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PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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Consent & Enrolment Training Module

Final version 1.0 20-Aug-2021

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Purpose of Training

- To provide an overview of the consent process

- To provide information on who can give consent

To explain the consent process for residents with capacity

- To explain the consent process for residents without capacity

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Care Home staff

As a valued member of the care home team, we need your help to identify residents who may wish to be part of the trial.

Your relationship with the residents in your care home is very important to help us identify whether residents are able to decide to take part in the trial themselves or whether they will need someone to do this on their behalf.

Full consent to take part in the trial will be taken by a trained research nurse.

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The PROTECT-CH Research Nurse role:

In PROTECT-CH, the role of the research nurse (RN) can be undertaken by other suitably qualified Allied Healthcare Professionals (AHP) or research coordinator/practitioner.

Therefore, where the RN is mentioned in any trial material it should be understood that this also refers to AHPs and research practitioners/coordinators unless stated otherwise.

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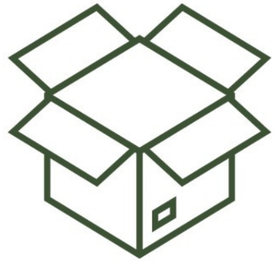
Starter Pack

- The trial team at the University of Nottingham will send a PROTECT-CH Care Home Pack to each participating care home.

- The PROTECT-CH Care Home Pack contains all documents and materials needed to set up the trial in your care home.



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Consent in Clinical Trials

Seeking consent is fundamental in any trial.

- It involves giving residents (or if they lack capacity their personal legal representatives (PLR):
  - Sufficient and clear information so they can make an informed choice about whether to take part and continue in the trial.
  - The opportunity to ask questions about any part of the trial
  - Time to consider whether the resident would like to take part in the trial

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Consent in Clinical Trials

Seeking consent is fundamental in any trial.

- It involves giving residents (or if they lack capacity their personal legal representatives (PLR):
  - Sufficient and clear information so they can make an informed choice about whether to take part and continue in the trial.
  - The opportunity to ask questions about any part of the trial
  - Time to consider whether the resident would like to take part in the trial
- It is important that the resident/PLR understands that participation is voluntary and that they have the right to withdraw from the trial at any time.
- It is legislated in UK law by the Medicines for Human Use (Clinical Trials Regulations) 2004.

Full consent must be taken by a trained research nurse

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Consent process

Consent is required:

- To join the trial.
- For the research team to contact resident's GP to confirm eligibility and request access to medical records.
- To join the part of the trial in which residents will be offered one of the trial medications or usual care, depending on the allocation of their care home.

Full consent must be taken by a trained research nurse

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This presentation will focus on…

The CONSENT & ENROLMENT Procedures

Who should be taking this training?

You are asked to complete this training because your role in the study is one of the following:

- Care home manager
- Care home research champion
- Care home staff responsible for facilitating the consent appointments

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Green Light

*The consent process should **not** begin until **after** your care home has received the "**Green Light**" approval email from the PROTECT-CH trial team at the University of Nottingham.*

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Consent material

The trial team will send you a PROTECT-CH Starter Pack that contains all relevant consent documents and materials needed for the consent process.

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Step 1:

Once your care home has received the "Green Light" email:

Care home staff should identify residents who are potentially eligible for the trial using the criteria below:

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Step 1:

Once your care home has received the "Green Light" email:

Care home staff should identify residents who are potentially eligible for the trial using the criteria below:

To be considered for the trial residents **must be**:

- ✓ Aged 65 or over

In addition, residents **cannot** be considered for the trial if any of the following apply:

- ✗ The resident is in the care home for short-term respite care
- ✗ The resident has been identified by care home staff to have entered end-stage palliative care
- ✗ The resident is in another COVID-19 prevention or treatment trial

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Step 2:

Approach residents/Personal Legal Representatives (PLRs)* to introduce the trial:

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Step 2:

Approach residents/Personal Legal Representatives (PLRs)* to introduce the trial:

- Give residents a **Participant Information Sheet**, access to a **video recording** about the trial, enough time to consider the information provided and an opportunity for discussion.

