University of Nottingham
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PROTECT-CH
Prophylactic Therapy in Care Homes Trial

PROTECT-CH Trial:

Data Entry

Final Version 1.0 22-Sep-2021

Your role

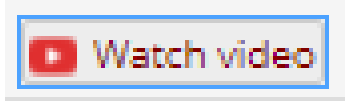
You will be asked to collect information about your residents and enter it into the secure trial database when the trial starts.

Database

- Data for this trial will be entered electronically into a database called **REDCap**.

- Please note that that if you see NCTU referenced on the trial database or the training material, this refers to the University of Nottingham Clinical Trials Unit (NCTU) where the PROTECT-CH trial team is based.

Video guidance

- Video guidance has been produced to support you with data entry for several data entry forms.
- Look out for the 

button at the top of the some of the data entry forms. Clicking on this will launch a demonstration video to help you with data entry.
- If you still require assistance or if you are unsure about a form that does not have video guidance, please contact a member of the trial team, we are always happy to assist.

Database access

- To gain access to the trial database (REDCap), you will be asked to complete a database access form.

- All staff involved with the trial will be required to sign the trial delegation log, which lists staff at the care home and their roles in the trial.

- You must have completed your trial specific training and have been added to the trial delegation log before you are granted access to the system.

Database access

- The trial database (REDCap) can be accessed by the below link:

  https://redcap01.nottingham.ac.uk/

- Or, if you're using a mobile device, you can scan the QR code

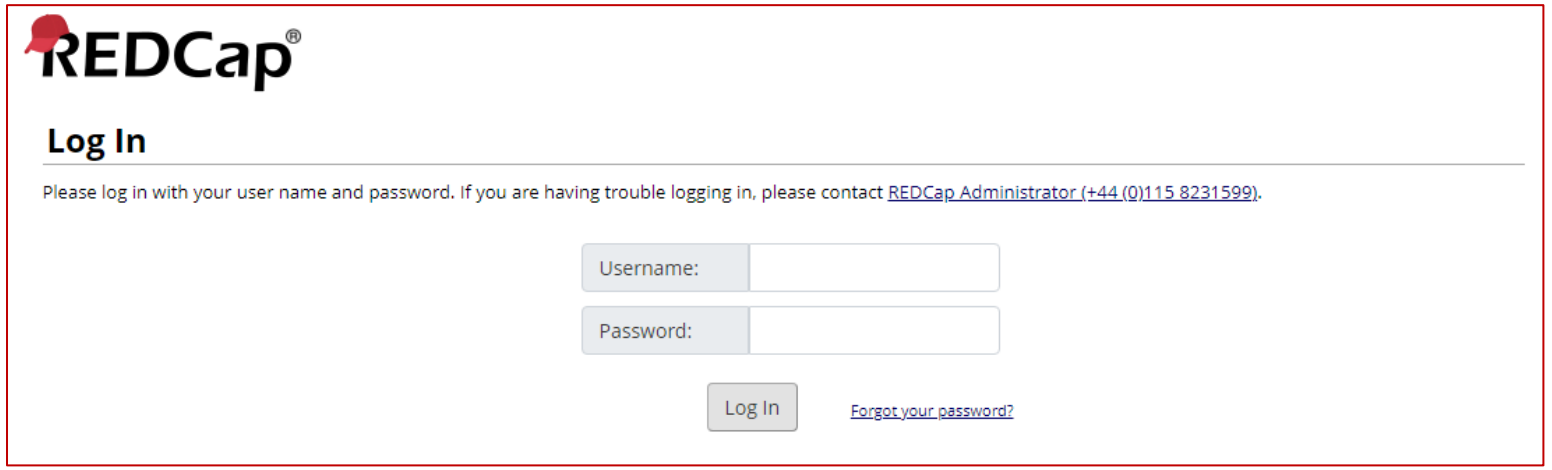
PROTECT-CH REDCap Database

Database access

- You will be provided with a username and password to gain access to the trial database.

- You will be prompted to change your password when you first log in.

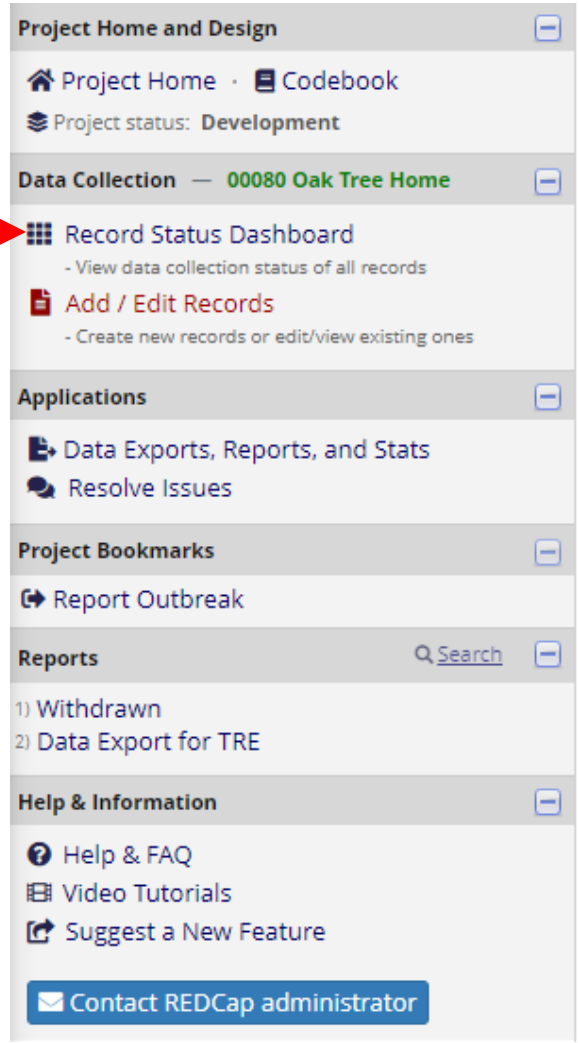
  *You can reset your password should you need to by clicking 'Forgot your password?'. You will then receive instructions to regain access to the trial database via email.

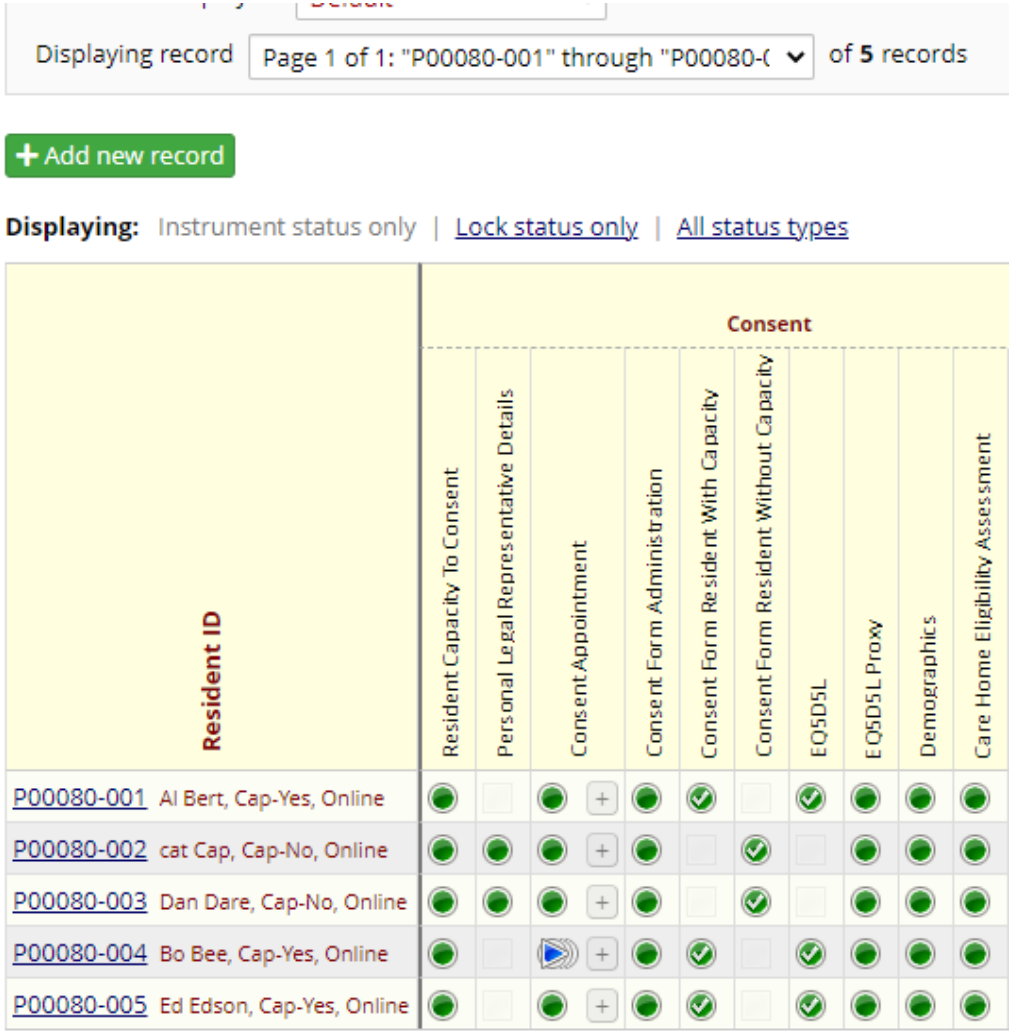


PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Database navigation (i)

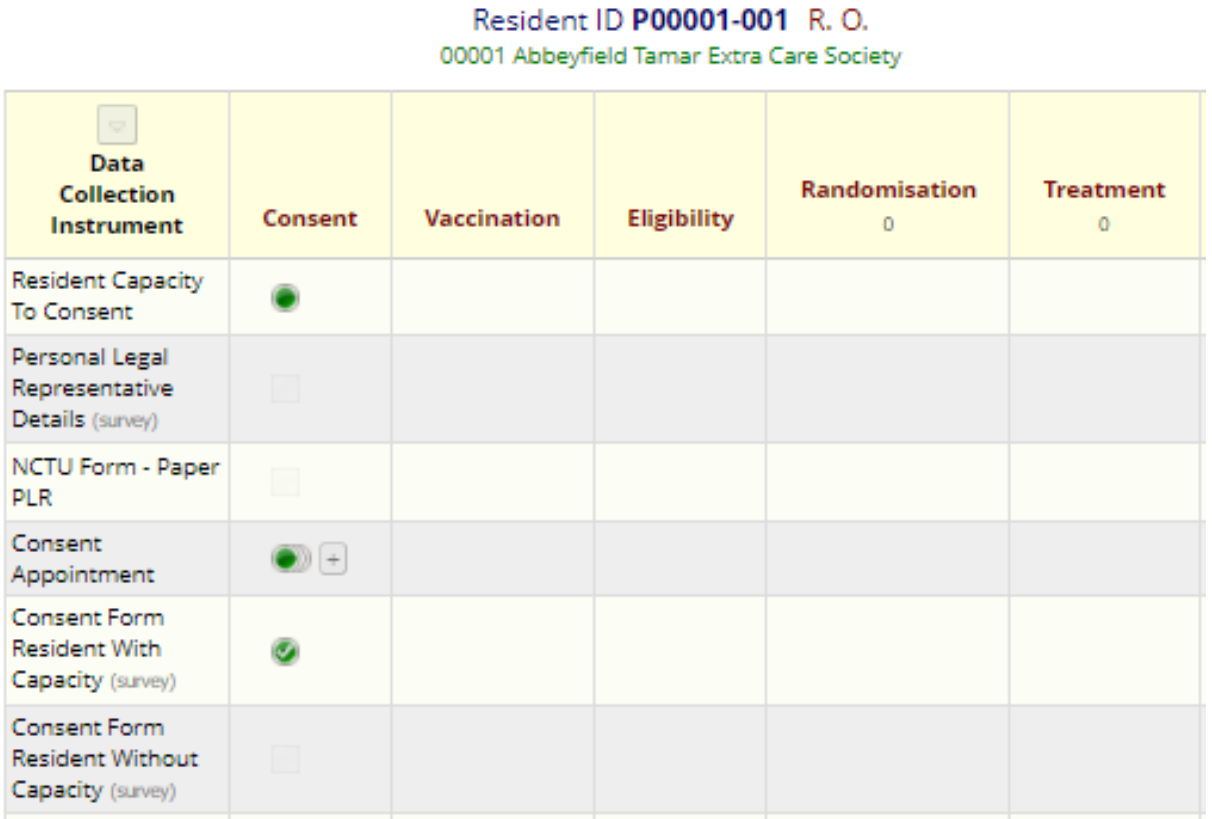
Clicking on 'Record Status Dashboard' will take you to a summary view of all residents entered into the database at your care home





Database navigation (ii)

Clicking on a resident's ID number will take you to the resident's individual data entry page.

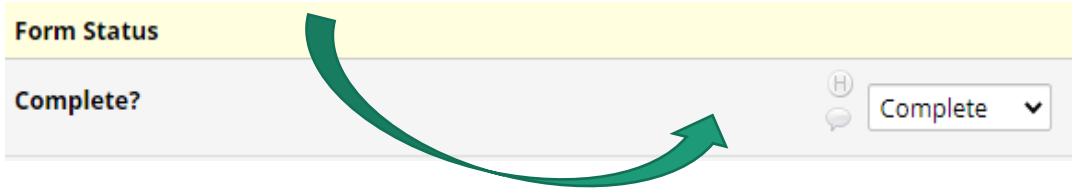


Database navigation (iii)

- Each form that requires data to be entered is represented in the database by an icon.

Icon	Meaning
	Data for form not yet entered
	Data entered but form not saved as 'complete'.
	Data entered and form is saved as 'complete'.

- When you have completed a form, you should set the form status to complete before saving.



Consent and eligibility

Consent & eligibility

- This section will focus on the **data entry** aspects of the consent process only.

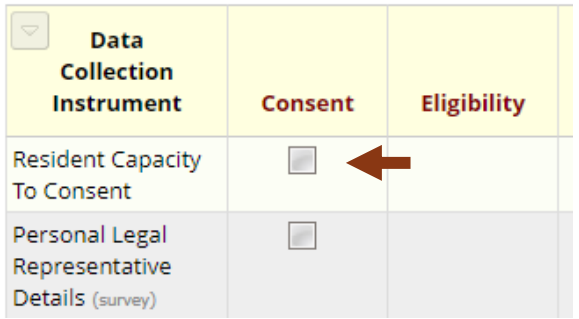
- Further information on the consent process can be found in the 'Consent and Enrolment' training module on the trial website.

Adding a new resident

- All residents considered for the trial must be added to the database in order to facilitate the consent process.

Please ensure residents / their Personal Legal Representatives (PLRs) **have expressed interest** in the trial and have **given verbal permission** for their details to be added to the database.

- Should a resident be added to the database, but then not wish to join the trial, this can be recorded using the 'Trial Status' form. This form is discussed in more detail later in this module.
- To add a new resident, log in to the trial database (REDCap) and ensure that you are on the 'Record Status Dashboard' section of the database and click + Add new record
- You will automatically be directed to the 'Record Home Page'. Click on 'Resident Capacity to Consent' (brown arrow)



Consent: Residents with capacity

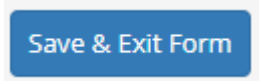
Resident capacity to consent form - with capacity

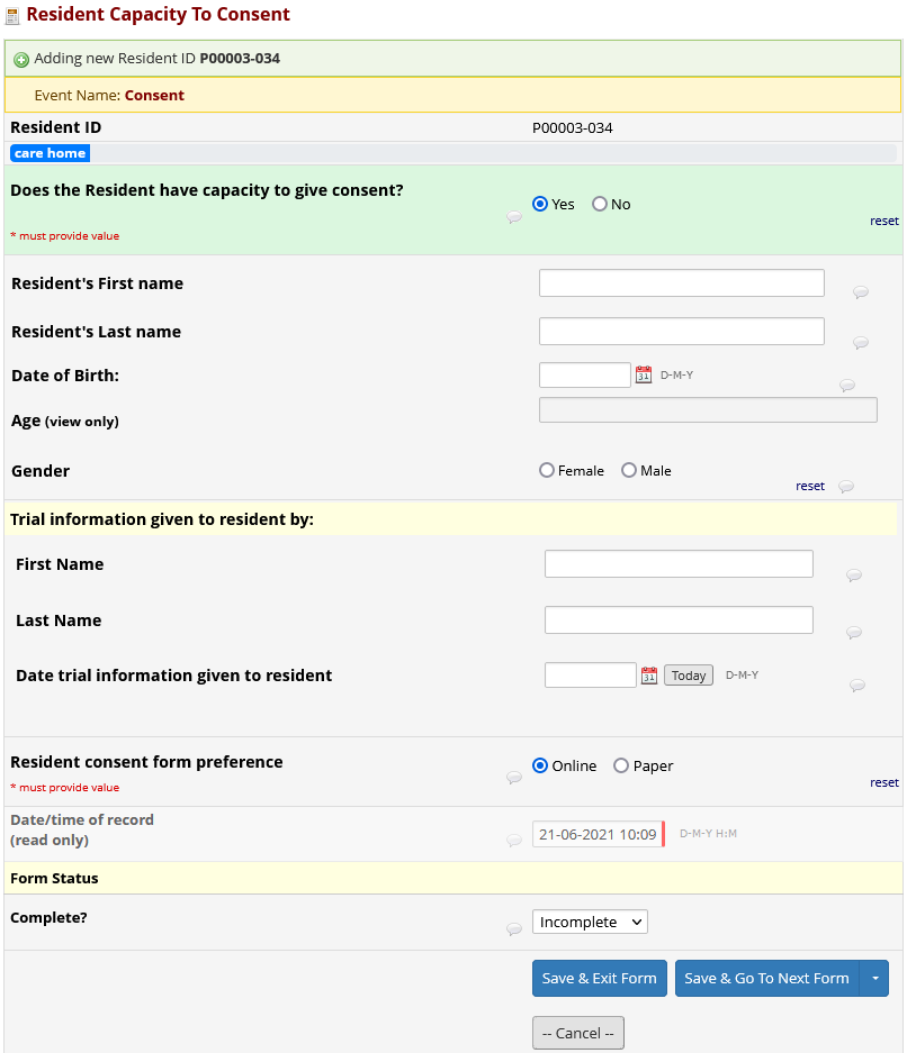
This is the first form that you will enter for each resident.

