





PR&TECT-CH Prophylactic Therapy in Care Homes Trial Research Nurse (RN) Data Entry User Guide











Final Version 1.0 26-Aug-2021





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

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











Logging onto the REDCap trial database



RNs will need to complete a database access form in order to be granted permissions to access the PROTECT-CH trial database, known as REDCap.

REDCap can be accessed via the following link: <u>https://redcap01.nottingham.ac.uk/</u> or

by scanning this QR code from a mobile device:







Database navigation (i)

- Click on 'Record Status
 Dashboard' to take you to a
 summary view of all
 residents entered into the
 database in your region.
- Clicking on 'Resident ID' number will allow you to navigate to the resident's individual data entry page.





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P00003-015 M. M. (a) (a) (a) (a)	



Database navigation (ii)

Click on the icons next to the form you need to complete in order to open the individual data entry page.

Data Collection Instrument	Consent	Vaccination	Eligibility	Randomisation 0
Resident Capacity To Consent	۲			
Personal Legal Representative Details (survey)				
NCTU Form - Paper PLR				
Consent Appointment				
Consent Form Resident With Capacity (survey)	•			
Consent Form Resident Without Capacity (survey)				





Resident ID P00003-018 B. B.







Database navigation (iii)

 Once you have opened an individual data entry page,





- you can navigate between the different forms under 'Data Collection' in the side bar on the left hand side of your screen.





Consent process

The regional team of RNs will receive an email notification that a consent appointment has to be arranged for a resident or personal legal representative.

Click on the link provided in the email in order to be directed to the 'Consent Appointment' form for the participant.











Scheduling consent appointment -Resident with capacity

- The **Consent Appointment** form will provide you with the phone number of the care home.
- Once you have scheduled the appointment make sure this is recorded on the form.
- Leave Form Status as 'Incomplete' and click Save & Exit Form

📱 Consent Appointment





)21 J. S.	
	P00003-021
	H 0 115 748 7713
ie	H D-M-Y H:M
d:	
\rightarrow	⊖ Incomplete ✓
	Save & Exit Form
	Save & Go To Next Instance 🔹
	Cancel



Overview of all scheduled consent appointments

- For an overview of all scheduled consent appointments with the care homes in your region click on 'Advance Report' under Project Bookmarks
- Select ' Consent Appointments With Research Nurse'



- Care Home To Uplo
- Advance Report



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Overview of all scheduled consent appointments

- This report shows the date and time of scheduled consent appointments with a research nurse for each resident, 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.
- For research nurses that work with multiple care homes: The report only displays appointments for residents of one care home. To switch between different care homes, please use the "SWITCH" button on top of the page and select the care home of choice from the drop down menu."



Appointment	Status	can	be	overd
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Record 🕈	Appointment 🕇	Appointment_Status 🕇	Proceed_To_Consent_Form
P00003-001	<u>24-05-21 15:12</u>	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	<u>17-06-21 15:54</u>	completed	yes
P00003-011	27-05-21 12:42	completed	yes
P00003-012	03-06-21 14:16	completed	yes
P00003-013	<u>10-06-21 14:08</u>	completed	yes
P00003-014	09-06-21 14:58	completed	yes
P00003-015	20-07-21 11:38	completed	yes
P00003-018	<u>16-06-21 11:51</u>	completed	yes
P00003-019	<u>10-06-21 16:09</u>	completed	yes
P00003-020	<u>11-06-21 16:50</u>	completed	yes
P00003-021	<u>15-06-21 16:15</u>	Overdue	



Current Data Access Group: 00003 Castle Grove Nursing Home Switch

Download report

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

lue, due, upcoming



During the consent appointment -Resident with capacity (i)

- Open the 'Consent Appointment' form at the beginning of the consent appointment.
- Explain the trial and answer the resident's questions.

• Once the scheduled appointment time has passed, the form will automatically display additional fields.