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Step 2:

Approach residents/Personal Legal Representatives (PLRs)* to introduce the trial:

- Give residents a **Participant Information Sheet**, access to a **video recording** about the trial, enough time to consider the information provided and an opportunity for discussion.

- For residents that lack capacity, care home staff should contact their PLR and ask if they would be interested in the trial.

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Step 2:

Approach residents/Personal Legal Representatives (PLRs)* to introduce the trial:

- Give residents a **Participant Information Sheet**, access to a **video recording** about the trial, enough time to consider the information provided and an opportunity for discussion.

- For residents that lack capacity, care home staff should contact their PLR and ask if they would be interested in the trial.

*A PLR is a family member or close friend who can give consent on the resident's behalf

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Step 2:

Approach residents/Personal Legal Representatives (PLRs)* to introduce the trial:

- Give residents a **Participant Information Sheet**, access to a **video recording** about the trial, enough time to consider the information provided and an opportunity for discussion.

- For residents that lack capacity, care home staff should contact their PLR and ask if they would be interested in the trial.

*A PLR is a family member or close friend who can give consent on the resident's behalf

More detailed information can be given, and questions answered by the research nurse at the time of consent if required.

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Step 3:

Once residents/ Personal Legal Representative (PLR)s have expressed interest in the trial:

The Research Champion or care home manager should obtain verbal permission from residents/PLRs to enter personal details (resident's name, date of birth, gender, PLR's contact details) into the trial database.

A research nurse will then arrange a "consent" appointment for any resident/PLR who wishes to know more about the trial.

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Step 4:

Virtual (or face-to-face if preferable/possible) appointments will be made for a trained research nurse to discuss the trial, answer any questions and consent residents/PLRs via a laptop or tablet.

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Step 4:

Virtual (or face-to-face if preferable/possible) appointments will be made for a trained research nurse to discuss the trial, answer any questions and consent residents/PLRs via a laptop or tablet.

Please remember that only a trained research nurse can take consent.

Assessing capacity

- The resident is deemed to have capacity, if they are able to **understand, retain** and **weigh** the information in order to make and communicate their **decision**.

(Mental Capacity Act, 2005)

- If the resident is deemed to lack capacity, their **Personal Legal Representative (PLR)** can give consent on their behalf.

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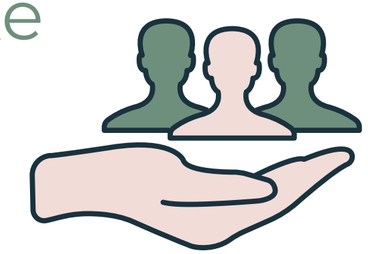
Who can give consent?

1. **The resident,**

if they **have capacity to give informed consent** to take part in the trial.
(We will discuss assessing capacity in a later slide)



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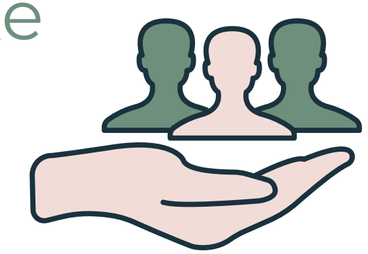
Who can give consent?

1. **The resident,**

if they **have capacity to give informed consent** to take part in the trial.
(We will discuss assessing capacity in a later slide)



✓ If the resident can listen and indicate their consent but is unable to physically sign, a care home staff member can witness their consent and sign on their behalf. It must be made clear that they are witnessing the resident's consent and **not giving consent themselves**.

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Who can give consent?

2. A Personal Legal Representative (PLR), if the resident lacks capacity.

PLR:

- ✓ Must not be connected to the trial.
- ✓ By virtue of their relationship with resident, they would know their wishes.
- ✓ Is able and willing to consent on behalf of the resident.
- ✓ Does not need to be next of kin.
- ✓ Does not need to have a Lasting Power of Attorney.
- ✓ Can be a family member or close friend.

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Who can give consent?

2. A Personal Legal Representative (PLR), (cont'd).

There needs to be <u>one</u> named PLR for the purposes of the PROTECT-CH trial.

If there is more than one, and they do not agree on participation, then the resident shouldn't take part in the trial.