- You should record whether the resident has the capacity to consent (more details on assessing capacity can be found in the 'Consent & Enrolment' training module).

Residents with capacity

- The form will collect the residents' details (Name, Date of Birth, Gender).
- You will be asked to enter your name and the date trial information (Participant Information Sheet) was given to the resident.
- We also ask how the resident would prefer to complete the consent form – online or on paper*
- Once all details have been added, mark form as 'complete' and click





*The online consenting process has been designed as a streamlined approach.

Paper consent should **only** be used for residents when online completion is not an option.

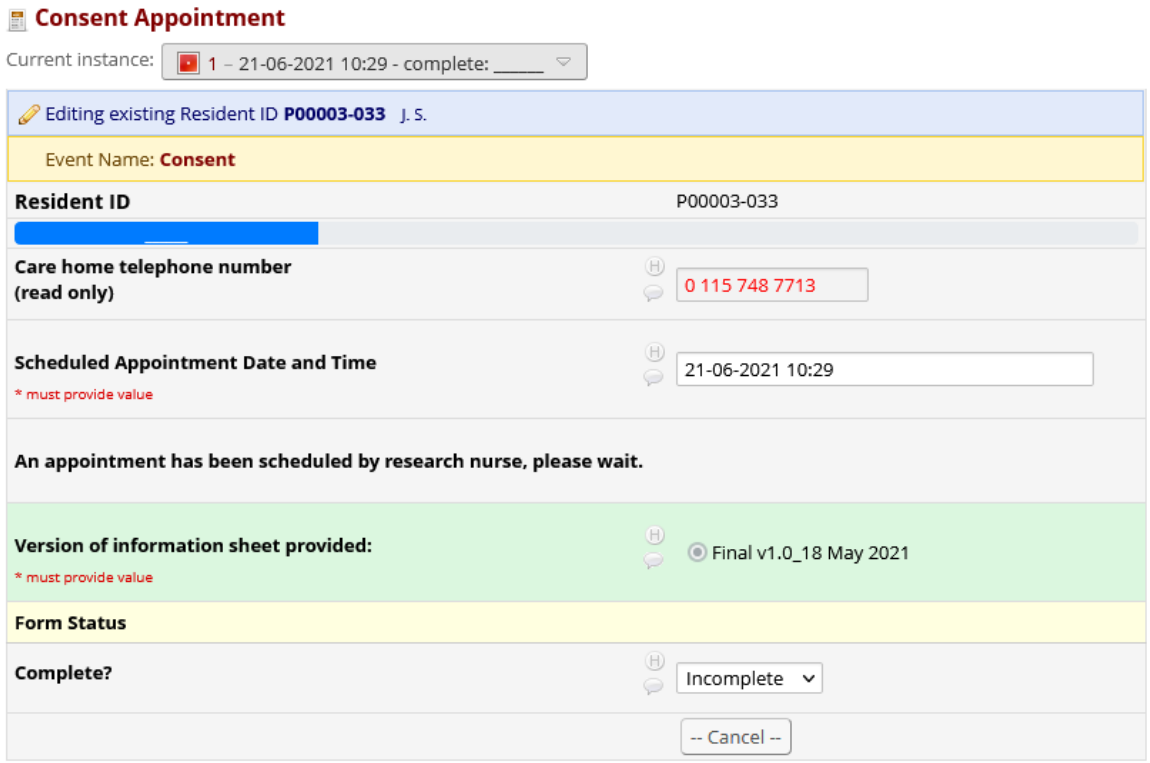
Residents with capacity

What happens next?

- For residents with capacity, once you have completed and saved the 'Resident Capacity to Consent' form, an automatic email will be sent to a member of the research nurse team.

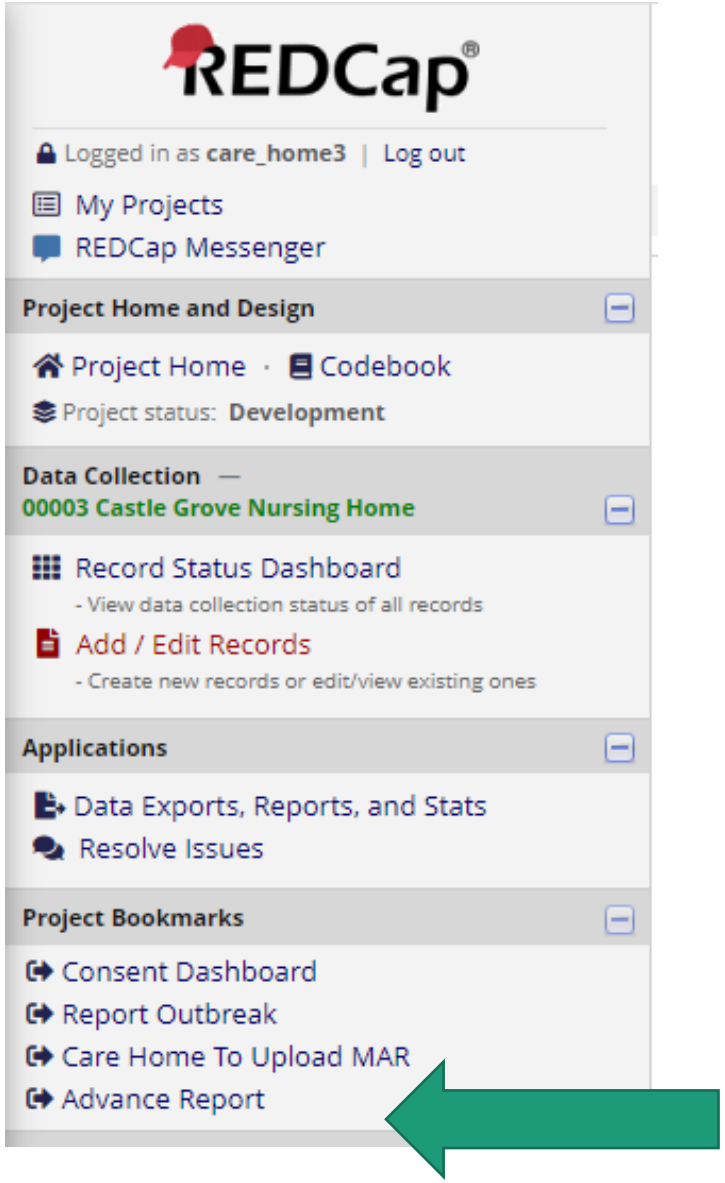
- A research nurse will contact you to schedule a consent appointment with the resident.

- The research nurse will complete the 'Consent appointment' form to document once the consent appointment is scheduled.



Overview of scheduled consent appointments

- For an overview of all consent appointments scheduled for your care home click on 'Advance Report' under Project Bookmark
- Select 'Consent Appointments with Research Nurse'



Overview of scheduled consent appointments

- This report shows the date and time of scheduled consent appointments with a research nurse for each resident in your care home, as well as the appointment status (completed, overdue, upcoming).
- Information about whether the resident / PLR was ready to proceed to the consent form is given in the "Proceed_To_Consent_Form" column.
- Each column can be sorted (smallest to largest / A-Z) by clicking on the arrows in the top row. To filter the columns, click the filter icon in the top row and type in your filter text. To filter for empty fields, type a space in the filter text box.

Consent Appointments With Research Nurse

Back to Advanced Reports Download report

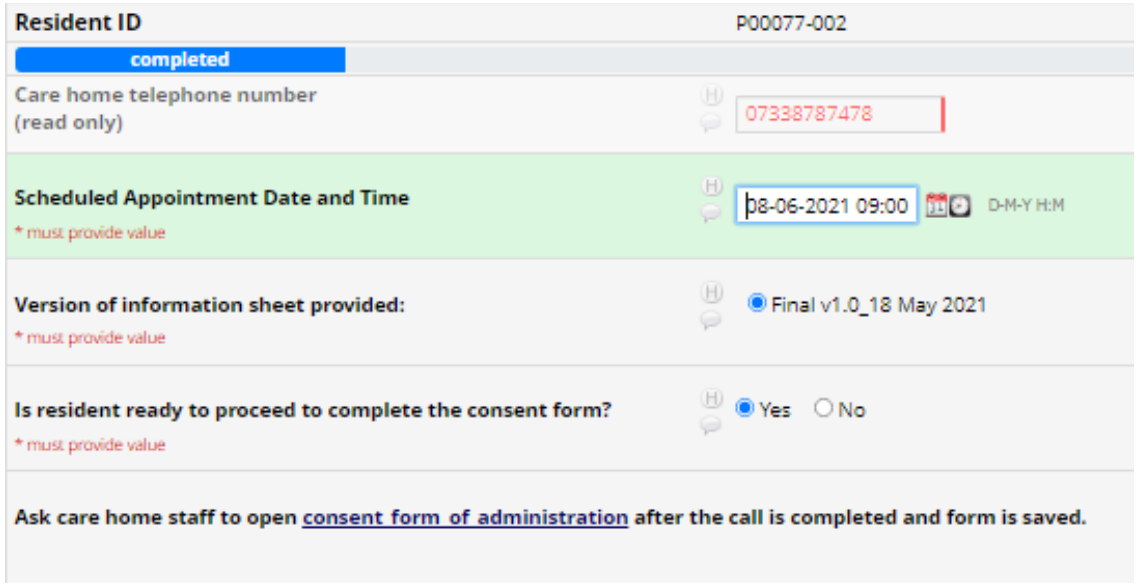
Showing consent video call is completed or not and the status of new appointment (due, overdue, upcoming)

Appointment Status can be overdue, due, upcoming

Record	Appointment	Appointment_Status	Proceed_To_Consent_Form
P00003-001	24-05-21 15:12	completed	yes
P00003-002	24-05-21 15:37	completed	yes
P00003-004	24-05-21 15:42	completed	yes
P00003-005	25-05-21 12:11	completed	yes
P00003-006	24-05-21 15:30	completed	yes
P00003-007	25-05-21 18:30	completed	yes
P00003-008	26-05-21 09:45	completed	yes
P00003-009	26-05-21 11:24	completed	yes
P00003-010	17-06-21 15:54	completed	yes
P00003-011	27-05-21 12:42	completed	yes
P00003-012	03-06-21 14:16	completed	yes
P00003-013	10-06-21 14:08	completed	yes
P00003-014	09-06-21 14:58	completed	yes
P00003-015	20-07-21 11:38	completed	yes
P00003-018	16-06-21 11:51	completed	yes
P00003-019	10-06-21 16:09	completed	yes
P00003-020	11-06-21 16:50	completed	yes
P00003-021	15-06-21 16:15	Overdue	

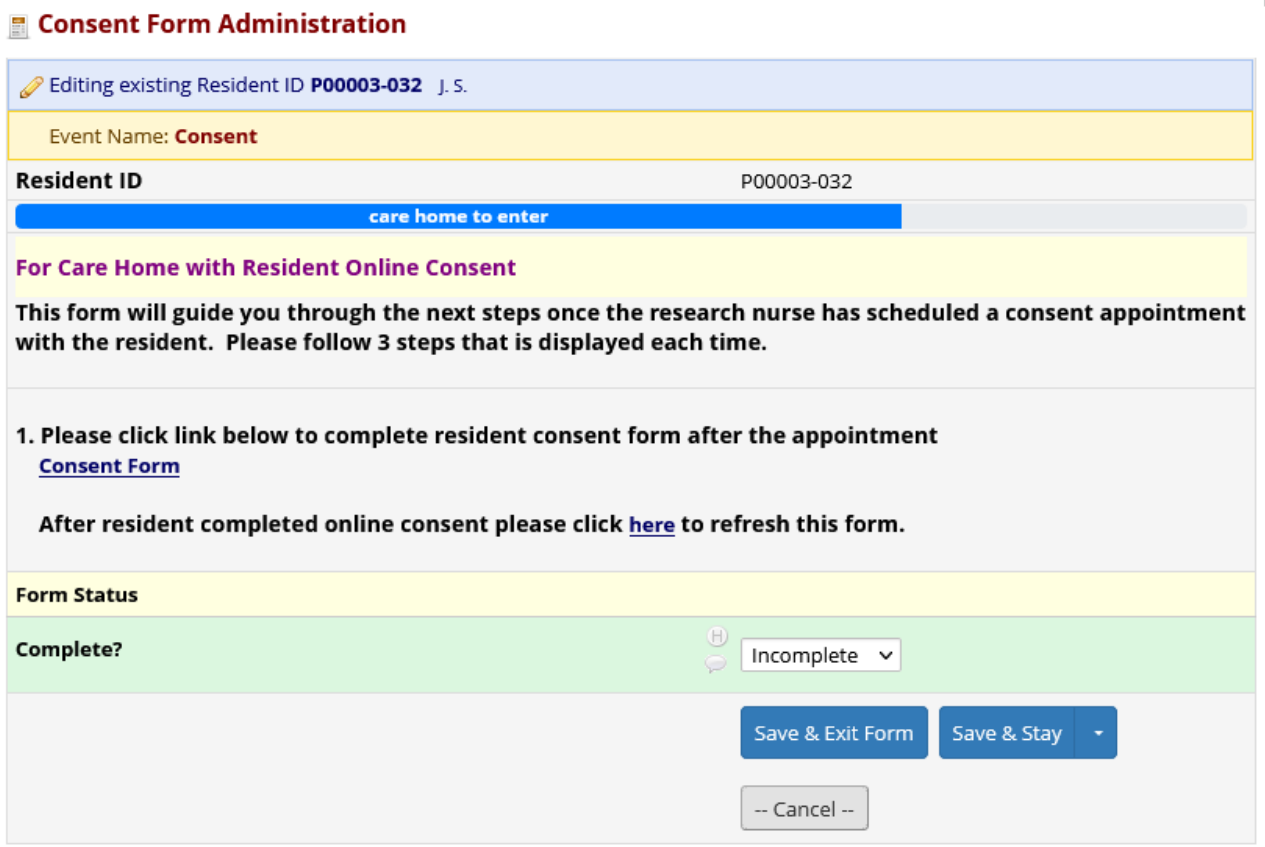
The consent appointment -Residents with capacity

- The research nurse (RN) will carry out the consent appointment at the agreed time. It is expected that these will be video calls and a member of care home staff should be available to assist the resident during the appointment.
- The RN will explain the trial and answer any questions the resident has.
- If the resident is happy to proceed to the consent form during the appointment, the RN will confirm this on the database, which will activate the online consent form. It will also trigger an email to you that contains the link to the 'Consent Form Administration' form.
- The RN will then ask you to open the 'Consent Form Administration' form using the link provided in the email (or navigate the database to open it).



Consent Form Administration
Residents with capacity –online consent

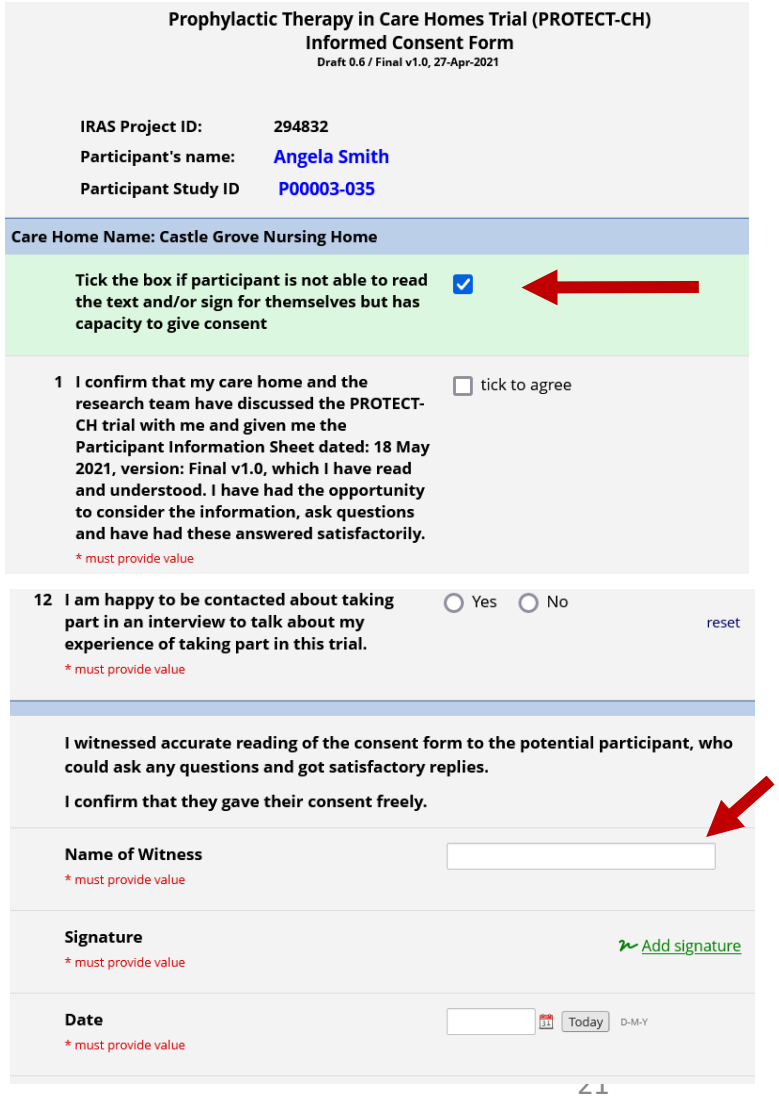
- Click on the link to open the 'Consent Form' so the RN can talk the resident through the consent form.
- The resident should then complete the form by completing the tick boxes, entering their name and signature and date.
- The RN will then check and countersign the consent form. This might not happen immediately after the appointment.
- Once countersigned, you will be notified by email to proceed with data entry as described on page 29.



Consent form – Witness completion

Residents **with capacity** who are unable to read the text or sign for themselves:

- A witness can complete the form and sign on the resident's behalf.
- To activate this, tick the box on top of the consent form.
- The form will now automatically ask for witness name and signature.



Prophylactic Therapy in Care Homes Trial (PROTECT-CH)
Informed Consent Form
Draft 0.6 / Final v1.0, 27-Apr-2021

IRAS Project ID: 294832
Participant's name: Angela Smith
Participant Study ID P00003-035

Care Home Name: Castle Grove Nursing Home

Tick the box if participant is not able to read the text and/or sign for themselves but has capacity to give consent ☑

1 I confirm that my care home and the research team have discussed the PROTECT-CH trial with me and given me the Participant Information Sheet dated: 18 May 2021, version: Final v1.0, which I have read and understood. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐ tick to agree
* must provide value

12 I am happy to be contacted about taking part in an interview to talk about my experience of taking part in this trial. ○ Yes ○ No reset
* must provide value

I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and got satisfactory replies.

