Request for Modification Form

Modifications to projects involving human research must be approved prior to being implemented. Modification requests should be submitted to the original approving review body (e.g., DUHREC, a HEAG or an external Australian ethics committee).

If your modification includes a waiver of the requirement for consent for potentially identifiable health or sensitive data (see Definitions at Part E), your application must be submitted to DUHREC even if it was originally approved by a HEAG. For HEAG approved projects where this is the case, please contact research-ethics@deakin.edu.au for further advice.

Please note: modifications to Previously Approved projects that have been approved by an external Australian HREC, only need to be provided to DUHREC where they involve a change to the Deakin personnel (see Part C Question 4).

- Deakin University HREC research-ethics@deakin.edu.au
- Arts and Education HEAG aeethics@deakin.edu.au
- Business and Law HEAG blethics@deakin.edu.au
- Health HEAG health-ethics@deakin.edu.au
- Science, Engineering and Built Environment HEAG sciethic@deakin.edu.au

Part A:
COVID-19

All research must comply with current COVID-19 restrictions, as well as with Deakin's COVIDSafe Management Plan. Any activities considered as having high COVID-19 risk (e.g. requiring safety measures over and above the COVIDSafe Management Plan and risks covered by the general requirements of entry to campus) must have an approved COVIDSafe Activity Plan in place. This includes any on-campus research involving a face-to-face element, as well as off-site research (e.g., site visits, fieldwork etc).

Part B:

Project details

1. **Project ID:** 2021-412
2. **Project title:** LISTEN – Low Intensity mental health Support via a Telehealth Enabled Network for adults with diabetes and CVD: Effectiveness and scalability
3. **Current Deakin Principal Investigator (PI):** Dr Edith Holloway
   NB: The PI is the Deakin staff member who takes responsibility for the project, i.e. receives correspondence, signs modification requests &/or the Annual/Final reports, provides updates to the project team etc.
4. **Project originally approved by:** (select one item from the drop-down list below by clicking on 'Choose an item')
   DUHREC

   For projects previously approved by an external Australian HREC (or other Australian ethics review body) and noted by DUHREC as a Previously Approved project, please seek approval from them for the proposed modification and ONLY submit this form if:
   - The external review body has provided approval for the modification AND

- The modification relates to a change of Deakin personnel. Please complete Appendix A. You are not required to inform DUHREC of any other changes approved by the external Australian review body, including the addition/removal of external research team members.

Part C:

Proposed modification details:

1. **Please explain the changes that you are intending to make** (e.g. change in methodology, recruitment, consent*, participant cohort or numbers, sample size, reimbursement, data collection, data analysis, data storage, conflict of interest etc):
   Click or tap here to enter text.
   *If you are seeking a waiver of consent, please complete Appendix B.

   1. Increase the trial sample size

2. **Please provide a reason/justification for the intended change/s:**

   We have reviewed the completion rates for the incoming 8-week follow-up survey. We currently have a 71% response rate (i.e., ~30% attrition rate) across both the control and intervention groups (N=142/198). We have discussed this with the project statistician and the attrition rate for the 6-month follow-up survey is expected to be similar. As such, we anticipate the attrition rate across both time points to be 40-50%. Based on a previous study we conducted with similar follow-up time points and recruitment strategy (Project reference: 2020-073; attrition rate 52%). To account for this, a protocol amendment is requested to increase the target sample size from N= 394 to N=454, which will provide 80% power, allowing for a 50% attrition rate. Doing so will allow the research team to evaluate the effectiveness of the LISTEN intervention with greater confidence.
   Increasing the sample size will not extend the project end date nor change the study methodology e.g. recruitment strategy).

   Attached is the study protocol with track changes on Version 5 – March 2023.

3. **Please consider the impact of the change/s. Does this raise any ethical issues such as increased risk/s to the participants, the research team or the overall ethical acceptability of the project (including any possible Conflict of Interest)? Please describe how additional risks will be mitigated and/or managed:**
   No.

4. **Are you changing the membership of the research team?** ☐Yes ☒No
   Please complete Appendix A for all investigators being added or removed, including Deakin and external investigators (e.g. research staff, research assistants and students). *NB: for projects approved by an external HREC, please do not include external investigators, please only include Deakin staff &/or students.*

   Are you adding people to your research team or changing the role of an investigator (e.g. change in PI)?
   ☐Yes ☒No
   If yes, please list investigators to be added and their role. Where applicable, please describe the change in role for any investigators already on the project:
   Click or tap here to enter text.

