**Participant Information Sheet – Patient sheet**

**The title of the research project**

Evaluating the effectiveness of remote photoplethysmography (Lifelight technology) for hypertension screening in individuals with darker skin tones.

**Invitation to take part**

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**Who is organising/funding the research?**

The researcher is:

Name: David Dasa an MSc Student in Bournemouth University Faculty: Science and technology

The research is part of my MSc dissertation.

**What is the purpose of the project?**

Data collection and explanation: Lifelight technology uses smart device cameras, not to take pictures or videos, but to analyse the little changes in the colour of the face as blood flows to estimate the heart rate and blood pressure.

As the colour of our skin affects how light is reflected from our faces, this study aims to understand if lifelight technology can be used for hypertension screening in individuals with darker skin tones and to see if it is acceptable for use as an alternative to current methods.

This study and the data collection is part of my master's degree studies.

Lifelight is an app which I have installed on an iPad. It does not take any identifiable data on an individual, it uses the reflected light from an individual's face, thus needs to be used in a well-lit environment.

The data collection should last for four weeks.

**Why have I been chosen?**

If you have expressed interest in participating either via contacting the MSc student researcher or visiting the study location, thank you for your interest!

Please keep in mind the following information.

Reasons for inclusion: Individuals aged 18 and above.

Reasons why you may not be able to participate:

Inability to provide consent for participation.

Pregnancy - There are unique factors which affect blood pressure in pregnancy and the current lifelight algorithm is not designed to capture those.

Individuals with skin conditions obscuring facial features (third degree burns, psoriasis etc) Individuals with heavy facial makeup obscuring facial features.

Individuals unable to stay still enough for forty seconds to get a Lifelight reading (e.g. static tremors). Individuals outside Fitzpatrick skin tone V and VI.

The Fitzpatrick skin tone is a scale medical personnel use to identify the colour of an individual’s skin, this is on a range from one to six based on how likely one is to tan when exposed to sunlight, this is important as different skin tones interact with light waves differently and the Lifelight app estimates blood pressure from light reflecting off of the face.

Target Sample Size: The study aims to recruit a total of 500 patient participants and 50 members of staff. This target sample size is informed by statistical considerations to make the research robust enough to reflect the population.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given/have access to this information sheet to read.

You can withdraw from participation at any time and without giving a reason, you can retain this information sheet for your reference, simply decline to sign the participant agreement form.

Please note that once you have completed and submitted your survey responses or participated in the blood pressure measurements, we are unable to remove your anonymised responses/data from the study.

Deciding to take part or not will not impact upon you or your service delivery in any way, please remember there is no obligation whatsoever to participate.

**Can I change my mind about taking part?**

Yes, you can stop participating in study activities at any time and without giving a reason.

You can withdraw from participation at any time and without giving a reason, you can retain this information sheet for your reference, simply decline to sign the participant agreement form.

Please note that once you have completed and submitted your survey responses or participated in the blood pressure measurements, we are unable to remove your anonymised responses/data from the study.

**If I change my mind, what happens to my information?**

After you decide to withdraw from the study, we will not collect any further information from or about you.

As regards to the information we have already collected before this point, your rights to access, change or move that information are limited. This is because we need to manage your information in specific ways in order for the research to be reliable and accurate. Further explanation about this is in the Personal Information section below.

**What would taking part involve?**

Have your blood pressure measured three times using both a traditional (arm cuff) OMRON blood pressure monitors and Lifelight technology - This is so we can compare the 2 methods.

We will take note of your skin tone using the Fitzpatrick skin types to help us understand its influence on our accuracy. The Fitzpatrick skin tone is a scale medical personnel use to identify the colour of an individual’s skin, this is on a range from one to six based on how likely one is to tan when exposed to sunlight, this is important as different skin tones interact with light waves differently.

We will also take note of whether you have facial tribal marks or not to better understand if this is something that might affect the accuracy of our measurements.

You will be asked to complete a brief questionnaire about your demographics (age, sex) and health information on your blood pressure monitoring habits, any history of hypertension, and on your experience having your blood pressure measured using Lifelight technology.

**Will I be reimbursed for taking part?**

There will be no form of compensation provided as part of participation.

**What are the advantages and possible disadvantages or risks of taking part?**

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will help improve our knowledge of using Lifelight technology for hypertension screening as an alternative to current methods.

There are no known risks of taking part in the study, however, please note some people do find having their blood pressure measured with an arm cuff device to be uncomfortable.

**What type of information will be sought from me and why is the collection of this information relevant for achieving the research project’s objectives?**

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This is a list of the information collected:

|  |
| --- |
| Questionnaire:   * Age * Gender * How often do you measure your blood pressure? * What type of blood pressure monitor do you currently use (if any)? * Do you currently own a blood pressure measuring device? * If you do not own a blood pressure measuring device, how often do you typically visit a facility to have your blood pressure measured? * Do you own a smartphone? Did you experience any difficulties using Lifelight technology for blood pressure measurement? * How comfortable did you find using Lifelight technology? * How confident are you in the accuracy of blood pressure readings obtained using Lifelight technology compared to traditional methods? * How useful do you think Lifelight technology would be for monitoring your blood pressure on a regular basis? * Do you have any concerns about using Lifelight technology? * Do you have any suggestions for improvement regarding Lifelight technology? |
| The researcher will document the following information on you:   * Fitzpatrick Skin type - Clinician Assessment (Your skin tone) * Facial Tribal Marks - (Whether or not you have tribal marks) * BP measurement - Cuff * BP measurement – Lifelight App on iPad. |

**Will I be recorded, and how will the recorded media be used?**

There are no identifiable photographs or images produced as part of this study.

**How will my information be managed?**

Bournemouth University (BU) is the organisation with overall responsibility for this study and the Data Controller of your personal information, which means that we are responsible for looking after your information and using it appropriately. Research is a task that we perform in the public interest, as part of our core function as a university.

Undertaking this research study involves collecting and/or generating information about you. We manage research data strictly in accordance with:

* Ethical requirements and
* Current data protection laws. These control use of information about identifiable individuals, but do not apply to anonymous research data: “anonymous” means that we have either removed or not collected any pieces of data or links to other data which identify a specific person as the subject or source of a research result.

BU’s Research Participant Privacy Notice sets out more information about how we fulfil our responsibilities as a data controller and about your rights as an individual under the data protection legislation. We ask you to read this Notice so that you can fully understand the basis on which we will process your personal information.

Research data will be used only for the purposes of the study or related uses identified in the Privacy Notice or this Information Sheet. To safeguard your rights in relation to your personal information, we will use the minimum personally-identifiable information possible and control access to that data as described below.

*Publication*

You will not be able to be identified in any external reports or publications about the research without your specific consent.

Research results will be published in an academic journal if the opportunity becomes available.

*Security and access controls*

BU will hold the information we collect about you in hard copy in a secure location and on a BU password protected secure network where held electronically.

Personal information which has not been anonymised will be accessed and used only by appropriate, authorised individuals and when this is necessary for the purposes of the research or another purpose identified in the Privacy Notice. This may include giving access to BU staff or others responsible for monitoring and/or audit of the study, who need to ensure that the research is complying with applicable regulations.

There is no personally identifiable data collected as part of this research.

*Sharing your personal information with third parties*

As well as BU staff and the BU student working on the research project, we may also need to share personal information in non-anonymised form with the Kebbi State Ministry of Health in case of a possible audit.

*Further use of your information*

The information collected about you may be used in an anonymous form to support other research projects in the future and access to it in this form will not be restricted. It will not be possible for you to be identified from this data.

*Keeping your information if you withdraw from the study*

If you withdraw from active participation in the study we will keep information which we have already collected from or about you, if this has on-going relevance or value to the study. This may include your personal identifiable information. As explained above, your legal rights to access, change, delete or move this information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. However, if you have concerns about how this will affect you personally, you can raise these with the research team when you withdraw from the study.

You can find out more about your rights in relation to your data and how to raise queries or complaints in our Privacy Notice.

*Retention of research data*

**Project governance documentation**, including copies of signed **participant agreements**: we keep this documentation for a long period after completion of the research, so that we have records of how we conducted the research and who took part. The only personal information in this documentation will be your name and signature, and we will not be able to link this to any anonymised research results.

Research results:

As described above, during the course of the study we will anonymise the information we have collected information about you as an individual. This means that we will not hold your personal information in identifiable form after we have completed the research activities.

You can find more specific information about retention periods for personal information in our Privacy Notice.

We keep anonymised research data indefinitely, so that it can be used for other research as described above.

**Contact for further information**

If you have any questions or would like further information, please contact:

MSc student researcher: David Dasa Email:[s5629479@bournemouth.ac.uk](mailto:s5629479@bournemouth.ac.uk)

Supervisor: Dr Phillip Davies

[Email: daviesp@bournemouth.ac.uk.](mailto:Email:%20daviesp@bournemouth.ac.uk.)

*In case of complaints*

Any concerns about the study should be directed to Professor Tiantian Zhang

Deputy Dean for Research & Professional Practice Faculty of Science and Technology, Bournemouth University by email to [researchgovernance@bournemouth.ac.uk.](mailto:researchgovernance@bournemouth.ac.uk)

**Finally**

If you decide to take part, you will be given a copy of the information sheet and a signed participant agreement form to keep.

Thank you for considering taking part in this research project.