APPENDIX A

PARTICIPANT INFORMATION SHEET – ADOLESCENT & YOUNG ADULT

An Online CBT-Based Self-Help Program For Eating Disorders: SkillED Pilot Evaluation

(for users 14-16 years of age)

Dear Participant,

Thank you for showing interest in participating in our research study. This page explains a little bit about the study and everything you need to know about your privacy and confidentiality. Once you have read it, you can decide if you would like to take part. Please talk to your parents or guardians about it too, as they will need to co-sign the consent form.

***(1)* What is this study about?**

You are invited to take part in a pilot study of an online self-help program, called *SkillED*, based on cognitive behavioural therapy (CBT) for the treatment of people experiencing eating disorder symptoms. *SkillED* is an interactive program with different modules, which have been developed by many people at the InsideOut Institute for Eating Disorders – including researchers, people with lived experiences, clinical psychologists, and mental health clinicians.

The InsideOut Institute has developed *SkillED* to help address barriers that make it hard for people to access treatment. We hope that by improving access to evidence-based skills and information from the *SkillED* modules, those with eating disorders may feel better about improving their eating disorder symptoms.

SkillED has 11 weekly learning modules that you can complete. These modules are organised into various topics, like information about eating disorder symptoms, skills in self-monitoring and managing your emotions and eating patterns. This study looks at how effective and useful these *SkillED* modules are for people experiencing eating disorder symptoms. We also want to use information from this study to keep developing and making the *SkillED* module content and delivery better for people.

The two most important things for you to know are:

- It is your choice to participate in this study, and you can decide not to continue participating at any time;
- Your answers will be deidentified, which means that your responses in this study will not be linked to any of your personal information. No one will be able to tell which answers are yours. Email addresses will be hidden behind a firewall-protected database.

This Participant Information Sheet tells you what this study involves. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and if you have any questions, the contact details of the research team are below.

***(2)* Who is running the study?**

This study is being conducted by the InsideOut Institute for Eating Disorders. The InsideOut Institute is a national institute that does research on eating disorders and aims to improve their clinical treatment, collaborating between the University of Sydney and Sydney Local Health District.

This study is being carried out by the following researchers:

- Prof Sarah Maguire, InsideOut Institute
- Dr Jane Miskovic-Wheatley, InsideOut Institute
- Dr Sarah Barakat, InsideOut Institute
- Dr Karen Spielman, InsideOut Institute
- Dr Shu Hwa Ong, InsideOut Institute
- Daniel Rogers, InsideOut Institute
- Marcellinus Kim, Sydney Local Health District
- Melissa Pehlivan, InsideOut Institute
- Peta Marks, InsideOut Institute
- Prof Stephen Touyz, InsideOut Institute
- Sally Corry, InsideOut Institute Sarah Horsfield, InsideOut Institute
- Rachel Simone, InsideOut Institute
- Rebecca Barnes, InsideOut Institute
- Stephanie Boulet, InsideOut Institute
- Sean Rom, InsideOut Institute
- Bridget Mulvet, InsideOut Institute
- Patrick Eades, InsideOut Institute
- Steven Castle, InsideOut Institute
- Parthey Bhatt, InsideOut Institute
- Jasmine Singh, InsideOut Institute

The researchers can be contacted at the InsideOut Institute for Eating Disorders on +61 2 8627 5690.
There are no conflicts of interest to declare.

***(3)* What do I have to do?**

To see if you are able to safely participate in this study, we will look at your responses to a brief online screening questionnaire (that takes 5 minutes to complete), and ask you to complete a phone interview with a someone from the study to understand your eating behaviours, current and previous mental health experiences. The phone interview may take around 30-60 minutes to complete.

If you are actively suicidal, are self-harming, or the researcher calling feels that you are at high risk of self-harm, we will encourage you to seek face-to-face counselling and you will not be invited to participate in the study.

Additionally, for you to enter the study, you will need your General Practitioner (GP) to fully assess your physical and mental health. Your GP will then have to sign a form (written, or

online) that confirms that the GP has seen you, thinks you are suitable to participate in the study, and they agree to keep checking you medically during the trial at different time points of their choosing. The GP must send this form to the study researchers. You will also have to give the contact details of the GP to the study researchers.

Once we have confirmed that you can complete this study, and you agree to participate, we will ask you to complete a Participant Consent Form. After this form, you will be asked to complete a few questions, before starting *SkillED.* The nature of the questions and others we will ask you during the study are summarised later below.

