



Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures			
SOP #104 Revision #	TITLE: Resting Electrocardiogram (ECG or EKG)		Page 1 of 6
Approved By: ORC Director	Signature 	Date June 17, 2019	Date First Effective: June 17, 2019
Approved By: Biomedical IRB Chair	Signature 	Date 6/14/19	Revision Date:
Approved By: Social / Behavioral IRB Chair	Signature	Date	Revision Date:
Expiration Date	June 17, 2022		

Please note: At least one IRB Chair and the ORC Director must review, approve and sign-off on the SOP for it to be in effect. Following review the SOP will be approved with a three (3) year expiration date.

## **OBJECTIVE**

To describe the policies and procedures for obtaining an electrocardiogram (ECG or EKG) on a research study participant.

## **GENERAL DESCRIPTION**

- a. *Brief description of the technique or procedure that could be used in the Project Outline Form.*

An electrocardiogram (sometimes called an ECG or EKG) is a noninvasive procedure to obtain a graphical representation of the heart's electrical activity derived by amplification of the minutely small electrical impulses normally generated by the heart. The tracing is obtained using 10 electrodes placed on the skin of the chest, arms, and legs. If any artifact (like static) occurs, some electrodes may need to be repositioned to ensure a clear recording of the heart.

- b. *Brief description of the technique or procedure that would be used in the Consent Form.*

An electrocardiogram (sometimes called an ECG or EKG) is a test that provides a measure of your heart's electrical activity. You may be asked to remove your shirt or change into a gown or scrubs to allow for proper placement of the electrodes on your chest. You will be asked to lie flat on a table, and 10 small electrode pads, like stickers, will be placed on the skin of your chest, arms, and legs. If any artifact (like static) occurs, some electrodes may need to be repositioned to ensure a clear recording of your heart. The test takes about 10

<b>Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures</b>		
<b>SOP #104 Revision #</b>	<b>TITLE: Resting Electrocardiogram (ECG or EKG)</b>	<b>Page 2 of 6</b>

minutes. The procedure is painless, but you may have some redness or itching afterwards where the pads are placed. If you have a lot of hair where the electrode pads are placed, we may need to shave small areas to make sure the pads stick well to your skin. There is a small chance you could have some skin irritation where you are shaved.

c. *Brief description of the technique or procedure that would be used in the Parental Consent Form.*

An electrocardiogram (sometimes called an ECG or EKG) is a test that provides a measure of the electrical activity in your child's heart. Your child will be asked to lie flat on a table, and 10 small electrode pads, like stickers, will be placed on the skin of your child's chest, arms, and legs. If any artifact (like static) occurs, some electrodes may need to be repositioned to ensure a clear recording of your child's heart. The test takes about 10 minutes. The procedure is painless, but your child may have some redness or itching afterwards where the pads are placed. If your child has a lot of hair where the electrode pads are placed, small areas may need to be shaved to make sure the pads stick well to your child's skin. There is a small chance of skin irritation where your child is shaved.

d. *Brief description of the technique or procedure that would be used in the Assent Form.*

We will do a test of how your heart is working called an ECG or EKG. The test lets us get a picture of how your body makes your heart beat. This test won't hurt at all, but we will have to put stickers with wires on your chest, arms, and legs during the test. If you have a lot of hair where the stickers are placed, small areas may need to be shaved to make sure the stickers stick to your skin, but this should not hurt. If any artifact (like static) occurs, some stickers may need to be moved. The test takes about 10 minutes. You may have some redness or itching where the stickers were placed or where we shaved your skin.

e. *Confirm the target age range for the technique or procedure, as needed.*

This SOP is for individuals three years of age and older.

**Definitions**

Electrocardiogram (ECG): A 12 lead ECG is a noninvasive procedure that is used to ascertain information about the electrophysiology of the heart.

