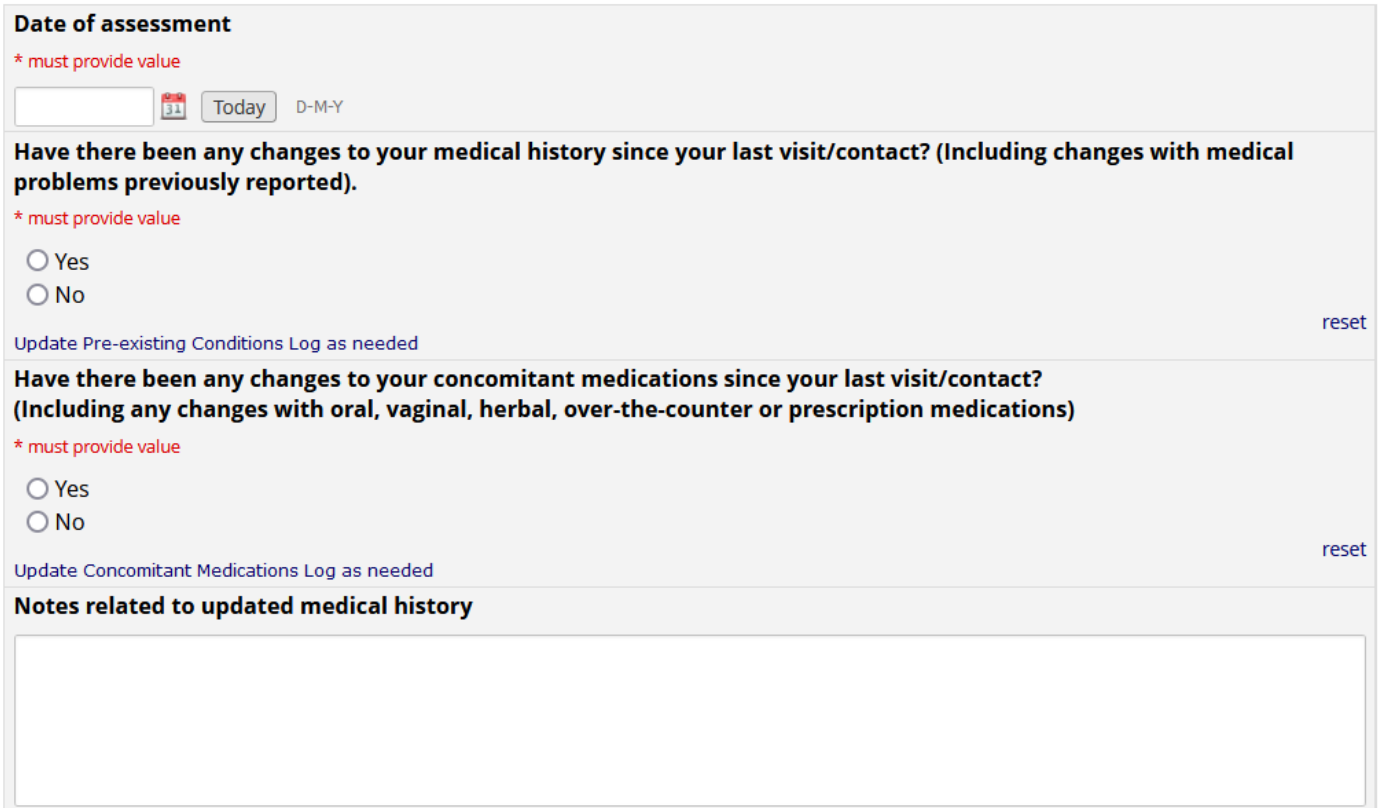


The following question is only asked at the Screening Visit:

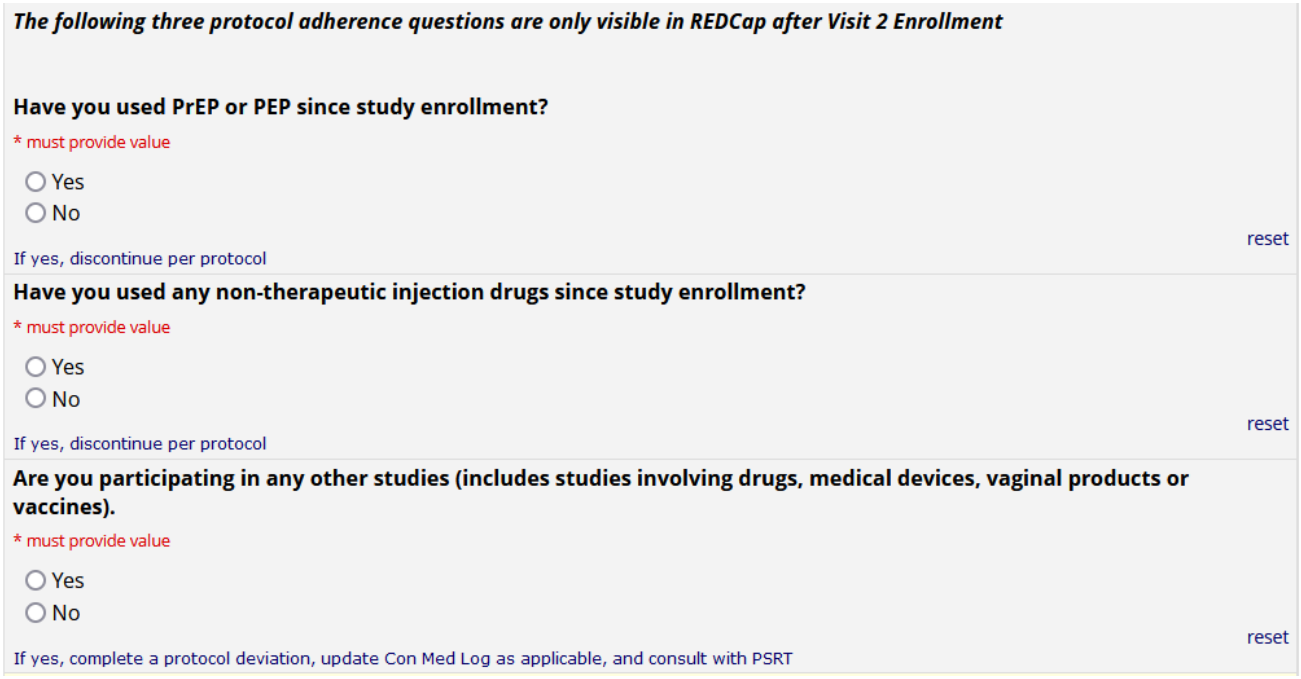


Updated Medical and Menstrual History CRF

This form allows the participant to report updates to their current medications, LMP, birth control method(s), and urinary and vaginal symptoms. The CRF follows the same line of questioning as the Screening Medical and Menstrual History CRF, except the questions are framed with "Have you… since your last visit?" Abide the notes to update concomitant meds and pre-existing conditions as needed.



The following sections are questions related to protocol adherence and social impacts. They only appear in REDCap when they are relevant to the visit:



The following three protocol adherence questions are only visible in REDCap after Visit 2 Enrollment

Have you used PrEP or PEP since study enrollment?

* must provide value

- ○ Yes
- ○ No

reset

If yes, discontinue per protocol

Have you used any non-therapeutic injection drugs since study enrollment?

* must provide value

- ○ Yes
- ○ No

reset

If yes, discontinue per protocol

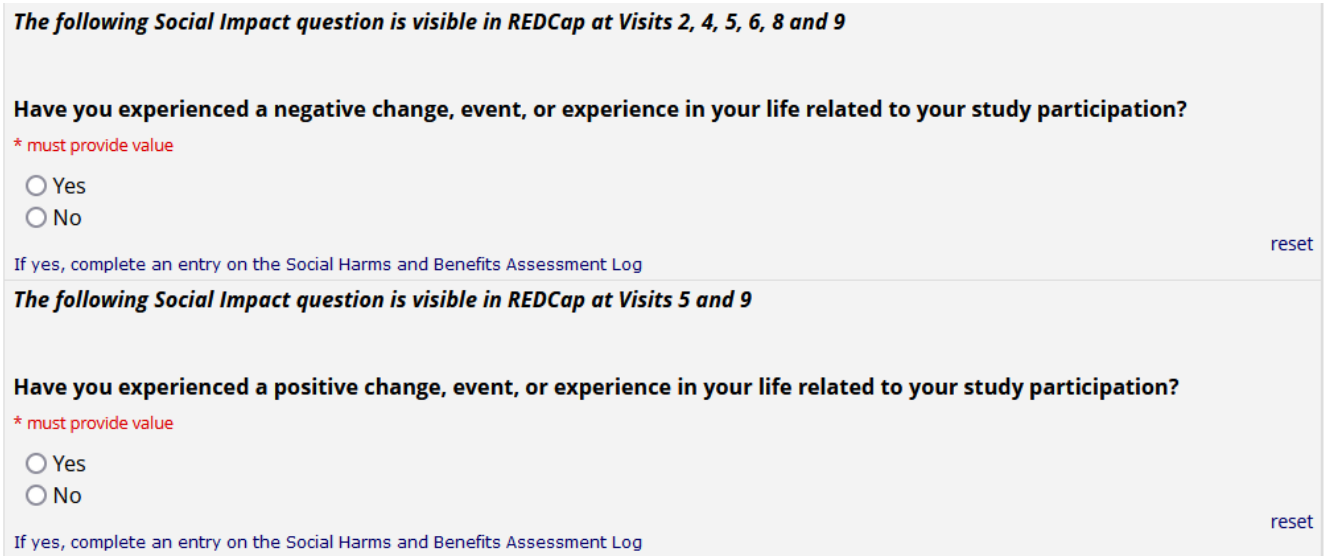
Are you participating in any other studies (includes studies involving drugs, medical devices, vaginal products or vaccines).

* must provide value

- ○ Yes
- ○ No

reset

If yes, complete a protocol deviation, update Con Med Log as applicable, and consult with PSRT



The following Social Impact question is visible in REDCap at Visits 2, 4, 5, 6, 8 and 9

Have you experienced a negative change, event, or experience in your life related to your study participation?

* must provide value

- ○ Yes
- ○ No

reset

If yes, complete an entry on the Social Harms and Benefits Assessment Log

The following Social Impact question is visible in REDCap at Visits 5 and 9

Have you experienced a positive change, event, or experience in your life related to your study participation?

* must provide value

- ○ Yes
- ○ No

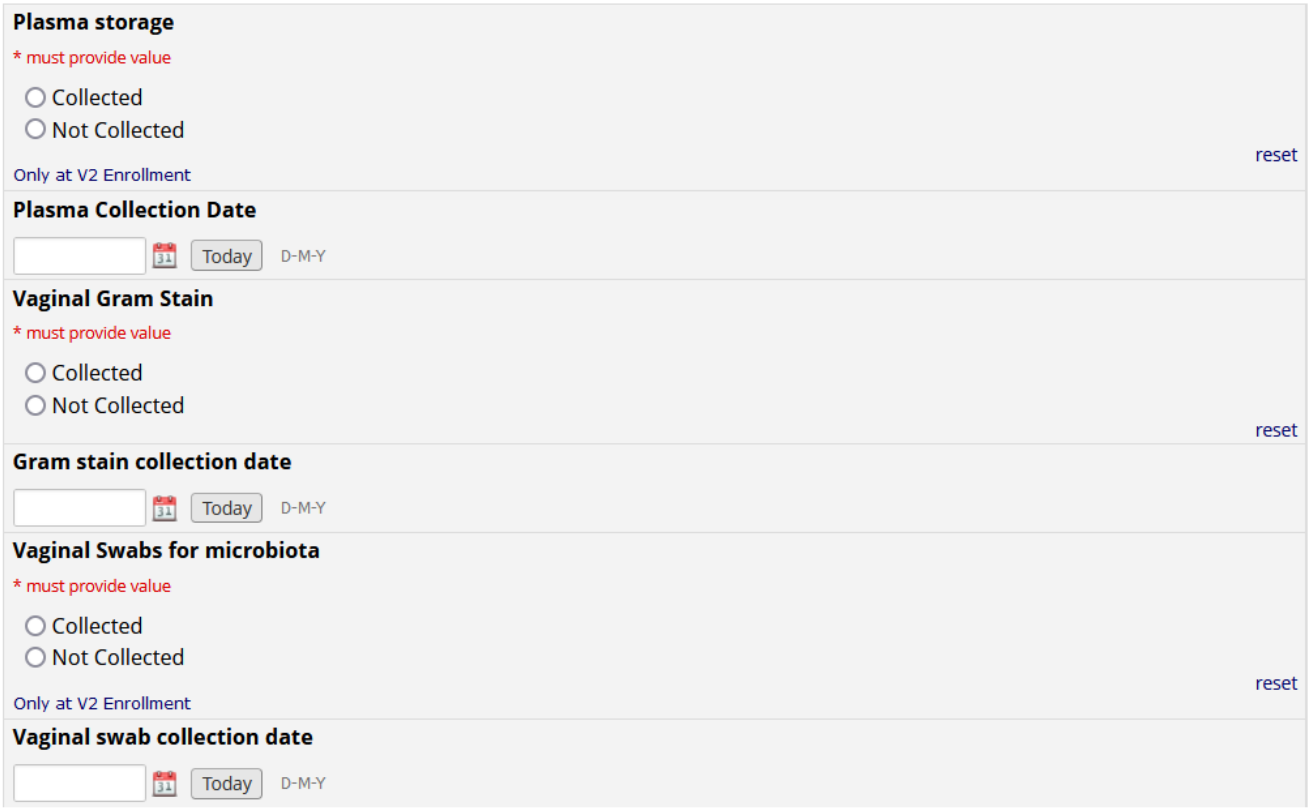
reset

If yes, complete an entry on the Social Harms and Benefits Assessment Log

Changes to the PTID's birth control method or new vaginal/urinary symptoms since the last visit, are documented on this CRF as well.