I confirm that they gave their consent freely.

Name of Witness
* must provide value

Signature
* must provide value
Add signature

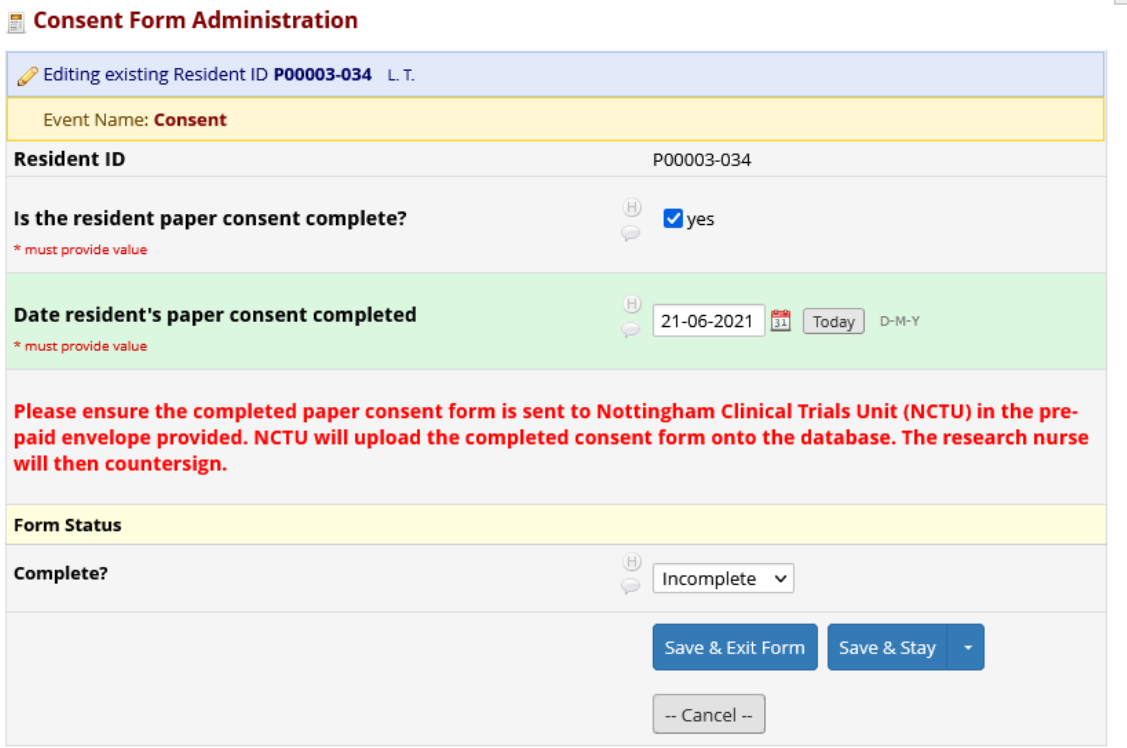
Date
* must provide value
Today D-M-Y

Consent Form Administration
Residents with capacity – paper consent

- If a resident wants to complete a paper consent form this should be completed during the consent appointment and returned to NCTU by post.

Please note: Paper consent has to be selected as preference on the '**Resident Capacity to Consent**' form.

- Open the '**Consent Form Administration**' form once the paper consent form has been completed and record the completion date.



- Once received, the research nurse (RN) will countersign the consent form. When this is completed, you will be notified by email to proceed with data entry (as described on page 29).

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Prophylactic Therapy in Care Homes Trial

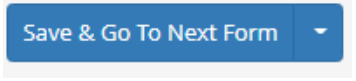
Consent: Residents without capacity

Resident capacity to consent form-without capacity

Residents without capacity

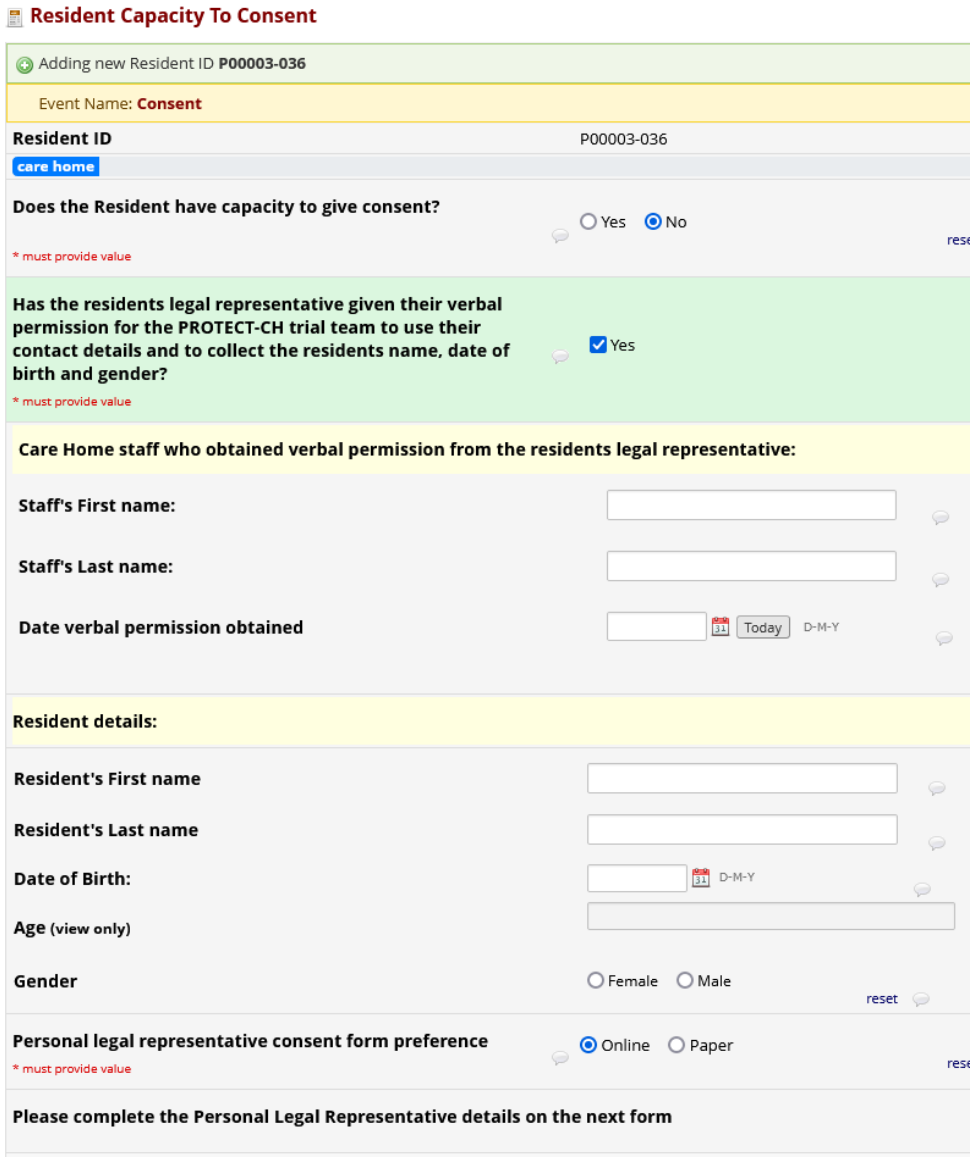
You will be asked to:

- Confirm whether the resident's Personal Legal Representative (PLR) has given verbal permission for their details to be shared, before entering the residents' details.
- Enter the name of the member of staff who obtained verbal permission from the PLR and the date it was obtained.
- Enter the residents' details (name, DoB, gender).
- Record how the PLR would prefer to complete the consent form – online or on paper.
- Online consent will require the PLR to have an email address and for them to be able to access and complete simple web-based forms.

Once all details have been added, mark form as 'complete' and click 

The online consenting process has been designed as a streamlined approach.

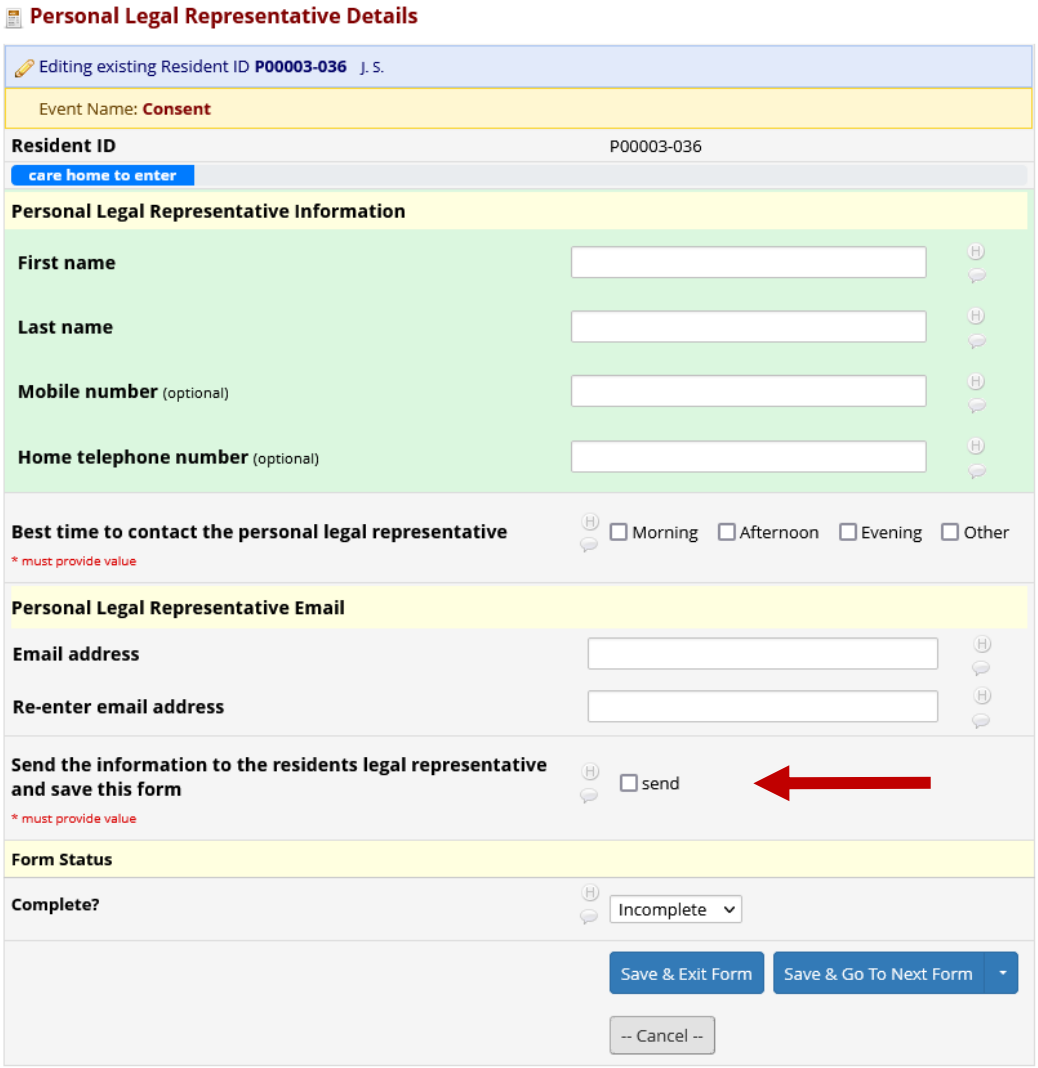
Paper consent should **only** be used for PLRs when online completion is not an option.



PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Personal Legal Representative Details form

- You are only required to complete this form for residents who **do not** have the capacity to consent.
- The Personal Legal Representative (PLR) must have given their verbal agreement for their information to be shared with the trial team before this form is completed.
- You will be prompted to enter the PLR details. If 'online' consent was selected on the previous form, you will be asked to enter the PLR's email address. If 'paper' consent was selected, you will be asked to record the PLR's postal address.
- For **online consent**, please make sure you tick the **'send'** box.
- Mark the form as complete and click Save & Exit Form



Residents without capacity

What happens next?

For Personal Legal Representatives (PLRs) completing online consent:

- Once you have saved the data on the PLR Details form, trial information will be automatically emailed to the PLR and an alert will be sent to notify the research nurse (RN) team.
- The research nurse team will arrange a video call with the PLR and will complete the 'Consent Appointment' form.
- The PLR will be emailed a link to the online consent form to complete, which will then be countersigned by the RN (RN).

For PLRs completing paper consent:

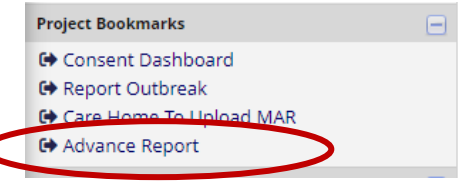
- Once you have saved the data on the PLR Details form, an alert will be sent to notify the RN team and the trial team (based at NCTU) who will post trial information to the PLR.
- The RN team will arrange a video/phone call with the PLR and will complete the 'Consent Appointment' form.
- The PLR will complete the paper consent form and post this to the trial team (based at NCTU) who will upload a copy to the trial database. This will then be countersigned by the RN.

- **In both cases, once the research nurse has countersigned the consent form you will receive an email notification to proceed with data entry.**

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Overview of Consent status

For an overview of the consent status of each residents in your care home that is taking part in the trial, open the 'Consent Tracking Report' (click on "Advance Report" under Project Bookmarks)



Consent Tracking Report

Back to Advanced Reports Download report

List of resident's consent status

Record	Resident_Name	Capacity	Consent_by	Consent_Type	Appointment_Completed	Consent_Completed	Consent_Date	RN_Signed_Date	Consent_Admin_Completed
P00003-001	Franzi Fran	yes	Resident	online	yes	yes	24-05-2021	24-05-2021	yes
P00003-002	Max Mustermann	yes	Resident	paper	yes	no			
P00003-004	John Johnson	no	PLR	online	yes	no	24-05-2021	26-05-2021	n/a
P00003-005	Anna Lena	yes	Resident	online	yes	no			
P00003-006	Jean Jones	yes	Resident	online	yes	yes	25-05-2021	25-05-2021	no
P00003-007	T Test	yes	Resident	online	yes	yes	27-05-2021	27-05-2021	no
P00003-008	JJ Josh	no	PLR	online	yes	no			n/a
P00003-009	TJ Friday	yes	Resident	paper	yes	yes	26-05-2021	26-05-2021	
P00003-010	Billy Baggins	yes	Resident	online	yes	yes	26-05-2021	26-05-2021	no
P00003-011	Paper Consent	yes	Resident	paper	yes	no			
P00003-012	Tania Paper	yes	Resident	paper	yes	yes	03-06-2021	03-06-2021	no
P00003-013	Lilly Smith	yes	Resident	paper	yes	yes	10-06-2021	10-06-2021	
P00003-014	Adam Driver	no	PLR	paper	yes	no	10-06-2021	10-06-2021	n/a

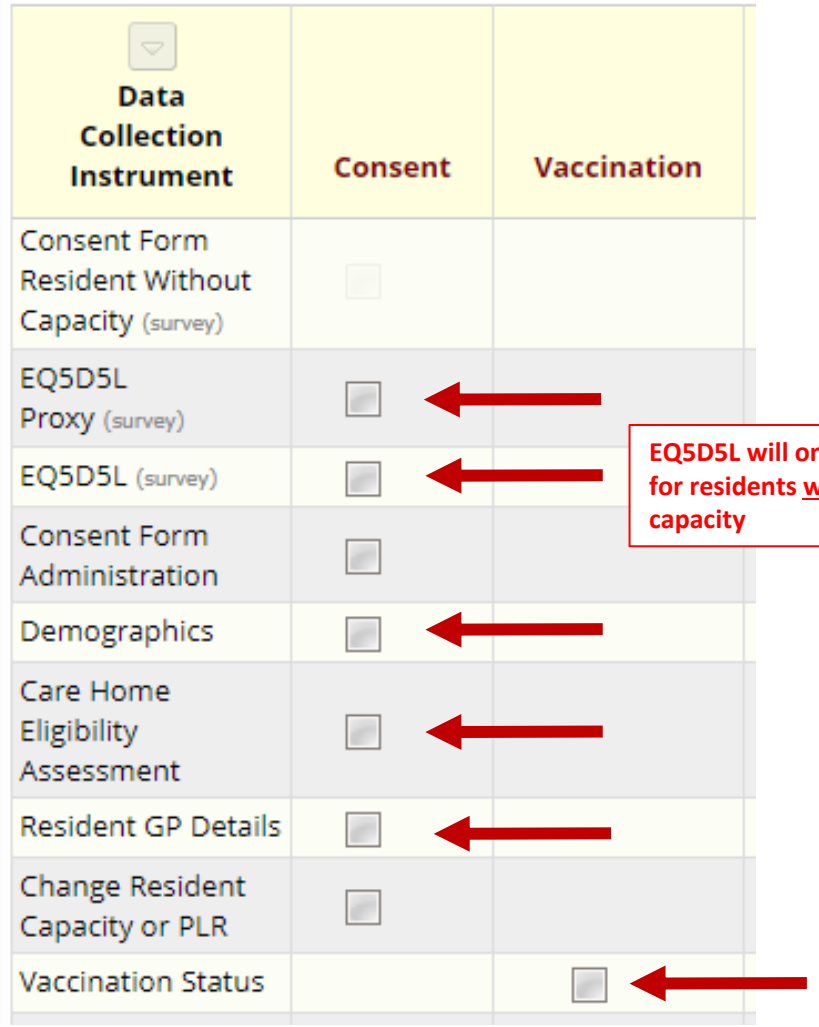
PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Consented residents: Next steps

After RN countersignature

- Once the research nurse (RN) has countersigned the consent form, the following forms should be completed:

1. EQ5D5L Proxy – Quality of Life form completed by staff on behalf of a resident
2. EQ5D5L – For residents **<u>with</u>** capacity **only. This should be completed by the resident themselves.**
3. Demographics – general information about the resident (e.g. height, weight, ethnic background)
4. Care Home Eligibility Assessment
5. Resident GP Details
6. Vaccination status

