## **Personal Legal Representative Email communication**

Email	Sent	Content
Email 1	and PLR details entered on REDCap	Email contains initial trial information including PLR Information sheet link, website and process for RN videocall
Email 2	After RN consent videocall	Email contains link to PLR Informed Consent Form to sign
Email 3	After GP performed initial eligibility check	GP Eligibility outcome and next steps
Email 4	Immediately Post outbreak at CH	Notification that CH ready to start trial and option to opt out link
Email 5	Post PI eligibility check	PI Eligibility outcome, CH randomisation confirmation
Email 6	PLR is identified, or if an existing	Email confirms resident participation in trial and contains trial information including PLR information sheet link and website, and contact details for research team.

# PROTECT-CH Legal Representative Email 1

Subject: PROTECT-CH COVID-19 prophylaxis trial information

Dear [Insert Legal Representative first name]

Thank you for your interest in finding out more about the PROTECT-CH trial. We are contacting you about the possible participation of [insert first name of resident] as you are their named Legal Representative for decisions about their care. You have recently been contacted by their care home to let you know that the care home is taking part in the PROTECT-CH trial and were interested in learning more about the trial.

A member of the research team/nurse will shortly be contacting you to arrange a call at your convenience, to talk to you in more detail about the PROTECT-CH trial, answer any questions that you may have, and explain the next steps. In the meantime, please do take a few moments to read the information on the trial which explains what participation means for you and [insert first name of resident].

Please find below a link to the Information Sheet which will tell you everything you need to know about taking part in the trial:

## [Insert web address for PROTECT-CH Legal Representative Information Sheet]

You can find more information about the PROTECT-CH trial on the trial website using the link below:

#### [Insert web address for PROTECT-CH website]

If you are not interested in your the person you are representing taking part in the trial and do not wish to receive any further communication please email: <a href="mailto:protect-trial@nottingham.ac.uk">protect-trial@nottingham.ac.uk</a> or telephone: 0115 748 7710

If you have any further questions, please contact the trial research team (contact details below) who will be more than happy to help.

Kind regards

PROTECT-CH trial research team

Telephone: [insert phone number for queries]
Email: protect-trial@nottingham.ac.uk
Website: http://www.protect-trial.net

Subject: PROTECT-CH trial – consent link

PROTECT-CH Legal Representative Email 2

Dear [Insert Legal Representative first name]

Thank you for your continued interest in the participation of [enter first name of resident] in the PROTECT-CH trial.

Further to your recent discussion with a member of the research team/nurse we hope that you now understand what taking part in the trial involves and have had your questions answered.

# What do I need to do next?

If after reading the information and speaking to a member of the research team/nurse, you decide that [enter first name of resident] would have no objection to taking part in the trial and taking the trial medication, please read, sign and submit the Informed Consent Form using the link below:

## [Insert link for PROTECT-CH Legal Representative Informed Consent Form]

Please complete the Informed Consent Form as soon as possible. If, however, you do not wish for [enter first name of resident] to take part in the trial and/or take the trial medication please email: <a href="mailto:protect-trial@nottingham.ac.uk">protect-trial@nottingham.ac.uk</a> or telephone: 0115 748 7710

# **Further information**

You can find more information about the PROTECT-CH trial on the trial website using the link below:

[Insert web address for PROTECT-CH website]

If you have any further questions, please contact the trial research team (contact details below) who will be more than happy to help.

Kind regards

PROTECT-CH trial research team

Telephone: [insert phone number for queries]

Email: protect-trial@nottingham.ac.uk Website: http://www.protect-trial.net

## PROTECT-CH Legal Representative Email 3

Subject: PROTECT-CH trial – Participation Update

Dear [Insert Legal Representative first name]

Thank you for your continued interest in the participation of the person you are representing in the PROTECT-CH trial.

## If Eligible

The GP of [enter first name of resident] has checked their medical records and we can confirm they are able to continue in the trial. We will contact you again when [Enter first name of resident]'s care home is ready to start the trial and remind you of the next steps. At this point a trial doctor will review the medical records again to ensure [enter first name of resident] is still able to continue in the trial.

#### <u>Or</u>

#### *If Not Eligible*

The GP of [enter first name of resident] has checked their medical records and unfortunately, they are not able to continue in the trial at this point. This is because [enter first name of resident] meets one or more of the exclusion criteria for the trial, which is used to ensure the safety of all participants.

If you would like to read the information about the trial and trial medication again, you can find it at the link below:

[Insert web address for PROTECT-CH Legal Representative Information Sheet]

You can find more information about the PROTECT-CH trial on the trial website using the link below:

## [Insert web address for PROTECT-CH website]

If you have any further questions, please contact the trial research team (contact details below) who will be more than happy to help.

