Survey Form

Atrial Fibrillation (AF) Detection With Wearable Device Enabled Continuous ECG Monitoring: A Clinical Study To Investigate The Receptiveness, Accuracy And Feasibility

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Name of site: NUH
DCF Version Number: 02
Date: 04/10/2018

DCF Completion Instructions

General

Complete the DCF using a **black or blue ballpoint pen** and ensure that all entries are complete and legible.

Avoid the use of abbreviations and acronyms.

Do not use subject identifiers anywhere on the DCF, such as name, date of birth etc., in order to maintain the confidentiality of the subject. Ensure that the header information (i.e. subject's ID number) is completed consistently throughout the DCF.

Each DCF page should be signed and dated by the person completing the form.
The 'completed by' Name in the footer of each page must be legible and **DCFs should only be completed by individuals delegated to complete DCFs on the Site Delegation log (and signed by the PI).**

Ensure that all fields are completed on each page:

- If a test was Not Done record **ND** in the relevant box(es)
- Where information is Not Known write **NK** in relevant box(es)
- Where information is not applicable write **NA** in the relevant box(es)

Corrections to entries

If an error is made, draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the DCF and initial and date the change.

Do NOT

- Obscure the original entry by scribbling it out
- Try to correct/ modify the original entry
- Use Tippex or correction fluid

Complete all **dates** as day, month, year i.e. 13/02/2015. Partial dates should be recorded as 13/FEB/2015.

All **times** are to be recorded in 24 hour format without punctuation and always use 4-digits; i.e. 0200 or 2130. Midnight is recorded as 0000.

Weights should be recorded to the nearest 0.1 kg.

If a subject prematurely withdraws from the trial a single line must be drawn across each uncompleted page.

The Principal Investigator is responsible for the accuracy of the data reported on the DCF. The CI/PI must sign and date the Principal Investigator's Sign Off page to certify accuracy, completeness and legibility of the data reported in the DCF.

DEMOGRAPHIC DATA

Date of Study Participation: __ __ / __ __ __ / __ __ __ __

(DD / MMM / YYYY)

Demographic Data:				
Age: ___ ___ years				
Ethnicity:				
Chinese ☐	Malay ☐	Indian ☐	Eurasian ☐	Other ☐ (please specify)
Sex: ☐ Male ☐ Female				
Height: ___ ___ ___ cm				
Weight: ___ ___ ___ kg				

DEVICE IDENTIFICATION

Device ID: _____ Phone ID: _____

5 mins after ECG Installation on Patient

Time of Installation: __ __ __ __

Patient's response	
ECG	Heart Rate (bpm): _____
Battery Life	Battery Status (Green/Yellow/Red): _____
ECG Display	YES\NO

Patient Survey After Data Collection

Are you comfortable wearing this device? Please rate (circle) for your receptiveness in score.	*(Less comfortable)1 2 3 4 5 6 7 8 9 10 (Comfortable)*
What is your rating for the weight of this device?	*(Heavy) 1 2 3 4 5 6 7 8 9 10 (Light)*
What is your rating for the thickness of this device?	*(Thick) 1 2 3 4 5 6 7 8 9 10 (Thin)*
What is your rating for the contact area of this device?	*(Large) 1 2 3 4 5 6 7 8 9 10 (Small)*
Is this device easy to operate?	*(Difficult) 1 2 3 4 5 6 7 8 9 10 (Easy)*
Does the attached device affect your normal daily routine?	*(Yes) 1 2 3 4 5 6 7 8 9 10 (No)*
Is this device easy to attach on your body if you were to apply it by yourself?	*(No) 1 2 3 4 5 6 7 8 9 10 (Yes)*
Do you think this device visible or noticeable to others?	(Noticeable*) 1 2 3 4 5 6 7 8 9 10 (Not* noticeable*)* *Maybe / Don't know*
Would you participate continuous monitoring for one week?	*(No) 1 2 3 4 5 6 7 8 9 10 (Yes)*
Would you spend time learning how to use a new wearable device?	*(No) 1 2 3 4 5 6 7 8 9 10 (Yes)* *Maybe / Don't know*
What is your comfortable range for continuous monitoring within 24 hours?	(1 Hour*) 1 2 3 4 5 6 7 8 9 10 (24 Hour)* *Maybe / Don't know*
How many hours later did you notice or felt that the device is no longer attached on your body?	*Half Hour / 1 Hour / 2 Hour / 4 Hour* Others: _____
Rank the importance from 1 to 4 as this will be important for our next design.	___ *Weight* ___ *Thickness* ___ *Area* ___ *Obstruction to body movements*
Any comments or feedback?	

INCIDENCE REPORTING

Early Withdrawal: please tick the most appropriate reason for participant not completing the trial:

☐ **Adverse Events related, specify:** _____

☐ **Participant's decision, specify:** _____

☐ **Investigator's decision, specify:** _____

Description of Incidences or Adverse Events NOT leading to early withdrawal