You will be provided with two options in completing the *SkillED* modules. Everyone who participates must complete the first 5 (core) modules of the 11-module program. For the other 6 modules, you can choose between two options: (1) **full program:** complete all of the 6 modules in a pre-designed weekly order, or (2) **choose your own adventure**: complete as many of the 6 modules as you like, in whichever order you want.

Please note that regardless of which of the two groups you join, the next module will be unlocked after you completed the previously selected module.

Many people who start self-help programs stop completing all module tasks and become disengaged with the program. To overcome this concern, this study will evaluate how effective strategies are in preventing disengagement.

Once you have picked your preferred option for completing the modules, you will be randomly given one of groups: (1) **engagement intervention**, where a clinician will contact you if we notice signs of possible disengagement, and (2) **no engagement intervention**, where no action will be taken in response to signs of disengagement.

Please note, the engagement intervention will be administered **before** you disengage from the program and is distinct from follow-up procedures that will be used should a participant actually disengage. That is, any participant – whether they are in the engagement or no engagement group – will be contacted by someone after two or three weeks of consistently not completing any tasks on the *SkillED* program.

To evaluate the *SkillED* program, we will ask you several questions at different times during the study:

Screening – Before you enrol into the program, we will ask you some screening questions to make sure that the program is safe and suitable for you to join.

Baseline – Before you start SkillED, this questionnaire should take about 20 minutes to complete and includes questions about your demographics (e.g., age) and general information. You will also be required to complete the Eating Disorder Examination-Questionnaire (EDE-Q), 4 Key Motivational Question, Readiness and Motivation Questionnaire (RMQ), Depression Anxiety Stress Scale (DASS-21), Self-harm and Suicidality Risk Assessment, adapted Help Seeking Behaviour, Eating Disorder Inventory-3 (EDI-3) Drive for Thinness subscale, EQ-5D-Y-5L Health questionnaire, Clinical Impairment Assessment (CIA), and Credibility/ Expectancy questionnaires. These questionnaires must

be completed to gain access to the program.

Weekly – You will be invited to complete a short version of both the Self-harm and Suicidality Risk Assessment and Eating Disorder Examination-Questionnaire whenever you start a new module in the program to monitor your safety and eating disorder symptoms, and also Kessler Psychological Distress Scale (K-10), Therapeutic Mechanism Questionnaire and 4 Key Motivational Questionnaire. These questionnaires should take approximately 5 – 10 minutes to complete.
Mid-treatment – After completing the 5 core modules, you will be asked about your health service utilization, and to complete the questionnaires consist of EDEQ, 4 Key Motivational Questionnaire, Readiness and Motivation Questionnaire (RMQ), Depression Anxiety Stress Scale (DASS-21), Self-harm and Suicidality Risk Assessment, Adapted Help Seeking Behaviour, EDI-3 Drive for Thinness subscale, EQ-5D-Y-5L Health questionnaire, CIA, and Credibility/Expectancy Questionnaire. These questionnaires should take approximately 20 minutes to complete.

Post-program – When you complete the core modules and the optional modules of *SkillED*, you will be asked to complete the EDE-Q, 4 Key Motivational questions, DASS-21, Self-harm, and Suicidality Risk Assessment, adapted help-seeking behaviour, EDI-3 Drive for Thinness subscale, EQ-5D-Y-5L Health questionnaire, CIA, Credibility/Expectancy Questionnaire, and Negative effects/events Questionnaire. We will also ask for your feedback on the program. Together, these will take about 20 minutes to complete. You will also be invited to participate in an optional interview (about 45 minutes in length) to help identify areas to further improve *SkillED.*

3-month, 6-month & 12-month follow up – You will be invited via email to complete a follow-up questionnaire to evaluate the long-term impact of the program on your eating disorder symptoms, psychological distress, and quality of life. These questionnaires will take about 20 minutes to complete. For each questionnaire, you will be sent two email reminders.

Program usage
Throughout the study we will also collect analytic information on your usage of the program, including your progress through the program, time spent in completing the program, and how you engage with the program. This information will help us to understand how use and adherence to the program is linked with outcomes from the program.