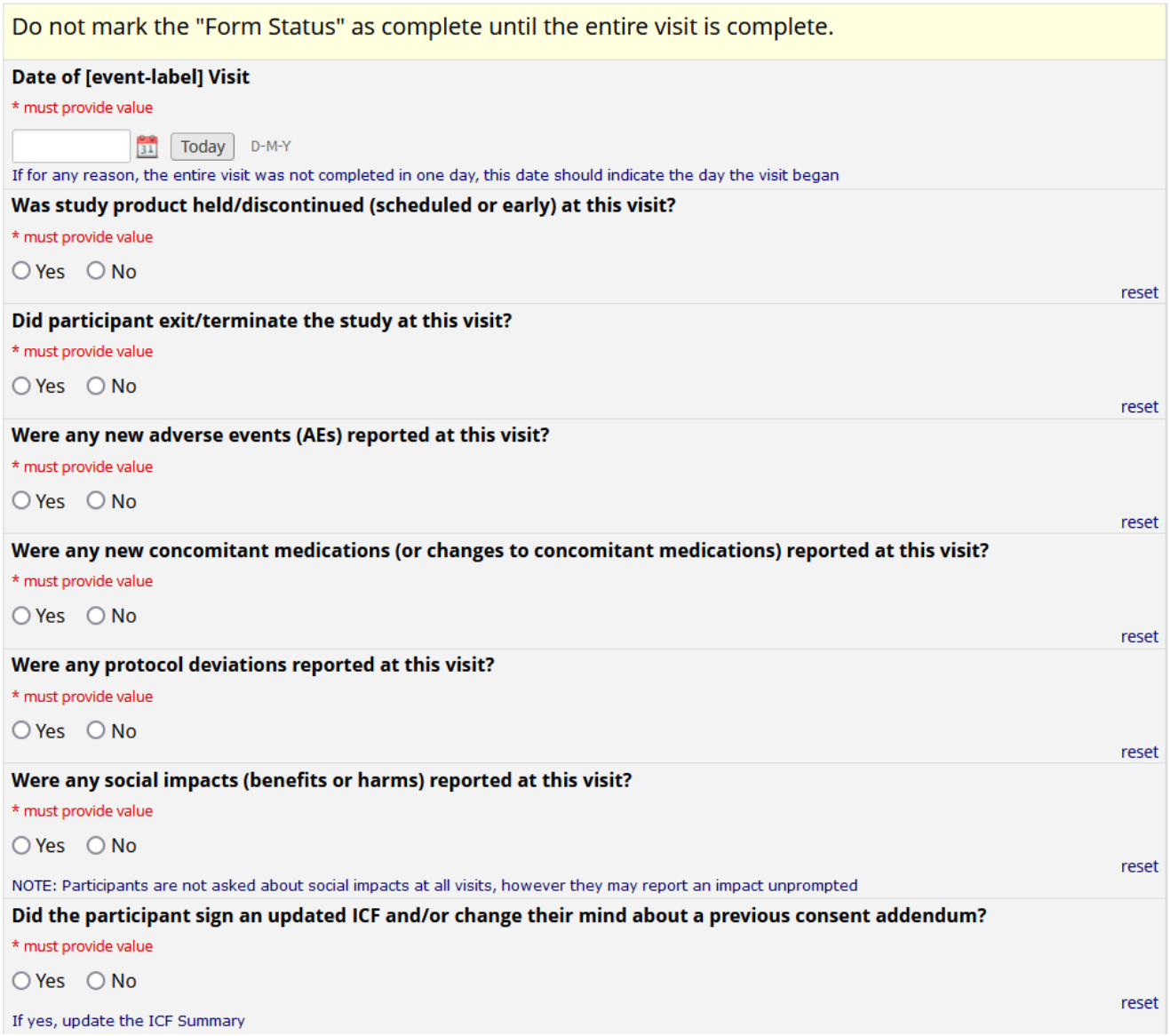
Specimen Storage CRF

Document the specimens collected at this visit. A collection date should also be entered.



Visit Summary CRF

The Visit Summary CRF is a review of what happened during the visit. Any “yes” answer indicates an expectation that a new entry would be documented on a CRF linked to Ongoing Logs or within the Product Hold/Discontinuation Folder on the Dashboard. The date entered here will be the date used by Data Management to determine if the regular study visits are within window.



Do not mark the "Form Status" as complete until the entire visit is complete.

Date of [event-label] Visit

* must provide value

Today D-M-Y

If for any reason, the entire visit was not completed in one day, this date should indicate the day the visit began

Was study product held/discontinued (scheduled or early) at this visit?

* must provide value

Yes No

reset

Did participant exit/terminate the study at this visit?

* must provide value

Yes No

reset

Were any new adverse events (AEs) reported at this visit?

* must provide value

Yes No

reset

Were any new concomitant medications (or changes to concomitant medications) reported at this visit?

* must provide value

Yes No

reset

Were any protocol deviations reported at this visit?

* must provide value

Yes No

reset

Were any social impacts (benefits or harms) reported at this visit?

* must provide value

Yes No

reset

NOTE: Participants are not asked about social impacts at all visits, however they may report an impact unprompted

Did the participant sign an updated ICF and/or change their mind about a previous consent addendum?

* must provide value

Yes No

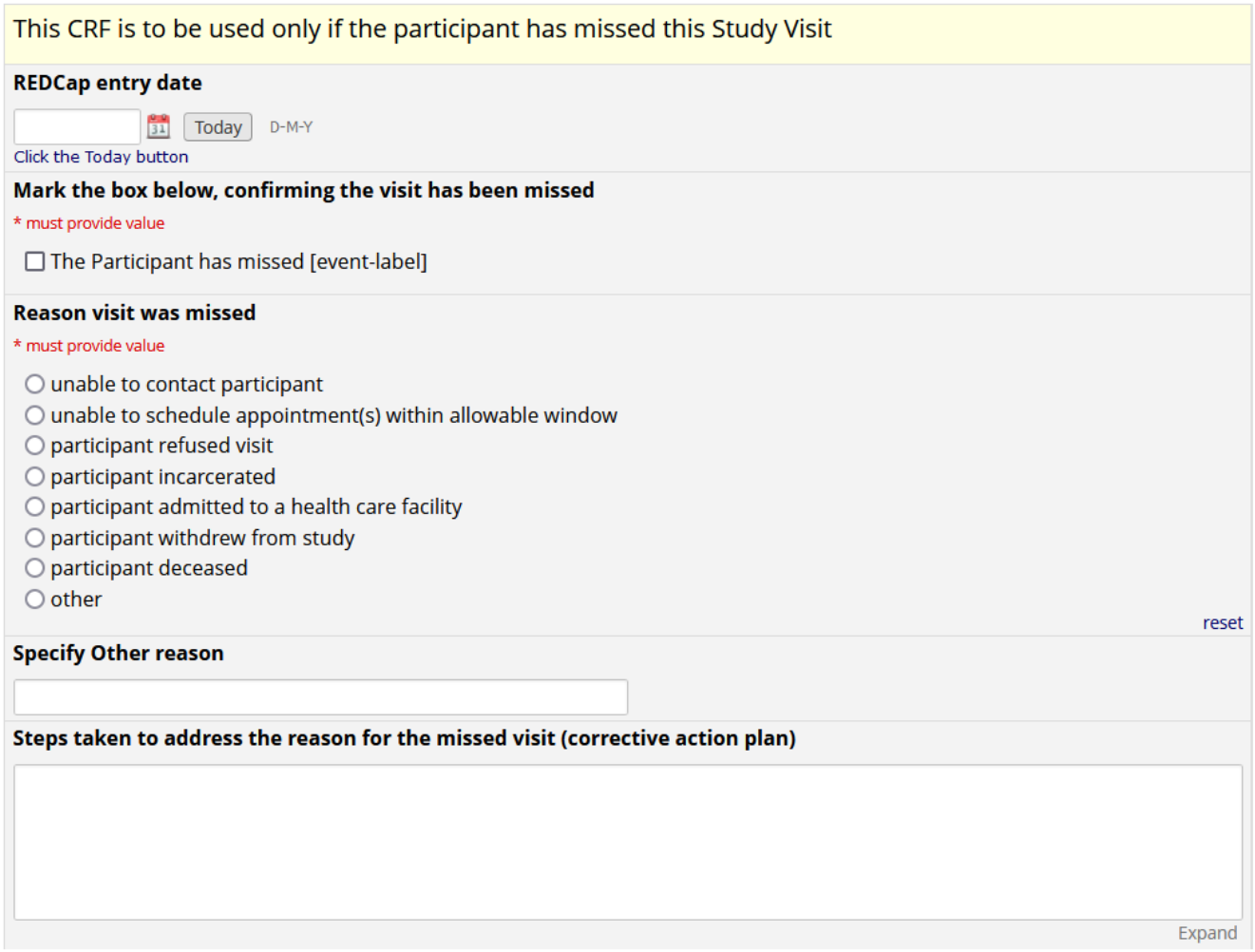
reset

If yes, update the ICF Summary

PRN Missed Visit CRF

The PRN missed visit CRF is only to be used if the participant missed a visit. The CRF is linked to all regularly scheduled visits after Enrollment. Note that missed visits do not require an entry on the Protocol Deviation Log CRF. If a Missed Visit is captured on a paper CRF, data should be entered into REDCap as soon as possible. Ideally, within 1-2 days of the visit, though up to 7 days is acceptable.

The visit that has been missed will auto-populate in the place of "[event-label]" below.


This CRF is to be used only if the participant has missed this Study Visit

REDCap entry date

Today D-M-Y

Click the Today button

Mark the box below, confirming the visit has been missed

* must provide value

☐ The Participant has missed [event-label]

Reason visit was missed

* must provide value

- ○ unable to contact participant
- ○ unable to schedule appointment(s) within allowable window
- ○ participant refused visit
- ○ participant incarcerated
- ○ participant admitted to a health care facility
- ○ participant withdrew from study
- ○ participant deceased
- ○ other

reset

Specify Other reason

Steps taken to address the reason for the missed visit (corrective action plan)

Expand

ONGOING LOGS – CRFs to be used and updated as needed

Concomitant Medications Log

All medications the participant is currently taking should be documented on the "Con Meds Log" shown below. To add more medications, use the "+" button on the dashboard next to the bubble, or the "+ Add new" button in the Repeating Instruments section below the dashboard.