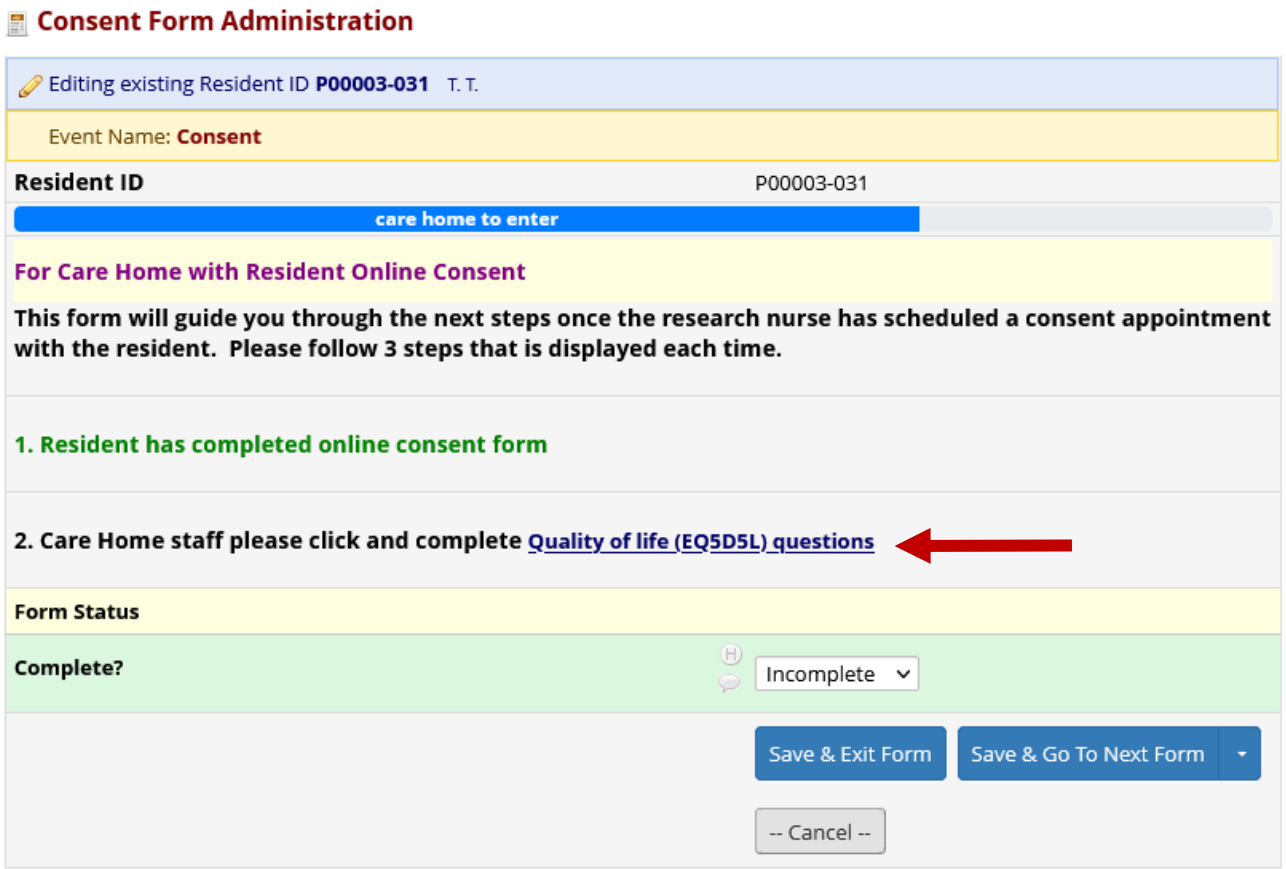


- Please see pages 30-43 for further details on these forms.
- It is important these forms are completed promptly as this will allow the resident to progress to the GP eligibility check.

Consent Form Administration – navigating to EQ5D5L

- Once the RN has countersigned the consent form, you will receive an email notification containing a link to the 'Consent Form Administration' form which will guide you through the next steps.
- Open the 'Consent Form Administration' form (use the link provided in the email or navigate the database).
- Use the link provided in step 2 to complete the 'Quality of life questionnaire'. This is for care home staff to complete for all residents.
- For residents **with** capacity - Please then ask the resident to complete the 'Quality of life questionnaire' using the link displayed in step 3.

-> please see pages 31-32 for further details about the quality of life questionnaires

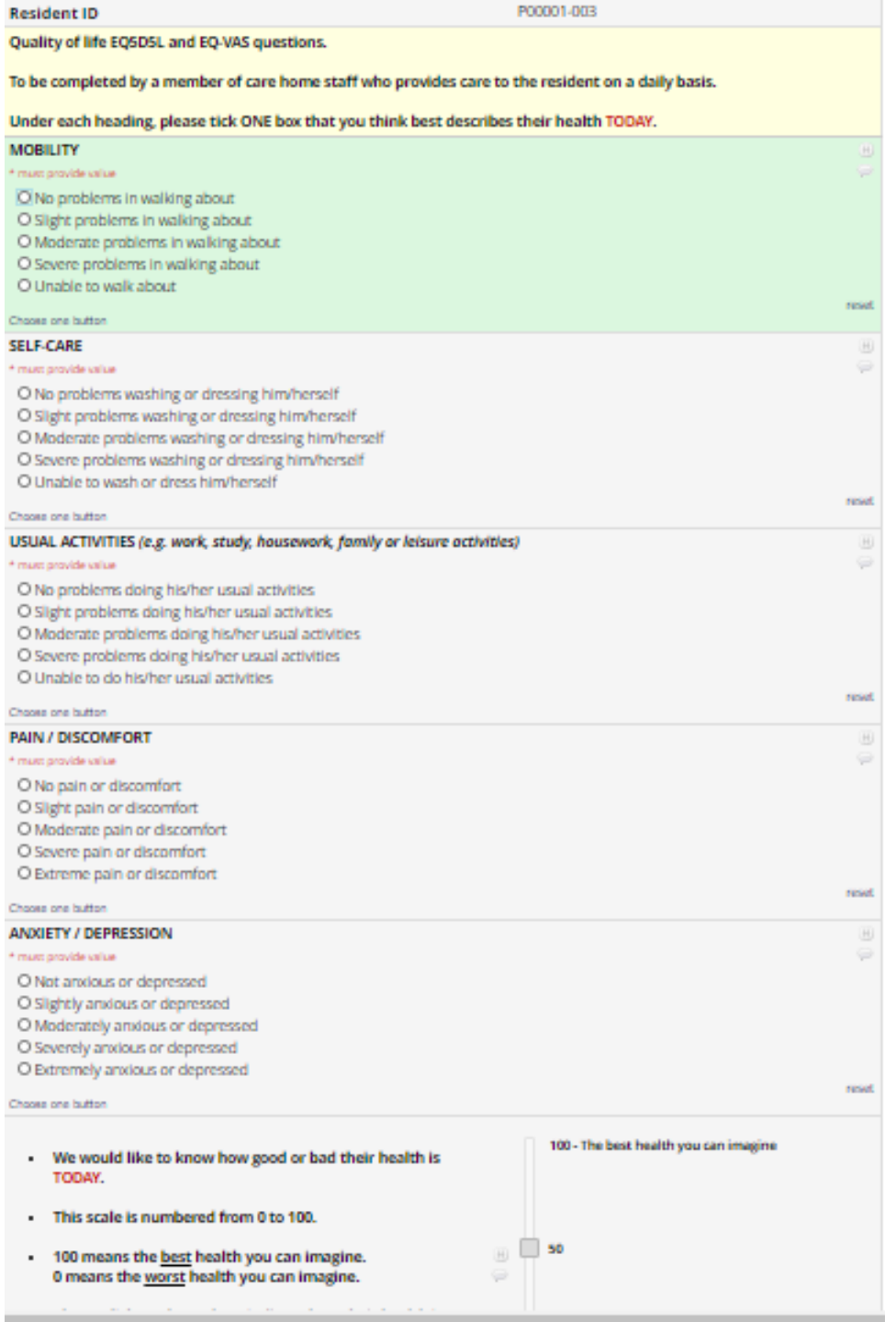


Quality of life questionnaire (EQ5D5L Proxy and EQ5D5L)

- Care home staff will be required to complete a quality of life questionnaire for all residents (including those with capacity). This form is called '**EQ5D5L Proxy**'**.**

- Residents **with** capacity should then complete a quality of life questionnaire themselves. We recommend you use an iPad or tablet and assist the resident in completing this. This form is called '**EQ5D5L**'.

- Please let the resident choose the answer they feel is appropriate and try not to influence their response.



Resident ID P00001-003

Quality of life EQ5D5L and EQ-VAS questions.

To be completed by a member of care home staff who provides care to the resident on a daily basis.

Under each heading, please tick ONE box that you think best describes their health TODAY.

MOBILITY
* must provide value
- No problems in walking about
- Slight problems in walking about
- Moderate problems in walking about
- Severe problems in walking about
- Unable to walk about

Choose one button

SELF-CARE
* must provide value
- No problems washing or dressing him/herself
- Slight problems washing or dressing him/herself
- Moderate problems washing or dressing him/herself
- Severe problems washing or dressing him/herself
- Unable to wash or dress him/herself

Choose one button

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*
* must provide value
- No problems doing his/her usual activities
- Slight problems doing his/her usual activities
- Moderate problems doing his/her usual activities
- Severe problems doing his/her usual activities
- Unable to do his/her usual activities

Choose one button

PAIN / DISCOMFORT
* must provide value
- No pain or discomfort
- Slight pain or discomfort
- Moderate pain or discomfort
- Severe pain or discomfort
- Extreme pain or discomfort

Choose one button

ANXIETY / DEPRESSION
* must provide value
- Not anxious or depressed
- Slightly anxious or depressed
- Moderately anxious or depressed
- Severely anxious or depressed
- Extremely anxious or depressed

Choose one button

- We would like to know how good or bad their health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.

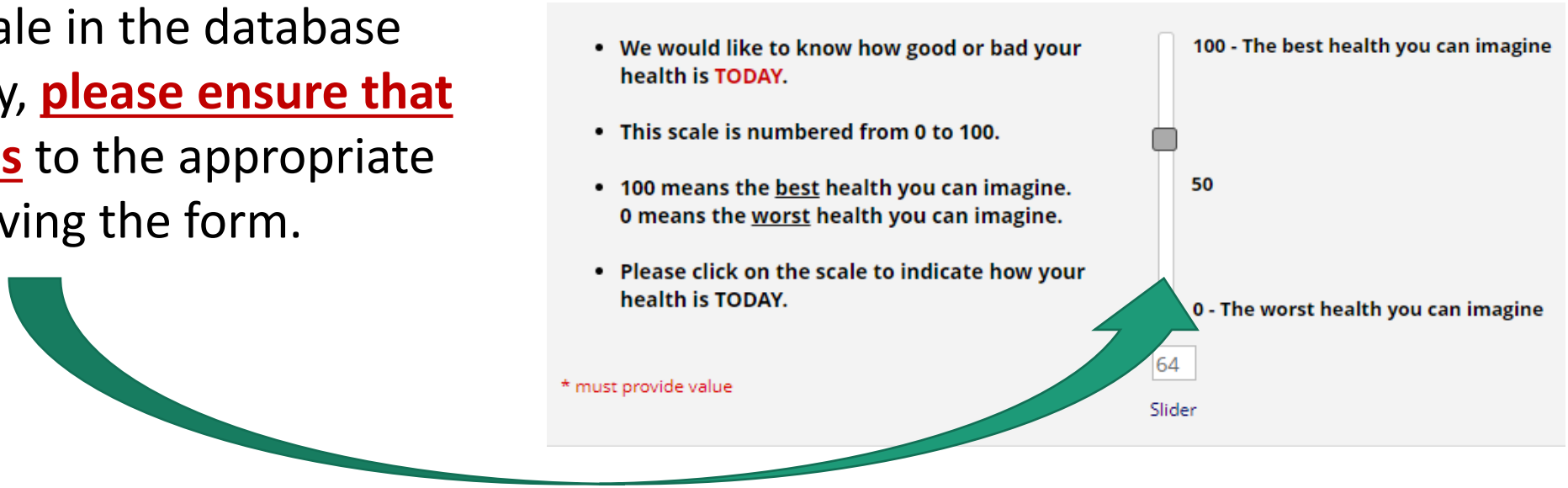
100 - The best health you can imagine

50

EQ5D5L Visual Analogue Scale (VAS)

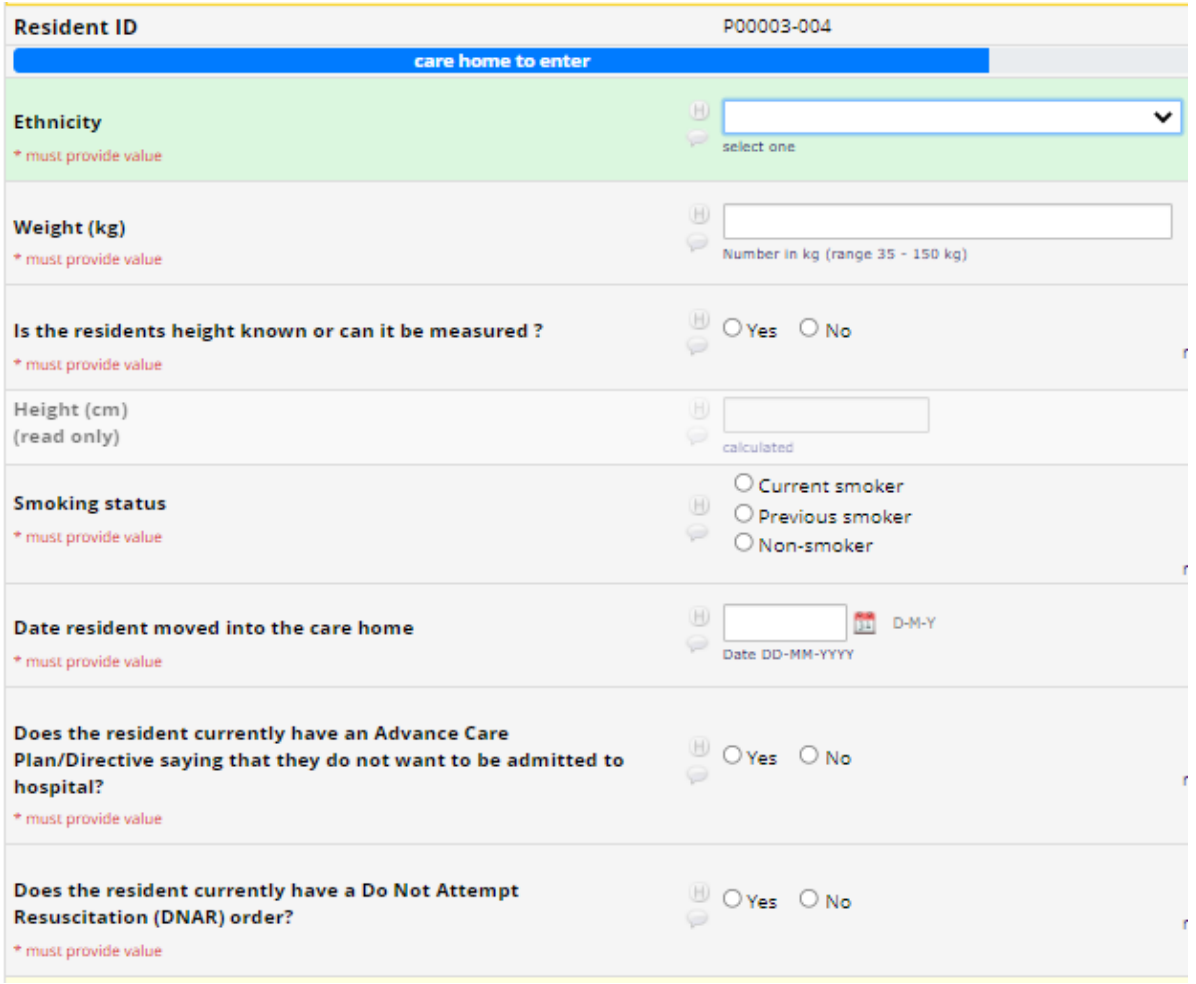
- At the end of the quality-of-life questionnaire, there is a Visual Analogue Scale (VAS). This should be completed by sliding the scale to the appropriate position, in order to reflect how good or bad the resident's health is **on the day of completion.**

- At times the scale in the database can stick slightly, **please ensure that the scale moves** to the appropriate place before saving the form.



Demographics

- This form will be used to collect information about your resident e.g., height, weight, ethnic background

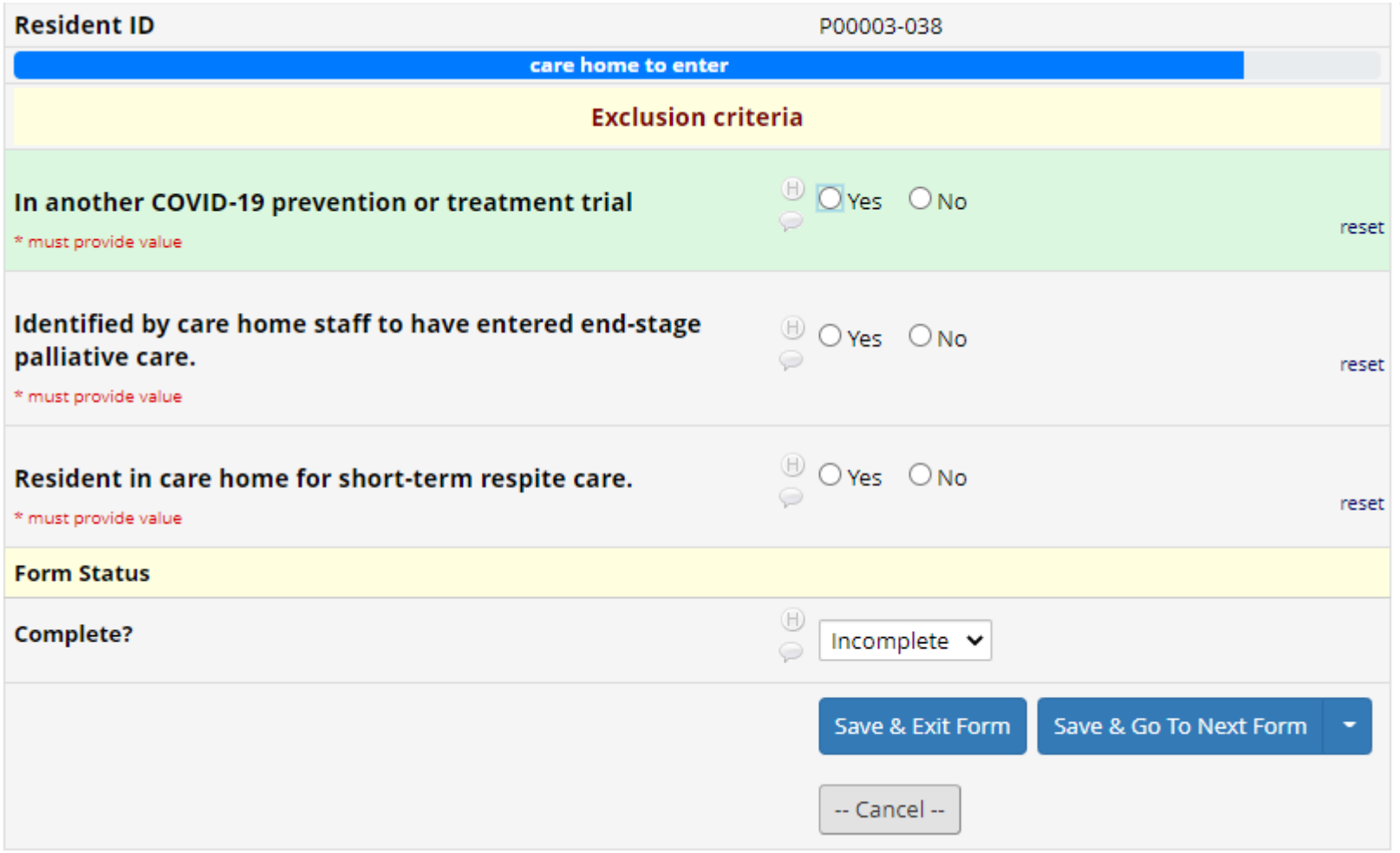


Care Home Eligibility Assessment

Residents **must** meet a certain criteria to be included in the trial.

