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Standard Operating Procedure (SOP) 005

Consent procedures

Scope

To outline the PICnIC feasibility study consent procedures in compliance with the principles of Good Clinical Practice (GCP).

Research involving children

- When carrying out research involving children, it is particularly important to ensure that, as far as possible, the research is not contrary to the individual's interests.
- Only the Principal Investigator (PI), and staff authorised by the PI on the study Delegation Log (Section 12: Site Staff Information, of the ISF) can obtain informed consent from the child's parent/guardian.
- If deemed appropriate, and the patient is sufficiently well during the consenting process, they should be provided with an age-appropriate information sheet and asked to sign an Assent form.

Obtaining informed consent

Procedure:

- Consent will be obtained by clinical/research team members who have undergone GCP training. If new safety information results in significant changes in the risk/benefit assessment, the consent form will be reviewed and updated if necessary and subjects will be re-consented as appropriate.
- Due to the emergency nature of these patients, once a patient is identified as being eligible for the study (meets all the inclusion criteria and none of the exclusion criteria), they will be assigned a study number prior to consent being obtained (see SOP 003_Patient Screening and Enrolment).
- The clinical/research nurse team will approach the parents/guardians as soon as practically possible (usually within 24-48 hours) after being identified as eligible and enrolled in the study to provide written information, discuss the study, and seek informed consent.
- If the patient has died prior to consent being sought, please see section 'consent for bereaved parents/guardians' below.

- Parents/guardians have the right to have their child's data removed if explicitly requested after reading the PIS, however it is in public interest to collect the data.

Consent required for:

- Any additional study-specific samples to be taken, stored, and analysed. Consent should be obtained prior to any samples being taken solely for the study and not as part of routine care.
- Identifiable data being collected and processed for qualitative aspects of the study (questionnaire and telephone interview).
- Monitoring of medical records.

Consent NOT required for:

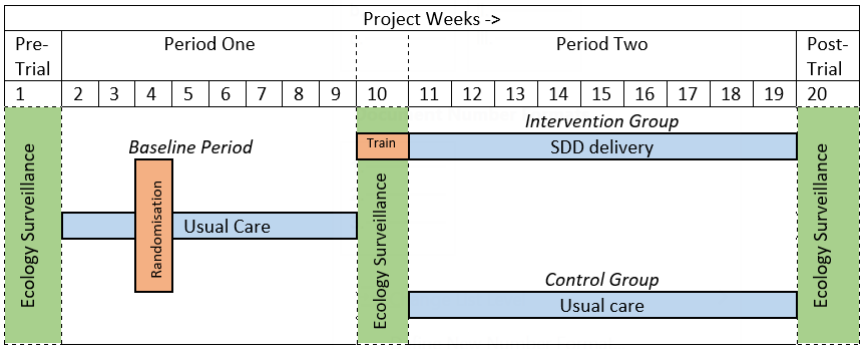
- Samples taken as part of routine care (e.g. admission samples).
- Anonymised data collection and processing from routine sources.
- Delivery of SDD. For paediatric intensive care units (PICUs) randomised to the intervention during Period Two (weeks 11-19), all children meeting the eligibility criteria will receive SDD as the standard practice for this time period.

Information sheets and consent forms

Consent Forms:
For current versions please refer to 'Section 5: Documents for participants' in the PICnIC Investigator Site File Checklist.

Patient Information Sheets:
For current versions please refer to 'Section 5: Documents for participants' in the PICnIC Investigator Site File Checklist.

- Ecology PIS should be used for patients admitted during the Ecology Surveillance weeks (1, 10 or 20).
- Baseline PIS should be used at all sites during Period One (weeks 2-9).
- Control PIS should be used during Period Two (weeks 11-19) if the PICU was randomised to usual care.
- Intervention PIS should be used during Period Two (weeks 11-19) if the PICU was randomised to deliver SDD treatment.



Participants will be provided with a separate consent form and information sheet for the Arctic study regarding the sampling that coincides with this.

Providing information to parents/guardians

- Consult nursing staff about child's condition and their views on how parents/guardians are coping. Also ask nursing staff to introduce you and ask if it is a convenient time for the discussion.

- Parents/guardians should be given the fullest possible information about the research, presented in a way and format that they can understand. This **must** include the current version of the relevant information sheet approved by the Research Ethics Committee. Information about the study should also be displayed via the Ecological Poster. The information provided to the child's parents/guardians must include:
  - why we are conducting the study
  - information about possible benefits and risks
  - evidence that a Research Ethics Committee has approved the research
  - information that participation is voluntary and that they can withdraw consent at any time without providing a reason and without prejudicing future medical care.

- Parents/Guardians should be invited and encouraged to ask questions about the research, which should be answered to the best ability of the person obtaining consent. If additional information is needed to answer questions to the parent/guardian's satisfaction, this should be obtained prior to completion of the consent process.

- Parents/guardians should be asked to complete the consent form to be invited to complete a follow up questionnaire and/or interview.

- The parent/guardian should be given enough time to read the information sheet.

- The person obtaining informed consent must assess the parent/guardian's understanding of what they are agreeing to, and that they fully understand the implications of decisions that may be made during the course of the research. An individual must not be pressured or coerced into giving consent for the study.

- The Consent Form must be signed and dated by the parent/guardian and the person obtaining informed consent as a witness; this should be done in each other's physical presence.

After consent has been obtained

- The child's study number should be recorded on the original signed Consent Form.
- Details of the Consent Form should be recorded on the relevant patient's page on Macro.
- The original signed Consent Form should be filed in Section 6: Screening and Enrolment, of the ISF. A copy should be given to the parent/guardian and a copy filed in the patient's medical notes. **A signed Consent Form should be kept regardless of how far the patient proceeds in the study.**
- Where possible, assent from the patient should be obtained prior to hospital discharge. This should be done with appropriate hospital staff and parents/guardians being involved.
- Note that Research Ethics Committees pay close attention to the informed consent process as described in the ethics application; this is an important factor in informing their decision to give a favourable opinion for the study to go ahead. Any deviation from the approved informed consent process must be reported immediately in writing to the ICNARC Clinical Trials Unit (CTU).

Non-consent / Withdrawal of consent

- If a parent/guardian withdraws consent at any time during the study or is approached and refuses to give consent ('non-consent'), their decision must be respected. This should be recorded in the patient's medical notes and no further data should be collected.
- All data up to the point of withdrawal will be retained and included in the study analysis.
- To monitor non-consent, details should be added on to the relevant patient's page on Macro. These will include the reason and date for non-consent.

Consent for bereaved parents/guardians

- If the patient has died, the parents/guardians will be approached for consent for the monitoring of medical records and identifiable data collected and qualitative aspects of the study (telephone interview).
- The site research team should work with colleagues/bereavement counsellors to establish whether the approach to obtain consent (using the bereaved consent form) is appropriate, who the most appropriate person to notify parents/guardians is, and if it is possible to do this before they leave hospital.
- At the least, the research team should attempt to provide the relevant Participant Information Sheet for bereaved parents/guardians should be used (either Ecology / Baseline / Control / Intervention), which explains that the child's information their medical records will be used in the PICnIC study.