Date documenting medication: Today D-M-Y

Medication name:	**Indication:**	**Was med taken for a reported AE?** ○ Yes ○ No reset
Dose:		
Units: ○ Grams ○ Micrograms ○ Milligrams ○ Milliliters ○ Capsules ○ Drops ○ Puffs ○ Sachets ○ Suppository ○ Tablets ○ Units ○ Unknown ○ Other (If "Other", specify) reset	**Frequency:** ○ prn ○ once ○ qd ○ bid ○ tid ○ qid ○ qm ○ qh ○ unknown ○ other (If "Other", specify) reset	**Route:** ○ Oral ○ Subdermal ○ Intramuscular ○ Intravenous ○ Topical ○ Subcutaneous ○ Inhalation ○ Vaginal ○ Rectal ○ Intrauterine ○ Epidural ○ Unknown ○ Other (If "Other", specify) reset
Other unit:	**Other frequency:**	**Other route:**
Date med started:	**Continuing at end of study?** ○ Yes ○ No reset	**Date med stopped:**

Start and Stop Dates are open entry text fields to accommodate participants who may only remember the month and/or year. Medications documented at Screening can be left with an "Incomplete" form status, as they are to be reviewed at the participant's final visit.

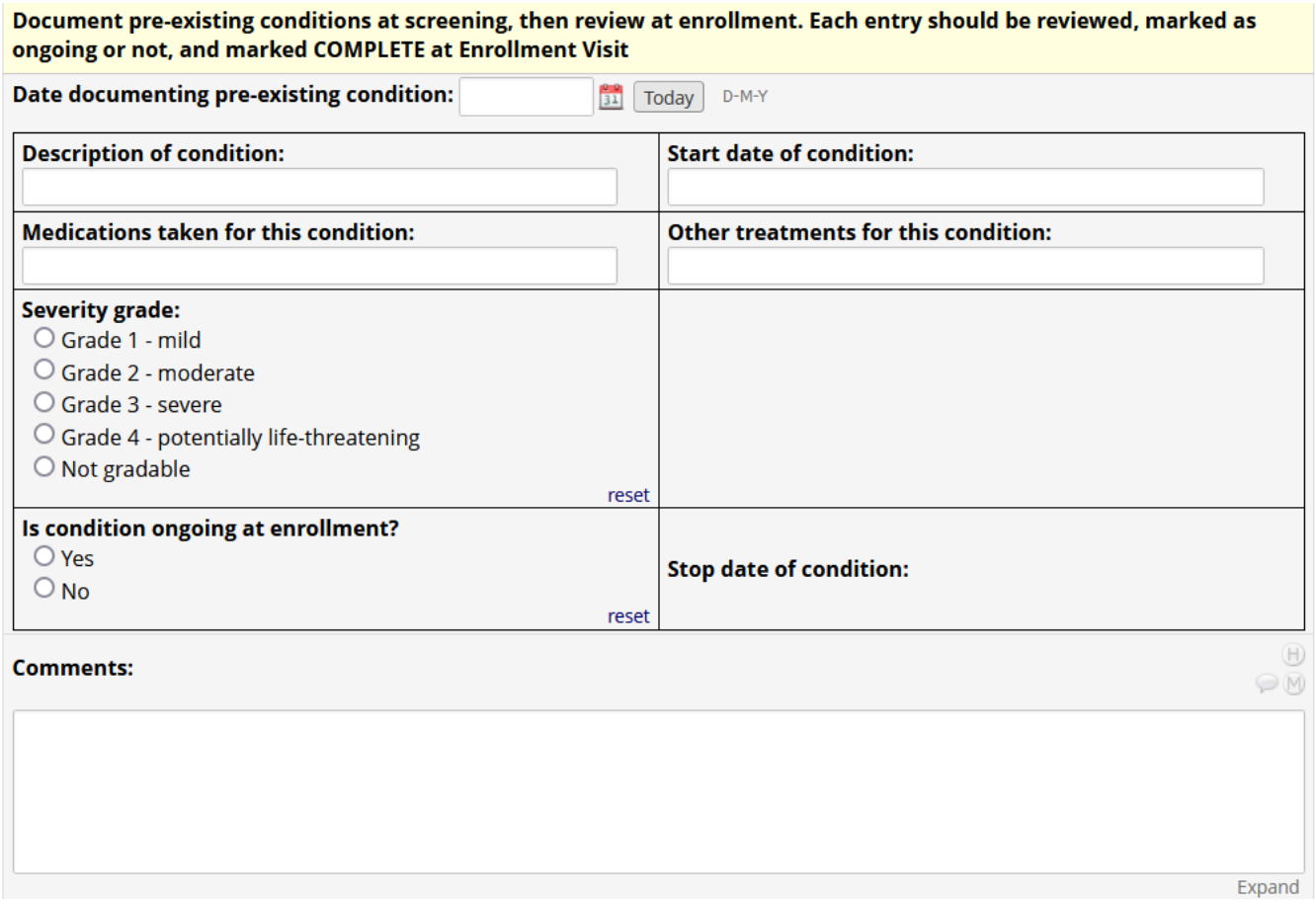
Form Status

Complete? Incomplete

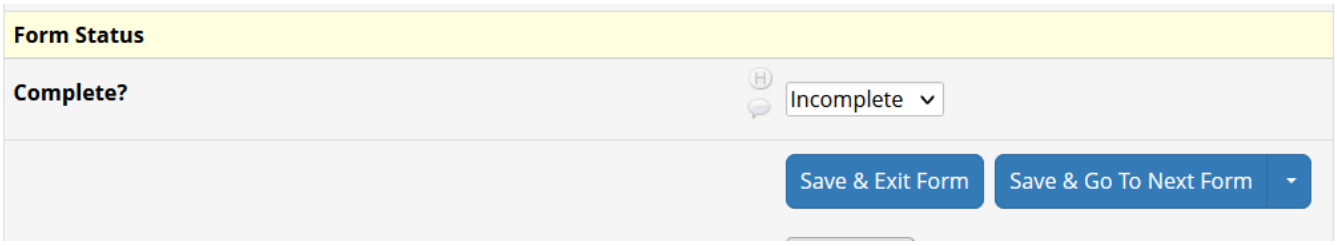
Save & Exit Form | Save & Go To Next Form

Pre-existing Conditions Log (Ongoing Logs)

All conditions or diagnoses the participant reports should be documented on the Pre-existing Conditions Log shown below. To add additional entries, use the "+" button on the dashboard next to the CRF status bubble, or the "+Add new" button in the Repeating Instruments section below the dashboard.

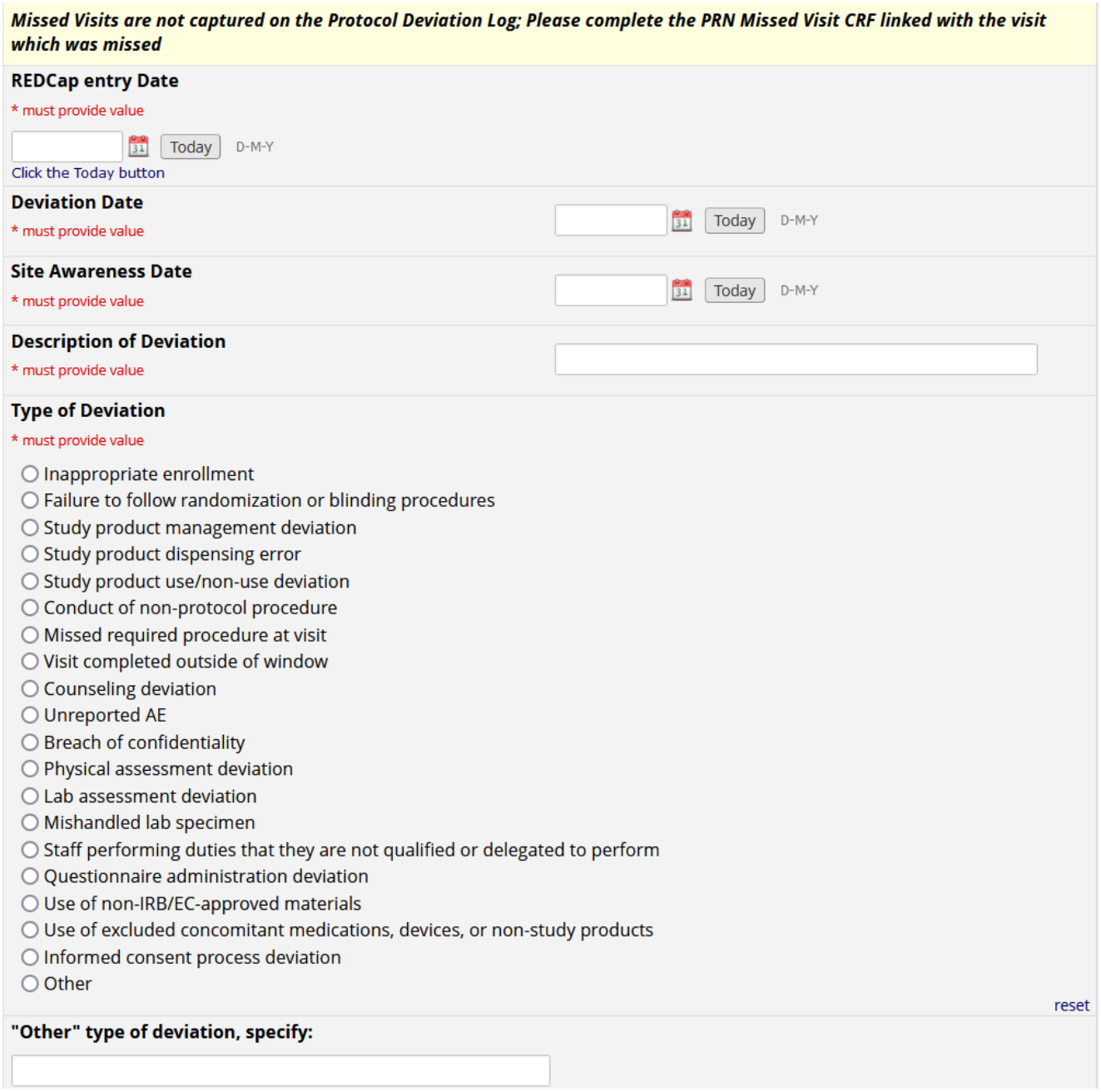


Start and Stop Dates are open entry text fields to accommodate participants who may only remember the month and/or year. These entries can have form status left as "incomplete" in the form status section, as all Pre-existing Conditions should be reviewed at enrollment, and marked "complete" then.



Protocol Deviations Log (Ongoing Logs)

Use this repeatable CRF to document each Protocol Deviation (other than missed visits which will be tracked with the "PRN Missed Visit" CRF). As Protocol Deviations are time-sensitive, please enter each one into REDCap as soon as possible. Please click the TODAY button on the eCRF to capture the entry date (this should not be back-dated if a deviation was first documented on a paper CRF).



