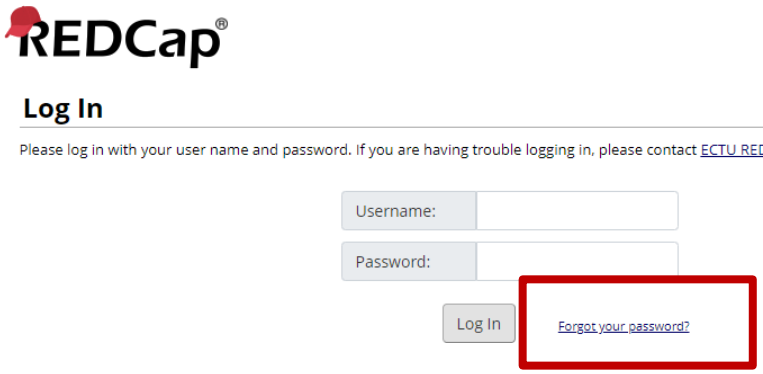
GRACE REDCap Guide

Setting Up a User Account

To obtain access, please complete the eCRF access form provided by the Trial Manager. REDCap can be accessed here: https://redcap.clinicaltrials.ed.ac.uk/. Once added to the system, you will receive a username and password by email. You will be prompted to set your password and a security question/answer when first logging on. Passwords must be 9 characters in length and must consist of one lower case letter, one upper case letter and one number.

Resetting Your Password

Passwords can be reset from the log in page by selecting 'Forgot your Password?'

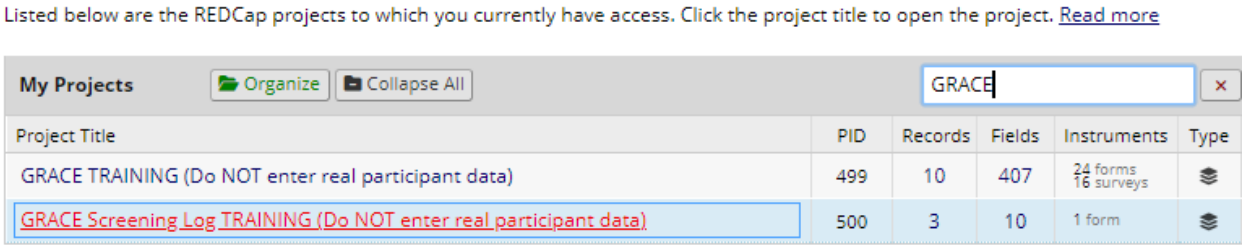


Enter your username and password to verify the account and answer your security question. Once these details have been provided, you will receive an email from REDCap with a link to reset your password.

You may change your password at any time by clicking on 'My Profile'. This page also allows you to reset your password recovery question and personal details.

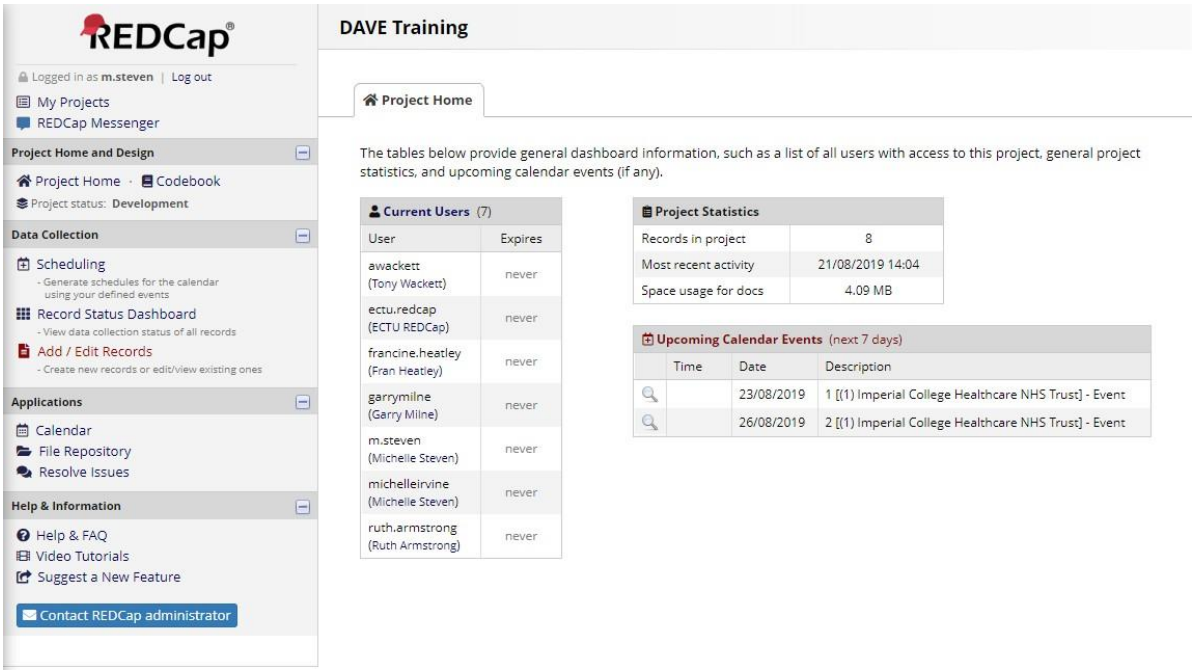
Accessing a Project

To access the GRACE database, click the 'My Projects' link at the top of the toolbar on the homepage. Projects may be a combination of both training and live databases. The 'Status' column displays whether a project is a training database ( ) or if it is a live database ( ). Training databases will also have **Training** in the Project Title. **Please ensure participant data is only entered in the LIVE database.**

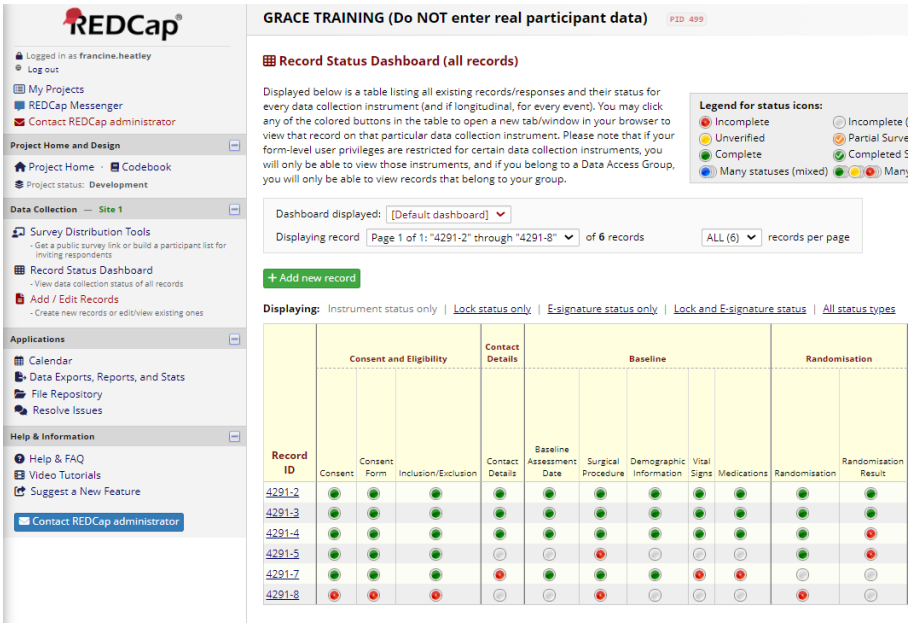


Navigating the Project Homepage

Selecting a project name from the REDCap homepage directs you to that project's homepage. The menu on the left of the screen allows you to navigate further within the project and access the Record Status Dashboard, and Data Quality applications.



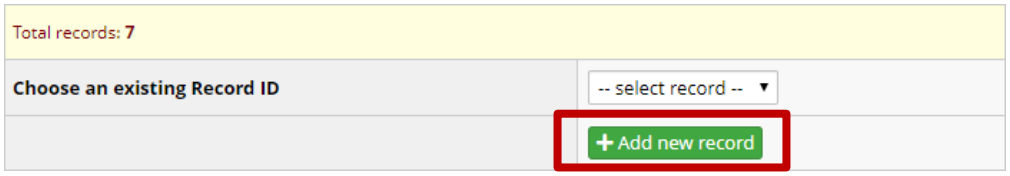
Record Status Dashboard



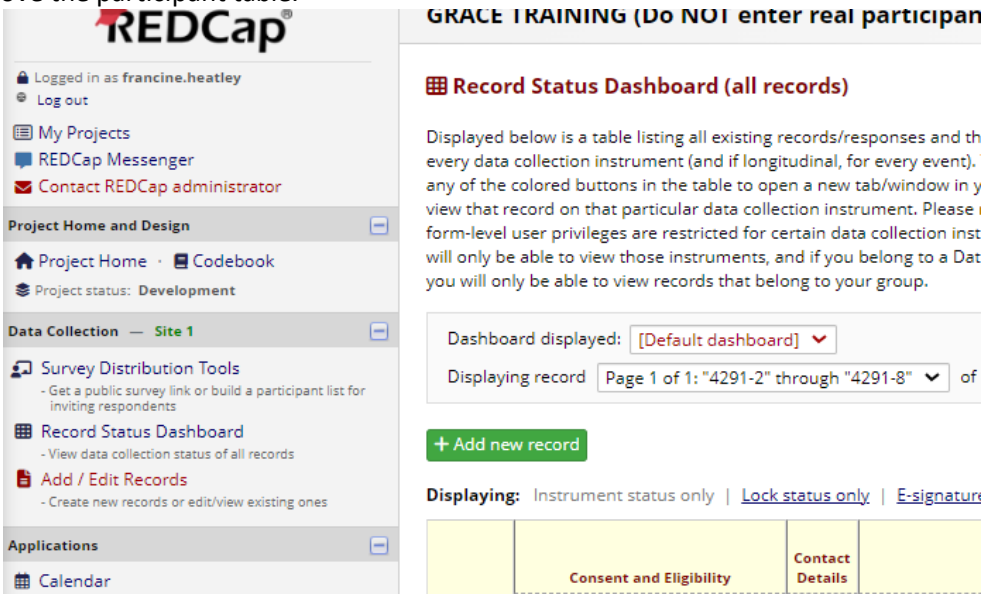
The Record Status Dashboard provides an overview of all participants at your site. Each row corresponds to a different participant. The Record Status Dashboard is accessed from the menu on the left of your screen.

Adding a Participant

To add a participant, click on Add/Edit Records in the menu on the left of your screen. You can also use this page to locate existing participants. Select the 'Add new record' button to add a participant. To search for an existing participant, choose the participant from the drop down menu.



Alternatively, you can add a participant from the Record Status Dashboard. Select the 'Add new record' button above the participant table.

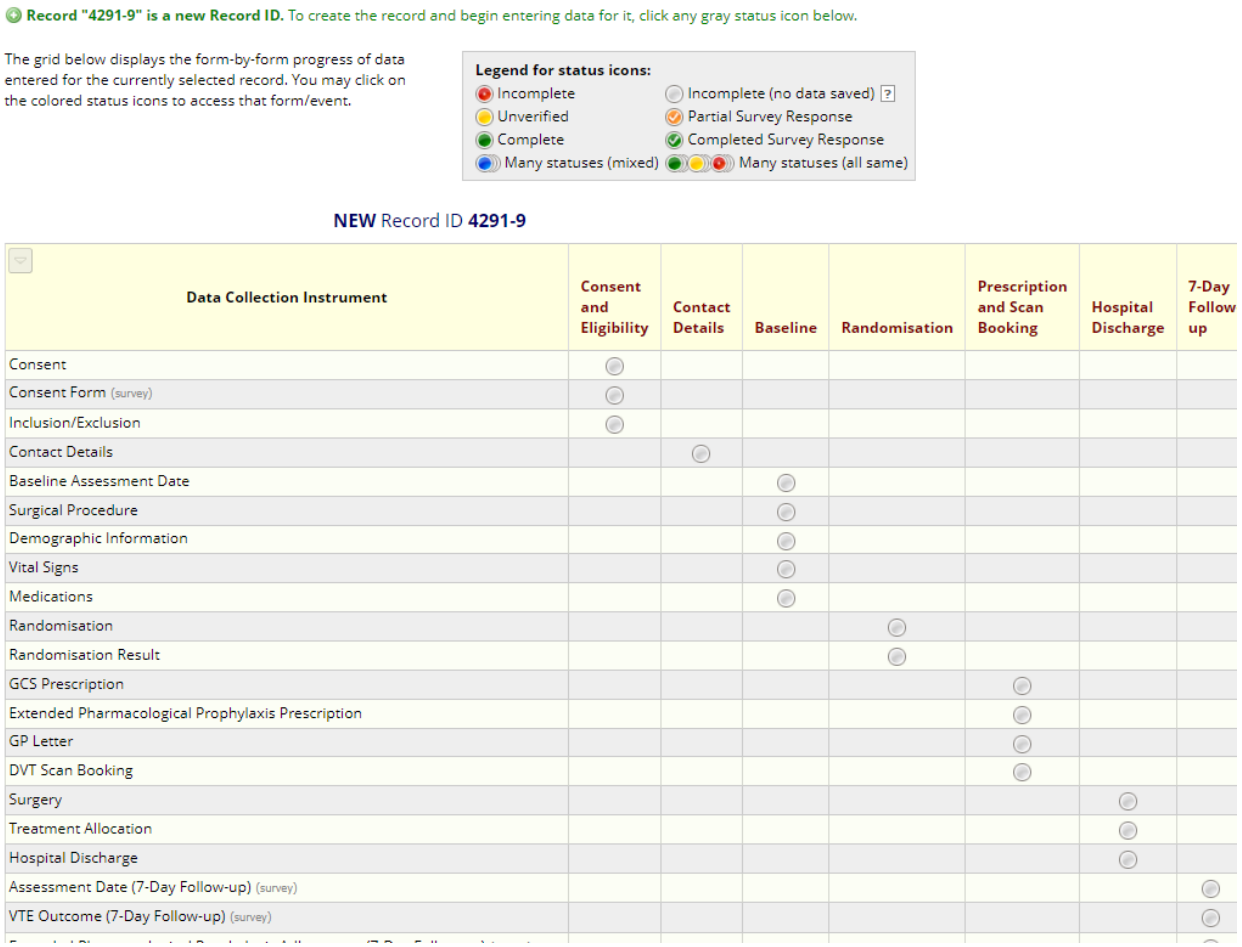


REDCap will automatically assign the participant's trial ID. The participant's ID is formatted as two parts: the first 3-digit number is unique to your site. The second number is unique to the participant and increases sequentially with each participant added to REDCap.

Data Entry: General Guidance

Once a participant has been successfully added to the system, the participant's visit schedule will be available for data entry. Each grey circle on the visit schedule represents a CRF (called 'Instruments' in REDCap). The column headers represent different visits or study activities within the study (e.g. *Consent, Inclusion/Exclusion, Contact details, Baseline).*

The participant's progress through the study can be visualised as movement from left to right across the grid.



Record "4291-9" is a new Record ID. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:

Incomplete	Incomplete (no data saved)
Unverified	Partial Survey Response
Complete	Completed Survey Response
Many statuses (mixed)	Many statuses (all same)

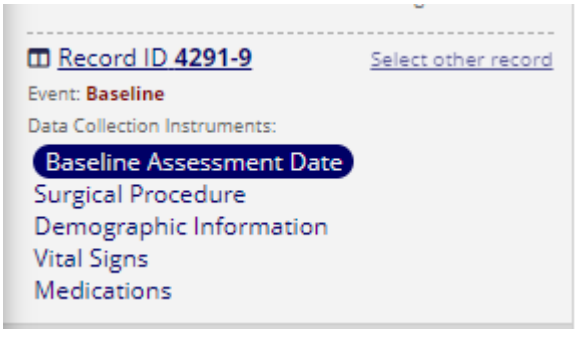
NEW Record ID **4291-9**

Data Collection Instrument	Consent and Eligibility	Contact Details	Baseline	Randomisation	Prescription and Scan Booking	Hospital Discharge	7-Day Follow up
Consent	●						
Consent Form (survey)	●						
Inclusion/Exclusion	●						
Contact Details		●					
Baseline Assessment Date			●				
Surgical Procedure			●				
Demographic Information			●				
Vital Signs			●				
Medications			●				
Randomisation				●			
Randomisation Result				●			
GCS Prescription					●		
Extended Pharmacological Prophylaxis Prescription					●		
GP Letter					●		
DVT Scan Booking					●		
Surgery						●	
Treatment Allocation						●	
Hospital Discharge						●	
Assessment Date (7-Day Follow-up) (survey)							●
VTE Outcome (7-Day Follow-up) (survey)							●

Data entry should ideally be completed starting at the top of the event column moving down.

To begin data entry, select the relevant grey circle and the CRF will open. Alternatively, you may select the participant's Record ID from the Record Status Dashboard screen.

If multiple CRFs are completed in an event, you can further navigate the CRFs in that event in the menu on the left of your screen. Select the CRF name to open that CRF. To return to the participant's visit schedule, select the participant's Record ID from the menu.

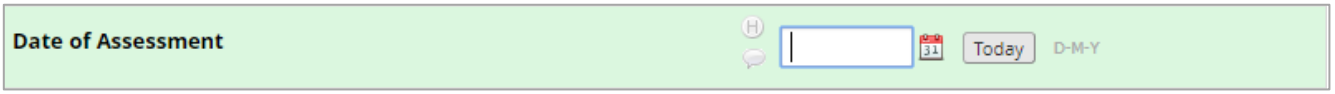


Data Entry: Field Types

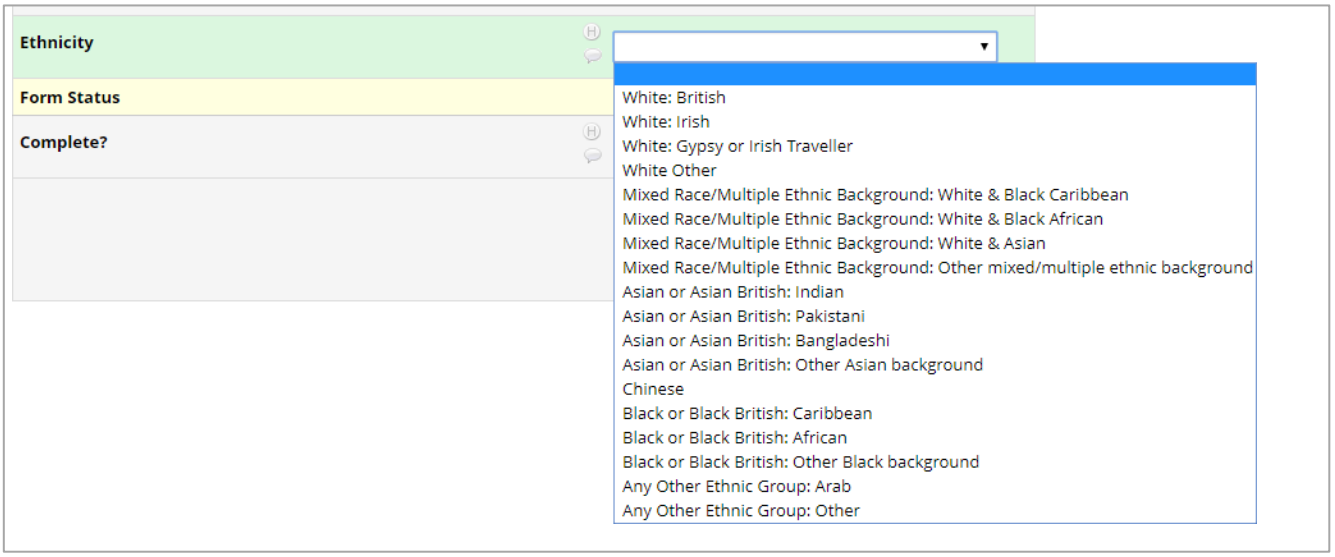
REDCap has several different data field types you may encounter:

Text Fields **text fields include fields where a numerical response is required, e.g. Weight*

