PROTECT-CH

Prophylactic Therapy in Care Homes Trial

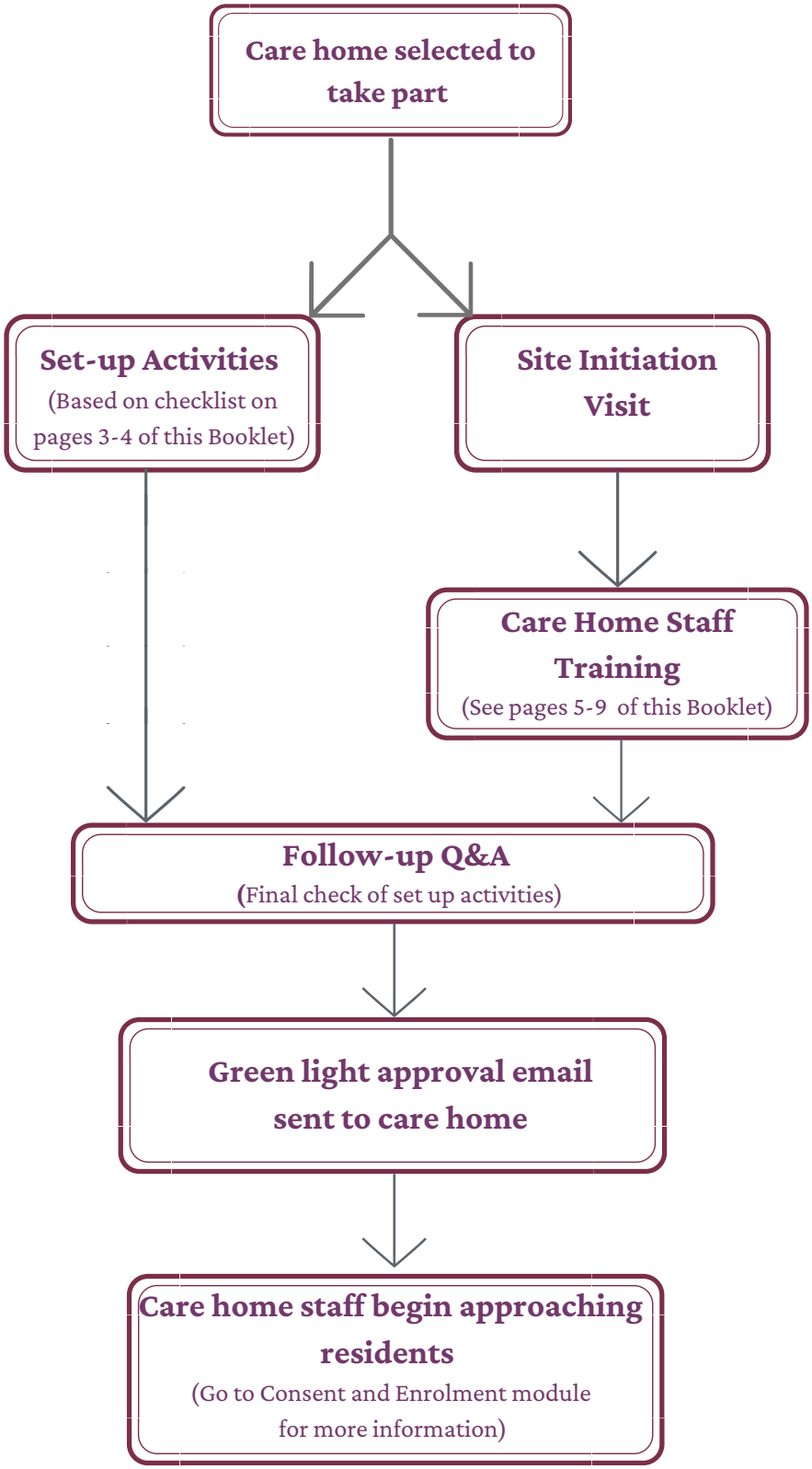
Care Home Set-up Guidance Booklet

This booklet will give you detailed information on how to set up your care home, what to expect during set up and where to find any further useful information in relation to set-up.