Kind regards

PROTECT-CH trial research team

Telephone: [insert phone number for queries]

Email: protect-trial@nottingham.ac.uk
Website: http://www.protect-trial.net

PROTECT-CH Legal Representative Email 4

Subject: PROTECT-CH trial – update information

Dear [Insert Legal Representative first name]

Thank you for your continued interest in the participation of [enter first name of resident] in the PROTECT-CH trial. Their care home is now ready to start the PROTECT-CH trial. A trial doctor will review [enter first name of resident]'s medical records to ensure they are able to continue in the trial, and if the care home is allocated to deliver a trial medication, [enter first name of resident] will start taking this in the next few days.

If you would like to read the information about the trial and trial medication again, you can find it at the link below:

[Insert web address for PROTECT-CH Legal Representative Information Sheet]

If you are satisfied that [enter first name of resident] would continue to have no objection to taking part in the trial, you do not need to do anything else.

If, however, you do not wish for [enter first name of resident] to take part in the trial please let us know as soon as possible using the contact details below:

You can find more information about the PROTECT-CH trial on the trial website using the link below:

## [Insert web address for PROTECT-CH website]

If you have any further questions, please contact the trial research team (contact details below) who will be more than happy to help.

Kind regards

PROTECT-CH trial research team

Telephone: [insert phone number for queries]

Email: <a href="mailto:protect-trial@nottingham.ac.uk">protect-trial@nottingham.ac.uk</a>
Website: <a href="mailto:http://www.protect-trial.net">http://www.protect-trial.net</a>

# PROTECT-CH Legal Representative Eligibility and Trial Medication Email 5

Subject: PROTECT-CH trial – Participation Update and Trial Medication Information

Dear [Insert Legal Representative first name]

Thank you for your continued interest in the participation of [enter first name of resident] in the PROTECT-CH trial.

# If Eligible

The PROTECT-CH trial doctors have checked the medical records of [enter first name of resident] and we can now confirm they are able to continue in the trial.

#### Or

#### If not Eligible

The PROTECT-CH trial doctors have checked the medical records of [enter first name of resident] and unfortunately, they are not able to take the trial medication at this point. This is because [enter first name of resident] meets one or more of the exclusion criteria for the trial, which is used to ensure the safety of all participants. Their care will continue as normal and we will continue to collect information about their health.

#### If eligible:

CH randomised to UC plus trial medication

[Enter first name of resident]'s care home has been allocated to deliver usual care plus the trial medication [Ciclesonide/Niclosamide].

#### Or

CH randomised to UC alone

[Enter first name of resident]'s care home has been allocated to deliver usual care alone.

If you would like to read the information about the trial and trial medication again, you can find it at the link below:

[Insert web address for PROTECT-CH Legal Representative Information Sheet]

You can find more information about the PROTECT-CH trial on the trial website using the link below:

#### [Insert web address for PROTECT-CH website]

If you have any further questions, please contact the trial research team (contact details below) who will be more than happy to help.

Kind regards

PROTECT-CH trial research team

Telephone: [insert phone number for queries]

Email: <a href="mailto:protect-trial@nottingham.ac.uk">protect-trial@nottingham.ac.uk</a>
Website: <a href="mailto:http://www.protect-trial.net">http://www.protect-trial.net</a>

PROTECT-CH Legal Representative Info Email 6

Subject: PROTECT-CH COVID-19 prophylaxis trial information

Dear [Insert Legal Representative first name]

Thank you for your interest in the continuing participation of [insert first name of resident] in the PROTECT-CH trial. We are contacting you as you have been identified as their named Legal Representative for decisions about their care. We would like to confirm that consent has already

been obtained for [insert first name of resident] to take part in the trial and that their participation is ongoing.

Please find below a link to the Information Sheet which will tell you everything you need to know about taking part in the trial:

# [Insert web address for PROTECT-CH Legal Representative Information Sheet]

Please do take a few moments to read the information on the trial which explains what participation means for you and [insert first name of resident].

You can also find more information about the PROTECT-CH trial on the trial website using the link below:

# [Insert web address for PROTECT-CH website]

If you have any further questions about taking part in the trial, please contact the trial research team (contact details below) who will be more than happy to help.

Kind regards

PROTECT-CH trial research team

Telephone: [insert phone number for queries]

Email: <a href="mailto:protect-trial@nottingham.ac.uk">protect-trial@nottingham.ac.uk</a>
Website: <a href="mailto:http://www.protect-trial.net">http://www.protect-trial.net</a>