



PROTECT-CH

Prophylactic Therapy in Care Homes Trial

Data Protection Training Module

Purpose of Training

In this module, you will learn the following:

- what data protection means and why it is important,
- what personal data and what research data are,
- the data we are collecting as part of the trial,
- the University of Nottingham's responsibilities, as the trial sponsor, in relation to data protection,
- who will have access to the data,
- where data will be stored throughout the trial and what the storage requirements are at the end of the trial

What does Data Protection mean?



By law,
the University of Nottingham (UoN) PROTECT-CH
trial team
must tell trial participants/personal legal
representatives (for residents lacking capacity to
consent for themselves)
what they are going to do with
the participant's (resident's) personal data.

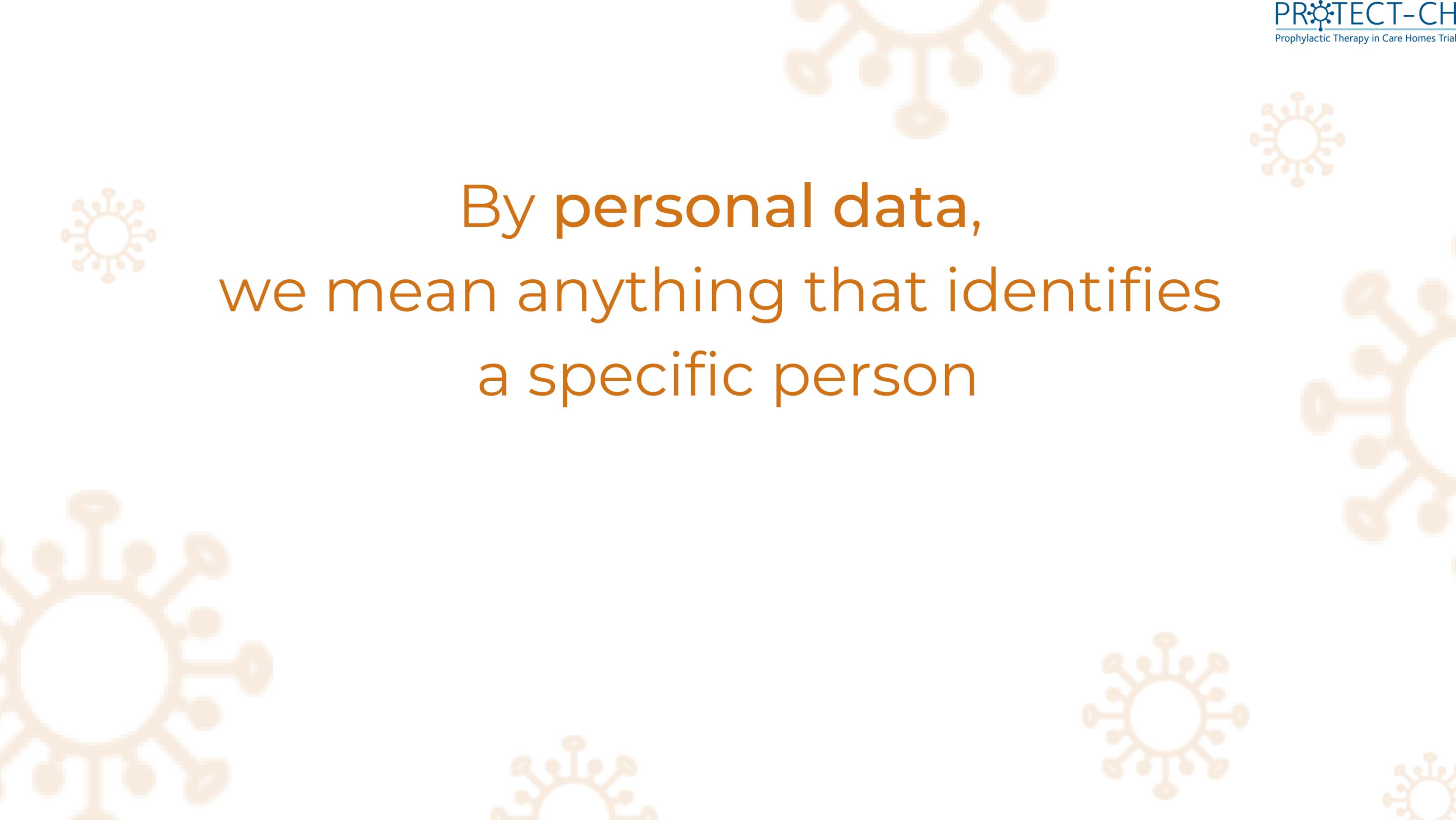
It's in the Data Protection
Act (2018)

