

Appendix D- The MindKind Study Informed Consent Form

RESEARCH STUDY INFORMATION

Title: Global Mental Health Databank Study (MindKind Study)

Protocol Number: 2020011231

Investigator: [Name of Local PI]

Contact Address: [Address]

Contact Phone Number: [study phone number]

Email Address: [study email address]

Principal Investigator: Lara Mangravite, PhD
Sage Bionetworks,
2901 3rd Avenue, Suite 330
Seattle, WA 98121

Sponsor: The Wellcome Trust

You are invited to participate in the MindKind study (the "Study"). This study uses a mobile application, the MindKind Study App, to record information about your mental health and wellbeing.

This form explains what the MindKind Study is about. Please read this form carefully. It should help you decide if you want to join. You should not join this research study until all of your questions are answered.

Participating in a research study is not the same as receiving medical care. The decision to join or not join the Study will not affect your medical care, insurance, or benefits.

OVERVIEW

The MindKind Study and the MindKind Study App are designed for users who've reached legal age (set between 16 and 21 depending on local laws), are less than 25 years old, and live in a country where the MindKind App is available.

We want to find out if young adults are willing to use a mobile application to participate in mental health research. We also want to find out what data they are willing to share for research and how. This information will help us determine whether data collected via the MindKind Study App can be used to create a global research databank about Mental Health.

Participation is voluntary. If you join the MindKind Study, we will ask you to answer questions about your mental health and wellbeing on the Mindkind Study App. We will also automatically collect information about your daily activities like how many steps you take or how much and how well you sleep. You may not directly benefit from taking part, but you may help researchers understand better ways to manage mental health. We expect the risks of participating in this research to be moderate. Answering questions about your mental health may cause a range of emotions.

This Study was developed by Sage Bionetworks (a not-for-profit research organization in the USA), in collaboration with researchers in India, South Africa, and in the United Kingdom. The Principal Investigator for the Study is Lara Mangravite, Ph.D. If you have any questions about the Study please contact the Study Team in the USA or in your country, listed above.

How long will the study last? The MindKind will last about one year. We would like you to participate for 12 weeks, but you can participate as long as you like.

How much time will it take you to participate?

After you join, participating in the MindKind Study should take you about 10 minutes per day. We'd like you to participate for the full 12 weeks.

How many people will take part in this study?

We expect more than 4,500 people from India, South Africa and The United Kingdom to join this study.

WHAT IS INVOLVED

We will ask you to download the free MindKind Study App onto your phone. In the app, we will ask you questions about your health and your medical history. We will also ask you to complete the simple activities described below. These questions and activities are important for the research study.

We will ask you to:

- **Register:** You can learn more about the study and about the risks and benefits of participating on the study website. If you want to participate in this study, you must complete the consent process. After you confirm your decision to participate you will create your study account. We will ask your name, email address, and other general information about yourself. You can cancel the registration process at any time.

- **A Health Survey:** To start, we will ask you questions about your general health, demographics, and mental health history. You can skip any questions you do not wish to answer. This should take about 15 minutes.
- **Digital Diary:** We will send you specific prompts about your mental wellbeing. You can skip or postpone any prompt you do not want to answer. These responses should take less than 10 minutes to complete.
- **Phone usage behavior:** We want to understand how your real-world behavior influences your mental wellbeing. To do this, we will ask you to allow us to passively collect data about your phone usage while you are not using the MindKind Study App. This could include your screen-time and your daily step count. We will not collect any phone usage data without your explicit consent. **Sharing data about your phone usage is completely voluntary. You can opt out of sharing phone usage data and still participate in the study.**

We may ask to know the location of your phone. We will use the location to see how the weather near you affects your mental wellbeing. We will not track or record your precise location. You can turn off the location data at any time. We will not access your location without your consent.

Occasionally we may re-contact you to ask for your feedback about using the MindKind Study App and about the kind of questions included in the study. Although we'd love to hear back from you, answering is up to you.

DATA COLLECTION, STORAGE, AND PRIVACY

Your privacy is important to us. We will make every effort to protect your privacy. We will process your data electronically.

The data we collect through the MindKind Study App is encrypted on your phone. This means your data is protected. Unauthorized people cannot easily understand your data when it is encrypted.

We will separate your account information that identifies you from your study data. Your account information will not be stored with your survey responses or other information we collect through the MindKind Stud App.

Your study data will not be labelled with your name or other information that directly identifies you. We will label the data you provide with a random code. There will be a master list linking the codes to names, but we will keep it separate and secure. Only key people from the study team will be able to link your identity to your coded study data.

We will combine the coded study data (without names) from all the study participants. We will store this combined dataset in the United States on the Synapse data analysis platform. Synapse is run by Sage Bionetworks (non-profit). We will limit and keep track of who sees the combined dataset on Synapse.

We need to transfer the data out of your home country in order to contribute to the international databank. By participating in the study, you consent to the transfer of your encrypted personal data, including your health information and app location data, to countries outside of your country of residence, including to the United States. Sage Bionetworks will receive your data and be responsible for keeping your information protected.

WE WILL NEVER SELL, RENT, OR LEASE YOUR CONTACT INFORMATION. Please read our Privacy Policy for more information.

DATA USE

The data you contribute belongs to you.

We will analyze the combined coded study data. We will look for patterns. These patterns may help us to better understand how to manage mental health. Also, we will investigate how mobile phones can be used in this type of research. We aim to publish the work in academic journals. Your identity will not be revealed in any report or publication.