Missed Visits are not captured on the Protocol Deviation Log; Please complete the PRN Missed Visit CRF linked with the visit which was missed

REDCap entry Date

* must provide value

Today D-M-Y

Click the Today button

Deviation Date

* must provide value

Today D-M-Y

Site Awareness Date

* must provide value

Today D-M-Y

Description of Deviation

* must provide value

Type of Deviation

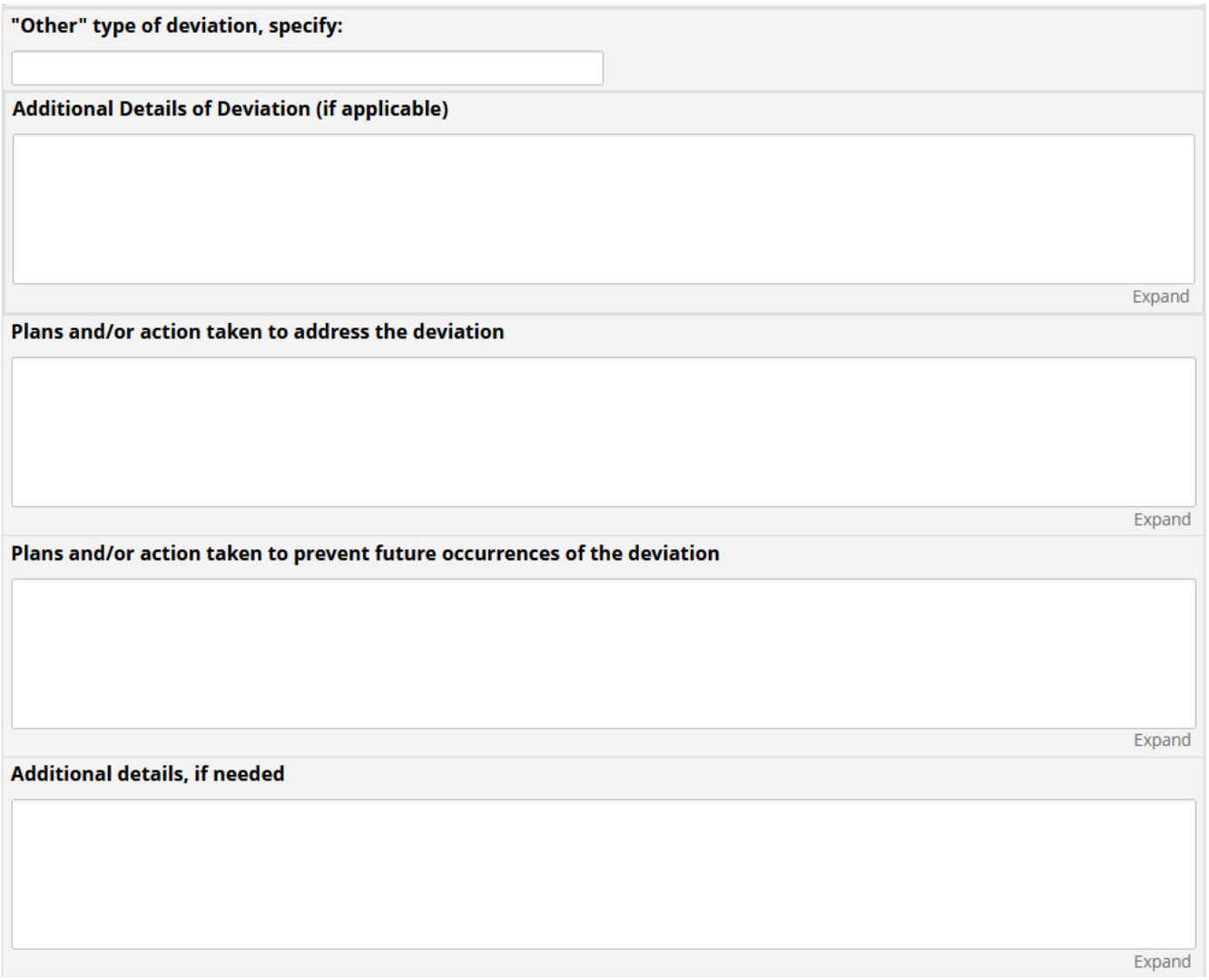
* must provide value

- ○ Inappropriate enrollment
- ○ Failure to follow randomization or blinding procedures
- ○ Study product management deviation
- ○ Study product dispensing error
- ○ Study product use/non-use deviation
- ○ Conduct of non-protocol procedure
- ○ Missed required procedure at visit
- ○ Visit completed outside of window
- ○ Counseling deviation
- ○ Unreported AE
- ○ Breach of confidentiality
- ○ Physical assessment deviation
- ○ Lab assessment deviation
- ○ Mishandled lab specimen
- ○ Staff performing duties that they are not qualified or delegated to perform
- ○ Questionnaire administration deviation
- ○ Use of non-IRB/EC-approved materials
- ○ Use of excluded concomitant medications, devices, or non-study products
- ○ Informed consent process deviation
- ○ Other

reset

"Other" type of deviation, specify:

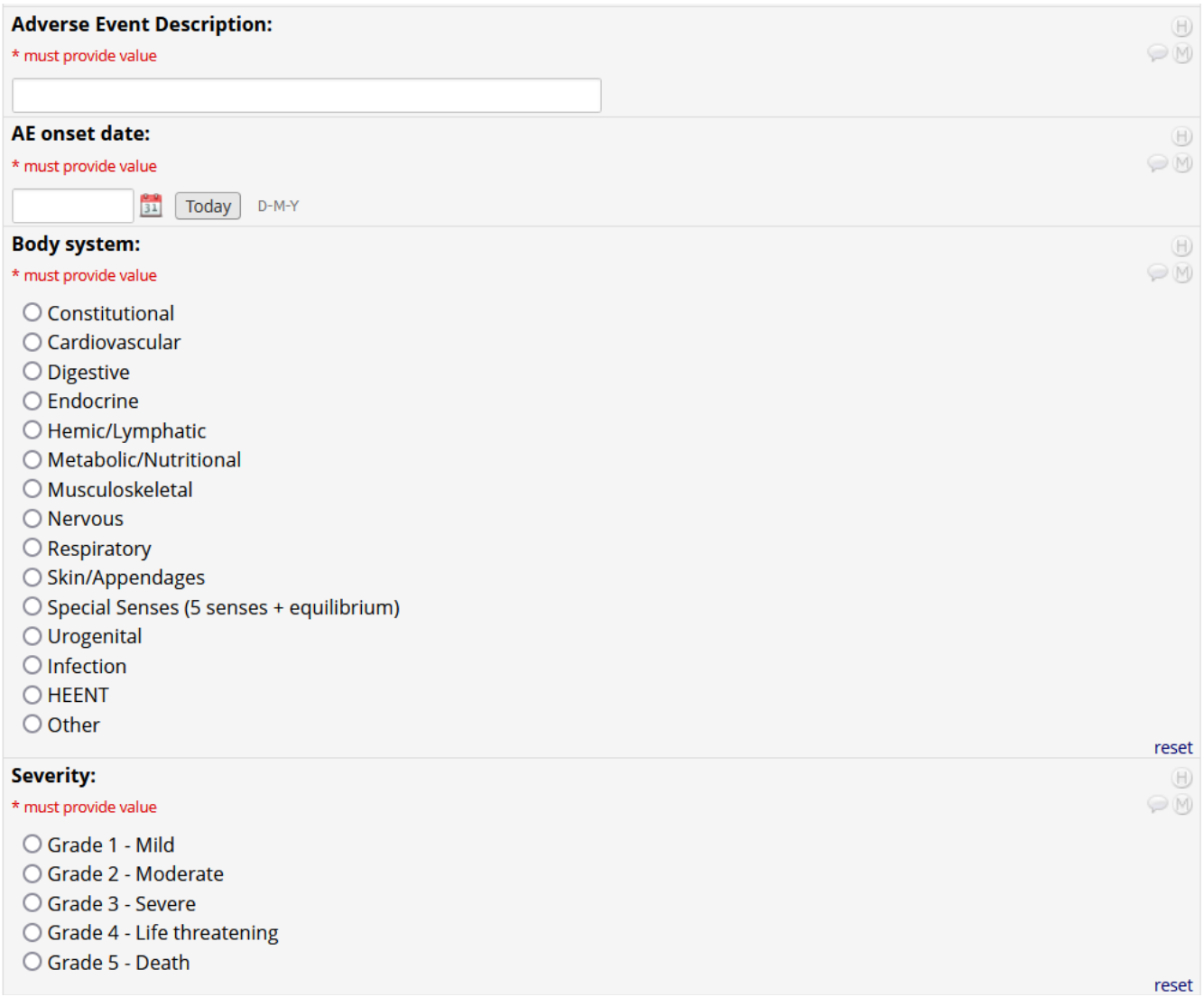
If “other” is chosen for type of deviation, a place to enter the “other” type is provided. Additional variables to enter long-form descriptions and action plans are then available and each should be completed for every deviation entered.

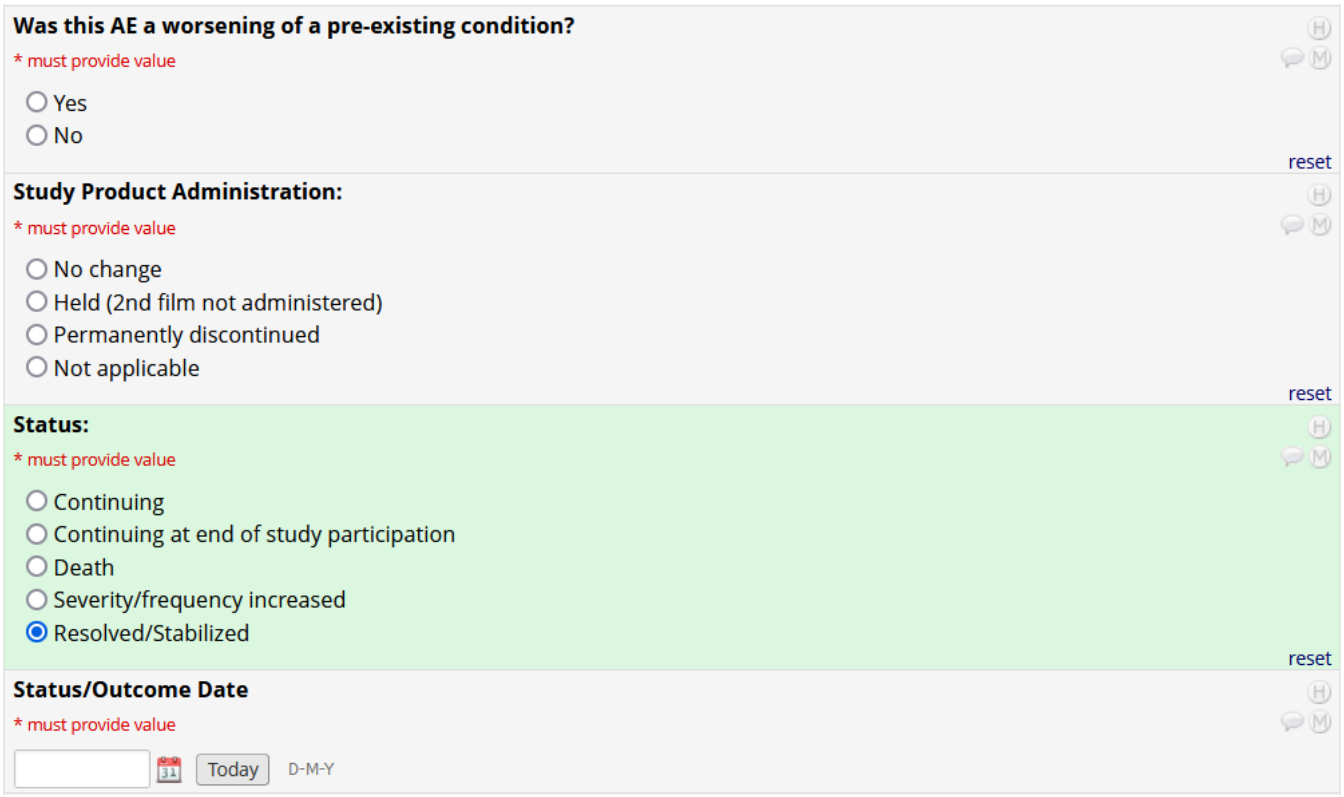


Adverse Event Log (Ongoing Logs)

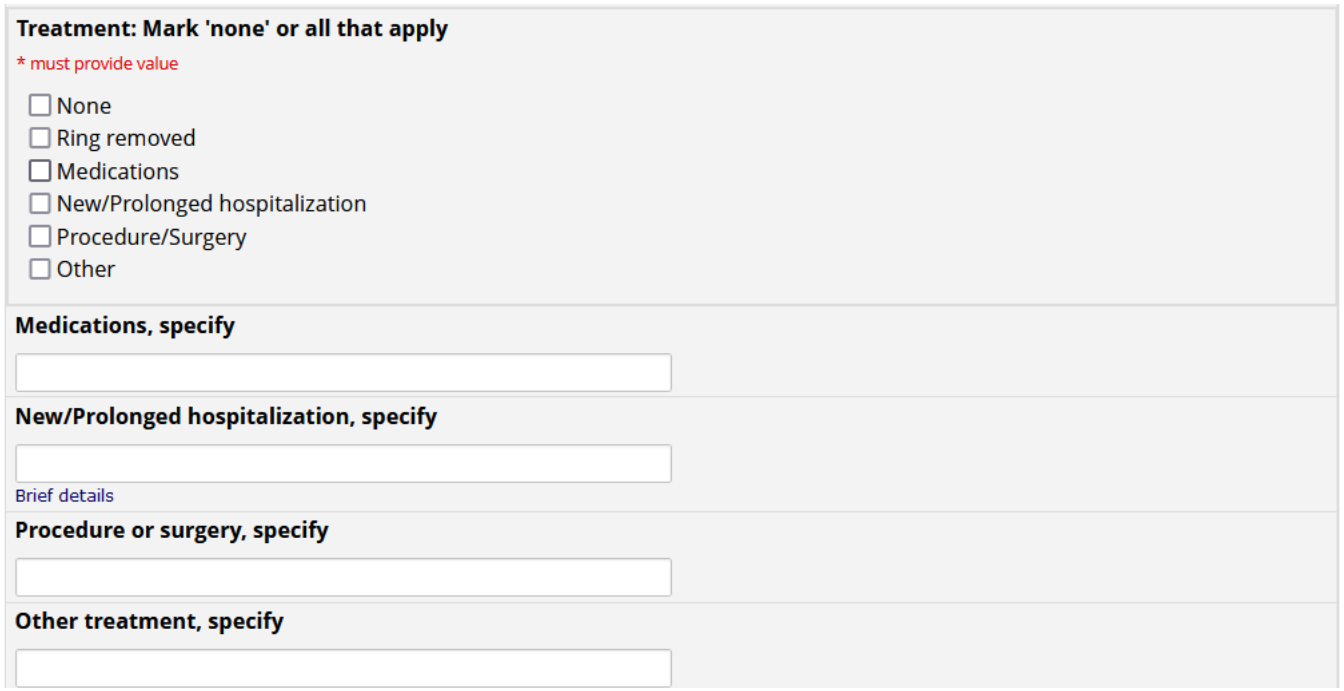
Adverse Events are time-sensitive and should be entered into REDCap as soon as possible. To track the date of entry, please click the TODAY button to capture the entry date (this should not be back-dated if AE was first documented on a paper CRF). Complete the CRF as best as possible, and update as needed.

