



REMAP-CAP

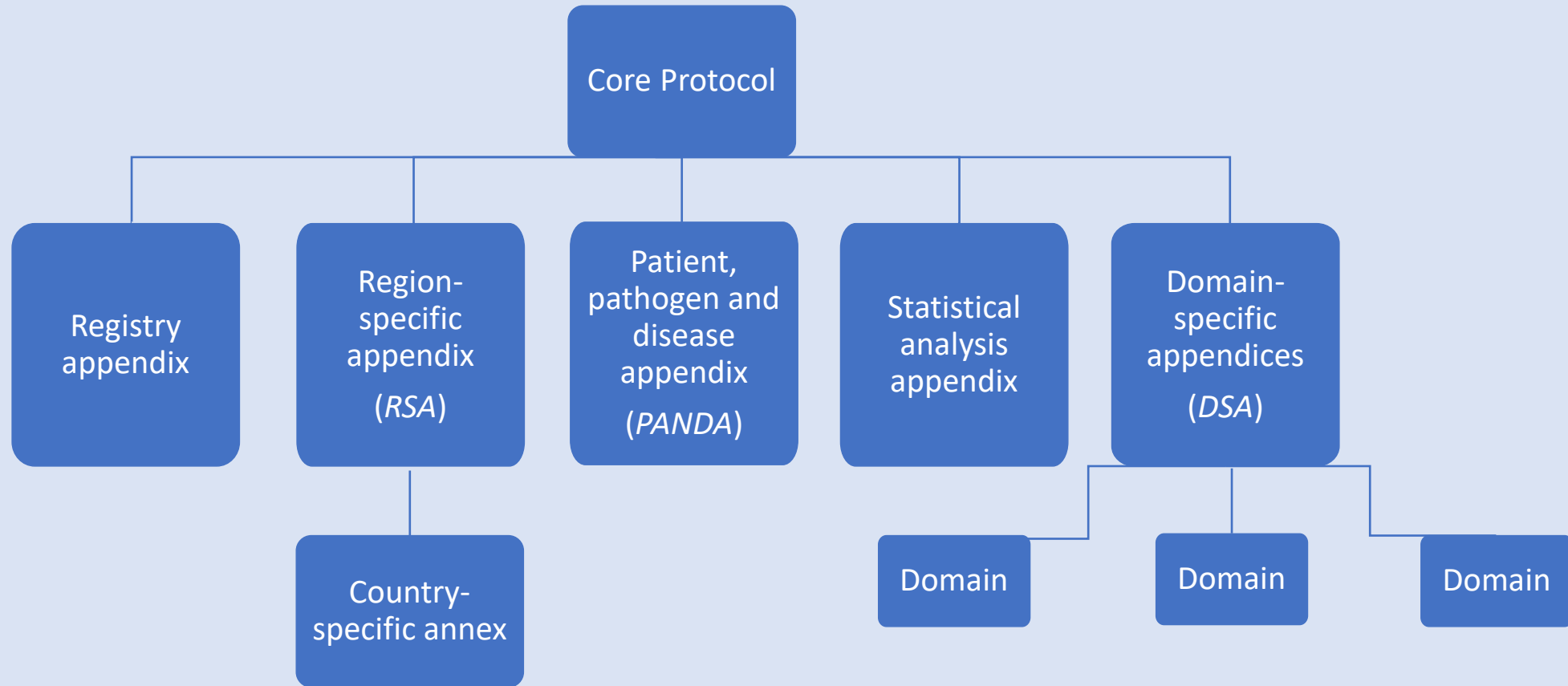
Training: Consent Process for Protocol V4.0

V3.0, 29-Sept-2026

+ Chief Investigator: Prof Anthony Gordon

Trial Management Team Email: ukremap-cap@icnarc.org

Trial design: modular protocol structure



Current open domains

Adults

ICU

Antibiotics
Macrolide Duration
Corticosteroid
Influenza Antiviral
Immune Modulation

