

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-27.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/30/2010	REV. C:
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1. PURPOSE

To standardize the procedure for obtaining an electrocardiogram (ECG) by study site personnel. Some sites may elect to outsource study-related ECGs to the Division of Cardiology, in which case a study-related cost sheet will be completed by the Clinical Research Office Director or Study Coordinator (SC) for incorporation into the overall study budget.

2. SCOPE

Applies to all personnel involved in the review and implementation of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigator(s), SCs, and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for obtaining ECG reports required by the study protocol, either through the use of the Cardiology ECG service (CMES), or by delegating ECG to study staff. If delegated to study staff, the PI is responsible for oversight and training of the application of the leads, collection of the ECG data, and medical interpretation of the ECG according to the study protocol.

4. BACKGROUND

The ECG procedure as required by the study protocol should be consistent between study visits.

5. PROCEDURE

5.1. Equipment

5.1.1. The ECG machine to be used allows the ECG to be printed with all 12 leads simultaneously, unless the study protocol states otherwise.

5.1.2. The ECG machine must have a documented biomedical check within 12 months.

5.2. General Comments

5.2.1. SP must be supine on a comfortable bed or exam table for a period of time prior to the ECG, as per study protocol.

5.2.2. The SP must have loose clothing and be free of excessive body hair.

5.2.3. Male SPs with excessive hair near the points at which the leads are connected must be shaved.

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- 5.2.4. Female SPs must remove upper undergarments to allow for lead placement.
- 5.2.5. It is recommended to instruct the SP to not use lotion on the day of the ECG.

- 5.3. 12-Lead Placement: Placement of the leads on the chest is as follows:
 - 5.3.1. Lead 1: In the 4th intercostal space to the right of the sternum
 - 5.3.2. Lead 2: In the 4th intercostal space to the left of the sternum
 - 5.3.3. Lead 3: In the interval between lead 2 and 4
 - 5.3.4. Lead 4: In the 5th intercostal space on the mid-clavicular line
 - 5.3.5. Lead 5: Straight across from lead 4 on the anterior axillary line
 - 5.3.6. Lead 6: Straight across from lead 4 on the mid axillary line

NOTE: In addition to the lead placement on the chest, one 'limb lead' should be placed on each arm and one on each leg. The position on the extremities is not crucial but should be consistent and placed on an area devoid of excessive hair. Care should be taken to be sure the left and right arm leads (aVR, aVL, lead I) are placed correctly. Reversal of the arm leads is the most common error in lead placement. The aVF and G leads are less critical.

- 5.4. Taking an ECG
 - 5.4.1. Attach limb and chest leads to SP, ensure proper placement, double check limb lead (right and left arm especially) electrode placement.
 - 5.4.2. Have SP lie still but continue breathing normally.
 - 5.4.3. Enter the subject's demographic data into the computer. This information can include birth date, weight, and age. Different machines may have different data requirements and slightly different instructions.
 - 5.4.4. The machine will print a '12 lead ECG.'
- 5.5. Documentation
 - 5.5.1. All ECGs must be reviewed, signed, and dated by the PI.
 - 5.5.2. ECGs may be interpreted internally or forwarded to a central reader if this is required by the study protocol.
 - 5.5.3. Any abnormal findings discovered may be examined by a cardiologist at the discretion of the study PI.

6. TERMS & ABBREVIATIONS

- ECG** Electrocardiogram (EKG is an acceptable alternative)
- PI** Principal Investigator

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SC Study Coordinator

SP Study Participant

V Leads The limb leads of an ECG forming the apices of Einthovens triangle

7. REFERENCES

7.1. [Creighton University and Creighton University Medical Center Cost Sheet Policy](#)

8. ATTACHMENTS

None