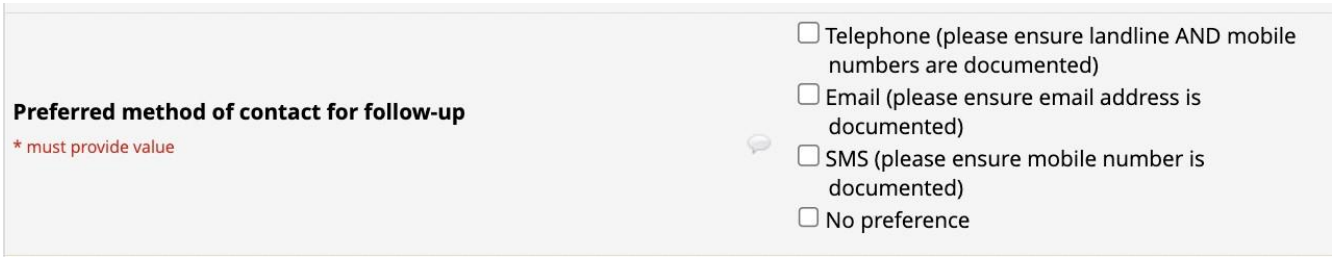
Date Fields



Drop Down Fields



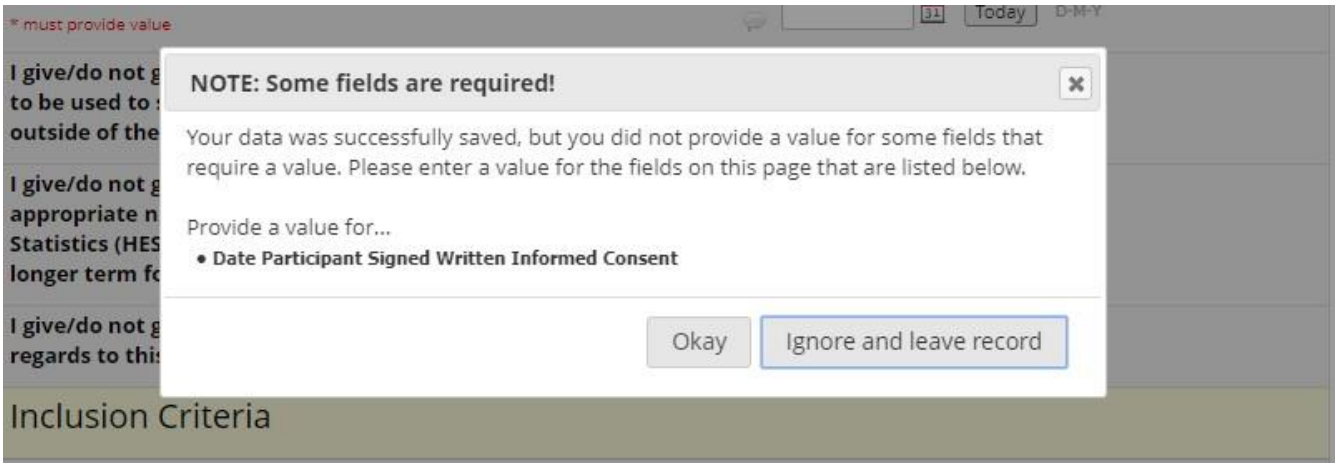
Checkbox Fields



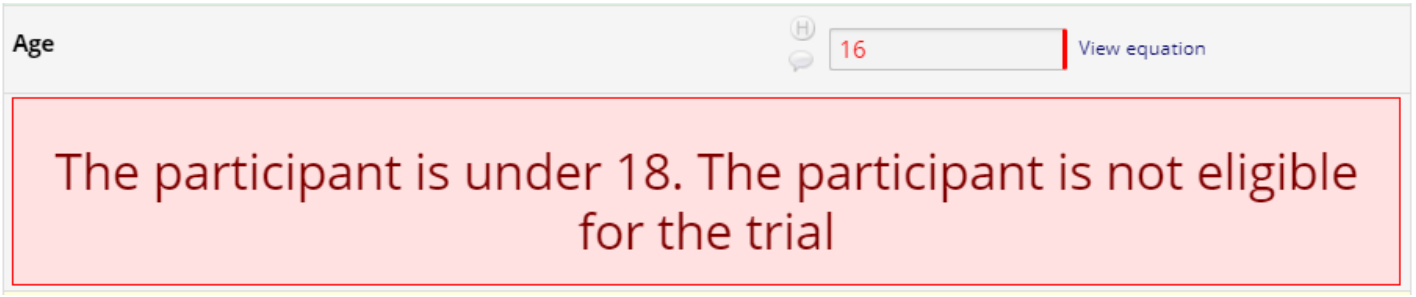
Calculated Fields **Calculated fields perform real time calculations based on entries in other fields*

Data Entry: Alerts

Some data entry fields are required fields. If left blank, a message will display reminding you to enter data in that field.



There may also be fields with pre-defined ranges. If a result is entered outside the pre-defined range, an alert will appear telling you the expected range of this field.



There may also be fields that are restricted to a certain format. This includes date fields (DD/MM/YYYY), integers, and fields with a required number of decimal places. **You will not be able to save the page until the non-conformant data has been removed or amended to the correct format.**

Completing a Form

At the end of each CRF, there is the option to complete the 'Form Status' field. The 'Form Status' has a drop down list of three options: Complete, Unverified, and Incomplete. CRFs can be saved at any time.

Incomplete

When the form status is marked 'Incomplete', the CRF icon on the participant's visit schedule changes to a red circle, as shown in the example below. The CRF will automatically default to 'Incomplete' when data entry begins. It is recommended that the 'Incomplete' option is used when further data entry is required on a CRF

Unverified

When the form status is marked as 'Unverified', the CRF icon on the participant's visit schedule changes to a yellow circle, as shown in the example below. **Nb. Please do not use the unverified option.**

Complete

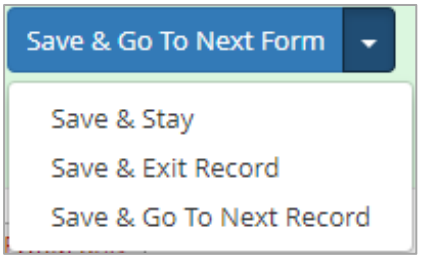
When the form status is marked as 'Complete', the CRF icon on the participant's visit schedule changes to a green circle, as shown in the example below. Please use the 'Complete' option when no further data entry will be performed for a CRF. **Nb. This option can be used if data fields are missing from the CRF. It should only be used when you are satisfied that further data cannot be entered.**

Data Collection Instrument	Consent	Screening & Eligibility
Assessment Date (survey)		
Consent Information	○	
Consent Form (survey)	●	
Screening		●
Contact Details		●
VTE Score		
Pregnancy (if female)		●
Inclusion / Exclusion Checklist		○
Confirmation of Eligibility		
Demographics		

Saving a CRF

Data can be saved at any time. You do not have to enter data in all fields on a CRF before saving.

At the bottom of the page is the save box. There are six save options available.



Save and Exit Form

- Saves the data and returns you to the participant's visit schedule

Save and Stay

- Saves the data and returns you to the top of the current page

Save & Go To Next Form

- Saves the data and takes you to the next CRF for that participant

Save & Exit Record

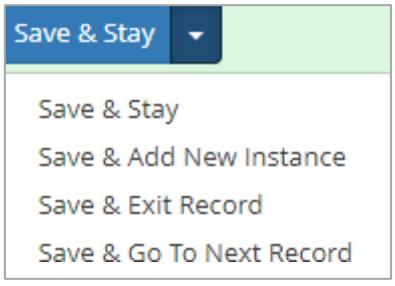
- Saves the data and takes you back to the 'Add/Edit Records' page

Save & Go To Next Record

- Saves the data and takes you to the 'Record home page' of the next existing participant number. This will only be an option if there are other participants already entered. **We recommend you do NOT use this option.**

Save & Add New Instance

- Saves the data for a repeating form and adds a new instance of that page. Each instance has identical data fields. This option will only appear if the CRF is set up as a repeating form.



Repeating Forms

It is possible for certain data entry pages to repeat as many times as required (e.g. Adverse Events with GCS).

A Repeating Instrument is an individual instrument that can be added multiple times for the same participant. This applies to the following instruments:

Contact Attempts Log
Addition scans
Serious Adverse Events Form
Protocol Deviation / Violation Form

A new data entry screen for repeating CRFs can be added from multiple places in REDCap.

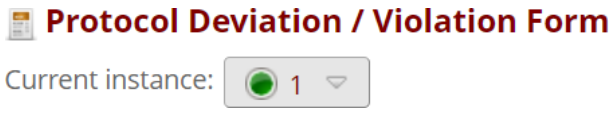
Method 1

1. Once the first dataset has been saved, Repeating Instruments will look like this on the Record Status Dashboard

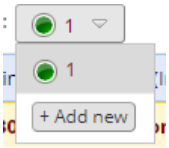
2. Clicking on the plus symbol next to the coloured orb will direct to a new blank instance of the instrument

Method 2

1. Access an existing instance of the instrument by clicking on the coloured orb and entering the page. The already entered dataset will appear with a Current Instance tab at the top of the page:



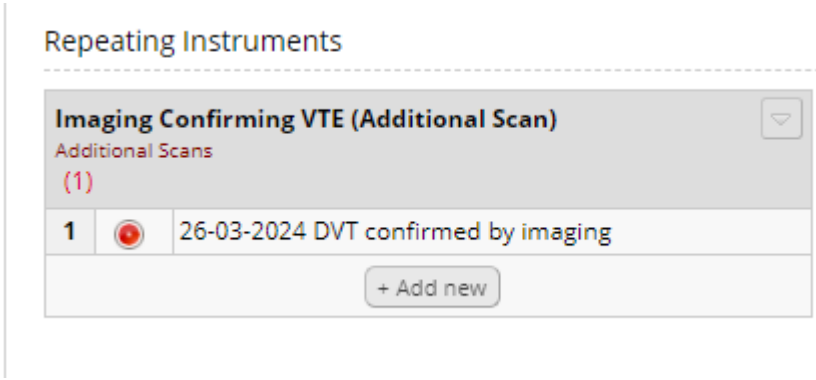
2. Click on the down arrow, and then the Add new box to be directed to a new blank instance of the instrument



Method 3

1. Click on the Record ID number on the Record Status Dashboard

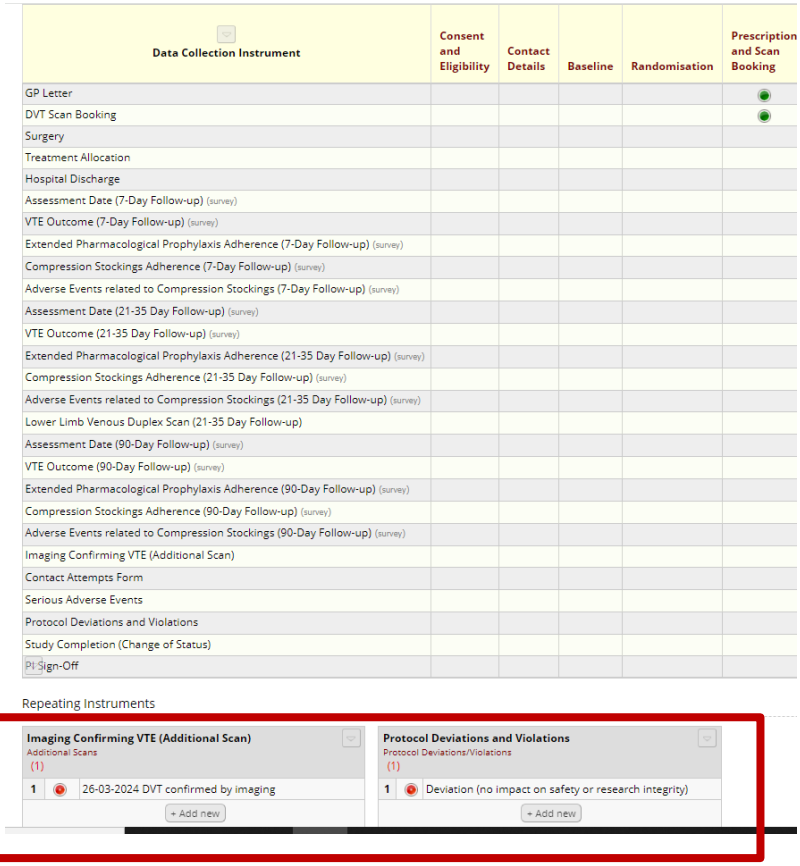
2. Repeating Instruments with existing data entered will be listed at the bottom of the Record Home Page



3. Click on Add New to be directed to a new blank instance of the instrument

4. Enter and save the data

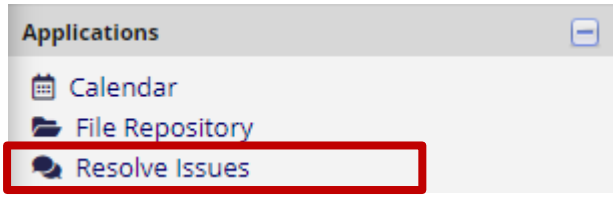
Once a repeating form has been entered, you can view existing repeating forms at the bottom of the participant's visit schedule page. You can also navigate to existing repeating forms if required. A new repeating form can also be added from this page by following the 'Add New' link at the bottom of each repeating instrument table.



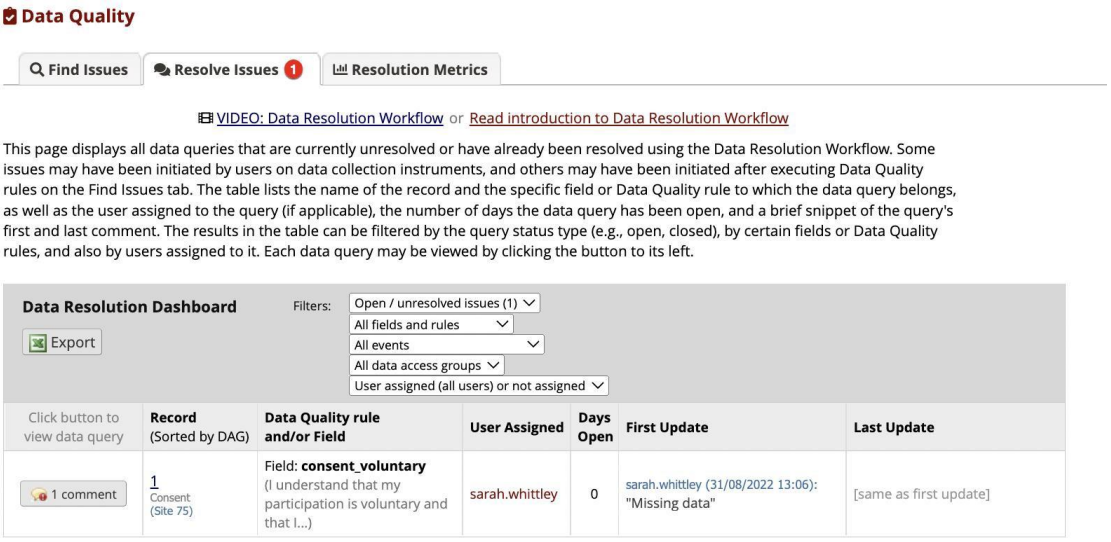
Accessing Data Queries

The Trial Manager or delegate will raise data queries for your attention.

To access a list of data queries at your site, select 'Resolve Issues' from the Application Section in the menu on the left side of your screen.

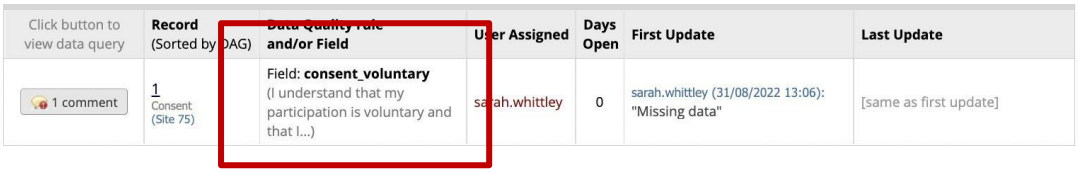


This directs you to a list of all unresolved data queries at your site.

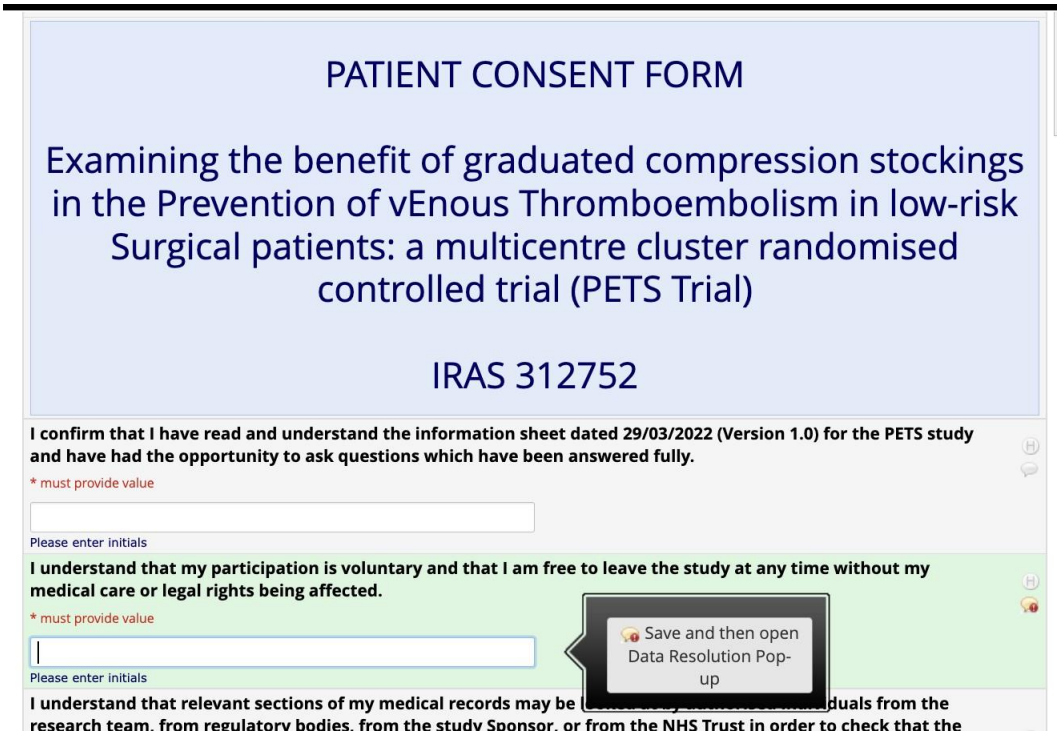


Queries can be filtered using the filter drop down options at the top of the table. You may also sort data queries by clicking on the column headers within the table.

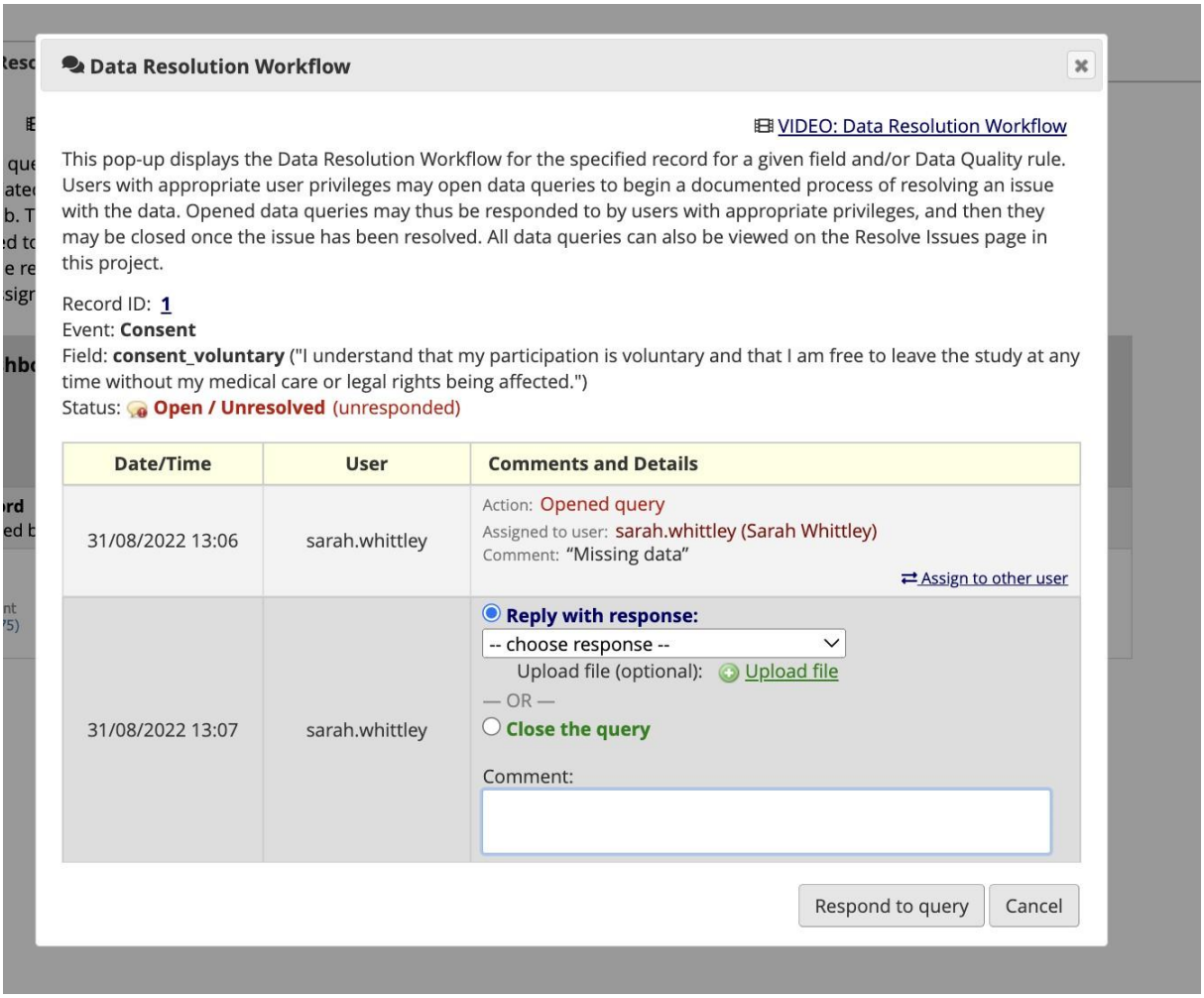
The reason for the query is listed in the 'First update' column. To view, respond and resolve data queries from the 'Resolve Issues' page, click on the participant number in the 'Record' column.