By law,

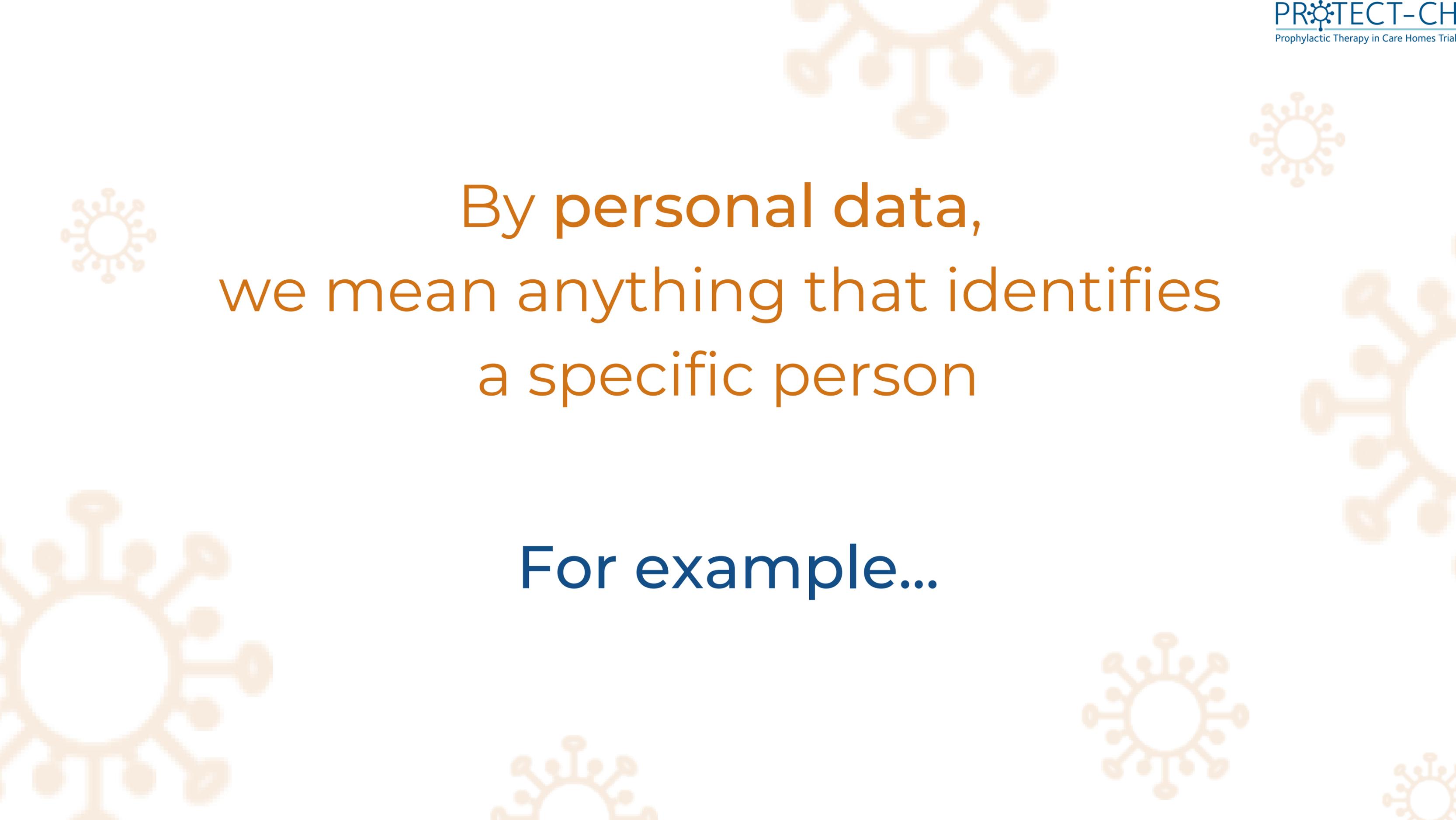
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must tell trial participants/personal legal
representatives (for residents lacking capacity to
consent for themselves)

what they are going to do with
the participant's (resident's) personal data.



By personal data,
we mean anything that identifies
a specific person

The background of the slide is white and features several stylized, light orange virus-like icons. These icons consist of a central circle with several lines radiating outwards, each ending in a small circle, resembling a simplified representation of a virus particle. They are scattered across the slide, with some being larger and more prominent than others.

By personal data,
we mean anything that identifies
a specific person

For example...

Name

HELLO
my name is



Date of Birth



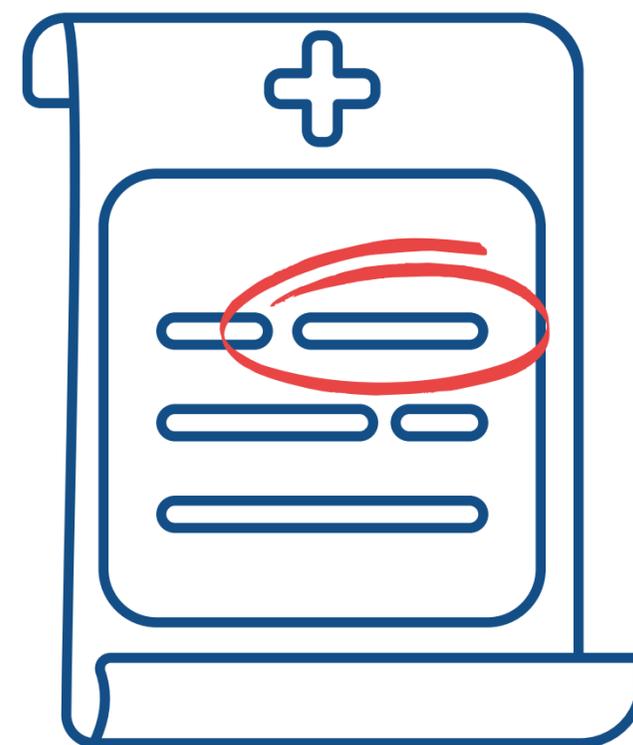
Address



Phone Number



NHS number



What personal data will the UoN PROTECT-CH trial team collect from each resident who agrees to take part in the trial?



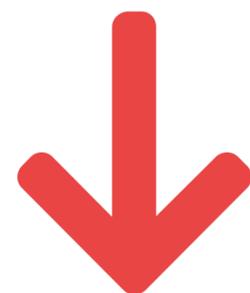
Name



To be able
to identify
the resident

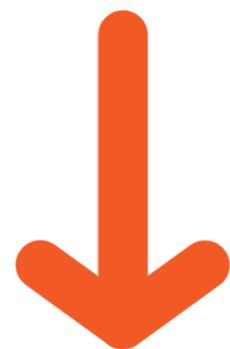


Name



To be able
to identify
the resident

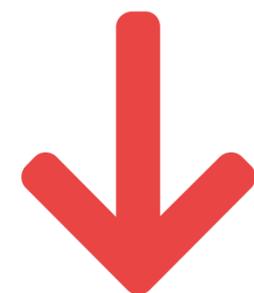
Date of
Birth



As there may be
more than one
person
with same initials

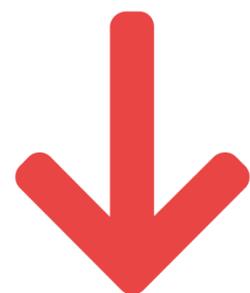


Name



To be able
to identify
the resident

Date of Birth



As there may be
more than one
person
with same initials

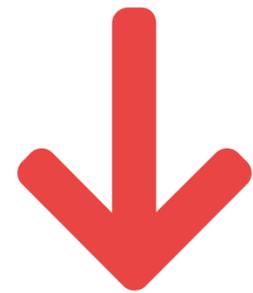
Address



To be used to
confirm identity
of resident

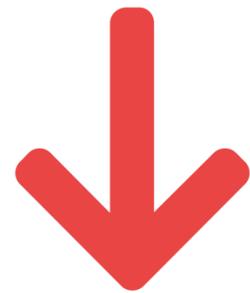


Name



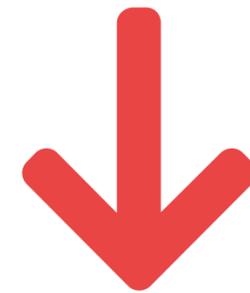
To be able
to identify
the resident

Date of
Birth



As there may be
more than one
person
with same initials

Address



To be used to
confirm identity
of resident

NHS
number
and
Relevant
medical
history



To confirm the
resident is eligible to
take part in the trial

What about research data?

Research data is information collected during the trial about a resident.



For example:

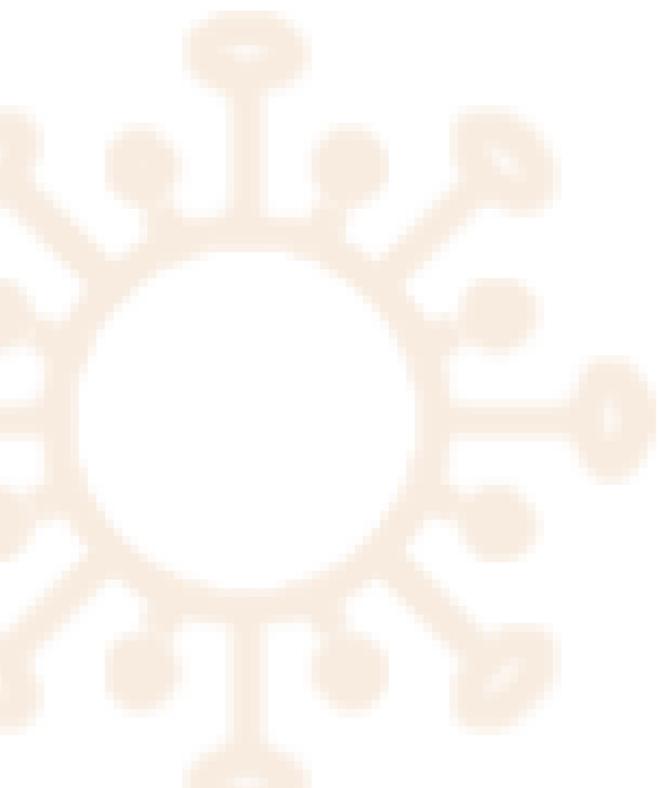
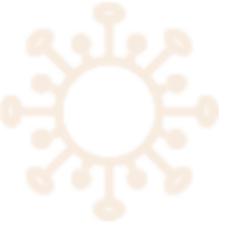
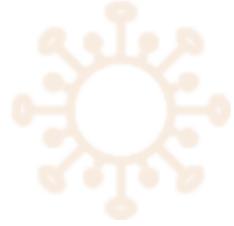
Whether they have taken the trial medication every day

OR

If they have had a side effect from the trial medication



Research data are **NOT** identifiable



Research data are **NOT** identifiable.

A unique identifier will be given to each resident which will be added to all trial documents for that resident.



It is essential that to collect and use a resident's personal data **AND** research data the research staff must have received consent from the:

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Resident



It is essential that to collect and use a resident's personal data **AND** research data the research staff must have received consent from the:

Resident

OR



It is essential that to collect and use a resident's personal data **AND** research data the research staff must have received consent from the:

Resident



OR

Personal Legal Representative

(PLR)



Without consent from
either a resident or their PLR (a resident's close
friend or family member),

NO research activities should take place
(including collection of resident's
personal or research data).



So what are the
University of Nottingham's
Data Protection
responsibilities?

Will follow legal
and ethical
practice

University of Nottingham

Will follow legal
and ethical
practice

Will follow
UK Data
Protection
Laws

University of Nottingham

Will follow legal
and ethical
practice

Will follow
UK Data
Protection
Laws

Is responsible for
data safety.
The chief investigator
(Prof Philip Bath)
is responsible
for managing
access to the data

University of Nottingham

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Please note:
Residents' personal
information is also
referred to as data

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University of Nottingham

Please note:
Residents' personal
information is also
referred to as data

Residents' information
will be stored
securely on a
password-protected
database

Will follow legal
and ethical
practice

Will follow
UK Data
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University of Nottingham

Please note:
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All information
about residents
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handled in
confidence

Residents' information
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securely on a
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database

Will follow legal
and ethical
practice

Will follow
UK Data Protection
Laws

Is responsible for
data safety.
The chief investigator
(Prof Philip Bath)
is responsible
for managing
access to the data

University of Nottingham

Please note:
Residents' personal
information is also
referred to as data

Will use the least
amount of
personally-identifiable
information possible

All information
about residents
will be
handled in
confidence

Residents' information
will be stored
securely on a
password-protected
database

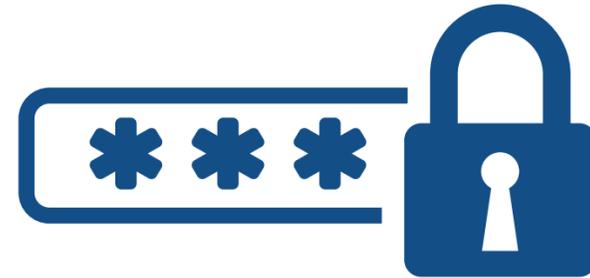
Further information can be found at:
www.nottingham.ac.uk/utilities/privacy.aspx



Where will the
data be stored?

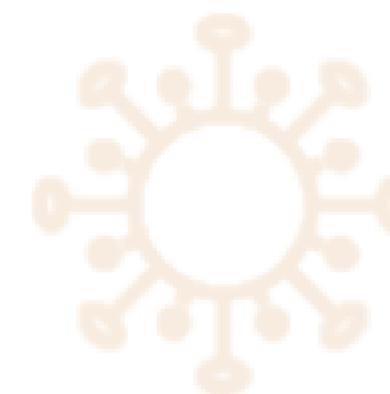
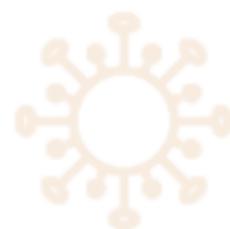
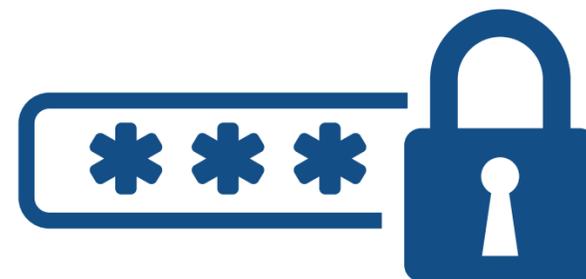
Personal data

All personal data will be entered into a password-protected database. Only the trial team will have access to this database



Research data

Research data containing the unique identifier will be stored on a separate platform to the personal data and will be password-protected



Personal data

Paper records containing a resident's personal data ie. consent forms completed on paper, will be kept in a locked cupboard in a restricted-access office at the University of Nottingham

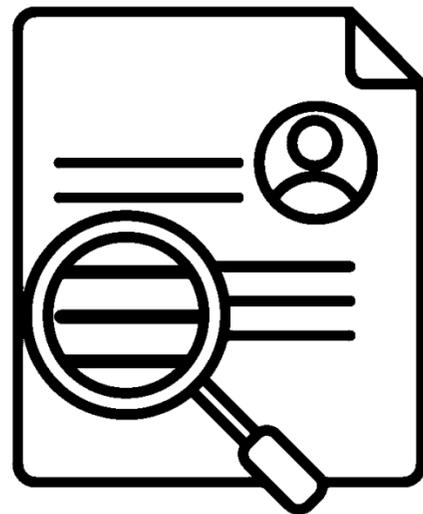




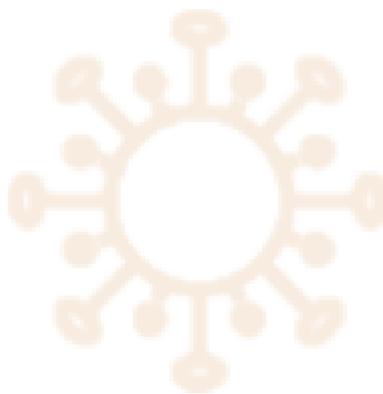
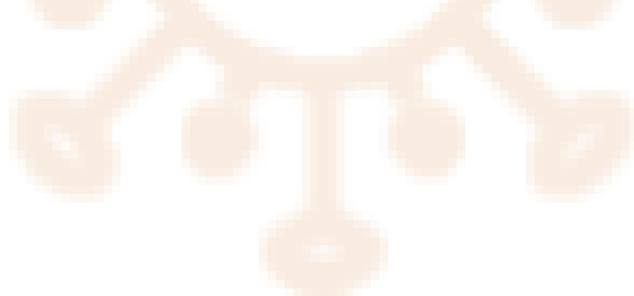
Research data

Paper records will be kept in a different locked cabinet to the personal data, also in a restricted-access office at the University of Nottingham

Who can look at residents' research data?