2021 14:12 - complete: Yes 🗢	
00003-029 P. P.	
	P00003-029
	0 115 748 7713
and Time	(н) — 17-06-2021 14:12 Вородинии странии ст
ent date and time is entered please sa n made.	ave the form. Please return to complete the rest of
rovided:	^ℍ ● Final v1.0_18 May 2021 reset
complete the consent form?	H OYes ONo
	⊖ Incomplete ✓
	Save & Exit Form Save & Add New Instance -
	Cancel



During the consent appointment -Resident with capacity (ii)

• During the consent discussion, check which <u>version</u> of the information sheet the resident has read. The database will display a drop down menu if more than one version exists.

* See later slide on what to do if resident has not read the latest version of the information sheet

- If the resident is happy to proceed to complete the consent form, make sure to record this on the database. Clicking "yes" will activate the residen'ts e consent form.
- If the resident is not happy to proceed to complete the consent form, select "no". The database will then display a field to provide a reason.





t	

8-2021 15:44 - complete: 🛛		
P00003-042 R. I.		
	P00003-042	
r	^ℍ ╒ 0 115 748 7713	
e and Time	н р 19-08-2021 10:31 🗒 🖸 D-М-Ү Н:М	
nent date and time is entered please en made.	save the form. Please return to complete the rest o	f
provided:	^ℍ	reset
to complete the consent form?	⊕ O Yes O No	reset
	⊖ Incomplete ►	
	Save & Exit Form Save & Add New Instance	•
	Cancel	



During the consent appointment -Resident with capacity (iii)

• Mark the form status as complete

and click

Save & Exit Form

- Saving the form will automatically email the care home a link to the 'Consent Form Administration' form. Ask the care home staff to open this form (either by using the link provided in the email or by navigating the database.
- Talk the resident through the consent form once he/she has it in front of them.

Editing existing Resident ID P00003-042 R. I.		
Event Name: Consent		
Resident ID	P00003-042	
completed		
Care home telephone number (read only)	H	
Scheduled Appointment Date and Time * must provide value	(Н) — 19-08-2021 10:31 В ⊡ D-м-Ү Н:м	
Version of information sheet provided: * must provide value	[⊕] ● Final v1.0_18 May 2021	rese
Is resident ready to proceed to complete the consent form? * must provide value	^ℍ ● Yes ○ No	rese

Form Status

Complete?



e C	Complete	~		
	Save & Exit	: Form	Save & Add New Instance	•
	Cancel			



Paper consent -**Resident with capacity**

- The process is the same as with e-consent, except that the resident will have the paper consent form in front of them.
- Check which version of the information sheet the resident has read and record this on the database.
- Ask care home staff to write down which version of the information sheet the resident has read on the paper consent form.
- If the resident is ready to preceed to complete the consent form, click 'Yes' and save the the form as 'Complete'. This will automatically email the care home a link to the 'Consent Form Administration' form.
- Ask the care home staff to open 'Consent' Form Administration' form (either by using the link in the email or by navigating the database).

Current instance: 💿 1 – 26-05-2021 11:24 - complete: Yes 🗢		
Editing existing Resident ID P00003-009 T. F.		
Event Name: Consent		
Resident ID	P00003-009	
completed Care home telephone number (read only)	⊕	
Scheduled Appointment Date and Time * must provide value	^Н р 26-05-2021 11:24 В Р-м-ч н:м	
Version of information sheet provided: * must provide value	^ℍ ● Final v1.0_18 May 2021	res
Is resident ready to proceed to complete the consent form? * must provide value	🛞 🖲 Yes 🛛 No	res
Once resident is ready to complete consent form click "Yes" abo Care home staff should then open the <u>Consent Administration F</u> complete.	ve and save the form. Form to access the consent form for the reside	ent to
Form Status		
Complete?	B	

ave & Exit Form

-- Cancel --

Save & Go To Next Instance



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	J	



Scheduling consent appointment -Resident <u>without</u> capacity (i)

- In the case where a resident lacks capacity to consent, consent will be taken from their Personal Legal Representative; a close friend or family member.
- Open the 'Personal Legal Representative Details' form to view the legal representative's contact details and preferred contact time.





