Ethics UID:	H15672
Title:	Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)
CI/PS:	Gaetano Gargiulo
Student:	

Please refer to the guidance document titled, *Guidance on Receiving and Responding to Ethics Committee Assessor Comments*, when formulating your response.

Please include the actual text of the changes you have made in any of the documents where relevant, as well as any justification needed to assist the committee in understanding your response i.e. It is not sufficient to say "see HREA form", actual text of your response must be included.

Summary of Application Issues and Responses

Issue Type	General comments
Issue Description	Thanks for submitting the response for review by the Executive committee. Your response has generated further queries. Could you consider the feedback below (in red) and send us the revised application? Your response will be reviewed by the ethics officer.
Researcher Response	
Review Comments	

Issue Type	General comments
Issue Description	Thanks for submitting the response for review by the Executive committee. Your response has generated further queries. Could you consider the feedback below (in red) and send us the revised application? Your response will be reviewed by the Executive committee.
Researcher Response	Please find our response in the appropriate field. Thank you
Review Comments	

Issue Type	General comments
Issue Description	Thank you for submitting an application for review by the HREC. Can you please consider the feedback below before submitting a revised application? Your responses will be reviewed by the Executive.
Researcher Response	Thank you for the time spent reviewing the application, we have addressed the concerns/comments as requested, details have been pasted in each field and noted with the "track changes on" on the relevant documents accompanying this submission.
Review Comments	

Issue Type	General comments

Issue Description	The reviewers have suggested that this project may not be a clinical trial, although health related outcomes are being collected, there is a lack of intervention. If the researchers consider that this study is a clinical trial then a protocol needs to be provided.
Researcher Response	As the reviewers have indicated, there is no direct intervention driven by this specific test, hence, there is no intervention section on procedure included in the Project description. However, this is a comparative trial of devices where the device under trial is compared against approved gold standard in "healthy" cohort. This trial is to support our approved and undergoing clinical trial for the same device on "un-healthy" (cardiac failure) cohort. The capability of the device to represent both "healthy" and "un-healthy" features such as the well-known dicrotic notch used to screen peripheral blood vessel diseases (so far 25% of the patients have been recorded and we have found that this is absent also on the gold standard). For the purpose of this review, we have compiled a detailed protocol and study plan, see document 20230811_FSRvsPiezo-CIP_v1.docx.
Review Comments	

Issue Type	Disclosure of Interests
Issue Description	HREA Q1.10.2 There are some errors in the response about Dr Gunawardana. Please clarify what the relationship of Dr Gunawardana is with Prof Gargiulo and Prof Breen?
Researcher Response	We apologies for the oversight. We have modified the relevant section of GG00049v01_01-Output form as: Data analysis and integrity of the findings will be evaluated by Dr. Gunawardana who has no financial or non-financial interests related to this research and or with Professors Gargiulo and Breen. Dr. Gunawardana will be also in charge of selecting the database that will be made publicly available. Data, once published, will be fully available to other researchers to conduct independent research. The document is supplied as attachment with the track-changes tool turned ON as requested
Review Comments	

Issue Type	Disclosure of Interests
Issue Description	Sites and Methodology Project Description 5.1 Please provide more information on where the study will occur on the campuses. There seems to be very little detail provided.
Researcher Response	We apologies for the oversight. We have modified the relevant section of the project description as: We intend to recruit and record the data at Western Sydney University Kingswood campus and Westmead campus. The recording setup is portable (laptop and small acquisition device composed by the BIOPAC MP36 and a small, dedicated sensor plugged to the MP36 directly), it requires only some desk space and a comfortable chair for the participant to seat in for the duration of the recording. We intend to use

	one of the "hot offices" at Kingswood campus as well as one of the dedicated human physiology labs (available for booking) at Wesmead campus. The document is supplied as attachment with the track-changes tool turned ON as requested
Review Comments	

Issue Type	Disclosure of Interests
Issue Description	HREA 1.15 – it appears that the study will take place on two campuses.
Researcher Response	
Review Comments	WSU is a multicampus structure, principal investigators are scattered across the campuses, specifically: Prof. Gargiulo is at Kingswood, Prof. Breen at Westmead and Dr. Gunawardana is at Parramatta City. Of the three locations, investigators have agreed that Westmead and Kingswood are the most convenient locations with the preference for Westmead (due to the dedicated lab that can be booked for multiple days at the time). For this reason, while we expect that most of the recordings will happened at Westmead, due to the large cohort of students attending the Kingswood campus particularly during the semester, we cannot exclude that some of the recordings will happen at the Kingswood campus.

Issue Type	Recruitment
Issue Description	Project Description 6.11 and HREA 2.1.1 and 2.1.2. Please provide more information. This is identical in both sections. It appears likely that Chief Investigator will be interacting with potential participants directly so it is unclear how coercion can be avoided. Especially as the researchers do have significant conflict of interest given their shareholder status in the company.
Researcher Response	
Review Comments	We apologise for the confusion. There will be no direct interaction or coercion by chief investigators. Interaction will happen only if a potential participant contacts a member of the research staff expressing intention to participate and/or to seek clarification. To remove the confusion, we have modified the Project description 6.11 as following: • Participants will be recruited by the Principal Investigator at either site through student internal email lists, poster affixed in public advertisement boards on campus and word of mouth e.g by student themselves that have been received/read the flyer. • Potential participants who approach a member of the research staff seeking further clarifications, will be advised about the study procedure, as to what the study entails, and any questions will be answered. • Research staff will then pre-screen potential participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study using hard copies of the PICF. • It is estimated that the study will take <30 minutes to complete. • We plan to offer the participants a $30 supermarket voucher.

	The document is supplied as attachment with the track-changes tool turned ON as requested. Similarly, we have modified HREA 2.1.1 as follow: • Participation to the study is voluntary. • Participants will be recruited by the Principal Investigator at either site through student internal email lists, poster affixed in public advertisement boards on campus and word of mouth e.g by student themselves that have been received/read the flyer. • Potential participants who approach a member of the research staff seeking further clarifications, will be advised about the study procedure, as to what the study entails, and any questions will be answered. • Research staff will then pre-screen potential participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study using hard copies of the PICF. • It is estimated that the study will take <30 minutes to complete. • We plan to offer the participants a $30 supermarket voucher. As well as the section 2.1.2 as follow: Participation to this study is voluntary. For this study, we target a healthy cohort (whereas healthy is defined as "never been diagnosed with a cardiovascular disease"). Any potential participant approaching the research team expressing intent to participate will be screened against the selection criteria and made aware that participation in the study does not offer a medical result/diagnosis. The document is supplied as attachment with the track-changes tool turned ON as requested.

Issue Type	Consent
Issue Description	Project Description 8.1 Please explain why the researchers have chosen unspecified consent?
Researcher Response	"unspecific consent" has been selected due to the need to utilise the collected signals in conjunction with the data collected during the ongoing "patient cohort" clinical trial. In addition, according to the HREA instructions, as we plan to release the waveform database into publicly available physiological databanks (e.g. Physionet), this is the current type of consent to seek: "**Unspecified consent** should be selected when there will be a need to use data or tissue in any future research. This also includes permission to enter original data or tissue into a data/tissue bank and needs to be clearly outlined to participants"
Review Comments	

Issue Type	Risk

Issue Description	Project Description 6.14, HREA 2.3.1 and 2.3.2 and Participant Information Sheet – What would happen with any abnormal findings in the 'healthy volunteers' if you are not interpreting the results of the ECG. This also needs to be made clear as participants will think this is a way of checking their heart. (This will also need to be included in a protocol).
Researcher Response	To avoid issues the Project Description 6.14 has been modified as follow: • Skin reaction/irritation due to the application to sensors – this is low risk as the sensors have already been used in a clinical trial in a hospital and/or are disposable (ECG electrodes). • Because this research is not medical/clinical test but rather a device test, it will be specifically explained to the prospective participant that participation in this research is not a mean to assess their heart/circulation as waveforms will not be clinically interpretated. The document is supplied as attachment with the track-changes tool turned ON as requested. Similarly, the statement section HREA 2.3.2 as been modified as follow: Risk associated, outlined above, will be disclosed to the prospect participant during the consenting procedure. In addition will be clarified to the prospective participant that Because this research is not medical/clinical test but rather a device test, it will be specifically explained to the prospective participant that participation in this research is not a mean to assess their heart/circulation as waveforms will not be clinically interpretated. The document is supplied as attachment with the track-changes tool turned ON as requested.
Review Comments	Project Description 6.14, HREA 2.3.1 & 2.3.2 & Participant information sheet The committee has acknowledged that the new method of measurement may not be easily understood by clinicians, which is why the research team has amended their explanation to the participants. However, the committee needs further clarification from the research team on whether the new method of assessment is being compared to established measures that are clinically interpretable. If this is the case, healthy volunteers may be assessed using both methods and could potentially be diagnosed as unhealthy based on the more established measures. In such a scenario, it is important that a protocol is provided by the research team for reviewing the gold standard measures to identify any possible adverse findings in healthy volunteers who may encounter difficulty during the assessment.
Researcher Response	Once again, the researchers would like to thank the reviewing panel for the valuable comments. Regarding your query, with this trial the new sensor is not compared against established measures that are clinically considered a gold standard to formulate diagnosis. However, in the eventuality that the ECG or PPG waveforms displayed during the recording should look evidently abnormal e.g. missing dicrotic notch in the PPG or irregular heart-beat in the ECG, the participant

	will be recommended to consult her/his GP and the PDF of the waveforms will be made available to the participant.
Review Comments	Project Description 6.14, HREA 2.3.1 & 2.3.2 & Participant information sheet - Please ensure that the researcher/s include these details in the Participant Information Sheet and present them in a clear and concise manner for all participants to understand. An updated participant information sheet should be submitted for review.
Researcher Response	Please find attached the requested modified documents.
Review Comments	

RESEARCH SERVICES | ETHICS AND INTEGRITY | Human Research Ethics | WESTERN SYDNEY UNIVERSITY

Project Description

To be submitted with a human research ethics application (HREA)

IMPORTANT

You must attach the project description to your online HREA before emailing the completed application to humanethics@westernsydney.edu.au.

The Project Description is the first form that the Human Research Ethics Committee will read. It is there to provide the committee with the context, scientific and academic background to your Human Research Ethics Application (HREA). It should be written in Plain English, using non-technical terminology so that committee members from non-academic backgrounds are able to understand your project. It should be written alongside your HREA and together the forms should give the committee insight into how you are dealing with ethical issues that might arise in your proposed project. The HREC may also review the research merit of your application through an expert drawn from outside the committee.

A brief definition should follow any technical term(s) that need to be included in your application. A glossary of terms should precede the background section if your application needs to include multiple technical terms. Your Project Description (without attachments A or B) should be no longer than 10 pages in length.

A guidance document has been developed to assist in completing this form.

Please contact the Human Research Ethics Officers if you are unsure about your requirements humanethics@westernsydney.edu.au

If you are unable to use the tick boxes on this template, please delete the option/s which do not apply.

Section 1: Overview

1.1.	Project Title:	Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)
1.2.	Project Acronym or short title (if applicable):	
1.3.	Version Number:	1
1.4	Does this project already have funding logged with the Grants Services team?	☒ Yes ☐ No
	If yes, what is the Project ID allocated by Research Services? (eg **P00012345):** (This information enables us to link your funding to your ethics approval)	P00027727

Section 2: Western Sydney University School or Institute approval

2.1.	Which Institute/School/Centre will be administering this project?	School of Engineering, Design and Built Management
2.2.	If your Institute/School/Centre has a requirement that human research projects are reviewed or agreed to before an ethics application comes to the ethics committee, has this occurred? See Guidance sheet for more information.	☐ Yes ☒ No ☐ NA

Section 3: Project Team Named in the HREA

(Provide names only. Additional details should be included in HREA Q1.9)

3.1.	Chief Investigator / Principal Supervisor:	Professor Gaetano Gargiulo
3.2.	Chief Student (if applicable):	
3.3.	Other Investigators/Supervisors:	Dr. Upul Gunawardana, Research Assistant, Prof. Paul P. Breen
3.4.	Other Students:	

3.5. Role/s yet to be assigned (e.g. future Research Assistant):

3.6. Will students be added to this project in the future? ☐ Yes ☒ No

If yes, what degree program will they be enrolled in, and what will their role/s be on the project? Will they be working on activities that are documented in this application, or

Section 4: Background (Limit to 500 words for all of section 4. Overly long entries will be returned to the researcher for editing.)

This section corresponds to Q1.2 in the HREA. The two sections can be written together whereby elements of the summary included the HREA form can be copied into the section here.

4.1. Literature Review (include citation details):

In the past 3 years, in collaboration with a sponsor industry partner we developed a novel wearable non-invasive sensor capable of detecting the small forces impressed to the skin by moving organs/vessels/muscles lying under the sensor, this sensor when placed over the heart or over a vessel has been named Forcecardiography sensor [Centracchio J, Andreozzi E, Esposito D, Gargiulo GD, Bifulco P. Detection of Aortic Valve Opening and Estimation of Pre-Ejection Period in Forcecardiography Recordings. Bioengineering. 2022; 9(3):89. https://doi.org/10.3390/bioengineering9030089]. There is an unmet need for new technologies that can improve the management of cardiovascular disease, and many researchers are trialing sensors which are not electrical (e.g. inertial, piezoelectric etc...) to replace/aid the traditional ECG in patient prognosis/assessment [Inan, O.T.; Migeotte, P.F.; Park, K.S.; Etemadi, M.; Tavakolian, K.; Casanella, R.; Zanetti, J.; Tank, J.; Funtova, I.; Prisk, G.K.; et al. Ballistocardiography and Seismocardiography: A Review of Recent Advances. IEEE J. Biomed. Health Inform. 2015, 19, 1414–1427]. Differently from the available sensors, the Forcecadiography sensor is small enough and sensitive enough to detect signals from fingers [Sponsor unpublished material].

4.2. Rationale/Justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice):

The sensor, placed over chest, neck, iliac crest and fingers is currently at trial in two major hospitals (approved by Alfred Hospital Ethics Committee with protocol number: HREC/90385/Alfred-2022, notified to WSU human ethics office in June 2023) where it is compared against gold standard such as: right-heart catheterization, ECG, Doppler (valves and chambers motility), PPG, non-invasive blood pressure as well as bodily sounds. With this trial we aim to recruit healthy (never diagnosed with cardiovascular diseases) participants to compare signals from the finger versus ECG and PPG. Specifically, we aim to:

1) Measure and compare (healthy versus patient) the delay between the R-peak (ECG signal) and the peak pulse force measured at the finger pad.
2) Assess the Forcecardiography capability to represent the so-called pulse dicrotic notch (PPG signal), which may be absent in the patients enrolled in our study.

Moreover, the Forcecardiography sensor is a fused sensor combining piezoelectric and piezoresistive sensors, with this study we also plan to assess the delay (if any) between the piezoelectric and piezoresistive components.

4.3. Research questions/aims/objectives/hypothesis:

- What is the Phase/Time delay from ECG of our sensor on healthy volunteers.
- What is the Phase/Time delay from PPG of the dicrotic notch.
- Assess the Phase/Time delay between the Forcecardiography sensor components.

4.4. Expected Outcomes:

- Confirmation that the signals from the test sensors are equivalent to the gold standard sensors.
- An understanding of the phase delay of pulse signals of piezo sensors vs force sensitive resistors.
- Add significance to the data collected from the unhealthy patient cohort.

Section 5: Sites and Methodology (Limit to 250 words for all of section 5)

5.1. List the *specific* sites based on your answers to HREA Q1.4. (e.g. *which* Universities, workplaces, schools or public places?):

We intend to recruit and record the data at Western Sydney University Kingswood campus and Westmead campus. The recording setup is portable (laptop and small acquisition device composed by the BIOPAC MP36 and a small, dedicated sensor plugged to the MP36 directly), it requires only some desk space and a comfortable chair for the participant to seat in for the duration of the recording. We intend to use one of the "hot offices" at Kingswood campus as well as one of the dedicated human physiology labs (available for booking) at Wesmead campus.

5.2. What methodologies will be used in this project?
(Delete the options which are not applicable)

Other:	Direct Time/Phase delay assessment between Forcecardiography components as well as gold standards.

5.2.1 Explain why these methodologies are appropriate for this study:

Due to the severity of the illness affecting the majority of our patient cohort, some common features of the pulse signal normally present at the fingers such as the dicrotic notch may be absent and/or altered/distorted, thus is important to include healthy data before concluding this study.

Section 6: Active Participant Details (YOU MUST copy questions 6.2. to 6.14 as a table for every participant group. Delete this Section if you are only collecting/using pre-existing data.

If there is more than one participant group, you must copy the table and complete questions 6.2 - 6.14 for each participant group.

6.1.	How many participant groups will be in this project? Examples of participant groups include teachers, students and parents. (You will need 1 table for each group.)	2

6.2.	**Participation Group Number (eg 1, 2 etc)**	1
6.3.	**Group name**	Younger Group
6.4.	**Characteristics of the group that are relevant to the aims of the project**	Healthy people with no diagnosed cardiovascular disease
6.5.	**Inclusion criteria**	• 18 to 30 years of age
6.6.	**Exclusion criteria**	• Participant has been diagnosed with cardiovascular disease. • Participant is pregnant or lactating. • Inability to place test and gold standard sensors.
6.7.	**Expected number and age of participants**	• Group 1: 15 of age 18 to 30
6.8.	**Sample size and statistical power issues** Justify the number of participants needed for this study.	• The agreement between biometric measurements by the test sensors the Biopac gold standard, will be assessed by Lin's concordance correlation coefficient (CCC). It is expected that CCC will be around 0.95 between paired data (Test sensors vs gold standard), with the lower side of the 95% confidence interval (CI) more than 0.75. With a probability of 80% (power) to obtain the 95% CI, a sample size of 13 (i.e. 13 paired data) is needed in Group 1 and Group 2 (i.e. total of 26 participants for both groups). To account for a drop out of 15%, a sample size of 15 is needed in each group (i.e. total of 30 participants in both groups).
6.9.	**Describe what these participants will be asked to do**	• Once eligibility is confirmed baseline data will be collected including age, weight and height. • Sensors will be put in place and data collected while the participant is sitting still. • Disposable ECG electrodes will be placed on left and right shoulder as well as on the right lower abdomen (or leg); the sensor under test sensor will be fitted on one finger, Biopac finger sensor on a different finger. • Sensors will then be removed

6.10.	**Follow up plans**	None required
6.11.	**Recruitment** How will you identify and recruit participants? Include whether screening takes place before or after consent; who will initially approach the participants; how participants will receive the recruitment documentation; how much time a participant will have to consider participation. **Will participants be offered any form of reimbursement?** This can be written in conjunction with question 2.1.1 of the HREA.	• Participants will be recruited by the Principal Investigator at either site through student internal email lists, poster affixed in public advertisement boards on campus and word of mouth e.g by student themselves that have been received/read the flyer. • Potential participants who approach a member of the research staff seeking further clarifications, will be advised about the study procedure, as to what the study entails, and any questions will be answered. • Research staff will then pre-screen potential participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study using hard copies of the PICF. • It is estimated that the study will take <30 minutes to complete. • We plan to offer the participants a $30 supermarket voucher.
6.12.	**Consent type** If you are seeking a waiver of consent for the use of pre-existing data, you must complete Section 11 of this form.	☒ Written ☐ Verbal ☐ Implied ☐ Waiver ☐ Opt-out ☐ Assent
6.13.	**Summary of consent process** The summary can be adapted from Question 2.2.1 of the HREA.	• An initial overview of the study will be described to the potential participant. • They will then be given the opportunity to ask for more details and they will then be run through an in-depth PICF ("Patient Informed Consent Form") • Subjects will be shown the devices being used in the study • They will then be asked to sign the PICF if they wish to participate and the study will then proceed.
6.14.	**Summary of project risks** (do not respond with N/A or 'none') The summary can be a condensed version of information included in question 2.3.1 of the HREA. This section should relate to risks to this group of participants.	• Skin reaction/irritation due to the application to sensors – this is low risk as the sensors have already been used in a clinical trial in a hospital and/or are disposable (ECG electrodes). • As the sensor under study is compared against established measures that are clinically considered a gold standard to formulate diagnosis, in the eventuality that the ECG or PPG waveforms displayed during the recording should look evidently abnormal e.g. missing dicrotic notch in the PPG or irregular heart-beat in the ECG, the participant will be recommended to consult her/his GP and the PDF of the waveforms will be made available to the participant. – this is low risk as the participant is supposedly healthy and never been diagnosed with a cardiovascular condition.

6.2.	**Participation Group Number (eg 1, 2 etc)**	2
6.3.	**Group name**	Older Group
6.4.	**Characteristics of the group that are relevant to the aims of the project**	Healthy people with no diagnosed cardiovascular disease
6.5.	**Inclusion criteria**	• 31 to 65 years of age
6.6.	**Exclusion criteria**	• Participant has been diagnosed with cardiovascular disease. • Participant is pregnant or lactating. • Inability to place test and gold standard sensors.
6.7.	**Expected number and age of participants**	• Group 2: 15 of age 31 to 65

6.8.	**Sample size and statistical power issues** Justify the number of participants needed for this study.	• The agreement between biometric measurements by the test sensors the Biopac gold standard, will be assessed by Lin's concordance correlation coefficient (CCC). It is expected that CCC will be around 0.95 between paired data (Test sensors vs gold standard), with the lower side of the 95% confidence interval (CI) more than 0.75. With a probability of 80% (power) to obtain the 95% CI, a sample size of 13 (i.e. 13 paired data) is needed in Group 1 and Group 2 (i.e. total of 26 participants for both groups). To account for a drop out of 15%, a sample size of 15 is needed in each group (i.e. total of 30 participants in both groups).
6.9.	**Describe what these participants will be asked to do**	• Once eligibility is confirmed baseline data will be collected including age, weight and height. • Sensors will be put in place and data collected while the participant is sitting still. • Disposable ECG electrodes will be placed on left and right shoulder as well as on the right lower abdomen (or leg); the sensor under test sensor will be fitted on one finger, Biopac finger sensor on a different finger. • Sensors will then be removed
6.10.	**Follow up plans**	None required
6.11.	**Recruitment** How will you identify and recruit participants? Include whether screening takes place before or after consent; who will initially approach the participants; how participants will receive the recruitment documentation; how much time a participant will have to consider participation. **Will participants be offered any form of reimbursement?** This can be written in conjunction with question 2.1.1 of the HREA.	• Participants will be recruited by the Principal Investigator at either site through student internal email lists, poster affixed in public advertisement boards on campus and word of mouth e.g by student themselves that have been received/read the flyer. • Potential participants who approach a member of the research staff seeking further clarifications, will be advised about the study procedure, as to what the study entails, and any questions will be answered. • Research staff will then pre-screen potential participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study using hard copies of the PICF. • It is estimated that the study will take <30 minutes to complete. • We plan to offer the participants a $30 supermarket voucher.
6.12.	**Consent type** If you are seeking a waiver of consent for the use of pre-existing data, you must complete Section 11 of this form.	☒ Written ☐ Verbal ☐ Implied ☐ Waiver ☐ Opt-out ☐ Assent
6.13.	**Summary of consent process** The summary can be adapted from Question 2.2.1 of the HREA.	• An initial overview of the study will be described to the potential participant. • They will then be given the opportunity to ask for more details and they will then be run through an in-depth PICF ("Patient Informed Consent Form") • Subjects will be shown the devices being used in the study • They will then be asked to sign the PICF if they wish to participate and the study will then proceed.
6.14.	**Summary of project risks** (do not respond with N/A or 'none') The summary can be a condensed version of information included in question 2.3.1 of the HREA. This section should relate to risks to this group of participants.	• Skin reaction/irritation due to the application to sensors – this is low risk as the sensors have already been used in a clinical trial in a hospital and/or are disposable (ECG electrodes). • Because this research is not medical/clinical test but rather a device test, it will be specifically explained to the prospective participant that participation in this research is not a means to assess their heart/circulation, as waveforms will not be clinically interpretated.

Section 8: Data

8.1. What is the scope of consent you will seek for this project? – relates to HREA 2.2.2.1

☐ **Specific consent** should be selected when consent is restricted to the specific project under consideration.
If seeking specific consent, what is the ethically justifiable reason for this approach? (see section 3.1.50 of the National Statement on Ethical Conduct in Human Research):

☐ **Extended consent** should be selected when there is intention to use data or tissue in future research projects (This refers to extended, closely related, ongoing projects or projects in the same general area of research). This also includes permission to enter original data or tissue into a data/tissue bank.

☒ **Unspecified consent** should be selected when there will be a need to use data or tissue in any future research. This also includes permission to enter original data or tissue into a data/tissue bank and needs to be clearly outlined to participants.

8.2. For prospective data collection, what information are you going to collect/gather?

Deidentified data under the form of Pulse signals – single lead ECG, finger PPG and finger Forcecardiography. Also, age (in years), weight and height.

8.3. How will you measure, manipulate and/or analyse the information that you collect/gather? When relevant include matching and sampling strategies, accounting for potential bias, confounding factors and missing information. Providing just the name of the software program is not enough information.

The data will be processed using techniques that have been developed in clinical trials of similar devices performed in various hospitals – St Vincents in Sydney and The Alfred in Melbourne. Signals will be manually annotated and timings plus amplitudes between pulse signals and ECG features will be calculated using Matlab and Excel for specific sensor/electrode pairs. Both age and heart rate effects will be considered.

8.4. Are any Data Linkages planned or anticipated? If yes, please describe. See Guidance sheet for more information.

Section 9: Results, Outcomes and Future Plans

9.1. Will the results or findings of the research, e.g. a summary of the findings, be returned to participants?

☒ Yes How? This section relates to question 3.16.1.1 of the HREA. A one-page summary will be prepared at the end of the project that will be shared with participants if they agree to sending

☐ No Why not?

What are your plans for the following activities?

9.2. Dissemination and publication of project outcomes (e.g. thesis, journals, Research Direct)

The project outcomes will be published in appropriate scientific journals/conferences.

9.3. Other potential uses of the data at the end of the project (e.g. Sharing or future use of the data, follow up research).

The data will then be used in product design leading to testing in other clinical trials in patients with cardiovascular disease

9.4. Summarise the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the data ownership and outputs of the research.
See Guidance sheet for more information.

Research projects are in place with Medical Monitoring Solutions Pty Ltd which assigns any IP to MMS. WSU are able to use the findings in future research

Conflicts of Interest

Have you disclosed any financial or non-financial interests at Q1.10 in the HREA which relate to a conflict *other than* a HREA Committee Member i.e. research-related commercial activity, Western Sydney staff members?

☒ Yes	please ensure that any conflicts of interest are recorded on the University's Conflict of Interest Register
☐ No	continue to next question

Research in Public Schools

Will you be conducting research in an Australian public-school setting?

☐ Yes		
	☐ In NSW	You may need to complete a SERAP application
	☐ In other state/s	Please contact the Department of Education (or equivalent) in the relevant state/s for advice about whether any specialist review is required.
☒ No	continue to next question	

Conducting research with children

Does your research require you to work with children?

☐ Yes	Anyone who works face-to-face with children in a paid, self-employed or voluntary capacity, must have a Working with Children Check (WWCC) clearance, unless they qualify for an exemption. Please ensure that your status is valid and up to date.
☒ No	continue to next question

Research in Public Health Organisations

Will you be conducting research in an Australian public health organisation, such as a hospital?

☐ Yes		
	☐ In NSW	You may need to apply for ethics approval via a Local Health District ethics committee.
	☐ In other state/s	please contact the relevant state Health Department for advice about whether any specialist review is required.
☒ No	continue to Attachment Checklist	

Attachment Checklist

The file names should reflect the contents of the document. Document formats should usually be Word or PDF.

Mandatory Attachments

- ☒ Project Description on WSU template https://www.westernsydney.edu.au/research/forms
- ☒ HREA form https://hrea.gov.au/
- ☒ WSU Data Management Plan (mandatory as per the University's Research Data Management Plan and Element 4 of the National Statement) https://researchdirect.westernsydney.edu.au/

Other possible attachments

The attachments required will depend on the project. Below are the most usual attachments.

- Participant information sheet(s) - Western Sydney template at https://www.westernsydney.edu.au/research/forms
- Participant consent form(s) - Western Sydney template at https://www.westernsydney.edu.au/research/forms
- Recruitment text/script/flyer
- An age-appropriate dialogue text for children's assent
- Copies of the documents you will use to collect the data eg survey, interview questions
- An e-mail confirming you have completed the Confirmation of Candidature (MPhil, PhD) or Evidence of

successful completion of Viva (MRes)
- Permission to access participants or a site or an existing dataset

Clinical Trials – Continue to Section 10 below
Requesting a Waiver of Consent – Continue to Section 11 below

This project description forms one part of your ethics application. It can either be uploaded to the online HREA system, or attached when you email your application to the ethics team.

Attachment A. Section 10 – Clinical Trial

Delete this section if not applicable or you will be supplying a clinical trial protocol instead. If completing this section you also need to have completed Sections 1-10.

10.1. Is this research a Clinical Trial? ☒ Yes ☐ No

The WHO defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." http://www.who.int/topics/clinical_trials/en

The National Statement says:
3.1.7 For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.

10.2. Will you register this trial on a publicly available register? ☒ Yes ☐ No

If no, why not?

10.3. Will the research require registration with the Therapeutic Goods Administration? ☐ Yes ☒ No

For information on how to register a clinical trial under the Western Sydney TGA account contact the human ethics team humanethics@westernsydney.edu.au

10.4. Will the trial seek registration under the CTN/CTX scheme? ☐ Yes ☒ No

10.5. **For research involving an investigational drug or device as part of a clinical trial, what is/are the drug(s) and/or devices:** (Copy text as needed)

The Investigational Devices include:
1. Test devices
    a. A finger sensor
2. Gold standard Devices
    a. Single lead ECG
    b. Photoplethysmography (PPG) finger sensor

10.5.1	Approved Name:	Not approved
10.5.2	Trade name (if any):	Research Morphic Dot
10.5.3	Manufacturer:	Medical Monitoring Systems
10.5.4	Supplier of drug/device (e.g. manufacturer/pharmacy):	Medical Monitoring Systems
10.5.5	Approved therapeutic indication, dosage/duration in Australia:	Not approved – currently being tested in a clinical trial at St Vincents and The Alfred Hospitals
10.5.6	Believed mode of action:	Measures the cardiac pulse from each sensor location
10.5.7	Dosage regimen:	Sensors positioned on skin surface on finger and chest using standard techniques

10.5.8 Mode of excretion: Not applicable

10.5.9 Known adverse events: None in other clinical trials to date

10.5.10 Known contra-indicators or warnings: Presence of open wounds on sensor locations

10.5.11 If arrangements have been made for the Pharmacy Department to receive or dispense the drugs involved in the project, explain how the drugs will be received and dispensed for the purpose of the research project.

Not applicable

Attachment B. Section 11 – Request for a Waiver of Consent

Delete this section if not applicable.
If completing this section one of the consent types in the Project Description must be 'waiver'.

Researchers should refer to Section 2.3 of the National Statement on Ethical Conduct in Human Research https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 *Qualifying or Waiving Conditions for Consent* and any relevant State or Federal legislation before completing this form.

11.1. Are you requesting a waiver of consent for (tick as many as apply):

- ☐ A de-identified dataset that it is not possible to re-identify (Under the Privacy Act, personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable.)
- ☐ Identifiable data
- ☐ A dataset which includes health information[1]. (Note that only an HREC can grant a waiver of consent for research using personal information in medical research or personal health information.)
- ☐ Research which is aiming to expose illegal activity

11.2. Does involvement in the research carry no more than low risk to participants?

- ☐ Yes
- ☐ No - the committee cannot waive the requirement to seek consent if the involvement of participants is not low risk. Please reassess the consent options for this project.

11.3. Why isn't it possible to seek consent for the use of the data?

11.4. Is there any reason for thinking that participants would not have consented if they had been asked?

- ☐ No
- ☐ Yes Why wouldn't participants have consented?

11.5. How will the participant's privacy and confidentiality be protected?

11.6. If using **identifiable data** without consent:
Why isn't it possible to only use de-identified data?

Why does the public interest in the research substantially outweigh the public interest in privacy?

11.7. For research aiming to expose illegal activity:
How does the value of exposing the illegal activity justify the adverse effects on the people exposed?

[1] From the NHMRC *Guidelines approved under Section 95A of the Privacy Act 1988*, 2014
Health information is a particular subset of personal information. Health information is personal information or an opinion:
• about an individual's health or disability at any time (that is past, present or future)
• about an individual's expressed wishes regarding future health services
• about health services provided or to be provided to the individual
• collected to provide or in providing a health service
• collected in connection with the donation or intended donation of body parts and substances; or
• genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.
As indicated above, health information includes any information collected by a health service provider during the course of providing treatment and care to an individual, including:
• medical information
• personal details, such as name, address, admission and discharge dates, billing information and Medicare number
• information generated by a health service provider, such as notes or opinions about an individual and their health
• information about physical or biological samples, where it can be linked to an individual; for example, where they have a name or identifier attached.

Human Research Ethics Application

Application Management Information
Application ID: GG00049
Created date: 04/09/2023
Originating Application ID:
**This is the earliest application from which this application (GG00049) was copied.*
Parent Application ID:
**This is the immediate predecessor from which this application (GG00049) was copied.*
Version Number: 1.1
Application submitted to: Western Sydney University; Western Sydney University Human Research Ethics Committee.

The applicant has requested that this ethics application be considered under the Negligible risk review pathway.

Section 1 – Core Information

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the National Statement.
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

Q1.1 Project Title:

Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)

Q1.2 Summary of the research project:

In the past 3 years, in collaboration with a sponsor industry partner we developed a novel wearable non-invasive sensor capable of detecting the small forces impressed to the skin by moving organs/vessels/muscles lying under the sensor. With this trial we aim to recruit healthy (never diagnosed with cardiovascular diseases) participants to compare signals from the finger versus ECG and PPG. Specifically, we aim to:
1) Measure and compare (healthy versus patient) the delay between the R-peak (ECG signal) and the peak pulse force measured at the finger pad.
2) Assess the Forcecardiography capability to represent the so-called pulse dicrotic notch (PPG signal), which may be absent in the patients enrolled in our study.
Moreover, the Forcecardiography sensor is a fused sensor combining piezoelectric and piezoresistive sensors, with this study we also plan to assess the delay (if any) between the piezoelectric and piezoresistive components.

Q1.3 Which category/ies of research best describes the project?

Comparison of test device versus gold standards

Q1.4 In what environments will the research be conducted?

University(ies)

Q1.5 What organisation/entity has overall responsibility for this project?

Western Sydney University

Q1.6 Describe how this research project is currently, or will be, funded.

Awarded grant

Q1.7 Anticipated starting date of the research project:

As soon as ethics and any other relevant approvals have been provided.

Q1.8 Anticipated duration of the research project:

3 Months

Project Team

Name: **Dr Upul Gunawardana**

Q1.9.4 Email Address:

u.gunawardana@westernsydney.edu.au

Q1.9.5 Is this person the contact person for this application?

No

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

Western Sydney University

Q1.9.8 Staff ID *(optional)***:**

Q1.9.9 ORCID Identifier *(optional)***:**

Q1.9.10 Position on the research project:

Chief Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

No

Q1.9.12 Research activities Dr Upul Gunawardana will be responsible for:

Data analysis

Q1.9.13 Expertise relevant to the research activity:

Expert in signal processing

Name: **Prof Paul Breen**

Q1.9.4 Email Address:

p.breen@westernsydney.edu.au

Q1.9.5 Is this person the contact person for this application?

No

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

Western Sydney University

Q1.9.8 Staff ID *(optional)***:**

Q1.9.9 ORCID Identifier *(optional)*:

Q1.9.10 Position on the research project:
Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
No

Q1.9.12 Research activities Prof Paul Breen will be responsible for:
Data collection and analysis

Q1.9.13 Expertise relevant to the research activity:
Expert Biomedical Engineer

Name: **Prof Gaetano Gargiulo**

Q1.9.4 Email Address:
g.gargiulo@westernsydney.edu.au

Q1.9.5 Is this person the contact person for this application?
Yes

Q1.9.5.1 Email Address:	g.gargiulo@westernsydney.edu.au
Q1.9.5.2 Telephone Number:	0487794311
Q1.9.5.3 Mailing Address	Building XB, room 2.50 Kingswood Campus; Kingswood 2747 (NSW)

Q1.9.6 Is this person a student on this project?
No

Q1.9.7 Institutional affiliation and position:
Western Sydney University

Q1.9.8 Staff ID *(optional)*:

Q1.9.9 ORCID Identifier *(optional)*:

Q1.9.10 Position on the research project:
Chief Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
No

Q1.9.12 Research activities Prof Gaetano Gargiulo will be responsible for:

Data collection and analysis

Q1.9.13 Expertise relevant to the research activity:

Biomedical Engineer

Disclosure of interests

Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

Yes

Q1.10.1 Explain the nature and extent of the interests and to which member of the team they apply.

Prof Gargiulo and Prof Breen are minority shareholders of Medical Monitoring Solutions; Medical Monitoring Solution owns the technology for the morphic sensing object of this study

Q1.10.2 Explain how you intend to manage these interests and any potential conflicts that may arise.

Data analysis and integrity of the findings will be evaluated by Dr. Gunawardana who has no financial or non-financial interests related to this research and or with Professors Gargiulo and Breen. Dr. Gunawardana will be also in charge of selecting the database that will be made publicly available. Data, once published, will be fully available to other researchers to conduct independent research.

Restrictions

Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

No

Evaluations

Q1.12 Has the scientific or academic merit of the research project been evaluated?

No

Q1.13 Has this research project had prior ethics review?

No

Q1.14 Will any further or additional specialised review of this application be sought?

No

Setting of research

Q1.15 Will this project be conducted at multiple sites?

No

Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?

No

Section 2 – Research Details and Participants

Q1.17 The following research methods will be used in the research project:

Research Method	Status
Action research	✗
Biospecimen analysis research	✗
Data linkage research	✗
Ethnographic research	✗
Epidemiological research	✗
Interventional/Clinical Trials research	✓
Observational research	✗
Survey/Interview/Focus Group research	✗
Textual analysis research	✗
None of the above	✗

Q1.18 The research will be conducted with the following:

Participation	Status
Human beings (via active participation), including their associated biospecimens and/or data.	✓
Human biospecimens only	✗
Data associated with human beings only (i.e. as the primary object of research)	✗

Q1.19 The research will involve the following participants:

Participants	Status
Women who are pregnant and the human fetus	✗
Children and young people	✗
People highly dependent on medical care who may be unable to give consent	✗
People with a cognitive impairment, intellectual disability or mental illness	✗
People in dependent or unequal relationships	✗
People who may be involved in illegal activities	✗
People in other countries	✗
Aboriginal and Torres Strait Islander peoples	✗

Method Specific Questions

Interventional/Clinical Trials Research

M6.1 Briefly describe the intervention/s that you will be using.

Comparison of Forcecardiography sensor device versus gold standard.
With this trial we aim to recruit healthy (never diagnosed with cardiovascular diseases) participants to compare signals from the finger versus ECG and PPG. Specifically, we aim to:

1. Measure and compare (healthy versus patient) the delay between the R-peak (ECG signal) and the peak pulse force measured at the finger pad.
2. Assess the Forcecardiography capability to represent the so-called pulse dicrotic notch (PPG signal), which may be absent in the patients enrolled in our study.

Moreover, the Forcecardiography sensor is a fused sensor combining piezoelectric and piezoresistive sensors, with this study we also plan to assess the delay (if any) between the piezoelectric and piezoresistive components

M6.2 Is your intervention related to the prevention, diagnosis, treatment or management of a health condition?

No

M6.3 With regard to your answers above, describe any ethical considerations related to your use of the intervention/s in this research project and your plans for addressing these issues.

The Forcecardiography sensor, placed over chest, neck, iliac crest and fingers is currently at trial in two major hospitals (approved by Alfred Hospital Ethics Committee with protocol number: HREC/90385/Alfred-2022, notified to WSU human ethics office in June 2023) where it is compared against gold standard such as: right-heart catheterization, ECG, Doppler (valves and chambers motility), PPG, non-invasive blood pressure as well as bodily sounds. This study is useful to balance the patient coohort dataset with healthy controls.

Participant Specific Questions

Recruitment Questions

Q2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

- Participation to this study is voluntary.
- Participants will be recruited by the Principal Investigator at either site through student internal email lists, poster affixed in public advertisement boards on campus and word of mouth e.g by student themselves that have been received/read the flyer.
- Potential participants who approach a member of the research staff seeking further clarifications, will be advised about the study procedure, as to what the study entails, and any questions will be answered.
- Research staff will then pre-screen potential participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study using hard copies of the PICF.
- It is estimated that the study will take <30 minutes to complete.
- We plan to offer the participants a $30 supermarket voucher

Q2.1.2 How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?

Participation to this study is voluntary. For this study, we target a healthy cohort (whereas healthy is defined as “never been diagnosed with a cardiovascular disease”). Any potential participant approaching the research team expressing intent to participate will be screened against the selection criteria and made aware that participation in the study does not offer a medical result/diagnosis.

Consent Questions

Q2.2.1 Indicate by reference the relevant section/s of your Project Description/Protocol that address/es consent.

- Research staff will advise participants as to what the study entails, and any questions will be answered.
- Research staff will then pre-screen participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study using hard copies of the PICF.
- It is estimated that the study will take <30 minutes to complete.
- We plan to offer the participants a $30 supermarket voucher.

Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research?

Yes for all participants

Q2.2.2.1 What is the scope of consent that you will be seeking?

Unspecified

Q2.2.2.2 How will consent be obtained?

Written

Q2.2.2.3 Are you proposing to obtain consent using limited disclosure?

No

Q2.2.3 Are family members, authorised representatives or any others involved in the participants’ decision to participate in the research?

No

Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project?

Yes

Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.

- An initial overview of the study will be described to the potential participant.
- They will then be given the opportunity to ask for more details and they will then be run through an in-depth PICF ("Patient Informed Consent Form")
- Subjects will be shown the devices being used in the study
- They will then be asked to sign the PICF if they wish to participate and the study will then proceed.

Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all of the participants?

No

Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants?

No

Risk Questions

Q 2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.

Skin reaction/irritation due to the application to sensors – this is low risk as the sensors have already been used in a clinical trial in a hospital and/or are disposable (ECG electrodes).
As the sensor under study is compared against established measures that are clinically considered a gold standard to formulate diagnosis, in the eventuality that the ECG or PPG waveforms displayed during the recording should look evidently abnormal e.g. missing dicrotic notch in the PPG or irregular heart-beat in the ECG, the participant will be recommended to consult her/his GP and the PDF of the waveforms will be made available to the participant. – this is low risk as the participant is supposedly healthy and never been diagnosed with a cardiovascular condition.

Q 2.3.2 Describe how these risks will be mitigated and managed.

Risk associated, outlined above, will be disclosed to the prospect participant during the consenting procedure. In addition will be clarified to the prospective participant that Because this research is not medical/clinical test but rather a device test, it will be specifically explained to the prospective participant that participation in this research is not a mean to assess their heart/circulation as waveforms will not be clinically interpretated. However, in the remote eventuality that a displayed waveform should look evidently abnormal e.g. missing dicrotic notch in the PPG or irregular heart-beat in the ECG, the participant will be recommended to consult her/his GP and the PDF printout of the waveforms will be made available to the participant.

Benefit Questions

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description as appropriate.

There is an unmet need for new technologies that can improve the management of cardiovascular disease, and many researchers are trialing sensors which are not electrical (e.g. inertial, piezoelectric etc…) to replace/aid the traditional ECG in patient prognosis/assessment [Inan, O.T.; Migeotte, P.F.; Park, K.S.; Etemadi, M.; Tavakolian, K.; Casanella, R.; Zanetti, J.; Tank, J.; Funtova, I.; Prisk, G.K.; et al. Ballistocardiography and Seismocardiography: A Review of Recent Advances. IEEE J. Biomed. Health Inform. 2015, 19, 1414–1427]. Differently from the available sensors, the Forcecadiography sensor is small enough and sensitive enough to detect signals from fingers [Sponsor unpublished material], this can benefit the community in the near future.

Q2.4.2 Explain how benefits of this research justify any risks or burdens associated with the research.

There are only negligible risk associated to this research, mostly rising from application of self adhesive ECG electrodes, on the other hand the potential benefit from this study including the advancement of the knowledge on the delay of the pulse at the periphery from the ECG greatly overcame the associated risks.

Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?

It will be explained to the participant during the consent process that there are no immediate benefit from this research, as the development of the full medical device will require time and more trials.

Section 3 – Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project.

Not personal information

Q3.2 Indicate the type of information/data you will be using in this project:

Not personal information

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.

Non-identifiable information

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.

Non-identifiable information

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

For this project we do not collect any personal information. Only non-identifiable information will be stored.

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.

Individual participants and/or relatives or associates of participants

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

For this project we do not collect any personal information. Only non-identifiable information will be stored.

Q3.8 Was the information/data that you are using previously collected for a purpose other than research?

No

Activities Planned for/with Data

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

No

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?

For this project we do not collect any personal information. Only non-identifiable information will be stored.

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?

No

Q3.12 Do you plan to share any individual research results obtained during this research to the participants?

No

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

For this study we do not expect any secondary or incidental findings, if an incidental condition is incidentally detected e.g. abnormal heart rate, we will invite the participant to visit their GP.

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

De-identified data will be shared using public physioloigical database e.g. Physionet and/or made available as additional material to the publications.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

There are no ethical implications as only de-identified data will be disseminated.

Q3.16 Will the outcomes of this project be disseminated to the participants?

Yes

Q3.16.1.1 Describe how the outcomes of the project will be disseminated to the participants, or refer to the relevant section/s of your Project Description/Protocol which deals with this matter.

A one page summary detailing the publication outcomes will be sent to the participant if they agree to receive it.

Q3.16.1.2 Describe any ethical considerations relating to any dissemination of outcomes to the participants.

There are no ethical implications as only de-identified data will be disseminated.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

De-identified data will be made available via public dataset can be used for future research in the field e.g. pulse transit time/arrival time.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

There are no ethical implications as only de-identified data will be disseminated.

Section 4 – Attachments and Declarations

Attachments

The following documents have been attached to this HREA.

Project Description/Protocol

See attachment *Project_Description_FSR vs Piezo_040914.docx*

Other attachments

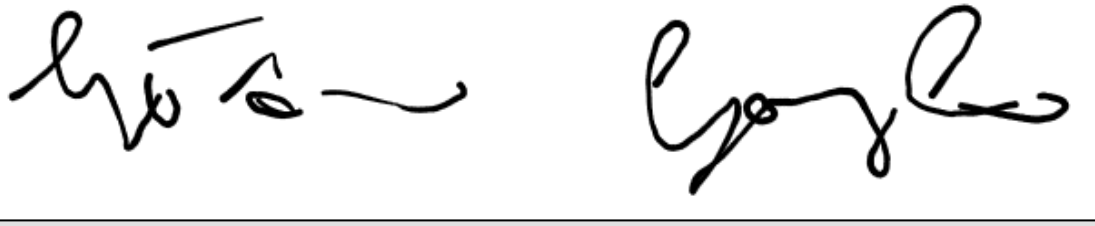
Attachment File Name	Attachment Description
2CM_Consent_Form - FSR vs Piezo.doc	Consent form
3PM_Participant_Information_Sheet_-_Medical_Unspecified_1148026.doc	Participant Information sheet
20230811_FSRvsPiezo-CIP_v1.docx	Clinical Investigation Plan
Project_Description_FSR vs Piezo_230814.docx	Cover page form
CRFs.zip	CRFs (zipped file)
confirmation_Upul_Paul.pdf	Confirmation from other investigators
invitationText.docx	Recruitment text
rdmp.pdf	Data management plan

Investigator Team Declarations

The research team has certified that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Dr Upul Gunawardana



Prof Paul Breen
See attachment *confirmation_Upul_Paul.pdf*.

Prof Gaetano Gargiulo
See attachment *confirmation_Upul_Paul.pdf*.

Re: H15672 Application GG00049_v1 declaration

Paul Breen <P.Breen@westernsydney.edu.au>
Mon 04-Sep-23 12:48
To:Upul Gunawardana <U.Gunawardana@westernsydney.edu.au>;Gaetano Gargiulo <G.Gargiulo@westernsydney.edu.au>

To Whom It May Concern:

I have reviewed this application and am happy to be nominated as an investigator on the project.

All the best
Paul

Prof Paul Breen
Research Professor | Health & Wellbeing Theme Champion
Biomedical & Human Technologies | International Centre for Neuromorphic Systems
The MARCS Institute for Brain, Behaviour and Development | Translational Health Research Institute
Western Sydney University

Western Sydney University and I acknowledge the peoples of the Darug, Tharawal, Eora and Wiradjuri nations. We also acknowledge that the teaching and learning currently delivered across our campuses is a continuance of the teaching and learning that has occurred on these lands for tens of thousands of years.



From: Upul Gunawardana <U.Gunawardana@westernsydney.edu.au>
Date: Monday, 4 September 2023 at 12:46 pm
To: Gaetano Gargiulo <G.Gargiulo@westernsydney.edu.au>, Paul Breen <P.Breen@westernsydney.edu.au>
Subject: RE: H15672 Application GG00049_v1 declaration

Dear all,

This is to confirm that I have reviewed the application, and I am happy to be nominated as an investigator for this project.

-Upul

From: Gaetano Gargiulo <G.Gargiulo@westernsydney.edu.au>
Sent: Monday, September 4, 2023 12:40 PM
To: Paul Breen <P.Breen@westernsydney.edu.au>; Upul Gunawardana <U.Gunawardana@westernsydney.edu.au>
Subject: H15672 Application GG00049_v1 declaration

Hi Upul and Paul, as per the human research ethics committee request, can you please confirm that you have reviewed the application in object and are happy to be nominated as investigator for this project?
Regards,
Gaetano

Prof. Gaetano D. Gargiulo (Ph.D)
Research Professor
Western Sydney University
Electrical & Electronic Discipline Leader
Kingswood campus
Room Xb.2.50
Phone 02 4736 0920
Mobile: 048 7794 311
g.gargiulo@westernsydney.edu.au
Office hours by appointment only: https://uws.zoom.us/j/99464521088

WESTERN SYDNEY
UNIVERSITY

Western Sydney University acknowledges the Darug, Eora, Dharawal (also referred to as Tharawal) and Wiradjuri peoples and thanks them for their support of its work on their lands (Greater Western Sydney and beyond).

We are seeking healthy participants (never been diagnosed with a cardiovascular disease) aged between 18-65 years old for a non invasive clinical trial testing a new device for pulse recording from the fingers. This study is being conducted by Professor Gaetano Gargiulo (g.gargiulo@westernsydney.edu.au) from the WSU School of Engineering, Design and Built. The research is to understand the differences in signal characteristics between three types of sensors (two types of test sensors and one gold standard) for recording pulse signals from the finger.

For the purpose of this research, you will be asked to:

- Provide your age
- Have your height and weight recorded
- Place ECG electrodes on your left and right shoulder and right side of the abdomen (or right leg if more convenient)
- Place the test sensor and the gold standard on your fingers
- Record signal from your fingers and ECG electrodes for approximately 5 minutes. The signals will be recorded while you are sitting on a chair

It is estimated that it will take up to 30 minutes of your time for us to complete the recordings. There is negligible risk or discomfort from participating in the study. You may have a mild reddening of the skin once the ECG electrodes are removed. This is normal and should dissipate without treatment. The ECG electrodes are disposable and the same as the ones used by doctors. You will be rewarded for your time, with a $30 grocery voucher.

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Participant Information Sheet

Project Title: Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)

Project Summary:

You are invited to participate in a research study being conducted by Professor Gaetano Gargiulo from the WSU School of Engineering, Design and Built. The research is to understand the differences in signal characteristics between three types of sensors (two types of test sensors and one gold standard) for recording pulse signals from the finger.

How is the study being paid for?

The project is supported by multiple grants from government organisations in collaboration with industry.

What will I be asked to do?

You will be asked to:

- Provide your age
- Have your height and weight recorded
- Place ECG electrodes on your left and right shoulder and right side of the abdomen (or right leg if more convenient)
- Place the test sensor and the gold standard on your fingers
- Record signal from your fingers and ECG electrodes for approximately 5 minutes. The signals will be recorded while you are sitting on a chair

How much of my time will I need to give?

It is estimated that it will take up to 30 minutes of your time for us to complete the recordings.

What benefits will I, and/or the broader community, receive for participating?

The study aims to further medical knowledge and may improve future monitoring and treatment for people at risk or with cardiovascular diseases, however it will not directly benefit you.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

There is negligible risk or discomfort from participating in the study. You may have a mild reddening of the skin once the ECG electrodes are removed. This is normal and should dissipate without treatment. The ECG electrodes are disposable and the same as the ones used by doctors. As the sensor under study is compared against established measures that are

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clinically considered a gold standard to formulate diagnosis, in the eventuality that the ECG or PPG waveforms displayed during the recording should look evidently abnormal e.g. missing dicrotic notch in the PPG or irregular heart-beat in the ECG, you will be recommended to consult your GP and the PDF of the waveforms will be made available to you.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission. Your name will not be recorded, and you will be deidentified by using a made up ID number.

Will the data and information that I have provided be disposed of?

No. Your data will be used as per Western Sydney University's Open Access Policy. This means that the non-identified data collected from this study can be made available online and world-wide in perpetuity.

Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason by asking for the researcher to stop the study. Whatever your decision, it will not affect any medical treatment you may be undergoing and/or your relationship with the WSU staff.

If you do choose to withdraw any information that you have provided will be deleted.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with Prof Gargiulo's contact details.

What if I require further information?

Please contact Prof. Gaetano Gargiulo should you wish to discuss the research further before deciding whether to participate.

Privacy Notice

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.

The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

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If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Services: humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep, and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee and NSW Department of Health Area Health Service *[Note this is only when Local Health District approval has been sought]*. The Approval number is *[enter approval number once the project has been approved]*.

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Explanation of Consent

What will happen to my information if I agree to it being used in other projects?

Thank you for considering being a participant in a university research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to Unspecified consent.

Unspecified consent

When you agree to unspecified consent it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in any future research.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use **will not** have information in it that makes you identifiable.

The researchers who are managing the data under this Plan will decide what types of future projects are suitable for this data to be used in. The projects may mean that the dataset is given to other researchers outside of the current research team. The researchers could also be from anywhere in the world and may, or may not, have affiliations with a university. The data will be held for a significant period of time – until it is felt that it is no longer needed for research. After this time the data will be securely destroyed.

The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

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Consent Form

Project Title: Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)

This study has been approved by the Human Research Ethics Committee at Western Sydney University. The ethics reference number is: H*[insert number]*

I hereby consent to participate in the above-named research project.

I acknowledge that:

- I have read the participant information sheet (or where appropriate, have had it read to me) and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s

- The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to:

☐ *My weight being measured*

☐ *My height being measured*

☐ *My age being recorded*

☐ *My blood pressure being taken*

☐ *My heart rate being monitored*

☐ *My pulse signal being recorded from my fingers from 2 separate devices*

☐ *My electrocardiogram being recorded from a single lead ECG – one electrode on each shoulder and one abdominal/leg electrode*

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I consent for my data and information provided to be used for this project.

I understand that my involvement is confidential, and that the information gained during the study may be published but no information about me will be used in any way that reveals my identity.

I understand that my participation in this study will have no effect on my relationship with the researcher/s, the medical staff, the University, any organisations involved or my medical treatment, now or in the future. I understand that I will be unable to withdraw my data and information from this project.

Signed:

Name:

Date:

Privacy Notice

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What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Services: humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

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CLINICAL INVESTIGATION PLAN

Trial Title:

Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)

Protocol Number:

DOT-CIP-01

Version:

01

Amendment No: 01

Date: 22nd August 2023

CONFIDENTIAL

All Contents of this document are confidential information belonging to Western Sydney University (WSU) and may not be used for any purpose whatsoever without written consent from Western Sydney University

Table 1: Key Trial Personnel

Study Sponsor	Western Sydney University
Principal Investigator	Prof Gaetano Gargiulo
Data analysis	Western Sydney University
Statistician	Western Sydney University
Core Lab:	Western Sydney University

Table 2: Protocol Revision History

Version	Description of Change	Date
1.0	Initial Release	22 August 2023

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List of Abbreviation

Abbreviation	Description
AE	Adverse Event
App	Application
BMI	Body Mass Index
CRF	Case Report Form
CFR	Code of Federal Regulations
ECG	Electrocardiograph
EDC	Electronic Data Capture
EOS	End of Study
FPFV	First Patient First Visit
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
LPLV	Last Patient Last Visit
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
TGA	Therapeutic Goods Administration
UADE	Unanticipated Serious Adverse Device Effect
WSU	Western Sydney University

CLINICAL INVESTIGATION PLAN

Sponsor Signature Page:

All parties hereby declare they have read, understood and agree to follow the Clinical Trial Protocol SENSOR CF in accordance with the Declaration of Helsinki, Good Clinical Practice (GCP), ISO 14155:2020 and local regulatory requirements.

Authorised Signature

Sponsor :
Western Sydney University

Name and Title: _____

Signature: _____

Date: _____

Investigator:

Name and Title:_____

Signature: _____

Date: _____

CLINICAL INVESTIGATION PLAN

1. Clinical Protocol Trial Synopsis

Trial Title	Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors
Short Title	SENSOR_CF
Protocol Number	DOT-CIP-01
Stage	Proof of Concept
Study Device	The study device is morphic dot combination sensors (Force Sensitive Resistor (FSR) and Piezoelectric)
No. of Participants	Thirty (30) participants
No. of Centres (per country)	Two centres. 1. WSU, Kingswood (lead site). 2. WSU, Westmead.
Study Duration	Approximately 3-months.
Primary Objective	The primary objective for the study is to measure, and compare, the delay between the R-peak (ECG signal) and the peak pulse force measured at the finger pad, for each of the finger sensors – ie the 2 test sensors (FSR and Piezo) and the gold standard (PPG) sensor.
Secondary Objective(s)	Assess the test and gold standard sensors capability to detect the so-called pulse dicrotic notch from the finger.
Primary and Secondary Endpoint(s)	1. Primary • Able to measure the pulse transit time (time from peak of ECG to peak of pulse wave) from both test sensors and the PPG sensor 2. Secondary • That a dicrotic notch can be recorded from all 3 sensors from the finger
Inclusion Criteria	1. 18-65 years of age.
Exclusion Criteria	1. Participant has been diagnosed with cardiovascular disease. 2. Participant is pregnant or lactating. 3. Inability to place morphic sensors.
Study Overview	Participants will be recruited by the Principal Investigator at each site. Research staff will initially pre-screen participants against the eligibility criteria to assess eligibility and once confirmed the participant will be invited to participate and consented into the study.

	The study will be completed in a Biomedical Engineering room and will take less than 30 minutes to complete. Age, height and weight will be recorded from each participant and entered into the Case Record Forms with a deidentified number allocated to each participant. During the study the participant - in a sitting position - will be monitored with several gold standard devices including off the shelf PPG and ECG sensors connected to the BioPac acquisition device. The signals obtained from the gold standard devices will be compared to the morphic dot sensor mounted on the participant's finger. Signals will be collected for less than a 10-minute period. At the completion of the study, all BioPac off the shelf sensors and morphic sensors, attached to the participant, will be removed from the participant. All adverse events, protocol deviations and device deficiencies will be collected from the time of consent up until the end of study.
Statistical Analysis	The agreement between biometric measurements by the test sensors the Biopac gold standard, will be assessed by Lin's concordance correlation coefficient (CCC). It is expected that CCC will be around 0.95 between paired data (Test sensors vs gold standard), with the lower side of the 95% confidence interval (CI) more than 0.75. With a probability of 80% (power) to obtain the 95% CI, a sample size of 13 (i.e. 13 paired data) is needed in Group 1 and Group 2 (i.e. total of 26 participants for both groups). To account for a drop out of 15%, a sample size of 15 is needed in each group (i.e. total of 30 participants in both groups).With a probability of 90% to obtain a 95% CI, for the paired difference between the morphic dot sensors and the gold standard system, with a distance from the mean paired difference to the limits that is less than or equal to 8, a sample size of 46 is needed if the correlation between paired data is 0.3 and the standard deviation of paired difference is 20. If a drop out of 10% is considered, a total sample size of 51 is needed.

2. Background Information

2.1. Name and description of the investigational product

The Morphic Dot sensors are being designed as an innovative, wearable signal monitoring solution able to detect ECG, pulse wave and sound waves from a single location. The devices are made up of sensors which may be embedded into a wearable system (e.g. waistband, wristband, finger sensor) or placed as single assembly. In the final product the sensors will have dedicated electronics for signal management and including data storage and data transmission capabilities. The sensor technology has been designed to monitor both cardiovascular and respiratory signals.

The devices used in this study will be the finger Morphic Dot sensor (refer to **Figure 1** below) containing a force sensitive resistor sensors (FSR), and a piezoelectric sensor.



Figure 1: Morphic Dot Sensor

In this study a finger mounted morphic sensor will collect signals together with a Biopac PPG finger cuff and 3 ECG electrodes. All will be connected to a BioPac MP36 Data Acquisition System – a commonly used system in Medical Clinical Research (see https://www.biopac.com/product/mp36r-systems/). The BioPac (with morphic sensors connected) will be positioned on a trolley.

Photos of the BioPac Acquisition System, the gold standard PPG, ECG and blood pressure sensors are shown in the table on the following page in Figure 2.

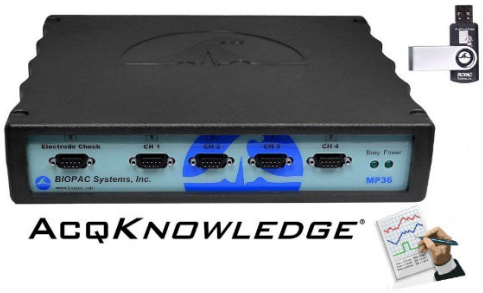
	
MP36 data acquisition and analysis system	**TSD200** Photo-electric plethysmograph (PPG)
	
SS2LB ECG Lead Set	

Figure 2: BioPac gold standard used

2.2. Introduction

In the past 3 years, in collaboration with a sponsor industry partner we have developed a novel wearable non-invasive sensor capable of detecting the small forces impressed to the skin by moving organs/vessels/muscles lying under the sensor. This sensor when placed over the heart or over a vessel has been named Forcecardiography sensor [Centracchio J, Andreozzi E, Esposito D, Gargiulo GD, Bifulco P. Detection of Aortic Valve Opening and Estimation of Pre-Ejection Period in Forcecardiography Recordings. Bioengineering. 2022; 9(3):89. https://doi.org/10.3390/bioengineering9030089].

There is an unmet need for new technologies that can improve the management of cardiovascular disease, and many researchers are trialling sensors which are not electrical (e.g. inertial, piezoelectric etc…) to replace/aid the traditional ECG in patient prognosis/assessment [Inan, O.T.; Migeotte, P.F.; Park, K.S.; Etemadi, M.; Tavakolian, K.; Casanella, R.; Zanetti, J.; Tank, J.; Funtova, I.; Prisk, G.K.; et al. Ballistocardiography and Seismocardiography: A Review of Recent Advances. IEEE J. Biomed. Health Inform. 2015, 19, 1414–1427]. Differently from the available sensors, the Forcecardiography sensor is small enough and sensitive enough to detect signals from fingers [Sponsor unpublished material].

2.3. Potential Risks and Benefits

The Morphic Dot sensors are considered a low-risk device due to their passive nature and positioning on the body surface. The devices will record pulse signals from the finger only together with gold standard PPG sensors from the finger and an ECG signal from the chest.

The risk analysis of the morphic dot sensors has identified the following as potential adverse events from wearing the sensors:

- Discomfort from sensors
- Localised skin irritation

Participation in this proof-of-concept study is not considered to be beneficial to the participant, however, data obtained from this study is anticipated to assist with the future development of the device and may be beneficial to the broader community at a later time.

2.4. Regulatory Compliance Statement

The trial conduct will comply with ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice (GCP) adopted by the Australia Therapeutic Goods Administration, the requirements of the Australian National Statement on Ethical Conduct in Human Research (2007; updated 27 March 2014), local regulatory requirements and in accordance with the Declaration of Helsinki. Prior to commencement of the study, the study must receive written approval from the HREC and from the appointed research governance offices for the institution. The study must be registered on the Australian New Zealand Clinical Trials Registry or similar trials registry before participants are screened.

2.5. Study Population

The aim of this study is to examine the difference in pulse characteristics of various sensors from the finger location. The study population will include people (anticipated to Western Sydney University students or personnel) in two different age groups – 18 to 30 years of age and 30 to 65 years of age. 15 from each group will be recruited.

Participants will undergo monitoring with the morphic dot sensors on the finger and the Biopac gold standard sensors on the finger (PPG) and chest ECG).

3. Purpose and Objectives

The primary objective for the study is to measure, and compare, the delay between the R-peak (ECG signal) and the peak pulse force measured at the finger pad, for each of the finger sensors – ie the 2 test sensors (FSR and Piezo) and the gold standard (PPG) sensor.

The secondary objective is to assess the test and gold standard sensors capability to detect the so-called pulse dicrotic notch from the finger.

4. Trial design

This study is a non-randomised, single arm, observational proof-of-concept study.

4.1. Minimisation of Bias

This is a non-randomised, non-blinded proof of concept study aimed at obtaining initial sensitivity and specificity data to establish whether the sensors can be used for detecting the pulse at the finger. All possible efforts will be made to reduce bias in the interpretation of data from the Finger Morphic Dot sensors.

Only de-identified data collected from the Morphic sensors will be analysed. Quantitative measurements compared to gold standard devices can be directly compared using standard statistical techniques by researchers.

4.2. Endpoints

1. Primary

- Able to measure the pulse transit time (time from peak of ECG to peak of pulse wave) from both test sensors and the PPG sensor

2. Secondary

- That a dicrotic notch can be recorded from all 3 sensors from the finger

4.3. Trial treatment

Patients who meet eligibility criteria and deemed as suitable candidates by the Principal Investigator will be enrolled in the study.

The participant will be connected to all morphic sensors and BioPac sensors and signals will be continuously collected for 5-10 minutes. Data from the BioPac will be collected from the research laptop and stored as a copy of the source record for the gold standard data.

4.4. Trial Duration

Participant duration in the study is not anticipated to be more than 30 minutes for each participant. Recruitment of participants from first patient to last patient is anticipated to be less than 3 months.

4.5. Stopping Rules

There are no stopping rules for this low-risk proof of concept study.

4.6. Investigational Product Accountability

All devices will be used under supervision of research staff. Each of the sensors will be numbered and the sensor number will be recorded in the device accountability log. Sensors will be cleaned with alcohol prior to being reused.

4.7. Source Documentation

De-identified data will be entered into an Excel spreadsheet from the CRFs. Data collected from the signals will be analysed in Matlab and the results entered into the Excel spreadsheets.

The investigator must ensure the accuracy, completeness, and timeliness of the data reported. Data reported in the Excel spreadsheets must be verifiable to source data, which necessitates access to all original recordings, reports and participant records. The investigator and site personnel must cooperate with the monitor for the periodic review of study documents, to ensure the accuracy and completeness of the data reported in the (e)CRFs.

During the study the study monitor will review the CRFs and Excel spreadsheets and evaluate them for completeness and consistency. The Excel spreadsheets will be compared with the source documents to ensure that there are no discrepancies. All entries, corrections and alterations are to be made by the investigator or designee.

5. Selection and Withdrawal of Patients

5.1. Inclusion Criteria

- 18-65 years of age.

5.2. Exclusion Criteria

- Participant has been diagnosed with cardiovascular disease
- Participant is pregnant or lactating.
- Inability to place morphic sensors.

5.3. Subject Withdrawal Criteria

As this is a short duration, observational trial, no participant withdrawal is anticipated. Participants who withdrawal voluntarily prior to completing the study protocol or are withdrawn by the investigator for any reason (e.g., safety concern) may be replaced with a new participant.

6. Treatment of Study Subjects

6.1. Schedule

Table 3: Follow-up schedule

	Screening & Baseline	Monitoring	End of Study (EOS)
Visit	**1**	**1**	**1**
Visit window	**Day 1**	**Day 1**	**Day 1**
Consent	X		
Eligibility Review	X		
Demographics	X		
Height/Weight and Anatomical Measurements	X		
BioPac gold standards – (ECG on limbs, PPG on finger)		X	
1 x Saiiv Morphic Dot Sensors – finger		X	
Protocol Deviations	X	X	X
AE/SAEs	X	X	X
Device Deficiencies		X	
EOS			X

6.2. Screening, Eligibility and Consent

Participants will be recruited by the Principal Investigator at each site. Research staff will initially pre-screen participants against the eligibility criteria to assess eligibility and once confirmed the participant will invited to participate and consented into the study.

Once eligibility is confirmed baseline data will be collected including age, height and weight.

6.3. Monitoring from Sensors

The finger morphic dot sensors, the BioPac finger PPG sensors and the Biopac chest ECG electrodes will be connected to the participant and signal strength and quality tested. Data will be continuously collected for 5-10 minutes.

6.4. Human Factors

The test device is a prototype only. It is anticipated that the design will change substantially before a final product is commercialised. Consequently no Human Factor data will be collected.

6.5. End of Study (EOS)

The end of the study will be when the participants have completed the recordings of their signals from both the test and gold standard sensors.

6.6. Reimbursement to Participants

In return for the participants time, each participant will receive a $30 supermarket voucher for being involved in the study.

7. Safety Assessment

7.1. Adverse Event Definition

ISO 14155 definitions will be used for this proof-of-concept study.

Adverse Event (AE): Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.

NOTE 1: This definition includes events related to the investigational medical device or the comparator.

NOTE 2: This definition includes events related to the procedures involved.

NOTE 3: For users or other persons, this definition is restricted to events related to investigational medical devices.

Serious Adverse Event (SAE): adverse event that
a) Led to death,
b) Led to serious deterioration in the health of the subject, that either resulted in
    1) A life-threatening illness or injury, or
    2) A permanent impairment of a body structure or a body function, or
    3) In-patient or prolonged hospitalization, or
    4) Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
c) Led to foetal distress, foetal death or a congenital abnormality or birth defect

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

Serious Adverse Device Effect (SADE): adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Unanticipated Serious Adverse Device Effect (USADE): serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

NOTE: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.

7.2. Events of Interest

There are no defined adverse events of interest.

7.3. Adverse Event Assessment

Adverse events will be assessed by the Principal Investigator. The Investigator will establish a Clinical Events Committee (CEC) to review any AEs/SAEs that occur during the study.

7.4. Adverse Event Reporting

All serious adverse events (SAEs) should be reported immediately except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.

8. Statistical Design

8.1. Statistical Methods

This study is a validation study to compare the morphic dot sensors on the finger and a comparison to a gold standard system (BioPac).

8.2. Sample Size

The agreement between biometric measurements by the test sensors the Biopac gold standard, will be assessed by Lin's concordance correlation coefficient (CCC). It is expected that CCC will be around 0.95 between paired data (Test sensors vs gold standard), with the lower side of the 95% confidence interval (CI) more than 0.75. With a probability of 80% (power) to obtain the 95% CI, a sample size of 13 (i.e. 13 paired data) is needed in Group 1 and Group 2 (i.e. total of 26 participants for both groups). To account for a drop out of 15%, a sample size of 15 is needed in each group (i.e. total of 30 participants in both groups).

9. Direct Access to Source Data and Trial Documents

The site agrees to allow the monitor and authorised representatives from Mobius Medical to access Case Record Forms for the purpose of source data verification of data. No identifiable information will be collected as a result of source data verification and or auditing purposes.

The Investigators will maintain accurate, complete, and current records relating to participation in this clinical study. Study records including CRFs and supporting data, signed Clinical Trial Agreement, protocols and protocol amendments, device tracking logs, EC approval letters, EC submissions, correspondence, including required reports, and other documents pertaining to the conduct of the study must be kept on file by the Investigator.

10. Quality Control and Assurance

10.1. Quality Control and Assurance

The study will be periodically monitored for compliance to the protocol and as per ISO 14155. Monitoring will occur as per the monitoring plan and site agreements. The monitor will be from a suitably qualified company such as Mobius Medical.

10.2. Trial Steering Committee

No Steering Committee or Data Safety Monitoring Board will be formed for this study.

11. Ethics

The protocol, participant information sheet and consent form, recruitment materials, and all participant materials will be submitted to the WSU HREC for review and approval. Approval of both the protocol and participant information sheet and consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the HREC before the changes are implemented to the study.

12. Investigator Responsibilities

The Investigator is responsible for ensuring that the study is conducted in accordance with the highest standards of medical and clinical research practice and the applicable regulations specifically ISO 14155. The Investigator is responsible for the day-to-day conduct of the clinical study and for the safety and well-being of participants enrolled.

13. Data Handling and Record Keeping

Data will initially be captured from paper-based Case Record Forms and the source of all data will be documented by the investigator on a source data location log. The data will be later entered into an Electronic Data system stored in the WSU secure server. Source documents will be securely stored by the investigator for at least 15 years. Data collected via a digital means will have no identifying information recorded.

13.1 Data Storage

Deidentified data will be entered and stored for an indefinite period of time on a WSU secure server. All communication to the server is Secure Socket Layer (SSL) encrypted and password protected for security of data.

13.2 Record Retention

Study documentation and data will be retained for 15 years after the completion of the trial and will be securely stored either at the site or at a secure document storage facility. The site will archive the study documents in accordance with good clinical practice.

13.3 Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, research staff, and all participating third parties. The study protocol, documentation, data and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorised third party, without prior written approval of Western Sydney University.

14. Financing and Insurance

The study is funded by grants received by WSU including funds from Medical Monitoring Solutions.

15. Publication Policy

A publication committee will be formed to manage publications resulting from the study. The committee will include the Principal Investigators from Western Sydney University (WSU) and representatives from Medical Monitoring Solutions. The committee will decide and approve all publications including the target journal/scientific symposium for publication, the number and order of authors on all publications. Medical Monitoring Solutions will not claim any authorship rights to publications arising from this study.

16. Supplements

None

17. References

Refer to literature review.

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Analysis of Pulse Characteristics from Force Sensitive Resistor Sensors, Piezoelectric Sensors and Photoplethysmography Sensors (SENSOR CF)

Description

In the past 3 years, in collaboration with a sponsor industry partner we developed a novel wearable non-invasive sensor capable of detecting the small forces impressed to the skin by moving organs/vessels/muscles lying under the sensor, this sensor when placed over the heart or over a vessel has been named Forcecardiography sensor [Centracchio J, Andreozzi E, Esposito D, Gargiulo GD, Bifulco P. Detection of Aortic Valve Opening and Estimation of Pre-Ejection Period in Forcecardiography Recordings. Bioengineering. 2022; 9(3):89. https://doi.org/10.3390/bioengineering9030089]. There is an unmet need for new technologies that can improve the management of cardiovascular disease, and many researchers are trialing sensors which are not electrical (e.g. inertial, piezoelectric etc…) to replace/aid the traditional ECG in patient prognosis/assessment [Inan, O.T.; Migeotte, P.F.; Park, K.S.; Etemadi, M.; Tavakolian, K.; Casanella, R.; Zanetti, J.; Tank, J.; Funtova, I.; Prisk, G.K.; et al. Ballistocardiography and Seismocardiography: A Review of Recent Advances. IEEE J. Biomed. Health Inform. 2015, 19, 1414–1427]. Differently from the available sensors, the Forcecadiography sensor is small enough and sensitive enough to detect signals from fingers [Sponsor unpublished material]. The sensor, placed over chest, neck, iliac crest and fingers is currently at trial in two major hospitals (approved by Alfred Hospital Ethics Committee with protocol number: HREC/90385/Alfred-2022, notified to WSU human ethics office in June 2023) where it is compared against gold standard such as: right-heart catheterization, ECG, Doppler (valves and chambers motility), PPG, non-invasive blood pressure as well as bodily sounds. With this trial we aim to recruit healthy (never diagnosed with cardiovascular diseases) participants to compare signals from the finger versus ECG and PPG. Specifically, we aim to:

1) Measure and compare (healthy versus patient) the delay between the R-peak (ECG signal) and the peak pulse force measured at the finger pad.

2) Assess the Forcecardiography capability to represent the so-called pulse dicrotic notch (PPG signal), which may be absent in the patients enrolled in our study.

Moreover, the Forcecardiography sensor is a fused sensor combining piezoelectric and piezoresistive sensors, with this study we also plan to assess the delay (if any) between the piezoelectric and piezoresistive components.

Expand/Collapse all

Project overview

Project ID
P00027727

Start date
11/01/2023

End date
03/31/2024

Funding source

Maridulu Budyari Gumal

Grant number(s)

P00027727

- People

People

Principal Investigator

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Data Creator

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School / Institute
School of Design, Engineering and Built Environment

Data Manager

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Collaborators (WSU)

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Professor	Paul Breen	P.Breen@westernsydney.edu.au	0000-0002-8860-2086
Doctor	Upul Gunawardana	u.gunawardana@westernsydney.edu.au	0000-0003-0932-5306

External Collaborators

Principal Supervisor (students only)

Title	Name	Email	ORCID

- Data

Data

What types of data will be produced and in what format will it be stored?
Non identifiable binary data (waveform)

What software if any is required to collect, collate or analyse your data?
BIOPAC Acknowledge;
Matlab

What third party data are you using and are there any special requirements around the use of the data?
none

- Data storage

Data storage

Expected size of the data collected
Less than 10GB

Research Data Storage options at Western (during the project)

In accordance with the University's Research Data Management Policy, infrastructure is available to researchers to use as a secure platform to store and share working data. Please contact ITDS for assistance with these options.

- Cloud storage via CloudStor. Log in using your Western staff or student credentials.
- Cloud storage via OneDrive. Access is available through the Microsoft Office 365 Online Portal with your Western account.
- University shared network drive or desktop computer. The advantage of using storage on the University's network is that it is backed up and access is secured with staff or student credentials.
- National Computational Infrastructure
- Personal equipment (temporary solution which must be backed up regularly on a separate secure device at a different location)

Storage location
University owned computer or external media

Data will be stored on computer, backed up on OneDrive

Physical Data

Where will physical research be stored?
no physical data available for this project

- Data retention

Data retention

What is the required retention period for your data?
Permanently

What do you intend to do with the research data and primary materials at the end of the retention period?
Retain

- Ethics and sensitivities

Ethics

Ethics approval number

Appropriate ethics approval and participant consent are required for sharing human data. Contact humanethics@westernsydney.edu.au for assistance.

Sensitivities

Type of sensitivity

Information about privacy, confidentiality or sensitivity to the data and how it will be managed

Can some or all of the research dataset be made accessible to other researchers?

Open Access

- Ownership, licensing and IP

Ownership, licensing and IP

Refer to Intellectual Property Policy for further clarification

Copyright and intellectual property owners

Please list any other owners

Information about contractual obligations that apply to this data