This directs you to the relevant CRF where the query has been raised. Click on the red comment bubble with an exclamation mark to view the query and open the Data Resolution Workflow ( ).



The Data Resolution Workflow displays the query details and the audit history of the field.



To reply to the data query, enter your comment in the 'Comment box'. You must select a response in the 'Reply with Response' drop down field. Select 'Respond to Query' to save your response and close the Data Resolution Workflow. Fields with query responses are indicated by a yellow comment bubble with a blue exclamation

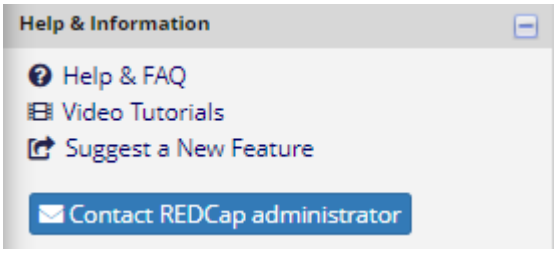
mark ( ). ****Don't forget that you will also have to physically change the data within the database (if required) as well as responding to the query****

The Trial Manager or delegate will review your query responses and either close the data query or send back to the site for further attention. A closed query is indicated by a yellow comments bubble with a green checkmark ( ).

Help & Information

For more information, REDCap has an inbuilt Help & FAQ section and Training Videos. These can be accessed via the toolbar on the main home page.

Alternatively, you may access the 'Help & Information' modules from the menu on the left hand side of your screen.



If you have further questions, please contact the Trial Manager in the first instance.

The ECTU REDCap team can be contacted Monday to Friday between 08:00 and 16:00 by emailing: redcap.ectu@ed.ac.uk.

Screening log

A paper screening log is provided in the CRF pack. This can be used to record any patients screened but they must be added onto the online screening log within the GRACE database. All screened patients must be added to the online log so that we have an idea of how many patients need to be screened to recruit and the reasons for exclusion. Please only screen patients for surgeries that usually require EDPTP. E.g. a particular surgery requires EDPTP use but the patient is on therapeutic thromboprophylaxis please record, but don't screen patients having surgeries that would not receive the EDPTP.

Imperial College London

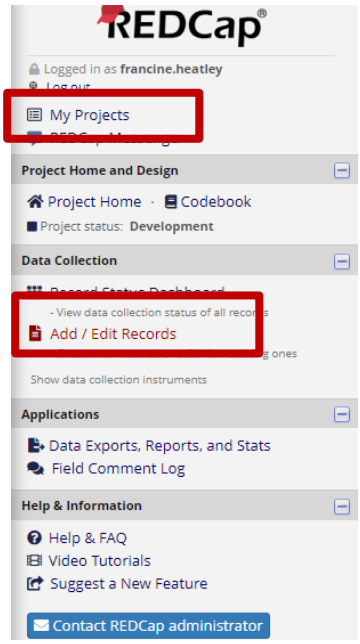
GRACE

GRACE SCREENING LOG

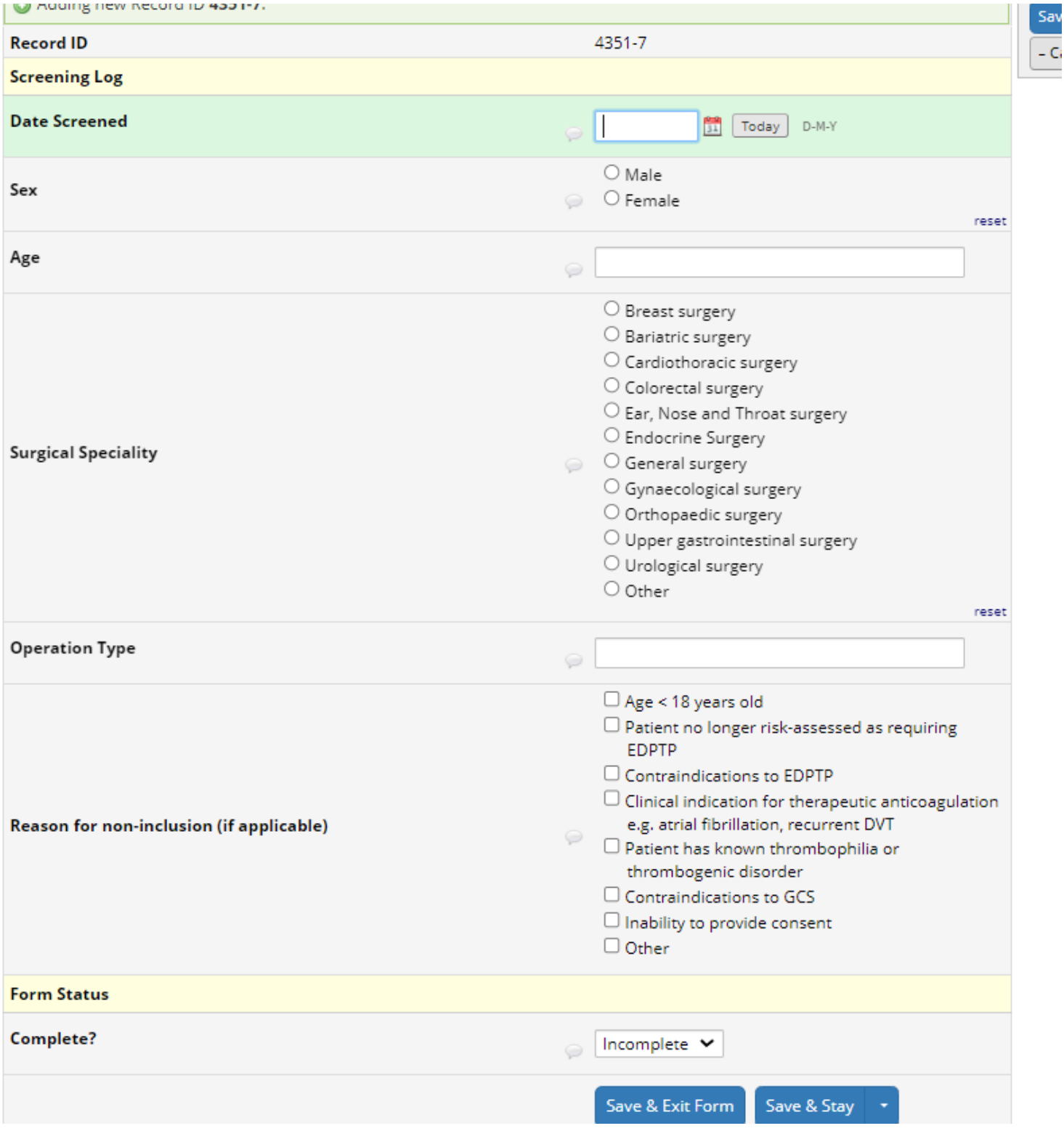
Sponsor:	IRAS No	PI Name	Site No
Imperial College, London	333539		

Date screened	Sex (M/F)	Age	Surgical speciality Breast surgery; Bariatric surgery; Cardiothoracic surgery; Colorectal surgery; Ear, Nose & Throat surgery; Endocrine surgery; General surgery; Gynaecological surgery; Orthopaedic surgery; Upper gastrointestinal surgery; Urological surgery; Other [___]	Operation type	Reason for non-inclusion (if applicable) • Age <18 years old • Patient no longer risk assessed as requiring EDPTP • Contraindications to EDPTP • Clinical indication for therapeutic anticoagulation e.g., atrial fibrillation, recurrent DVT • Patient has a known thrombophilia or thrombogenic disorder • Contraindications to GCS • Inability to provide consent • Other (please detail)

For access to the online screening log, click on 'GRACE screening log' in 'My projects' and then click on 'Record status dashboard' and click on 'add new record'



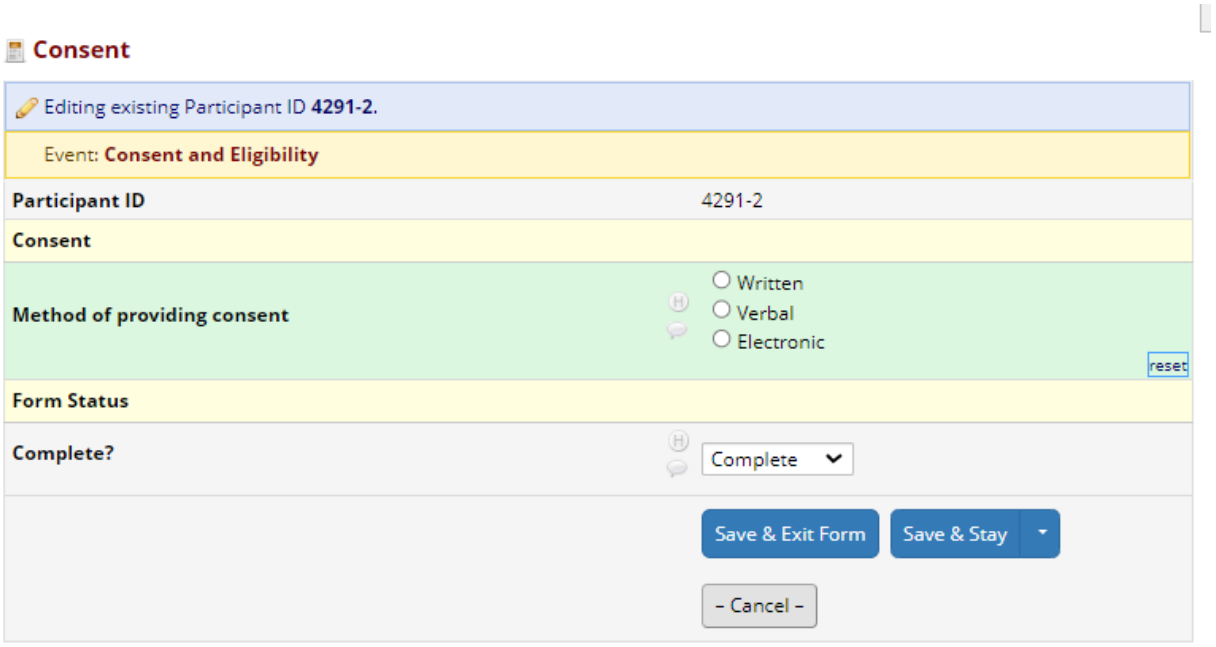
Please complete all the details within the log and Tick all the reasons that the patient did not meet the exclusion criteria and mark as complete so the record shows as green:



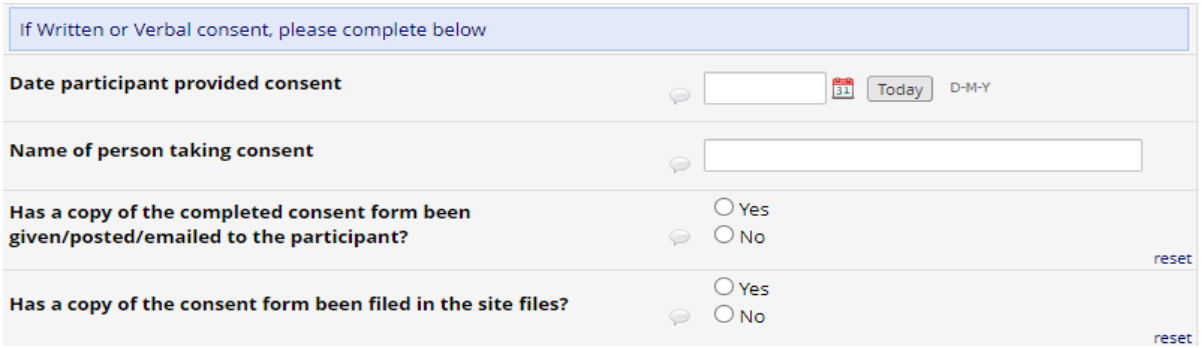
Consent

Participants can provide consent verbally (over the phone), in written form or electronically.

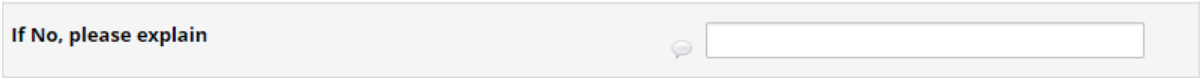
The *Consent Information* CRF initially looks like this:



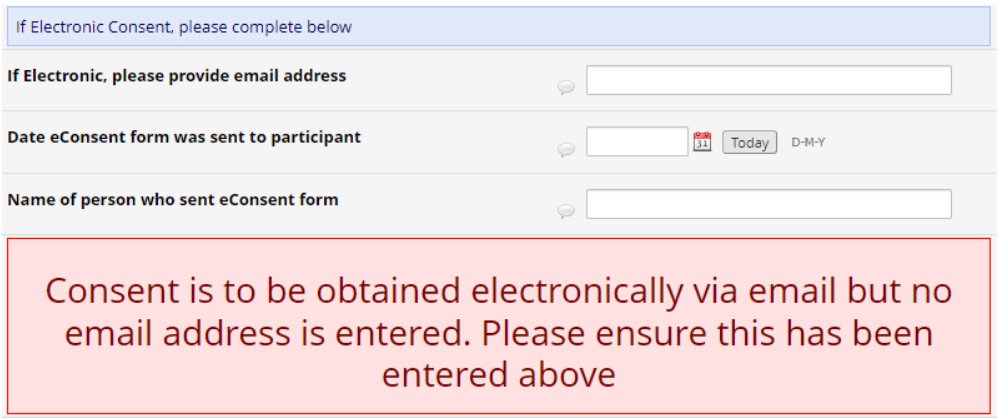
If 'Method of providing consent' is 'Written' or 'Verbal', the following fields will appear:



If 'Has a copy of the completed consent form been given/posted/emailed to the participant?' or 'Has a copy of the consent form been filed in the site files?' is 'No', the following field will appear:

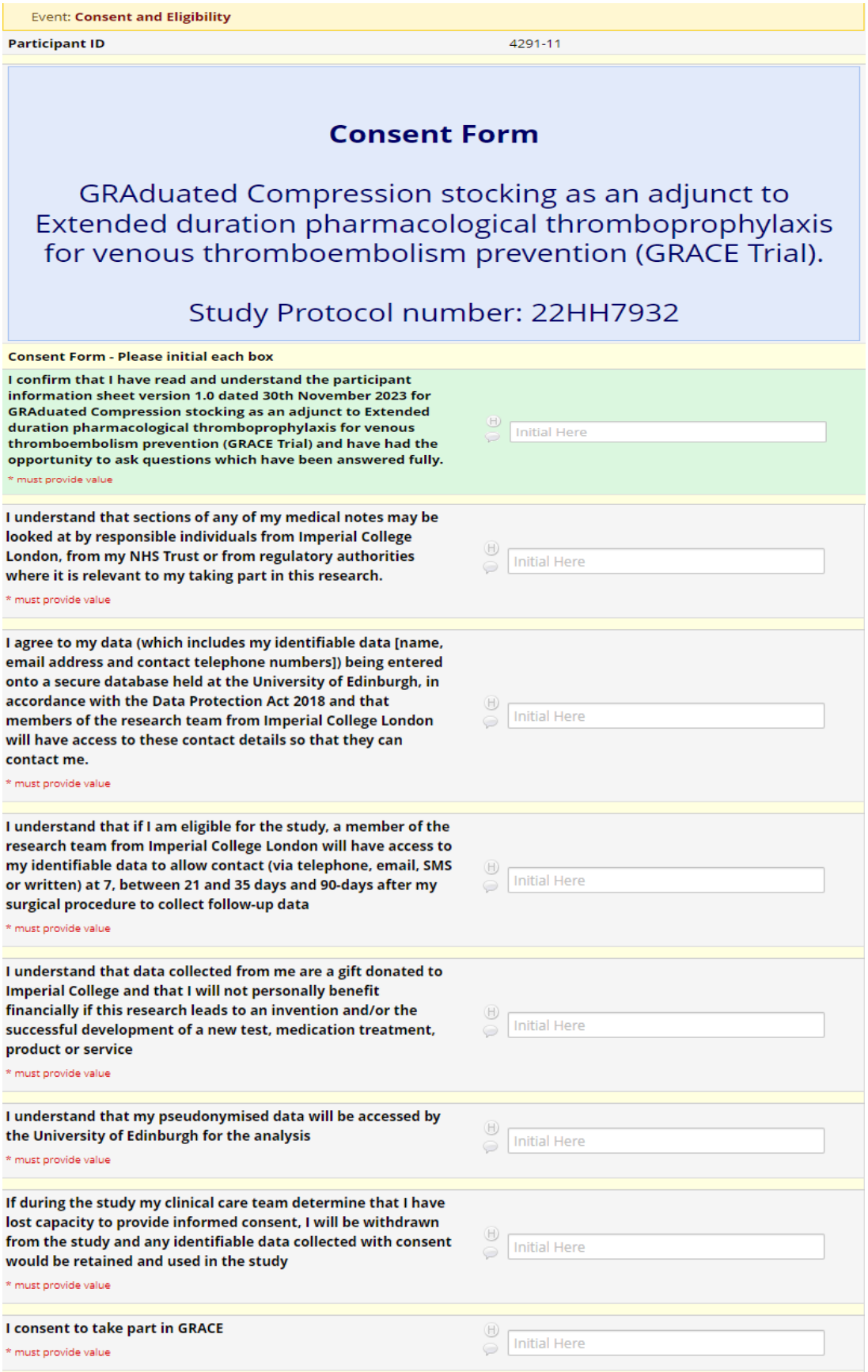


If 'Method of providing consent' is 'Electronic', the following fields will appear:



Once the field is completed with an email address, the alert in red text will disappear. Once the page is saved a survey link will be automatically emailed to the participant allowing them to electronically complete the Consent Form CRF

The *Consent Form* CRF looks like this:



Event: **Consent and Eligibility**

Participant ID 4291-11

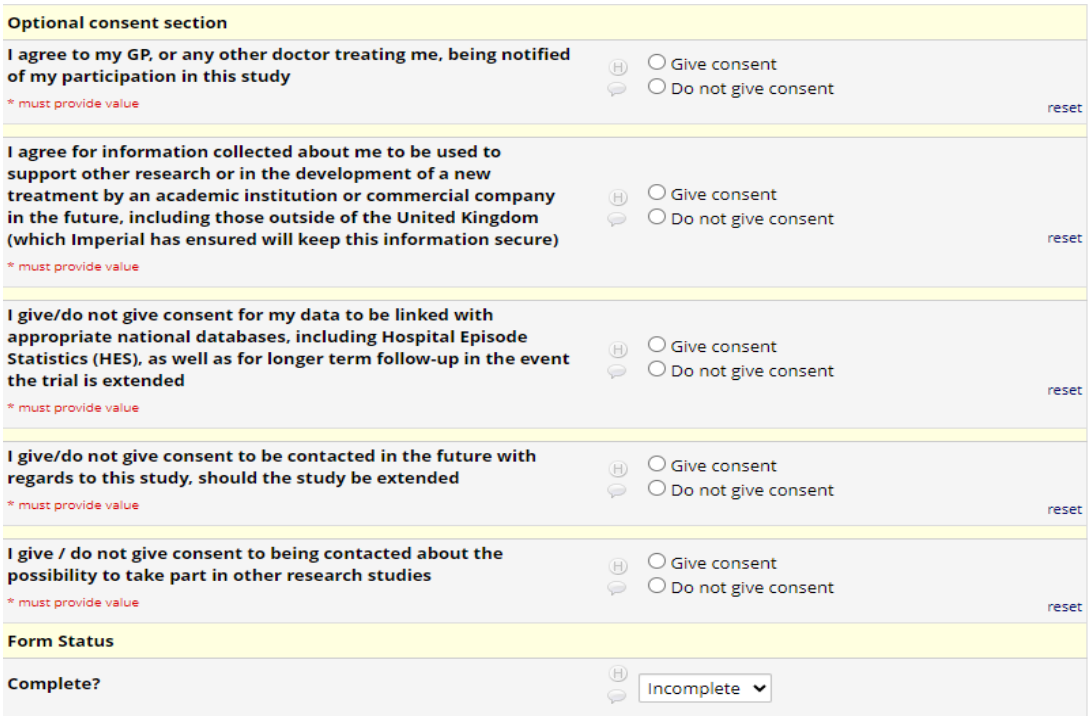
Consent Form

GRAduated Compression stocking as an adjunct to Extended duration pharmacological thromboprophylaxis for venous thromboembolism prevention (GRACE Trial).

