INFORMATION SHEET

PROJECT TITLE: Reliability and validity of salivary cortisol levels of healthy adults measured using a point of collection analysis method (POCSS)

You are invited to take part in a research project which will test out the reliability and validity of *IPRO*©, a collection and analysis method for human saliva. This method calculates how much of the hormone known as cortisol is present in saliva, and this is one of several indicators of how much stress a person is experiencing. *IPRO*© is a 'point of collection' method, meaning that collection and analysis can be conducted in places where this sort of testing has not traditionally been possible. By comparing the *IPRO*© method to a traditional laboratory-based saliva analysis method we hope to find out if this 'point of collection' method is valuable for future research and clinical use.

The study is funded by James Cook University (JCU), and is being conducted by Dr Carol Ann Flavell, Associate Professor Anne Jones, Dr Michael Crowe, Associate Professor Donna Rudd, Miss Amy Combers, Ms Gitte Nielson, and Mrs Rachel Pappas.

This information sheet will tell you about the study and what it involves so you can decide whether to volunteer. Please read this information and ask questions if you do not understand what you read, or you want more details. Before you decide whether to take part, you may wish to discuss the study with a relative, friend, or other support person/carer/health professional.

Participation in this research is voluntary. If you decide to volunteer for the research project, you will be asked to sign a consent form to confirm that you:

- Understand everything that you have read in this information sheet.
- Consent to take part in the research described.
- Consent to the collection of some of your personal information.

You will be given a copy of this Participant Information Sheet to keep.

What is the purpose of this research?
This research involves adults of all ages and has two purposes:

- To find out if *IPRO*© methods show the same amount of cortisol from a saliva sample when it is tested more than once using the same process.
- To find out if *IPRO*© measures the amount of cortisol as accurately as a traditional laboratory method which is considered to be the 'Gold Standard' for accuracy.

This will provide evidence of whether the *IPRO*© method has scientific soundness to use as a 'point of contact' method to collect and analyse human saliva for future research and by clinicians working 'on field' or in rural and remote settings.

What does participation in this research project involve?
Volunteers for this research will be asked to attend the exercise and rehabilitation sciences building (43) at JCU Bebegu Yumba campus in Townsville, on one occasion, and provide a saliva specimen. The session will occur at a time and date which is acceptable to the volunteer.

If you are interested in taking part, a member of the research team will check if you are eligible during a pre-arranged screening session. This will take approximately 5 minutes and can be conducted via phone. If the initial screening shows that you cannot be in the research project, this will be discussed with you and an explanation provided. If you are suitable to take part, we will provide you with information advising the time, date, and location of the data collection session, including information on what to expect, and how to prepare. On attendance we will ask you to read and sign a consent form, then you will be enrolled as a participant.

The duration of the data collection attendance is estimated at 30 minutes. Data collection will be conducted in a private area by one of the research team members, who will:

- Answer any questions you have
- Gain your written consent

- Take a saliva sample using a technique where you place three sponge swabs under your tongue until sufficient saliva is collected. Saliva testing will be conducted using a sterile technique and the collected specimen will be processed using both the *IPRO*© and the 'Gold Standard' laboratory method.

Other relevant information about the research project

Saliva samples will be collected under strict health and safety protocols. A member of the research team will make sure you have all the instructions and help you need to complete the collection task. The research team will protect your right to privacy, your cultural needs, and wishes. All data and information that you agree to provide for this research will remain private and confidential. Your participation in this research will be complete following the data collection session unless you choose to withdraw from the study prior to then.

The research project aims to recruit around 60 participants. This research will interpret the results in a fair and appropriate way, to avoid any research team members or participants jumping to conclusions. There are no costs associated with participating, nor will you be paid.

Do I have to take part in this research project?
Participation in this research project is entirely voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw at any stage. If you decide to participate, you will be given a copy of the Research Consent Form that you signed.

Your decision to take part, not to take part, or to take part and then withdraw, will not affect any future relationship with academic and technical staff, or James Cook University.

What are the possible benefits of taking part?
The researchers anticipate that this study will lead to distinct benefits for healthcare professionals, researchers and individuals who require saliva sampling as part of their healthcare or sporting performance, but the benefits will not be realised immediately by the individual participants of the study. Benefits will be realised in future as they will provide an understanding of how scientifically sound the *IPRO*© method is. This will assist researchers to plan future studies and guide services which require saliva collection and analysis at 'point of collection' which will be of benefit to providers and users of health and sports science testing.

What are the possible risks and disadvantages of taking part?
The research team do not expect that you will experience any discomfort, upset, or distress by the data collection process. However, if this should occur, and you do not wish to continue, you may withdraw completely.

What if I withdraw from this research project?
If you consent to participate, you may withdraw at any time for any, or no reason, and without explanation. If you withdraw there will be no repercussions for you, or prejudice against you. If you decide to leave the research project, no more information will be collected from you. However, a copy of your signed consent form will be retained for study monitoring and audit purposes. Any existing data we have collected prior to your withdrawal will also be retained and form part of the research project results. If you do not want this data to be included, you may advise one of the researchers either verbally or in writing so that we can remove it.

Could this research project be stopped unexpectedly?
This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as a change in circumstances for the research team, or James Cook University. However, there are no current reasons for the research project to be stopped.

What happens when the research project ends?
You can request a summary of your individual test results when the research ends, this will be reported in nanomoles per litre of your saliva sample (nmol/L). However, it is important that you understand that ***the testing carried out was only intended for the*** *purposes of this research, and that laboratory and equipment used in this research does not meet the required accreditation* for clinical pathology purposes.
The data from the study will be used in research publications and reports such as peer reviewed journal articles and conference presentations. You will not be identified in any way in these publications. Information will be provided in such a way that you cannot be identified, except with your expressed permission.

What will happen to information about me?
Any information obtained in connection with this research that can identify you will remain confidential and securely stored at James Cook University for at least fifteen (15) years. All data will be disposed of according to the Australian National Health and Medical Research Councils, National Statement on Ethical Conduct in Human Research, 2007 **https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018**. Your

information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as

required by law. In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained during the research project is subject to inspection (for the purpose of verifying the procedures and the data) by the Human Research Ethics Committees of James Cook University, as relevant to this Participant Information Sheet, or as required by law. By signing the Consent Form, you authorise release of, or access to this confidential information to the relevant authorities noted above.

If you have any questions about the study, please contact **Dr Carol Flavell or Dr Michael Crowe.**

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If you have any concerns regarding the ethical conduct of the study, please contact:

Human Ethics, Research Office
James Cook University, Townsville, Qld, 4811
Phone: (07) 4781 5011 (ethics@jcu.edu.au)