APPENDIX A

PARTICIPANT INFORMATION SHEET – ADULT

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

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

You are invited to take part in a pilot study of an online self-help program based upon cognitive behavioural therapy for the treatment of people with eating disorder symptoms. The program, named *SkillED*, is an interactive, modularised program that has been developed by a group of subject matter experts at the InsideOut Institute for Eating Disorders including eating disorder researchers, lived experience consultants, clinical psychologists, and mental health clinicians.

The InsideOut Institute has developed *SkillED* to help address the barriers associated with accessing treatment. We hope that by improving access to evidence-based skills, knowledge and resources, individuals with eating disorders will feel more equipped to improve their eating disorder symptoms.

SkillED is structured into 11 weekly learning modules organised into various topics, such as psychoeducation about eating disorders symptoms, self-monitoring skills, practical skills for management of emotions and dietary intake. This study aims to evaluate how effective, acceptable and useful *SkillED* is for individuals experiencing eating disorder symptoms by assessing the program's impact on people's eating disorder symptoms. We would also like to use the feedback and information gained to inform ongoing development and improvement of the program's content and delivery.

Participation in this research study is voluntary. By participating in this study, you will be provided with access to *SkillED* free of cost.

This Participant Information Statement tells you about the evaluation study. 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 joint collaboration between the University of Sydney and Sydney Local Health District, and is a national institute for research and clinical excellence in eating disorders.

The study is being carried out by the following researchers:

- Prof Sarah Maguire, InsideOut Institute
- Dr Sarah Barakat, InsideOut Institute
- Dr Jane Miskovic-Wheatley, 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

There are no conflicts of interest to declare.

***(3)* What will the study involve for me?**

Your eligibility to participate in the study will be determined based upon your responses to a brief online screening questionnaire (approximately 5 minutes in length), in conjunction with a clinical assessment, where you will be asked to complete a phone interview with the study's research assessing your eating behaviours, mental health history, your current risk and mental health status. If you have an active suicidality or self harm plan or the interviewer deems you to be at high risk of self-harm, you will be advised to seek face to face counselling and will not be invited to participate in the study. However, if the study is considered suitable for you, you will be provided with the details to register and start the program. The phone interview may take approximately 30-60 minutes to complete.

Additionally, in order for you to be eligible to enter the study you will need to have a General Practitioner (GP) complete a full assessment of your physical and medical status. A form signed by your GP (either written or digital) must be returned to the research staff which confirms that the GP has seen you, considers you suitable to participate to the study and that they agree to medically monitor you for the duration of the trial at intervals which they specify. You will also be required to provide the contact details of your nominated GP.

Once your eligibility has been confirmed, and you agree to participate in this study, you will be asked to complete a Participant Consent Form.

Then, you will be directed to a complete a set of online questionnaires before starting *SkillED*. The nature of these questionnaires and others that you will be asked throughout the study are summarised further below.

You will be provided with two options for completing *SkillED*. All participants are required to complete the first 5 core modules of the 11-module program, however, for the remaining 6 modules, you will be asked to choose between 2 options: (1) **full program**: complete all 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 group you are joining, the next module will be unlocked on a weekly basis given you have completed the previous selected module.

Once you have selected your preferred option, you will then be randomly assigned to one of two engagement-based conditions. A common barrier to completion of self-help programs is the low rates of adherence: (1) **engagement intervention**, where a clinician will contact you if we detect signs of potential disengagement and (2) **no engagement intervention,** where we will not monitor disengagement risk, and no action will be taken.

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. All participants, regardless of assignment, will be contacted by research staff after two to three consecutive weeks of inactivity on the program.

For the evaluation, we will ask that you complete questionnaires at different times during the study:

Screening – Before enrolling into the program, this screening questionnaire will be administered to ensure the program is safe for you to join.

Baseline – Administered before you start *SkillED*, these questionnaires should take about 20 minutes to complete and include questions regarding demographic and general information. You will also be asked to complete the Eating Disorder Examination-Questionnaire (EDE-Q), 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, Eating Disorder Inventory-3 (EDI-3) Drive for Thinness subscale, EQ-5D-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, Kessler Psychological Distress Scale (K-10) and Eating Disorder Examination-Questionnaire-Short version, Therapeutic Mechanism Questionnaire and 4 Key Motivational Questionnaire at the beginning of each module during the participation of the program for monitoring your safety and eating disorder symptoms. 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-5L Health questionnaire, CIA and Credibility/ Expectancy questionnaires. These questionnaires should take approximately 20 minutes to complete.

Post-program – Upon completion of core modules and also upon completion of optional modules of *SkillED*, you will be asked to complete the health service utilisation, EDE-Q, 4

Key Motivational Questionnaire, RMQ, DASS-21, Self-harm and Suicidality Risk Assessment, Adapted Help Seeking Behaviour, EDI-3 Drive for Thinness subscale, EQ-5D-5L Health questionnaire, CIA, Credibility/Expectancy questionnaire, Negative effects/events questionnaire, and program feedback. Together these will take approximately 20 minutes to complete. You will also be invited to participate in an optional interview (approximately 50 minutes in length) to help us identify areas for further improvement of *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 approximately 20 minutes to complete.

You will be sent two email reminders for each questionnaire.

Program usage
Throughout the study we will also collect analytic information regarding your usage of the program, including your progress through the program, time spent in completing the program, and pattern of engagement. This information will help us to understand how usage patterns and adherence are associated with program outcomes.