The Adverse Event Description should be kept brief. If symptoms led to a diagnosis, the diagnosis should be entered as the Adverse Event Description rather than the symptom(s).

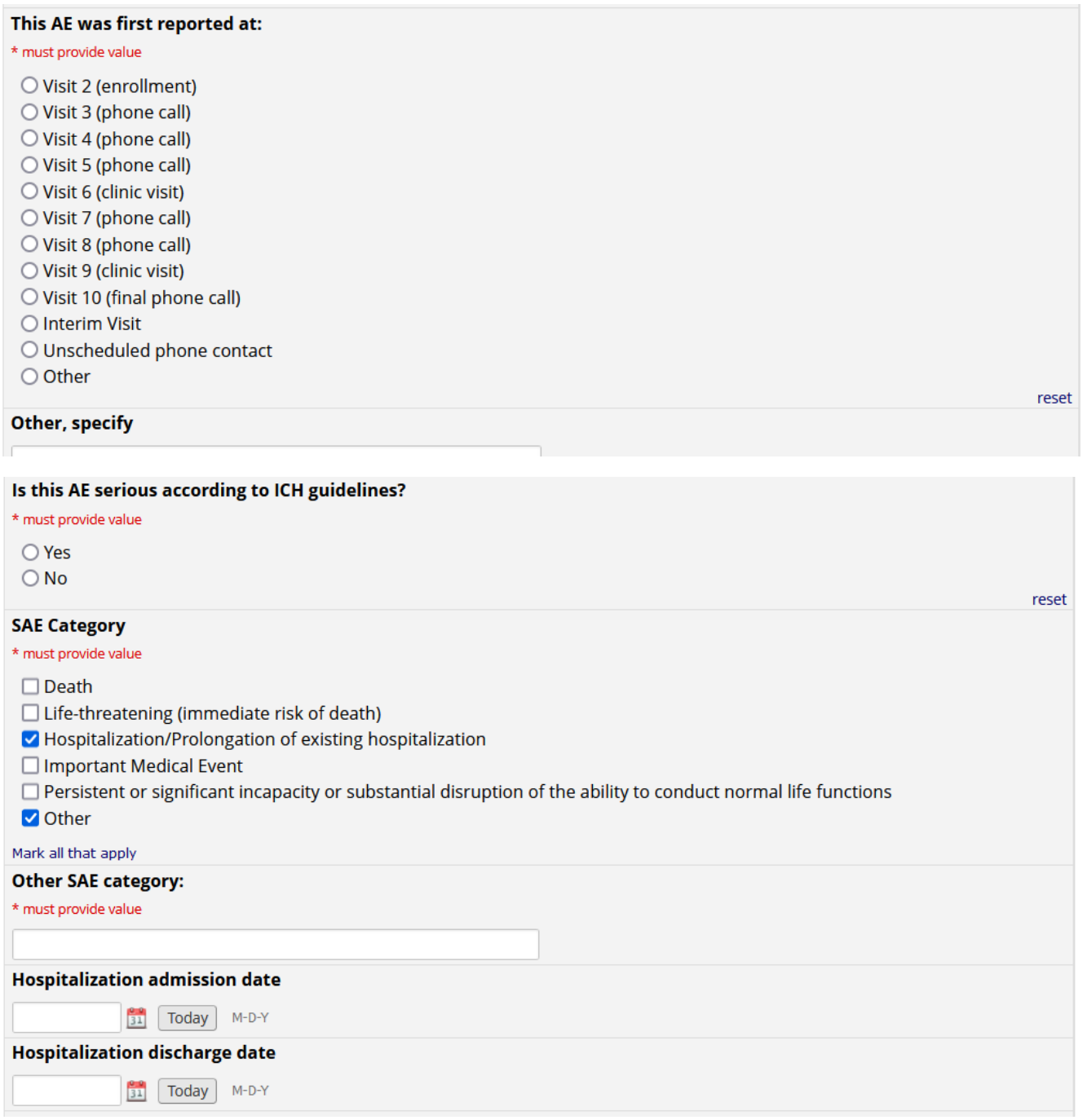




The Status/Outcome Date field is available if “Death” or “Resolved/Stabilized” is marked as the Status.



Some treatment options require additional specification.



The SAE Category Field is only visible if Yes is marked for "Is this AE serious according to ICH guidelines?" If the SAE Category is "Other," indicate the other category. If the SAE is a Hospitalization, additional details regarding admission and discharge dates are required. Next, there is a section for Diagnostic testing/labs.

Has the participant had any diagnostic testing or labs done related to this SAE?

* must provide value

○ Yes
○ No

reset

Indicate diagnostic tests and labs done, including results if known

Expand

Update as needed

(Additional space for notes, if needed)
Indicate diagnostic tests and labs done, including results if known

Dates of film use help safety physicians when reviewing SAEs and Grade 3 or higher related AEs.

Date participant had first intravaginal ring study product inserted?

* must provide value

Today D-M-Y

Has participant had 2nd intravagina ring study product inserted?

* must provide value

○ Yes
○ No

reset

Date participant had second intravaginal ring study product inserted?

* must provide value

Today D-M-Y

Relatedness is to be determined by a Clinician. An ongoing narrative documenting testing and outcomes is to be updated as more information becomes available. Each comment is to be initialed and dated (next section).

Relatedness

Relatedness to Study Product/Procedure:

* must provide value

- ○ Not related
- ○ Related

reset

Relatedness to be determined by a study clinician

Justification of relatedness (for both related and not related)

* must provide value

Expand

Name of Clinician determining relatedness

* must provide value

Please include a narrative documenting any additional treatment, hospitalization, or outcomes for this AE/SAE. Add additional notes as needed. End each note with your name or initials and the date.

Comment (1):

Expand

Comment (2):

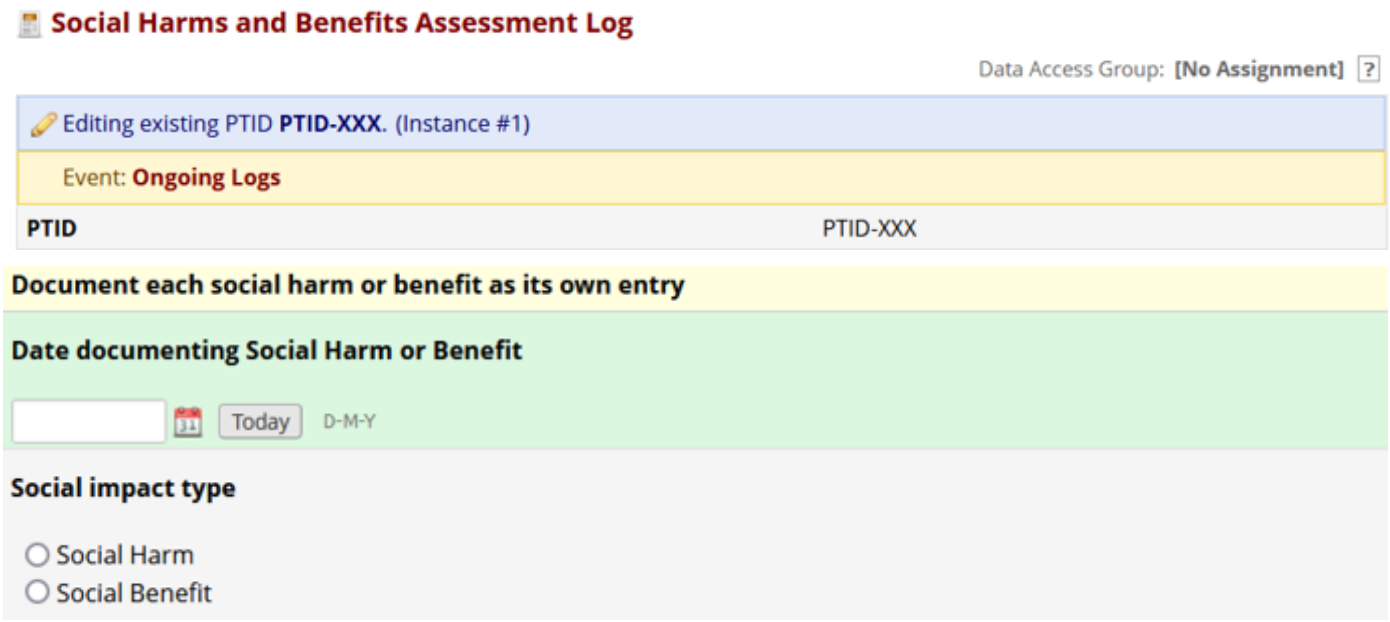
Expand

Comment (3):

Expand

Comment (4):

Social Harms and Benefits Assessment Log (Ongoing Logs)



Social impact type: Indicate whether you are documenting a social harm or a social benefit.

Definition of Social Harm: Social harms are non-medical adverse consequences experienced by study participants that are related to their participation in the study. This includes psychological, physical, sexual, legal, and economic harm.

Definition of Social benefit: Social benefits are positive impacts experienced by study participants that are related to their participation in the study. This includes psychological or physical benefits, relationship improvements, and general well-being benefits to self or community.

Depending on which is marked (harm vs benefit), the CRF will skip to the appropriate and relevant questions.

When documenting a **social harm**, follow these prompts:

Concisely describe the social harm including date(s)

Expand

How was the participant impacted by the social harm?

- ☐ Personal Relationships (Family) - Had negative experiences with family (excluding partner)
- ☐ Personal Relationships (Partner) - Had negative experiences with significant other, spouse, or sex partner
- ☐ Personal Relationships (Other) - Had negative experience with friends, neighbors or other community members
- ☐ Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country
- ☐ Employment - Was turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work
- ☐ Education - Was turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school
- ☐ Medical/Dental - Was refused medical or dental treatment, or treated negatively by a health care provider
- ☐ Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing
- ☐ Other - Had other problems not covered in the codes above

Mark all that apply

Did this involve physical harm to the participant?

- ○ Yes
- ○ No

reset

What impact did this situation have on the participant's quality of life?

