Subject Number:	**Subject Initial**	

CASE REPORT FORM

Study No. ERIS/OS/ Version No.: 00 Dated:

Investigator Name :

Site Name and Address :

SITE NO :

Subject ID :

General instructions for CRF filing

- Entries in the CRF are to be made using Black ink ballpoint pen (preferably).
- Ensure all the entries are to be made accurately, legible, and verifiable with the source data.
- In case of corrections:
  - Do not over write or erase
  - Do not use corrections materials (Whiteners, cello tapes, bleaching).
  - Delete the incorrect entry with single line over it without obscuring original entry text, write the correct information nearby with dated sign if required, and explain reason for correction.
  - Dates should be recorded (preferably) as DD/MMM/YYYY.
  - Enter 3 letters Subject initials considering first letter of First Name/ Middle Name /Last Name (e.g. SKN for Suresh Krishna Nagraj). In case of absence of middle name, initial should be written as first 02 letters of First name and first letter of Last Name (e.g. SUN for Suresh Nagraj).
- Acceptable abbreviations are the following:
  - Unknown: UNK, Not Done: ND & Not Applicable: NA, Not Available-Not available
- Wherever required, always use "√" a tick mark symbol for choosing the appropriate answer.
- For Inclusion and Exclusion Criteria, put "√" in YES/NO column, as applicable.
- Avoid the use of symbols or abbreviations for medical terminologies.
- Please do not leave any fields blank. The answer to any question if not known or unavailable mention "Unknown" or UNK or not available and if not applicable mention NA.
- Any errors should be stricken out with a single line so that original entry is not obscured; the new entry made above or adjacent should be dated signed.
- Enter Site Number according to the number/instruction provided by Sponsor/Sponsor's representative.

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- Assign 10 digits Subject ID number in chronological order serially. Among ten-digit number, first eight digits stand for site number and last two digits for serial no. of subject at a particular participant hospital. E.g. for Site Number 00000001, Subject ID will be e.g. 0000000101, 0000000102, 0000000103, etc.

Visit Type: Enrollment/Follow up visit **Visit Date:** | | | | | | | | | |

Written Informed Consent taken : **YES** ☐ **NO** ☐

Demographics/ Anthropometric Assessment

- Always mention age in completed years

Age (years)	
Gender	**Male** ☐ **Female** ☐ **Others** ☐
Height (in cm)	_____**cm**
Weight (in kg)	_____**kg**
BMI (kg/m^2)	_____**kg/m^2**
Waist Circumference (cm)	_____ **cm**
State	_____
City/District	_____
Contact No.	

Lifestyle Factors: (Please mark √ in the relevant boxes)

Sr. No.	Lifestyle factor(s)		Present (Yes/No)		
1	**Alcohol Consumption**		Yes [ ]	No [ ]	
	If yes, since _____years				
	If yes, During past 12 months ; how frequently have you had at least one alcoholic drink?				
	Quantity	30 ml	30 – 60 ml	More than 60 ml	
	Frequency	Daily [ ]	Weekly [ ]	Monthly [ ]	
2	**Tobacco Consumption**		Yes [ ]	No [ ]	
			If yes, since _____years		
3	**Smoking**		Yes [ ]	No [ ]	
			If yes, since _____years		
	Number of cigarettes per day		> 20 [ ]	10-20 [ ]	<10 [ ]

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4	**Dietary Habits**	Vegetarian [ ]	Non-vegetarian [ ]	Vegan [ ]

Family History: (Please mark √ in the relevant boxes)

Sr. No.	Family history	Present -Yes/No		On Treatment	
1	Cardiovascular events	Yes [ ]	No [ ]	Yes [ ]	No [ ]
2	Hypertension	Yes [ ]	No [ ]	Yes [ ]	No [ ]
3	Dyslipidemia	Yes [ ]	No [ ]	Yes [ ]	No [ ]
4	Diabetes	Yes [ ]	No [ ]	Yes [ ]	No [ ]
5	**Any other (Please Specify)**				

Subject Number:		**Subject Initial**	

Medical History: (Please mark √ in the relevant boxes)

Co-morbid conditions	Lab Investigations*	Present [Yes/No]		If Yes, since how many years
Diabetes Mellitus	HbA1c (%)	Yes [ ]	No [ ]	
Hypertension	SBP____DBP_____ (mmHg)	Yes [ ]	No [ ]	
Dyslipidemia**	TC_____, HDL-C____ , LDL-C_____(mg/dl),	Yes [ ]	No [ ]	
Obesity (BMI ≥25kg/m^2)		Yes [ ]	No [ ]	
Chronic Kidney Disease		Yes [ ]	No [ ]	
Rheumatoid Arthritis		Yes [ ]	No [ ]	
Any other (Please Specify)				

*** Mention last 3 months' lab reports**

**** Required**

Medication History (Please mark √ in the relevant boxes)

Ongoing Hypertension therapy	Yes [ ]	No [ ]
Ongoing Diabetes therapy	Yes [ ]	No [ ]
Ongoing Dyslipidemia therapy	Yes [ ]	No [ ]
Any other (Please Specify)		

Subject Number:	**Subject Initial**	

Eligibility Criteria:

Inclusion Criteria			
Sr. No.	**Inclusion Criteria (Please mark √ in the relevant boxes against each inclusion criteria)**	**YES**	**NO**
1	Adult Men or Women aged ⩾ 40 years	☐	☐
2	Asymptomatic subjects with aleast 3 CV risk factors visiting to the OPD for routine clinical checkup	☐	☐
3	Symptomatic subjects with suspected CVD visiting to the OPD for further assessment	☐	☐
4	Subjects willing to provide written informed consent form	☐	☐

Sr. No.	**Exclusion criteria (Please mark √ in the relevant boxes for each exclusion criteria)**	**YES**	**NO**
1	Subjects with Implanted devices like pacemaker, external cardiac defibrillator	☐	☐
2	Subjects with known CVD (Arrhythmias, MI, Angina, Stroke, Peripheral Artery Disease, CHF etc.)	☐	☐
3	Pregnant women	☐	☐

Note: If any of the Exclusion criteria marked as "YES" and/or Inclusion criteria as "NO", then, the patient will not be eligible for the study.

KardiaMobile ECG test

Reason for recommendation of ECG	**Asymptomatic patients with High CV risk (Presence of atleast 3 risk factors given below) (Please mark √ in the relevant boxes)** 1. Age ≥40years ☐ 2. Hypertension ☐ 3. Diabetes☐ 4. Tobacco Use (Chewing/Smoking)☐ 5. Obesity (BMI ≥25kg/m^2)☐ 6. Dyslipidemia ☐ 7. CKD☐ 8. Family History of ASCVD (MI, Stroke, CAD, PAD)☐ 9. Waist Circumference (≥ 90 cm in male & ≥80 cm in female)

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	10. Any others ☐ **Symptomatic patients with suspected CVD: (Please mark √ in the relevant boxes)** 1. Chest Pain ☐ 2. Syncope ☐ 3. Palpitation ☐ 4. Shortness of breath ☐ 5. Dizziness or Light headedness ☐ 6. Weakness or Fatigue ☐ 7. Nocturnal Symptoms (Palpitations, Chest Pain, Shortness of breathe ☐ 8. Post-prandial Symptoms (Chest Pain) ☐ 9. Diaphoresis (Excessive Sweating) ☐ **10.** Any other if investigator thinks _____

Investigator's Interpretation					
Timeline	**ECG Record Date**	**ECG Abnormality (Yes/No) (Please mark √ in the relevant boxes)**		**If yes, please describe the abnormalities**	**Occurrence of any event (please specify) *(Stable Angina, MI, Stroke, Left Ventricular Dysfunction, Any other)***
1. Baseline		Yes[ ]	No [ ]		
2. At 12 month (1st year)		Yes[ ]	No [ ]		
3. At 24 month (2nd year)		Yes[ ]	No [ ]		
4. At 36 month (3rd year)		Yes[ ]	No [ ]		
5. At 48 month (4th year)		Yes[ ]	No [ ]		
6. At 60 month (5th year)		Yes[ ]	No [ ]		

ECG reports to be uploaded individually in pdf during each timeline:

Recorded by Investigator (Name with Dated Sign): _____

Co-Investigator's Interpretation*

Subject Number:	**Subject Initial**	

Timeline	ECG Abnormality (Yes/No) (Please mark √ in the relevant boxes)		If yes, please describe	Intervention based on ECG abnormality
1. Baseline	Yes[ ]	No [ ]		
2. At 12 month (1st year)	Yes[ ]	No [ ]		
3. At 24 month (2nd year)	Yes[ ]	No [ ]		
4. At 36 month (3rd year)	Yes[ ]	No [ ]		
5. At 48 month (4th year)	Yes[ ]	No [ ]		
6. At 60 month (5th year)	Yes[ ]	No [ ]		

***Co-investigator will be blinded with screen results and Investigator's interpretation**

Reviewed and approved by Co-investigator (Name with Dated Sign): _____

Dropout if any:

Months	No. of patients	Reason of drop out
1. 12 month (1st year)		
2. At 24 month (2nd year)		
3. At 36 month (3rd year)		
4. At 48 month (4th year)		
5. At 60 month (5th year)		