



Final Approval for Ethics Application

6 June 2018

A/Professor Niranjan Bidargaddi
Associate Professor of Digital Psychiatry & Personal Health Informatics
Flinders University
1284 South Road
Clovelly Park
SA 5042

Dear A/Professor Bidargaddi,

OFR Number: 165.17
HREC number: HREC/18/SAC/168
Project title: Mindtick app psychiatric care study – Digital signal indicators to enhance capacity of psychiatric services to predict distress in advance
Chief Investigator: A/Professor Niranjan Bidargaddi
Ethics Approval Period: 04/06/2018 to 04/06/2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process.**

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

Public health sites approved under this application:

- Central Adelaide Local Health Network, SA
- Country Health SA Local Health Network, SA
- Southern Adelaide Local Health Network, SA

The below documents have been reviewed and approved:

- Protocol v4 05/06/2018
- HREA 05/06/2018
- Clinician Information Sheet v4 06/06/2018
- Clinician Registration Email v1 15/05/2018
- Hard copy recruitment flyer V1 23/05/2018
- Participant email template V1 23/05/2018
- Participant information sheet and consent v4 06/06/2018
- goAct SAIL ethics letter 19/08/2017
- Dashboard Screenshots v1 23/05/2018

- Amendments List 23/05/2018
- Updated Screenshots (participants) 23/05/2018
- SAIL website design v3 20/04/2018
- Homepage pictures v1 23/05/2018
- Response from meeting in Office for Research 02/05/2018 (received 23/05/2018)
- Response from meeting in Office for Research 12/04/2018 (received 02/05/2018)
- Response to subcommittee 04/12/2017 (received 12/04/2018)
- GoAct Terms of Service and Privacy Policy (30/05/2018)

The following documents have been noted:

- Draft protocol commented on by Dr Camille Short 05/01/2017

Terms and Conditions Of Ethics Approval:

It is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5*.

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research (2007)* & the *Australian Code for the Responsible Conduct of Research (2007)*.
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.

For any queries about this matter, please contact The Office for Research on
(08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely



A/Professor Bernadette Richards
Chair, SAC HREC