- ○ Minimal disturbance
- ○ Moderate disturbance; no significant impact
- ○ Major disturbance with significant impact
- ○ Unknown

reset

Describe what was done by staff and participant to address social impact

Expand

Current status:

- ○ Unresolved
- ○ Unresolved at end of study
- ○ Unable to resolve; no further action taken
- ○ Resolved

reset

When documenting a **social benefit**, follow these prompts:

Concisely describe the social benefit including date(s)

Expand

The social benefit was related to

- ☐ Pride about project participation: Feels pride about participation in research
- ☐ Feeling better about oneself: Improved self-esteem or feeling of empowerment
- ☐ Education: The study educated the participant or inspired /enabled participant to restart school or improve school performance.
- ☐ Housing: The participant obtained better or improved her housing situation
- ☐ Nutrition/food: The participant was able to improve nutrition or amount of food intake for self or family.
- ☐ Improved communication: Participant learned more effective ways of communicating with family, friends, employers or others
- ☐ Work: Obtained or improved employment situation (includes informal work)
- ☐ Income: Obtained or increased income (includes getting study reimbursement)
- ☐ HIV testing: The participant received regular HIV testing
- ☐ Treatment of STIs: The participant was able to treat STIs
- ☐ Treatment of other illnesses: The participant was able to treat/consult with a doctor about other illnesses (non-STIs)
- ☐ Family Planning/Contraception: The participant was able to access contraception and family planning services
- ☐ Preventative care services: The participant was able to receive preventative health care such as pap smears.
- ☐ Staying HIV free: study provided more effective ways for the participant to avoid becoming infected with HIV
- ☐ Altruism: Participant helping community/others by participating in research
- ☐ Activities: Participant became involved in community activities
- ☐ Peer Support: Participant felt supported by or was able to provide support to peers
- ☐ New relationships: Participant created new relationships
- ☐ Other

What impact did this situation have on the participant's quality of life?

- ○ Minimal
- ○ Moderate - no significant impact
- ○ Major - significant impact
- ○ Unknown

reset

Did this involve social benefit to someone other than the participant?

- ◉ Yes
- ○ No

reset

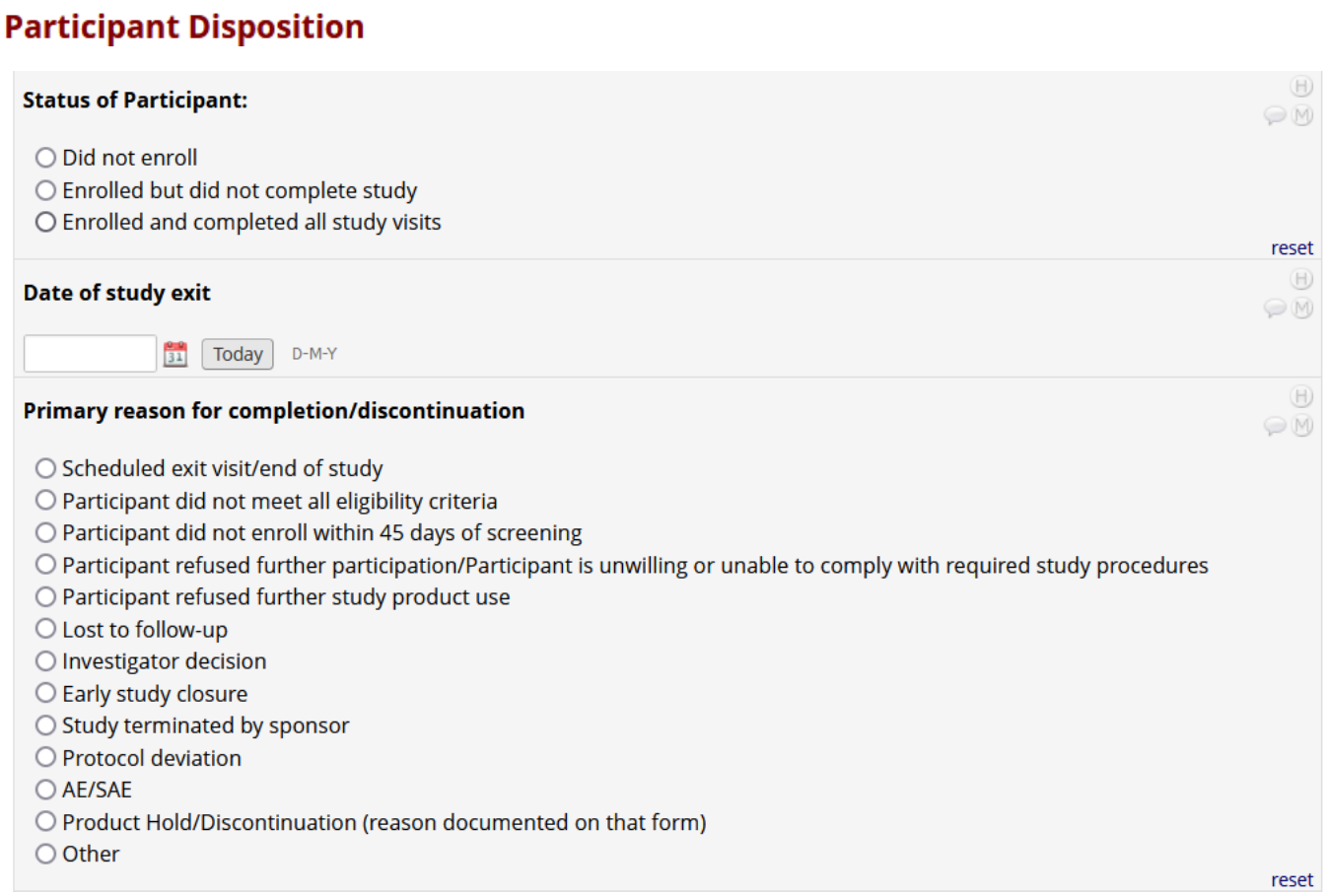
Indicate who else benefitted

Product Hold/Discontinuation Folder (CRFs available for completion as needed)

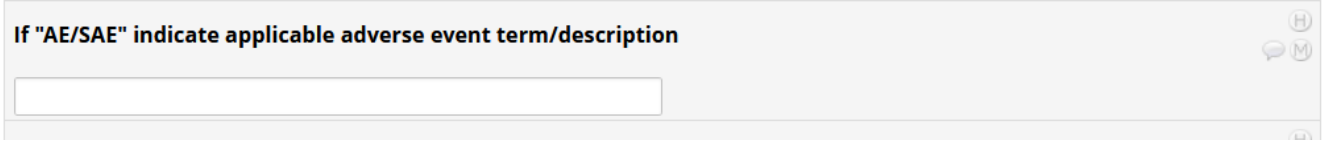
Participant Disposition CRF

All participants who have been assigned a "PTID" in REDCap must have this CRF completed once their participation in the study has ended. Usually this will occur at Visit 9 (Study Exit Visit), unless the participant exits the study prior to completion.

Shown below as viewed upon opening in REDCap. Additional questions populate based on the answer to the Primary reason for completion/discontinuation. If the participant has completed the study, the only other question to complete is related to evaluability, with an option to document additional relevant details below.

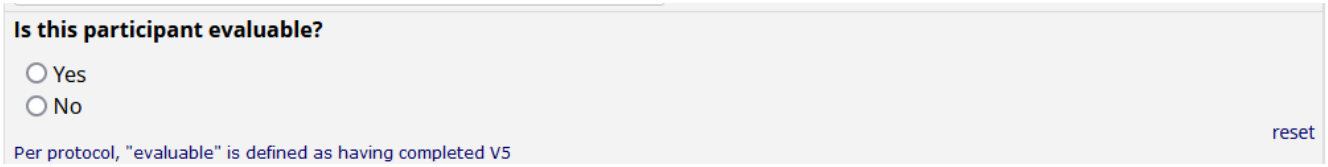


If AE/SAE is marked as the reason, there is an additional question to indicate which AE:

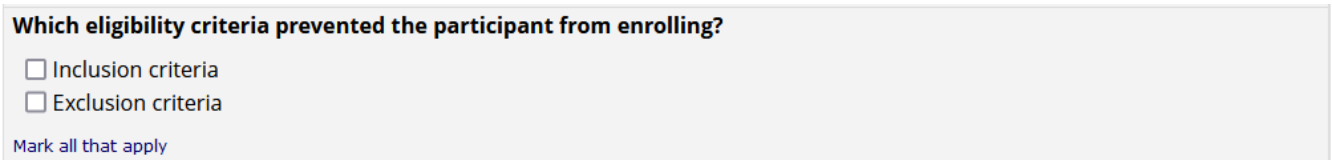


And if Other is marked, specify other reason:

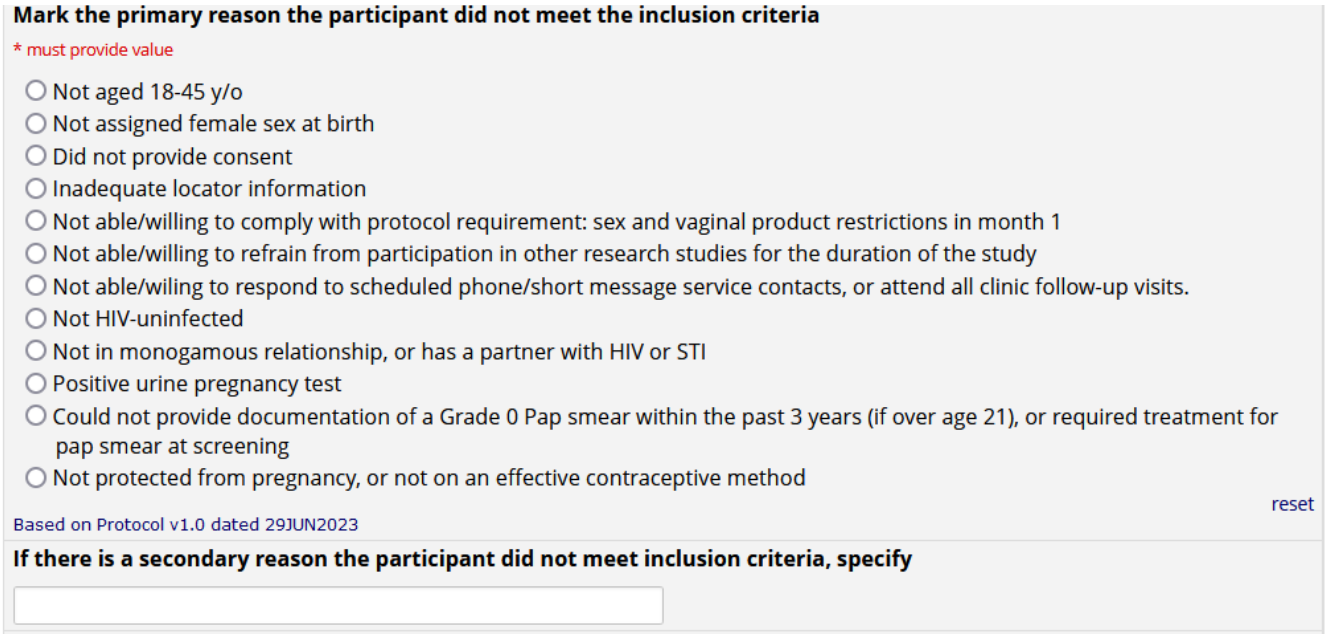
If the participant did enroll, the question “Is the participant evaluable?” will appear. As indicated in the footnote of the question, per protocol, evaluable is defined as having completed V5. This question is only skipped if the participant did not enroll.



