Consent training

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Deferred consent model / Research Without Prior Consent

Key points

- Recruit patient into trial before consent
- Acknowledged acceptable method of consent
- HRA & REC approved
- This protects patients and you
- Designed for use in trials where patients are likely to lack capacity and time is important - delaying would impact care and trial
- Used in critical care & emergency research

- Discussion of generic principles then specific to T4P

Ensures vulnerable group are not excluded from opportunities to participate in research

- HRA: "Emergency research is when treatment needs to be given urgently, and it is necessary to take urgent action for the purposes of the study"

- HRA: "Adults who are not able to consent for themselves should be included in research, provided that you do this in line with relevant legal frameworks and ethical principles".

NIHR: Emergency Research

- Guidance issued by the HRA
- Consideration whether or not the trial is a CTIMP (T4P is not)
- In some emergency situations potential participants may lack capacity to give consent themselves
- Obtaining consent from a legal representative / consulting others may not be reasonably practicable.

Adults not able to consent for themselves in other intrusive emergency research

In England and Wales the law allows adults not able to consent for themselves to be recruited into other intrusive research i.e. research other than CTIMPs, without prior advice from a consultee, in emergency situations if:

- treatment needs to be given urgently
- it is also necessary to take urgent action to administer a drug for the purposes of the trial
- it is not reasonably practicable to seek advice from a consultee
- the procedure is approved by a NHS Research Ethics Committee
- a consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings.

A person is not prevented from being a consultee if they are an attorney authorised under a registered Lasting Power of Attorney or are a deputy appointed by the Court of Protection; but that person must not be acting in a professional or paid capacity (for example, person';s solicitor).

Glossary

Capacity

- Consider what patient capacity is relevant to:

- Patients eligible for T4P are likely to lack capacity to undertake a fully informed decision on whether to participate in clinical trial
- within the required timeframe (ie so not to delay their treatment)

NIHR: Establishing Capacity .1

A person is **Competent** (able to make a decision for themselves) if they are able to:

- **understand** information relevant to the decision
- **retain** the information
- **use** or **weigh** the information
- **communicate** their decision (by any means)

NIHR: Establishing Capacity .2

- Capacity may depend on **type of decision** (assess for each particular decision - don't assume!)
- Incapacity may be temporary or fluctuate
- Presumption of capacity (MCA 2005)
- Researchers must be able to assess capacity when recruiting participants - or seek expert advice - DOCUMENT this!
- With deferred consent, assess capacity when approaching for retrospective consent.

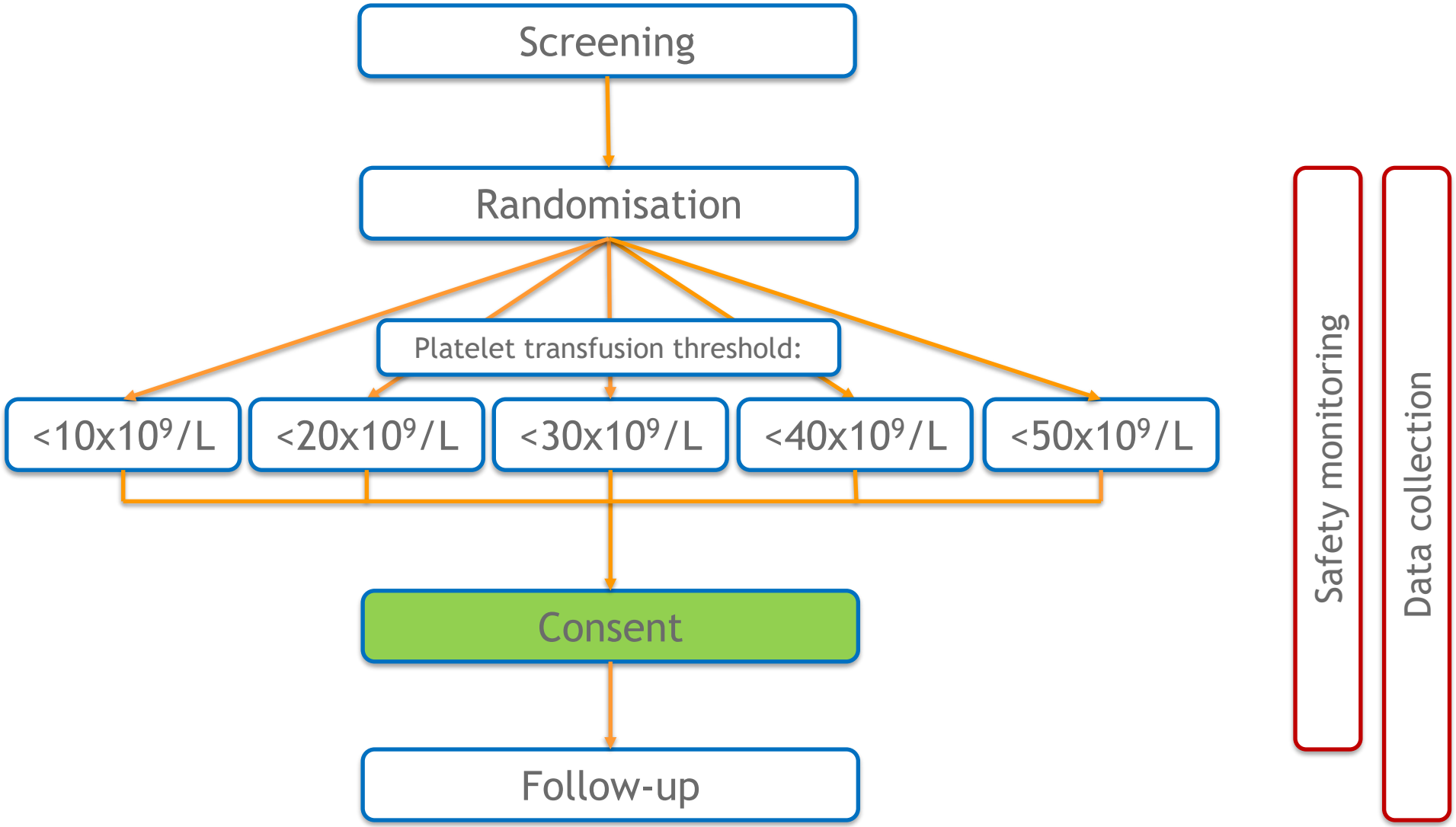
NIHR: Adults lacking capacity

- Voluntary consent is a fundamental principle underpinning the ethical conduct of all clinical research

- When a person is unable to volunteer for themselves it is essential that their **presumed will** informs any decisions made on their behalf – would they volunteer to participate if they were unable to make the decision for themselves ?

- There are different processes in place to support and record decision making for CTIMPs and non-CTIMPs, though representation of the potential participant's presumed will is at the heart of both

T4P: Patient flow



Deferred consent model / Research Without Prior Consent

- Patients likely to lack capacity at time of randomisation
- Emergency waiver of consent granted by REC (Mental Capacity Act)

- After randomisation - once patient's medical situation is considered no longer an emergency, the consent procedures should begin
  - Consent sought after randomisation by GCP-trained delegated team member
  - *Expected to be within 24-48 hours of randomisation : should be considered, not strict timeline*

See T4P Study Manual section 6

Consent procedures

See T4P Study Manual section 6

In situation where patient has capacity: seek verbal/other non-written consent to randomise if appropriate, (document) otherwise consent is deferred

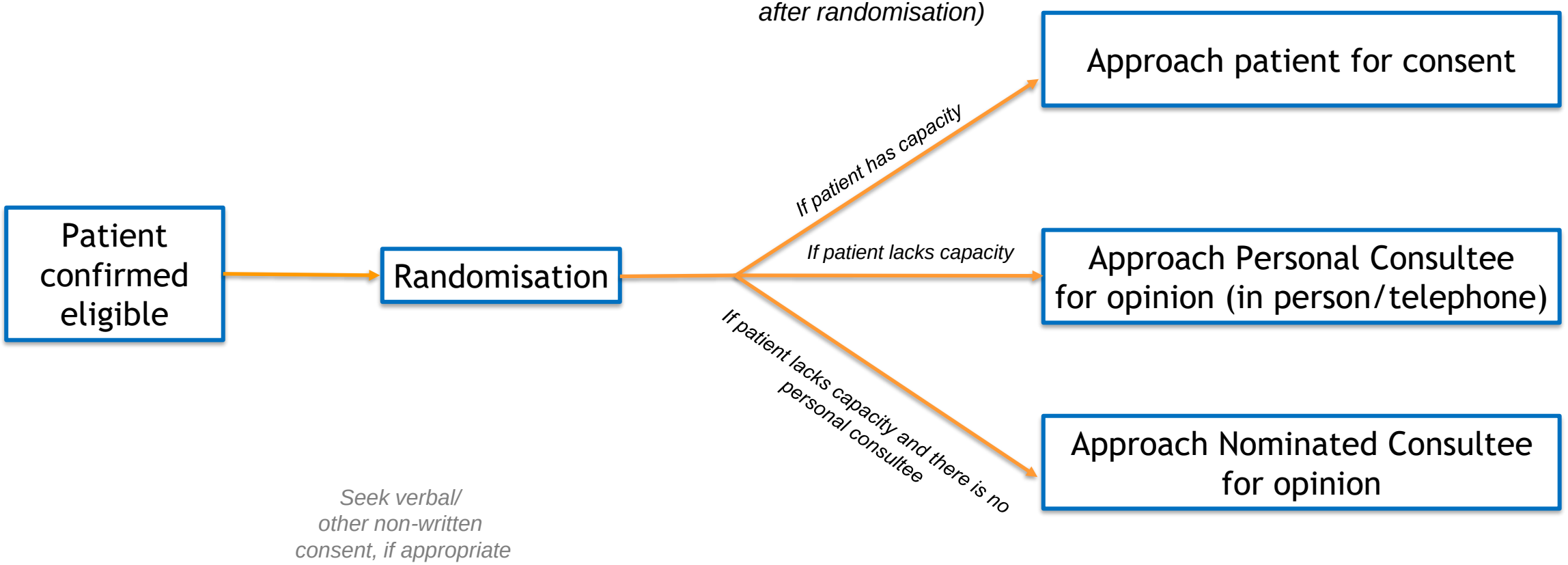
Patient confirmed eligible

In the situation where a Personal Consultee is available, in person, at the time the patient becomes eligible for inclusion, and if deemed appropriate, the Personal Consultee can be presented with an Information Leaflet. If no objection to patients' participation, they are randomised and deferred consent process followed

Consent procedures

See T4P Study Manual section 6

Once medical situation is no longer an emergency (around 24-48 hours after randomisation)



Seek verbal/ other non-written consent, if appropriate

Personal Consultee opinion

See T4P Study Manual section 6

- If patient lacks capacity, approach Personal Consultee
  - Relative/close friend - not restricted to next of kin
- Consultee advises on patient's likely wishes/feelings regarding participation in the trial
- Approach:
  - In person (preferred)
    - Give **Patient Information Sheet (PIS)** with **Personal Consultee PIS Cover Sheet** attached and use **Personal Consultee Opinion Form**
  - Postal (if unable to visit)
    - Offer to send **PIS** and **Personal Consultee PIS Cover Sheet** via post
    - Personal Consultee completes **Postal Personal Consultee Opinion Form** and returns in pre-paid envelope
  - Telephone (if unable to visit)
    - Offer to send **PIS** and **Personal Consultee PIS Cover Sheet** via email or post
    - Complete **Remote Personal Consultee Opinion Form** over the phone
    - Must be witnessed

Nominated Consultee opinion

See T4P Study Manual section 6

- Approach Nominated Consultee if:
  - Patient lacks capacity and no personal consultee is available, i.e.:-
    - there is no personal consultee, or
    - they are not contactable / visiting, or
    - they lack capacity, or
    - they don't want to act as consultee
  - Patient has died

- Nominated Consultee can include:
  - Appropriately qualified clinician independent of the trial (not on Delegation/Training Log)
  - Independent Mental Capacity Advocate

- Purpose
  - To advise on patient's likely wishes/feelings regarding participating in the trial
  - To reduce stress on grieving relatives

Nominated Consultee opinion

- Do not need a Nominated Consultee opinion prior to randomisation
- Do not need to get a Nominated Consultee opinion before a Personal Consultee
- If you do receive Nominated Consultee opinion & later find there is a Personal Consultee, and the patient still lacks capacity, you should approach the Personal Consultee.

If patient dies prior to consent

See T4P Consent Guide

If approach has already been made to family:

- Go back to them to check agreement.
- No requirement for them to sign opinion form.
- Ask Nominated Consultee to sign opinion form.
- Document all discussions

If approach has not already been made to family:

- Inform family of patient's involvement in trial as 'routine' procedure (good practice / duty of candour)
- Ask Nominated Consultee to sign consent form.
- Document all discussions

Patient informed consent

See T4P Study Manual section 6

- Upon recovery, patient should be approached directly
  - Give **Patient Information Sheet (Deferred)**
  - Approach with **Consent Form (Deferred)**
    - Explain consent options
- If patient wishes to have more time or is discharged, approach by telephone/post after discharge
  - Complete **Remote Consent Form (Telephone)** or send **Postal Consent Form**
  - Telephone consent must be witnessed
- Patient's decision is final

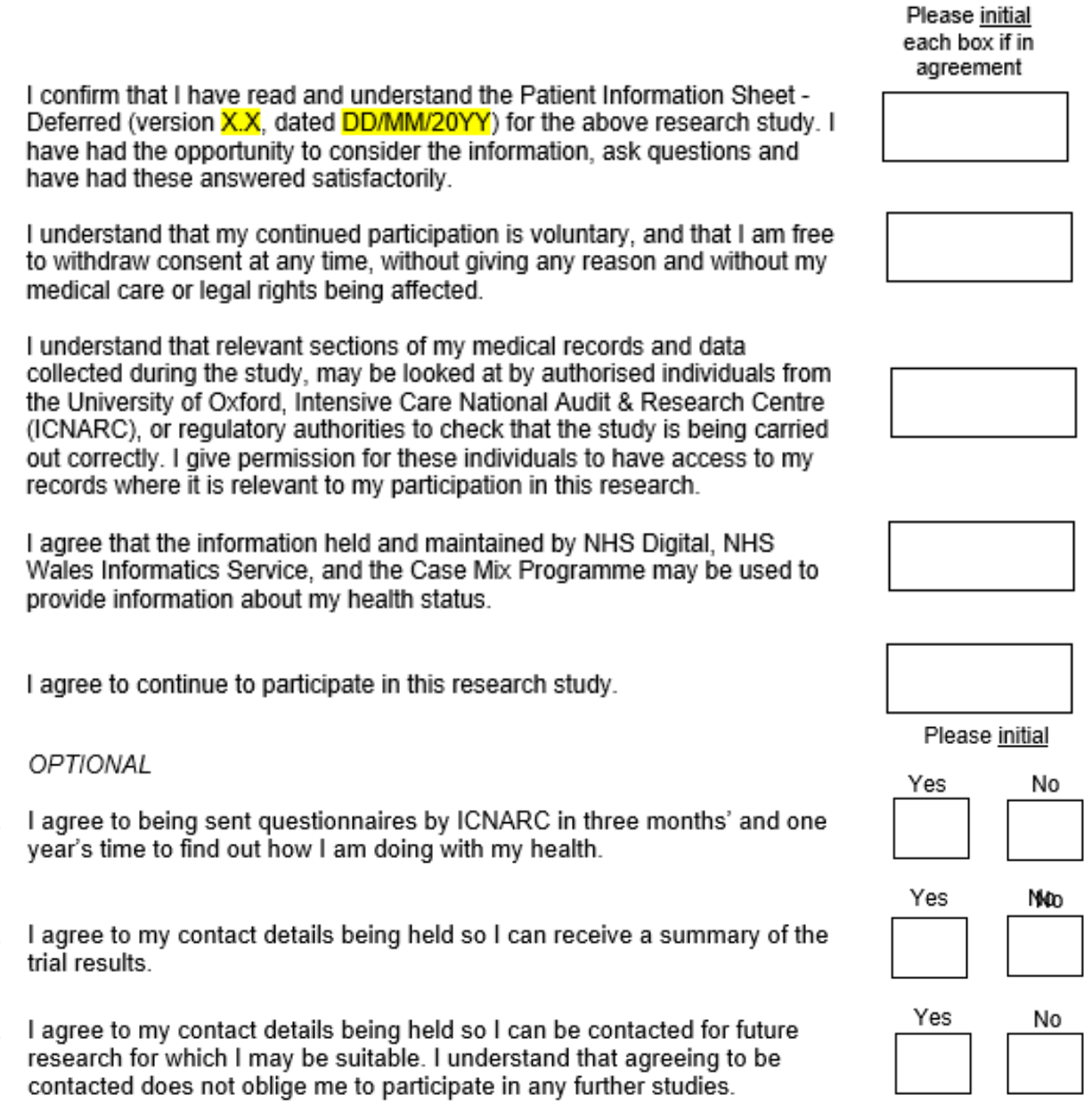
Explaining the trial

See T4P Consent Guide

- Information should be clear, concise and not medicalised
- Explain:
  - Why we are doing the trial
  - Why consent cannot be sought in emergency situations
  - Explain platelet transfusions and the allocated thresholds in easy to understand terms
  - Note that all thresholds are **within usual care across the UK** – the trial is about finding out which is best
- Allow time to think about the trial, discuss with friends/family and ask questions
- *NB: We have noted slightly higher refusal rates for T4P compared to other trials….thoughts ?*
- Trial consent guide provided to sites for support

Completion of consent/opinion forms

- Signing indicates agreement with points 1-5
- Points 6-8 (follow up, receiving trial results and future research) should be initialled to indicate Yes or No
  - Optional but should be encouraged
- Patient/consultee completes first, then person seeking consent checks form is completed correctly and countersigns in their presence
- If patient unable to physically sign the form, an independent witness may sign on their behalf
- A copy given to the patient/consultee, a copy for medical notes and original stored in ISF



Please initial each box if in agreement

1. I confirm that I have read and understand the Patient Information Sheet - Deferred (version X.X, dated DD/MM/20YY) for the above research study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my continued participation is voluntary, and that I am free to withdraw consent at any time, without giving any reason and without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical records and data collected during the study, may be looked at by authorised individuals from the University of Oxford, Intensive Care National Audit & Research Centre (ICNARC), or regulatory authorities to check that the study is being carried out correctly. I give permission for these individuals to have access to my records where it is relevant to my participation in this research. ☐
4. I agree that the information held and maintained by NHS Digital, NHS Wales Informatics Service, and the Case Mix Programme may be used to provide information about my health status. ☐
5. I agree to continue to participate in this research study. ☐

Please initial

OPTIONAL

Yes ☐ No ☐

6. I agree to being sent questionnaires by ICNARC in three months' and one year's time to find out how I am doing with my health.

Yes ☐ No ☐

7. I agree to my contact details being held so I can receive a summary of the trial results.

Yes ☐ No ☐

8. I agree to my contact details being held so I can be contacted for future research for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.

Consent procedures

See T4P Study Manual section 6

Documents:

- **Prospective patient consent**
  - In person only
    - Patient Information Sheet – Prospective
    - Consent Form – Prospective
- **Deferred patient consent**
  - In person
    - Patient Information Sheet – Deferred
    - Consent Form – Deferred
  - By post
    - Patient Information Sheet – Deferred
    - Patient Enrolment Covering Letter
    - Consent Form – Postal
  - By telephone
    - Patient Information Sheet – Deferred
    - Consent Form – Remote (Telephone)
- **Personal consultee opinion**
  - In person
    - Patient Information Sheet – Deferred
    - Personal Consultee PIS Cover Sheet
    - Personal Consultee Opinion Form
  - By post
    - Patient Information Sheet – Deferred
    - Personal Consultee PIS Cover Sheet
    - Personal Consultee Enrolment Covering Letter
    - Personal Consultee Opinion Form – Postal
  - By telephone
    - Patient Information Sheet – Deferred
    - Personal Consultee PIS Cover Sheet
    - Personal Consultee Opinion Form – Remote (Telephone)
- **Nominated consultee opinion**
  - In person
    - Patient Information Sheet – Deferred
    - Nominated Consultee PIS Cover Sheet
    - Nominated Consultee Opinion Form

Refusals and Withdrawals

See T4P Study Manual section 6

- If patient/consultee declines (refuses) or withdraws consent, clarify which aspects they are declining/withdrawing from
  - Total vs. partial - may be willing to allow continued data collection (must be documented)
  - Not obliged to provide a reason

- Data on events occurring up to refusal/withdrawal retained in trial, unless patient/consultee requests otherwise
  - Data entry on MACRO should be completed up until point of refusal, i.e., up until 16:00 on Observations Day [2] if refusal/withdrawal occurred at 16:00 on Obs Day [2]

Completing eCRF (MACRO) : Consent

- Consultee opinion
  - Enter all details following approach
  - If a consultee is never approached, select consultee approached? “NO”

- Patient consent
  - Enter all details following approach
  - If a consultee agrees, then a patient refuses, this is a refusal not a withdraw – all data entered on ‘consent page’

- If a nominated consultee is approached and then a personal consultee is approached (NB this should not happen)
  - Complete details of opinion from the nominated consultee. **Save**.
  - Then update the page by completing the personal consultee opinion details – overrides the nom consultee information – add a comment. We can see as audit trail.

Withdrawal

Withdrawal is when favourable opinion or consent has been given and then, later, withdrawn **by the same person.**

- e.g. A consultee provided favourable opinion and has signed the opinion form. Later, the same consultee changed their mind and withdrew this for any or all of the opinion options.
- e.g. A patient provided consent, has signed the consent form. Later, the patient changed their mind and then withdrew this for any or all of the consent options.

Completing eCRF (MACRO) : Complete “withdrawal of consent” page

Documentation of consent

Document all consent approaches in the patient's medical records.

Including:

- assessment of mental capacity
- details of discussions
- that agreement to continued trial participation was provided.
- detail if there is agreement to some aspects of the trial and not others,
- refusal, including any reasons if given.
- incidences of non-approach or delay in approach, with rationale.

National Data Opt-out (NDOO)

- NHS service that allows patients in England to opt out of their confidential information being used for research and planning.
- T4P trial recruitment prior to consent is approved - includes patients who may have a NDOO.
- You do not need to check for a NDOO prior to screening & randomisation.
- Consent overrides NDOO including consultee opinion.

- If you discover that a patient recruited into T4P has a NDOO and approach for opinion/consent has not yet been made, still approach for opinion/consent – the patient or consultee can decide whether they agree to trial participation and this will override the NDOO.

Trial resources

- Consent guide
- T4P CRF Guidance

Recommended training:

- NIHR ‘valid informed consent’ course (half day)
- NIHR Informed Consent with Adults Lacking Capacity course (on line)

Both via NIHR learn: https://learn.nihr.ac.uk/

Recommended reading:

ENHANCE: Guidance to inform communication with bereaved families about their relatives' participation in emergency or critical care research without prior informed consent. August 2024

ENHANCE,Guidance_Version,1.0,Aug,2024.pdf (liverpool.ac.uk)

Next steps

If you would like a certificate for this consent training, please email T4P@icnarc.org with your full name, designation and site/hospital.

Thank you

- Any questions?

T4P@icnarc.org

020 7831 6878

Icnarc.org/Our-Research/Studies/T4P