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	John	H P
	Smith	H P
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	011574 87710	H
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Scheduling consent appointment -Resident <u>without</u> capacity (iii)

 Record Date and Time of the scheduled appointment on the 'Consent Appointment' form

 Leave Form Status as 'Incomplete' and click Save & Exit Form

Consent Appointment Editing existing Resident ID PO Event Name: Consent Resident ID Care home telephone number (read only) Scheduled Appointment Date a must provide value An appointment has been sche Version of information sheet pr * must provide value Form Status Complete?





0003-028 N. O.	
	P00003-028
	(H)
nd Time	н) 23-06-2021 13:46 В № D-м-Ү н:м
duled by research nurse, please wait	t.
ovided:	
\rightarrow) Incomplete V
•	Save & Exit Form
	Save & Go To Next Instance 🔹
	Cancel



During the consent appointment -Resident <u>without</u> capacity (i)

- Open the 'Consent Appointment' form at the beginning of the consent appointment.
- Explain the trial and answer the legal representative's questions
- Once the scheduled appointment time has passed, the form will automatically display additional fields

🖪 Consent Appointment	
Current instance: 💽 1 – 24-05-2021 15:42 - complete: Yes 🗢	
Editing existing Resident ID P00003-004 J. J.	
Event Name: Consent	
Resident ID	P00003-004
completed	
Scheduled Appointment Date and Time * must provide value	Н 24-05-2021 15:42 В □-м-ү н:м
Version of information sheet provided: * must provide value	^ℍ O Final v1.0_18 May 2021
Is personal legal representative ready to proceed to complete the consent form? * must provide value	⊖ Yes ○ No reset
Send the consent form link to resident's legal representative (tick the box and save the form and consent link will be emailed automatically)	⊖ send
Form Status	
Complete?	⊖ Complete ✓
	Save & Exit Form Save & Add New Instance •
	Cancel







During the consent appointment -Resident <u>without</u> capacity (ii)

 During the consent discussion, check which version of the information sheet the legal representative has read. The database will display a drop down menu if more than one version exists.

* See later slide for guidance if PLR has not read the latest version.

- If case the PLR is not ready to proceed, select "no". The database will then display a field to provide a reason. In this case click 'Save & Exit Form' and do not proceed with the next steps.
- If the PLR is ready to proceed to complete the consent form, select 'Yes' on the database.
- Make sure to tick the 'send' box, mark the form as 'Complete' and click
 Save & Exit Form

The system will automatically email the PLR a link to the e-consent form.

- If the PLR is able to do so, they should then use the link to open the consent form
- Talk them through the consent form.

🖀 Consent Appointment	
Current instance: 🜘 1 – 24-05-2021 15:42 - complete: Yes 🗢	
Editing existing Resident ID P00003-004 J. J.	
Event Name: Consent	
Resident ID	P00003-004
completed	
Scheduled Appointment Date and Time * must provide value	н
Version of information sheet provided: * must provide value	H O Final v1.0_18 May 2021
Is personal legal representative ready to proceed to complete the consent form? * must provide value	⊕ Yes ○ No
Send the consent form link to resident's legal representative (tick the box and save the form and consent link will be emailed automatically)	⊖ send
Form Status	
Complete?	⊖ Complete ►
	Save & Exit Form Save & Add New Instance
	Cancel





Paper consent -Resident without capacity

- The process is the same as with the e-consent described in previous slides, except that the legal representative will have been sent the paper consent form by the University of Nottingham trial team via post. The consent form should contain the version of the information sheet that has been sent to the legal representative.
- Check which version of the information sheet the legal representative has read and record this on the database.
- Confirm with the legal representative that the correct version of the information sheet has been written on the consent form.