If you are unsure, please ask a member of the PROTECT-CH trial team.

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Assessing capacity

How can capacity be assessed in this trial?

Where it is unclear if the resident has capacity, the following test can be used.

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Assessing capacity

How can capacity be assessed in this trial?

Where it is unclear if the resident has capacity, the following test can be used:

Read/show the resident this statement:

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Assessing capacity

How can capacity be assessed in this trial?

Where it is unclear if the resident has capacity, the following test can be used:

Read/show the resident this statement:

"The trial is trying to reduce COVID-19 with a medicine that reduces the chances of infection"

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Assessing capacity

- Ask the resident these three questions:

✓ What is the trial about?

✓ What is being tested?

✓ What does the trial hope to do?

The resident is <u>deemed to have capacity</u>
if they answer **all three** questions correctly.

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TAKING CONSENT FROM RESIDENTS WITH CAPACITY

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Taking consent from resident

Care home staff will:
- Obtain **verbal permission** from **the resident** to enter their personal details on to the **electronic database** (name, date of birth, gender)

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Taking consent from resident

Care home staff will:
- Obtain **verbal permission** from **the resident** to enter their personal details on to the **electronic database** (name, date of birth, gender)

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Taking consent from resident

Care home staff will:
- Obtain **verbal permission** from **the resident** to enter their personal details on to the **electronic database** (name, date of birth, gender)

This verbal permission is just to enter the above details in the database; and not to participate in the trial

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Taking consent from resident

Care home staff will:
- Obtain **verbal permission** from **the resident** to enter their personal details on to the **electronic database** (name, date of birth, gender)

This verbal permission is just to enter the above details in the database; and not to participate in the trial

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Taking consent from resident

Care home staff will:
- Obtain **verbal permission** from **the resident** to enter their personal details on to the **electronic database** (name, date of birth, gender)

Database will:
- Automatically generate the resident **a new ID number**

- Alert **research nurse** to contact the care home to arrange consent appointment

This verbal permission is just to enter the above details in the database; and not to participate in the trial

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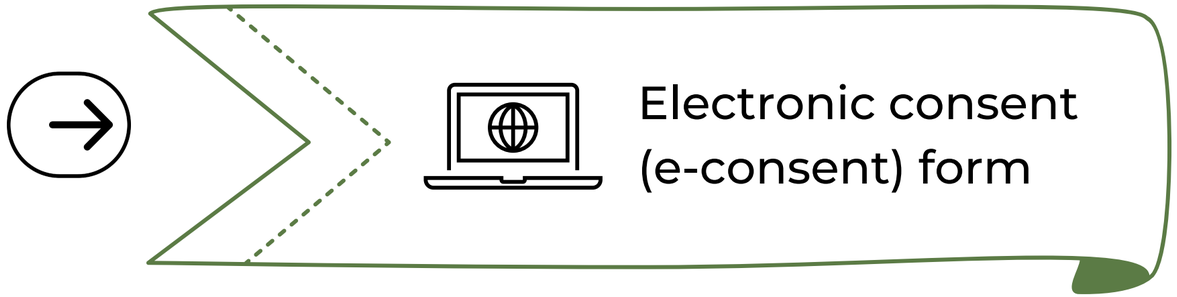
Taking consent from resident

A trained nurse will take consent from the **resident** who has capacity using:



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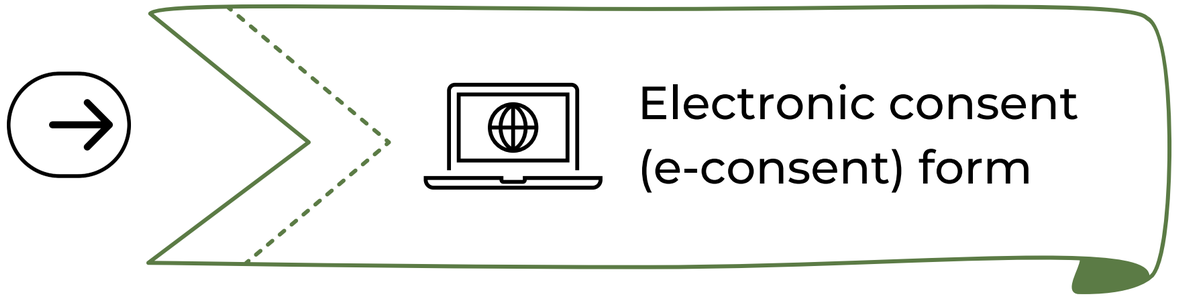
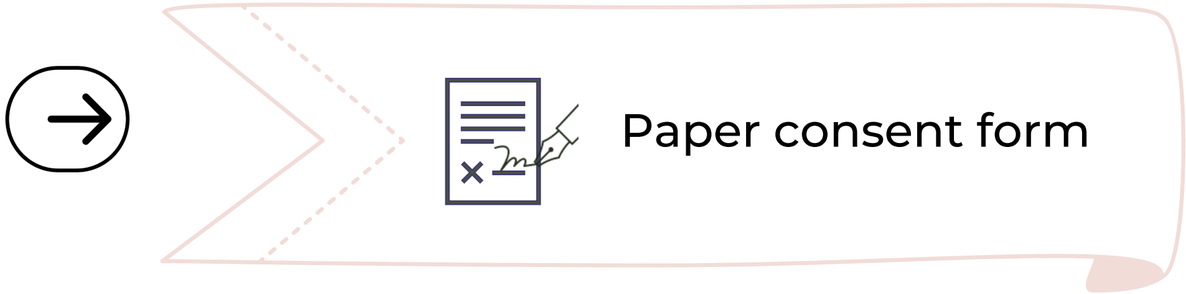
Taking consent from resident

A trained nurse will take consent from the **resident** who has capacity using:



In the unusual case the database is down or if there are any other issues with e-consent:



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Taking consent from resident

Electronic consent
(e-consent) form

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Taking consent from resident

Electronic consent
(e-consent) form

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Taking consent from resident

Electronic consent (e-consent) form

Trained research nurse will:

- Discuss the trial with the resident
- Ensure the resident has enough time to consider the information provided
- Answer all questions the resident has
- Check which version of the information sheet the resident has read
- Activate **e-consent form.**

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Taking consent from resident

Electronic consent (e-consent) form

Trained research nurse will:

- Discuss the trial with the resident
- Ensure the resident has enough time to consider the information provided
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- Check which version of the information sheet the resident has read
- Activate **e-consent form.**

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Taking consent from resident

Electronic consent (e-consent) form

Trained research nurse will:

- Discuss the trial with the resident
- Ensure the resident has enough time to consider the information provided
- Answer all questions the resident has
- Check which version of the information sheet the resident has read
- Activate **e-consent form.**

Resident or **a witness** (if resident unable to physically sign) will:

- Complete and sign the **e-consent form** on a tablet.

Trained research nurse will:

- Countersign **the e-consent form.**

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Taking consent from resident

Paper consent form

Only if completion of e-consent is not possible

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Taking consent from resident

Paper consent form

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Trained research nurse will:

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- Answer all questions the resident has
- Check which version of the information sheet the resident has read

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- Complete and sign **a paper consent form.**

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Taking consent from resident

Paper consent form

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Taking consent from resident

Paper consent form

Only if completion of e-consent is not possible

Trained research nurse will:

- Discuss the trial with the resident.
- Ensure the resident has enough time to consider the information provided
- Answer all questions the resident has
- Check which version of the information sheet the resident has read

Resident or **a witness** (if resident unable to physically sign) will:

- Complete and sign **a paper consent form.**

Care home staff will:

- Enter the **identifiers** onto the **paper form.**
- Post it to the trial team using the pre-paid envelope.
- Send it to **the trial team.**

Trial team will:

- Upload the form to **the database**.

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Taking consent from resident

Paper consent form

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Taking consent from resident

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- Send it to **the trial team.**

Trial team will:

- Upload the form to **the database**.