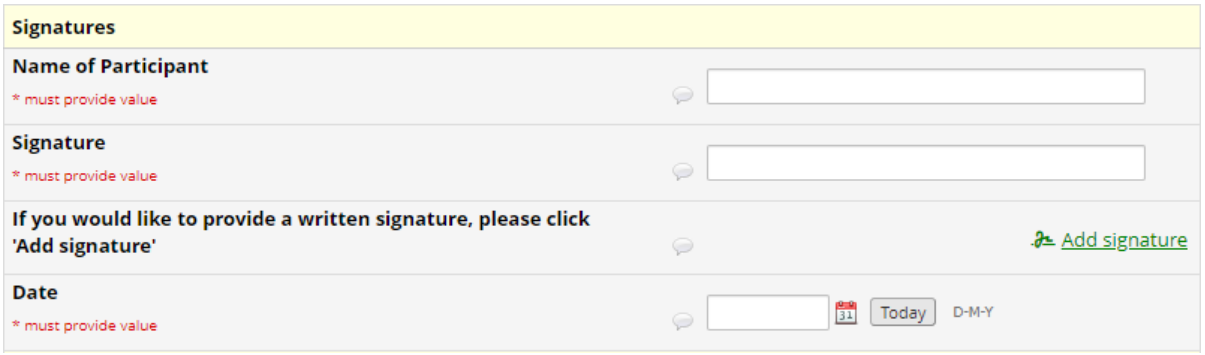
Study Protocol number: 22HH7932

Consent Form - Please initial each box

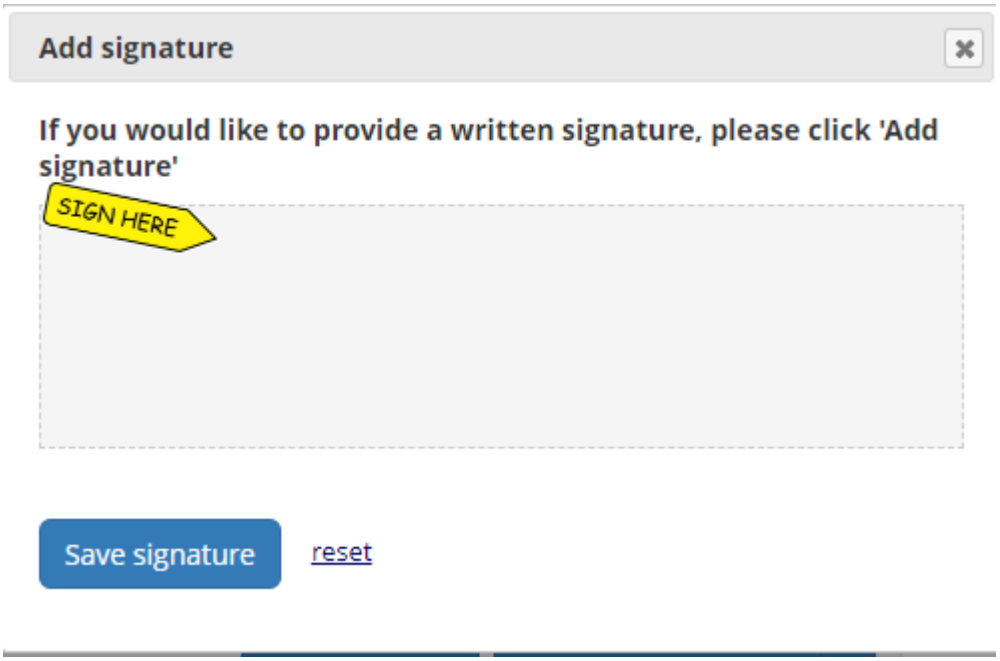
I confirm that I have read and understand the participant information sheet version 1.0 dated 30th November 2023 for GRAduated Compression stocking as an adjunct to Extended duration pharmacological thromboprophylaxis for venous thromboembolism prevention (GRACE Trial) and have had the opportunity to ask questions which have been answered fully. * must provide value	Initial Here
I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London, from my NHS Trust or from regulatory authorities where it is relevant to my taking part in this research. * must provide value	Initial Here
I agree to my data (which includes my identifiable data [name, email address and contact telephone numbers]) being entered onto a secure database held at the University of Edinburgh, in accordance with the Data Protection Act 2018 and that members of the research team from Imperial College London will have access to these contact details so that they can contact me. * must provide value	Initial Here
I understand that if I am eligible for the study, a member of the research team from Imperial College London will have access to my identifiable data to allow contact (via telephone, email, SMS or written) at 7, between 21 and 35 days and 90-days after my surgical procedure to collect follow-up data * must provide value	Initial Here
I understand that data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service * must provide value	Initial Here
I understand that my pseudonymised data will be accessed by the University of Edinburgh for the analysis * must provide value	Initial Here
If during the study my clinical care team determine that I have lost capacity to provide informed consent, I will be withdrawn from the study and any identifiable data collected with consent would be retained and used in the study * must provide value	Initial Here
I consent to take part in GRACE * must provide value	Initial Here



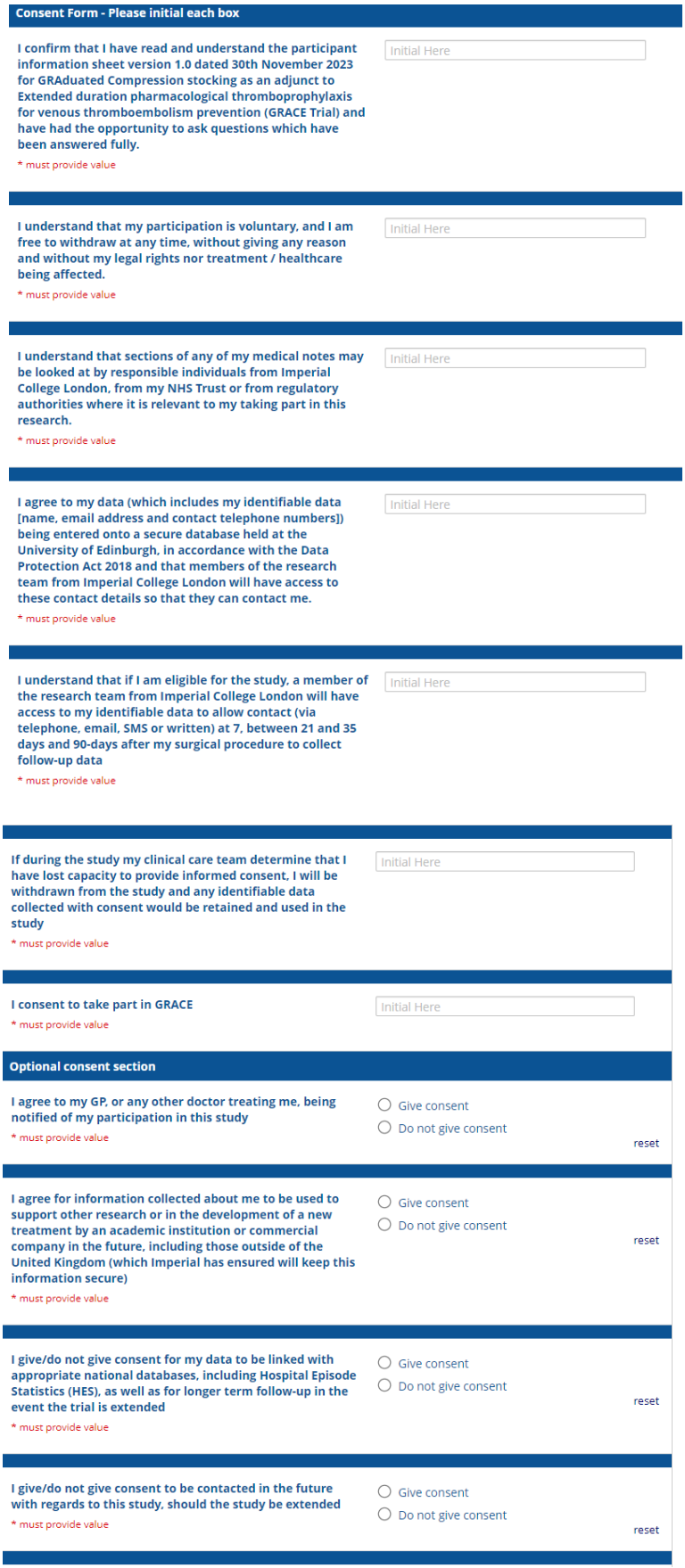
Once all mandatory consent questions have been completed, the following fields will appear:



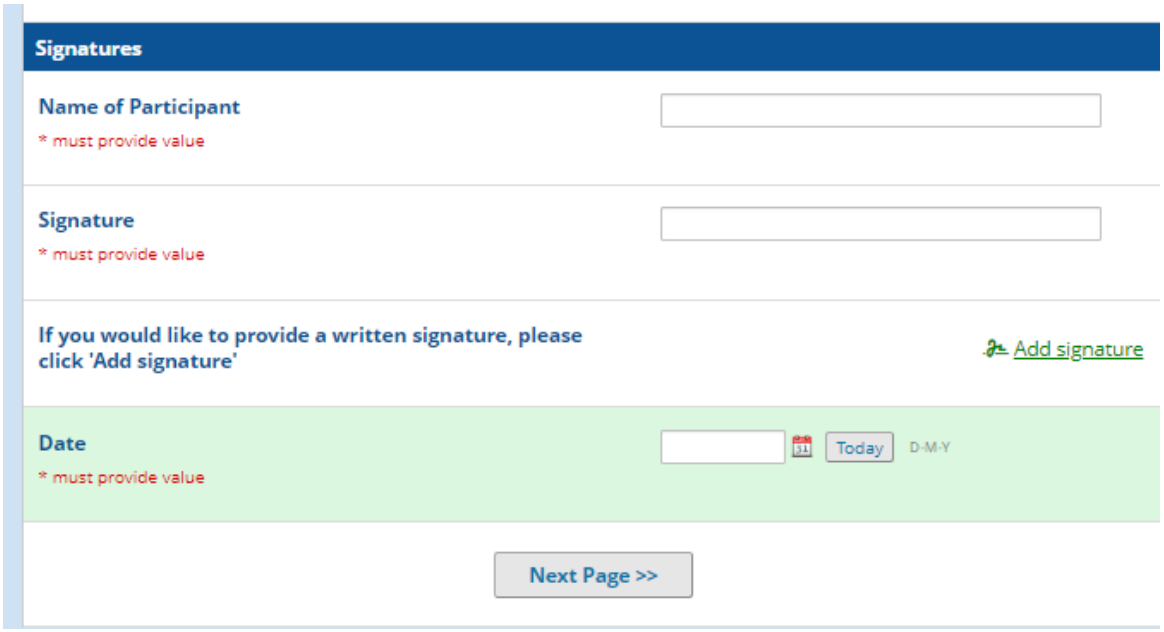
Clicking the ‘Add signature’ link allows a written signature to be saved:



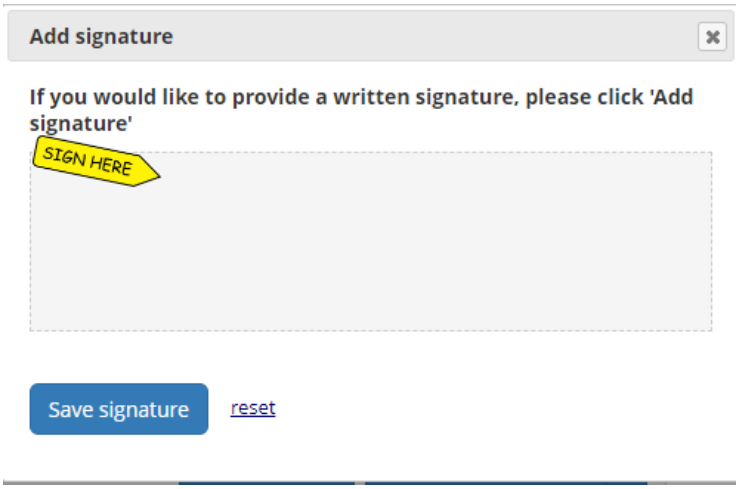
If participant opted to complete the consent form electronically, they will be emailed a link to this form for them to complete themselves. Once they have completed the form and the data has been submitted to REDCap, a PDF copy of the consent form is automatically sent to the participant. A PDF copy is also saved to the File Repository on REDCap to be used by the site or trial team, if needed for their records. The survey consent emailed to the participant looks like this:



Once all mandatory consent questions have been completed, the following fields will appear:

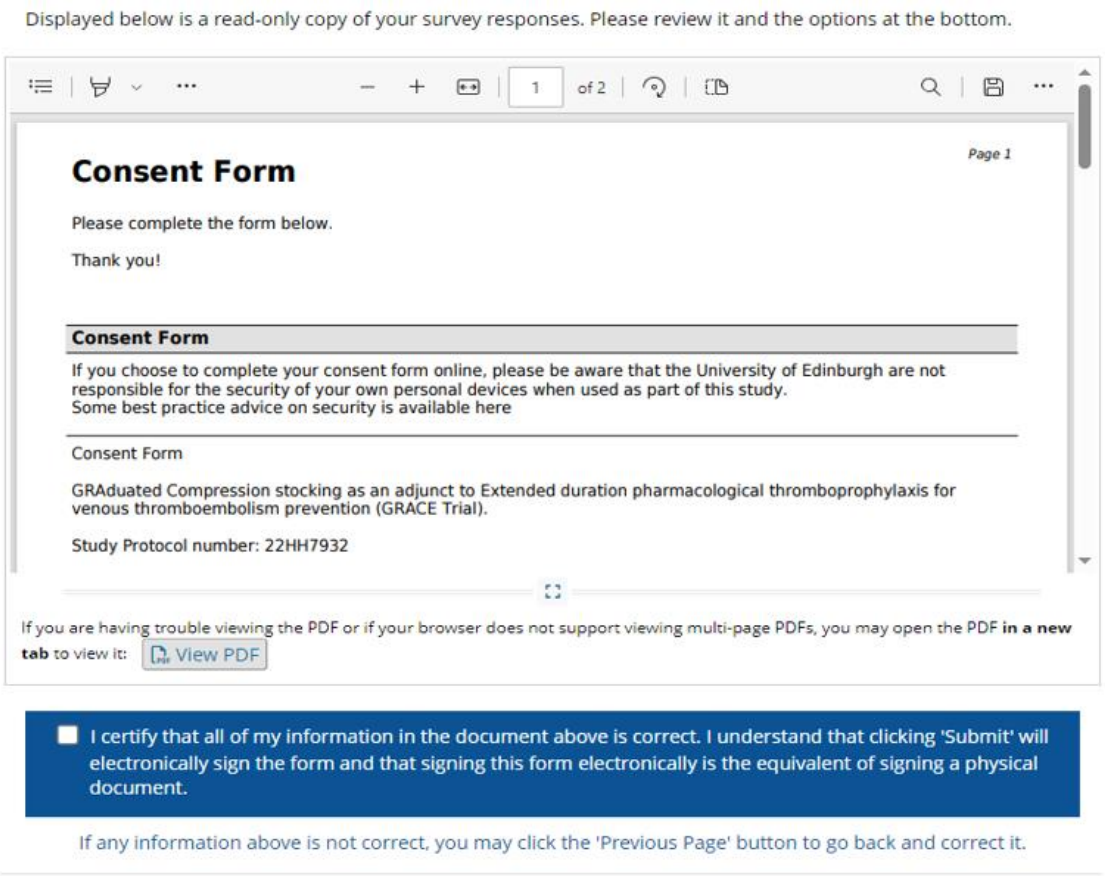


Clicking the ‘Add signature’ link allows a written signature to be saved:

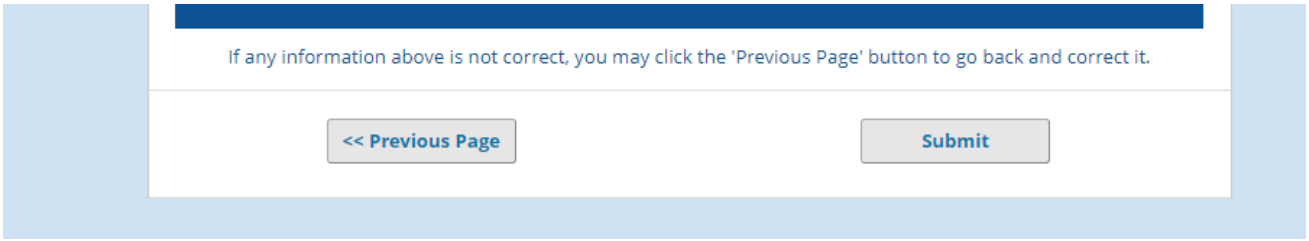


They need to Click ‘Next Page’ to save the data and progress to the confirmation page as below:

The following option must be ticked before the Consent Form can be submitted. The ‘Submit’ button will remain inaccessible until this is completed:



Once ticked, click 'Submit' to save the form. You will be directed to the following screen and a pdf version of the Consent Form will be emailed to the participant:



Imperial College London

Delete this line, then print on Hospital/Trust headed paper

Consent form

GRACE

Site ID: 432	Initials: PJT
Participant Trial ID: 432-04	Principal Investigator Name: PROF SMITH

Full Title of Project: GRAduated Compression stocking as an adjunct to Extended duration pharmacological thromboprophylaxis for venous thromboembolism prevention (GRACE Trial).
Study Protocol number: 22HH7932

Is verbal consent being provided via telephone? (please initial one option):

☐ Yes – Please read each statement to the participant. Once the participant agrees to each statement, please provide the initials of the person taking consent (i.e. the researcher) in each box

☐ RJ No – Participant to read the consent form and they write their own initials in each box

	Please initial box
1. I confirm that I have read and understand the participant information sheet version ..... dated 30/11/23 for **GRAduated Compression stocking as an adjunct to Extended duration pharmacological thromboprophylaxis for venous thromboembolism prevention (GRACE Trial)** and have had the opportunity to ask questions which have been answered fully.	PJT
2. I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights nor treatment / healthcare being affected.	PJT
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London, from my NHS Trust or from regulatory authorities where it is relevant to my taking part in this research.	PJT
4. I agree to my data (which includes my identifiable data [name, email address and contact telephone numbers]) being entered onto a secure database held at the University of Edinburgh, in accordance with the Data Protection Act 2018 and that members of the research team from Imperial College London will have access to these contact details so that they can contact me.	PJT
5. I understand that if I am eligible for the study, a member of the research team from Imperial College London will have access to my identifiable data to allow contact (via telephone, email, SMS or written) at 7, between 21 and 35 days and 90-days after my surgical procedure to collect follow-up data	PJT
6. I understand that data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service.	PJT
7. I understand that my pseudonymised data will be accessed by the University of Edinburgh for the analysis	PJT
8. If during the study my clinical care team determine that I have lost capacity to provide informed consent, I will be withdrawn from the study and any identifiable data collected with consent would be retained and used in the study	PJT
9. I consent to take part in GRACE	PJT

Optional consent section (please initial the appropriate box)

10. I agree to my GP, or any other doctor treating me, being notified of my participation in this study.

Give consent ☐ PJT Do not give consent ☐

11. I agree for information collected about me to be used to support other research or in the development of a new treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).

Give consent ☐ PJT Do not give consent ☐

12. I give/do not give consent for my data to be linked with appropriate national databases, including Hospital Episode Statistics (HES), as well as for longer term follow-up in the event the trial is extended.