Wards

Corticosteroid
Influenza Antiviral

Paeds

ICU

Corticosteroid
Influenza Antiviral
Immune Modulation

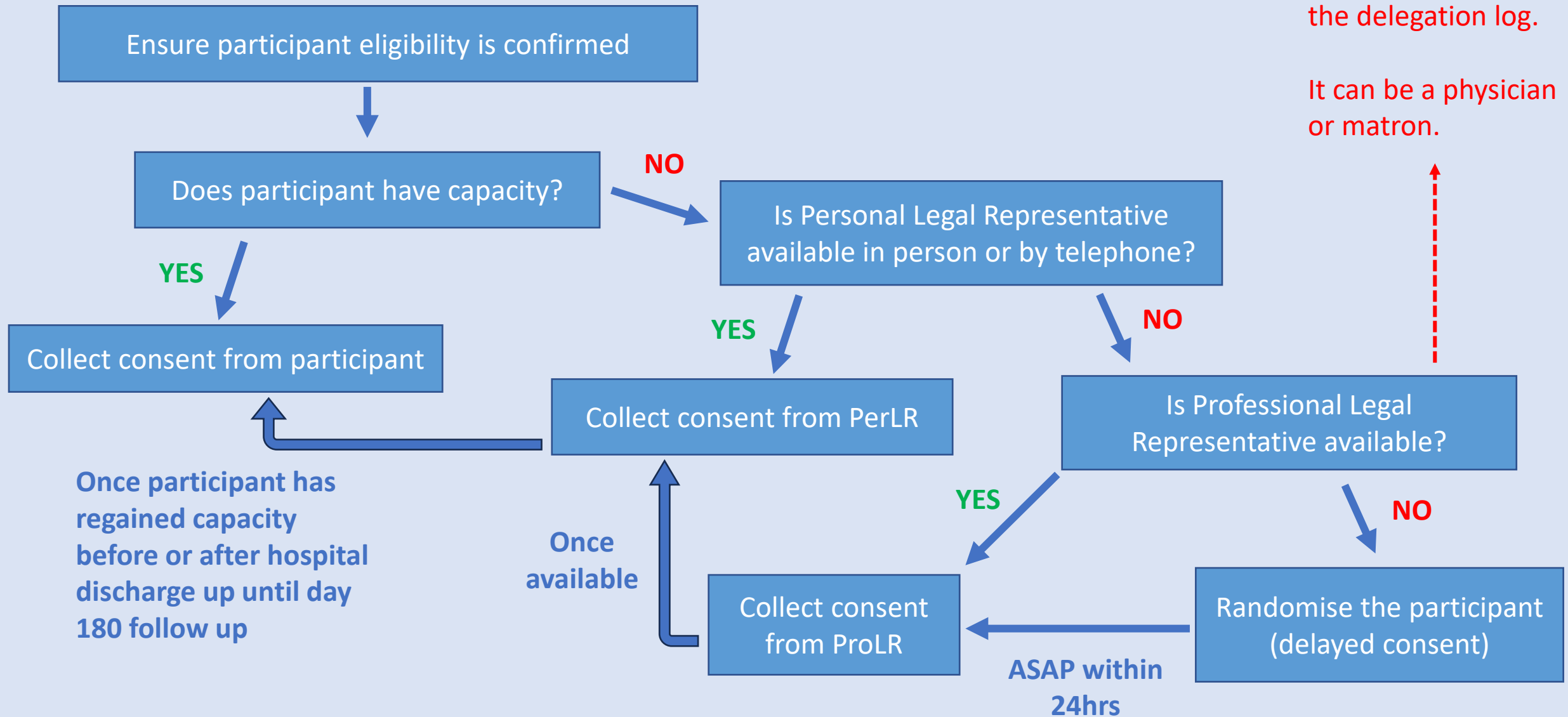
Wards

Corticosteroid
Influenza Antiviral

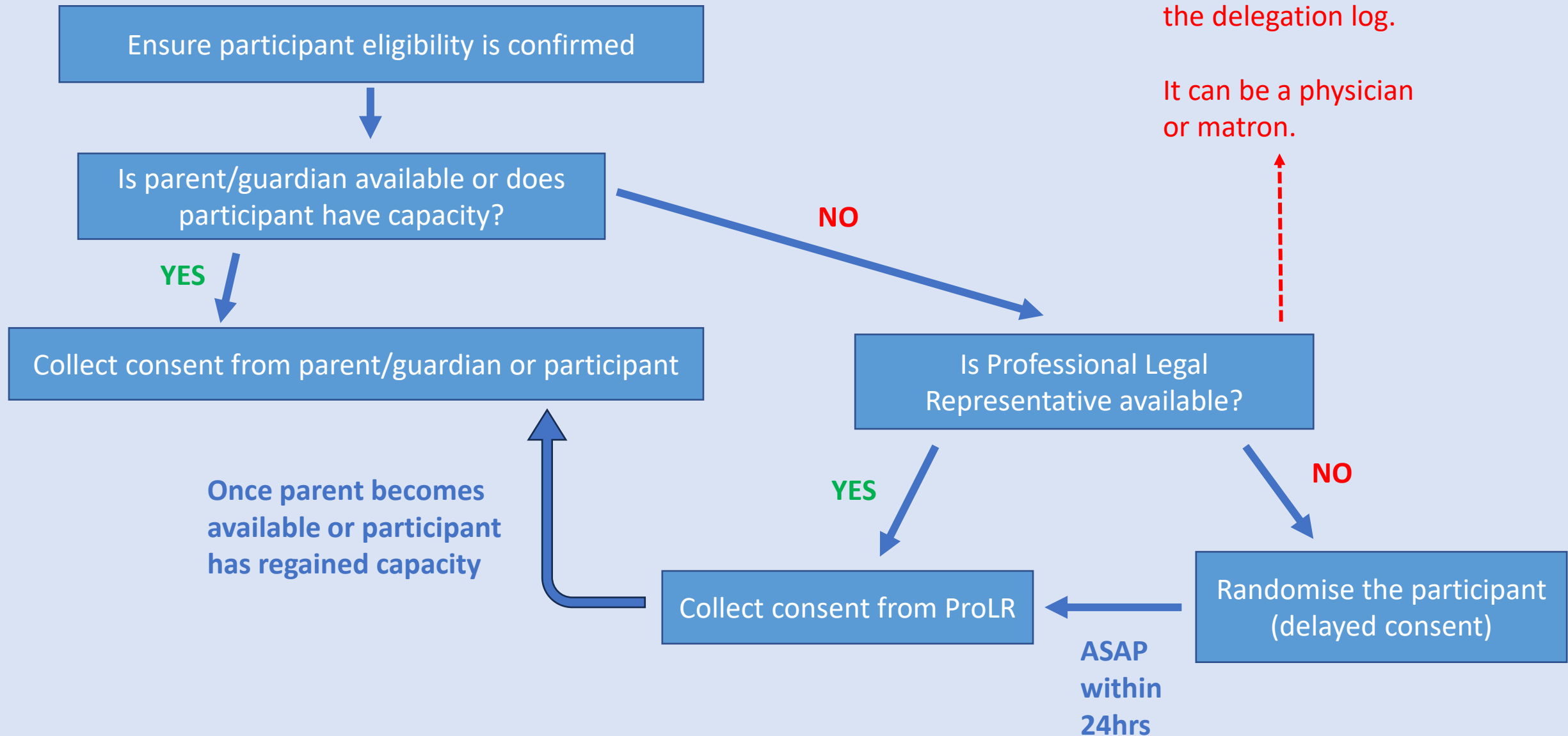
Consent Documentation

- + The person collecting consent is required to be listed on the **delegation log** and must have completed **a training log for this consent process training**.
- + **If this is your only study duty**, the training log will ask for your **registration number** (i.e. GMC/NMC No.) to confirm you are qualified to collect consent - therefore a CV / GCP certificate is not required to be filed in the ISF.