Trained research nurse will:
Countersign **the uploaded consent form.**

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COLLECTING CONSENT FROM RESIDENTS WITHOUT CAPACITY VIA PERSONAL LEGAL REPRESENTATIVE (PLR)

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Taking consent from PLR

Care home staff will:

- Obtain **Personal Legal Representative (PLR)** permission to enter details to the electronic database.
- Resident's personal details (name, date of birth, gender).
- PLR's name, email or postal address.
- PLR's availability for contact.

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Taking consent from PLR

Care home staff will:

- Obtain **Personal Legal Representative (PLR)** permission to enter details to the electronic database.
- Resident's personal details (name, date of birth, gender).
- PLR's name, email or postal address.
- PLR's availability for contact.

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Taking consent from PLR

Care home staff will:

- Obtain **Personal Legal Representative (PLR)** permission to enter details to the electronic database.
- Resident's personal details (name, date of birth, gender).
- PLR's name, email or postal address.
- PLR's availability for contact.

Database will:
- Generate **a new ID number**

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Taking consent from PLR

Care home staff will:

- Obtain **Personal Legal Representative (PLR)** permission to enter details to the electronic database.
- Resident's personal details (name, date of birth, gender).
- PLR's name, email or postal address.
- PLR's availability for contact.

Database will:
- Generate **a new ID number**

If **PLR** has an email address, they will be contacted via **email by the trial team**

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Taking consent from PLR

Care home staff will:

- Obtain **Personal Legal Representative (PLR)** permission to enter details to the electronic database.
- Resident's personal details (name, date of birth, gender).
- PLR's name, email or postal address.
- PLR's availability for contact.

Database will:
- Generate **a new ID number**

If **PLR** has an email address, they will be contacted via **email by the trial team**

If **PLR** does <u>NOT</u> have an email address, they will be contacted via **post by the trial team**

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Taking consent from PLR

If PLR has an email address:

The database will automatically email the **PLR a link to the information sheet.**

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Taking consent from PLR

If PLR <u>has</u> an email address:

The database will automatically email the **PLR a link to the information sheet.**

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Taking consent from PLR

If PLR <u>has</u> an email address:

The database will automatically email the **PLR a link to the information sheet.**

Trained research nurse will:

- Contact the **PLR** to arrange a video call.

- During the video call:

- Discuss the trial with the **PLR and ensure they are happy to proceed**.

- Activate **e-consent form for the PLR**.

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Taking consent from PLR

If PLR <u>has</u> an email address:

The database will automatically email the **PLR a link to the information sheet.**

Trained research nurse will:

- Contact the **PLR** to arrange a video call.

- During the video call:

- Discuss the trial with the **PLR and ensure they are happy to proceed**.

- Activate **e-consent form for the PLR**.

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Taking consent from PLR

If PLR <u>has</u> an email address:

The database will automatically email the **PLR a link to the information sheet.**

Trained research nurse will:

- Contact the **PLR** to arrange a video call.

- During the video call:

- Discuss the trial with the **PLR and ensure they are happy to proceed**.

- Activate **e-consent form for the PLR**.

PLR will:

- Complete and sign the **e-consent form** online and submit electronically.

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Taking consent from PLR

If PLR <u>has</u> an email address:

The database will automatically email the **PLR a link to the information sheet.**

Trained research nurse will:

- Contact the **PLR** to arrange a video call.

- During the video call:

- Discuss the trial with the **PLR and ensure they are happy to proceed**.

- Activate **e-consent form for the PLR**.

PLR will:

- Complete and sign the **e-consent form** online and submit electronically.

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Taking consent from PLR

If PLR <u>has</u> an email address:

The database will automatically email the **PLR a link to the information sheet.**

Trained research nurse will:

- Contact the **PLR** to arrange a video call.

- During the video call:

- Discuss the trial with the **PLR and ensure they are happy to proceed**.

- Activate **e-consent form for the PLR**.

PLR will:

- Complete and sign the **e-consent form** online and submit electronically.

Trained research nurse will:

- Check the **e-consent form.**

- Countersign **the e-consent form.**

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Taking consent from PLR

If PLR does NOT have an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

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Taking consent from PLR

If PLR does NOT have an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

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Taking consent from PLR

If PLR does NOT have an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:

  - Discuss the trial with the **PLR**.