Are you removing people from your research team? ☐Yes ☒No
If yes, please list investigators to be removed:
Click or tap here to enter text.

5. **Are you requesting an extension of time beyond the ethics approval expiry date** (as stated in the original approval memo) **to complete your data collection?** ☐Yes ☒No
NB: changes to internal timelines for data collection that remain within the ethics approval period do not require the submission of a modification/approval as long as there are no other changes and this does not affect the ethical acceptability of the project. Also, if your research has been delayed for a period of time due to COVID-19 and its completion will therefore exceed the approval period, you do not need to submit a modification/seek approval as long as there are no other changes and this does not affect the ethical acceptability of the project. Once you are able to continue your research, you may extend your approved end date for the length of time that your research was delayed. Please note: You should indicate in your next Annual/Final Report that you have adopted such measures without approval.

   If you are seeking an extension, tick the relevant box below to indicate the reason:
   ☐The extension is required due to delays (not COVID-19 related). Please provide details below.
   Click or tap here to enter text.

   ☐The extension is required because the project design has changed. Please summarise the key changes below. **DUHREC approved projects only:** Attach an up-to-date **Protocol/Project Description** (with tracked changes). If an extension is approved, the maximum extension period provided by DUHREC is 4 years.
   Click or tap here to enter text.

Part D:

Please combine as a single PDF with this form:

- All amended participant documents with tracked changes as appropriate (e.g. Plain Language Statement, questionnaire, advertisement etc): ☒Yes ☐N/A
- A completed Privacy Supplement if required according to Appendix B: ☐Yes ☐N/A

Part E:

Definitions:

***Health Data:**

(a) information or an opinion about:

i. the physical, mental or psychological health or a disability (at any time) of an individual; or

ii. an individual's expressed wishes about the future provision of health, disability or aged care services to him or her; or

iii. a health, disability or aged care service provided, or to be provided, to an individual; that is also personal information; or

(b) other personal information collected to provide, or in providing, a health, disability or aged care service; or

(c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or

(d) personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or any of his or her descendants.

***Sensitive Data:**

means information or an opinion about an individual's:

- racial or ethnic origin; or
- political opinions; or
- membership of a political association; or
- religious beliefs or affiliations; or
- philosophical beliefs; or
- membership of a professional or trade association; or
- membership of a trade union; or
- sexual preferences or practices; or
- criminal record; or
- health information about an individual, or
- genetic information about an individual that is not otherwise health information; or
- biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or biometric templates.

Part F:

Declaration

I/we confirm and declare that:

a. the information supplied in this application is true and accurate to the best of my/our knowledge.
b. I/We have read the *National Statement on Ethical Conduct in Human Research* and accept responsibility for the conduct of the project detailed in this application in accordance with the principles contained in the Statement and any other conditions laid down by Deakin University Human Research Ethics Committee or Faculty HEAG.
c. where the research project may involve contact with a child or young person under the age of 18, I/we have a current Working with Children Check
d. in the event the project is discontinued prior to the expected completion date, this information will, if possible, be communicated to any participants in the research and that the reason for this will be explained.
e. I/We will inform Deakin Research Integrity of any complaints received in relation to this project immediately. Details of the complaints will be forwarded to: The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au
f. Where the PI is signing on behalf of a team, that all team members are informed of any changes where there are implications for their role in the project.

NB: Only include signatures once per form.

Principal investigator

Name: **Dr Edith Holloway**

Human Ethics Quiz (please complete the appropriate box below):

☒successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☐exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID: Click here to enter text*

Signature:  Date: 09/03/2023

ACKNOWLEDGMENT OF HEAD OF SCHOOL/DIRECTOR OF RESEARCH**

I, the undersigned, acknowledge that the School/Faculty/Institute has considered and approved the academic worth of the project described in this application.

Name: **Professor Jane McGillivray**

Signature: Jane McGillivray Digitally signed by Jane McGillivray Adobe Acrobat version: 2022.003.20322 Date: **10/03/2023**

**If the Head of School (or similar) is also a member of the research or supervisory team, a more senior member of University staff e.g. Dean or Associate Dean (Research) must sign the project as authorising officer.

Please note: if the hyperlinks in this form result in an error message, return to the form and:

1. *right click on the hyperlink*
2. *click on Edit Hyperlink*
3. *copy the URL to your browser.*

For further information on modifications to low-risk applications, contact your faculty HEAG .