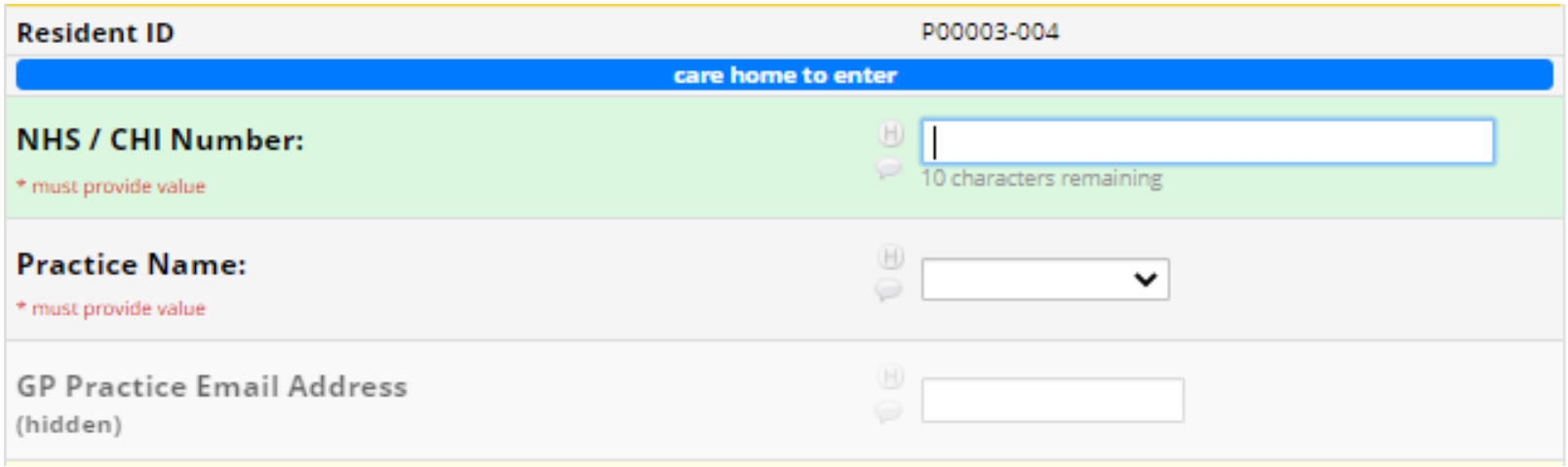
Care home staff are required to answer these **three questions** for **all residents**.

If the answer to **any** of these questions is **'yes'** then the resident **will not** progress to GP eligibility assessment.



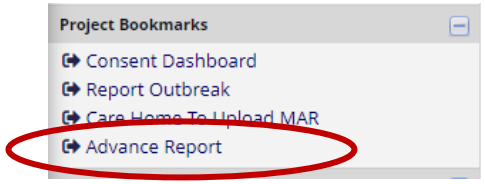
Resident GP details

- You are required to enter the GP details for each resident who is eligible to progress in the trial (as determined by your answers to the 'care home eligibility assessment' questions).
- You should enter the resident's NHS or CHI number and select the resident's GP from the drop-down list.
- Once the resident's GP details have been saved, the GP will receive an email notification advising them to carry out their eligibility assessment.



GP eligibility check

- Once the care home eligibility and GP details forms are completed the resident's GP will be notified to complete the eligibility check.
- Please inform the resident of the outcome of the GP eligibility check once available. The PROTECT-CH trial team will send you regular email reminders to do so.
- To view the outcome of the GP eligibility check, click on 'Advance Report' under Project Bookmarks and select 'Resident Eligibility Information'.



GP eligibility check

- This report shows the outcomes of residents' GP and PI eligibility checks.
- Your resident's GP will be asked to check the resident's medical records and confirm whether the resident is able to continue in the trial. The outcome of this check will be displayed in the 'Continued' column (yes/no).
- After a reported COVID-19 outbreak, the PI will check the resident eligibility for the trial medication. The outcome of this check will be displayed in the "Eligibility_From_PI" column (eligible for ciclesonide /eligible for niclosamide / eligible for either ciclesonide or niclosamide / ineligible).
- Please remember to inform the residents of the outcomes of both eligibility checks once they are available. Personal Legal Representatives will be informed of the eligibility outcomes by the trial team.
- Each column can be sorted (smallest to largest / A-Z) by clicking on the arrows in the top row. To filter the columns, click the filter icon in the top row and type in your filter text. To filter for empty fields, type a space in the filter text box."

Resident Eligibility Information

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Showing resident's eligibility in GP eligibility form and PI eligibility form

Record	Practice_Name	Practice_Email	GP_Eligiblity_Complete	Continued	Eligiblity_From_PI	Randomised_Date	PI_Form_Lock	Treatment
P00003-001								
P00003-002								
P00003-004								
P00003-005								
P00003-006		mszccm@nottingham.ac.uk	yes	yes				
P00003-007								
P00003-008								
P00003-009			no					
P00003-010		mszccm@nottingham.ac.uk						
P00003-011								
P00003-012			no					
P00003-013			no					
P00003-014		protect-trial@nottingham.ac.uk	yes	yes				

Vaccination Status – COVID-19

- You will be asked to give us information on the COVID-19 vaccination status for each of your residents who are participating in the trial.
- For COVID-19 vaccinations, you must record **all vaccinations** that your residents have received, even if they were prior to the start of the PROTECT-CH trial.
- Open the vaccination form and enter the details of the residents first COVID-19 vaccination.

Vaccination Status – COVID-19

- Once you have entered and saved the data for the resident's first COVID-19 vaccination, you can click on the '+' icon to add details of other vaccinations (e.g. the resident's second vaccination)

- If a resident has any additional vaccinations in the future (e.g. boosters), you should enter them in the same way at the time of the vaccination.

Vaccination Status – non-COVID-19

- Resident's may not be eligible to take PROTECT-CH trial treatments if they have recently received a live vaccination.

It is crucial that you record **any vaccinations that a resident has received in the 14 days prior to consent**. You should then continue to record **any additional vaccinations that the resident receives following consent**.

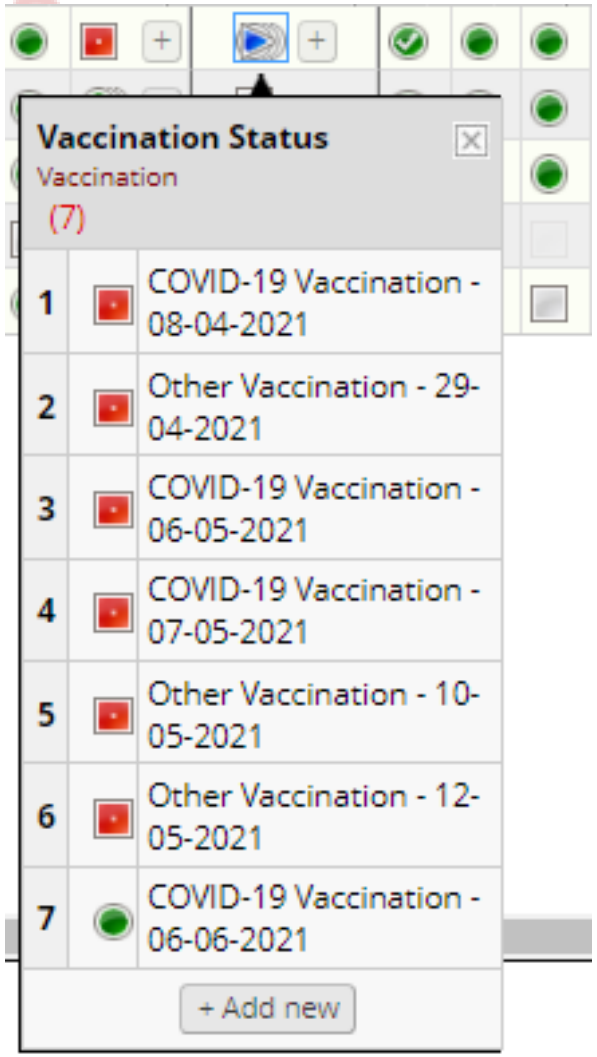
- You should record all non-COVID vaccinations using the options provided on the vaccination form, by selecting **'other vaccination'**.
- If the vaccine that the resident has received is not on the list provided, then you should select 'other' and provide the name of the vaccine given.
- A trial doctor will use this information to determine whether it is safe for the resident to be given trial medication.
- You will not be required to report non-COVID vaccinations after your care home has been randomised*.

*Randomisation is the process during which a computer randomly assigns your care home to one of two groups: 1) a trial treatment (and standard care) or 2) standard care alone

Vaccination Status – non-COVID-19

Resident ID	P00003-006
Received Vaccination * must provide value	○ COVID-19 Vaccination ◉ Other Vaccination
Please specify the type of vaccination * must provide value	○ Pneumococcal vaccine ○ Influenza vaccine ○ Varicella-zoster vaccine ○ Other vaccine
Date of vaccination * must provide value	D-M-Y Date DD-MM-YYYY

Vaccination Status



- Once you have entered multiple vaccinations into the database, the vaccination status icon will change to a blue arrow. This simply means there are multiple entries.
- You can click on the blue arrow icon to display a list of all vaccinations that have been entered for that resident.
- Click '+ Add new' to add another vaccination.

Vaccination history

- When adding a new vaccination, a table will be displayed at the top of the screen to show a detailed summary of all vaccinations that have been entered to date.

Resident ID P00001-001

Vaccination History

COVID-19 Vaccine	Other Vaccine Type	Vaccine Name	Other	Administration	Date of vaccination
yes		Pfizer		Injection	08-04-2021
No	Varicella-zoster	Zostavax		Injection	29-04-2021
yes		Novavax		Injection	06-05-2021
yes		Other	J&J	Injection	07-05-2021
No	Pneumococcal	TEST		Injection	10-05-2021
No	Other	TEST2		Injection	12-05-2021
yes		Pfizer		Injection	06-06-2021

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Consented residents: Overview of form statuses

To open the report, click ‘Advance Report’ under Project Bookmarks and select ‘Forms to complete after research nurse countersigned’

- This report shows an overview of all forms that need completing after signed consent as well as their completion status.
- Each column can be sorted (smallest to largest / A-Z) by clicking on the arrows in the top row. To filter the columns, click the filter icon in the top row and type in your filter text. To filter for empty fields, type a space in the filter text box.

Forms to complete after research nurse countersigned

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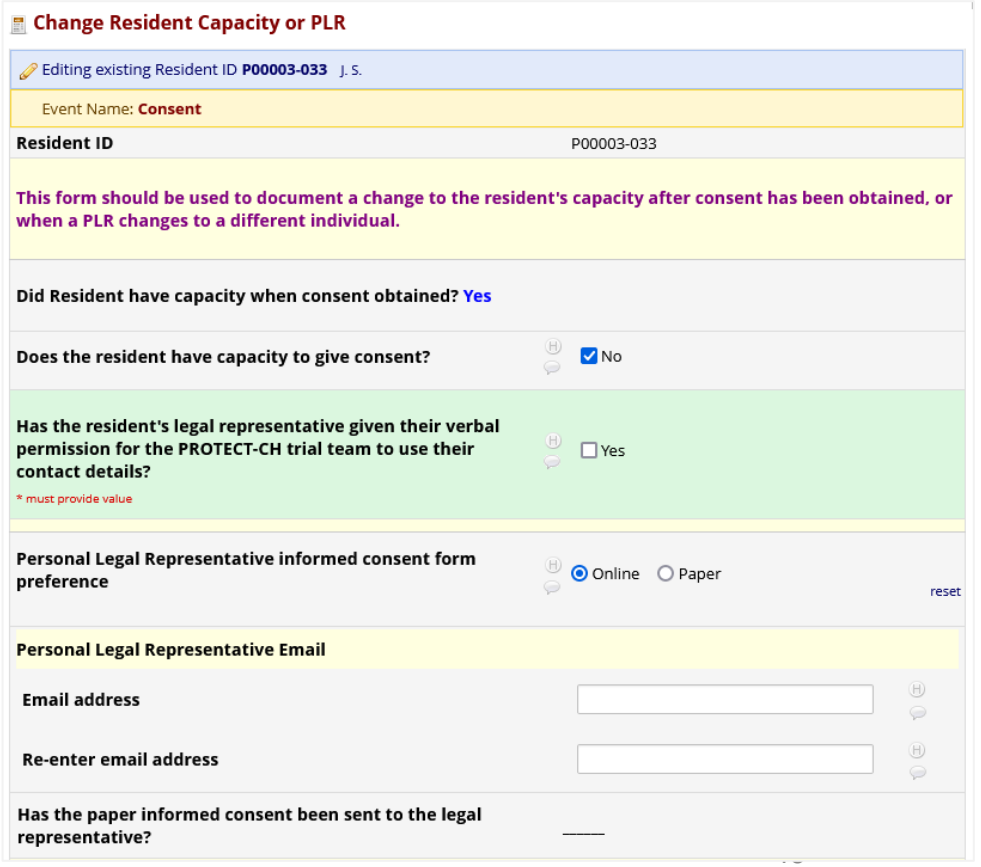
Record	Capacity	Consent_by	Consent_Completed	RN_Signed	EQ5D5L_Proxy_Complete	EQ5D5L_Complete	Demographics_Complete	Care_Home_Eligibility_Assessment	Resident_GP_Details_Complete	vaccination__form_Complete
P00003-001	yes	resident	yes	yes	yes	no	no			yes
P00003-002	yes	resident		no						
P00003-004	no	PLR	yes	yes	no	n/a	no			
P00003-005	yes	resident		no						
P00003-006	yes	resident	yes	yes	yes	yes	yes	eligible	no	
P00003-007	yes	resident	yes	yes	yes	no	no			
P00003-008	no	PLR		no						
P00003-009	yes	resident	yes	yes	no	no	no			
P00003-010	yes	resident	yes	yes	yes	yes	yes	eligible	yes	
P00003-011	yes	resident		no						
P00003-012	yes	resident	yes	yes	no	no	no			
P00003-013	yes	resident	yes	yes	no	no	no			
P00003-014	no	PLR	yes	yes	yes	n/a	yes	eligible	yes	
P00003-015	no	PLR		no						

Recording changes after consent

Loss of capacity after consent

If the resident loses capacity after they have given their consent, you will be required to enter this into the database. A Personal Legal Representation (PLR) should be identified so they can be kept informed of the resident's involvement in the trial, but they will not need to give consent as this has already been obtained from the resident. Please note that this does not apply if the loss of capacity is expected to be temporary.

- Open the 'Change Resident Capacity' form.
- The new PLR will need to give verbal permission for their details to be shared with the PROTECT-CH trial team, but they will not need to complete another consent form.
- You will be prompted to enter the name of the member of staff who obtained verbal permission from the PLR and the date it was obtained.
- Record how the PLR would prefer to receive the trial information – online or on paper
- Enter the PLR's details.
- For **online**, please make sure you tick the '**send**' box, so the system will automatically email trial information to the PLR
- Once all details have been added, mark form as 'complete' and click Save & Exit Form



The online process for providing trial information has been designed as a streamlined approach.
Paper trial information should **only** be selected for PLRs when online is not an option.

