PROTECT-CH
Prophylactic Therapy in Care Homes Trial

Consent Guidance Booklet

This booklet will give you information on **how to assess resident capacity** to consent to take part in the trial in principle and **how to take consent** from those with capacity and from those who lack capacity to consent.

The trial team at the University of Nottingham are available to assist with taking consent and any other questions you may have.

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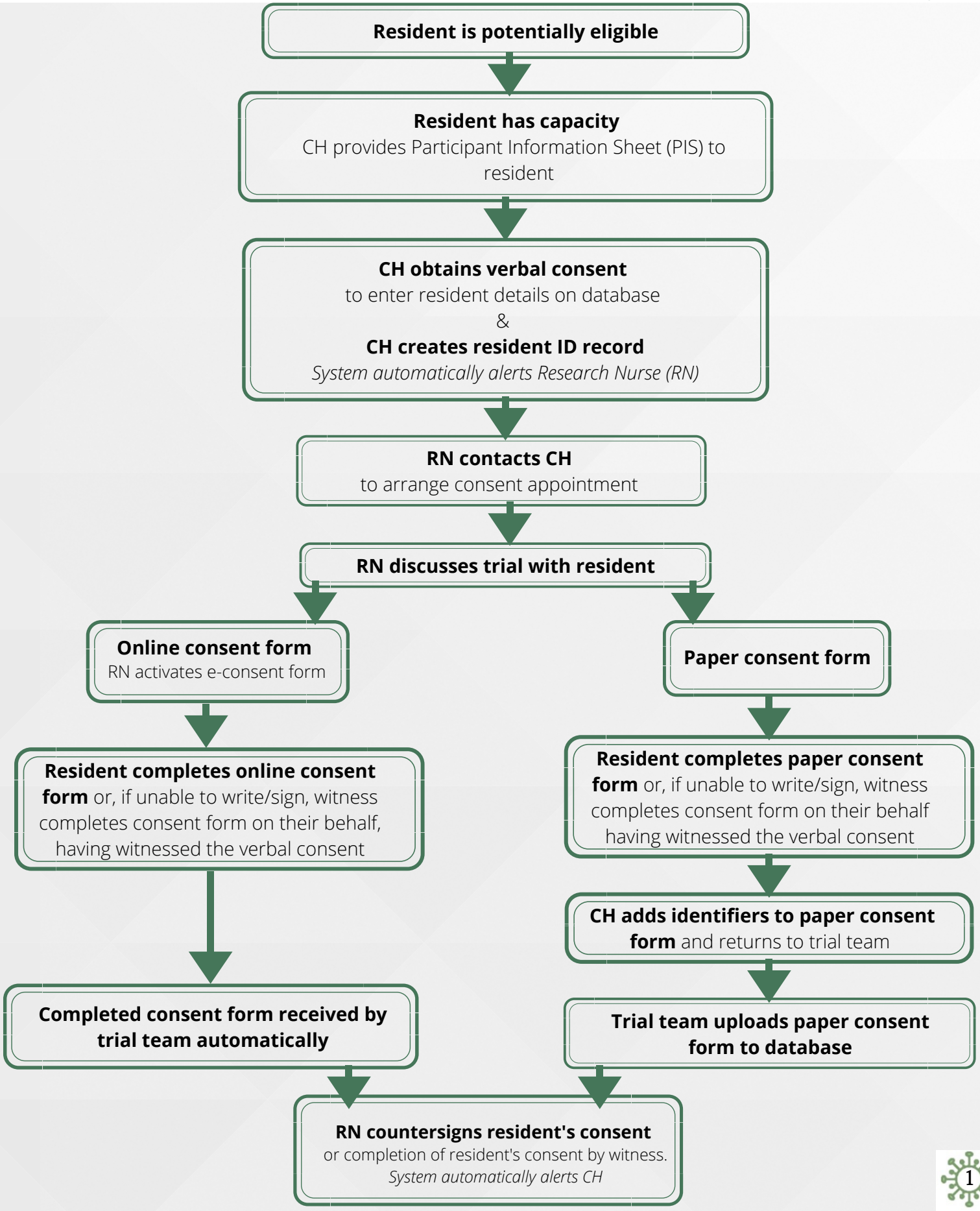