Regulatory Organisations

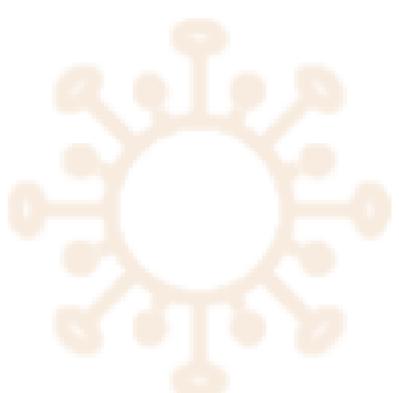
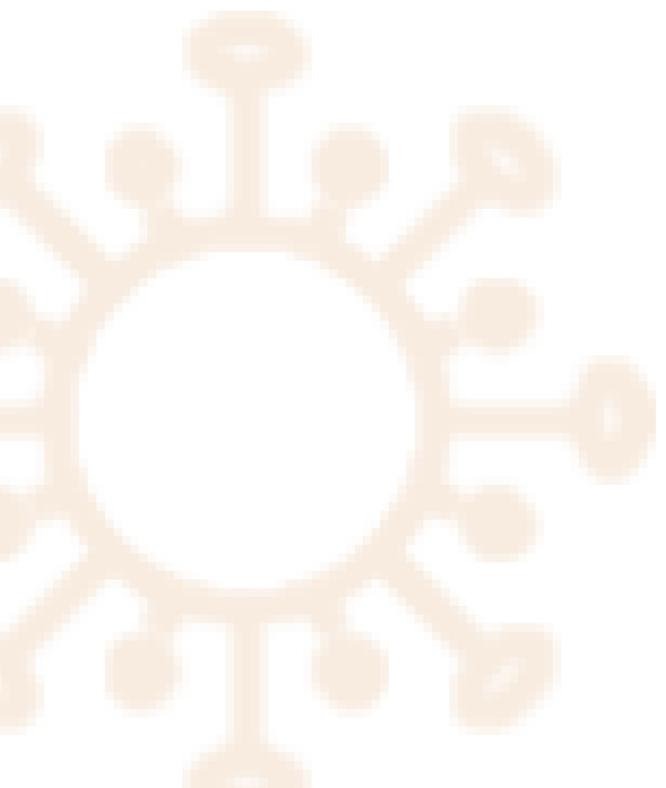
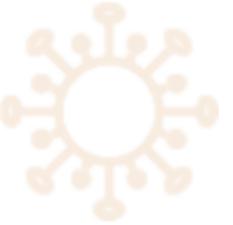
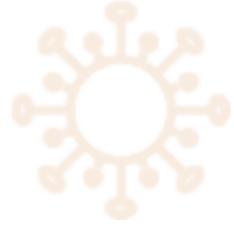


Regulatory Organisations



- University of Nottingham (UoN) Sponsor Team
- Medicines and Healthcare Regulatory Agency (MHRA)

Research Staff working on trial



Research Staff working on trial



- Care Home Staff
- UoN PROTECT-CH Trial Team
- Trial Doctors, known as
Principal Investigators (PIs)
and Research Nurses

Where possible resident data shared by the UoN for authorised research purposes will have name and address removed.

What happens at the end of the trial?

Resident research data will be kept securely for at least 7 years, then disposed of securely as per UoN policy and clinical trials laws.



Data may be shared with other researchers outside the UoN for authorised research purposes but will be anonymised (personal details removed).



In this module we have covered the following:

- What we mean by Data Protection
- What is classed as Personal Data
- What Personal Data the University of Nottingham (UoN) will be collecting as part of this trial
- What is classed as research data
- The UoN data protection responsibilities
- Where data will be stored
- Who has permission to view residents' data
- How long data will be stored after the end of the trial



Thank you for watching!

You have now completed the
Data Protection
Training Module





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=2&ModuleVersion=1](https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=2&ModuleVersion=1)

Or you can access it
via mobile here:





Please get in touch with us
if you have any questions:



protect-trial@nottingham.ac.uk



0115 74 87710

*Thank
you*