Re-gaining capacity after PLR consent

If a resident re-gains capacity after their PLR has given consent on their behalf, please contact the PROTECT-CH trial team:

Protect-trial@nottingham.ac.uk

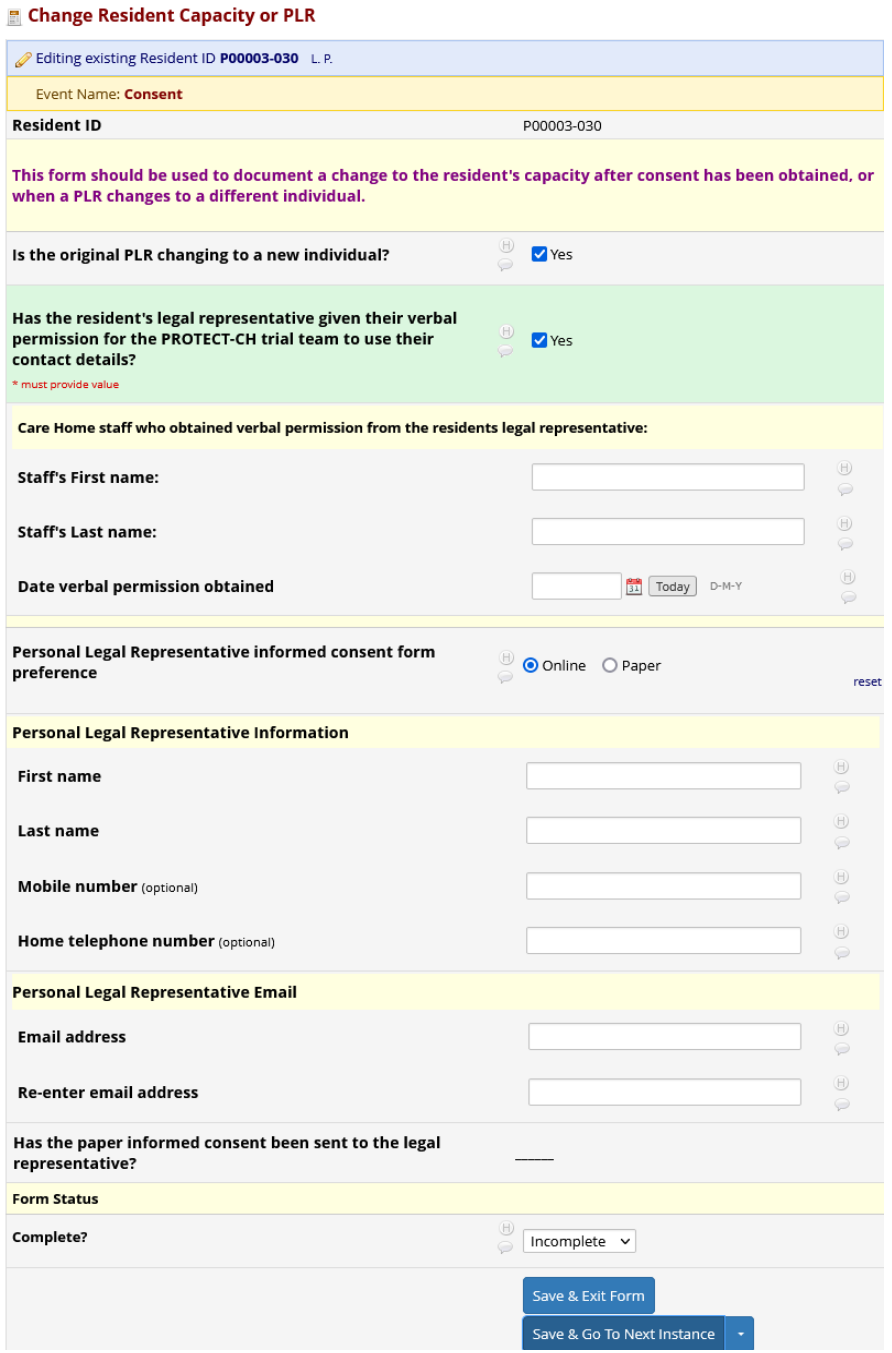
0115 74 87710

Change of PLR after consent

If the PLR who gave consent is no longer able to act on behalf of the resident e.g. if the PLR loses capacity themselves, a new PLR should be identified.

- If a new PLR is identified this should be documented on the 'Change resident Capacity or PLR' form.
- The new PLR will need to give verbal permission for their details to be shared with the PROTECT-CH trial team, but they will not need to complete another consent form.
- You will be prompted to enter the name of the member of staff who obtained verbal permission from the PLR and the date it was obtained.
- Record how the PLR would prefer to receive the trial information – online or on paper
- Enter the PLR's details.
- For **online** , please make sure you tick the '**send**' box, so the system will automatically email trial information to the PLR
- Once all details have been added, mark form as 'complete' and click Save & Exit Form

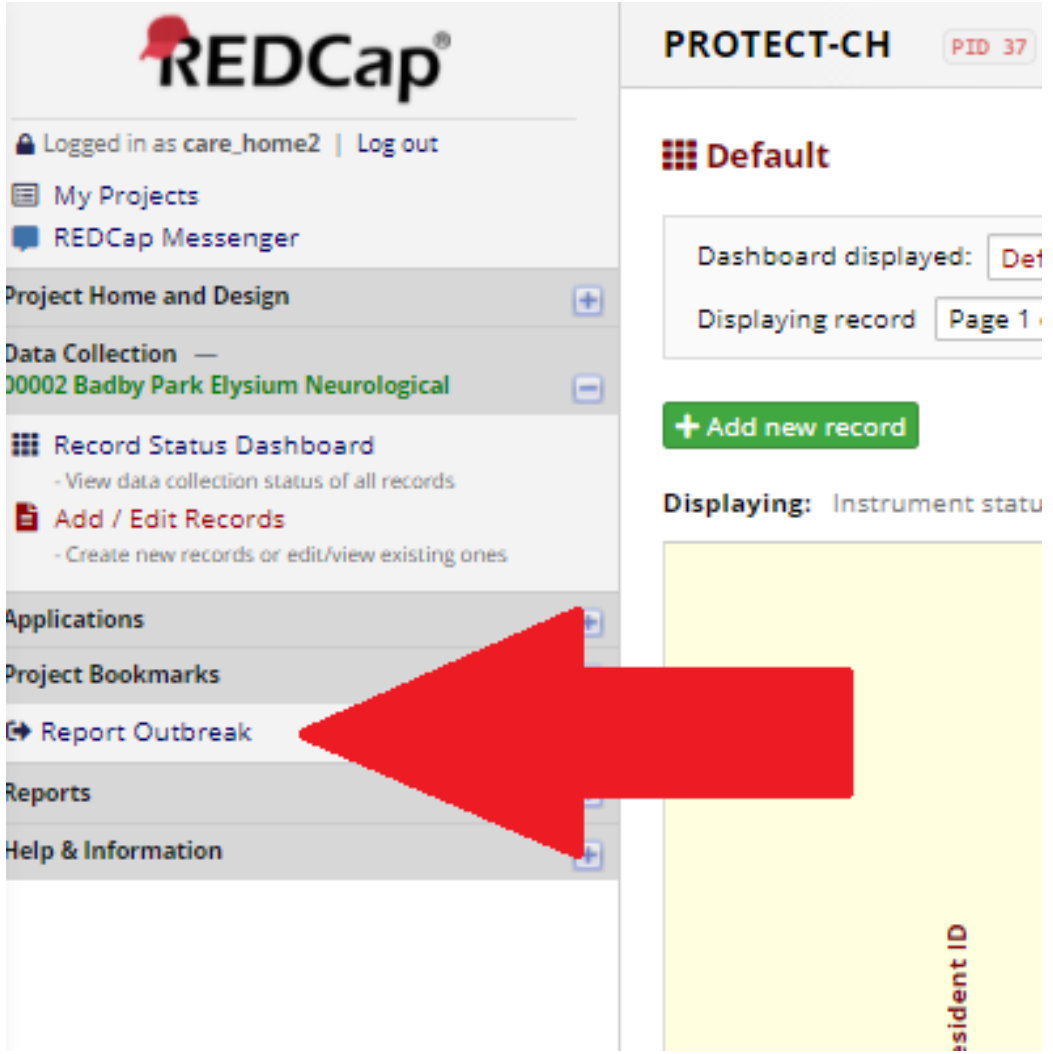
In case further PLR changes are required later on, open the form and click Save & Go To Next Instance to record the new PLR's details as described above.



COVID-19 Outbreak

COVID-19 Outbreak

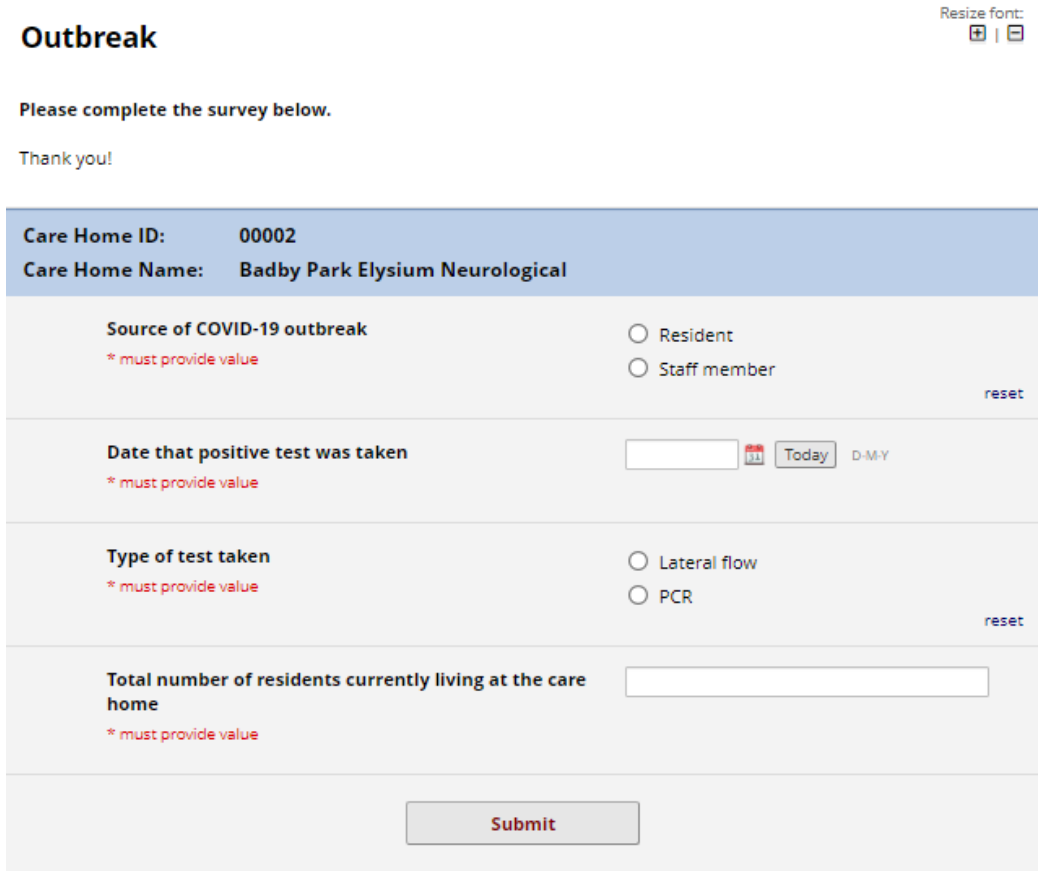
- A COVID-19 outbreak is defined as a positive PCR or lateral flow test [or equivalent] in any resident or member of staff.
- To report an outbreak, you must log in to the trial database (REDCap) and click on 'Report Outbreak' under project bookmarks.
- Complete and submit the outbreak survey to report your outbreak.



COVID-19 Outbreak

- The COVID-19 outbreak form is simple. You must complete this as soon as you become aware of a COVID-19 outbreak in your care home.

- Once you have reported a COVID-19 outbreak, you should not consent any further residents into the trial.



COVID-19 Outbreak – false positive

What if you have reported an outbreak on a positive lateral flow test, but the confirmatory PCR is negative?

- You must inform the PROTECT-CH trial team as soon as you become aware of the negative PCR.
- You will be asked whether any other residents or staff members have received a positive PCR result. If there are no positive cases confirmed by PCR in the care home, the trial team will halt the delivery of your trial medication if possible.
- If trial medication has already been delivered to the care home, you **must not** administer the medication to your residents.
- If you have already started treating your residents, **administration of trial medication must be stopped immediately**.

Uploading MAR charts

- If your care home reports an outbreak of COVID-19, you will be required to upload a copy of the Medication Administration Record (MAR) chart for each resident who remains in the trial.

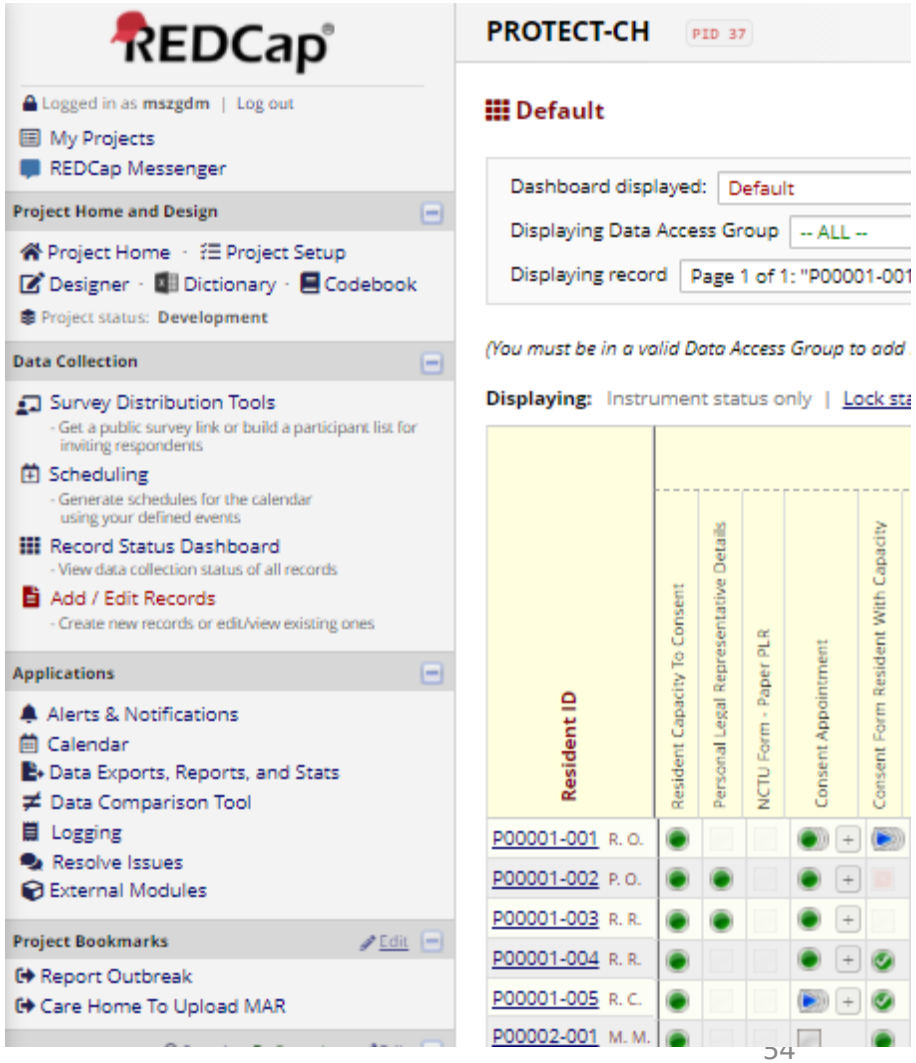
- **7 days of MAR must be uploaded for each resident** as soon as possible after you report an outbreak.

- MAR charts are uploaded to a secure vault, known as the **'PROTECT-CH Documents Vault'.**

Uploading MAR charts

- Some of your residents may have withdrawn from the trial, or been excluded from entering the trial following eligibility assessment carried out by their GP. You will not be required to upload a MAR for such residents.

- To view which residents you are required to upload a MAR for, you should log into the trial database (REDCap) and click on 'Care Home to Upload MAR' under 'Project Bookmarks'.



Uploading MAR charts

- You will be provided with a report, which details a list of all residents for whom a 7-day MAR chart must be uploaded to the PROTECT-CH Documents Vault.
- To upload MAR charts for these residents, navigate to the PROTECT-CH Documents Vault by following the below link, or scanning the QR code.

Care Home To Upload MAR

Back to Advanced Reports Download report

Record	Firstname	Lastname	Outbreak_Date
P00001-001	Res1	Online	2021-05-13
P00001-002	PLR	Online	2021-05-13
P00001-003	Res3	Res3	2021-05-13
P00002-001	Mickey	Mouse	2021-06-07
P00003-006	Jean	Jones	2021-05-07
P00003-014	Adam	Driver	2021-05-07
P00005-001	Res	Paper	2021-05-25
P00005-002	Res2	Paper	2021-05-25
P00005-003	Resident	PLR_Paper	2021-05-25
P00005-005	Tom	Riddle	2021-05-25