**RESPONSIBILITY**

The Principal Investigator (PI) is responsible for ensuring the standard 12 lead ECG is recorded according to protocol. The PI or delegated study staff will refer to the protocol to ensure specific requirements for obtaining a 12 lead ECG reading are identified. This

Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures		
SOP #104 Revision #	TITLE: Resting Electrocardiogram (ECG or EKG)	Page 3 of 6

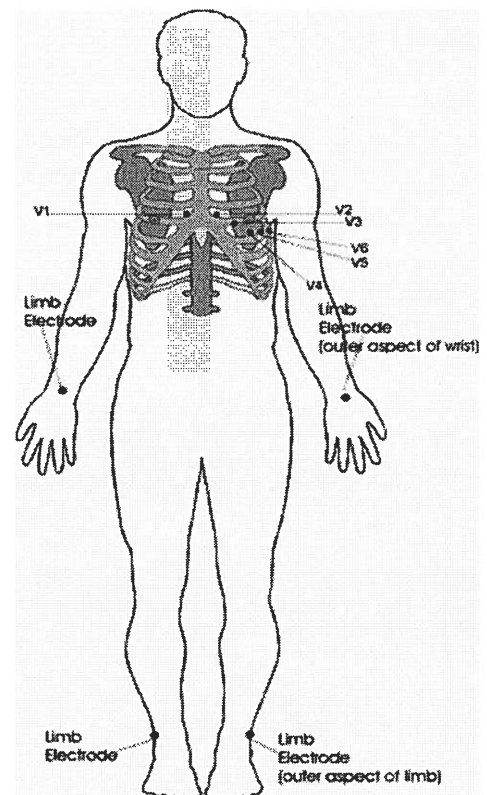
may include the use of a specific machine solely for individual study use. In this case, the PI or sponsor will dictate the ECG procedure. If nothing is specified in the protocol, then the PI or delegated person should follow the procedure below.

## PROCEDURES

- a. *Detailed description of the list of steps needed to use the technique or complete the procedure.*
  1. Assemble all equipment required (ECG machine, leads, paper, electrodes) and ensure it is clean and appears to be in good working order.
  2. Ask the participant to remove any clothing that may restrict access to the upper body or limbs and ask them to lay down in a comfortable position.
  3. Turn on the ECG machine. If the machine has a self-test capability, wait for the self-test to be performed.
  4. Enter the participant details and study-specific data into the ECG machine as outlined in the study protocol.
  5. Attach the ECG electrodes to the chest and limbs; if necessary, skin should be prepared by cleaning with an alcohol wipe or shaving to ensure good contact.
  6. Attach the ECG cables to the electrodes in the correct order. The tab electrodes are to be used. They should be placed on to the patient and the limb leads then connected.

### Lead Placement:

- V1: In the 4th intercostal space to the right of the sternum
- V2: In the 4th intercostal space to the left of the sternum
- V3: In the interval between lead 2 and 4
- V4: In the 5th intercostal space on the mid-clavicular line
- V5: Straight across from lead 4 on the anterior axillary line
- V6: Straight across from lead 4 on the mid axillary line
- RA: On the right arm, avoid thick muscle
- LA: In the same location where RA was placed, but on the left arm
- RL: On the right leg, lateral calf muscle
- LL: In the same location where RA was placed, but on the left leg



<b>Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures</b>		
<b>SOP #104 Revision #</b>	<b>TITLE: Resting Electrocardiogram (ECG or EKG)</b>	<b>Page 4 of 6</b>

**DIAGRAM 1: Electrode Placement**

7. Instruct the participant to relax and remain as still as possible for the ECG recording to take place.

8. Wait 10 seconds and observe the tracing displayed in the ECG display screen to ensure good electrode contact identified by a good tracing. The screen should also be observed for any error messages that may be displayed. If not satisfactory due to static or artifact, remove the corresponding electrodes demonstrating the artifact, clean the area again and replace the electrode for a clearer recording.

9. Review the recording and if it is satisfactory remove the ECG electrodes from the participant and ask them to get dressed.

10. Ask the appropriate person to review the recording if they are not qualified to do so themselves. The qualified staff must sign and date ECG.

11. Document that the ECG recording has been performed on the relevant study source data, the case report form and in the participant's medical notes.

