

Peter MacCallum Cancer Centre

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Peter Mac

Peter MacCallum Cancer Centre
Victoria Australia

PETER MACCALLUM CANCER CENTRE AUTHORISATION TO CONDUCT A RESEARCH PROJECT

HREC Reference No: LNR/16/PMCC/11
SSA Reference No: LNRSSA/16/PMCC/72
Peter Mac Project No: 16/07L

Project Title: Second Ears: Development of an app for audio-recording hospital consultations for oncology patients

Principal Investigator: Ms Amelia Hyatt

Approval Date: 3 April 2017

I am pleased to advise that the above project has **received ethical approval and satisfies Peter Mac research governance requirements** and may now be conducted at Peter MacCallum Cancer Centre. Conduct of the project is subject to compliance with the conditions set out below.

Approved Documents:

Document	Version	Date
Protocol	2	18 February 2017
PMCC Participant Information and Consent Form - App Developer	2	23 March 2017
PMCC Participant Information and Consent Form - Consumer	2	23 March 2017
PMCC Participant Information and Consent Form - Clinician	2	23 March 2017
PMCC Participant Information and Consent Form - Patient	2	23 March 2017
PMCC Participant Information and Consent Form - Family Member	2	23 March 2017
PMCC Invitation Letter - Patient	2	23 March 2017
App Use Survey - Clinician	1	8 February 2016
App Use Survey - Patient	1	8 February 2016
Telephone Interview - Patient	1	8 February 2016

In order to comply with the National Statement on Ethical Conduct in Human Research (2007 and updates), Guidelines for Good Clinical Research Practice and local research policies and guidelines, you are required to:

- Submit an Annual Progress Report every 12 months for the duration of the project. *Note: Continuation of ethics approval is contingent on submission of an annual report in a timely manner;*
- Submit a comprehensive Final Report upon completion of the project;
- Submit any proposed amendments to the project including any proposed changes to any of the approved documents;

- Notify any unexpected developments in the project with ethical implications;
 - Notify any change in Principal Investigators/Associate Investigators involved in the project at Peter MacCallum Cancer Centre;
 - Notify if a decision is taken to end the project prior to the expected date of completion.
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The Peter MacCallum Cancer Centre Ethics Committee may conduct an audit of the project at any time.

Please refer to the Peter MacCallum Cancer Centre Ethics Committee Secretariat website (<http://www.petermac.org/research>) for access to forms, policies and guidelines and other information and news concerning research at Peter MacCallum Cancer Centre.

The Peter MacCallum Cancer Centre Ethics Committee is organised and operates according to the NHMRC National Statement on Ethical Conduct in Human Research (2007) and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and the Health Privacy Principles enumerated in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Please be advised that the Principal Researcher and any Associate Researchers named on the application did not participate in deliberative discussions or decision-making regarding the project.

Yours sincerely,



Dr. Dianne Snowden
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