(4) How much of my time will the study take?
Baseline, post-treatment and follow-up questionnaires will each take about 20 minutes to complete, and the weekly questionnaires will take around 5-10 minutes. Therefore, the time taken to complete all program and module questionnaires per the 12-month time period will be approximately 6.5 hours.

(5) Who can take part in this study?
To take part in this study, you will need to show signs of a clinical level of an eating disorder. The research staff will look for these signs through a clinical assessment when they call you on the phone during the screening process.

Because the program is online, you will need access to a computer or device with internet connection, and live in Australia. You also must be not pregnant, medically stable, not have experienced rapid changes in weight (loss or gain) or be very underweight, no actively receiving psychological treatment for an eating disorder or disordered eating; not currently using any stimulant medications, and not been diagnosed with Avoidance/Restrictive Food Intake Disorder, Rumination Body Dysmorphia, or Psychosis. You must also be at least 12 years old.

(6) Can I withdraw from the study once I've started?

Participation in this study is entirely voluntary and you do not have to take part. Your responses, or your decision not to participate, will not impact your current or future relationship with the researchers or other people at the InsideOut Institute, Sydney Local Health District or the University of Sydney. **You can choose to not participate at any time in this study, and you can sign up for notifications on the public release of the program if you would like to.**

If you decide to take part in the study and change your mind later, you are free to withdraw your responses to questions anytime during the three months when you have access to the program. You can also withdraw your responses to the follow-up questions before you submit the responses. If you do take part in the follow-up interview, you can contact us at any time up until one month after you completed the interview, and we will withdraw your data. One month after you complete the interview, all data will be locked so that we can analyse it. To withdraw your data, contact us on 02 8627 5690 or by email at skilledstudy@sydney.edu.au.

If it appears that you have engaged with the program for two or three weeks in a row, the research staff with email or call you to help you engage back with the program. If you do not respond to this or engage with the study, you will be considered disengaged.

If you appear to be at risk of severe medical or psychiatric instability, we will encourage you to speak with your GP and get face-to-face counselling and/or medical monitoring. In this case, you might not be allowed to participate in the study, as more intensive treatment options may be more effective for you.

(7) Are there any risks associated with being in the study?

While you do give up your time, we do not expect that there will be any risk or costs associating with taking part in this study. As you will have to complete a standard GP medical examination, we anticipate very little or no physical discomfort or stress from this. Potentially, you may feel some emotional distress from doing the questionnaires. In this situation, your GP can be your support person, who will monitor your risk of distress as frequently as clinically indicated. Your GP can be contacted should you feel distressed or upset during or after the assessments, or at any time during the program. If you are feeling distressed, we suggest that you do not continue to participate in this study and seek help by calling the Butterfly Foundation at 1800 334 673 or Kids Helpline (1800 551 800), using Headspace's e-headspace chat service (https://headspace.org.au/eheadspace/connect-with-a-clinician/) or reaching out to a trusted healthcare professional (your GP, Psychologist, or Psychiatrist). If

you feel quite distressed, please let the research assistant, clinician investigator, or practice staff know and they will get the clinician who is treating you to see you.

Although there are no known risks for participating in the study, if you experience any difficulties or problems, we recommend that you contact your GP who can arrange some appropriate help for you. Every fortnight, your GP will be sent a report that summarises how you are doing medically and psychologically, to help them monitor your health during the study. If your responses to the questions from this study indicate that you are at a high risk of medical and/or psychiatric instability, your GP will also be informed. The research staff might reach out to you and your GP, to encourage you to contact your GP and make sure that your GP is monitoring your health appropriately. If your responses suggest you may need emergency help, the research team will contact the most relevant crisis teams.

Please note: *SkillED* is an online, self-help program which does not replace any medical or mental health treatment you might receive. If you are experiencing serious medical and/or psychological symptoms, please speak to a medical practitioner or other health professional to discuss whether *SkillED* is right for you. While you complete the study, you must follow your GP's advice on how and when they wish to monitor you. The responsibility for your psychiatric and physical care is between you and your medical health professional.

Participating in this study will not cost you anything, and you will not be paid for participating.

(8) Are there any benefits associated with being in the study?

While you will not get any direct benefits from being in the study, we hope you will gain benefits from using *SkillED.* We hope this study will provide evidence to show how effective *SkillED* is in treating eating disorder symptoms, and guide improvements in the program's content and delivery.

