

## Madhuri Venigalla

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**From:** Karen Mathews  
**Sent:** Tuesday, 14 March 2023 12:33 PM  
**To:** APHLID-M  
**Subject:** FW: 2022/ETH02515: Please submit SSA application in REGIS for all SWSLHD sites prior to commencing any research activities

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**From:** Malina Peng (South Western Sydney LHD) <[Malina.Peng@health.nsw.gov.au](mailto:Malina.Peng@health.nsw.gov.au)> on behalf of SWSLHD-Ethics <[SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)>  
**Sent:** 13 March 2023 16:46  
**To:** David Simmons <[Da.Simmons@westernsydney.edu.au](mailto:Da.Simmons@westernsydney.edu.au)>  
**Cc:** SWSLHD-Ethics <[SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)>  
**Subject:** [External] RE: 2022/ETH02515: Please submit SSA application in REGIS for all SWSLHD sites prior to commencing any research activities

Dear David,

Congratulations on receiving ethics approval for your below study. We note that a SSA application has not yet been submitted for governance review. Please ensure a SSA is submitted in REGIS for **all SWSLHD ethically approved sites prior to commencing any research activities**. We note that no research activities can commence at SWSLHD sites until site authorisation has been obtained via REGIS.

This is a responsibility outlined in the research code of conduct: [\*\*SWSLHD Research Code of Conduct\*\*](#)

Identifier	Title	Program
2022/PID02828 ↑2022/STE04097	Apps and Peer support for a Healthy futu...	Site
2022/PID02828 ↑2022/STE04098	Apps and Peer support for a Healthy futu...	Site
2022/PID02828 ↑2022/STE04099	Apps and Peer support for a Healthy futu...	Site

Please don't hesitate to contact me if you have any questions 😊

Kindest Regards,

**Malina Peng**

Administrative Officer | **Research Directorate**  
South Western Sydney Local Health District (SWSLHD)  
Locked Bag 7279 Eastern Campus Liverpool BC NSW 1871  
Tel 02 8738 8304 | Fax 02 8738 3552 |  
E-mail: [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)  
<https://www.swslhd.health.nsw.gov.au/ethics/>

Research Workshops: <https://www.swslhd.health.nsw.gov.au/ethics/workshops.html>



**From:** [no\\_reply@regis.health.nsw.gov.au](mailto:no_reply@regis.health.nsw.gov.au) [[mailto:no\\_reply@regis.health.nsw.gov.au](mailto:no_reply@regis.health.nsw.gov.au)]  
**Sent:** Monday, 13 March 2023 4:40 PM  
**To:** David Simmons <[Da.simmons@westernsydney.edu.au](mailto:Da.simmons@westernsydney.edu.au)>  
**Subject:** 2022/ETH02515: Application HREA - Approved \*\*\*\* ETHICS APPROVAL ONLY \*\*SITE SPECIFIC AUTHORISATION REQUIRED\*\*

Date of Decision Notification: 13 Mar 2023

Dear David Simmons,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review; 2022/ETH02515: Apps and Peer support for a Healthy future and Living Well with Diabetes – Mental Health (APHLID-M)

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the South Western Sydney Local Health District Human Research Ethics Committee at its meeting held on 12 December 2022.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED**.

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been Approved to be conducted at the following sites:

- Campbelltown Hospital
- Bankstown Lidcombe Hospital
- Liverpool Hospital
- St George Hospital
- Prince of Wales Hospital
- St Vincent's Health Sydney
- Sydney Children's Hospitals Network
- Goulburn Valley Health

The following documentation was reviewed and is included in this approval:

<b>Documentation Title</b>	<b>Version</b>	<b>Date</b>
Human Research Ethics Application	Version 3.0	10/02/2023
Protocol	Version 3.0	20/02/2023
MASTER Participant Information Sheet and Consent Form – Adult	Version 2.0	20/02/2023
MASTER Participant Information Sheet and Consent Form – Child	Version 2.0	20/02/2023
MASTER Study Poster	Version 1.0	25/11/2022
MASTER Interview Participant Schedule	Version 1.0	25/11/2022

MASTER Health Care Provider Participant Schedule	Version 1.0	25/11/2022
MASTER Participant Data Collection	Version 1.0	25/11/2022
MASTER Process Evaluation Survey	Version 1.0	25/11/2022
Kessler Psychological Distress Scale (K10)	No Version	No date
The Diabetes Distress Screening Scale	No Version	No date
EQ-5D-5L Health Questionnaire	No Version	2009
Diabetes Empowerment Scale-Short Form (DES-SF)	Version 1.0	26/06/2020
Eating Disorder Screening (DEPS-R Scale)	Version 1.00	11/2020
The Summary of Diabetes Self- Care Activities	No Version	No date
Victorian Specific Module	Version 1.0	19/01/2023

[Application Documents](#) - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.03

Date: 20 Feb 2023

The approval is for a period of 5 years from the date of this e-mail (13 Mar 2023)

Please note the following conditions of approval:

***\*\*Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are followed until the restrictions have been lifted\*\****

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
5. The Principal Investigator must reassure participants about confidentiality of the data.
6. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
7. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from: <https://www.swslhd.health.nsw.gov.au/ethics/policies.html>

**Interpreter use:** If this study will involve the use of interpreters, you are required to contact SWSLHD Interpreter Services on 8738 6088 and/or [Interpreters.Bookings@sswahs.nsw.gov.au](mailto:Interpreters.Bookings@sswahs.nsw.gov.au). This is required even if you have access to interpreters for clinical purposes, as SWSLHD Interpreter Services are required to review and approve the use of interpreters for any research work. Once you have contacted SWSLHD Interpreter Services, please ensure that you include the provided quote/s (if any) with your SSA submissions for your project.

Should you have any queries about your project please contact **our office** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <https://www.swslhd.health.nsw.gov.au/ethics/>

Please quote the above Ethics number in all correspondence. The HREC wishes you every success in your research.

Yours faithfully,

**Dr Shakti Shukla**

*on behalf of*

**Professor Murray Killingsworth**

Chairperson, SWSLHD Human Research Ethics Committee

**This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.**

Kindest Regards,

**Malina Peng**

Administrative Officer | **Research Directorate**

South Western Sydney Local Health District (SWSLHD)

Locked Bag 7279 Eastern Campus Liverpool BC NSW 1871

Tel 02 8738 8304 | Fax 02 8738 3552 |

E-mail: [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)

<https://www.swslhd.health.nsw.gov.au/ethics/>

Research Workshops: <https://www.swslhd.health.nsw.gov.au/ethics/workshops.html>

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