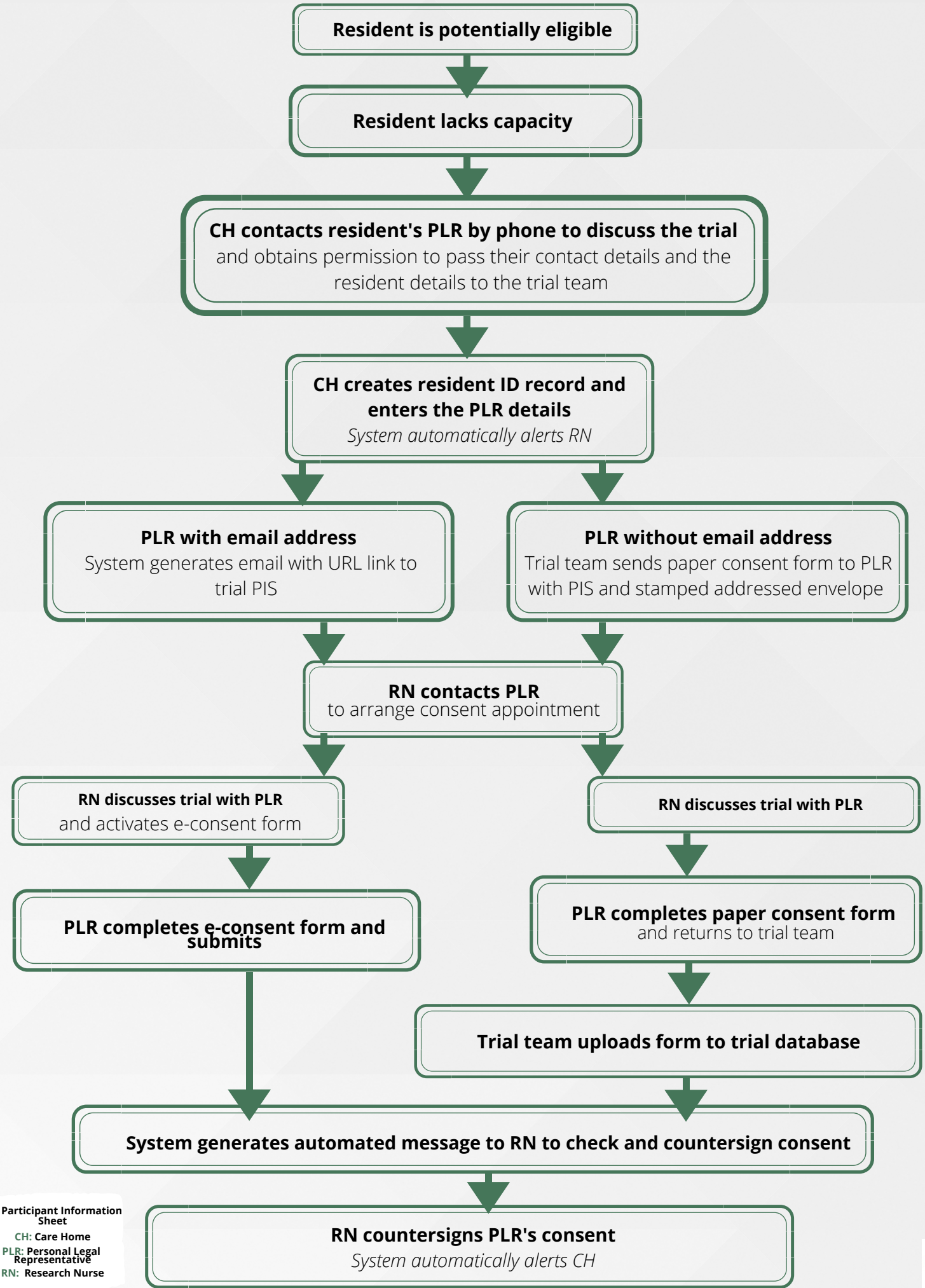
Phone: 0115 74 87710

**Care Home (CH) ready to begin approaching residents following "Green Light".
CH to first check that residents are potentially eligible
and assess resident capacity.**

Consent Flowchart: Resident with capacity



Consent Flowchart: Resident without capacity



PIS: Participant Information Sheet
CH: Care Home
PLR: Personal Legal Representative
RN: Research Nurse

How to identify potentially eligible residents?