The trial team are available to help assist with set up and answer any questions you might have.

Email: protect-trial@nottingham.ac.uk
Phone: 0115 74 87710

Set-up Flowchart



Do not begin approaching residents until your care home has received a "Green Light" approval email from the trial team.

All required documents and FAQs are available on the trial website (www.protect-trial.net)

Set-up Checklist

Please feel free to use the checklist below as a tool to assist you with activities which require completing before you can begin approaching residents about participating in the trial.

Things to do:

Tick when complete

-  Ensure **written approval** from Head Quarters in place ☐
-  Identify correct person to **sign** the trial contract on behalf of your care home ☐

  This might be the care home owner and/ or the care home manager
-  Check that **contract** has been fully signed by your care home and the University of Nottingham ☐
- 

Check your **insurance** covers participation in trial ☐

  If it doesn't, please let us know!
-  Identify a member of staff at your care home to act as **research champion** ☐
-  Provide contact details of all **GPs** associated with residents at your care home ☐
-  Confirm your care home has the **space to store** trial medication and equipment ☐
-  Check care home has access to a **printer, computer and electronic tablet** that you can use during trial ☐
-  Confirm if you require any documents **translating** (and which language) ☐
-  Book a **Site Initiation Visit** online. (Attendance required for care home manager and research champion or second staff member - if same person) ☐
-  Two staff members who attended the SIV and a third staff member to **complete all training modules*** and **associated self-certification forms** ☐

**Completing the Close-out and Archiving Training Module before Green Light is not required.*

Set Up Checklist (Cont'd)

Things to do:

Tick when complete

Care home manager to **sign delegation log** and be signed off by the Principal Investigator (PI) ☐

Trained staff members to be **delegated their duties on the trial** by the care home manager ☐

Check that the **care home site file** and **pack** have arrived at care home ☐

Complete **source data location** log ☐

Trial database (REDCap) login received (at least by one trained staff member) ☐

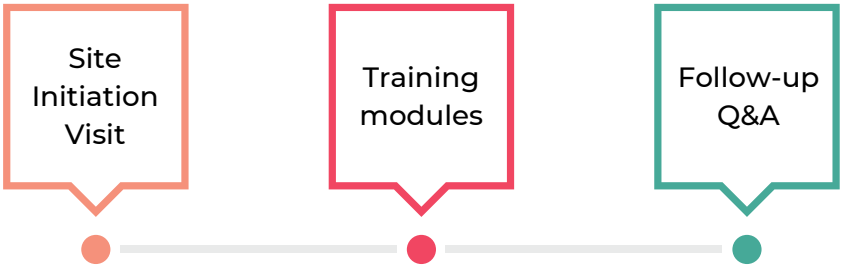
PROTECT-CH Documents Vault login received (at least by one trained staff member) ☐

Follow-up Q&A online meeting has been attended (at least by one trained staff member) ☐

Fully signed **Green light approval email** received from the University of Nottingham ☐

Training Information Sheet

The PROTECT-CH Training consists of 3 steps:



1 Site Initiation Visit (SIV)

- Care home manager and research champion or second staff member (if manager and champion are the same person) will be **required** to attend the SIV. More care home staff members may attend should they wish to.
  Staff members may attend SIVs on different dates if they are not available at the same time.

The SIV:
1) will take place online over Teams or Zoom,
2) will last up to one hour and,
3) comprises a) an up to 30 mins presentation with voiceover by the lead researchers in the trial and b) a brief Q&A (up to 30 mins) focusing on general questions you may have on the trial.

At the end of the SIV, each attendee should complete a self-certification form - the link will be provided at the end of the SIV presentation.

1

Site Initiation Visit (SIV) (Cont'd)

Following the SIV meeting, the trial team will email you the link to the SIV presentation so you can easily consult the material again at any time in the future and share with other staff members.

Additionally, the team will provide further information on the next steps you need to take to complete your training, deadline for completion of training and link to book your Follow-up Q&A.

2

Training Modules

- Once the two key staff members mentioned above have attended a SIV, care home staff may start completing their training modules and the self-certification form at the end of each module to confirm completion.