🖀 Consent Appointment	
Current instance: 🜘 1 – 09-06-2021 14:58 - complete: Yes 🗢	
Editing existing Resident ID P00003-014 A. D.	
Event Name: Consent	
Resident ID	P00003-014
completed	
Scheduled Appointment Date and Time	[⊕] ⊖ 09-06-2021 14:58 ஹ р-м-ү н:м
* must provide value	
Version of information sheet provided:	Final v1.0_18 May 2021
* must provide value	reset
Is personal legal representative ready to proceed to complete	🖲 🔍 Yes 🔿 No
* must provide value	
Form Status	
Complete?	⊖ Complete ►
	Save & Exit Form Save & Add New Instance 🔹
	Cancel





Additional consent appointments

- In case an appointment has been missed, select 'No' for the question if the resident is ready to proceed to complete the consent form.
- Provide details why the resident is not ready
- Mark Form Status as 'Complete' and

click

Save & Go To Next Instance

This will open a new Consent
 Appointment form for entering new appointment details.

🖪 Consent Appointment
Current instance: 🜔 1 – 24-05-2021 15:12 - c
Editing existing Resident ID P00003-001 F.
Event Name: Consent
Resident ID
appointment not completed
Care home telephone number (read only)
Scheduled Appointment Date and Time * must provide value
Version of information sheet provided: * must provide value
Is resident ready to proceed to complete th * must provide value
Please provide details if selected no * must provide value
If the scheduled appointment is not comple & Add New Instance" to enter new appoint
Form Status
Complete?



- complete: Yes 🗢		
F. F.		
	P00003-001	
	[⊕]	
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the consent form?	⊖ OYes ONO	reset
	⊕ ♀) (
pleted and an additional a intment details.	appointment needs to be scheduled, please click "	Save
	Complete V	
	Save & Exit Form Save & Add New Instance	-
	Cancel	



Additional consent appointments -Troubleshooting

- In case an additional consent appointment form has been added by mistake, it is not possible to delete the new form.
- This form should be left blank and can be ignored.
- Please make sure the Form Status is left as 'Incomplete', otherwise the resident/PLR will not be able to access the e-consent form.

Consent Appointment	
Current instance: 2 – complete: 🗢	
Editing existing Resident ID P00003-015 (Instance #2) M.	М.
Event Name: Consent	
Resident ID	P00003-015
RN to enter	
Version of information sheet provided: * must provide value	🕒 💽 Final v1.0_18 May 2021
Form Status	
Complete?	Discomplete Y
	Save & Exit Form Save & Add New Instance <
	Cancel





Resident has not read latest version of information sheet

- If there have been only minor changes to the information sheet, explain the changes to the resident or their legal representative.
- Then give the resident or their legal representative the latest version of the information sheet.
- Scheduling an additional appointment is only required if the resident or their legal representative would want more time to consider the new information.









Resident / Legal representative does not wish take part (i)

- If a resident / Legal representative decides that
 - they do not wish
 - to take part
 - during the consent appointment open their '**Trial Status**' form.

																																		•	
Resident ID	Resident Capacity Ti	Personal Legal Repr	NCTU Form • Paper	Consent Appointme	Consent Form Resic	Consent Form Resic	E Q5D5L Proxy	EQ5D5L	Consent Form Admi	Demographics	Care Home Eligibilit	Resident GP Details Change Resident Ca	Vaccination Status	GP Confirmation Of	NCTU form - SCR	Central PI Confirma	Randomisation Stat	Start of Treatment	Weekh Data	COMD-19, Hospital.	COVID-19 PCR Confi Readmission to Car	Serious Adverse Eve	Serious Adverse Eve	E O5D5L Proxv	EQ5D5L	Healthcare Support	60 Day Check	Trial Status							
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<u>P00003-002</u> M. M.				+				(
<u>P00003-004</u> J. J.				+		0	-																												
<u>P00003-005</u> A. L.				+				[-																										
<u>P00003-006</u> J. J.				+		(0		•	•	•			e	e												0							
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<u>P00003-031</u> T. T.				+					-																										