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Taking consent from PLR

If PLR <u>does NOT have</u> an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:

  - Discuss the trial with the **PLR**.

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Taking consent from PLR

If PLR <u>does NOT have</u> an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:

  - Discuss the trial with the **PLR**.

PLR will:
- Complete and sign the **paper form** manually and send it to **the trial team** in the post.

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Taking consent from PLR

If PLR <u>does NOT have</u> an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:

  - Discuss the trial with the **PLR**.

PLR will:
- Complete and sign the **paper form** manually and send it to **the trial team** in the post.

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Taking consent from PLR

If PLR <u>does NOT have</u> an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:

  - Discuss the trial with the **PLR**.

PLR will:
- Complete and sign the **paper form** manually and send it to **the trial team** in the post.

Trial team will:
Scan and upload the **form** to **the database**.

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Taking consent from PLR

If PLR <u>does NOT have</u> an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:

  - Discuss the trial with the **PLR**.

PLR will:
- Complete and sign the **paper form** manually and send it to **the trial team** in the post.

Trial team will:
Scan and upload the **form** to **the database**.

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Taking consent from PLR

If PLR does NOT have an email address:

Trial Team will post a paper consent form and information sheet to the PLR.

Trained research nurse will:

- Contact the **PLR** to arrange a video/phone call.

- During the call:
  - Discuss the trial with the **PLR**.

PLR will:
- Complete and sign the **paper form** manually and send it to **the trial team** in the post.

Trial team will:
Scan and upload the **form** to **the database**.

Trained research nurse will:

- Check the **form.**

- Countersign **the form.**

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Final steps

- Consent forms will be available for the care home staff to view in the database.
- Once the research nurse has countersigned the consent form, care home staff should check that the correct PLR has been consented.
- They should also print two copies of the form:
  - One for the resident if they have capacity (PLRs will be emailed a copy/keep a signed paper copy).
  - One for the resident's record at the care home.

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CHANGE OF PLR OR CAPACITY DURING PARTICIPATION

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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.

- Once a new PLR is identified verbal permission will need to be obtained to record their personal data, but they will not need to complete another consent form.

- Change of PLR should be documented in the trial database.

<u>Care Home Staff:</u>

To record changes of PLR, please login to the trial database and complete the Change Resident Capacity or PLR form.

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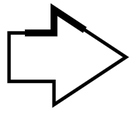

Please refer to the 'Data Entry' Training Module for more details on how to complete the form

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Loss of capacity after consent

- Assessment of capacity should be ongoing throughout the trial.
- If a resident who initially had capacity loses it after they have given their consent, care home staff will be required to record this in the trial database.
- A 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.
- Verbal permission will need to be obtained from the PLR to record their personal data.

Care Home Staff:

- To document loss of capacity after consent has been provided, please login to the trial database and complete the *Change Resident Capacity or PLR form.*

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Care Home Staff:

- To document loss of capacity after consent has been provided, please login to the trial database and complete the *Change Resident Capacity or PLR form.*

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Re-gaining capacity after PLR consent

If a resident re-gains capacity after their PLR has given consent on their behalf, consent will need to be obtained from the resident themselves.

Please contact the PROTECT-CH trial team:

Protect-trial@nottingham.ac.uk

0115 74 87710

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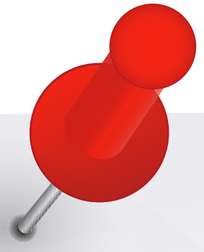
What happens after consent is completed?



To find out more about data collection and what to do after consent is taken, please complete the 'Trial Assessments & Follow-up' training module.

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In this module, we have covered the following:

- Capacity Assessment
- Consent Process for resident with capacity
- Consent Process for resident without capacity (via PLR)
- Consent captured online
- Consent captured on paper
- Change of PLR
- Change in Capacity

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Thank you for watching!

You have now completed the
Consent and Enrolment
Training Module.

NEXT

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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=4&ModuleVersion=1

Or you can access it via mobile here:

University of Nottingham
UK | CHINA | MALAYSIA

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Any questions?

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

protect-trial@nottingham.ac.uk

0115 74 87710

Thank you