Give consent ☐ PJT Do not give consent ☐

13. I give/do not give consent to be contacted in the future with regards to this study, should the study be extended.

Give consent ☐ Do not give consent ☐ PJT

14. I give / do not give consent to being contacted about the possibility to take part in other research studies.

Give consent ☐ PJT Do not give consent ☐

Paul Thomas	P Thomas	11/04/2024
Name of participant	Signature	Date
Rebecca Jones	Rebecca Jones	11/04/2024
Name of person taking consent (if different from Principal Investigator)	Signature	Date

1 copy for participant; 1 copy for Principal Investigator 1 copy for hospital notes

To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented and stored in double sided format

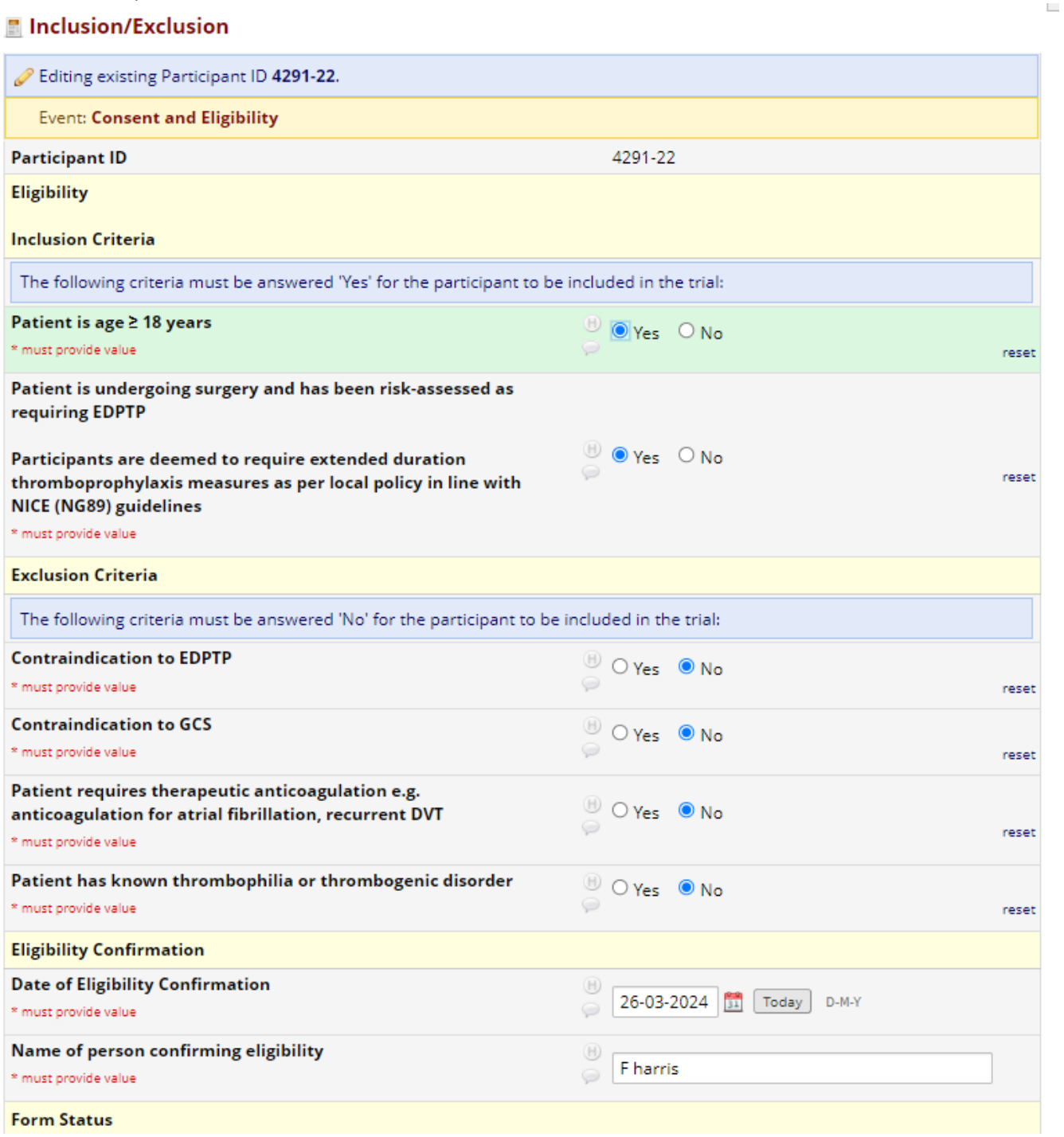
GRACE Consent Form Version V2.0, 19/12/2023; Approved by Wales REC 3 on 20/12/2023
IRAS: 333539; Sponsor Ref: 22HH7932

Please check that the participant has:

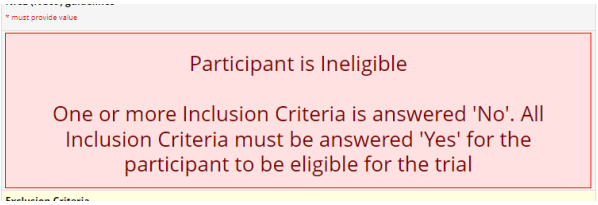
a) initialled every box from 1 to 9
b) completed one of the options boxes on questions 10 to 14
c) signed and dated the consent form

Inclusion / exclusion

Complete the inclusion / exclusion criteria, date of eligibility confirmation and who confirmed eligibility and mark the form as complete:

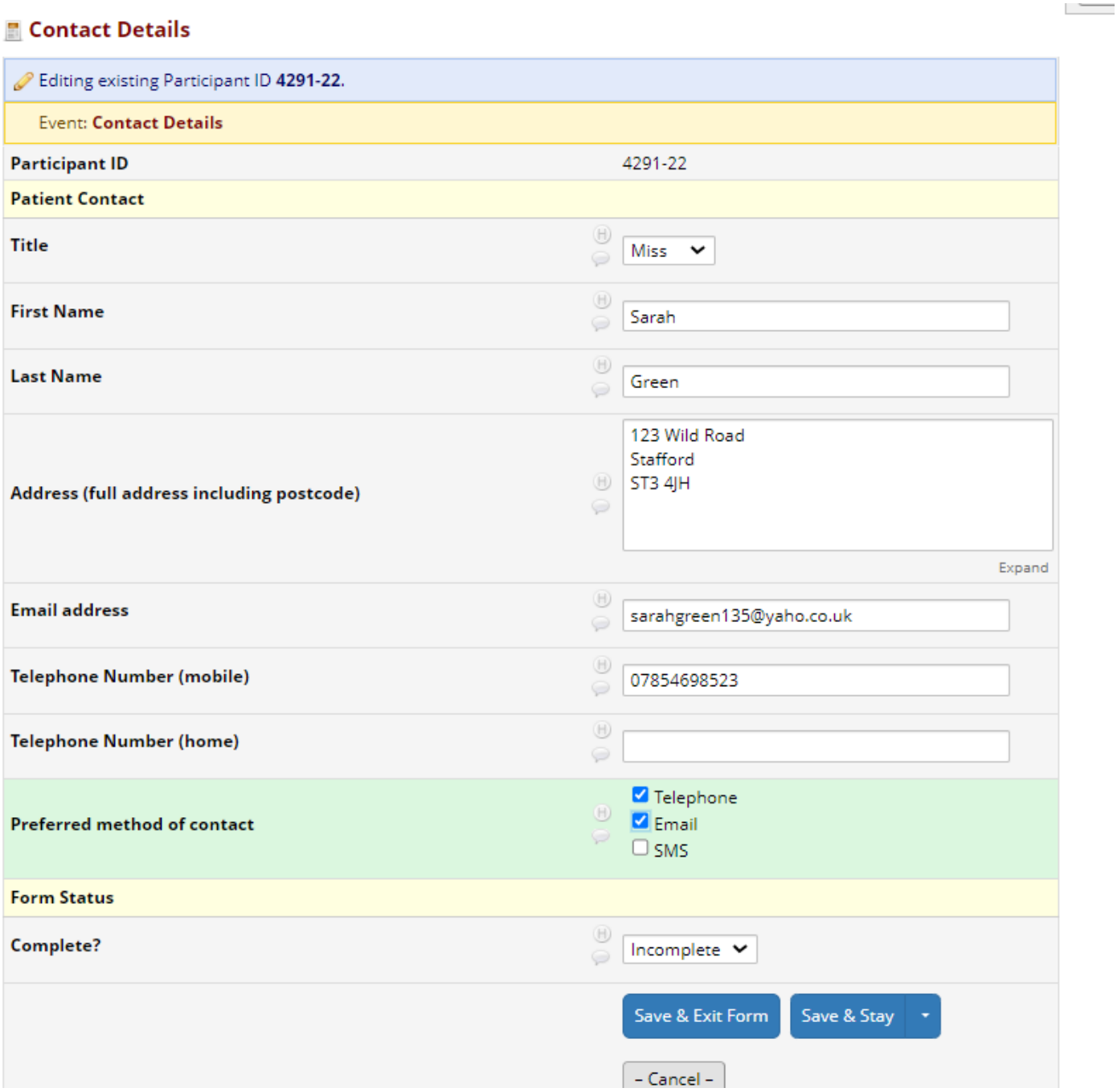


An alert will fire if the inclusion criteria is answered no, or the exclusion criteria is marked yes.



Contact details

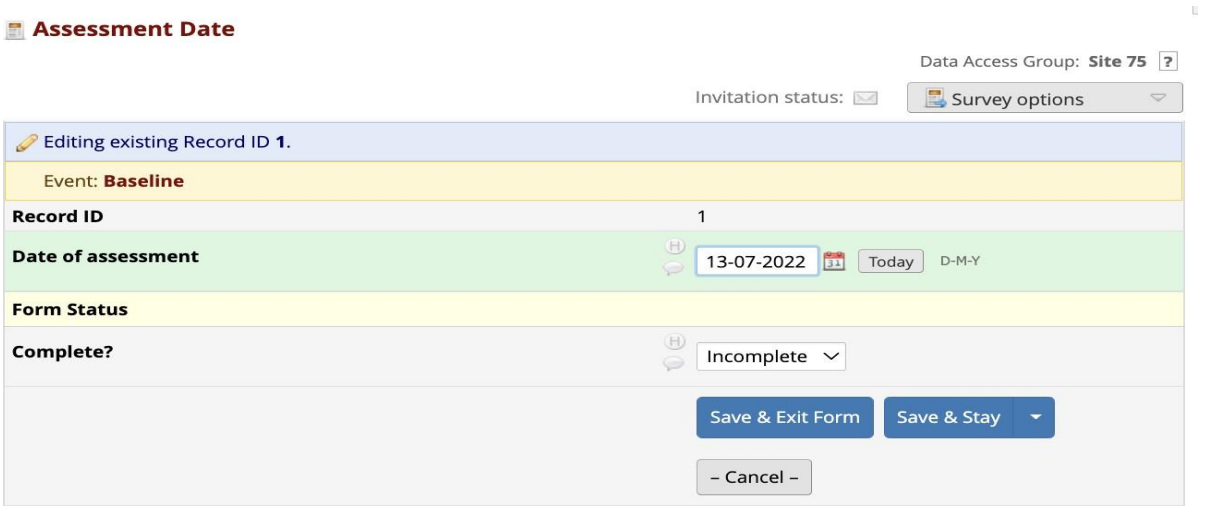
Enter the relevant information on the Contact Details CRF:



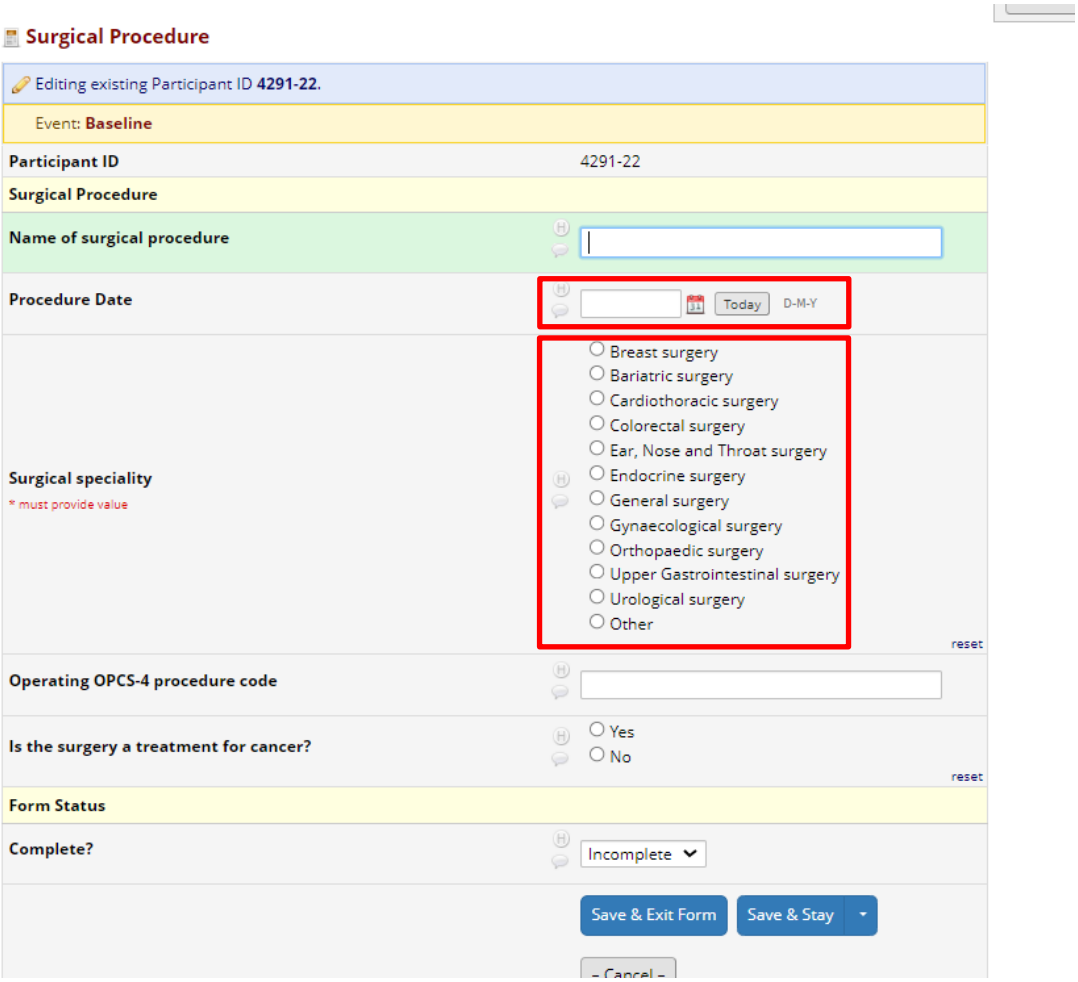
It is preferable for the participant to complete the survey by email as this reduces the number of telephone calls we need to make. SMS messages can only be sent once but email reminders are scheduled. If email and telephone are both ticked an email will always been sent and we can follow-up if this is not completed. As long as the participant agrees, please always enter a telephone number so that we can follow-up with the participant if they do not complete the email /SMS survey. **The preferred method of contact and email, and /or mobile number must be completed so that the remote follow-up can occur. <u>The surgical procedure date must also be completed to send the remote follow-up as the system uses this date to calculate the follow-up dates.</u>**

Baseline

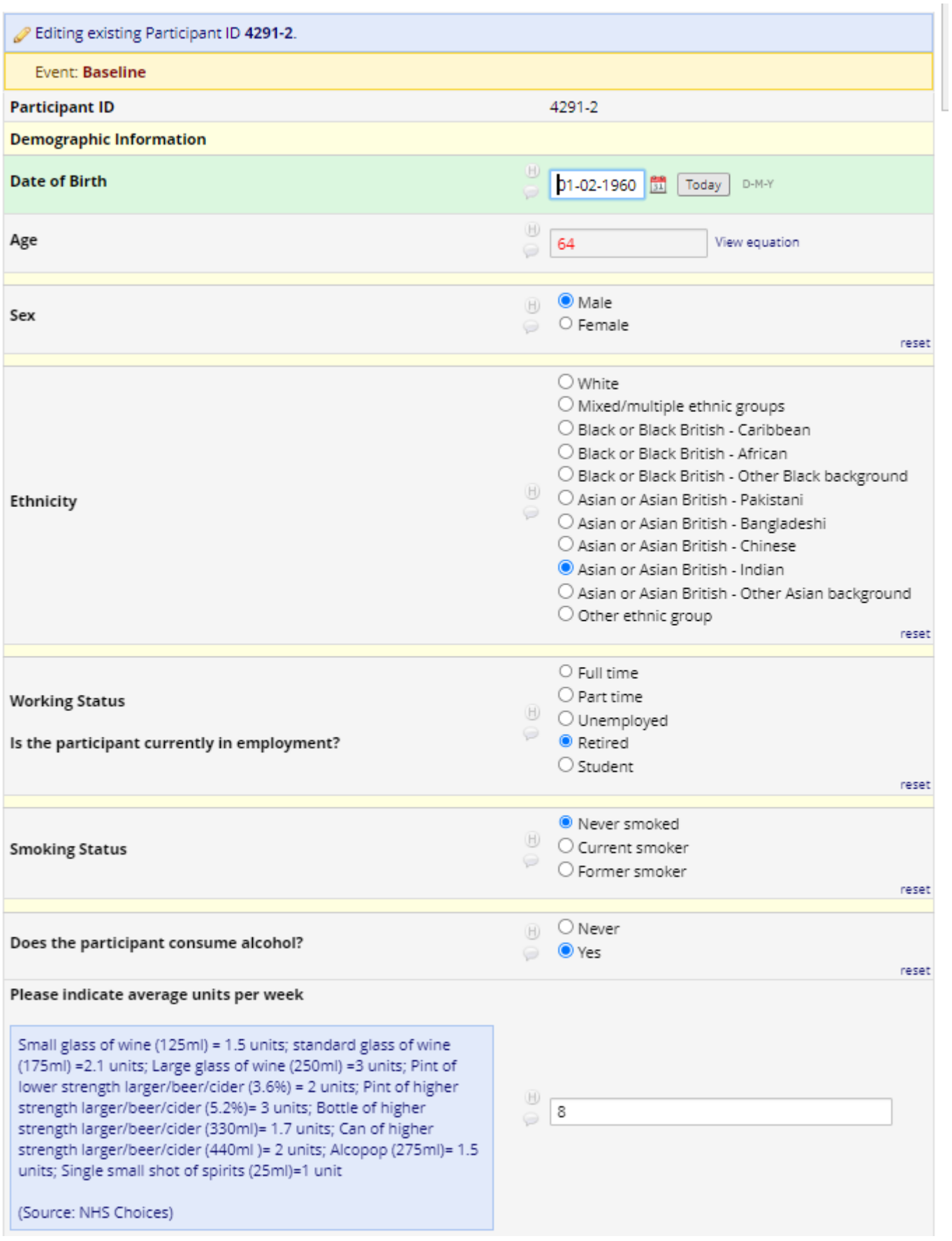
With the exception of the surgical specialty, the baseline section can be completed after randomisation if required. Enter the date the baseline assessment took place:



Please complete the surgical details. N.B. Surgical specialty is a required field before randomisation can occur as randomisation is stratified by specialty. **Please also ensure that the date of procedure (surgery) is complete as the follow-up are sent according to this date**:

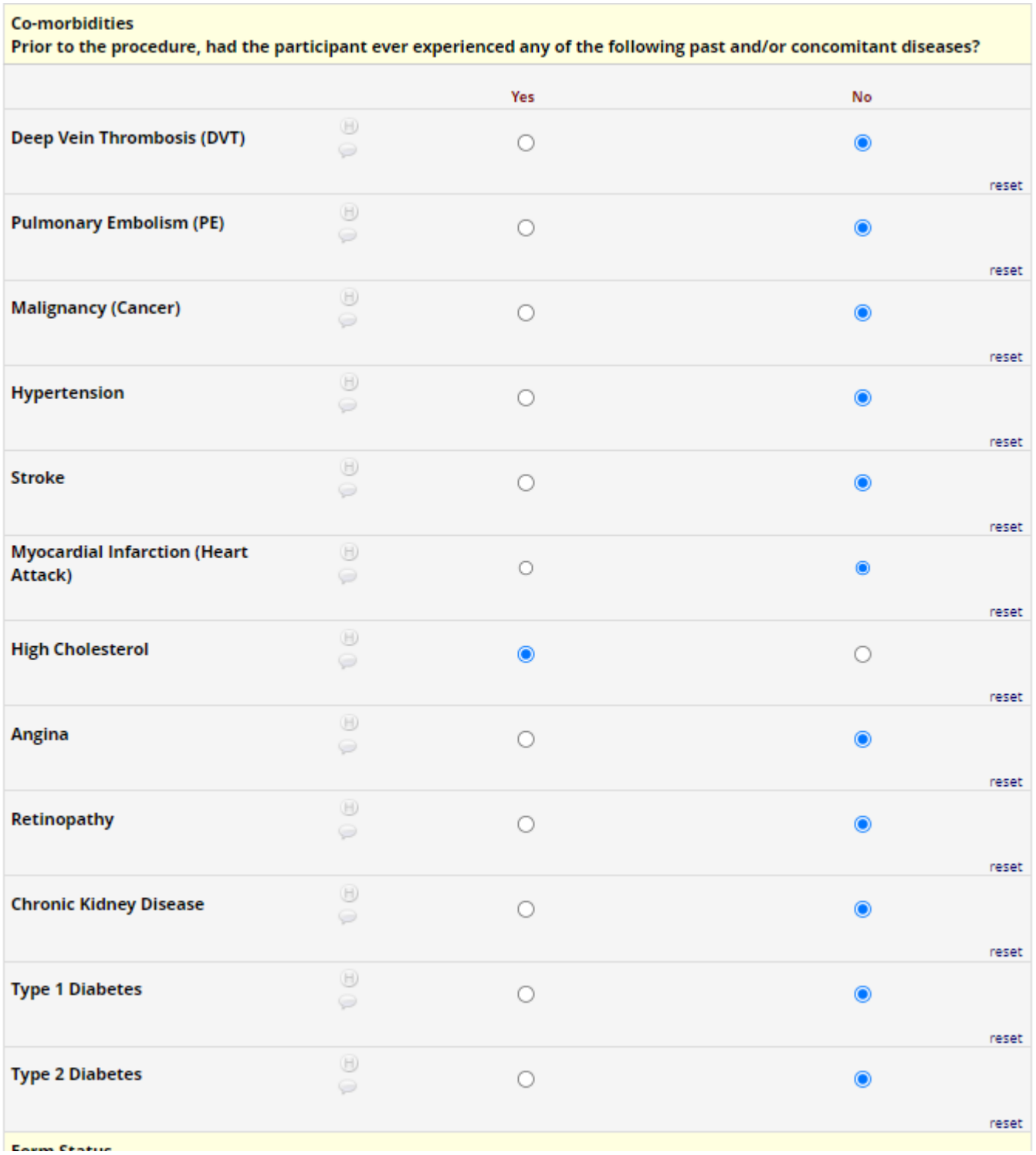


Enter the participant's demographics, including date of birth, sex, ethnicity, working status and smoking / alcohol habits:

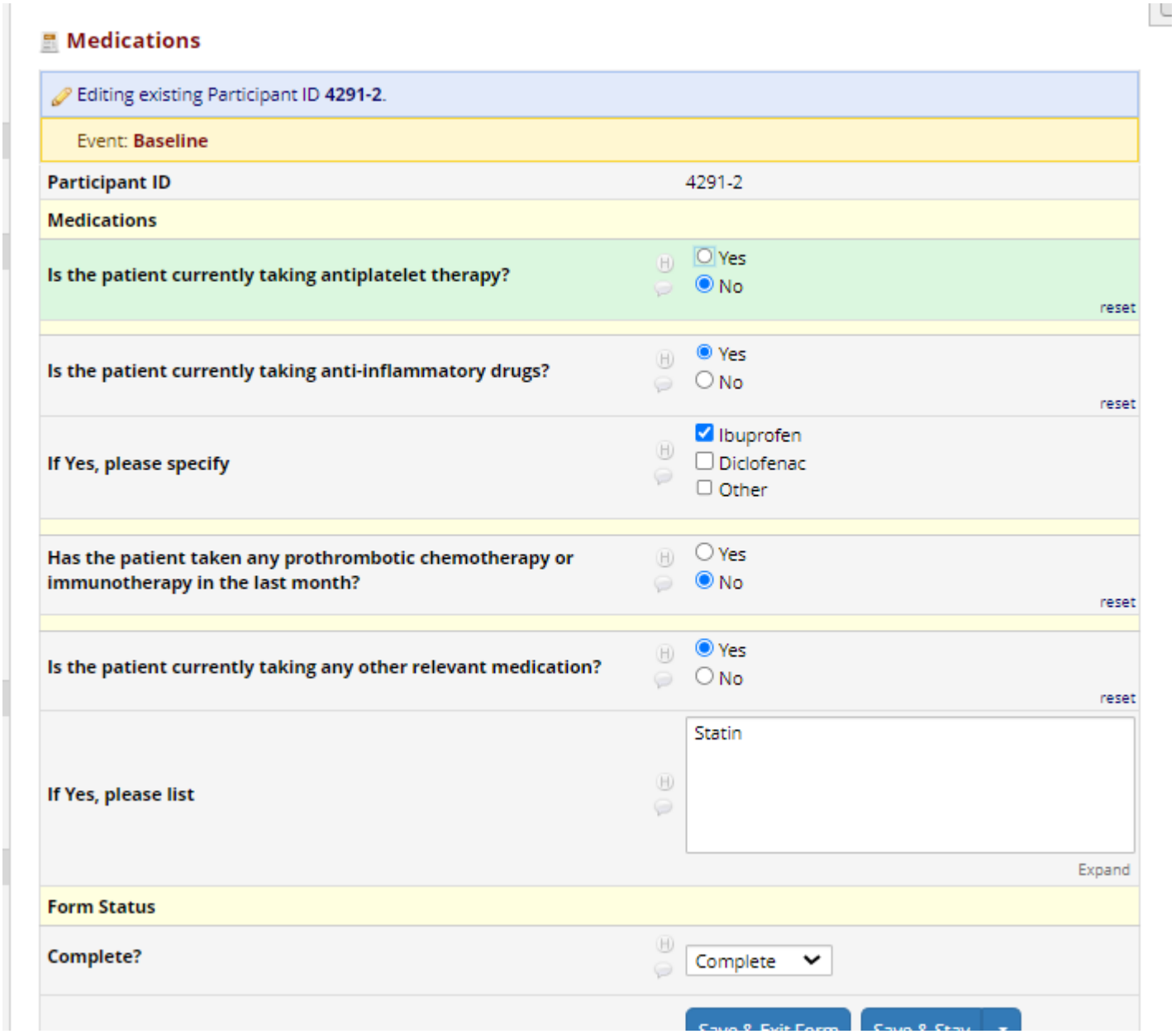


Enter the vital signs into the Vital Signs CRF, the BMI will autocalculate:

Enter the relevant co-morbidities into the CRF:



Please complete any relevant medication:

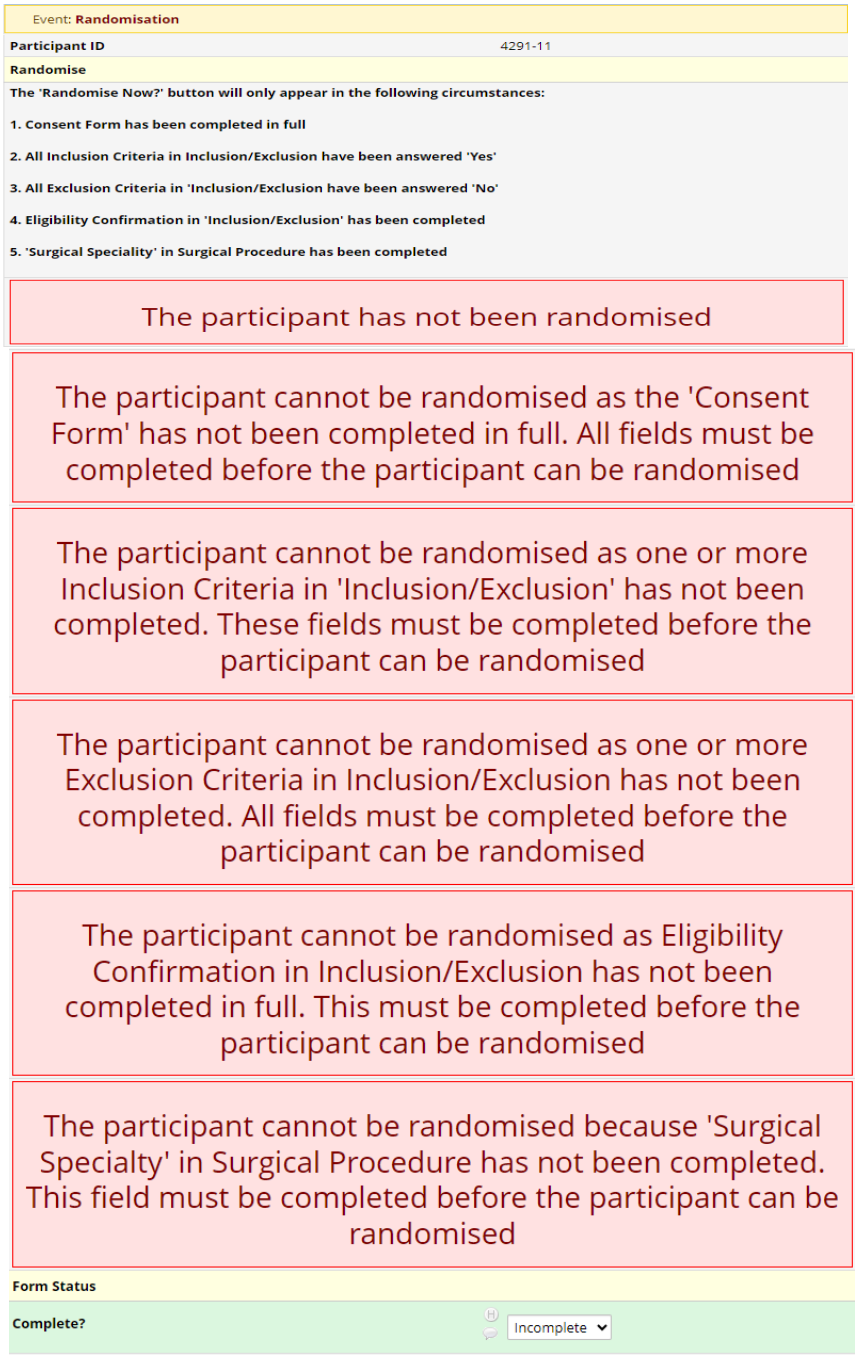


Randomisation

In order to complete the randomisation the following must be completed:

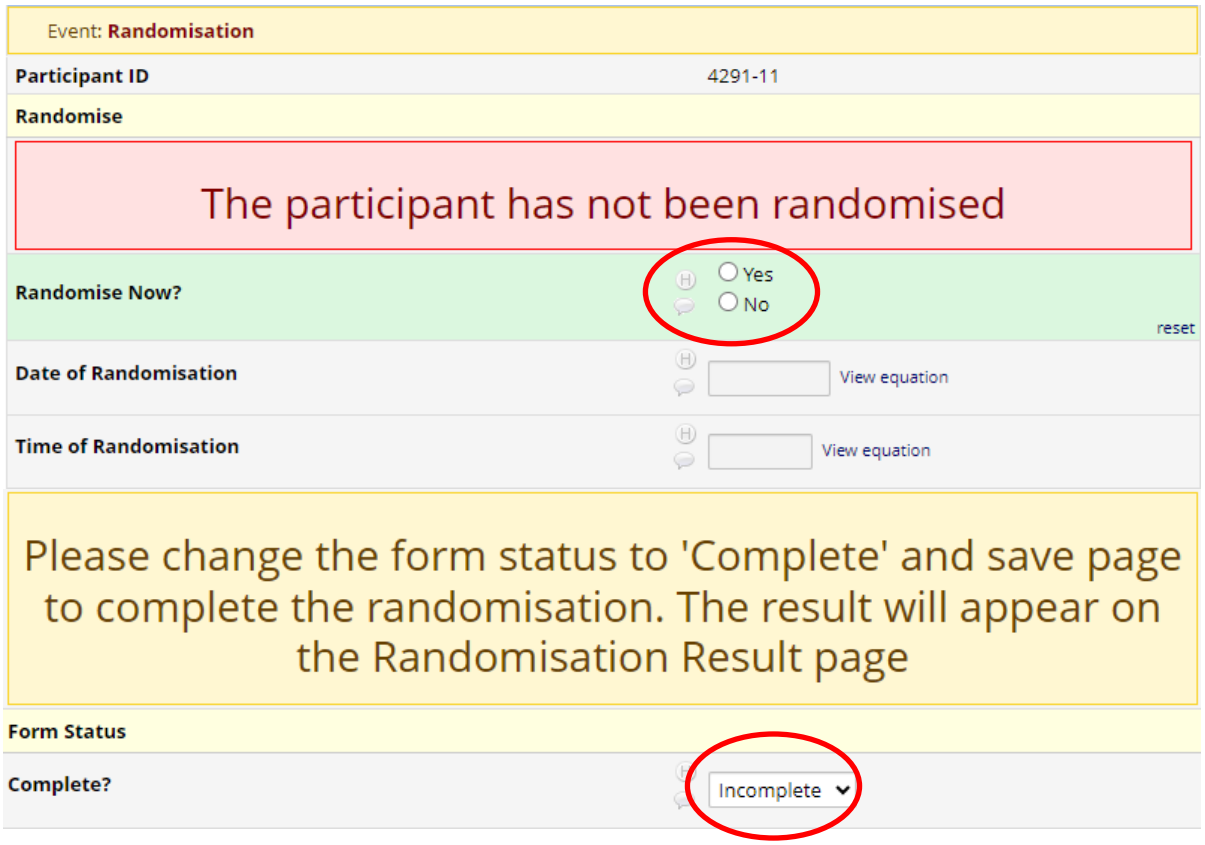
- All fields in Consent Form must be completed
- All Inclusion Criteria in Inclusion/Exclusion must be answered ‘Yes’ / All Exclusion Criteria Inclusion/Exclusion must be answered ‘No’ and all fields must be completed
- ‘Surgical Speciality’ field in Surgical Procedure must completed

If none of these key data fields have been completed, the instrument will initially look like this:



The appearance of this instrument will change depending on which key data fields are entered. The information box and alerts will disappear as the fields are completed.

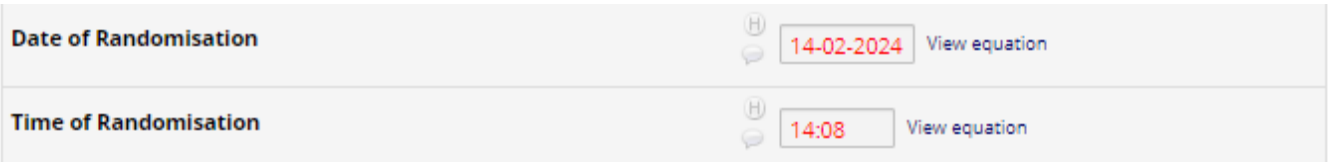
If all of the above data has been completed as required, the instrument will look like this:



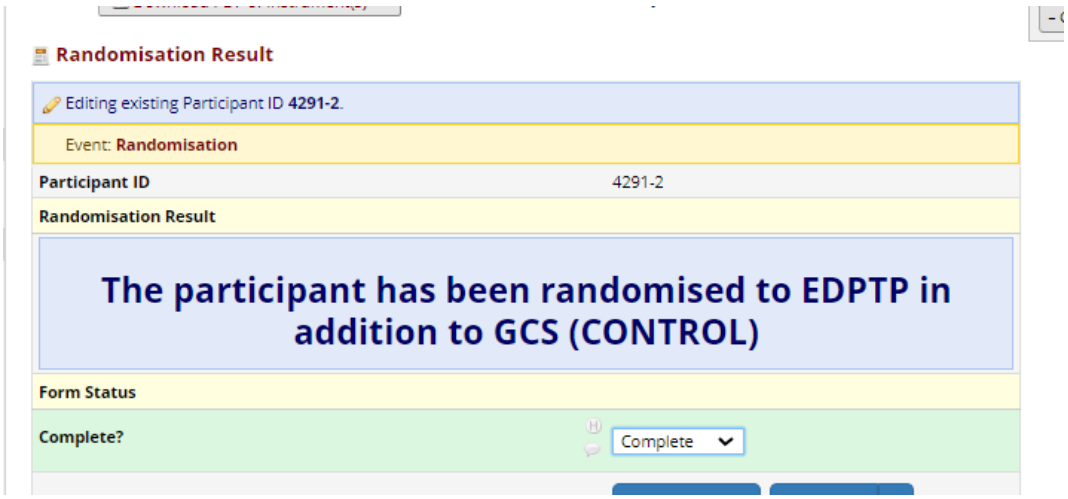
The 'Randomise Now?', 'Date of Randomisation', 'Time of Randomisation' and the completion information alert will only appear once all of the key data fields above are completed.

<u>Click 'yes' to 'randomise now?' And mark the form as complete in order for the randomisation to be successful.</u>

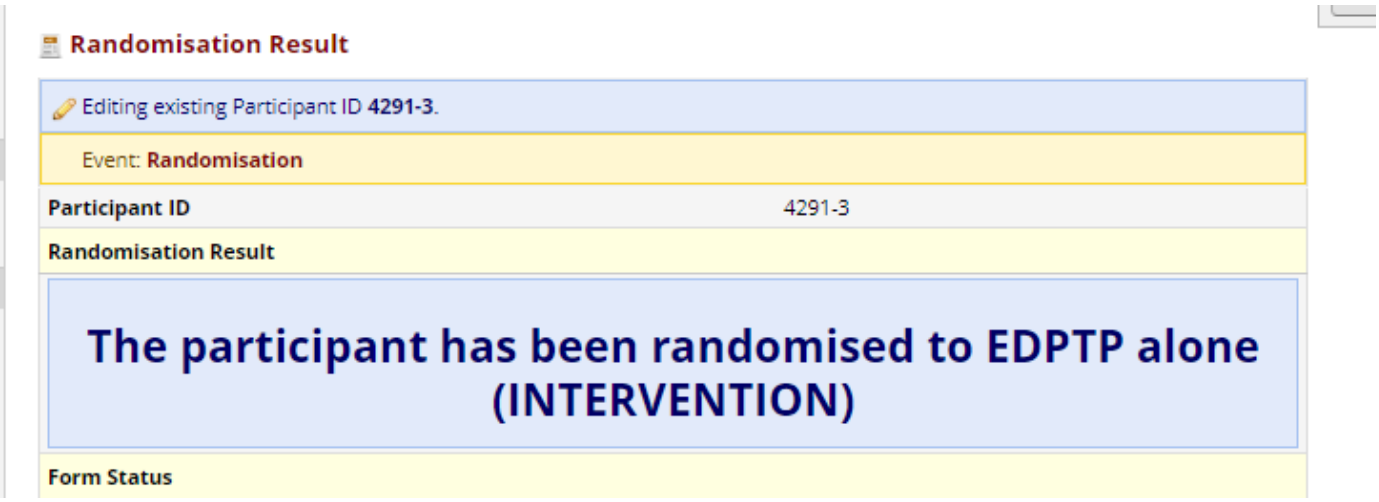
The date and time of randomization will autocomplete and the allocation will appear on the next form (randomisation result).



The Randomisation allocation will appear on the 'randomisation' result page:
The control arm (EDPTP and GCS) looks like this:

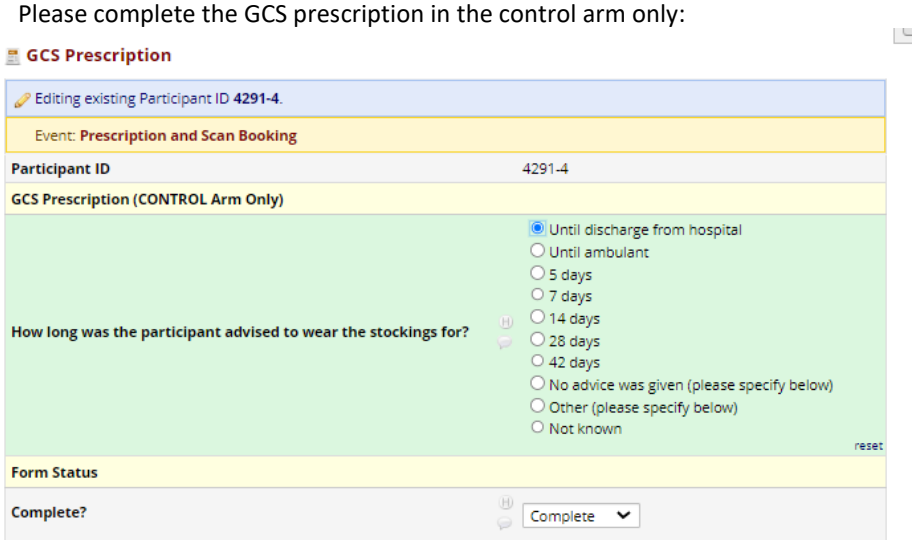


The intervention arm (EDPTP alone) looks like this. Please ensure that the participant is not provided with GCS. If they are already wearing them, they must be removed prior to surgery.



Prescription and Scan Booking

Please complete the GCS prescription in the control arm only:



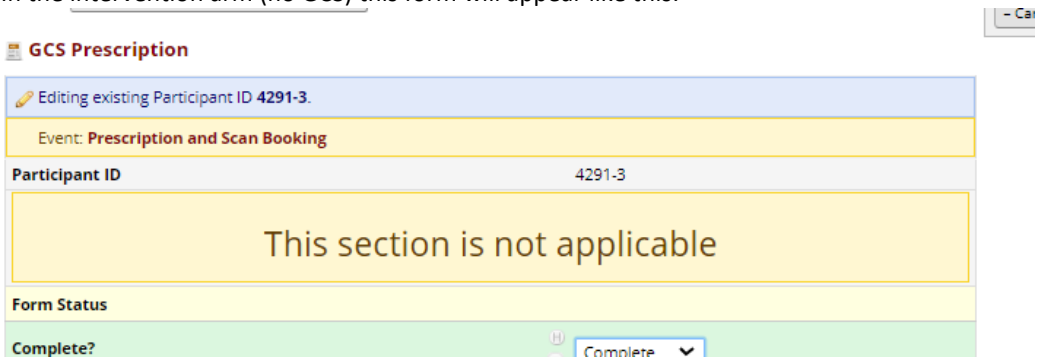
GCS Prescription

Editing existing Participant ID **4291-4**.