Resident / Legal representative does not wish take part (ii)

- Tick the box next to 'Resident is no longer interested'
- Mark Form Status as 'Complete'

Click

Save & Exit Form

📱 Trial Status











Countersigning e-consent

- Once a resident / PLR has submitted an e-consent form the regional team of RNs will receive an email notification.
- The RN who consented the resident/PLR will need to electronically countersign the consent form
- Click on the link provided in the email to be directed to the 'Consent Form **Resident With Capacity'** form
- Check the consent form and then click at the top of the page Edit response

Consent Form Resident With Capacity

Survey response is editable Edit response Response was completed on 17-06-2021 18:12. You have permission to edit this survey response from its original values. In order to begin editing the response, you must click the Edit Response button above. View all contributors to this response.

Resident ID P00003-031 – Consent T.T.

Resident ID

research nurse countersigns

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:	T Test
Participant Study ID	P00003-
Care Home Name: Castle Grov	e Nursing Hom



P00003-031

-031



Countersigning e-consent

- You can now add your countersignature at the bottom of the form.
- Make sure you **DO NOT** edit any responses provided by the resident /PLR.
- Mark Form Status as 'Complete'
- Click

Save & Exit Form

For Research Nurse Countersign	
Please click Edit response at the top of page before countersign.	
Name of person taking consent (You must be on the delegation log)	H P RN
Signature * must provide value	⊕ ≁ <u>Add signature</u>
Date * must provide value	H D-M-Y
Form Status	
Complete?	⊖ Complete ∨
	Save & Exit Form Save & Go To Next Form 🔹
	Cancel





Countersigning paper consent

- Paper consent forms will be posted to NCTU and uploaded to the database.
- Once uploaded the regional team of RNs will receive an email notification.
- The RN who consented the resident/PLR will need to electronically countersign the consent form
- Click on the link provided in the email to be directed to the 'Consent Form Resident With Capacity' form
- Check the consent form including making sure the information sheet version that is written on the scanned form matches what was entered on the database during the appointment



Please upload the completed consent

Date of the uploaded the par file

* must provide value

For Research Nurse Count

Name of person taking cons (You must be on the delegation

Signature

* must provide value

Date

* must provide value

Form Status

Complete?



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l participant paper informed	Dummy paper consent form.pdf (0.03 MB)
	Upload new version or III Remove file or Send-It
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ent log)	⊖ P RN
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	Н 17-06-2021 31 Тоday D-М-Ү
) Incomplete V
	Save & Exit Form Save & Go To Next Form 🔹
	Cancel



Countersigning paper consent

- Countersign the consent form at the bottom of the form
- Mark Form Status as 'Complete'
- Click

Save & Exit Form

For NCTU Upload Paper Co

Please upload the completed consent

Date of the uploaded the par file

* must provide value

For Research Nurse Count

Name of person taking conse (You must be on the delegation

Signature

* must provide value

Date

* must provide value

Form Status

Complete?





onsent	
l participant paper informed	Dummy paper consent form.pdf (0.03 MB)
	Upload new version or III Remove file or I Send-It
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) Incomplete V
	Save & Exit Form Save & Go To Next Form 🔹
	Cancel



Following Consent

- Following consent, care home staff will check the PLR consent and confirm the correct PLR has been consented.
- Following consent and the completion of the relevant questionnaires and forms on the trial database, the resident's GP will be carrying out the eligibility assessment.
- The outcome of this assessment will be communicated to Personal Legal Representatives (PLRs) of residents lacking capacity (to consent for themselves) by the trial team.
- For residents with capacity, care home staff will inform the residents of the GP of the outcome of the eligibility check.









If you have any questions, please do not hesitate to contact us:













