**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

**Main Participant**

|  |  |
| --- | --- |
| **Title** | Pragmatic Trial of a Targeted Digital Intervention for Youth with Suicidal Thoughts and Behaviours Attending Youth Mental Health Services |
| **Short Title** | Affinity |
| **Protocol Number** | 2022.82198 |
| **Project Sponsor** | Orygen |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof. Simon Rice |
| **Associate Investigator(s)** | Mr. Derek English |
| **Location** | Primary Site  Orygen Specialist Program (Youth Mood Clinic)  Secondary Study Sites  Orygen Primary Services (headspace Sunshine; headspace Werribee; headspace Craigieburn; headspace Glenroy, and headspace Melton |

**Part 1 What does my participation involve?**

You are invited to take part in this research project as you are receiving treatment in the Youth Mood Clinic (YMC) at Orygen Specialist Program (OSP), or from a headspace centre, and have experienced suicidal ideation (SI) within the past four weeks. The research project is testing a new treatment for young people experiencing SI. The new treatment is an online social networking platform called Affinity. The project is being run by researchers at Orygen, Melbourne.

This Participant Information Sheet/Consent Form tells you about the research project and explains what is involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your clinician at YMC or headspace.

Participation in this research is **voluntary**. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section of this form. By signing it you are telling us that you:

* Understand what you have read;
* Consent to take part in the research project;
* Consent to have the tests and treatments that are described;
* Consent to the use of your personal and health information as described on page 6 of this form.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Suicide is a major public health problem and is the leading cause of death in Australians under the age of 25. Despite this, there is a lack of evidence regarding potentially effective treatments for young people who experience SI.

Often young people who experience SI also experience feelings of loneliness or isolation, and don’t feel like they have much social support. They may also feel at times like they are a burden on others. Therefore, potentially helpful interventions might assist young people to feel more socially connected and supported, and also feel able to support others in return. Given young Australians’ high internet use, specifically designed and carefully moderated online social networking platforms may be a beneficial in addition to traditional fact-to-face treatment. We conducted a pilot study of a new online program called Affinity and it was found to be feasible and safe, effective and acceptable to young people experiencing SI.

Affinity is an online social-networking platform developed by researchers at Orygen that is open to young people receiving treatment at youth mental services who experience SI. We have called the platform “Affinity” because it is designed to bring young people together and help them feel connected to, and understood by, other people on the platform.

Affinity allows users to display their own profile and interact online with other young people in the Affinity community. There are online coaches in the community, based at Orygen, whose job is to help users make the most of the system and to encourage a positive and supportive experience. In addition, there are peer support workers who are young people who have been through an experience of depression and who are available in Affinity to provide encouragement. It will be up to each user whether or not they use their real name, although everyone on the system will be a real person, including the coaches. All communication on the platform is conducted via text.

In addition to being a social networking website, the Affinity program includes lots of online therapy material that we call “journeys”. Journeys have different tracks, and each track has different information and activities. This therapy content has been especially designed to help

young people who are experiencing depression, burdensomeness, a lack of belonging as well as those who may feel hopeless about these experiences changing.

The journeys include information and interactive activities about depression, burdensomeness, belongingness and hopelessness, how to identify and use personal strengths, how to build social confidence, how to stay well, and other topics such as managing stress and stigma. Users of the Affinity program will be able to complete the journeys in their own time and in their own preferred order. Completion of all activities within a journey is not mandatory.

We have designed Affinity because we believe it is important to have a resource that young people who are experiencing depression and SI can use when and where it is convenient for them. We also thought it would be helpful for young people to have a safe online space where they can share their experiences and receive positive encouragement from others going through similar experiences.

This study will examine whether Affinity is more effective in the speed and effectiveness in reducing suicidal ideation compared to treatment as usual. Treatment as usual is access to the MOST platform without the new Affinity intervention content. If the results of the study are positive, they will hopefully enable us to make Affinity available to a much larger group of young people in the future.

The MOST (moderated online social therapy) platform is an online social networking site that provides mental health support for young people.

There are also additional optional components of participation if you are interested.

Optional psychosocial recovery group

One of these is participating in an online, fortnightly psychosocial recovery group with other participants that is facilitated by a clinician and expands on the content found on the Affinity platform.

