IMPERIAL

Sarnat Staging SOP

Parental Consent

Video file drop-off

box

Video Recording of Neurological Examination and Data Transfer

Standard operating procedure

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COMET

Cooling in Mild Encephalopathy Trial

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1. Purpose

To standardize the process for conducting and video recording neurological examinations within six hours of birth under deferred consent, and for securely transferring data to Imperial College London via SharePoint after parental consent is obtained.

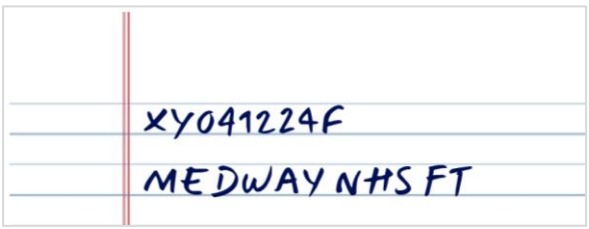
2. Scope

This SOP applies to all personnel involved in performing, recording, and transferring video data of neurological assessments for newborns in compliance with ethical standards and institutional guidelines.

3. Procedure

3.1 Pre-examination preparation

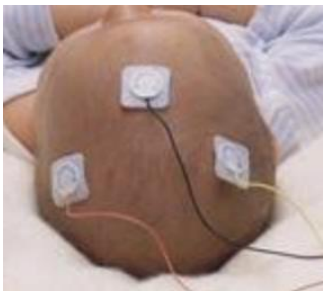
1. Deferred Consent for Video Recording: Acknowledge that video recording is conducted under deferred consent due to the necessity of capturing the examination within six hours of birth. Document this process in compliance with ethical guidelines.
2. Prepare Equipment: Verify the functionality of video recording devices and aEEG equipment. Ensure sufficient storage space and battery power.
3. Set the Environment: Ensure proper lighting and minimal background noise. Position the baby securely and comfortably.
4. Identify the Baby: Place a piece of paper in the video frame with: Mother's Initials (e.g., XY), Baby's Date of Birth (e.g., 04/12/24) and Baby's Gender (e.g., Female). Ensure the information is clearly visible without obstructing the baby. The identification code can be handwritten and please include site name. An example is shown below.



3.2 Neurological Examination and Video Recording

The video must capture the entire neurological examination, including observation and active manipulation phases. (A) Observation Phase: Record spontaneous activity, posture, respiratory pattern, and heart rate. (B) Active Manipulation Phase: Film responses to stimuli, tone assessments, reflex tests (suck and Moro), and pupil evaluations.

(C) aEEG Integration: Record aEEG lead placements and a 30-second EEG trace running on the monitoring screen. Here is an example of how the aEEG lead placement should appear in the video, as shown in the photo. ⟶



3.3 Post-Examination and Recording

1. Review Recording: Ensure the video is complete and clear.
2. Label the Video: Use a standardized format, e.g., identification code used in 3.1.
3. Log Details: Document metadata (e.g., examiner name, time, consent status).

3.4 Obtaining Parental Consent for Data Transfer

1. Post-Examination Consent: Within 24 hours of recording, formally obtain written or digital parental consent for data transfer to Imperial College London. Document the consent process in the patient's file.
2. Verify Consent: Confirm consent documentation before proceeding with data transfer.

3.5 Data Transfer to Imperial College London

1. Use the provided QR code link to navigate to the Box
2. Select the video file
3. Click submit and wait for upload
4. Confirm successful upload with COMET team

3.6 Summary Flow Diagram

On the next page, a flow diagram summarizes the steps involved in data transfer to Box. This visual guide provides a clear overview of the process for quick reference.

Accessing box

1 **Open iPad Camera**

2 **Scan QR code**

3 **Select video files**

4 **Click Submit**

5 **Wait for upload**

6 **Inform COMET team**

Include details:

- Identification code
- Date/time of upload
- NHS site name