Informed Consent Flow - ADULTS



Informed Consent Flow - PAEDS



PIS/CFs

- Ensure the correct **type** of consent form is being used and **all fields are completed**:
 - Written PIS/CF, which also has a section for in-person verbal consent - requires independent witness
 - Telephone CF if consent is obtained remotely - also requires independent witness
 - Summary PIS/CF if info is requested in a shorter format
 - Video CF if info is requested in a different format
 - Translated PIS/CF if requested and language is available
- Ensure **latest ethically approved and local R&D approved version of PIS/CF** is being used, with local contact details/PALs details and Trust header present.
- **For paediatrics**, if a child has capacity and is able to they must read/complete the age appropriate 'assent' section of the PIS/CF.

Consent Process Documentation

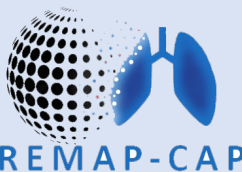
- Document **ALL conversations and info** regarding consent in the participant notes, including participant capacity, who was approached, type of consent taken and who took the consent.
- This can be done by completing a **‘consent statement’ template** (signed/dated) or a direct entry in the **participant medical records**.
- All consent discussions must be entered as separate **‘consent events’** on the **eCRF**.
- All participants/families **MUST be aware of and informed of their inclusion**, where possible and appropriate.

Good Clinical Practice (GCP) R3

- International, ethical and scientific quality standard to which all research involving human participants is conducted
- Comprises of **11 core principles** as per latest GCP R3. It applies to all clinical investigations that could affect safety and well-being of human participants, providing international assurance that:
 - Data and reported results of clinical investigations are credible and accurate
 - Rights, safety and confidentiality of participants in clinical research are respected and protected
- You are encouraged to obtain GCP certification, such as that available through NIHR:
<https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>

11 Principles of Good Clinical Practice (GCP)

- 1.Ethical Conduct:** Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure the rights, safety and well-being of participants.
- 2.Informed Consent:** Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed.
- 3.Independent Review (IRB/IEC):** Clinical trials should be subject to an independent review by an IRB/IEC.
- 4.Scientific Soundness:** Clinical trials should be scientifically sound for their intended purpose and based on adequate and current scientific knowledge and approaches.
- 5.Qualified Individuals:** Clinical trials should be designed and conducted by qualified individuals.
- 6.Quality by Design:** Quality should be built into the scientific and operational design and conduct of clinical trials.
- 7.Proportionality of risks (NEW):** Clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected and that avoids unnecessary burden on participants and investigators.
- 8.Clear Protocol:** Clinical trials should be described in a clear, concise, scientifically sound and operationally feasible protocol.
- 9.Reliable results:** Clinical trials should generate reliable results.
- 10.Roles and responsibilities (NEW):** Roles and responsibilities in clinical trials should be clear and documented appropriately.
- 11.IMP / GMP:** Investigational products used in a clinical trial should be manufactured in accordance with applicable Good Manufacturing Practice (GMP) standards and be managed in accordance with the product specifications and the trial protocol



GCP: Consent, re-consent and withdrawal

- Informed consent may take place in person or remotely with electronic sign off
 - Identity of participant and legally authorized representative should be assured
- If re-consent is needed new information should be clearly identified in the revised informed consent form
- Discuss reason for withdrawal with participant and address concerns and value of continuation
 - Do not unduly influence participant
 - In case of withdrawal, participant's data will be handled as described in protocol and informed consent form

GCP: Data Governance

- Ensure appropriate management of **data integrity, traceability and security**, allowing accurate reporting, verification and interpretation of clinical trial-related information
 - Ensure **source data** records are accurate, complete and contemporaneous
 - Facilitate timely and accurate **data entry** into eCRFs
 - Implement appropriate measures to **protect privacy and confidentiality** of personal information of trial participants per regulatory requirements on personal data protection
 - Ensure **record retention** as per regulatory requirements and sponsor agreements