Optional caregiver psychoeducation sessions

Another other optional component is allowing your caregiver (parent or guardian) to attend educational sessions that aims to help your caregiver better understand and support you.

Optional provision of Medicare and Pharmaceutical Benefits Schedule information

As well, to conduct an economic analysis on the Affinity intervention, the team will seek to access your information from Medicare and the Pharmaceutical Benefits Schedule (PBS) to collect routine data on the use of primary health care services. Consent to the collection of Medicare and PBS data and to the collection of health data via data linkage will be optional.

Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC). You will be asked to sign a separate consent form authorising the study to access your Services Australia information, see the separate Services Australia Participant Information Document and Participant Consent Form.

Optional feedback interview

Lastly you will be invited to participate in a semi-structured interview about your experiences whilst participating in the trial.

Not wanting to consent to any or all of these optional components does not stop you participating in the Affinity intervention.

**3 What does participation in this research involve?**

If you agree to participate you will be taking part in a randomised controlled trial of an online program, called Affinity, for young people experiencing SI. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). For this trial there are two conditions - a control condition and an

intervention condition. You have a 50% chance of being randomised to the intervention condition.

If you are randomised to the intervention condition, you will be given access to the MOST platform with Affinity intervention content for a period of 12 weeks, and will be able to use the platform as much or as little as you like during this time, although you will be encouraged to login at least weekly if possible. If you are randomised to the control condition, you will be given access to the MOST platform without Affinity specific intervention content for 12 weeks. You will be able to use the MOST platform as much or as little as you like during this time, although you will be encouraged to login at least weekly if possible. As a member of the control group you will not be able to participate in the psychosocial groups, or allow your caregivers to participate in the psychoeducation groups.

To take part in the Affinity trial, you will also need to attend a research interview before your period of access to the online program. In order to participate you must be willing and able to provide the details of two emergency contacts, and have access to the internet and a mobile telephone.

You will first have a short meeting with the study research assistant to check that the study is suitable for you. If you are not eligible, you will be informed and the short meeting will conclude. This meeting should take between 15 – 30 minutes. If eligible, you will complete a set of questionnaires with the study research assistant that will collect demographic information, measure level of suicidal thoughts, symptoms of depression, social wellbeing and functioning, coping strategies, and use of support services. This research assessment will take no more than 2 hours, and can be organised to be conducted in person, over the phone or via telehealth. You will be able to take a break during these assessments and resume where you left off if you require. Demographic information collected may be supplemented by review of your clinical file or via discussion with your clinician.

After your research interview you will meet with an Affinity coach, who will be an experienced clinician responsible for helping participants to make the most of the online intervention. The coach will show you how Affinity works and give you guidelines on the appropriate use of the online program. You will then be given your own account so that you can log on to the system. After this meeting you will be able to access Affinity from any internet-enabled device.

You will be able to work through the Affinity therapy steps and pathways, along with the other young people in the Affinity community. It will be up to you when and how often you log on, and what you do when you log on. Communication with other users, peer and clinical moderators is

through text messaging on the platform. You will continue to receive all of your usual treatments, in addition to having access to Affinity for 12 weeks.

In order to keep the Affinity program safe and private, there will be some rules that all users will be expected to follow, such as being respectful to other users and keeping messages in Affinity private. Please note that inappropriate use of the Affinity system (e.g. derogatory or disrespectful statements) may lead to your Affinity account being temporarily or permanently suspended. You will be given a complete list of rules when you are signed up to the website.

It is also important to note that online coaches or moderators will monitor Affinity twice a day during weekdays and once a day during weekends. This means that Affinity has not been designed and is not equipped to respond to emergency situations. However, the Affinity system automatically detects and blocks any posts that include key words that might indicate your post could be distressing to other users. If this happens, a moderator will be able to see this during their scheduled safety checks (twice per week day, once per weekend day and public holidays), and if they are concerned for your safety they will contact you to check in.

At weeks 4, 8 and 12 you will be asked to meet with the study research assistant via phone, teleconference or in person to repeat some of the questionnaires included in your first interview. You will also be contacted to repeat some of the questionnaires at week 26 and week 52. These

are referred to as ‘follow up’ assessments and are conducted to see what the long-term effects of being involved in the trial are.