For more information on modifications to higher than low risk applications, contact the Human Research Ethics Unit.

Deakin University is collecting your personal information on this form for the primary purpose of processing your human research ethics application. It will also use this information for monitoring your compliance with the approved protocol. For these purposes Deakin may also provide this information to potential research participants, past or current research participants, or other interested parties in your research. You are not required to provide the information requested, however if the information is not provided, Deakin may not be able to process your ethics application. Deakin manages personal information it holds, including requests by individuals for access to their personal information, in accordance with the Privacy and Data Protection Act 2014 (Vic). Deakin's Privacy Policy may be viewed on Deakin's Policy Library. Information on privacy at Deakin is available at http://www.deakin.edu.au/footer/privacy. Questions about privacy may be directed to the Privacy Officer on (03) 5227 8524 or by email to privacy@deakin.edu.au.

Appendix A: Adding/removing Deakin and external investigators (including research staff, research assistants and students)

Name: Click or tap here to enter text. Email address: Click or tap here to enter text.

Affiliation (please select from the drop-down list by clicking on 'Choose an item'): Choose an item.

^Deakin Staff OR Student ID (Leave this field blank for external investigators): Click or tap here to enter text.

Human Ethics Quiz (please complete the appropriate box below):

☐successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☐exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID: Click here to enter text*
☐external researcher (exempt from completing the Quiz)

For Projects Previously Approved by an External Australian HREC only: Please confirm that the external HREC has approved the involvement of this investigator: ☐Yes ☐No
Please seek approval from the external HREC to add any Deakin researchers to the research team prior to submitting this form.

*Signature: Click or tap here to enter text. Date: Click or tap here to enter text.

***Where researchers being removed are unavailable to sign (e.g. they have left Deakin), please indicate this in writing above.**

Please copy and paste the above for each researcher.

^Deakin Staff ID or, where the researcher being added will be a Deakin student researcher on the project, Student ID, is now required to facilitate migration of application data into OmniStar, the new system for Research Integrity and Governance at Deakin. This will ensure applications and existing approvals are correctly associated with the researcher/s within OmniStar and also that migrated data about an application or an approval is accurate and complete.

APPENDIX B: Complete this section if you are now seeking a waiver of consent to access **pre-existing, potentially identifiable collections** of human data.

Waiver of consent

1) **Are the data you wish to access via a waiver of consen**t (tick the appropriate box/es below):
   ☐Health Data (please see Definitions Part E). Please submit this form to DUHREC along with a completed Privacy Supplement. If your project was originally approved by a HEAG, please also include a copy of the original approved application and the original approval memo.
   ☐Sensitive Data (please see Definitions Part E). Please submit this form to DUHREC along with a completed Privacy Supplement. If your project was originally approved by a HEAG, please also include a copy of the original approved application and the original approval memo.
   ☐Neither health nor sensitive data (please see Definitions Part E). Please submit this form to the original committee responsible for approving the project. If submitting to DUHREC, please include a completed Privacy Supplement.

NB. (*Modifications involving a waiver of consent that are reviewed by DUHREC will be subject to the published DUHREC deadlines. You will be contacted after the corresponding DUHREC meeting with the committee's response*.)

2) **Please demonstrate how waiving the requirement for consent to access the data complies with National Statement 2.3.10 a-i * below. Note that for a waiver to be approved, all of these criteria must be met:**
   a) Involvement in the research carries no more than low risk to participants.
      Click or tap here to enter text.
   b) The benefits from the research justify any risks of harm associated with not seeking consent.
      Click or tap here to enter text.
   c) It is impracticable to obtain consent (for example due to the quantity, age or accessibility of records).
      Click or tap here to enter text.
   d) There is no known or likely reason for thinking participants would not have consented if they had been asked.
      Click or tap here to enter text.
   e) There is sufficient protection of their privacy.
      Click or tap here to enter text.
   f) There is an adequate plan to protect the confidentiality of data.
      Click or tap here to enter text.
   g) In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them.
      Click or tap here to enter text.
   h) The possibility of commercial exploitation of derivatives of the data or tissue* will not deprive the participants of any financial benefits to which they would be entitled. (Please note waivers of consent involving *human tissue or biospecimens are not eligible for low risk review.)
      Click or tap here to enter text.
   i) The waiver is not prohibited by State, federal or international law.
      Click or tap here to enter text.

   ***If the waiver of consent relates to research aiming to expose illegal activity please address NS 2.3.11 a-d:** Click or tap here to enter text.