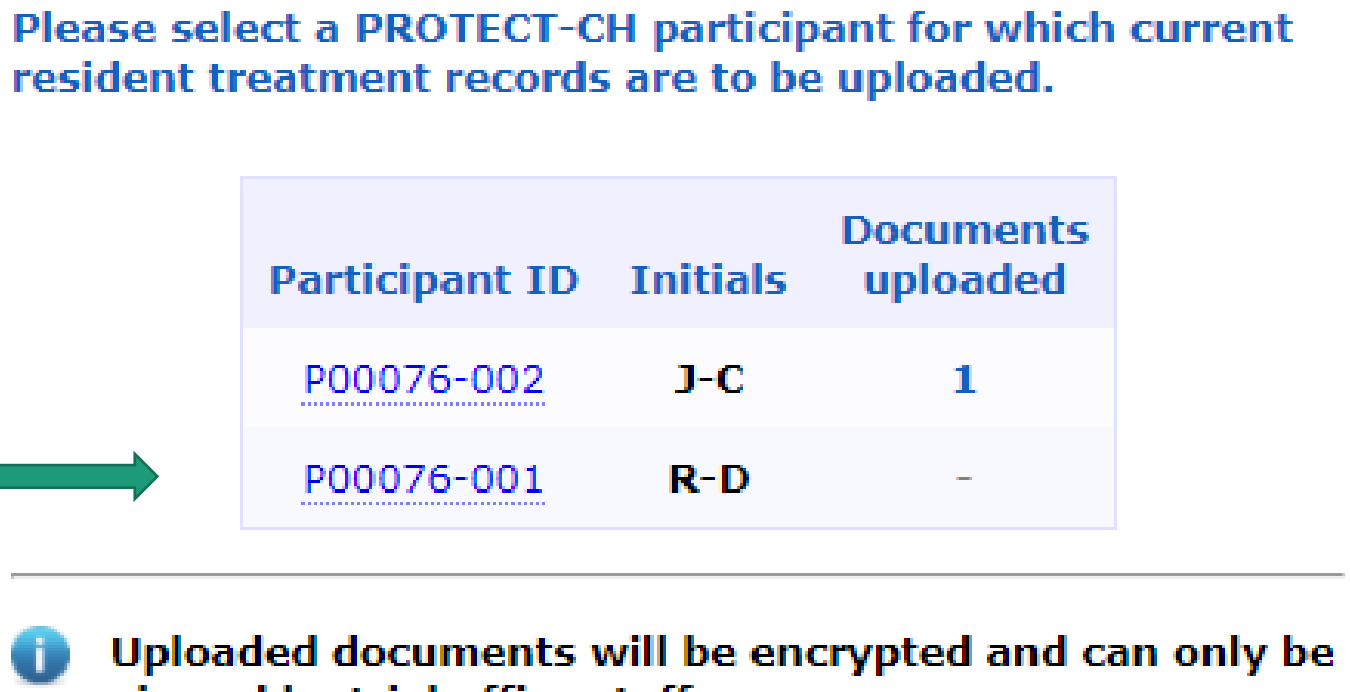
PROTECT-CH Documents Vault

https://protect-vault.nottingham.ac.uk

PROTECT-CH Documents Vault

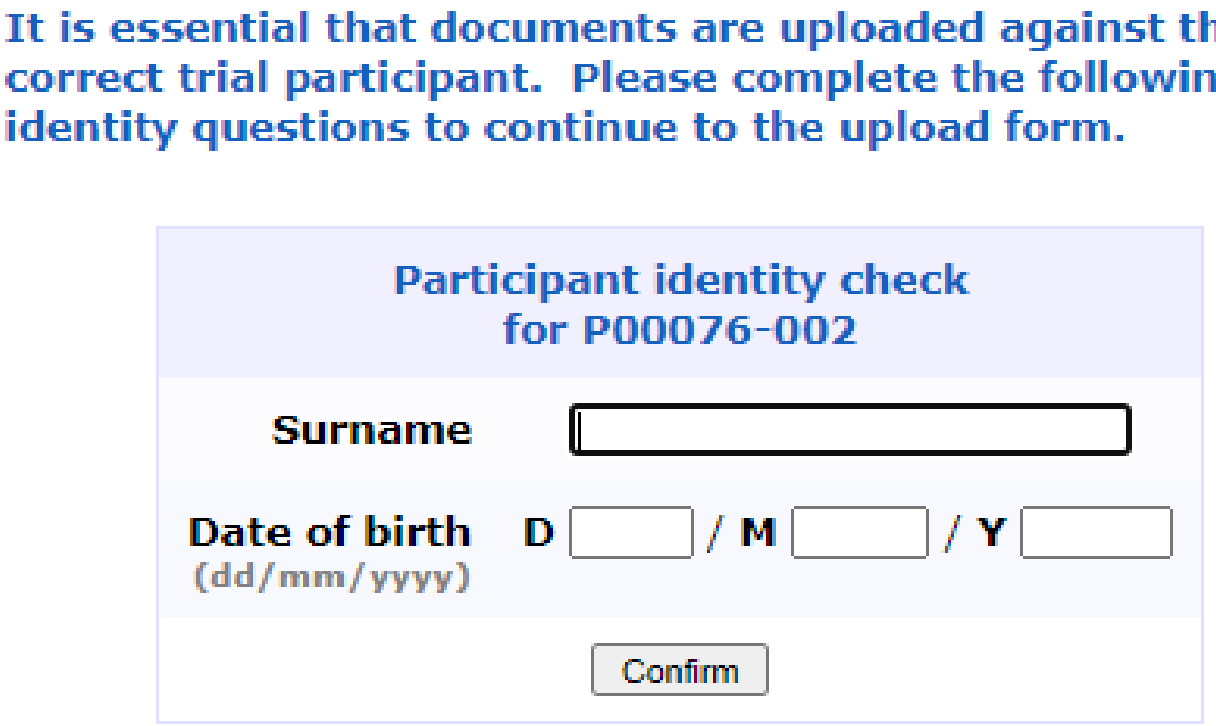
During trial set-up, a member (or members) of your care home staff will have been granted access to the PROTECT-CH Documents Vault.

You must log into the vault and click on a resident's trial ID number to upload the MAR document(s) for that resident.



Documents Vault

- To ensure that documents are uploaded for the correct resident, you will be asked to provide the surname and date of birth of the resident.
- 'Surname' is **not** case sensitive.



Documents Vault

Click to choose a file

Please upload current resident treatment records relating to this clinical trial participant.

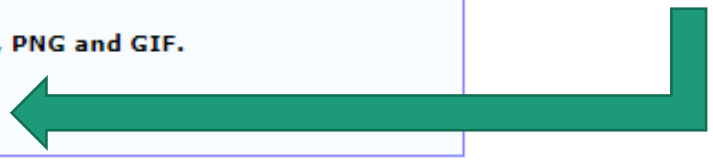
PROTECT-CH participant ID: P00076-002

Joseph Cocker

Choose file | No file chosen

Accepted file formats are PDF, JPEG, PNG and GIF.

Upload file



Click to upload chosen file

If you wish to upload a Microsoft Word document, please 'print' it to a PDF and then upload the PDF file.

Important!
Accepted file format are PDF, JPEG, PNG and GIF

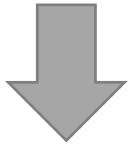
Previously uploaded files for P00076-002
Joseph Cocker

Date/time received	File type	File size	User ID	
8 May 2021 12:58	image/jpeg	14 MB	00076	(2 days ago)

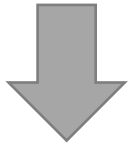
All uploaded files for the resident are shown here

Randomisation

After you have reported a COVID-19 outbreak, the central team of trial doctors known as Principal Investigators (PIs) will carry out a final eligibility check of your residents



The central PIs will then randomise* your care home to one of two groups:
1) a trial medication (and standard care) or
2) standard care alone

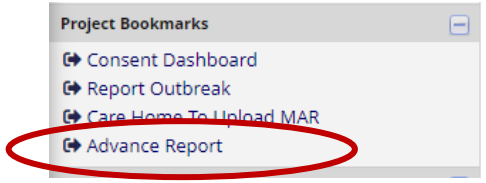


Your care home will be notified of the allocation via email

* The group your care home is given will be decided by computer software based on chance, a process called randomisation.

Eligibility status of residents

- To view the outcome of the PI eligibility check, click on 'Advance Report' under Project Bookmarks and select 'Resident Eligibility Information'.



- The outcome of the PI eligibility check will be displayed in the 'Eligibility_From_PI' column. This will either be ineligible, eligible for ciclesonide only, eligible for niclosamide only or eligibile for ciclesonide and niclosamide.

- Please remember to inform the residents of the outcome of the PI eligibility check once available.

Resident Eligibility Information

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Showing resident's eligibility in GP eligibility form and PI eligibility form

Record	Practice_Name	Practice_Email	GP_Eligiblity_Complete	Continued	Eligiblity_From_PI	Randomised_Date	PI_Form_Lock	Treatment
P00003-001								
P00003-002								
P00003-004								
P00003-005								
P00003-006		mszccm@nottingham.ac.uk	yes	yes				
P00003-007								
P00003-008								
P00003-009			no					
P00003-010		mszccm@nottingham.ac.uk						
P00003-011								
P00003-012			no					
P00003-013			no					
P00003-014		protect-trial@nottingham.ac.uk	yes	yes				

Start of treatment

- If your care home is randomised to one of the trial medications (treatments), you should use this form to record the date on which each resident started the trial medication.

- If a resident did not start trial medication (treatment), you will be asked to give a reason why.

Weekly data

For care homes randomised to trial medication (treatment) groups:

1. The number of doses of trial medication (treatment) that the resident received
2. Any reason for missed doses
3. Whether the resident is continuing with trial medication
4. Any reason for stopping trial medication early

For ALL care homes (regardless of which group your care home is in):

Whether the resident has started any steroid inhalers or oral steroids

1. A record of any adverse events experienced
2. A link is provided at the bottom of the screen to the Serious Adverse Event (SAE) form, should any of the weekly adverse events meet the criteria of a SAE
3. (more information on the recording of adverse events is given in the safety training module).

- The dates for the reporting period will be shown at the top of each 'weekly data' form. Dates are inclusive.
- The dosage questions will only appear at the end of the reporting period, to ensure that the full week of doses are reported.
- If doses are missed due to hospital admission or death, you will also be prompted to complete the 'Event log'. The Event log is discussed in more detail later in this presentation.

PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Weekly data

Week 1 - 11-03-2021 to 17-03-2021 (inclusive)

How many doses of the trial treatment were taken during this period?
* must provide value
4
Enter a number

Main reason for missing doses of the trial treatment
* must provide value
- ○ Suspected adverse reaction (side effects)
- ○ Resident decision
- ○ Primary care decision
- ○ Care home staff decision
- ○ Personal legal representative decision
- ○ Awaiting delivery of trial treatment
- ○ Admitted to Hospital
- ○ Death
- ○ Other

reset

Is the resident continuing with the trial treatment?
* must provide value
○ Yes ○ No
reset

Has the resident been treated with any of the following as a part of their routine care outside the trial during this period?

Steroid inhalers (e.g. budesonide, beclometasone,fluticasone, mometasone, ciclesonide)
* must provide value
○ Yes ○ No
reset

Oral Steroids (e.g. prednisolone, hydrocortisone, dexmethasone, methyprednisolone)
* must provide value
○ Yes ○ No
reset

Chest/Respiratory

- Cough
- Hoarse voice (dysphonia)
- Wheeze, new onset
- Haemoptysis (coughing blood)

◉ Yes ○ No
reset

* must provide value

Which of the following chest/respiratory symptoms did the resident experience and to what severity?

	none	mild	moderate	severe	
Cough * must provide value	○	○	◉	○	reset
Hoarse voice (dysphonia) * must provide value	◉	○	○	○	reset
Wheeze, new onset * must provide value	◉	○	○	○	reset
Haemoptysis (coughing blood) * must provide value	○	○	○	○	reset

Trial medication (treatment) dose

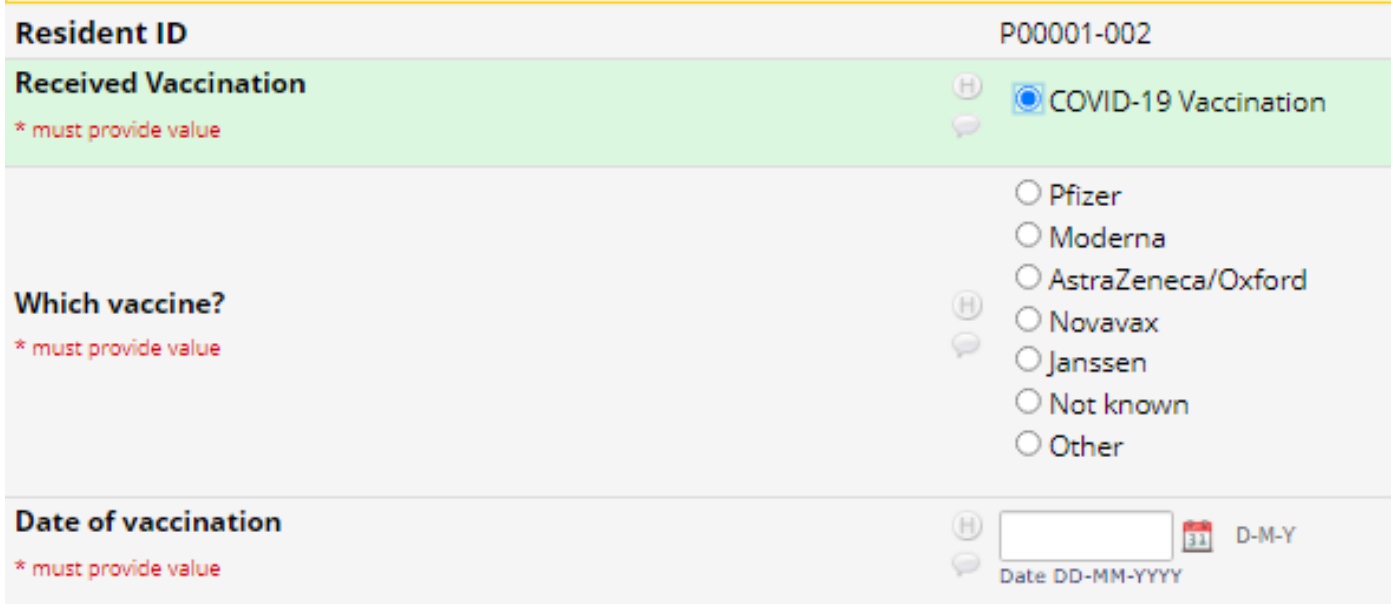
Trial medication (treatment) doses should be recorded on the resident trial Medication Administration Record (MAR) chart. Each the total number of doses given must be entered into the 'Weekly data' form.

What should be reported as a medication dose?

- For Ciclesonide:
  - Dosage is once daily, administered as follows:
  - Two puffs (320 µg) inhaled via mask via mouth sequentially. Participants who are unable to tolerate a face mask will use the spacer mouthpiece taking two puffs.
  - One puff (160 µg) inhaled via mask via nose. Participants who are unable to tolerate a face mask will not receive the intranasal puff.
  - **If you were unable to administer the dose exactly as described above, any puff or attempted puff via the nose or mouth should still be reported as a dose.**
- For Niclosamide:
  - Dosage is twice daily, administered as follows:
    - Intranasal 140 µL spray into each nostril = one push of the nozzle.
  - **If you were unable to administer a spray into each nostril, a spray or attempted spray into at least one nostril should still be reported as a dose.**

COVID-19 Vaccination Status

- You will have already provided the vaccination status for your residents at baseline.
- It is important that you continue to report any additional COVID-19 vaccines that your resident receives throughout the duration of the trial.
- After you care home has been allocated a group (trial medication and standard care **or** standard care alone), you will only be required to report vaccinations for COVID-19



Event log

- All events that relate to important outcomes for the trial are to be reported using an 'Event Log' form.

This form must be used to report:

1. **COVID-19 events**
2. **Admissions to hospital**
3. **Death**

- The form is set up as a repeating form, meaning that multiple events can be reported for a single resident as required e.g. if a resident tests positive for COVID-19 and is also admitted to hospital, then both the COVID-19 event and the admission to hospital must be reported.

UNLIKE THE WEEKLY DATA, THESE EVENTS SHOULD BE REPORTED IN REAL-TIME, AS SOON AS POSSIBLE AFTER BECOMING AWARE OF THE EVENT.

Event log – COVID-19

- A COVID-19 event must be reported for each resident who has tested positive for COVID-19 OR is being treated as having COVID-19.

- If a resident has more than one episode of COVID-19 during the 60 days following randomisation, a separate COVID-19 event must be reported for episode.

- The following data must be included in the report:
  - Any symptoms experienced
  - Resident test results (if tested)*
  - Received Dexamethasone in the care home
  - Received Oxygen in the care home
  - If any healthcare support was needed for the COVID-19 event (e.g. 111, paramedic)

***It is important to note that only tests associated with the COVID-19 event should be reported. You are not required to report all routine COVID-19 tests for your residents.**

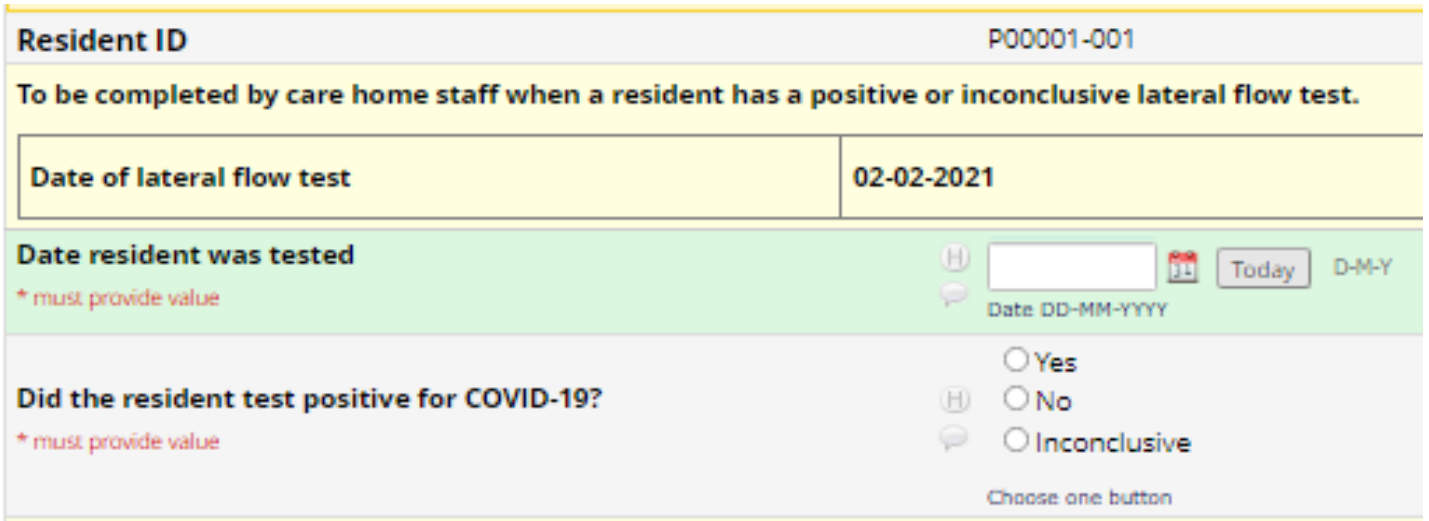
Event log – COVID-19

- There are certain data fields that may require updating after you have reported a COVID-19 event for a resident.
- Examples:
  - *Resident had not received Dexamethasone in the care home to treat the COVID-19 event at the time of your report, but received Dexamethasone the following day*
  - *The resident had not been tested for COVID-19 at the time of your report, but was tested the following day*

Is it crucial that for situations such as those above, you navigate back to the <u>same COVID-19 event</u> in the trial database and update the data accordingly.

Event log – COVID-19 PCR confirmation

- If a COVID-19 event is reported in the event log based on a lateral flow test, a separate form will be generated in the database called 'COVID-19 PCR confirmation'.
- This form should be used to report the outcome of the confirmatory PCR test.
- The data of the reported lateral flow test will be displayed at the top of the screen, to ensure that you are reporting the correct PCR.



Event Log – Admissions to hospital

- You must report each time a resident is admitted to hospital during the 60 day period following randomisation.

- Please ensure the following data are reported:
  - Main reason for admission
  - Date of admission

IMPORTANT: The resident will need to discontinue the trial medication during hospital admission. Trial medication MUST NOT accompany a resident to hospital.

Admission to hospital must also be reported as a Serious Adverse Event. You will be prompted to navigate directly to the SAE reporting form in the database.

Event Log – readmission to care home

- For each report you create for an 'admission to hospital', a separate form will be created to record if/when the resident was discharged from hospital and has returned to the care home.