Once your participation in the trial is complete you will be able to access the platform until the trial has concluded. When the trial concludes, the close out of the platform is handled with the same consideration as the end of any therapeutic relationship. Participants will be given sufficient notice that the platform will be closing and offered opportunity to discuss the closing of the platform with the therapy and peer work teams respectively. If the MOST platform is still live, participants from Affinity could be offered access to the platform. Participants may also be assisted in engaging with other services.

**Costs and Reimbursement**

There are no additional costs associated with participating in this research project. All treatment and tests required as part of the project will be provided to you free of charge.

You will be eligible to receive reimbursement for assessments and the feedback interview at a rate of $30 per hour. The majority of assessments are expected to last no longer than 1 hour. Although it is not expected that any travel will be required as part of trial participation, any transportation costs incurred can be reimbursed

**Avoiding bias**

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study personnel or participants making assumptions about the meaning of findings.

**4 What do I have to do?**

You are not required to change anything about your lifestyle to participate in the trial. It is a requirement to participate that you are willing to engage in safety planning and use crisis supports if they would be required. Safety planning involves creating a plan with your clinician on how to keep yourself safe if your distress levels begin to increase. Utilisation of

crisis supports may include willingness to call crisis support services if you are feeling distressed. If you are already participating in an intervention to reduce SI you are ineligible to participate. While participating in the trial you are not allowed to commence participation in another intervention to reduce SI. By this we mean any other research project or trial investigating a new intervention for SI.

As part of participation it is encouraged that you engage with the website at least one hour a week, although this is not obligatory and you are allowed to use it as much or as little as you like. If you agree to participate in the optional psychosocial recovery group then you are expected to attend as many of the six sessions as possible. It is expected that you will complete as many of the scheduled assessments as possible.

**5 Other relevant information about the research project**

This trial is a follow on from a pilot of Affinity which established it as safe, acceptable, effective and feasible. We are aiming to have 154 people participate in the trial. We expect that around 50% of participants will be clients of the OSP and 50% will be headspace. The trial involves research collaborators from Orygen, University of Melbourne, Australian Catholic University and Monash University.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with OSP or headspace.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at OSP or headspace. Apart from Affinity, there are other online programs currently available for mental health problems. You are encouraged to discuss your treatment options with your clinician before deciding whether or not to take part in the project.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits from participating in Affinity may include reduced symptoms of depression, including SI, and increased social functioning (such as increased confidence in relating to friends). In addition, you will be assisting the researchers to find out if the study intervention is effective and whether it can assist other young people who experience SI.

**9 What are the possible risks and disadvantages of taking part?**

Mental health interventions can sometimes have unintended side effects and online therapy has some specific risks. Affinity has been designed to be a private social networking site. It is important to understand however that no website is completely “hacker proof”, so there is an

extremely small chance that the privacy of Affinity users could be put at risk. Other risks to privacy could include Affinity users passing on details of other Affinity users, for example via the internet. For these reasons we are encouraging all participants to think about whether they would like to use their real name or an alternative name on Affinity. If you choose to use an

alternative name, your real name will be kept confidential so that only the Affinity coach is aware of your personal details.

It is also possible that users might break the rules in Affinity and communicate things that may upset others. For this reason, we have set up a “report button” in Affinity, which will allow any user to let the coach know about anything offensive or upsetting that has been posted. If you become concerned about how Affinity is being used by other users you can report this to us via the website, or you can also contact us by phone to report your concerns.

Users of Affinity should also be aware of their personal safety when meeting other people through the social networking functionality. We recommend that all users of the Affinity program follow cybersmart safety guidelines. A copy of these guidelines will be provided to you, and the Affinity website will contain a link to cybersmart information.

If you become upset or distressed as a result of your participation in this research project you will be able to talk to a member of the research team, who will arrange appropriate counselling and support. The Affinity website will also provide telephone numbers that you can call for personal assistance if you become distressed. Any counselling or support will be provided by

staff who are not members of the research team, such as your clinician OSP or headspace. In addition, you can suspend or end your participation in the research at any time.