Please do not complete any training (apart from this Care Home Set-up guidance) before you have attended your SIV and self-certified to confirm attendance.

- Training can be undertaken by an individual or in a group setting (coordinated by the research champion/ care home manager). If in group setting, all attendees should self-certify individually at the end of each module.

- The training modules are split in two types: a) mandatory and b) role-dependent.

- The two key staff members who attended the SIV (**care home manager and care home research champion o**r second individual if manager and champion are the same person) **and one more nominated care home staff member** should complete **all training modules** (mandatory & role-dependent) except for "close-out & archiving", prior to Green Light.

- All other staff members will need to complete all the mandatory training modules **and** any role-dependent training modules (see relevant tables on page 7) depending on the duties they will be undertaking as part of the trial at the care home.

2

Training Modules (Cont'd)

Mandatory Training

- **Background to trial**
- **Trial Specific Good Clinical Practice (GCP)**
- **Data Protection**
- **Safety**
- **COVID-19 Outbreak Guidance**

- All training modules (mandatory and role-dependent) will be available on the PROTECT-CH website (www.protect-trial.net).
- The mandatory training modules can be found on the trial website under the **'Getting started'** section (Background to trial, Trial Specific GCP and Data Protection), the **'Trial medications'** section (COVID-19 Outbreak Guidance) and the **'Safety reporting'** section (Safety).

Role-Dependent Training

- **Consent and Enrolment**
- **Data Entry**
- **Therapy (Information on each specific trial medication)**
- **Trial Assessments and Follow-up**
- **Close out & Archiving**

- All training slides and booklets will be available on the trial website for download at any point in the trial .
- The role-dependent training modules can be found on the trial website under the **'Enrolling residents'** section (Consent and Enrolment), the **'Trial medications'** section (Therapy (individual modules) and the **'Collecting trial data'** section (Data Entry, Trial assessments and follow-up).

Please note:

- Individuals can undertake more than one role on the trial but **training must be completed on the specific topic before undertaking the activity**.
- For those giving trial medication, this role should only be performed by those who have completed the Therapy training **AND** be usually involved in giving medication to residents.
- **All** individuals involved in trial at care home are responsible for reporting any safety events to the appropriately trained individual or on the trial database (if trained themselves).
- Completing the **self-certification form** at the end of each module is **critical** as this is how the trial team, your care home manager, PI etc. can verify that you have been trained to undertake your role in the trial.

3

Follow-up Q&A

- Follow-up Q&As are an opportunity for you to ask any questions you may have on specific processes, following the completion of all training modules by (at least) the three key staff members mentioned on page 6 of this booklet).

- Once you have completed your SIV, the trial team will email you the link to book the Follow-up Q&A session you will be attending. You should pick a session approximately **two weeks** from the date of your SIV.

- The two attendees of the SIV and the third trained staff member should have completed all the training modules (except for Close out and Archiving) within this two week-period and prior to any care home staff member attending the Follow-up Q&A.

- One or more care home staff may attend the Q&A session.

- The sessions will be led by the PIs and multiple care homes may attend. Where possible, care home staff should attend the session led by their local PI.

- A member of the trial management team will be present to assist with any queries you may have.

- Frequently asked questions and answers from these sessions will appear in the relevant section (FAQ) of the trial website which you can access at any point.

Final steps

- Other key trial team members, your PI and at least one GP (if your residents are registered to more than one GP practice), should be trained prior to your Green Light. The trial team will ensure training of all trial team members has been completed as needed prior to your Green Light.

Final steps (Cont'd)

- The care home manager and research champion should be monitoring that all staff who will be involved in the trial have undertaken the appropriate training for their role and have completed the delegation log as needed.

- Once three key members of staff (the two SIV attendees; care home manager and research champion or second staff member, and a third staff member) have completed their training modules, self-certification forms, the delegation log and all other activities listed on pages 3-4 have been completed, the University of Nottingham will give you the Green Light to approach residents about the trial.

- It is important that the **delegation log is up-to-date throughout the trial** so it accurately reflects the trained staff members working on the trial at any point.

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

protect-trial@nottingham.ac.uk

0115 7487710