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

(5) Who can take part in the study?
To take part in this study, you will need to exhibit a clinically significant level of eating disorder symptoms. These will be determined by our research staff who will carry out a clinical assessment with you over the phone as part of the screening process. Participants will also need to access to a computer or digital device with internet connection; not pregnant; living in Australia; not currently suicidal or engaging in self-harm, medically stable; not have experienced rapid changes in weight (loss or gain) and/or are very underweight; not actively engaged in any psychological treatment for an eating disorder or disordered eating; not current stimulant medication use; no diagnosis of Avoidance/Restrictive Food Intake Disorder, Pica, Rumination Body Dysmorphia, or Psychosis, and be at least 12 years of age.

(6) Do I have to be in the study? 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 anyone else from the InsideOut Institute, Sydney Local Health District or the University of Sydney. **You can decline consent at anytime and you will be given the option to sign up for notifications on the public release of the program.**

If you decide to take part in the study and then change your mind later, you are free to withdraw your questionnaire data anytime within the three-month course access period. You

can withdraw your three-month follow up questionnaire data up until the point of submitting the responses. If you do take part in the follow-up interview, you can contact us any time up until one month after completing the interview and your data will be withdrawn. After this period, all data will be locked for analysis. You can withdraw by contacting us on 02 8627 5690 or by email at skilledstudy@sydney.edu.au.

If it is noted that you have not engaged with the program for two to three consecutive weeks, the research staff will contact you via telephone/email to prompt re-engagement with the study. Following a consecutive period of absence of contact and participation in the study, you will be considered disengaged. Alternatively, if it becomes apparent during the trial that you are at risk of severe medical or psychiatric instability, you will be advised to speak with your GP and seek face to face counselling and/or medical monitoring. In this case, you may no longer be allowed to participate in the study as other more intensive treatment options are evidenced to be more effective in such situations.

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

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. As a standard GP medical examination is required, we anticipate very little to no physical discomfort and undue stress is not foreseen. However, it is possible that as a result of doing the questionnaires you may feel some emotional distress. Your nominated GP will serve as an appropriate support person who will monitor your risk as frequently as clinically indicated and can be contacted should you become distressed or upset after or during the questionnaires, or at any time during the program. If at any time you feel distressed, you can also call the Butterfly Foundation at 1800 33 4673 to get support from an eating disorder specialist, the Mental Health Access Line for NSW at 1800 011 511, or LifeLine at 13 11 14 for crisis support, or by contacting your regular healthcare professional (GP, Psychologist, Psychiatrist).

Although there are no known risks for participating in the study, if there are any difficulties or complications you encounter, we recommend you contact your GP who can arrange appropriate help. Your GP will be sent a fortnightly report of your medical and psychiatric status to assist with their monitoring of your condition for the duration of the study. If it is indicated through your questionnaires that you are at increasing risk of medical and/or psychiatric instability, your GP will also be informed. The research staff may contact you to prompt reengagement with your GP and may also contact your GP to ensure that you are being monitored appropriately. If it is indicated that emergency intervention is required, the research team will contact the appropriate crisis teams.

Please note: *SkillED* is an online, self-help program and is not in lieu of medical or mental health treatment. If you are experiencing significant serious medical and/or psychological symptoms, please speak to a medical practitioner or other health professional to discuss whether *SkillED* is right for you. Whilst you are in the study will be required to follow your nominated GP's advice regarding ongoing input and/or monitoring you will need from them for the duration of your involvement. 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, nor will you be paid.

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

We cannot guarantee that you will receive any direct benefits from being in the study, however, we hope you will gain benefits from using *SkillED*. We hope this study will provide evidence supporting the effectiveness of the *SkillED* and provide directions for ongoing development and improvement of 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 with 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 screening, baseline, mid-treatment, end of treatment and follow-up questionnaire data will be collected via REDCap (Research Electronic Data Capture), a secure web application that ensures all data is encrypted and stored behind a hardware firewall, all accounts are password protected and data is transferred over a secure SSL (HTTPS) secure connection and keyed 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, a secure purpose-built web-platform designed to meet all Sydney Local Health District requirements for online privacy and confidentiality of user data..

While the study is still active, the information you provide in the questionnaires 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 secure and encrypted University-licensed servers within NSW and they meet University standards for security, data ownership and privacy. REDCap projects are backed up automatically on the University of Sydney's servers on a regularly scheduled 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 policy.

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 will be given an 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 deidentified data set in a group format.

To ensure appropriate management of your safety, the GP will be sent a fortnightly report of your medical and psychiatric status 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 reports of your questionnaire scores if there are any concerns regarding your safety. Note that we will always endeavour to speak with you 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 research 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 via the InsideOut website. In any publication and/or presentation, information will be provided in such a way that you cannot be identified as we will not use any of your personal information as part of this research study. Participants will not be given their individual results but if requested we will send a copy of the academic publications pertaining to this study.

(13) **How is this study funded?**
The development of *SkillED* was funded by NSW Federal Government, Department of Health. This study has not received any other dedicated funding.

(14) **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). This study has been approved by the Human Research Ethics Committee - RPAH of the Sydney Local Health District. 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 have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee, on (02) 9515 6766 and quote protocol number [X22-0396]. The conduct of this study at the InsideOut Institute has been authorised by the University of Sydney. Any person with concerns or complaints about the conduct of

this study may contact the study coordinator on (02) 8627 5690 and quote the protocol number [X22-0396].

This information sheet is for you to keep.