If you become unwell during the research project you may speak with the research team, or the research team may speak with you about taking a break from your involvement with Affinity until both you and the research team agree that it is a good idea for you to resume participation. The team may also discuss this with your doctor or clinician.

By consenting to participate in this project you consent to the research team contacting other mental health professionals involved in your care if necessary to ensure your wellbeing.

Because Affinity is a new type of therapy program, there may be additional risks that the researchers do not expect or do not know about. Please tell a member of the research team immediately about any problems you experience as a result of Affinity.

**10 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your treating team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your treating team will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your treating team might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

**11 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you will continue treatment as usual with your clinician, however you may not participate in another intervention with the aim of reducing SI. If you have the opportunity to participate in another intervention with the aim of reducing SI you are able to withdraw from this study to do so. You are encouraged to discuss this with your referring clinician if the situation arises. You can however commence new medications, or resume using a medication you had previously been prescribed. If you do

commence a new medication, or resume a medication you were previously on, we would ask that you please try and notify the study team.

**12 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team. This notice will allow that person or the study coordinator to discuss any health risks or special requirements linked to withdrawing. You do not have to provide a reason for why you would like to withdraw.

If you do withdraw during this research project, you will still be able to access Affinity if you would like to, for the duration that you would have otherwise been able to if you had stayed in the trial. The study coordinator and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

If you withdraw you will be given the following options regarding assessments and data

* You can withdraw from the trial, and allow the researchers to keep the data you have provided for analysis, and also continue to complete assessments and be reimbursed for them until you would have otherwise stopped completing assessments.
* You can withdraw from the trial and allow the researchers to keep the data you have provided for analysis, but not complete any further assessments
* You can withdraw from the trial and request that your previous data be deleted, and not complete any further assessments.

**13 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

**14 What happens when the research project ends?**

You will continue to receive any relevant health care you require via your clinician at YMC or headspace, after your involvement in this research project has ended.

If you would like, we will provide you with a summary of the results of the project when it is concluded.

We will ask you for some contact details so that we can post or email it to you. We will also publish results of the research project in publicly available scientific journals. Generally, these can be accessed through institutional libraries. Your will not be identified in any publications.

**Part 2 How is the research project being conducted?**

**15 What will happen to information about me?**

By signing the Consent Form you consent to the study research assistant and relevant research staff collecting and using personal information about you for this research project. Any

information obtained in connection with this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

The Affinity website will be stored on an Australian server of Amazon Web Services, which will allow the researchers to track which aspects of the program you have used and how often you have logged on. Information collected by the research assistant will be stored in a secure computer file at Orygen and in a locked filing cabinet in the office of Associate Professor Simon Rice at Orygen.

Information about you collected for this research will be stored using **a unique number** and will not include any personally identifying information, such as your name. This includes information collected through research interviews and from your use of the Affinity system. No personally identifiable information about you (for example, on the Consent Form) will be kept together with this de-identified research information. Information collected for this study will only be re-identifiable using a coding system, which will be stored in a separate password-protected computer file at Orygen.

Personally, identifying information will be kept for 15 years after the results of this study have been published, and then destroyed. We will also ask your permission to store de-identified research information indefinitely in a secure computer file, so that it can be used in future research studies at YMC. *You do not need to agree to this to take part in the Affinity study.*

Information may be obtained for this research from your clinician and from your health records held at YMC. Information about you may also be obtained from other health services after your discharge from YMC for the purpose of this research. By signing the Consent Form you agree to the research team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during this research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of Orygen, The Royal Melbourne Hospital Human Research Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information that is published from this research project will only include summary information that describes the whole group

of participants and not any individual participant. Your data may be uploaded to an online repository as part of the publication review process in a de-identified manner (i.e. you will not be identifiable by any of the data that is provided).

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

**16 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible. You will then be assisted with arranging appropriate medical treatment. You can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**17 Who is organising and funding the research?**

This research is funded by the NHMRC Clinical Trials and Cohorts 2020 Scheme.

Orygen may benefit financially from this research project if, for example, the Affinity program is commercialised.

You will not benefit financially from your involvement in this research project. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Orygen there will be no financial benefit to you from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**18 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Royal Melbourne Hospital.

This research project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**19 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this research project or if you have any medical or mental health problems which may be related to your involvement in the project (for example, any side-effects), you can contact:

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| --- | --- |
| **Name** | Associate Professor Simon Rice |
| **Position** | Research Fellow |
| **Telephone** | (03) 9966 9100 |
| **Email** | [simon.rice@orygen.org.au](mailto:simon.rice@orygen.org.au) |

The Royal Melbourne Hospital Human Research Ethics Committee (HREC) has approved this study. If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| **Reviewing HREC name** | The Royal Melbourne Hospital HREC |
| **HREC Executive Officer** | Manager HREC |
| **Telephone** | (03) 9342 8530 |
| **Email** | [Research@mh.org.au](mailto:Research@mh.org.au) |

If you have any complaints about any aspect of the project then you may contact:

|  |  |
| --- | --- |
| **Name** | Director Research Governance and Ethics |
| **Position** | Complaints Manager |
| **Telephone** | (03) 9342 8530 |
| **Email** | [Research@mh.org.au](mailto:Research@mh.org.au) |

**Consent Form – Main Participant -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Pragmatic Trial of a Targeted Digital Intervention for Youth with Suicidal Thoughts and Behaviours Attending Youth Mental Health Services |
| **Short Title** | Affinity |
| **Protocol Number** | 2022.82198 |
| **Project Sponsor** | Orygen |
| **Coordinating Principal Investigator/**  **Principal Investigator** | A/Prof Simon Rice |
| **Associate Investigator(s)** | Mr. Derek English |
| **Location** | Primary Site  Orygen Specialist Program (Youth Mood Clinic)  Secondary Study Sites  Orygen Primary Services (headspace Sunshine; headspace Werribee; headspace Craigieburn; and headspace Glenroy, headspace Melton |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Orygen concerning my mental health condition/s and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

**Optional Consent**

As mentioned above there are additional optional components of the trial. You can decide to not consent to both, or consent to either one, or consent to both. Your decisions regarding consent to the optional components do not affect your participation in the trial. You can also choose to withdraw from the optional components at any time during the trial, without withdrawing from the trial.

Psychosocial Recovery Group

I consent to participate in the optional psychosocial recovery group

I do not consent to participate in the optional psychosocial recovery group

Caregiver Education Sessions

I consent for my caregiver to be contacted about participating in the caregiver education sessions.

I do not consent for my caregiver to be contacted about participating in the caregiver education sessions.

Post Intervention Feedback Interview

I consent to be contacted about the post intervention feedback interview.

I do not consent to participate in the post intervention feedback interview.

Permission to store de-identified information indefinitely for the purposes of future research.

I consent for my de-identified information to be stored indefinitely for the purposes of future research.

I do not consent for my de-identified information to be stored indefinitely for the purposes of future research.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Declaration - for participants unable to read the information and consent form  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Telehealth or Telephone Consent**

* Consent was obtained using telehealth with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written
* Consent was obtained via telephone with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_\_
* Participant’s signed consent form received by the Investigator on \_\_\_/\_\_\_/\_\_\_\_\_

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Pragmatic Trial of a Targeted Digital Intervention for Youth with Suicidal Thoughts and Behaviours Attending Youth Mental Health Services |
| **Short Title** | Affinity |
| **Protocol Number** | 2022.82198 |
| **Project Sponsor** | Orygen |
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| **Location** | Primary Site  Orygen Specialist Program (Youth Mood Clinic)  Secondary Study Sites  Orygen Primary Services (headspace Sunshine; headspace Werribee; headspace Craigieburn; and headspace Glenroy, headspace Melton |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Orygen.

Although I am withdrawing from participating, I allow for my previously provided data to be kept and used in analysis. I would also like to complete upcoming assessments that I would have otherwise completed if I had chosen to continue in the trial.

Although I am withdrawing from participating I allow my previously provided data to be kept and used in analysis. However, I do not want to complete any upcoming assessments that I would have otherwise completed If I had chosen to continue in the trial.

I am withdrawing from participating, and wish for my previously provided data to not be used in analysis, and for my data to be deleted. I do not wish to complete any additional assessments that I would have otherwise completed if I had chosen to continue in the trial.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

Documentation of verbal withdrawal

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.