Event: **Prescription and Scan Booking**

Participant ID	4291-4
GCS Prescription (CONTROL Arm Only)	
How long was the participant advised to wear the stockings for?	◉ Until discharge from hospital ○ Until ambulant ○ 5 days ○ 7 days ○ 14 days ○ 28 days ○ 42 days ○ No advice was given (please specify below) ○ Other (please specify below) ○ Not known reset
Form Status	
Complete?	Complete

In the intervention arm (no GCS) this form will appear like this:



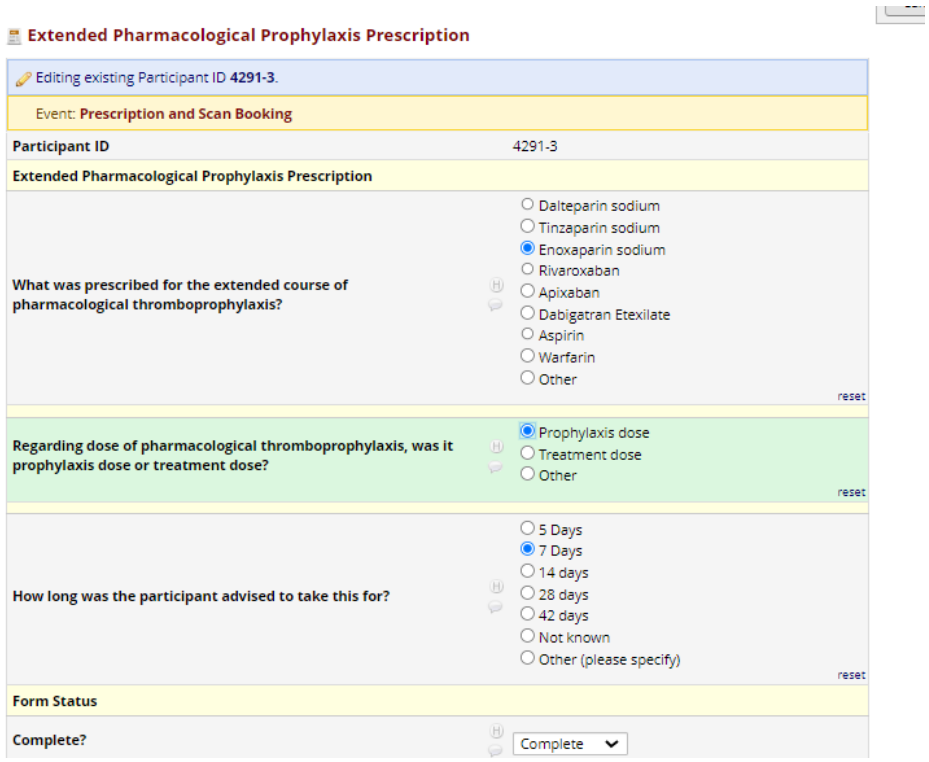
GCS Prescription

Editing existing Participant ID **4291-3**.

Event: **Prescription and Scan Booking**

Participant ID	4291-3
This section is not applicable	
Form Status	
Complete?	Complete

Complete the EDPTP prescription:



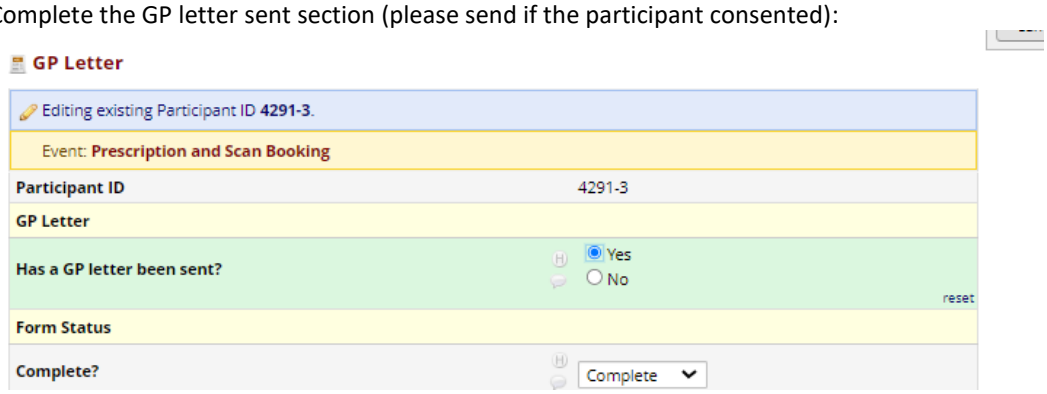
Extended Pharmacological Prophylaxis Prescription

Editing existing Participant ID **4291-3**.

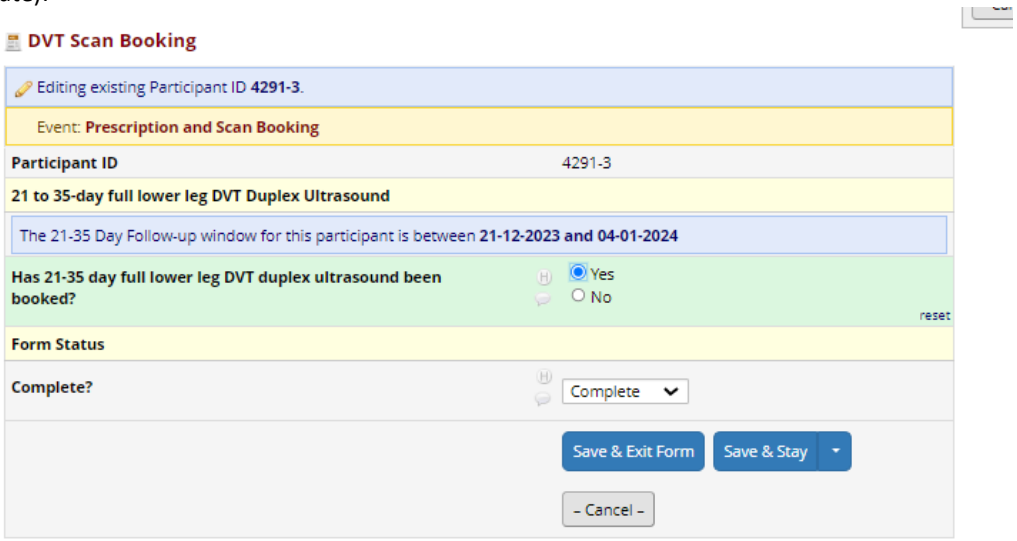
Event: **Prescription and Scan Booking**

Participant ID	4291-3
Extended Pharmacological Prophylaxis Prescription	
What was prescribed for the extended course of pharmacological thromboprophylaxis?	○ Dalteparin sodium ○ Tinzaparin sodium ◉ Enoxaparin sodium ○ Rivaroxaban ○ Apixaban ○ Dabigatran Etexilate ○ Aspirin ○ Warfarin ○ Other reset
Regarding dose of pharmacological thromboprophylaxis, was it prophylaxis dose or treatment dose?	◉ Prophylaxis dose ○ Treatment dose ○ Other reset
How long was the participant advised to take this for?	○ 5 Days ◉ 7 Days ○ 14 days ○ 28 days ○ 42 days ○ Not known ○ Other (please specify) reset
Form Status	
Complete?	Complete

Complete the GP letter sent section (please send if the participant consented):

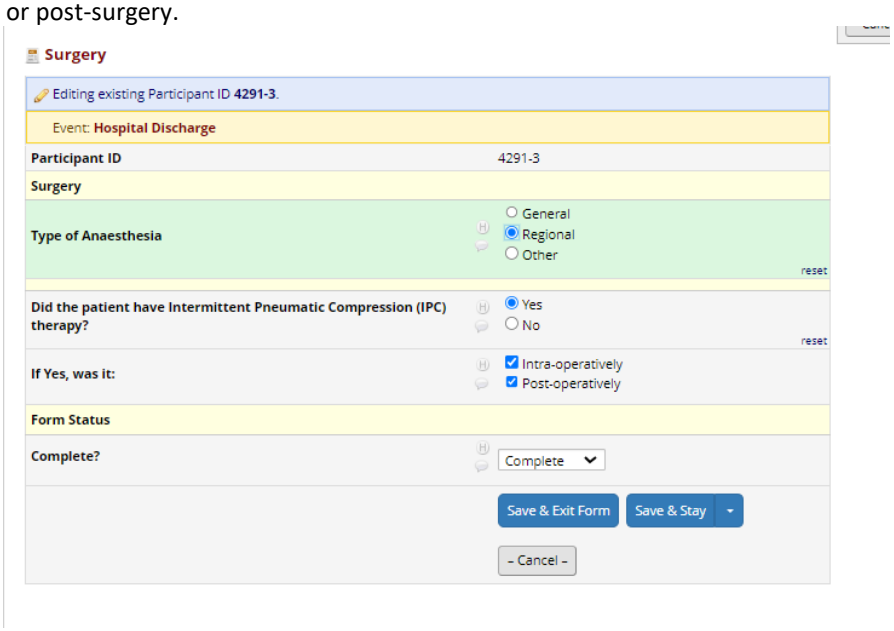


Please confirm the DVT scan has been booked in. The form will calculate the window for the scan (21 to 35 days post surgery date):

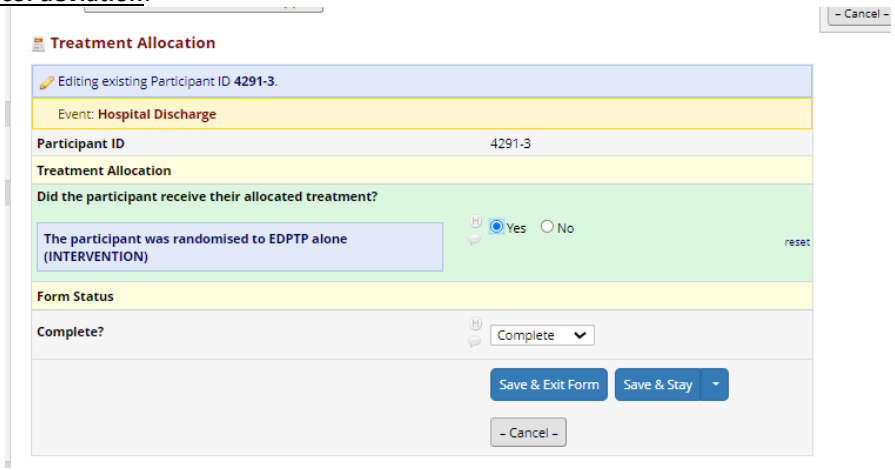


Hospital discharge

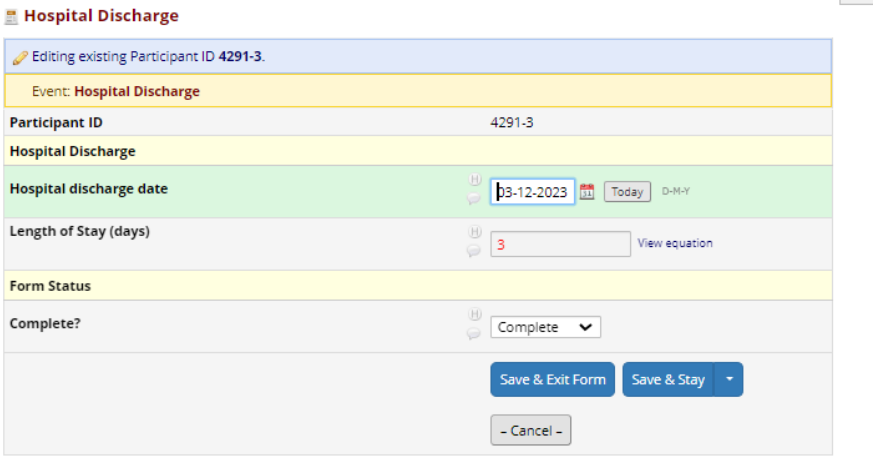
Please confirm the anaesthesia type used in the surgery and whether the participant had Intermittent Pneumatic Compression (IPC) during or post-surgery.



Please complete whether the patient received the allocated treatment during the hospital admission. **<u>If not, please complete a protocol deviation</u>**:

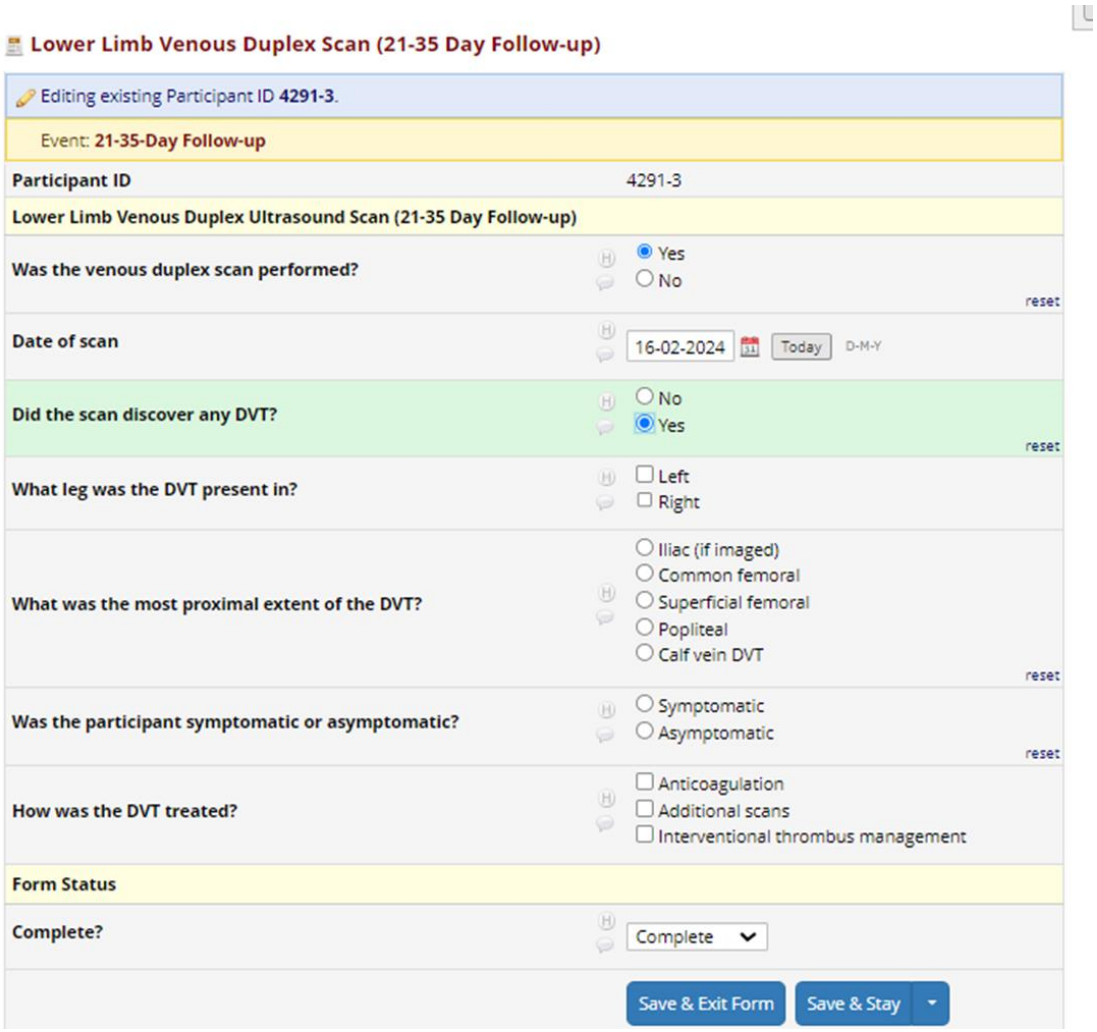


Please complete the hospital discharge date, the length of stay will autocomplete from the day of surgery:



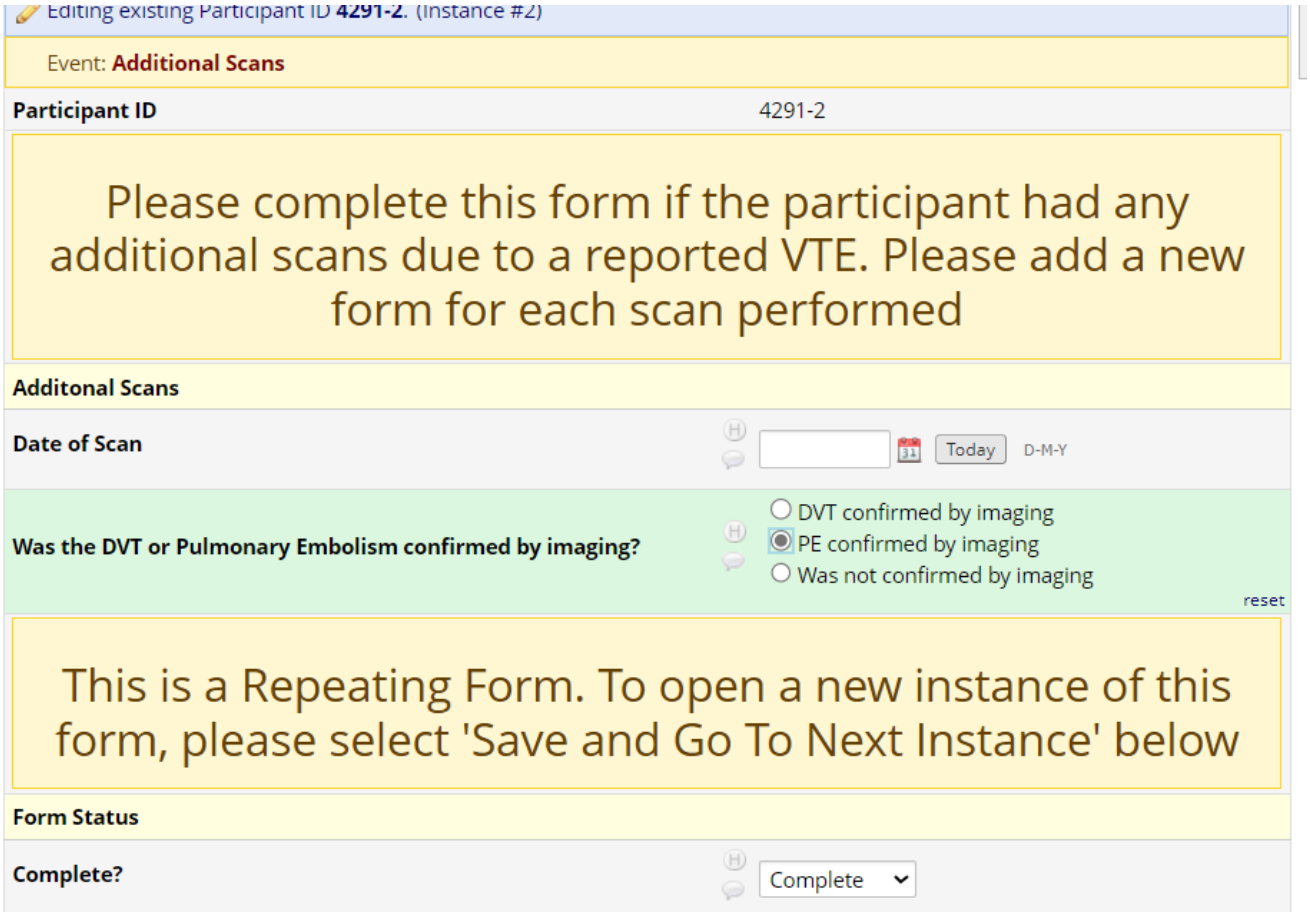
Lower Limb Venous Duplex Scan (21-35 Day Follow-up)

All randomised participants should have a full lower limb DVT ultrasound between 21 and 35 days post surgery. Please complete the Lower Limb Venous Duplex Scan (21-35 Day Follow-up) form to indicate that the scan was completed and the findings.



Additional scans

If the participant reports to us that they have had a DVT or PE outside the 21 to 35 day scan we will ask you to complete the additional scan form to confirm this has been confirmed by imaging (this should occur as part of standard care):

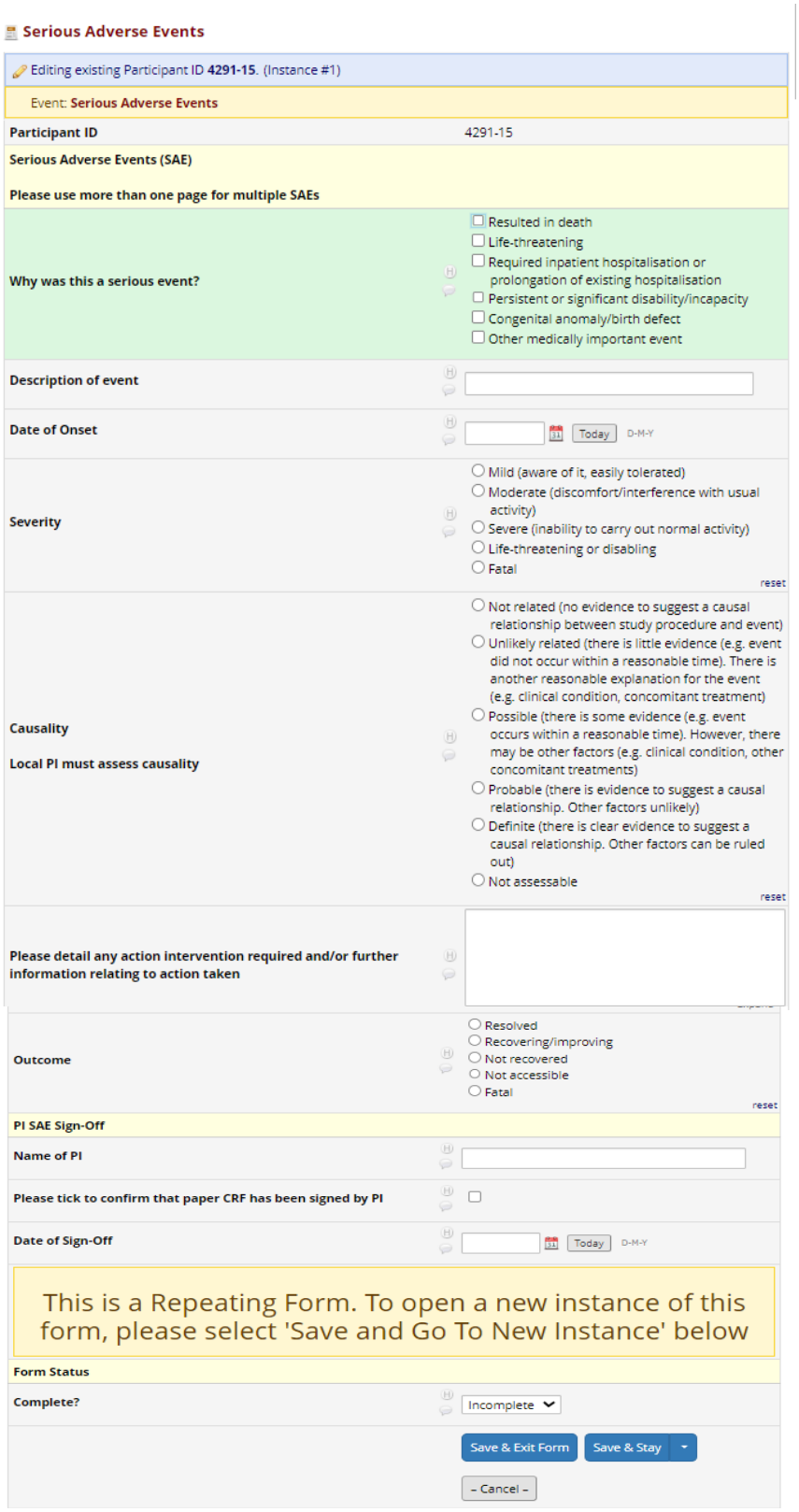


Adverse Events Form

Only adverse events related to GCS will be collected in this study and this is participant reported during the follow-ups performed by the Imperial College team. In the event that you do become aware of an adverse event related to the GCS please do notify us.

Serious Adverse Events Form

The *Serious Adverse Events Form* instrument looks like this. Causality and expectedness must be assessed by the Principal Investigator and they should sign the paper form to confirm this:



Serious Adverse Events

Editing existing Participant ID **4291-15**. (Instance #1)

Event: **Serious Adverse Events**

Participant ID	4291-15
Serious Adverse Events (SAE) **Please use more than one page for multiple SAEs**	
Why was this a serious event?	☐ Resulted in death ☐ Life-threatening ☐ Required inpatient hospitalisation or prolongation of existing hospitalisation ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/birth defect ☐ Other medically important event
Description of event	
Date of Onset	Today D-M-Y
Severity	○ Mild (aware of it, easily tolerated) ○ Moderate (discomfort/interference with usual activity) ○ Severe (inability to carry out normal activity) ○ Life-threatening or disabling ○ Fatal reset
Causality **Local PI must assess causality**	○ Not related (no evidence to suggest a causal relationship between study procedure and event) ○ Unlikely related (there is little evidence (e.g. event did not occur within a reasonable time). There is another reasonable explanation for the event (e.g. clinical condition, concomitant treatment) ○ Possible (there is some evidence (e.g. event occurs within a reasonable time). However, there may be other factors (e.g. clinical condition, other concomitant treatments) ○ Probable (there is evidence to suggest a causal relationship. Other factors unlikely) ○ Definite (there is clear evidence to suggest a causal relationship. Other factors can be ruled out) ○ Not assessable reset
Please detail any action intervention required and/or further information relating to action taken	
Outcome	○ Resolved ○ Recovering/improving ○ Not recovered ○ Not accessible ○ Fatal reset
PI SAE Sign-Off	
Name of PI	
Please tick to confirm that paper CRF has been signed by PI	☐
Date of Sign-Off	Today D-M-Y

This is a Repeating Form. To open a new instance of this form, please select 'Save and Go To New Instance' below

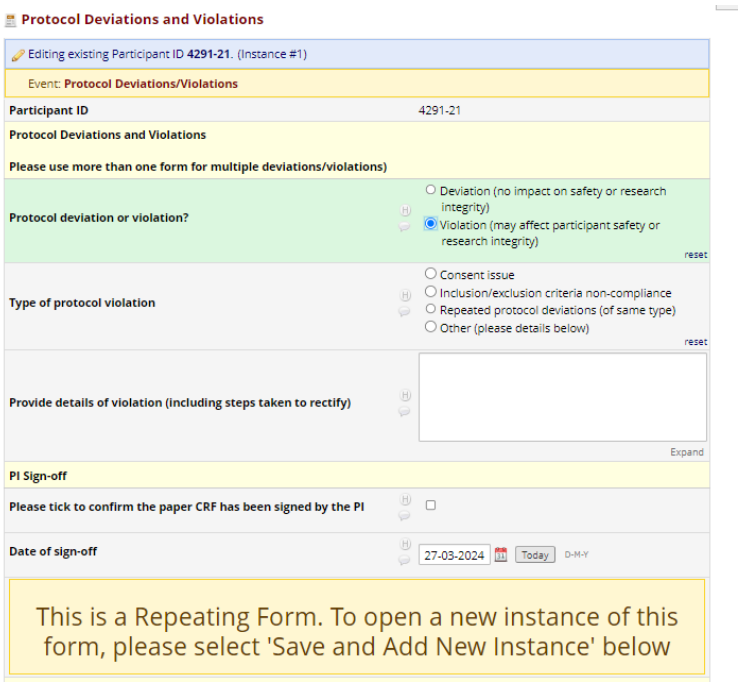
Form Status	
Complete?	Incomplete

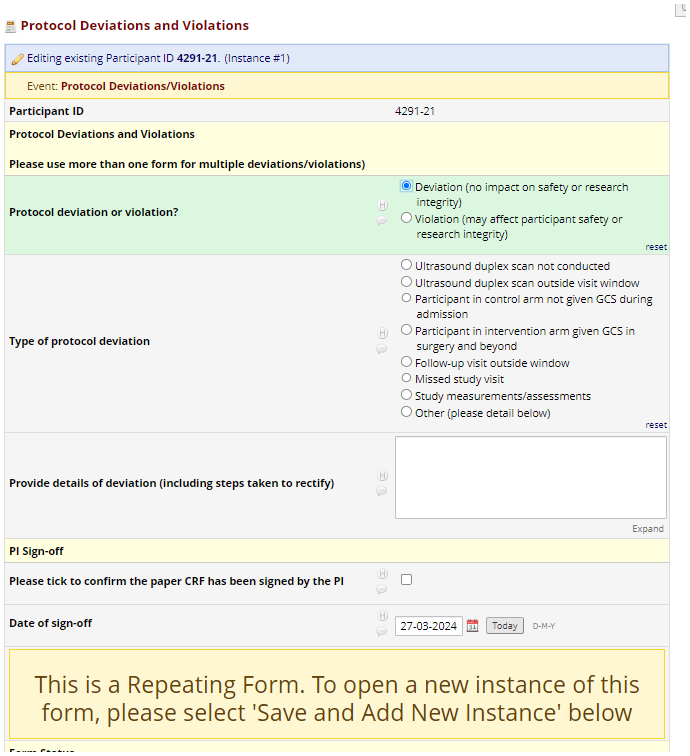
Save & Exit Form | Save & Stay | - Cancel -

The SAE Form can be repeated as many times as required. Please see above ‘Repeating Forms’ section for further information.

Protocol Deviations

If a protocol deviation or violation occurs at any point while on the study, the *Protocol Deviation* CRF should be completed with the relevant information as soon as the site becomes aware of the deviation.

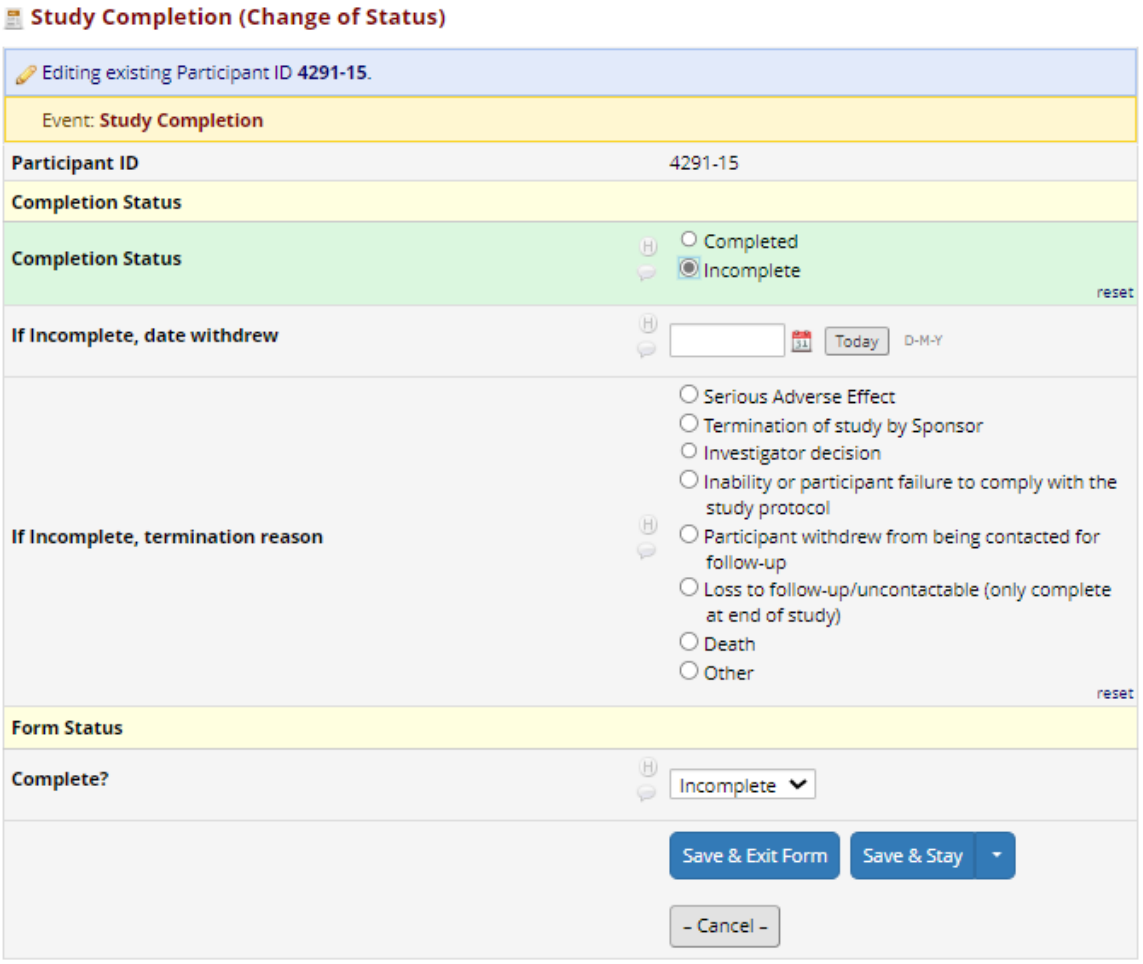




This information can be updated at a later date if needed (eg. If steps were taken to rectify the deviation/violation).

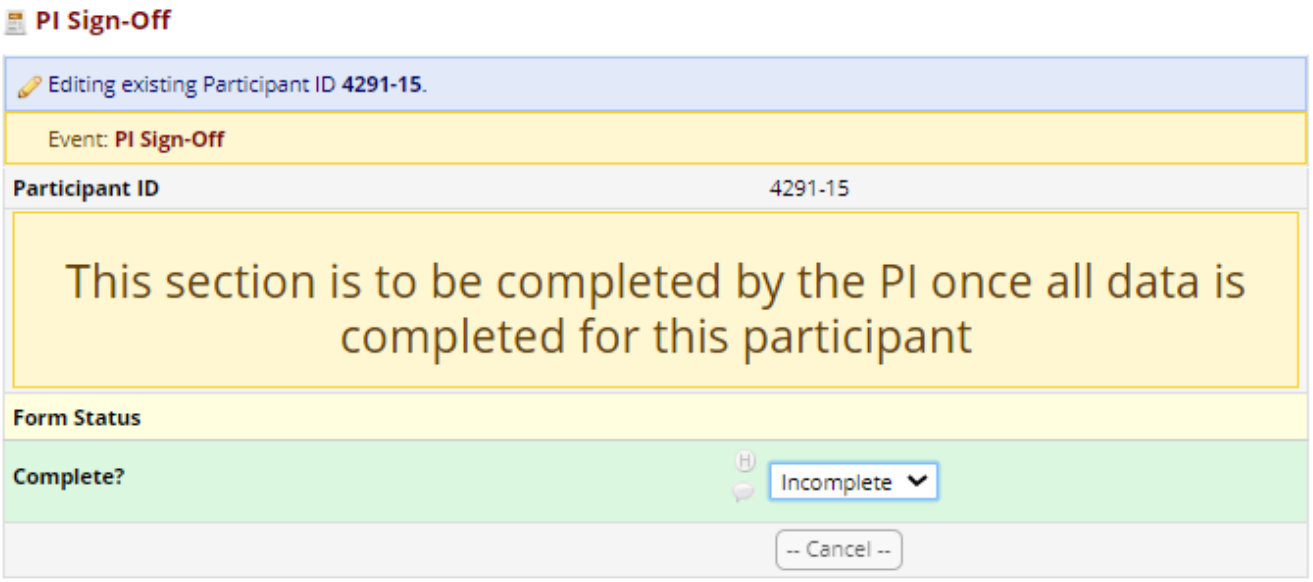
Study Completion

If the participant has been withdrawn from the trial, the *Study Completion / Termination* CRF should be completed with the date they were withdrawn. The trial team is mostly responsible for this unless the participant was withdrawn by the Principal Investigator:

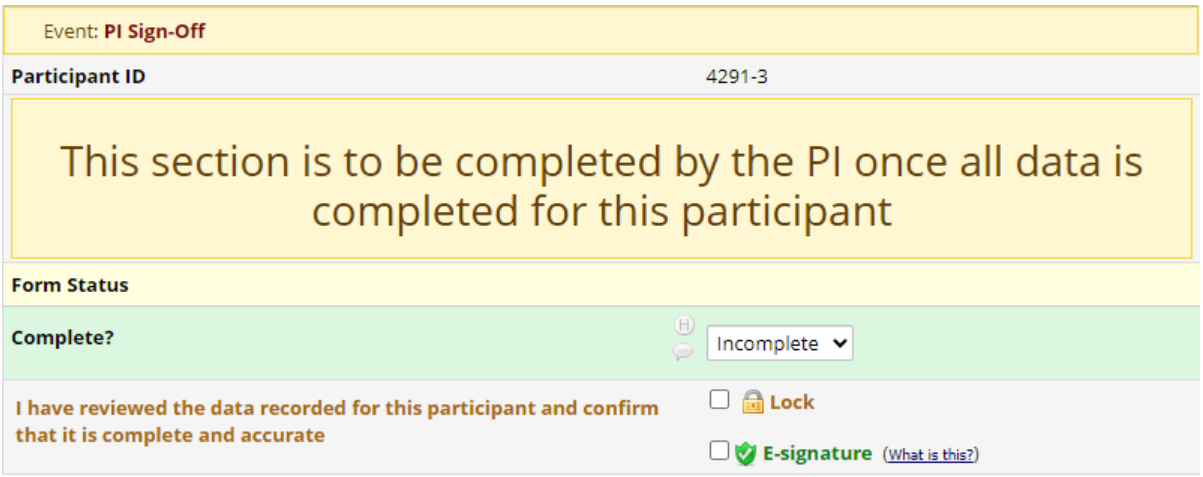


PI Sign-off

Once the participant has completed the 90 days and all the data is complete the PI should sign off the CRF. They will have a login which will allow them to do this. To the research team the form will look like this:

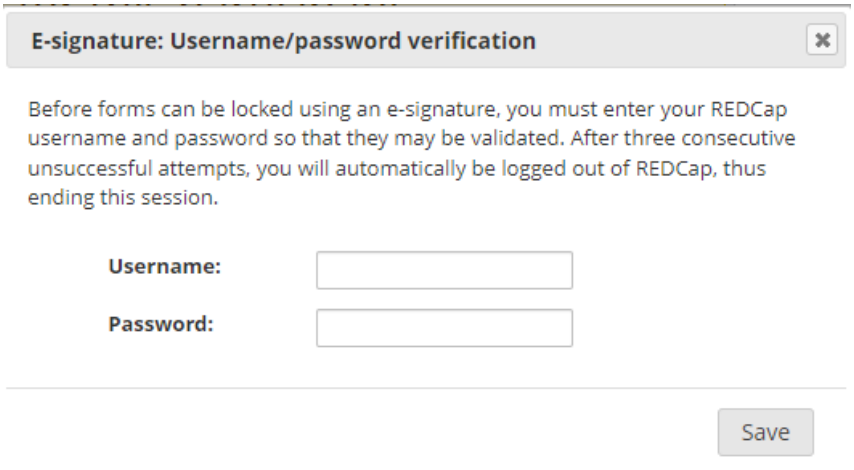


Under the PI login the form will look like this:

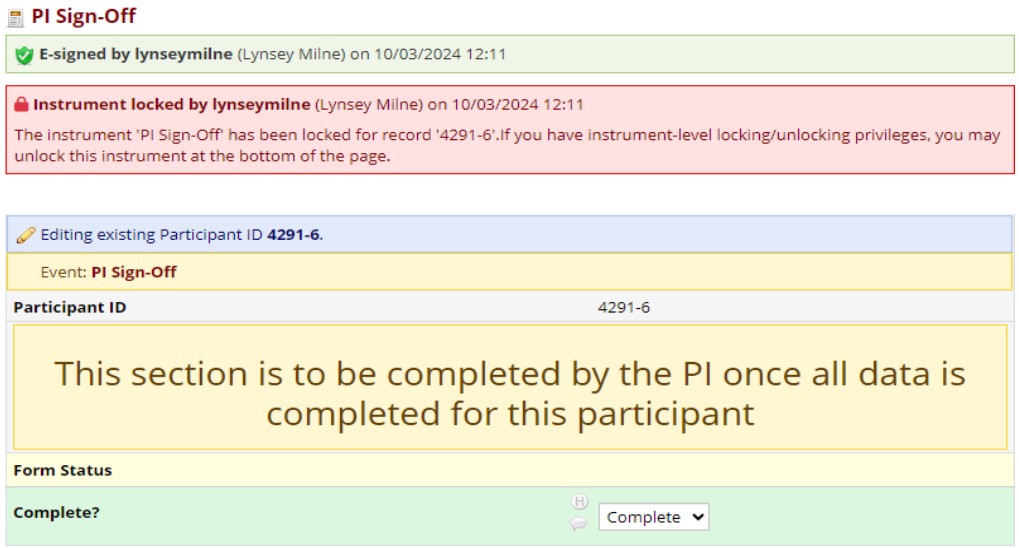


Both 'Lock' and 'E-signature' fields must be ticked before the form is completed.

Once both fields are ticked, the following alert will appear once the page is saved:



Once locked, the instrument will look like this:



Once locked, the instrument can only be unlocked by those in the 'Site PI' user role.
The fields below appear for those in this role: