DRAFT3-CASP Screening/Randomisation Procedure

This guide runs through the screening and randomisation procedure from start to finish and details what to do if you need to randomise manually through RRAMP in the event that REDCap doesn't work.

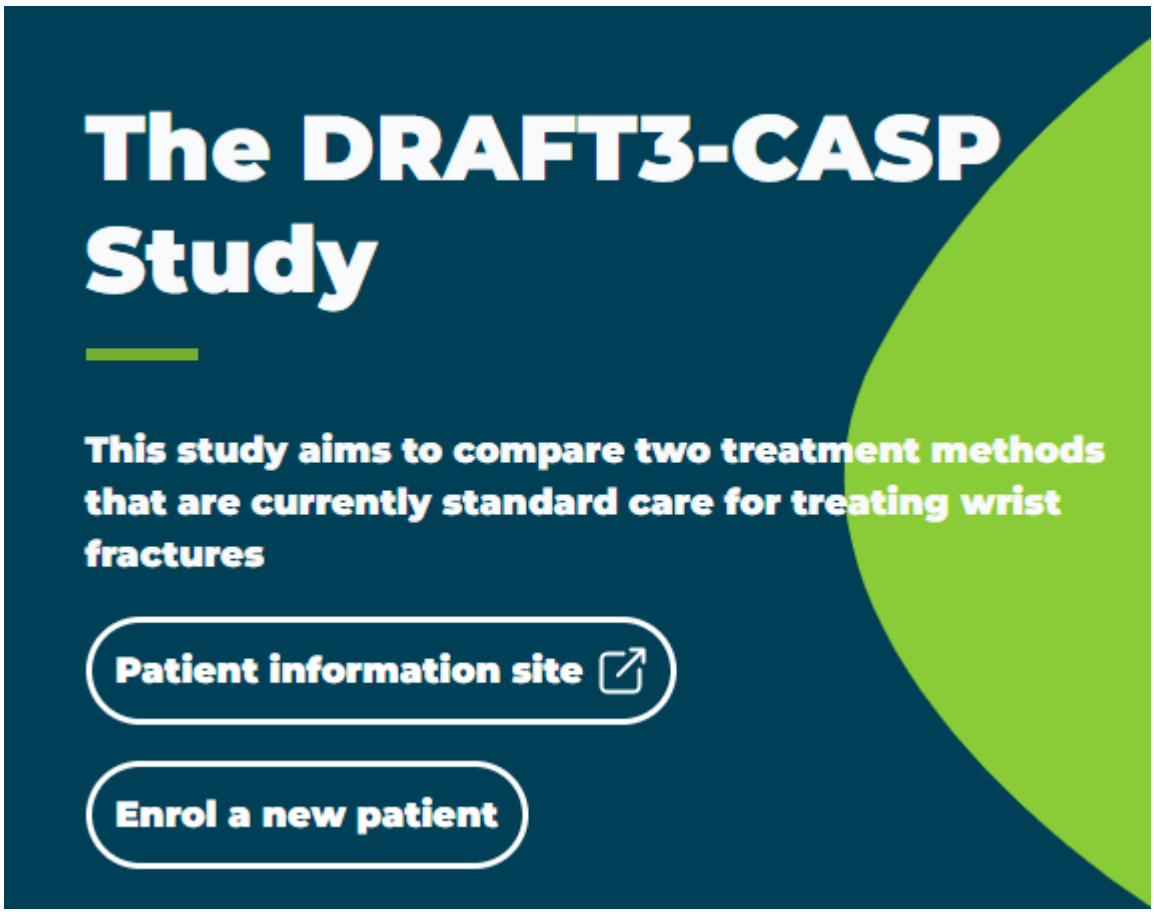
If you are struggling at any point throughout the randomisation process please either call the Trial Manager Heather on 01865 (2)23113 or the Trial Administrator Elli on 01865 612709 so that we can help you. Alternatively, you can contact the study team in the DRAFT3 Whatsapp group.

DO NOT TRY TO RANDOMISE PATIENTS DIRECTLY INTO REDCAP (i.e. NOT VIA THE WEBSITE) - THIS WILL NOT WORK.

Procedure

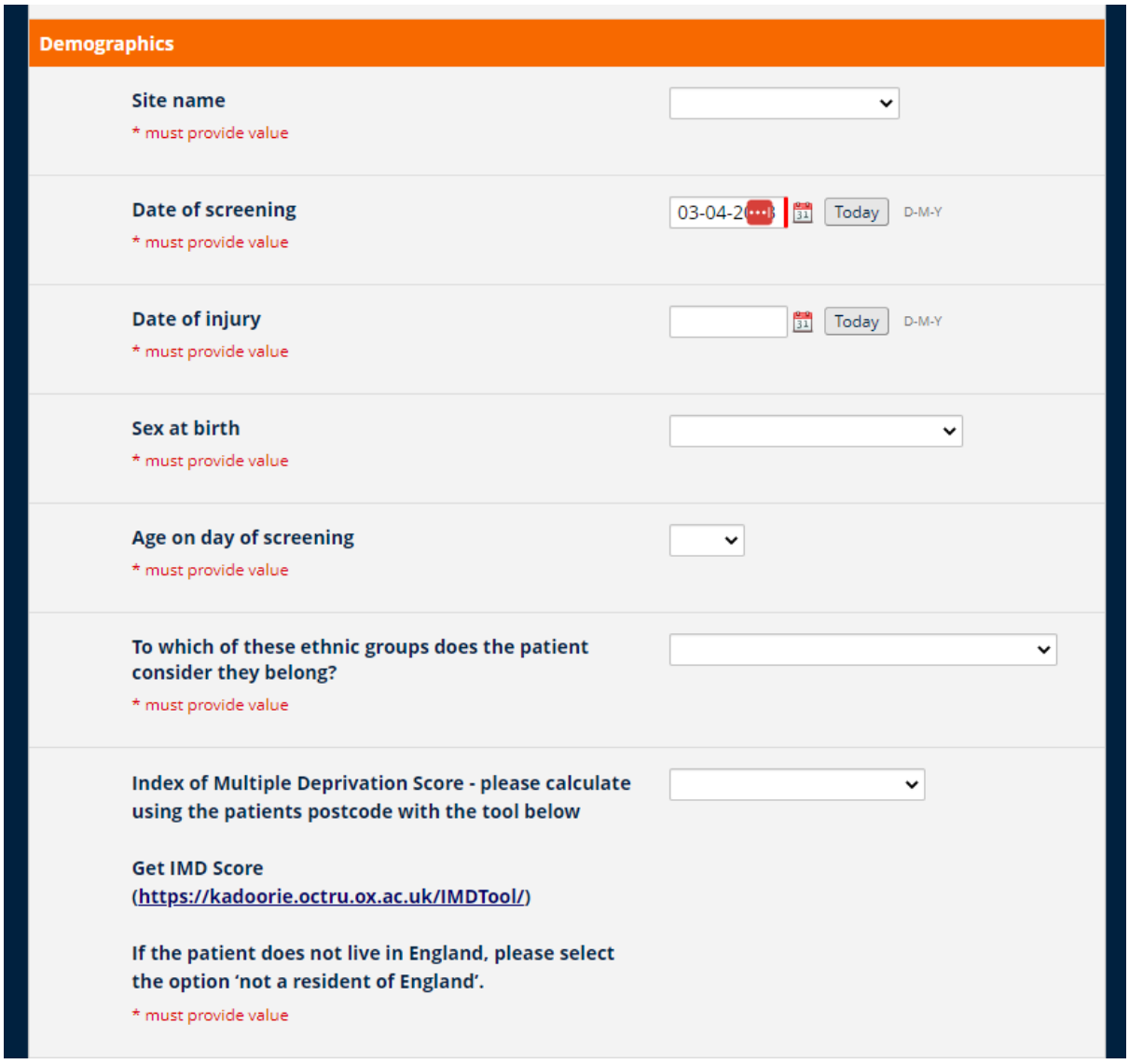
To begin the screening and randomisation procedure, go to the draft3-casp website at the below link.

www.draft3casp.org

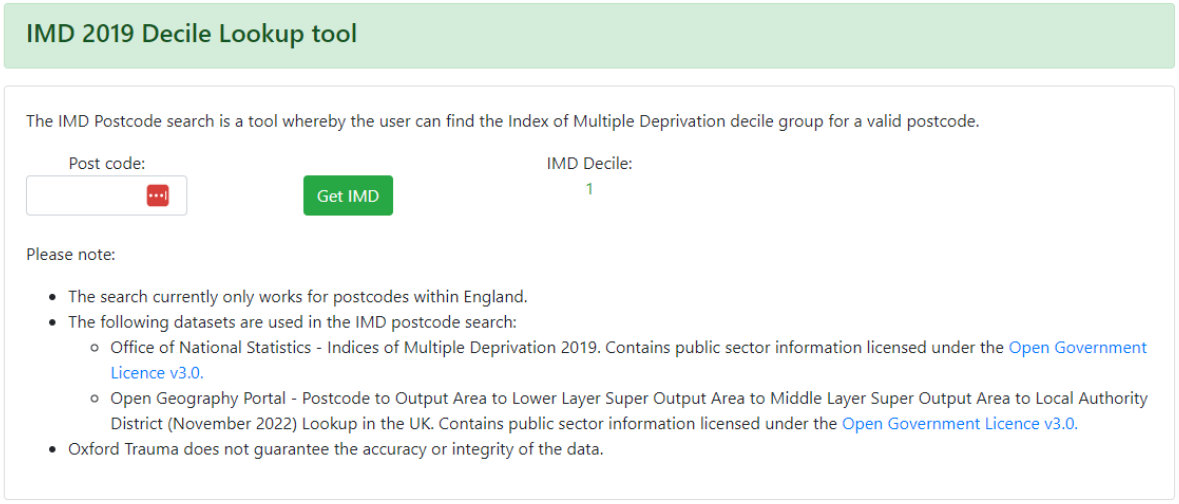


On this page, click the 'Enrol a new patient' button.

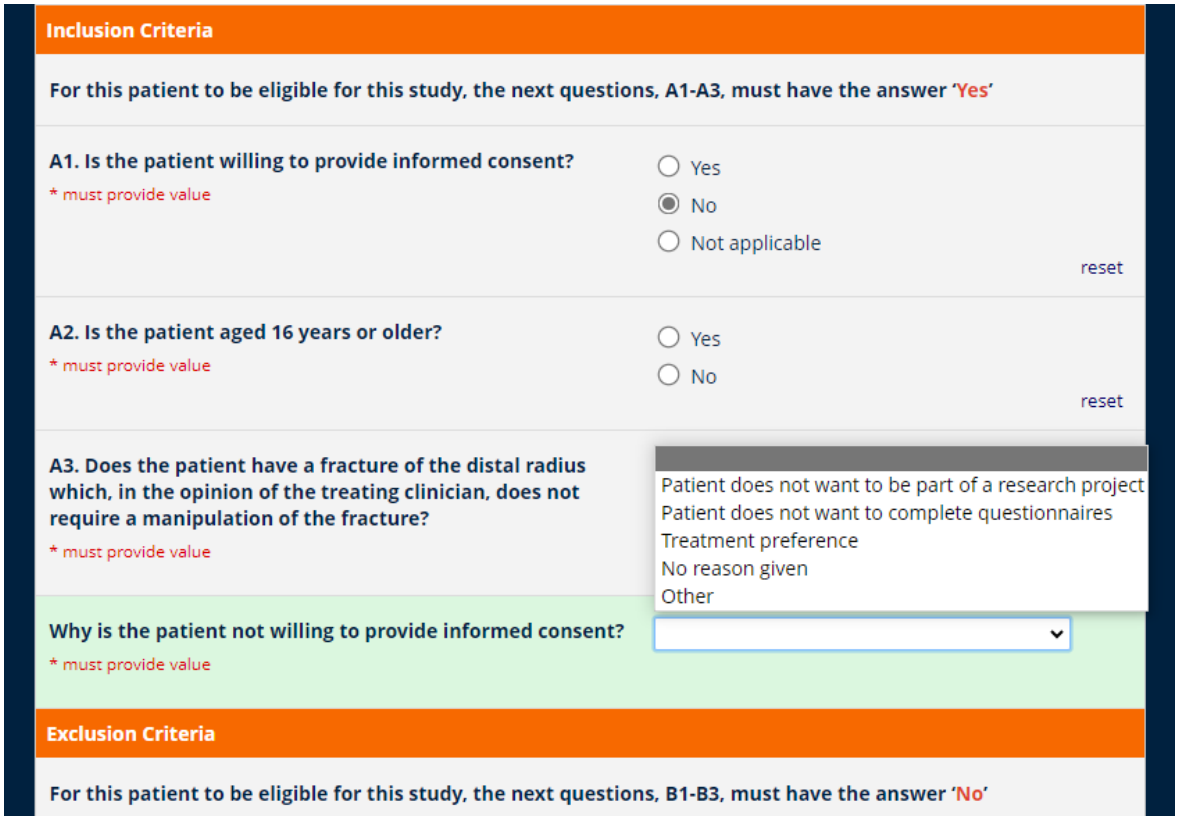
This will take you to another page where you can enter the generic password, which will be sent to you in your **greenlight activation email**. Once you submit the password, it will open the REDCap screening form.



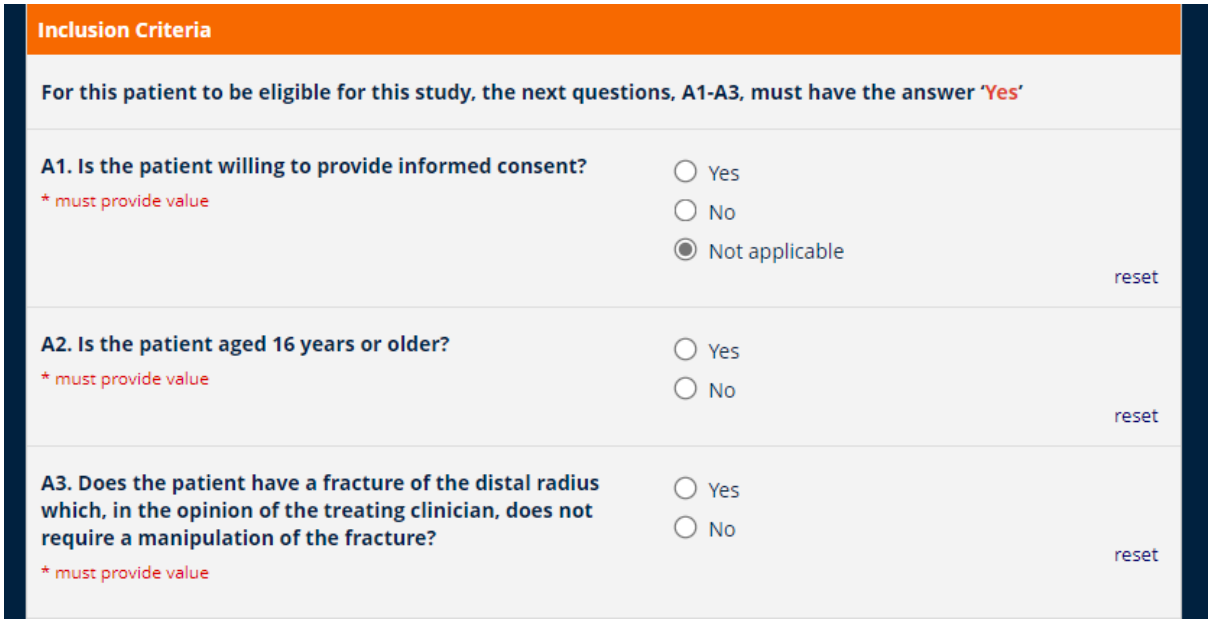
Choose your site name from the drop down and fill in all of the remaining information on the screening form.



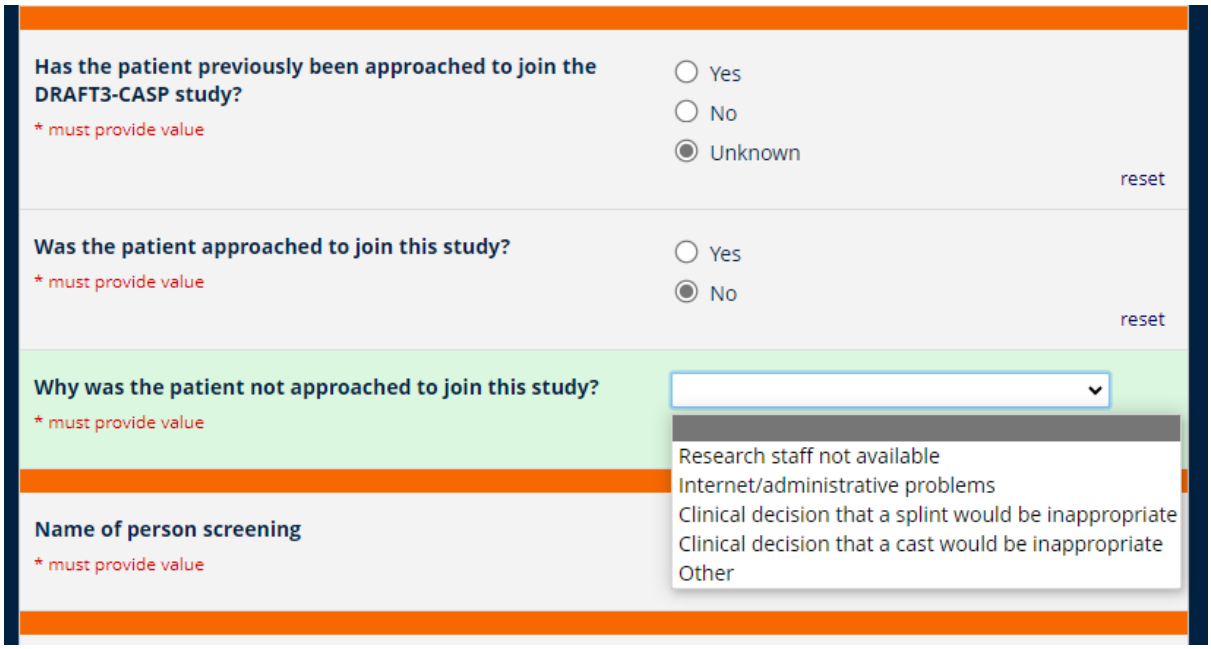
To enter the IMD score, follow the link provided. Please use this tool specifically, if you use google it will give you a different scale that won't work.



If the patient has a treatment preference or doesn't want to take part for another reason, tick no to A1 and specify using the dropdown that will pop up.

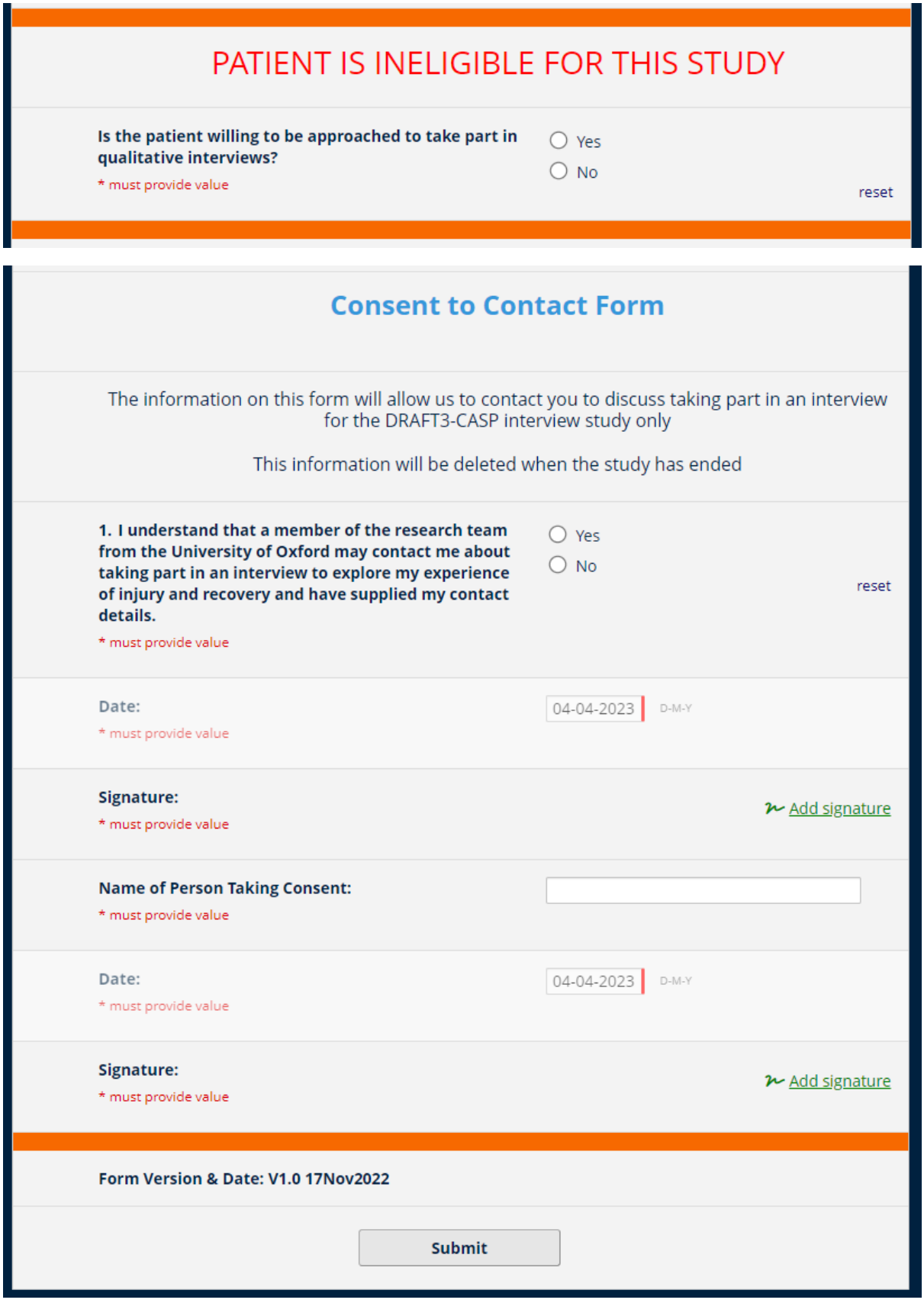


If the patient was not approached, you can select 'Not applicable' for question A1. You can then select 'no' to "Was the patient approached to join this study?" which will pop up a bit further down the form underneath the exclusion criteria. **Please select this option if the patient is ineligible for any other reason as only eligible participants should be approached for consent.** Always ensure to complete the entire screening form.



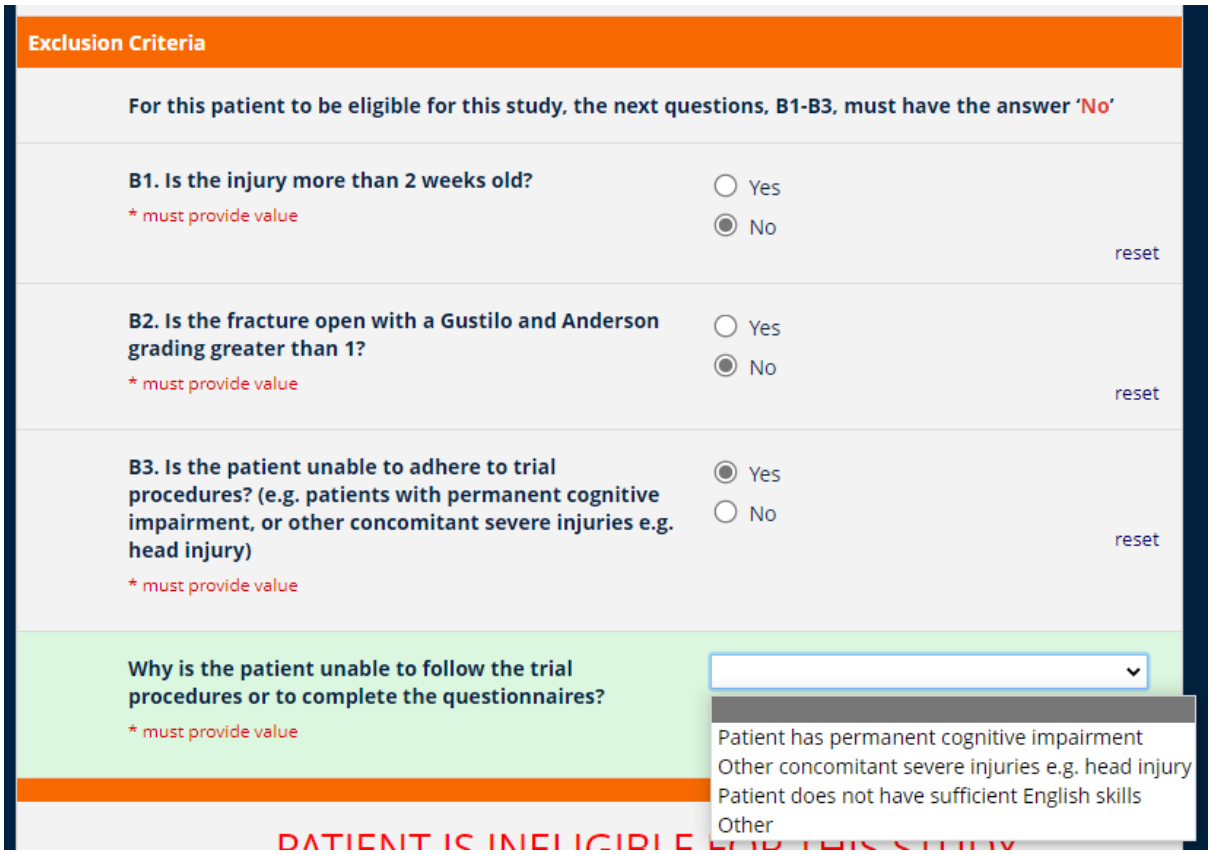
It will ask you whether the patient has previously been approached for the DRAFT3-CASP study – as the study recruitment will last a while there is a chance that a patient might break their wrist (or the other one) again. These patients can't be recruited into the study again.

If the patient wasn't approached for the study, please select no to this question and select the reason from the dropdown – this is where you will record if research staff were not available or due to clinician decisions/treatment preferences. If it is unknown whether the patient was approached, please select 'unknown'.



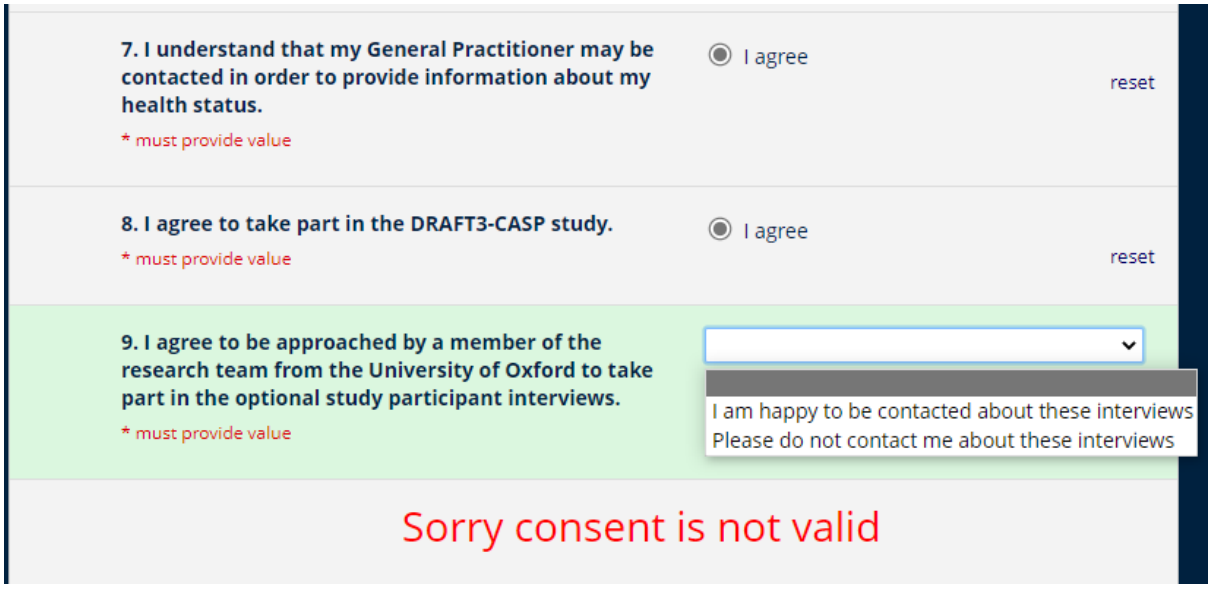
If this is ticked, the patient will not be eligible but they can still take part in the qualitative interviews. If you tick yes to 'Is the patient willing to be approached to take part in qualitative

interviews' and press submit, it will take you to the Consent to Contact Form so that you can collect the contact details without having to consent them into the main study.



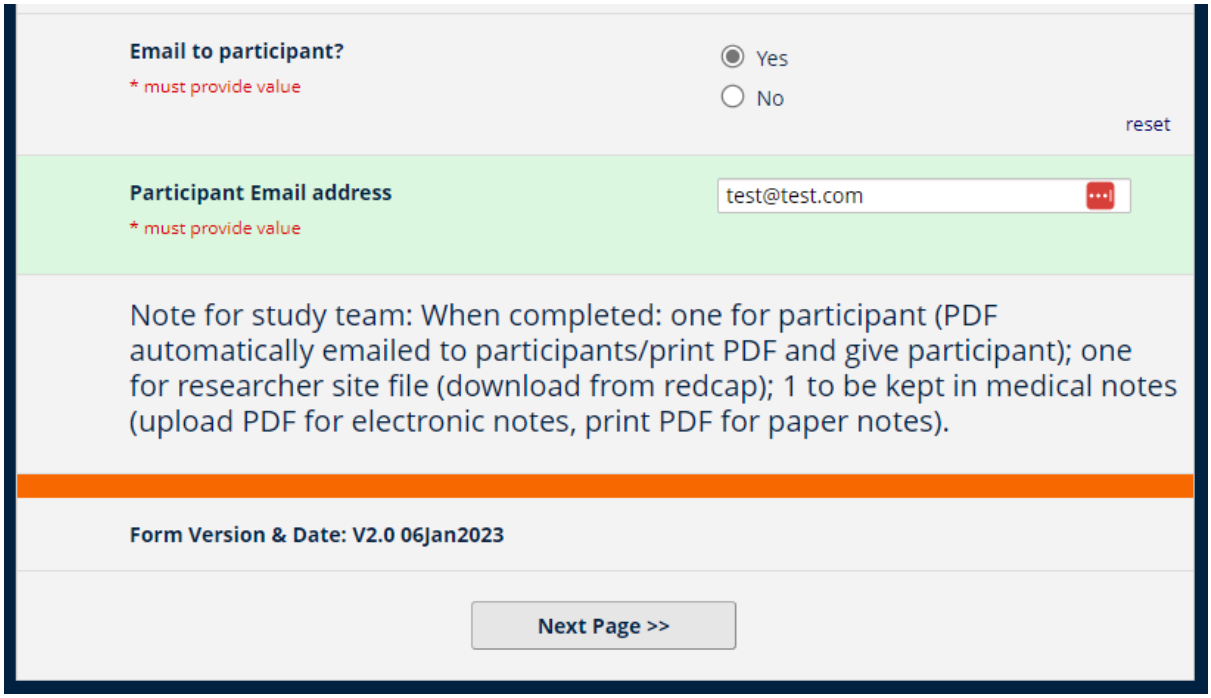
If the patient has a cognitive impairment, concomitant severe injuries, insufficient English or cannot adhere for any other reason, then tick no to B3 and specify using the dropdown. (N.B. Treatment preference is not a reason that a patient is unable to follow trial procedures).

Submit this form and it will take you to the consent form.

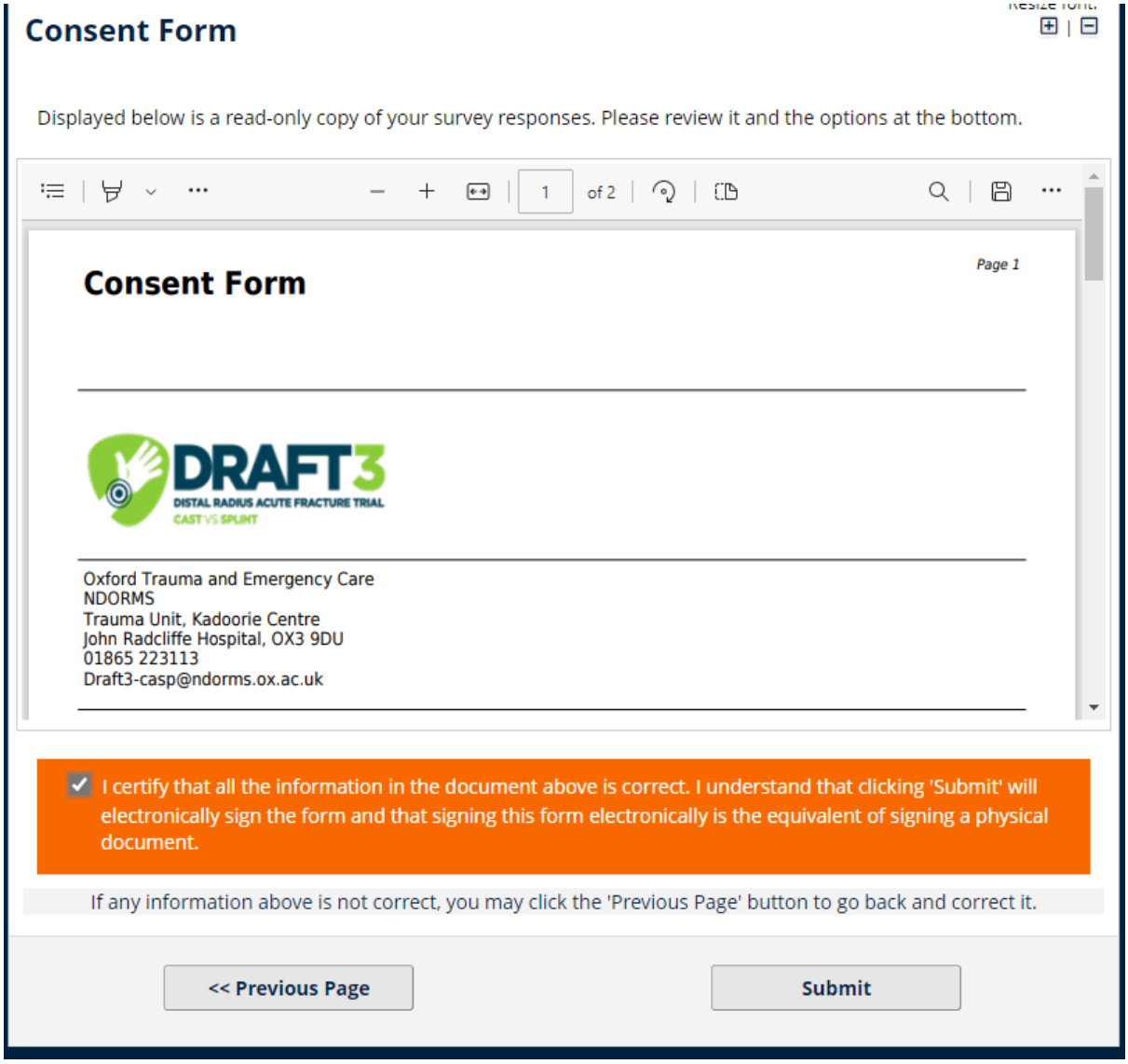


The consent will not be valid until it has been signed so don't worry about the Sorry consent is not valid message because it should go away once the form is valid and complete. The patient can also

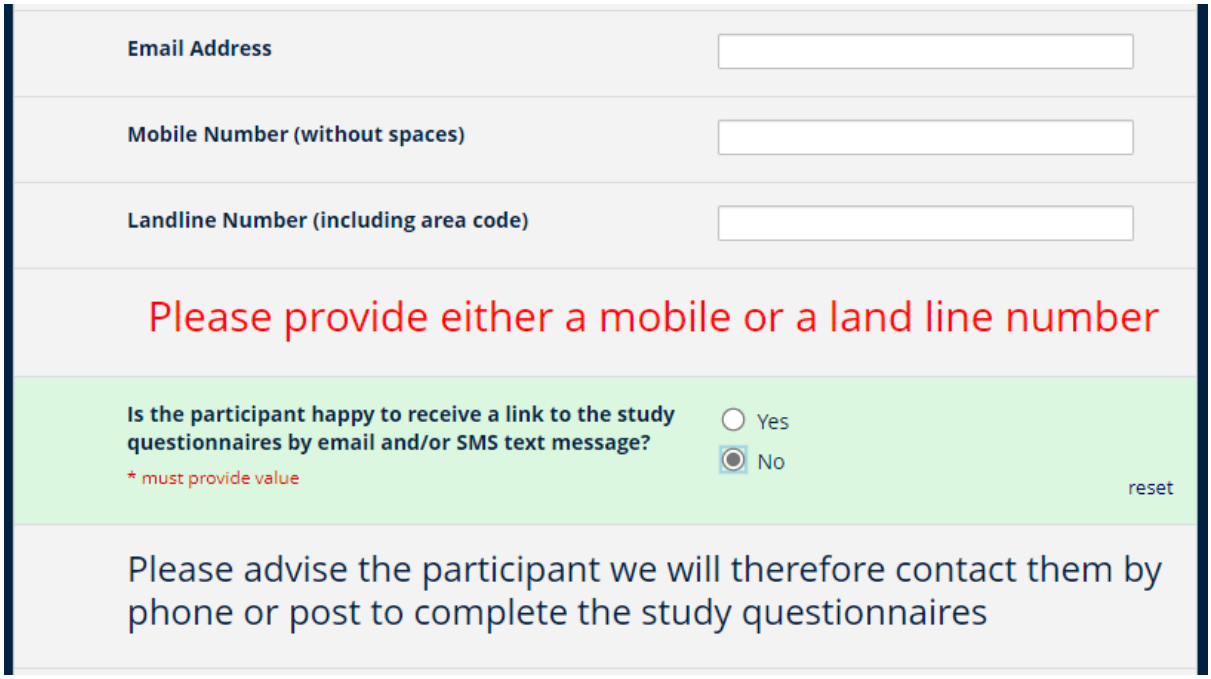
choose to take part in the optional qualitative interviews at this point by selecting 'I am happy to be contacted about these interviews' to question 9. This has no bearing on being a part of the main study or the questionnaires for this.



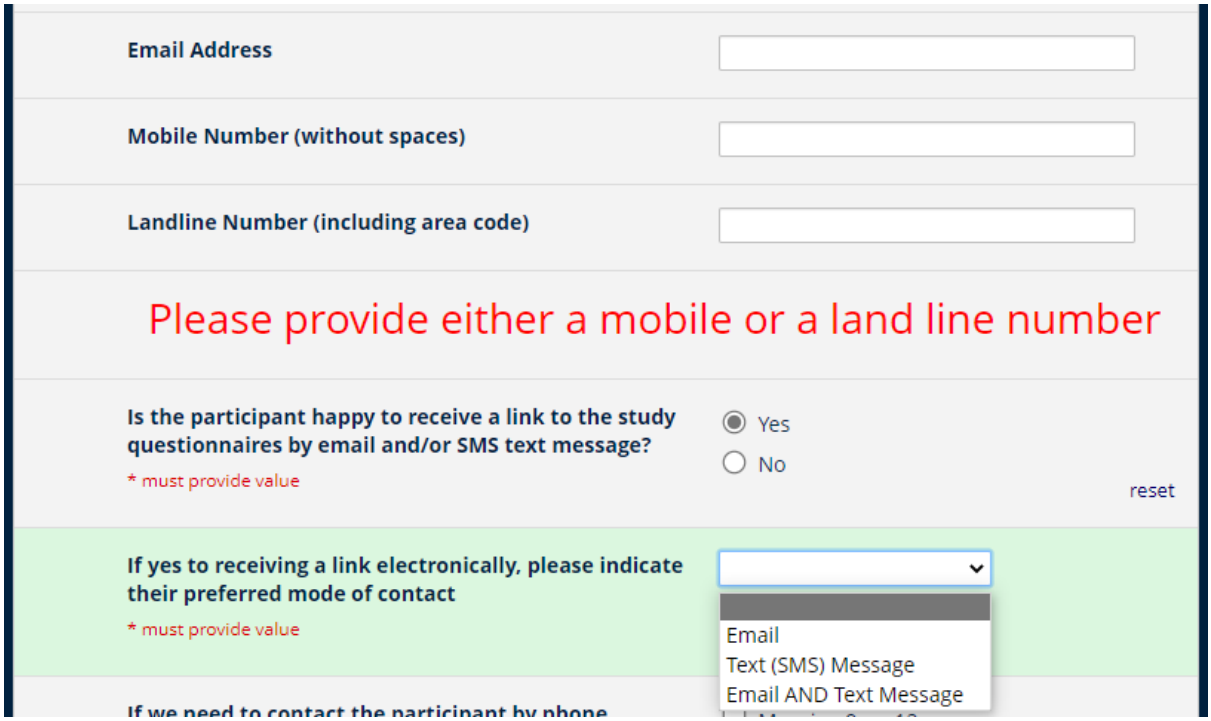
If the patient would like the consent form to be emailed to them, tick Yes to 'Email to participant' and enter their email address below. **NOTE: Please make sure the patient double-checks this email address as if the consent form is sent to another person this could constitute a serious data breach.** If the patient does not want the consent form to be emailed to them, tick no to this and then make sure you print the consent form off on the next screen to give a copy to the patient.



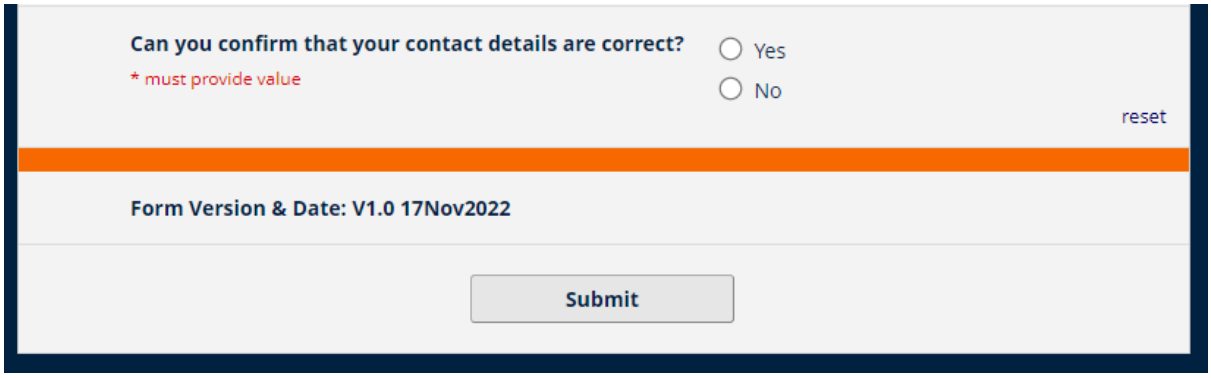
Tick to certify the document is correct, if it isn't go back to << Previous page and correct the information. If it is, submit the consent form and it will take you to the contact details form.



Enter the patient's contact details carefully. If the patient doesn't have the ability to receive SMS messages or emails, or they just don't want them, select No to 'is the participant happy to receive the questionnaires by email and/or SMS text message?' This will prompt us to follow them up by phone and/or post.

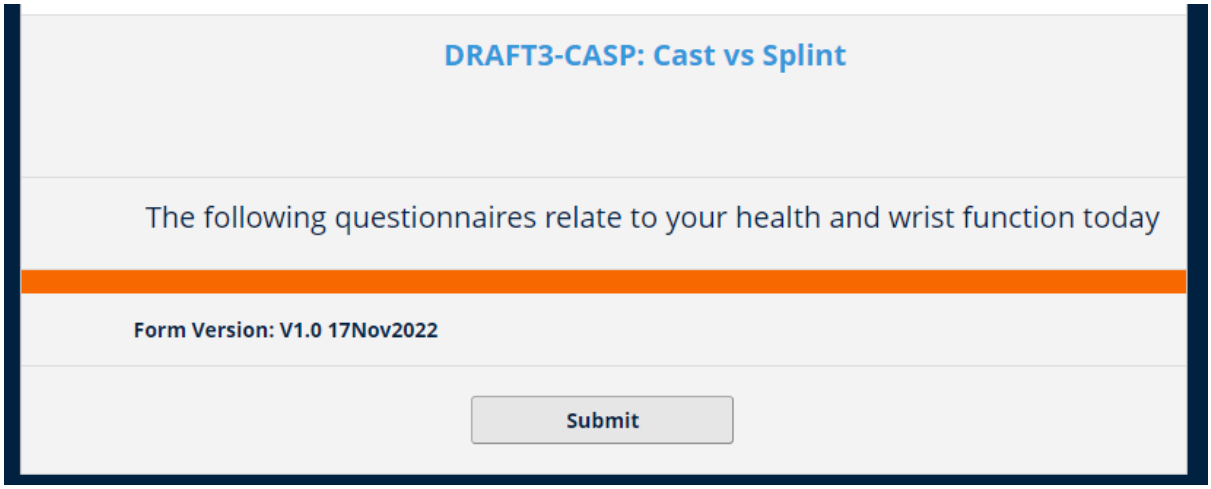


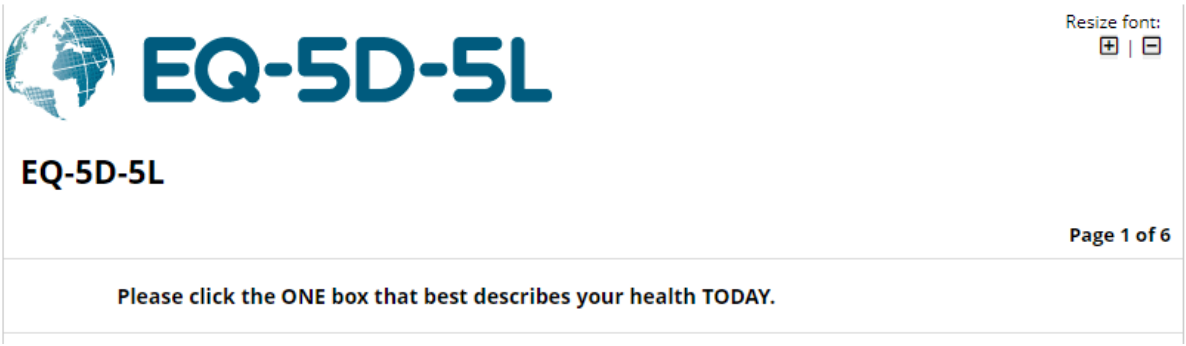
If the patient would prefer to complete the follow-ups electronically, select Yes to this question and then choose the specific contact using the dropdown that will pop up. Once all information has been entered, submit this form.



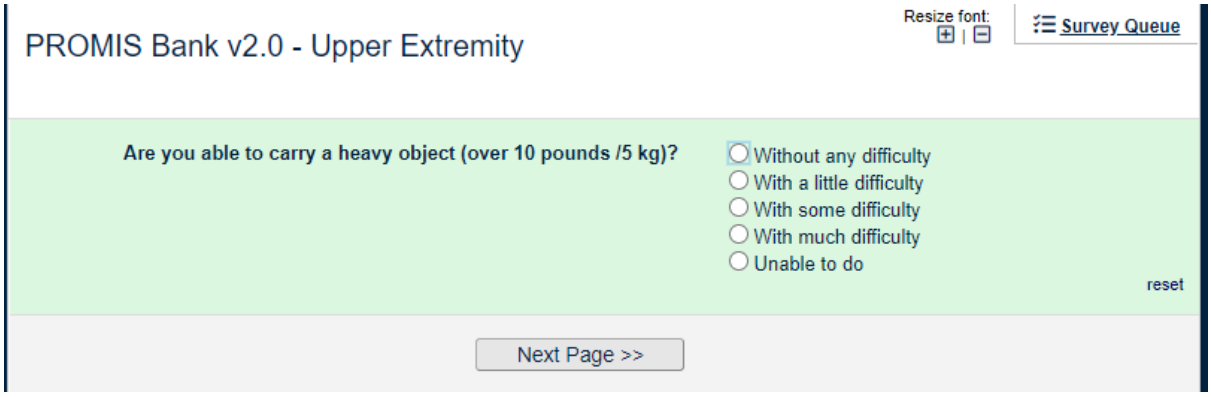
This will take you to the contact details check form. Ensure that all of the patient's details are correct, confirm this and submit the form.

After the contact details have been entered and checked, it will take you to the baseline CRF forms. These should be completed by the patient. The first forms will relate to the patient's wrist and general health **before** their injury. Please ensure that the patient is aware of this before they begin completing their questionnaires.



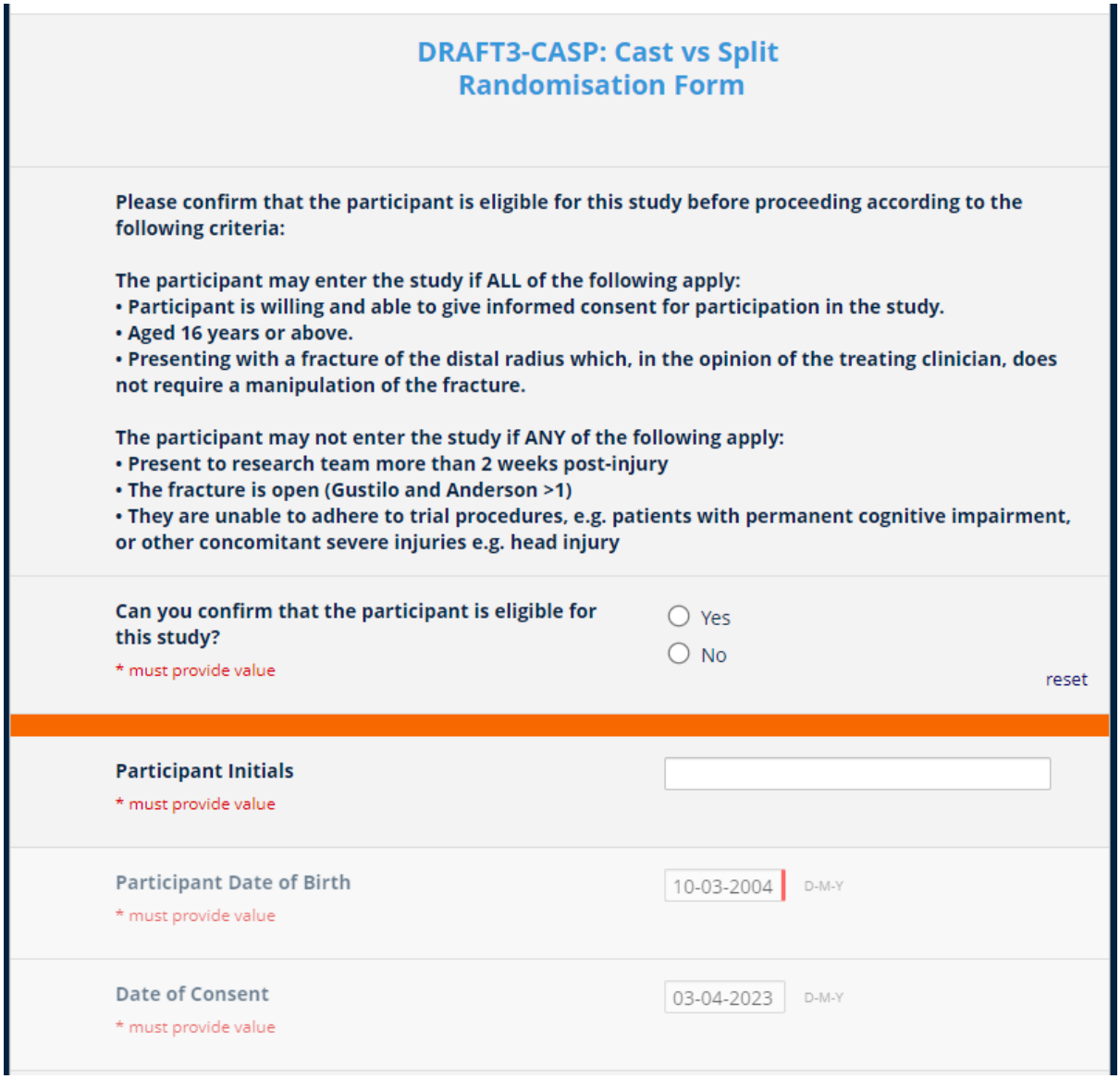


It will then ask the patient the same questions but regarding their wrist and general health **after** their injury (i.e. Today).

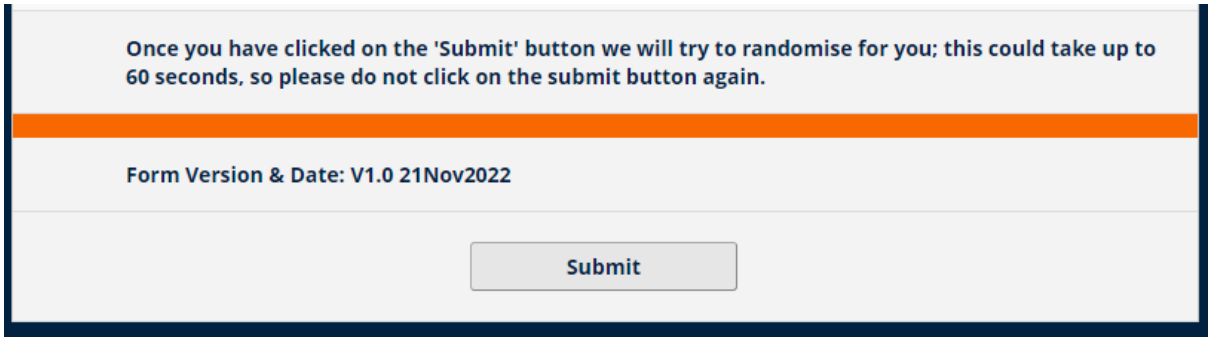


The PROMIS questionnaire is a variable questionnaire which asks questions based on the answers that the patient enters (i.e. it will not ask them if they can lift a heavy object if they cannot lift a light one).

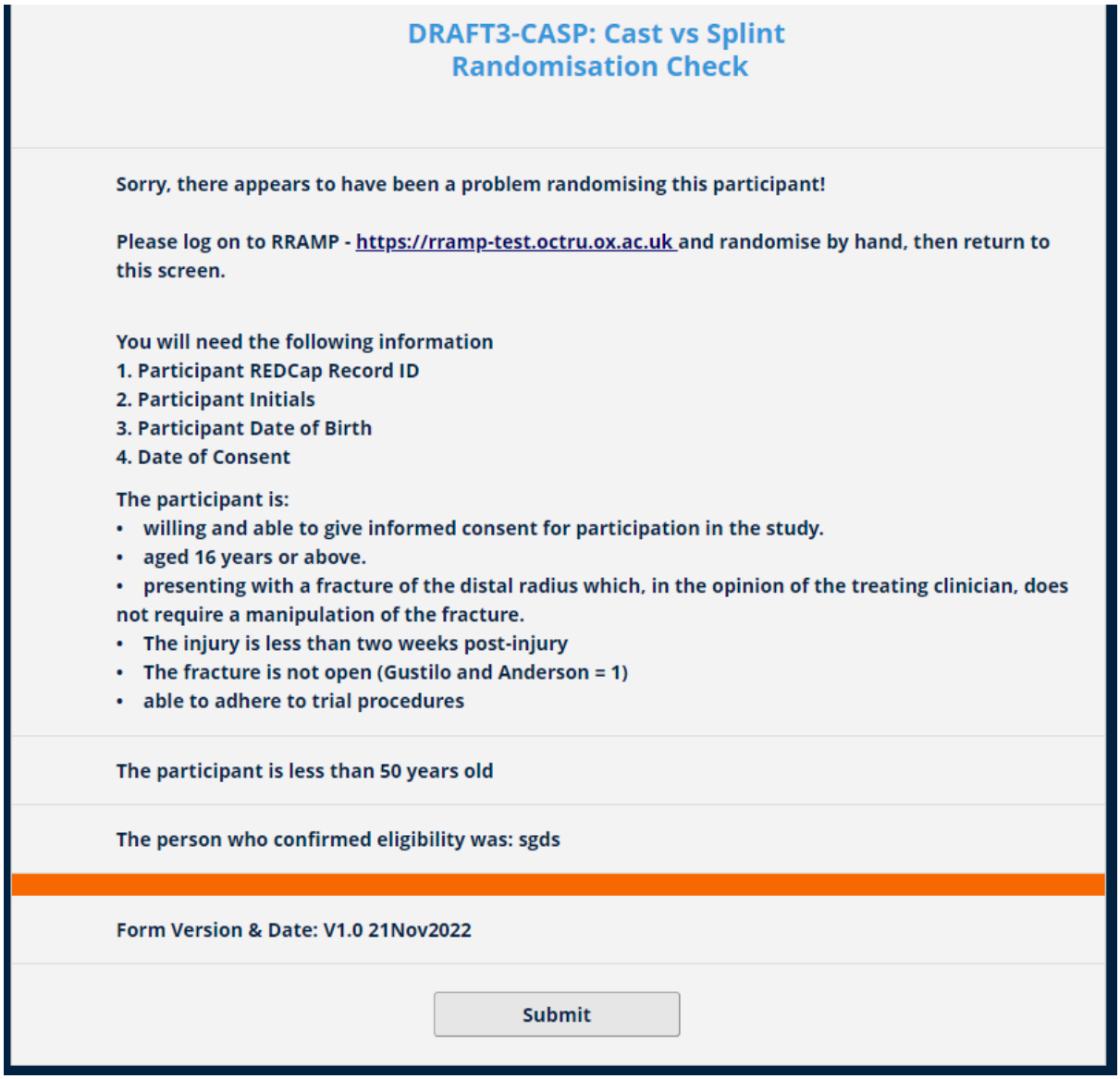
In the baseline CRF, it will ask the patient for their weight and height, which cannot be left blank - their best guess is fine. There is a link to a converter if the patient needs this.



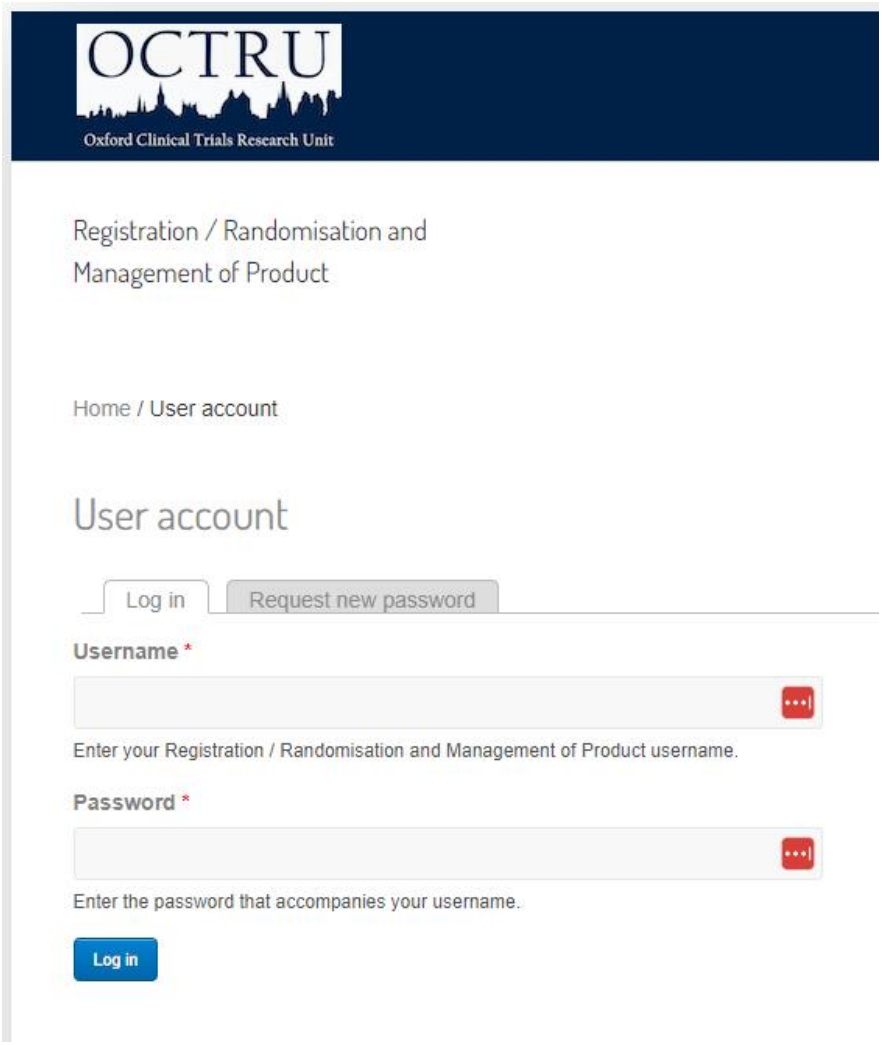
Once the patient submits their final baseline form it will take you to the randomisation form. Firstly it will ask you to double check the patient's eligibility for the study. If this is no, please stop the randomisation and contact the trial management team.



Fill in the rest of the form and press submit. REDCap will then talk to the randomisation platform (RRAMP) in the background, which may take up to a minute, so please be patient.

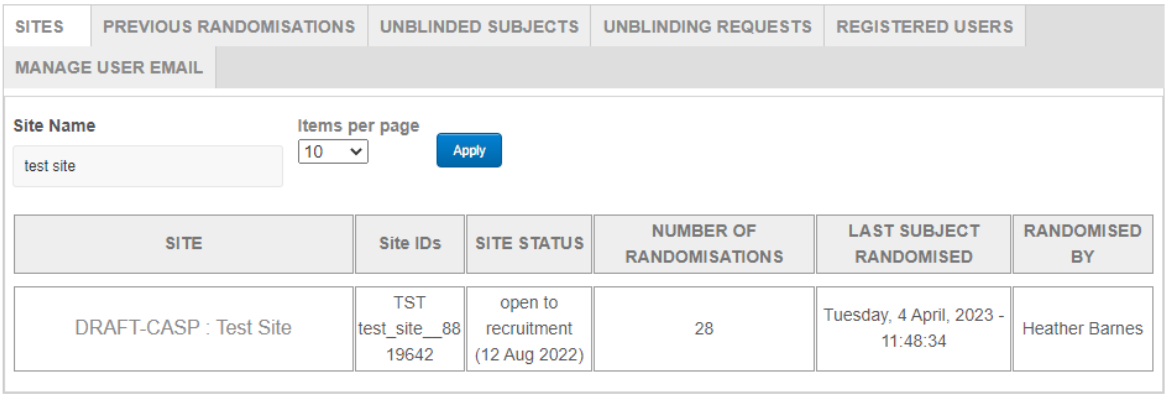


If the process is not successful, you will see the Randomisation Check page and will need to manually randomise the patient via RRAMP.

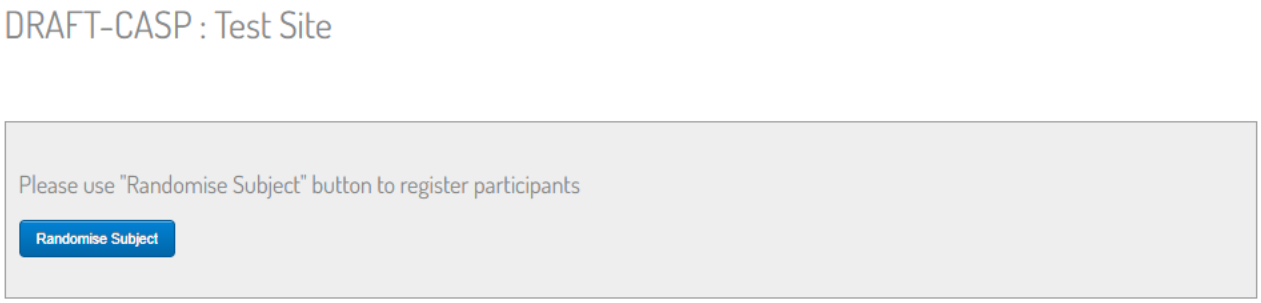


To do this, follow the link https://rramp.octru.ox.ac.uk and enter your RRAMP login. (This login should have been requested during set up of your site. If you do not have access and would like it for possible use in the future, please email draft3-casp@ndorms.ox.ac.uk. If you do not have access and are in the process of randomising a patient, please either call the Trial Manager Heather on 01865 (2)23113 or the Trial Administrator Elli on 01865 612709 so we can do it for you).

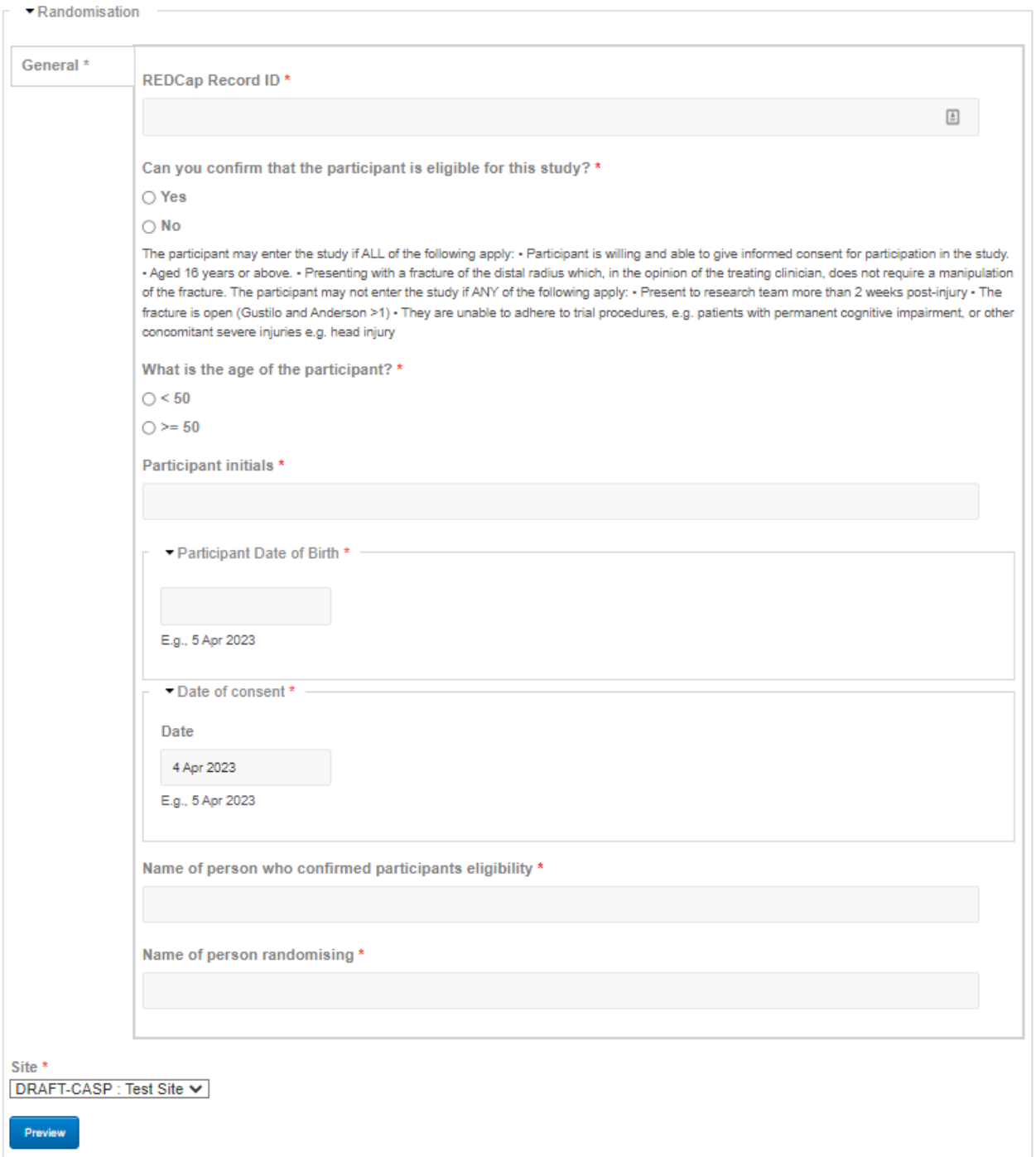
On your home page, click on the DRAFT3-CASP project. You may have multiple studies in your list depending on the studies you are involved in.



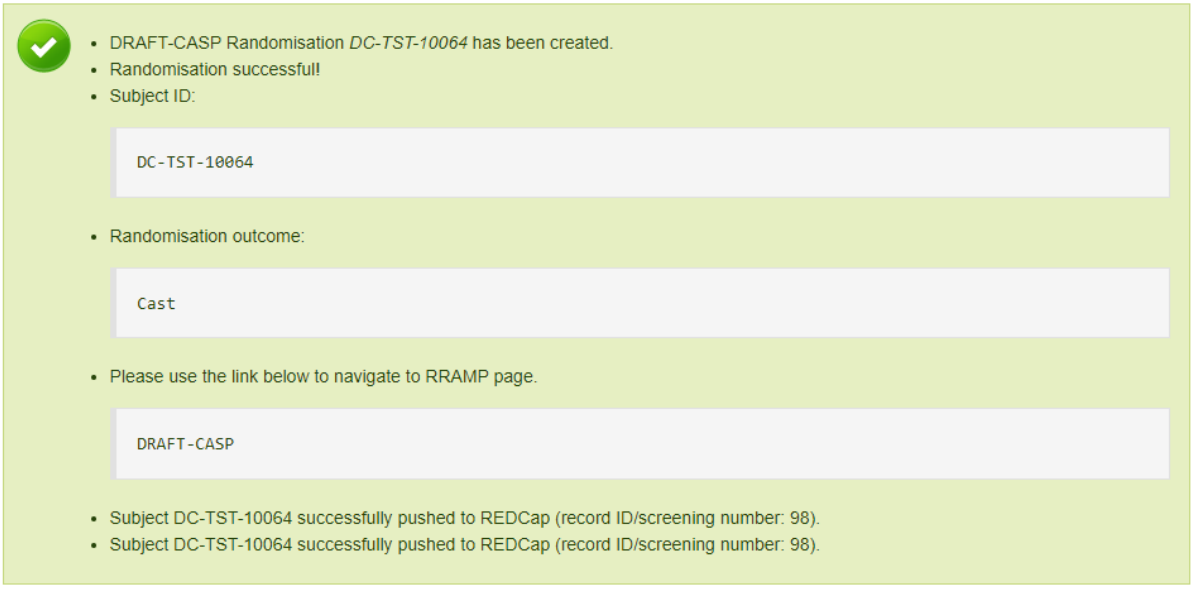
The page should already be on the SITES tab but if it isn't navigate to this tab and then choose your site from the list or type it into the Site Name search bar and click Apply. Click on the grey name of the site to enter.



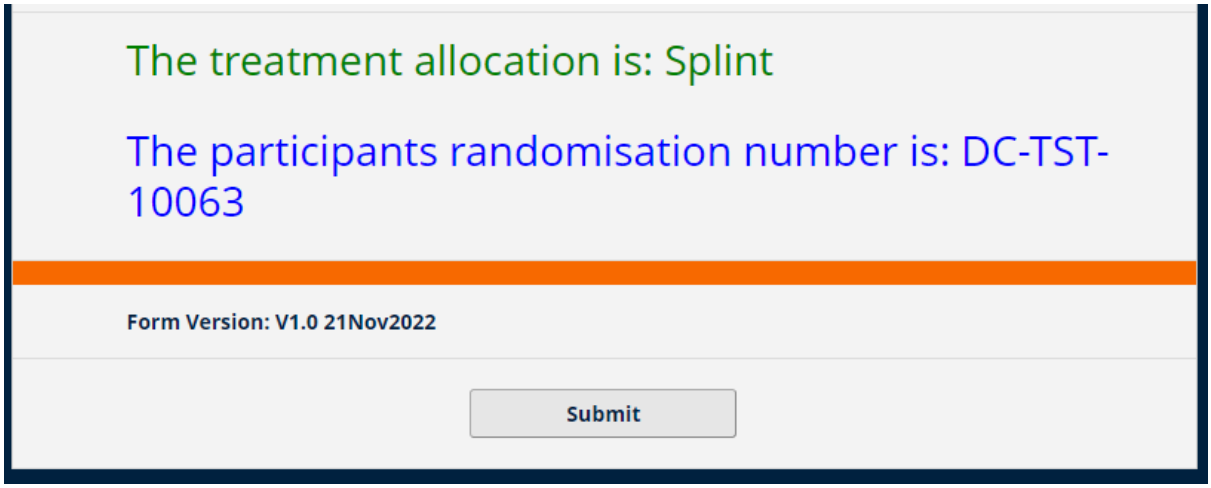
At the top of the next page, please click the blue 'Randomise Subject' button.



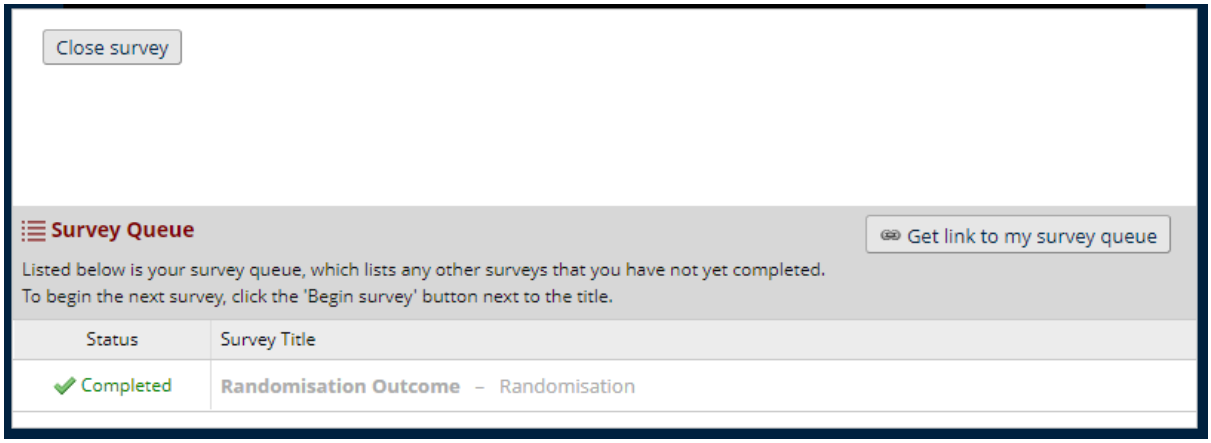
At this point, you will need to enter the REDCap Record ID, confirm that the patient is eligible, whether they are older or younger than 50 and the patient's initials. When you enter the date of birth and date of consent, make sure you enter the date in the format specified. Finally, enter the name of the person confirming eligibility and randomising. Please click the blue 'Preview' button at the bottom of the page and check the details on the following page. You will then need to scroll to the bottom of the following page and click the blue 'Randomise' button.



If this is successful, RRAMP will confirm the treatment allocation. You will then be able to navigate to the 'Randomisation Outcome' form on REDCap (it should be the last record in the list) and view the randomisation number and treatment allocation.



If the randomisation process is successful and you don't need to go through RRAMP, the randomisation outcome form will pop up with the treatment allocation. Please ensure you press submit on this page. Please do not go back in to REDCap manually and complete the Randomisation Check form, this form will appear in sequence if randomisation is unsuccessful.



The randomisation is now complete and you can close the survey.

A couple of points to note:

- Please only screen patients that are over the age of 16 and have a confirmed distal radius fracture
- All activities above will occur in the Emergency Department. Once the treatment has been received, the Cast group are then followed up as per usual care, and the splint group are immediately discharged with no planned follow-up
- The only time you will need to go back into the REDCap system directly (i.e. not via the website) is to complete the treatment form, or to answer any unresolved queries raised by the Trial Management team.
- Please only recruit patients via the link on the website at www.draft3casp.org
- If you have any problems, don't hesitate to ask any questions and contact the Trial Management team below:

Draft3-casp@ndorms.ox.ac.uk

01865 223113

DRAFT3 Whatsapp group