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

Who can take consent?

Consent can only be taken by a trained **research nurse** or suitably qualified **Allied Health Professional (AHP)**.

They will be automatically alerted once a resident's record has been created and will be in contact with the care home staff or the PLR to arrange the consent appointment.

How to assess a resident's capacity

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

Read/show the resident this statement:

*"The study is trying to **reduce Covid-19** with a **medicine** that **reduces the chances of infection**"*

Residents are deemed to have capacity to consent if they answer the following 3 questions correctly:

- What is the trial about?
- What is being tested?
- What does the trial hope to do?

Residents who have capacity

Trial information

Care home staff provide the resident with the participant information sheet (PIS), a video, enough time to consider the information provided and an opportunity for discussion. A research nurse will arrange (virtual) appointments with care home staff for residents who wish to take part in the trial. The research nurse will discuss the trial with the resident and allow time for them to ask questions and consider if they would like to take part.

For those residents who are able to write and sign

e-consent

- Research nurse activates the consent form.
- Resident completes consent form on a tablet.
- Research nurse taking consent countersigns the consent form electronically.

Paper consent (if online completion is not an option)

- Resident completes paper consent form.
- Care home staff add unique identifiers (generated by trial database) to the paper consent form before returning to the trial team.
- The trial team uploads the consent form to the trial database.
- Research nurse taking consent countersigns the consent form electronically.

For those residents who are unable to write and sign

A person not involved in the trial witnesses the resident's permission to be involved in the trial.

e-consent

- Research nurse activates the consent form.
- Witness completes consent form on resident's behalf on a tablet.
- Research nurse taking consent countersigns the consent form electronically.

Paper consent (if online completion is not an option)

- Witness completes paper consent form.
- Care home staff add unique identifiers to the paper consent form before returning to the trial team.
- The trial team uploads the consent form to the database.
- Research nurse taking consent countersigns the consent form electronically.

Consent form copies

Please provide a copy of the consent form to the resident and remember to keep a copy in the care home notes.

Residents who lack capacity

Contact resident's PLR by phone

- Care home staff contact the resident's PLR by phone and ask if they would be interested in the trial.
- Obtain permission to pass on the PLR contact details to the trial team (preferably email address but postal address is also OK) and PLR's availability for contact.

- Obtain permission to collect the resident's details (name, date of birth, care home details).
- Create the resident's record in the database.

PLR e-consent

- The resident's PLR will receive the URL link to the participant information sheet via email.
- A research nurse will arrange a virtual appointment with the PLR.
- The research nurse will discuss the trial and allow time for the PLR to ask questions and consider if they would like the resident to take part.

- The PLR will be emailed with link to e-consent form.
- The PLR completes e-consent form and submits.
- The research nurse countersigns the consent form electronically.

PLR paper consent

- Trial team sends the resident's PLR trial information, the paper consent form and a return stamped addressed envelope in the post.
- A research nurse will arrange a video/ phone appointment with the PLR.
- The research nurse will discuss the trial and allow time for the PLR to ask questions and consider if they would like the resident to take part.

- PLR completes the consent form and posts back to the trial team.
- Trial team uploads a scanned copy of the form to the database.
- Research nurse countersigns the consent form electronically.

Consent form copies

Please remember to keep a copy of the consent form in the care home notes once available.

What happens next?

A message is automatically triggered to the resident's GP informing them that their patient has consented to the trial, providing them with a copy of the consent form and asking them to complete an eligibility checklist and upload a summary of their medical record to the database.

Care home staff, residents and PLRs will be informed of the outcome of the eligibility assessment.

Remember

A copy of the consent form should be provided to the resident and a copy kept in the care home notes.

Any questions?

www.protect-trial.net

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