12. Dispose of the used electrodes in to waste bin and any razor used into a sharps container if used.

- a. *Description of calibration steps needed to check the performance of the device or instrument and documentation that it is maintained.*

Calibration and inspection should be performed according to the manufacturer's directions.

- b. *Description of cleaning needed to maintain and / or sterilize the device or equipment.*

Cleaning should be done according to the manufacturer's directions.

- c. *Brief summary of the procedure that would be used for the Project Outline Form.*

Electrodes will be placed on the participant's chest, arms, and legs in standard locations. The participant will be instructed to relax and remain still for the duration of the procedure. The tracing will be obtained and the operator will make sure the tracing is without artifact. If any artifact occurs, some electrodes may need to be repositioned to ensure a clear recording of the heart. Electrodes will be removed from the participant. The tracing will be given to the PI or delegated person for interpretation.

**Ohio University Office of Research Compliance and Institutional Review Board  
Standard Operating Procedures**

**SOP #104  
Revision #**

**TITLE: Resting Electrocardiogram  
(ECG or EKG)**

**Page 5 of 6**

- d. *Brief summary of the procedure that would be used for the Consent Form.*  
An electrocardiogram (sometimes called an ECG or EKG) is a test that lets us get a picture of how your body makes your heart beat. You will be asked to lie flat on a table, and 10 small electrode pads, like stickers, will be placed on the skin of your chest, arms, and legs. If any artifact (static) occurs, some electrodes may need to be repositioned to ensure a clear recording of the heart. The test takes about 10 minutes. The procedure is painless, but you may have some redness or itching afterwards where the pads are placed. If you have a lot of hair where the pads are placed, we may need to shave small areas to make sure the pads stick well to your skin. There is a small chance you could have some skin irritation where you are shaved.
- e. *Brief summary of the procedure that would be used for the Consent Form.*  
An electrocardiogram (sometimes called an ECG or EKG) is a test that provides a measure of the electrical activity in your child's heart. Your child will be asked to lie flat on a table, and 10 small electrode pads, like stickers, will be placed on the skin of your child's chest, arms, and legs. If any artifact (static) occurs, some electrodes may need to be repositioned to ensure a clear recording of your child's heart. The test takes about 10 minutes. The procedure is painless, but your child may have some redness or itching afterwards where the pads are placed. If your child has a lot of hair where the electrode pads are placed, small areas may need to be shaved to make sure the pads stick well to your child's skin. There is a small chance of skin irritation where your child is shaved.

**RISK**

- a. *Description to be used for the Project Outline Form.*  
Risks include possible redness and itching at the sites of electrode placement, and possible minor skin irritation secondary to shaving.
- b. *Description to be used for the Consent Form.*  
The procedure is painless, but you may have some redness or itching afterwards where the pads are placed. If you have a lot of hair where the pads are placed, we may need to shave small areas to make sure the pads stick well to your skin. There is a small chance you could have some skin irritation where you are shaved.
- c. *Description to be used for the Parental Consent Form.*  
The procedure is painless, but your child may have some redness or itching afterwards where the pads are placed. If your child has a lot of hair where the electrode pads are placed, small areas may need to be shaved to make sure the

<b>Ohio University Office of Research Compliance and Institutional Review Board Standard Operating Procedures</b>		
<b>SOP #104 Revision #</b>	<b>TITLE: Resting Electrocardiogram (ECG or EKG)</b>	<b>Page 6 of 6</b>

pads stick well to your child's skin. There is a small chance of skin irritation where your child is shaved.

### **REFERENCES**

Potter, P.A., & Perry, A. G. (Eds.). (2009). Fundamentals of nursing (7th ed.), p. 909. St. Louis, MO: Mosby.

### **SUBMITTER**

Please note that the name of the submitter of the SOP is provided for a reference for follow-up, as needed.

Lee Ann Williams, MEd, CCRP, Associate Director, Clinical Research Operations, Clinical & Translational Research Unit, Ohio University Heritage College of Osteopathic Medicine.