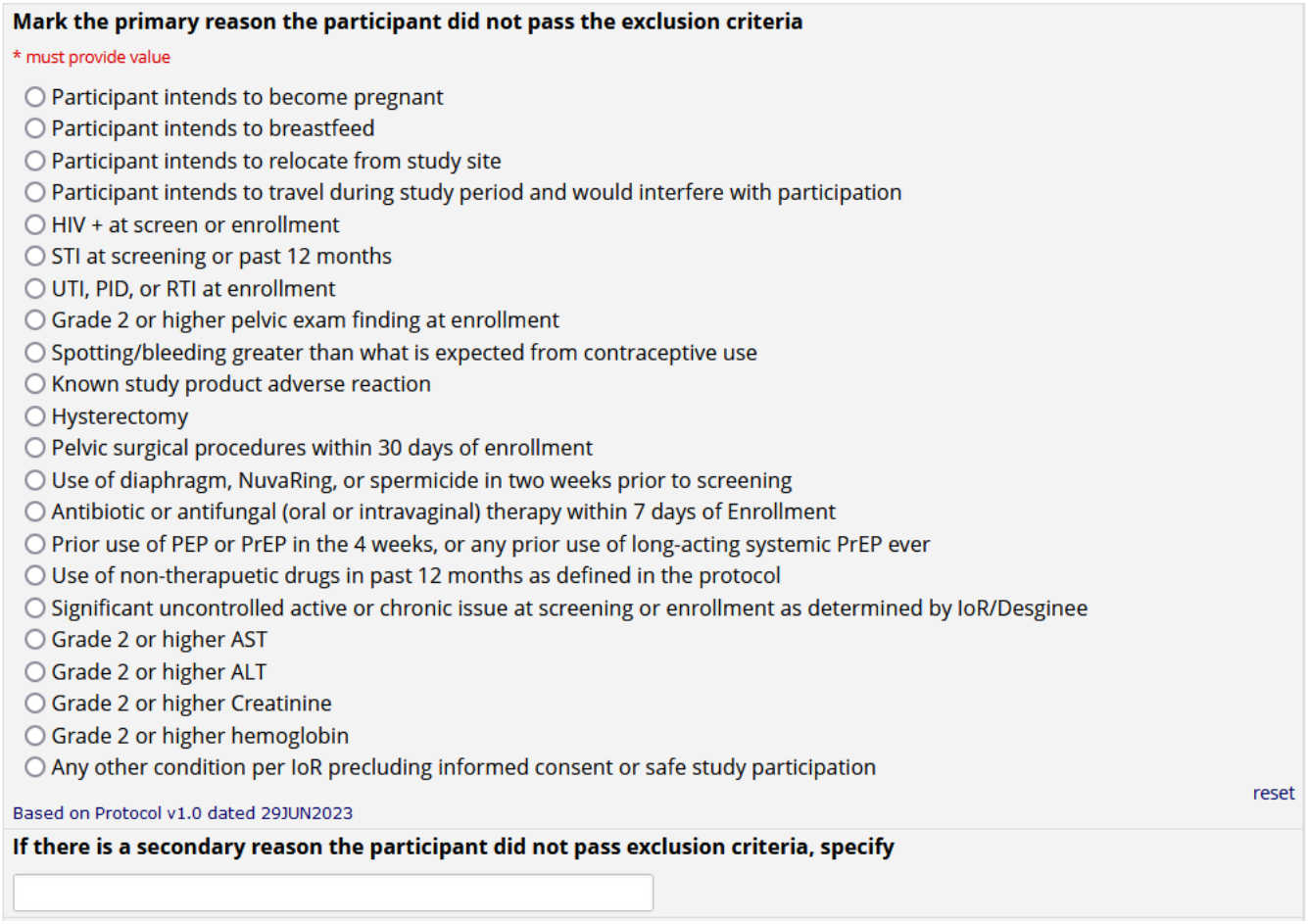
If “Participant did not meet all eligibility criteria” from above, the following question is to be answered:



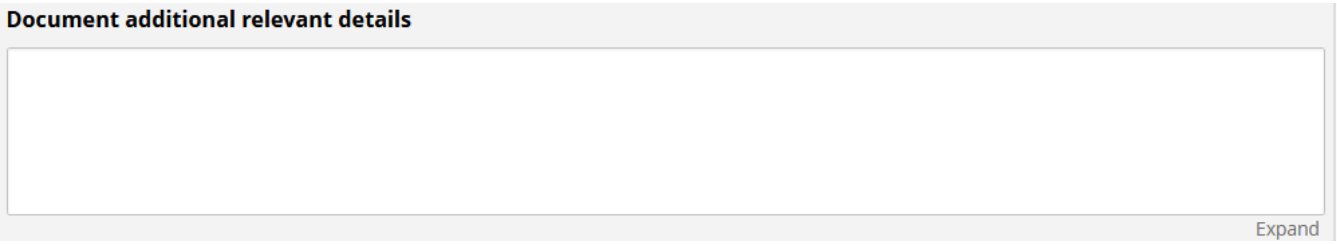
If “Inclusion criteria” is marked, the following question asks the primary reason, and there is a place to indicate a secondary reason, if applicable:



If “Exclusion criteria” is marked, the following question asks the primary reason, and there is a place to indicate a secondary reason, if applicable:

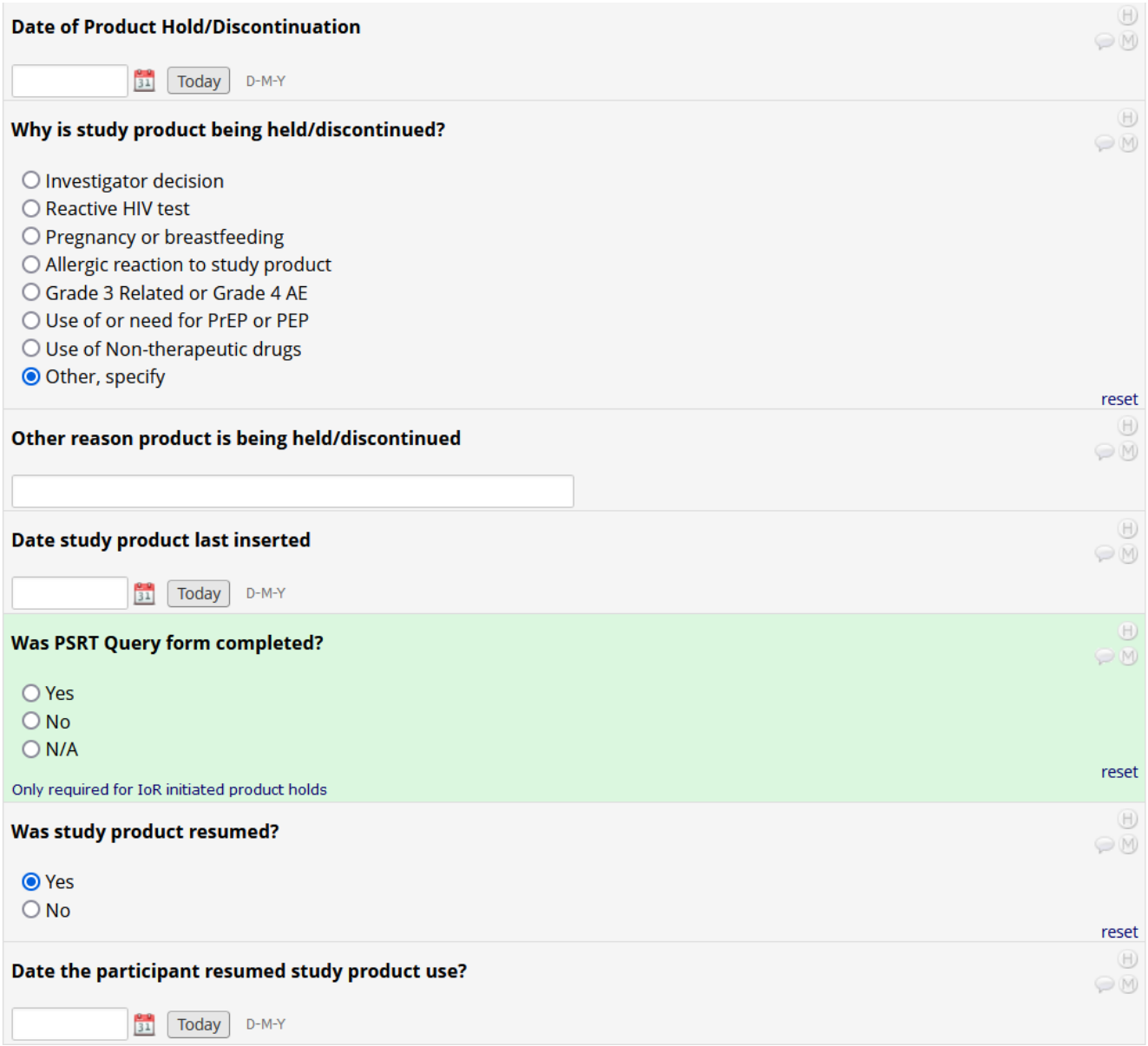


Additional details can be added in a narrative note box:



Study Product Hold/Discontinuation Log (repeatable CRF to be used as needed)

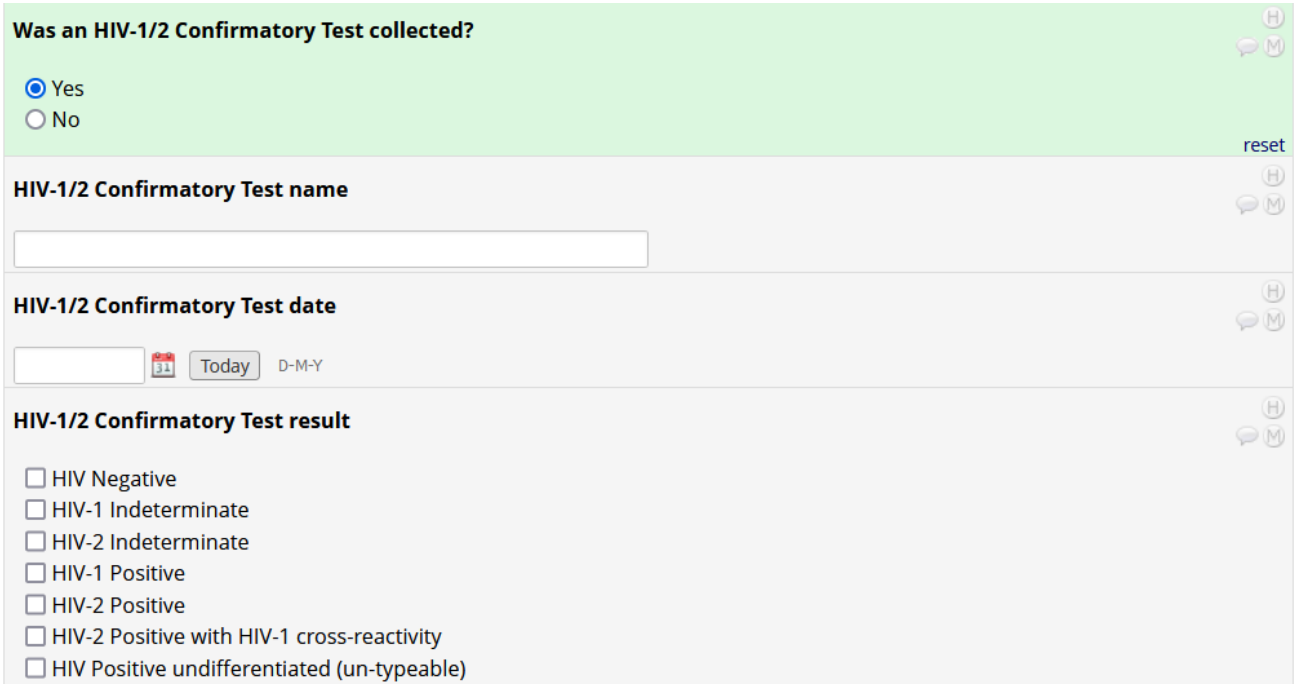
Use this CRF if study product has been held/discontinued. If study product is not resumed, then complete the Participant Disposition CRF as well.



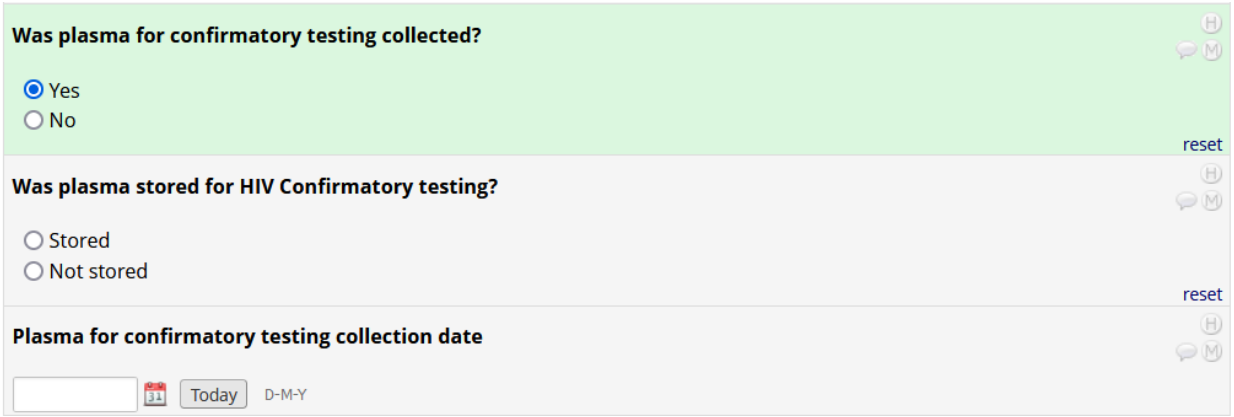
HIV Confirmatory CRF

If a participant tests positive for HIV, this CRF documents the confirmation of the positive test.

