GENERAL INFORMED CONSENT

INFORMED CONSENT FOR CLINICAL RESEARCH

STUDY TITLE	Stress level monitoring using sensor-derived signals from non-invasive wearable devices and dataset development.
INFORMED CONSENT FOR	Volunteer Participants.
NAME OF RESEARCH INSTITUTION	Smart Sensors Lab at National University Ireland Galway and University Hospital Galway.
NAME OF PRINCIPAL INVESTIGATORS	Prof. William Wijns; Dr Jane Walsh; Dr Gerard Molloy.
NAME OF SPONSOR	Science Foundation Ireland.
NAME OF INVESTIGATORS	Talha Iqbal; Dr Sandra Ganly; Eileen Coen; and members of Professor Wijns research team.
Participant ID	

This informed consent has two parts:

- INFORMATION SHEET.
- CONSENT FORM.

You will be given a copy of the full Informed Consent form for your records.

PART I: INFORMATION SHEET

INTRODUCTION

My name is Talha Iqbal. I am a researcher based at the Smart Sensors Lab, National University Ireland Galway. I am an electronic engineer conducting stress monitoring research for my PhD qualification, under the supervision of Professor W. Wijns. This research study focuses on detecting and monitoring stress in healthy people using commercially available smartwatches. I will give you information on this study and invite you to be part of this important research. You do not have to decide today if you would like to participate. I encourage you to speak with your family and friends or your family doctor to help make your decision to participate. There may be words or terms you do not understand in this information sheet, or you may have questions. If you do, please contact me, or any member of the study team. We are happy to answer any of your questions and provide further explanations. You can ask questions throughout the study and leave the study at any time.

PURPOSE OF THE RESEARCH

The purpose of this research is to prove that stress levels can be efficiently monitored using photoplethysmogram (PPG) signals.

Study Objectives:

- To monitor stress levels through PPG signals in a healthy population.
- To collect PPG signals using a "smart" watch (a wrist-worn device).
- To develop a dataset from these collected PPG signals that can be analysed by the research team.

Study outcomes:

The results of this research study will help us to:

- Develop a new classification technique to distinguish between PPG signals detected in a stress condition and PPG signals detected in a non-stress condition.
- Develop a novel, optimized technology for the accurate measurement of stress disorders.

RESEARCH STUDY DESCRIPTION

If you decide to participate in this research study, you will be provided with a "smart" watch to wear on your wrist during the study. While wearing this watch, you will be invited to perform a series of time-constrained tasks. There will be three different types of tasks, with a break in-between each task to rest and relax. You will also be asked to complete a paper-based questionnaire before, and after, the time-constrained tasks. The overall study will take approximately 60 minutes to complete. You will be guided through each task by the research team, who will provide clear instructions about each task in advance of completing it. The research team will be present at all times to answer your questions or assist you in any way.

STUDY PARTICIPANT SELECTION

To be included in this study, you must fulfil the following eligibility inclusion criteria. The participant must be:

(a) healthy with no known disease or underlying medical conditions,

(b) aged between 18 and 75 years,

(c) able to complete both the questionnaires and stress tasks in the English language,

(d) able to provide informed consent.

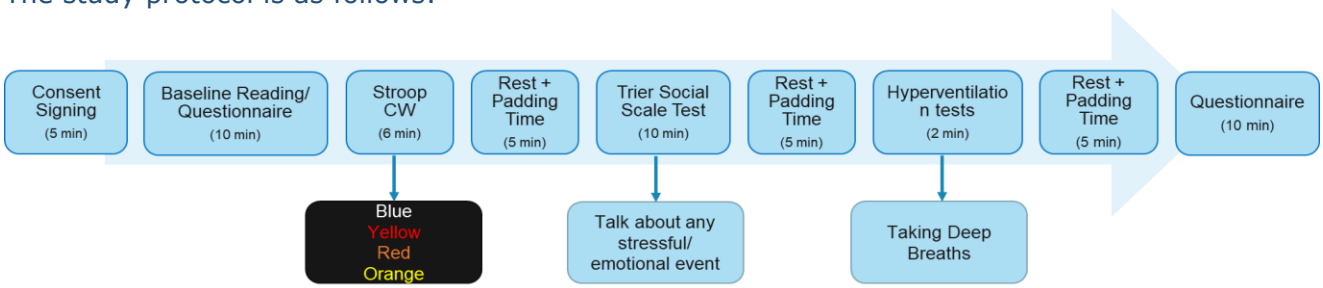
The following exclusion criteria apply. Anyone with any issue interfering with giving informed consent or has previously had any underlying stress-related (triggering) condition is not eligible to participate in the study. Moreover, breastfeeding mothers, pregnant women and colour-blind participants are also excluded.

VOLUNTARY PARTICIPATION

We ask you to participate in this study voluntarily. There is no travel allowance, daily subsistence allowance or any additional benefits provided to the study participant(s).

RESEARCH PROCESS OVERVIEW

The study protocol is as follows:



Step 1: The participant arrives at the laboratory located in the Lambe Institute.

Step 2: The participant sits for **5 minutes**. One of the research team members will ask the participant if they have any questions about the digital patient information sheet and consent form provided to the participant in advance. Once the participant confirms that they are satisfied to proceed with the study tasks, the signed consent form (hard copy) will be collected.

Step 3: The participant will be given a watch to wear. The participant will also be asked to provide a saliva sample (saliva collection 1) by being asked to spit into a test tube provided by the clinical research nurse.

Step 4: Once the participant has completed Step 3, the research team will start to collect the baseline readings from the watch while the participant sits in a relaxed environment. During this time the participant will complete the Perceived Stress Scale (PSS) and State-Trait Anxiety Inventory (STAI) questionnaires. This step will take approximately **10 minutes** to complete.

Step 5: Once Step 4 is completed, the participant will be invited to complete a series of tasks as follows:

Step 5.1: Stroop Colour Word Task: **6 minutes**.
- Name the ink colour, not the word.
- Do as many as possible within the time (at least 200).
- Please note that the researchers may ask the participant to be quick (rush). Once this task is completed, the participant will be invited to rest & relax for approximately **5 minutes**.

Step 5.2: Trier Social Scale Test: **10 minutes**.

- The participant will be asked to describe a stressful event in their life. Once this task is completed, the participant will be invited to rest & relax for approximately **5 minutes**.

Step 5.3: Hyperventilation Task: **2 minutes**.

- The participant will be asked to take several deep breaths while the clinical research nurse counts the respiratory rate: **30-40 sec**.

Step 6: Once the final hyperventilation task is completed the participant will be guided by the research team in a guided breathing exercise to bring the participant's respiratory rate to a normal range.

Step 7: As a final step, the participant will be asked to provide another saliva sample (saliva collection 2) by being asked to spit into a test tube provided by the clinical research nurse.

Step 8: Once Step 7 is completed, the participant will be invited to rest & relax for approximately **5 minutes**.

Step 9: After the final rest period, the research team will invite the participant to complete the Perceived Stress Scale (PSS) and State-Trait Anxiety Inventory (STAI) questionnaires again. This will take approximately **10 minutes** to complete.

Step 10: Finally, the participant will be asked to remove the watch and return it to a member of the research team. The clinical research nurse will be present at all times for any questions the participant may have after the study is completed. The participant is welcome to rest and relax for as long as necessary before leaving the study location.

Note: The study only requires wearing a wrist-worn watch and to provide two saliva samples. There will be no blood collection, no needles, no pills, no medications. The study is completely non-invasive.

STUDY DURATION

The study will take approximately **60 minutes** to complete.

RISK/SIDE EFFECTS

The tasks in the study are time-constrained and are designed to make you feel "stressed". However, the level of stress should only be what you may experience in everyday life. For example, how you might feel when you may be late for an appointment or meeting. However, at no time should the tasks induce a level of stress that makes you feel uncomfortable, over-anxious or overwhelmed. Periods of relaxation are included before you start the study, after each time-constrained task as well as after the study is completed until you are ready to leave and go home. You can stop participating in the study at any time. There will be clinical research nurses present at all times to assist you if you have any concerns or are feeling unwell.

BENEFITS

This study will allow us to better understand how stress can affect the body. It will give us valuable data to develop better classification techniques and in the longer term, better technologies to detect stress

levels. As a result, we will be able to monitor the effects of stress in people and how we can prevent and manage long-term chronic medical conditions which will benefit all of society.

RIGHT TO REFUSE OR WITHDRAW

Participation in this research study is voluntary. You have the right to withdraw from the study at any stage of the process. You will be able to do this by contacting Talha Iqbal at t.iqbal1@nuigalway.ie, or by alerting any of the research team members during the study itself.

DATA CONFIDENTIALITY

The sensor data will initially be stored on the watch. After completion of the session, the data from the watch will be transferred to the investigator's personal computer (secured with a password and only accessible to one person). The data collected will be allocated a unique identifier number and will be recorded as anonymous data. All questionnaires will only have unique identifier numbers and no personal information is recorded on the questionnaires. Once completed by the participants, the hard copies of the questionnaires will be kept in a locked filing cabinet in the secured offices of the clinical research team at the Lambe Institute.

The collected data will be stored in the personal computer of the investigator and will be password secured (only accessible to the investigator). The data will be anonymized and will be labelled by the unique participant ID.

DATA PROTECTION

1. The purpose or reason for processing their personal data.

We will be using your data in our research to prove the principle that stress can be monitored efficiently using photoplethysmogram (PPG) signals.

2. The legal basis under which you are processing their data.

The lawful basis is the valid legal reason to process and use data under GDPR. For this study the following two Articles from the General Data Protection regulation 2018 represent the legal basis for use of personal data:

- Article 6(1) (e): Processing is necessary for the performance of a task carried out in the public interest.
- Article 9(2) (j): Processing is necessary for scientific research purposes.

1. **Who are the recipients of the data e.g., who will have access to the research participants' information?**

All the information will solely be collected by the investigator and will not be shared with anyone before anonymization.

2. **How long will the data be stored for and, if it is not possible to say, please give the criteria which will be used to determine that period.**

The data will be kept stored for 5 years and will then be removed.

3. **You should inform the data subject of any risks and/or implications that might arise for the data subject because of the data processing e.g., a data breach that could cause them harm.**

We are going to collect raw photoplethysmogram (PPG) signal against the participant ID rather than any other identifier that might lead to the specific person. We will make sure that no data breach occurs but if it happens no harm will be caused to the participant.

4. **That the data subjects have a right to withdraw consent. Please explain how they can go about doing this or what the withdrawal mechanism is.**

The participant reserves the right to withdraw their consent at any stage of the study as well as after the study is concluded. To do so, the participant can contact *Talha Iqbal* at *t.iqbal1@nuigalway.ie*.

5. **That the data subjects have a right to lodge a complaint with the Data Protection Commissioner.**

We ensure that all the data will be used rightfully. If a participant thinks their data has been misused, they can ask Talha Iqbal at t.iqbal1@nuigalway.ie to delete their data. If they do not their confirmation email, they may complain to the Data Protection Commissioner.

6. **That the data subjects have a right to request access to their data and a copy of it unless their request would make it impossible or make it very difficult to conduct the research.**

The participants will have the right to access. This enables you to check what type of personal data we hold about you and what we do with that personal data and to receive a copy of this personal data.

7. **That data subjects have a right to restrict or object to processing unless their request would make it impossible or make it very difficult to conduct the research e.g., the data subject doesn't want their data shared but doesn't mind having it collected and stored.**

The participants will have the right to restrict or object to the processing of your data where that processing is carried out based on our legitimate interests. We will stop using your data unless we can demonstrate an overriding legitimate ground for the continued processing of this personal data.

8. **That the data subjects have a right to have any inaccurate information about them corrected or deleted unless their request would make it impossible or make it very difficult to conduct the research.**

The participants will have the right to rectification. This enables you to correct any inaccurate or incomplete personal data that we hold about you.

9. **That the data subjects have a right to have their personal data deleted unless their request would make it impossible or make it very difficult to conduct the research. e.g., they wanted to delete their data at the end of a research project just before it is due to be published.**

The participants will have the right to erasure their data. This enables you to request that we erase personal data held about you in certain circumstances.

10. **That the data subjects have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.**

The participants will have the right to data portability. This enables you to receive your data in a structured, commonly used, and machine-readable format and to have that personal data transmitted to another data controller.

11. Will there be automated decision making, including profiling? Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to the person, to analyse or predict aspects of their performance at work, health or behaviour.

The data collected from all the participants will be processed and automated decision making about their stress/nonstress state will be predicted.

12. That the data subjects have a right to object to automated processing including profiling if they wish.

The participants will have the right to object to automated processing. This enables you to request that we erase the personal data that we hold about you.

13. You must inform the data subject if you intend to further process their personal data and provide the data subject with information on that other purpose.

All the participants will be informed beforehand if we intended to further use their data for any other purpose besides this study.

14. You must inform the data subject if you wish to transfer their data to a country outside of the EU or an international organisation and advise them of the safeguards you have in place to protect their data.

All the participants will be informed beforehand if we wished to transfer their data to a country outside of the EU or an international organisation and will advise them of the safeguards, we have in place to protect their data.

WHO TO CONTACT?

The research study proposal, as well as the protocol, has been approved by the University Hospital Galway Ethics Committee. The study is completely safe and has no follow-up. If you agree and give consent for the participation in the study, please contact:

Name: Talha Iqbal.

Email: t.iqbal1@nuigalway.ie.

or

Name: William Wijns.

Email: william.wyns@nuigalway.ie.

or

Name: Eileen Coen.

Email: eileen.coen@nuigalway.ie.

Contact: +353861455568.

PART II: CERTIFICATE OF CONSENT

I, the undersigned, confirm that (please tick the box as appropriate):

1.	I have read and understood the information about the study, as provided in the Information Sheet.	
2.	I have been allowed to ask questions about the study and my participation.	
3.	I voluntarily agree to participate in the study.	
4.	I understand I can withdraw at any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn.	
5.	The procedures regarding confidentiality have been clearly explained (e.g., use of names, pseudonyms, anonymisation of data) to me.	
6.	If applicable, separate terms of consent for interviews, audio, video, or other forms ofdata collection have been explained and provided to me.	
7.	The use of the data in research, publications, sharing and archiving has been explainedto me.	
8.	I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data and if they agree to the terms I have specified in this form.	
9.	I, along with the Researcher, agree to sign and date this informed consent form.	

STATEMENT OF CONSENT

I have read the study information, or it has been read to me. The risks of the study process have been explained to me and are also identified in this documentation. Any questions I have about the study, its benefits, and its risks have been explained to my satisfaction. I give my informed consent to voluntarily participate in this research study.

Print Name of Participant

Signature of Participant *Date*

STATEMENT BY THE RESEARCHER TAKING CONSENT

I have accurately read the information sheet to the potential participant and have ensured, to the best of my ability, that they understand the research study. I confirm that the participant was given adequate opportunity to ask questions about the study and I provided the answers to the best of my ability. I confirm that this individual has not been coerced into providing consent, and their consent has been given willingly and freely.

Print Name of Researcher

Signature of Researcher *Date*

A copy of this Informed Consent must be provided to the participant.