Event log - Death

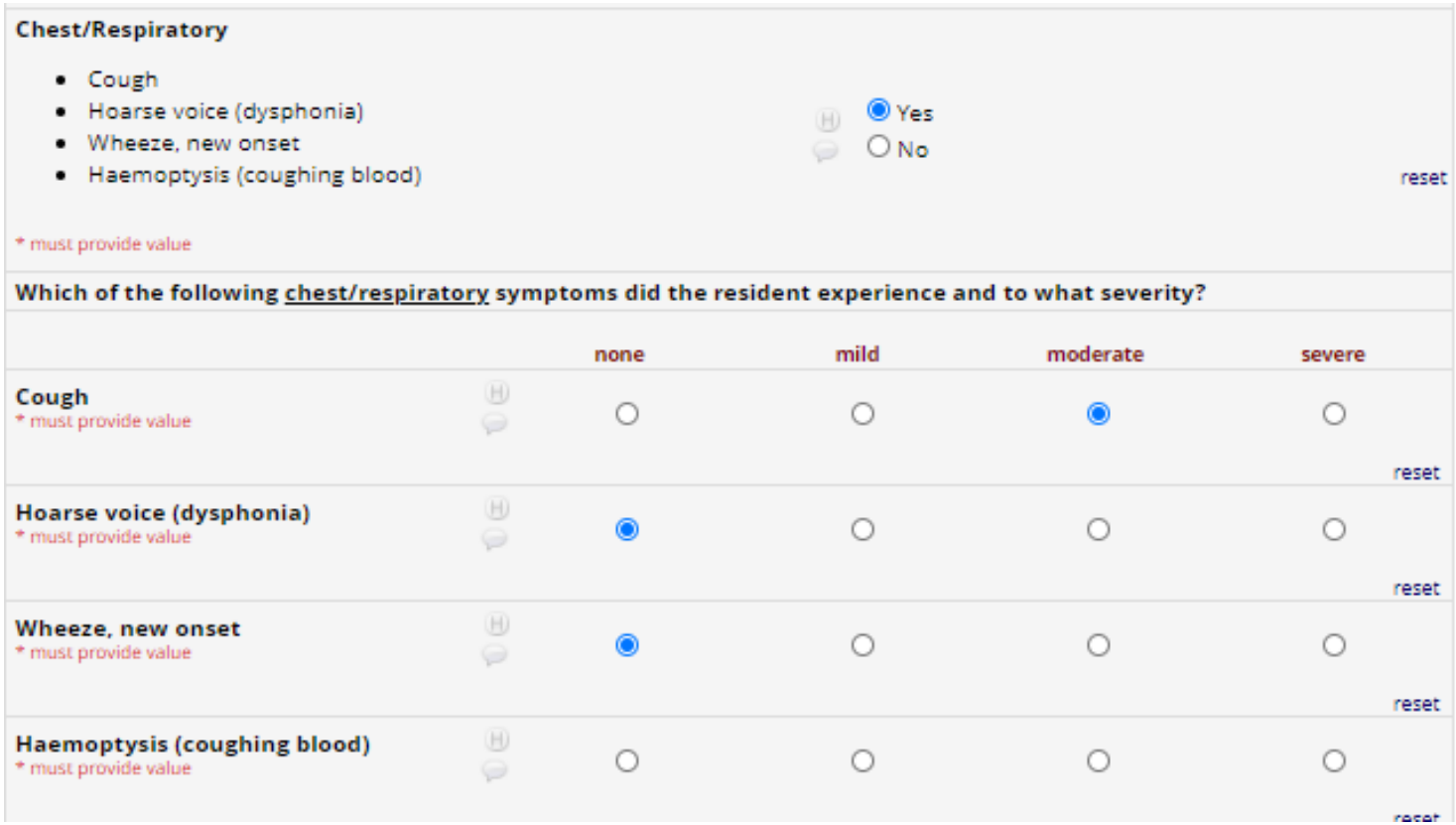
If the resident dies within the 60 day period following randomisation, this should be reported as soon as possible. You will need to record:

- Date of death
- Cause of death
- Whether the resident died whilst in the care home*

***Death within the care home must also be reported as a Serious Adverse Event. You will be prompted to navigate directly to the SAE reporting form in the database.**

Safety reporting – adverse events

- A summary of any adverse events to be reported on a weekly basis for each resident via the '**weekly data**' form.



Chest/Respiratory

- Cough
- Hoarse voice (dysphonia)
- Wheeze, new onset
- Haemoptysis (coughing blood)

(H) ◉ Yes ○ No

reset

* must provide value

Which of the following chest/respiratory symptoms did the resident experience and to what severity?

	none	mild	moderate	severe	
Cough * must provide value	○	○	◉	○	reset
Hoarse voice (dysphonia) * must provide value	◉	○	○	○	reset
Wheeze, new onset * must provide value	◉	○	○	○	reset
Haemoptysis (coughing blood) * must provide value	○	○	○	○	reset

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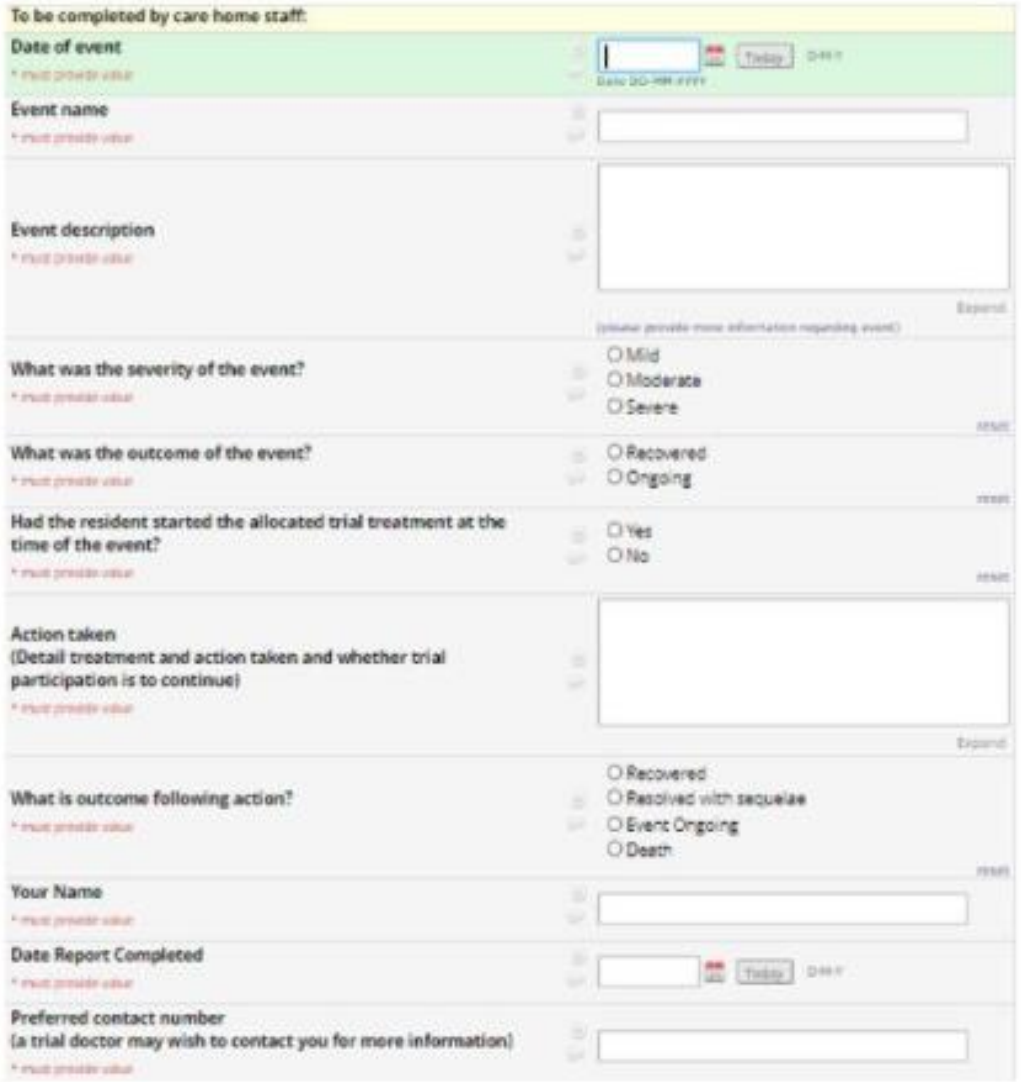
Prophylactic Therapy in Care Homes Trial

Safety reporting – Serious Adverse Events

SAEs must be reported using the Serous Adverse Event form in the REDCap database. Details must include.....

- **Date of the event**
- **Event name** (e.g. 'fall' or ' heart attack')
- **Event description** - please include as much information about what happened, this will help the trial doctor with their assessment of the event
- **Severity** - you will be asked to make a judgement on whether you think the event is mild, moderate or severe
- **Name and contact details of person completing the form** - the care home Principal Investigator may need to contact them to obtain more information



60 day follow-up

At 60 days following care home randomisation, you will need to:

1. Complete another Quality of Life questionnaire (EQ5D5L proxy to be completed by care home staff **and** EQ5D5L to be completed by residents who have capacity. **IMPORTANT: the member of staff completing the EQ5D5L proxy should be directly involved in the resident's care where possible.**

2. Healthcare Support from randomisation to 60 days

3. A final '60 day check' to confirm that all data have been reported.

Healthcare Support

- If the resident received any healthcare support it must be recorded in this form.
- You must report the total number of each healthcare support visits for each resident for the period up to and including 60 days post-randomisation.
- Please note that only **non-routine** healthcare visits from **external** healthcare providers should be reported.
- The following information will be required:
  1. Whether remote or face-to-face
  2. Which healthcare professionals/services were used
  3. The number of times contact was made

Healthcare Support

The healthcare support form looks like this…

Has the resident had any contact with any of these healthcare professionals or services, or contact been made on their behalf (face-to-face/remote)?

- GP
- Hospital Doctor
- Nurse
- Nurse Specialist
- Allied Health Professional (Physiotherapist or Occupational Therapist or Speech Language Therapist or Respiratory Therapist)
- Calls to 111
- Calls to 999

* must provide value

○ Yes
○ No

reset

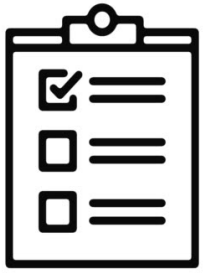
	Face-to-Face	Remote	No contact
GP * must provide value	☐	☐	☐
Hospital Doctor * must provide value	☐	☐	☐
Nurse * must provide value	☐	☐	☐
Nurse Specialist * must provide value	☐	☐	☐
Allied Health Professional (Physiotherapist or Occupational Therapist or Speech Language Therapist or Respiratory Therapist) * must provide value	☐	☐	☐

	Calls made to	No contact
111 * must provide value	☐	☐
999 * must provide value	☐	☐

60 Day check

- The '60 day check' form is a final confirmation that everything has been reported for each resident

- Care home staff must confirm that reporting for the following is accurate and complete:
  - Resident health events (e.g. COVID-19, hospital admissions, death)
  - Resident vaccination status
  - Trial medication (treatment) doses and adverse event

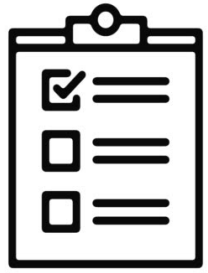


  - If any residents have discontinued their participation in the trial, or died during the trial, you should confirm that all data up to that point is entered accurately.

Protocol violations

It is important that you tell us if something happens at your care home that goes against the processes outlined in the protocol.

- You must complete a protocol violation form as soon as possible if:
  - Trial medication is given to a resident who has not given their consent to take part in the trial
  - Trial medication is given to a resident who was not eligible to take part in the trial
  - You didn't report important data (hospital admission, COVID-19 event or death)
  - You didn't report a serious adverse events



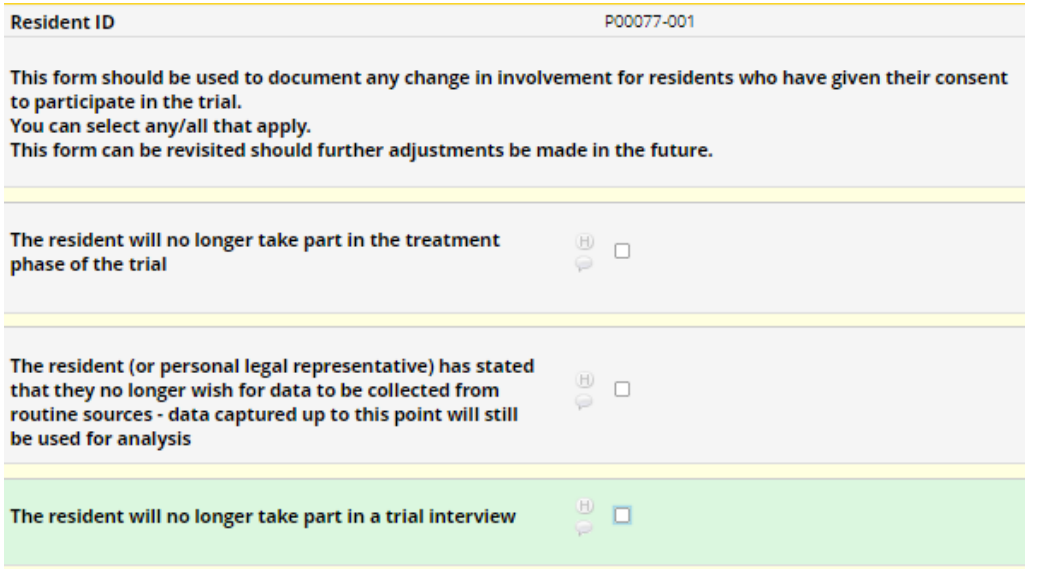
Please make sure you provide as much information as possible. If you are unsure whether you need to report something as a protocol violation, please contact the trial team who will be happy to assist.

Protocol violations form

Resident ID	P00078-004
To be completed by care home staff or research nurse or PI on becoming aware of a suspected protocol violation	
Date of suspected violation * must provide value	Today D-M-Y Date DD-MM-YYYY
Describe the suspected protocol violation * must provide value	Expand
Name of person reporting suspected protocol violation * must provide value	
Role of person reporting suspected protocol violation * must provide value	
Date report completed * must provide value	30-07-2021 12:11 D-M-Y H:M Date DD-MM-YYYY

Trial status

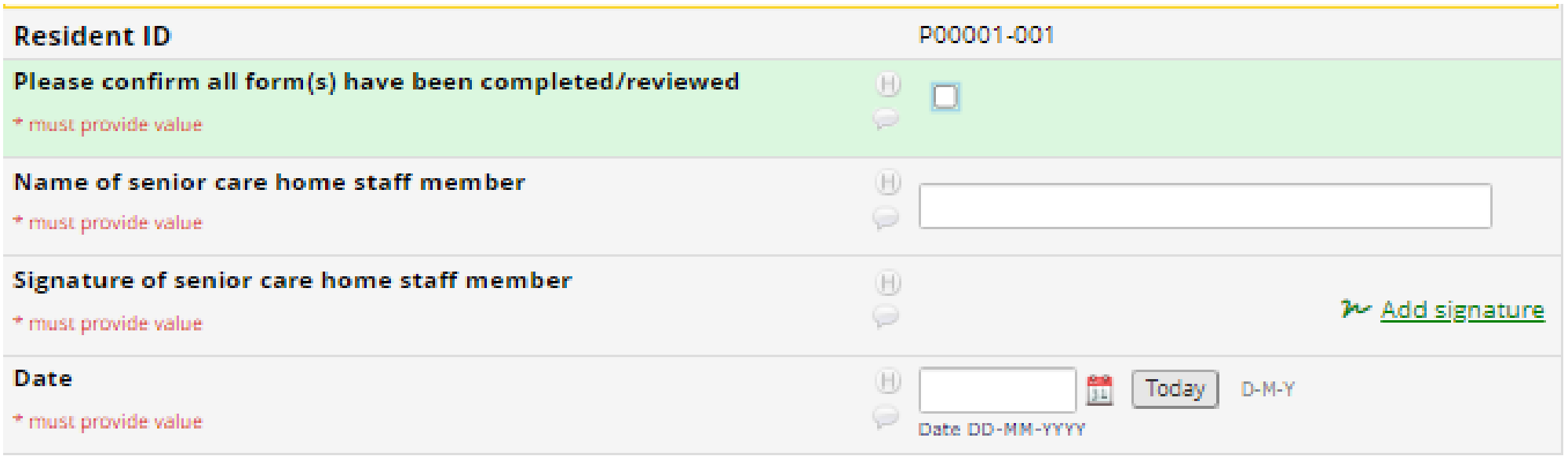
- This form will be used to record if there is a change in the trial activities the resident does not want to take part in.
- The resident can still take part in the trial even if they do not wish to take the trial medication, their data is still important to the trial.
- You will be asked to provide the reason for stopping trial activities.
- Residents should only be marked as 'withdrawn' if they no longer wish to partake in any trial activities, including providing trial data. Data from routine sources for these residents will still be used for trial analysis, unless they specifically state otherwise.



Please remember:
any data collected up until their change in activity will be used

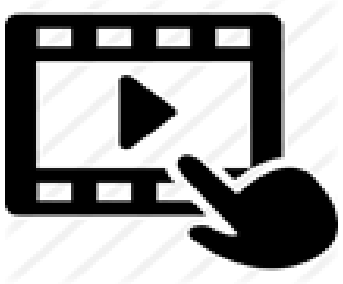
Verification statement

- This form must be completed by the care home manager once all other data forms have been completed for the resident.
- This is a final sign-off for each resident and acts as a confirmation that all data reported are complete and accurate.



Further Guidance

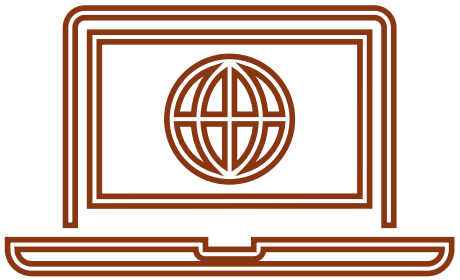
- There are videos on the system to help you through forms.
    - Click on the video link at the top of the relevant form in the trial database (REDCap) to access the video guidance



Thank you for reading!

You have now completed the **Data Entry** User Guide.

Please remember to complete **your self-certification form** to confirm you have undertaken this training.



This can be found at:

https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=81&ModuleVersion=1

Or you can access it via mobile here:

University of Nottingham
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Any questions?

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