Glasgow Clinical Trials Unit Standard Operating Procedure

| SOP number | 17.008 | Version | 5.0 |
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| Title | | | |

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| SOP category | 17 NHS GG&C Clinical Research Facility - Clinical | | | | | |
|----------------|---|---|---|---|----|--|
| Staff category | Staff Category | R | Α | С | -1 | |
| | Nursing | Х | | | | |
| | Principal Investigator | Х | | | | |
| | Clinical Research Fellow | Х | | | | |
| | GCRF Manager | | Χ | | | |
| | GCRF Associate Director | | | | Χ | |
| | Senior R&I Manager | | | | Χ | |

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

2. Purpose

To describe the procedure for recording an Electrocardiograph (ECG) on patients and volunteers participating in a research study ensuring standardisation in the conduct of the procedure.

3. Procedures

3.1. Preparation

- Identify and prepare equipment required for procedure.
- Explain the procedure to the participant and obtain verbal consent prior to starting procedure.
- Follow current NHS Greater Glasgow & Clyde Hand Hygiene Policy.
- Recognise and take appropriate action to meet cultural requirements of the participant.
- Ask the participant to remove any clothing that may restrict access to the upper body or limbs and lie on their back on the bed/examination couch in a comfortable position.
- If required the skin should be prepared by cleaning or shaving to ensure good electrode contact.
- Ensure electrodes are not outwith expiry date and still viable
- Use a study specific ECG machine if required as part of the protocol

3.2. Procedure

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- Plug in and check that the ECG machine is working as per manufacturer's instructions.
- Input participant information as defined in study specific procedures.
- Apply disposable electrodes to the participant.
- Attach ECG cables to the electrodes in the correct order, referring to manufactures instruction.

3.3. Recording of ECG

- Ensure the individual is as relaxed as much as possible before recording.
- Ask the participant to remain as still as possible for the ECG recording.
- Start ECG tracing and print/save when good clear quality tracing is confirmed.
- Check the ECG is complete; repeat if necessary.
- Review ECG, (Who reviews any clinically significant abnormal ECG may require immediate action
- and medical intervention
- Once the ECG is completed remove electrodes and leads allowing the participant privacy to dress.
- Document and complete procedure as described in study protocol
- Maintain source data, Case Report Form and patient health records

4. Referenced documents

• NHS GG&C Hand Hygiene Policy

5. Related documents

None

6. Document history

| Version | Date | Description | |
|---------|------------|--|--|
| Draft | 10/10/07 | Creation of SOP | |
| 1.0 | 22/11/07 | Release of v1.0 | |
| 1.1 | 19/05/08 | Released to staff | |
| 1.2 | 30/09/09 | General update | |
| 2.0 | 25/11/13 | Periodic review & change of author | |
| 3.0 | 15/07/16 | SOP restructure | |
| | | Update SOP template v1.4 | |
| | | Minor process and admin changes | |
| 4.0 | 26/08/2019 | Minor change to move study specific ECG machine reference from 5.2 | |
| | | to 5.1 | |
| 5.0 | 18/08/2023 | Update to GCTU SOP template v2.0 | |
| | | Addition of RACI matrix | |

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