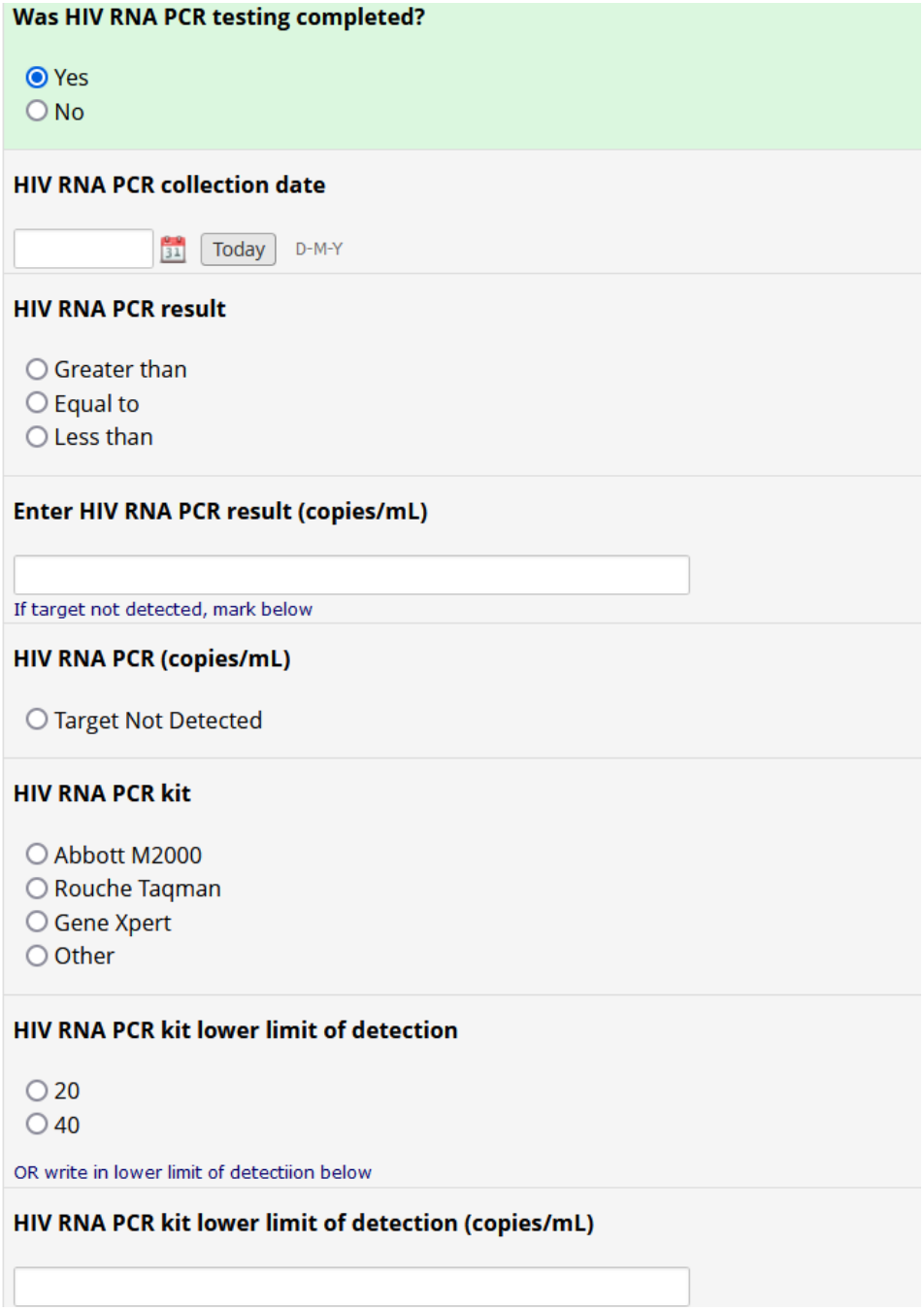
When YES is marked for “Was an HIV Confirmatory Test Collected?” additional questions appear in REDCap:



Additional questions also appear if a plasma confirmatory test was collected:



And if an HIV RNA PCR test was completed:

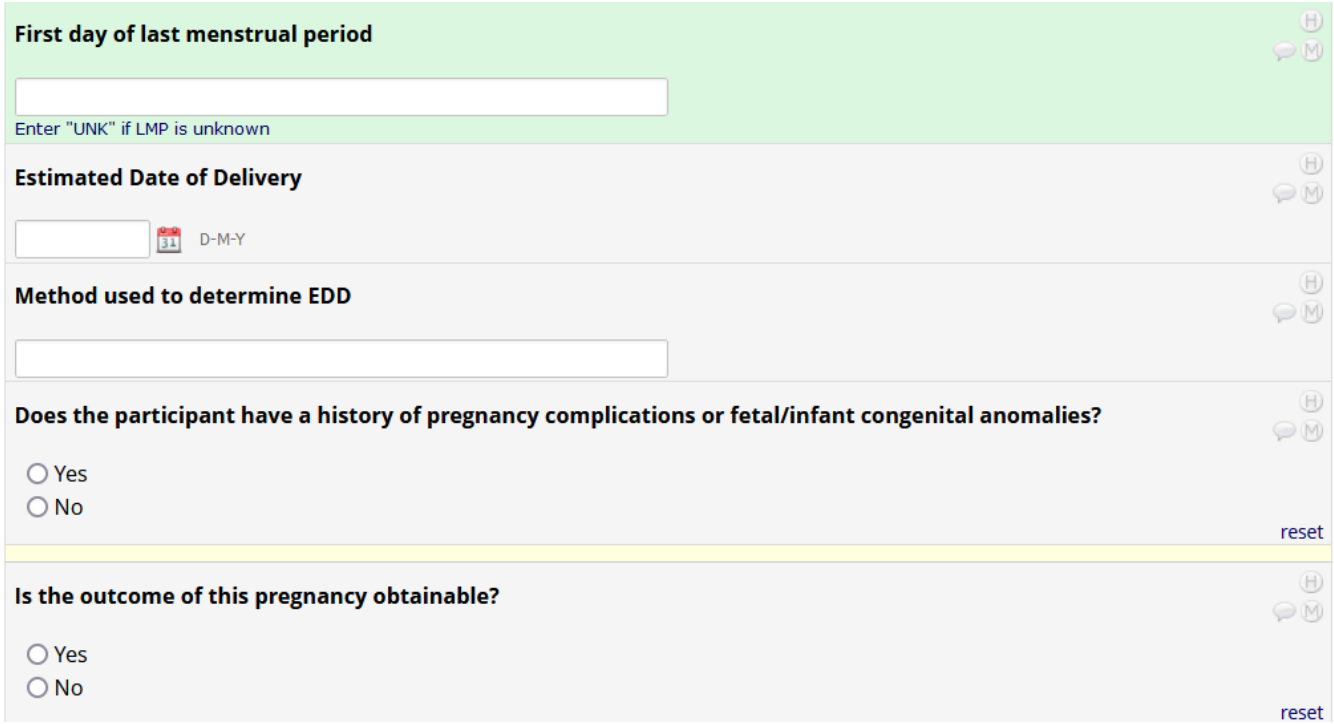


Most importantly, the Final HIV Status field must be completed:

Pregnancy Report and Outcome CRF

This CRF is only used if a participant becomes pregnant

- This form is used to report a pregnancy and pregnancy outcome(s) reported post-enrollment.
- Every effort should be made to follow the pregnancy to outcome.
- Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that the outcome is unobtainable.
- A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact the Data Manager for guidance on how to complete this form.

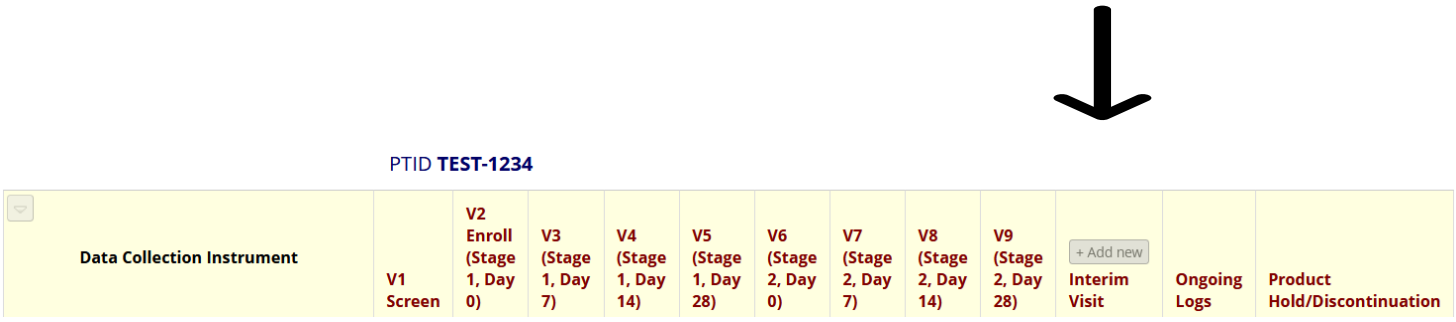


Additional questions related to the pregnancy outcome will populate in REDCap, once "Is the outcome of this pregnancy obtainable?" is answered. As pregnancy and pregnancy outcome information may be limited, it is expected that many of the variables on the Pregnancy Report and Outcome CRF will be blank. The CRF should be completed as thoroughly as possible when the pregnancy is first reported. Updates to the CRF can be made with each follow-up attempt as appropriate.

Interim Visits

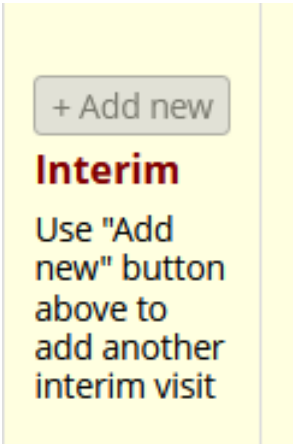
Interim Visits can occur at any time once the participant is randomized. Each instance of an Interim Visit allows access to all clinical follow-up CRFs, though only those CRFs needed should be used. However, the Updated Medical and Menstrual History CRF should be completed for every Interim instance (unless the CRF was completed at a regularly scheduled study visit within the past 24 hours). The Visit Summary CRF should also be completed for all instances of an Interim Visit.

Interim Visits have their own folder on the REDCap participant Dashboard (after V19):



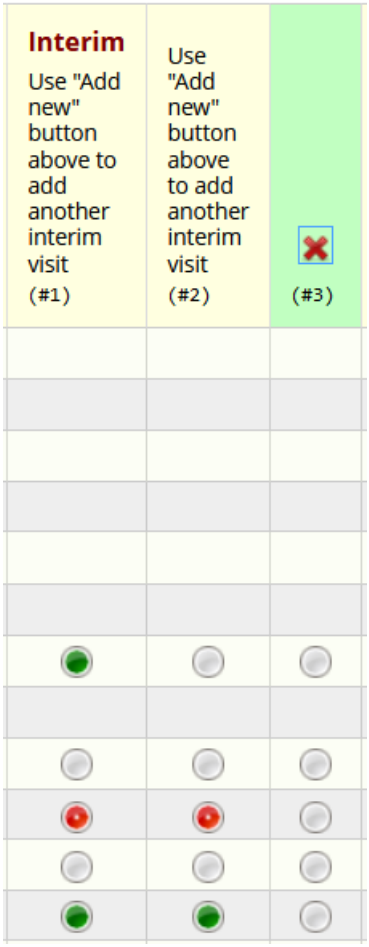
Enlarged View:

To add another interim visit instance, you click the “+Add new” button at the top of the Dashboard Folder.



Each Interim Visit must be documented as its own instance.

This partial screen grab of the PTID's dashboard indicates 2 Interim visits have already occurred, and another (#3) is about to be entered into REDCap. Each Interim visit has its own column on the PTID's dashboard in REDCap.



Remember, regardless of what CRFs are needed to document the procedures completed at an Interim Visit, the Visit Summary CRF must be completed for each instance of an Interim Visit.

DocuSigned by:
Leslie Meyn
Signer Name: Leslie Meyn
Signing Reason: I approve this document
Signing Time: 1/19/2024 | 11:41:59 AM EST
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