1. Date and Time of ECG: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)
2. Ventricular rate / Heart rate (beats per minute)
3. PR interval (milliseconds):
4. QRS duration (milliseconds):
5. QT interval (milliseconds):
6. QTc interval (milliseconds):
7. ECG results (Choose one):

Normal

Abnormal, not clinically significant

Abnormal, clinically significant

Unable to evaluate

1. Heart Rhythm:

Normal sinus rhythm

Sinus tachycardia

Sinus bradycardia

Supraventricular tachycardia

Atrial arrhythmia, specify type

Atrial fibrillation

Atrial flutter

Ventricular arrhythmia,

specify type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ventricular fibrillation

Ventricular tachycardia

Other, specify:

1. ST segment abnormality:

Absent

Present

1. T wave abnormality:

Absent

Present

1. Right ventricular hypertrophy:

Absent

Present

1. Left ventricular hypertrophy:

Absent

Present

1. Patterns of previous myocardial infarction:

Absent

Present

1. Patterns of complete bundle branch block:

Absent

Present

## **General Instructions**

An electrocardiogram (ECG) is often used during the screening visit of a study to evaluate a participant’s/subject’s cardiac health and determine whether the participant/subject is eligible for the study. Follow up ECGs may be performed to continue to monitor the participant’s/subject’s heart rhythms over the course of the study.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are supplemental and should be collected only if the research team considers them appropriate for their study.

## **Specific Instructions**

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* Data and time ECG performed – Record the date (and time) the electrocardiogram (ECG) was performed. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Ventricular rate/ Heart rate – Record the ventricular rate/ heart rate in beats per minute.
* PR interval – Measure and record the PR interval in milliseconds (msec).
* QRS duration – Measure and record the QRS duration in milliseconds (msec).
* QT interval – Measure and record the QT interval in milliseconds (msec).
* QTc interval – Measure and record the QTc interval in milliseconds (msec).
* ECG results – Choose the response that best describes the overall ECG results.
* Heart rhythm – Choose all that apply. If 'Normal sinus rhythm' is chosen no other values can be chosen.
  + Atrial arrhythmia type – Choose all that apply.
  + Ventricular arrhythmia type – Choose all that apply.
* ST segment abnormality – Choose one.
* T wave abnormality – Choose one.
* Right ventricular hypertrophy – Choose one.
* Left ventricular hypertrophy – Choose one.
* Patterns of previous myocardial infarction – Choose one.
* Patterns of complete bundle branch block – Choose one.