Participants who have completed and returned their 3-month follow-up questionnaires will gain a chance to win one of the 10 visa gift cards valued at $100 each. Each participant will be assigned a participant code number. The lucky draw will be conducted using the "Wheel of Names" online platform for a random pick number assigned to each participant. A total of 10 spins will be conducted. The selected number will be removed from the subsequent spin for a fair distribution chance to all participants. Participants will be eligible for the lucky draw if they complete and return all questionnaires at both baseline and follow-up. Participants will still be eligible for the lucky draw prize even if they dropout during the study but return to complete the follow up assessment.

(9) What will happen to the information about me that is collected during the study?

Your responses to the screening, baseline, mid-treatment, end of treatment, and follow-up questions will be collected on REDCap (Research Electronic Data Capture), a secure web application that ensures all data is encrypted and stored behind a hardwire firewall. REDCap also makes sure that all accounts are password protected, data is transferred to a secure SSL (HTTPS) secure connection and keyewed with a private certificate to ensure all information is fully protected and GDPR compliant. The weekly questionnaire will be collected via the online eClinic platform.

Confidentiality

All information that we collect from you during the study will be confidential, and only the researchers that are involved will have access to it. Unique identification codes will be used to protect your identity when storing data. Only de-identified health information is given to researchers for healthcare research. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in these presentations. Please be assured that your identity will not be revealed at any time and that details of individual participants will not be identifiable if data from this study is combined with other institutions.

Storage of Data

Weekly questionnaires and program usage data will be collected via the eClinic platform where the *SkillED* program is hosted, which is a secure, firewall protected web platform that meets all Sydney Local Health District requirements for online privacy and confidentiality of data. All personal information (i.e., name, date of birth, email address) will be stored in a separate location to participants' responses, which can only be re-identified by a unique identification code to link baseline and future data.

While the study is still active, your responses to questions will be stored in a secure network data management system (REDCap) compliant with the University of Sydney Research Data Management Policy. The University of Sydney licence for REDCap is hosted on a secure, encrypted server within NSW, which meet the University standards for security, data ownership and privacy. REDCap projects are backed up automatically on the University of Sydney's servers on a regular basis. The backup data files are kept in a secure environment and are available for recovery. REDCap has been approved by ICT as suitable for data classified as "highly protected" under the University's data classifications.

Upon completion of the study, all electronic data and study materials will be downloaded from REDCap and stored on the University's Research Data Store (RDS). The RDS is a secure, enterprise-grade Network Attached Storage Device located within NSW. The RDMP on DashR associated with this project will provide the network path to the RDS folder for this project. All electronic data and study materials will be stored for 15 years and then all files will be permanently destroyed in accordance with the University Police.

Your information will be kept strictly confidential, except as required by law. The data will be identifiable only during the data linkage action to link pre and post measures. As part of our data management plan, the identity of each participant (including their registration email address) is maintained in one password-protected spreadsheet, and each participant given a unique ID code. The data will then be entered in the main data set identified by the ID code. The questionnaires will be analysed via the de-identified dataset in a group format.

To ensure appropriate management of your safety, the GP will be sent a fortnightly report of your medical and psychiatric health according to the most recent questionnaires you have completed. The GP may also contact the research staff or be contacted by the research staff, and/or send report of your questionnaire scores if there are any concerns regarding your safety. Note that we will always endeavour to speak with your first if we are concerned about your safety.

(10) **Can I tell other people about the study?**
Yes, you are welcome to tell other people about the study.

(11) **What if I would like further information about the study?**
When you have read this information, one of our team members will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please contact us by email at skilledstudy@sydney.edu.au.

(12) **Will I be told the results of the study?**
It is anticipated that the results of this research study will be published in academic journals and policy documents, and be presented at local and international scientific conferences. Results will also be communicated to the wider community through public talks, social media networks and print media, as well as the InsideOut website. In any publication and/or presentation, the information presented will not have your personal information, and you will not be identifiable in the information. This also means that participants will not be given their individual results but if requested, we will send a copy of the academic publications that come from the results of this study.

This development of *SkillED* was funded by the NSW Federal Government, Department of Health. This study has not received any other dedicated funding.

(13) **What if I have a complaint or any concerns about the study?**
Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by approved by the Human Research Ethics Committee - RPAH of the Sydney Local Health District ([X22-0396]). As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, you may contact the Executive Officer of the Ethics Committee, on (02) 9515 6766 and quote protocol X22-0396.

This information sheet is for you to keep.