Appendix 3

Cardiology Research Team

Investigator: Dr Austin Gibbs

Clinical Investigations Unit

General Hospital

St Helier

Jersey

PARTICIPANT INFORMATION SHEET LOIS0306/19

The use of Virtual Reality to reduce pain, anxiety and acute complications during pacemaker Insertion

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

To determine whether experiencing a relaxing Virtual Reality generated experience has an effect on reducing anxiety and pain during pacemaker insertion, as well as lowering the heart rate during the procedure.

Why have I been invited?

- You have been invited as a representative individual undergoing pacemaker insertion

Do I have to take part?

- The answer is 'No': It should be clear that taking part is entirely voluntary.
- You can withdraw at any time, without giving a reason;
- Withdrawal will not affect any ongoing participations, clinical or legal rights.

What will happen to me if I decide to take part?

You will be required to fill out a survey form. You will then undergo the standard practice for pacemaker insertion. If you are randomised to the intervention group the only difference will be you will have a Virtual Reality (oculus GO) headset placed on your head. You will have the opportunity to try this on and engage prior to the procedure. You will be in complete control able to stop/ remove the headset at anytime. This will not affect the standard

procedure for pacemaker insertion in anyway. Once the procedure is complete you will be required to fill out the same survey again.

There will be no long term follow-up, once the study has been completed there will be no further participation required.

What should I consider?

- If you suffer from epilepsy, claustrophobia, seizure disorder, motion sickness, stroke within the past year, dementia, nausea, isolation status for infection control please make the investigator aware as you may need to be excluded from this study.
- You can continue to take your regular medication or other prescribed or over-thecounter medicines;
- You can participate if you are involved in other research studies.

Are there any possible disadvantages or risks from taking part?

There is the risk of nausea and motion sickness. You will have the opportunity to try the experiences prior to the procedure and if you experience this removal of the headset will result in immediate termination of the symptoms. You will be monitored continuously by an Advanced Life Support Provider with full resus prehospital equipment.

What are the possible benefits of taking part?

- The study may reveal medical conditions that your GP can be made aware of. ● There is the possibility of requiring lower doses of drugs used in the normal procedure ● You will have distraction from the normal clinical environment.
- A lower heart rate during the procedure will reduce the risks of the procedure

Will my General Practitioner/family doctor (GP) be informed of my participation?

- There may also be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance.
- If the GP will be informed of participation or to be notified of findings requiring follow up, this will be on your expressed consent only.

Will my taking part in the study be kept confidential?

- Your Data will be de-identified from the point of collection, you can be given an exact mirrored copy of your data if you desire. Should you wish to exercise your right to destruction the data mirrored in that copy will be digitally shredded. The data will be stored encrypted (AES 256 standard) on local storage devices with weekly audited cyberscore penetration testing.

- Your data will be identified by study code only, the data will be published only after statistical analysis and not be reconstructable at the point of publication. Your data may be used in future research.
- Responsible members of the Cardiology Research Team and HSS Governance team may be given access to anonymous data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

- Any video/audio-recording taken during the study may be used for presentation purposes. If you do not wish to be recorded please identify this on the accompanying consent form and no recording will take place, without any effect of you participations, legal or clinical rights.

Will I be reimbursed for taking part?

- There will be no direct monetary reimbursement for participation.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. Although these regulations do not directly apply to non identifiable data, to assure your rights against potential future advances all GDPR considerations have been adhered to. In the case of research, this is 'a task in the public interest.' The Lab Director Dr Austin Gibbs is the data controller and is responsible for looking after your information and using it properly.

We will be using information from the study and will use the minimum personally-identifiable information possible. We will keep information about you for 1 year after the study has finished. We will store the de-identified research data and any research documents with personal information, such as consent forms, securely in your medical records for 6 years. These will be archived at the end of the 1 year study period.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at *https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-dataprotection-regulation-gdpr/individual-rights/*

You can find out more about how we use your information by contacting the Lead Investigator.

What will happen if I don't want to carry on with the study?

- Participation is voluntary and you may change your minds at any stage.
- Withdrawal will not affect your care from any relevant service
- If you withdraw from the study, we will destroy all your data from that decision, but will use the data collected up to your withdrawal.

What will happen to the results of this study?

- You will not be identified from any report or publication placed in the public domain.
- The data may be constitute part of published research papers
- The findings may be presented at medical conference
- You will provided with both a summary, and exact mirrored copy of the data collected from yourself if requested.

What if we find something unexpected?

The result will discussed with you under strict confidentiality, only the lead investigator and yourself will be privy to the finding. Any clinical significance will be explained to yourself and you may choose to engage with medical professionals accordingly.

Who is organising and funding the study?

The Allan Gift Fund is funding the study, there is no other source of income or conflicts of interest. The Allan Gift Fund is a legacy donated to HCS Cardiology department for the purpose of advancing Cardiology Research. The Immersive Technologies Research Lab is organising and carrying out the study, this lab was set up to fulfill the legacy purpose of performing Cardiology Research and is currently wholly funded by that legacy.

Who has reviewed the study?

- HCS Research Ethics Committee

Complaints: Please contact
Dr Austin Gibbs by email :a.gibbs@health.gov.je
OR: feedback@health.gov.je

Further information and contact details:

Please contact Dr Austin Gibbs by email :a.gibbs@health.gov.je
Alternate email: feedback@health.gov.je

Thank you for reading this information.
Thank you for considering taking part.

Appendix 4

Cardiology Research Team

Investigator: Dr Austin Gibbs

Clinical Investigations Unit

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Jersey

Study Code:				*Site ID Code:*					*Participant identification number:*				
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CONSENT FORM

The use of Virtual Reality to reduce pain, anxiety and acute complications during pacemaker Insertion

Name of Researcher: Dr Austin Gibbs	*If you agree, please initial box*
1.I confirm that I have read the information sheet dated..26/03/19..... (version.....1.0.....) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my data collected during the study may be looked at by individuals from the Allan Lab, from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to donate “anonymous physiological data” I consider these samples a gift to the Allan Lab and I understand I will not gain any direct personal or financial benefit from them	
5. I agree to non identifiable audio/video recording and the use of anonymised quotes in research reports and publications.	

6. I agree to my General Practitioner being informed of my participation in the study, where there it fulfills the principle of vital importance.		
7. I understand that the information held and maintained by the Allan Lab may be used to help contact me or provide information about my health status*.*		
8. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies*.*		
9. I agree for my anonymised data to be used in future research, here or abroad. I understand this research may involve commercial organisations.		
10. I agree to take part in this study.		
Any Additional Comments:		

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes* (if participant is a patient).