



22 May 2020

Associate Professor Victoria Palmer
General Practice
The University of Melbourne

Dear Associate Professor Palmer

I am pleased to advise that the Medicine and Dentistry Human Ethics Sub-Committee approved the following Project:

Project title: **A phase II, open label non-randomised clinical trial of the safety and efficacy of the CovidCare app to support self-monitoring for Covid19 symptoms in self-isolation and to determine the impacts on mental health**

Researchers: **Professor M Haikerwal, Prof L A Sancu, Dr P Chondros, Ms D K Densley, A/Prof K M Gray, Professor B Thompson, A/Prof V J Palmer, A/Prof A E Borda, Ms R Kritharidis, Prof V Kostakos, Dr M S Lewis, Ms M Potiriadis, Ms X Camacho, Prof W W Chapman, Dr D Capurro, Mrs E Knights, A/Prof J E Manski-Nankervis, Dr M J Layton, Dr C J Kaylor-Hughes, Dr A D Carpenter, Associate Professor J Goldin, E Davey**

Ethics ID: **2056765**

The Project has been approved for the period: **22-May-2020 to 31-Dec-2020**

In line with government directives on social distancing during the COVID-19 pandemic, research activity that involves researchers being physically present for data collection with human participants (such as face-to-face field work, experimental and cohort studies, clinical trials etc) cannot currently commence and will need to be deferred and rescheduled. In exceptional circumstances, where such activities are part of priority research, including that directly related to the University's COVID-19 response, approval to commence may be given by the relevant Dean and endorsed by the Deputy Vice-Chancellor Research.

Desk-based elements of your research project can commence now, as can data collection that can be conducted online or via telephone, subject to necessary approvals or amendments to ethics applications.

Researchers will be advised by the University when other elements of planned and approved data collection can commence. Please consult the COVID-19 website for research guidance, FAQ and updates. <https://staff.unimelb.edu.au/covid-19-response/research-activity>

It is your responsibility to ensure that all people associated with the Project are made aware of what has actually been approved.

Research projects are normally approved to 31 December of the year of approval. Projects may be renewed yearly for up to a total of five years upon receipt of a satisfactory annual report. If a project is to continue beyond five years a new application will normally need to be submitted.

Please note that the following conditions apply to your approval. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

(a) **Limit of approval:** Approval is limited strictly to the research as submitted in your Project application.

(b) **Variation to project:** Any subsequent variations or modifications you might wish to make to the Project must be notified formally to the Human Ethics Sub-Committee for further consideration and approval. If the Sub-Committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised Project.

(c) **Incidents or adverse effects:** Researchers must report immediately to the Sub-Committee anything which might affect the ethical acceptance of the protocol including adverse effects on participants or unforeseen events that might affect continued ethical acceptability of the Project. Failure to do so may result in suspension or cancellation of approval.

(d) **Monitoring:** All projects are subject to monitoring at any time by the Human Research Ethics Committee.

(e) **Annual report:** Please be aware that the Human Research Ethics Committee requires that researchers submit an annual report on each of their projects at the end of the year, or at the conclusion of a project if it continues for less than this time. Failure to submit an annual report will mean that ethics approval will lapse.

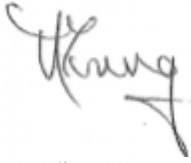
(f) **Auditing:** All projects may be subject to audit by members of the Sub-Committee.

If you have any queries on these matters, or require additional information, please contact me using the details below.

Please quote the ethics registration number and the title of the Project in any future correspondence.

On behalf of the Sub-Committee I wish you well in your research.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Hilary Young', with a stylized flourish at the end.

Ms Hilary Young - Secretary
Medicine and Dentistry HESC
Phone: 03 8344 8595, Email: hilary.young@unimelb.edu.au