We will not use the coded study data for commercial advertising. There is no expiration for your permission. You may take away your permission to collect, use and share information about you at any time. You just need to give notice to the study investigator in your country of the Principal Investigator listed above. If you do this, you will not be able to stay in this study.

SHARING FOR FUTURE RESEARCH

Sharing your coded study data broadly (without information such as your name) may benefit future research.

You may be presented options for who can use your study data in the future and how your data can be accessed. Any decisions to share data for future research are completely up to you.

POTENTIAL RISKS

This is not a medical treatment study. We do not expect medical side effects from participating in this study. The MindKind Study App is not a tool for self-managing your mental health. Your responses will not be monitored in real time.

We take great care to protect your information. However, if there is a data breach it may be possible to re-identify you. This risk is moderate.

Answering questions about your mental health may be tiring, frustrating, boring or may make you feel uncomfortable. Seeing your data may generate a wide range of emotions. It could affect your mood.

Be aware that other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study.

Participation in the MindKind study may involve risks that are not known at this time. You will be told of any new information that might change your decision to be in this study.

POTENTIAL BENEFITS

You may or may not benefit from volunteering for this research study. You will be helping scientists make discoveries that may lead to better management of mental health in the future. We will be looking for health patterns across large groups, not individual health trends.

COSTS AND PAYMENT

You will not be paid for participating in the study and/or sharing your data. Research may lead to patentable discoveries or commercial product(s). You will not profit from future research and discoveries.

Transmitting data collected in this study may count against your mobile data plan. You may configure the MindKind Study App to only use Wi-Fi connections to limit the impact this data collection has on your data plan.

You may be eligible to receive compensation for the cost of the MindKind Study App data usage in your country.

NOT MEDICAL CARE

This is a research study. The MindKind Study App is not a diagnostic tool. It shouldn't be used for medical care, diagnosis, or treatment. If you have questions or concerns related to your health, you should see a healthcare provider. You should not use the MindKind Study App in place of seeing a healthcare provider.

The MindKind study does not provide therapy. The MindKind Study App is not directly monitored nor supported by clinicians or therapists. If you report increased distress or thoughts of harming yourself in the MindKind Study App, we will give you automated advice and point you to sources of help. You can also contact us for further advice at any time and we will (wherever possible) respond within 2 working days.

RESOURCES

If you are experiencing distress or feel that you are going to hurt yourself or others, please contact your physician.

You can also find mental health resources in your region at <https://befrienders.org> or see resources provided below.

In India:

iCallHelpline provides free counseling. <https://icallhelpline.org/>

The iCallHelpline is available Monday- Saturday, 10am-8pm. Call: 022-25521111

You can also email iCallHelpline for a response from a counselor within 24 hours.

In South Africa:

SADAG provides assistance for those in need. <https://www.sadag.org/>

24/7 support hotline Call: 0800456789

You can also email SADAG at zane@sadag.org in non-emergency situations for information about counseling.

In the United Kingdom:

Samaritans UK is available for emotional support. <https://www.samaritans.org/>

The Samaritans UK hotline is available 24/7.

For English, call 116 123

For Welsh, call 1 0808 164 0123

You can also email Samaritans UK for a response from a counselor within 24 hours.
jo@samaritans.org

LEAVING THE STUDY

You may leave the study at any time for any reason. The study will last one year. We hope that you can participate for 3 months (12 weeks), but it is up to you. You can participate for as long as you like. No matter what you decide, now or in the future, you will not get penalized or lose benefits you are otherwise entitled.

If you leave the study, you withdraw your consent. You will be logged out of your account and no more data will be collected. If you wish to re-enroll at a later date you will be asked for your informed consent again. By default, your de-identified, coded study data provided prior to your withdrawal will remain in the Study.

The study team may also withdraw you from the study at any time for any reason.

You can choose to leave the study directly from your MindKind Study App profile page, or you can notify us by phone or email. You can also uninstall the MindKind Study App from your phone at any time.

SOURCE OF FUNDING FOR THE STUDY

The Wellcome Trust is funding the MindKind research study.

Sage Bionetworks, a non-profit research organization and its partners are developing the MindKind Study App and conducting the research study.

CONTACTS

You can choose whether or not you'd like us to contact you. We might want to alert you to research events, like webinars. We might want to tell you about other research opportunities. You can still participate in the Study even if you opt out of these follow-up notifications.

There are two ways to opt out of notifications. You can adjust the "permissions" setting in your MindKind Study App profile, or you can delete the App.

Feel free to contact us to ask questions, express concerns or complaints, notify us of a research-related problem or to leave the study.

The study contacts are: In India, contact: Dr. Soumitra Pathare at spathare@cmhlp.org
In the South Africa, contact: Dr. Zukiswa Zingela at zingelaz@mweb.co.za or Mr. Melvyn Freeman at melvynfreeman57@gmail.com
In UK, contact: Dr. Mina Fazel at mina.fazel@psych.ox.ac.uk or Dr. Tamsin Ford at tjf52@medschl.cam.ac.uk
In the USA, contact: Lara Mangravite, email at MindKindSupport@sagebase.org.

Ethical oversight contacts

If you would like to speak to someone other than us about this study, if you feel that your human rights are violated in the MindKind study, or if you are not satisfied with the response of the research team, contact the Institutional Review Board (IRB) or Committee for Human Research (CHR). The IRB and CHR are groups of experts who independently review research. The IRB and CHR will address any questions, concerns or complaints you have about this study. They will also help with any questions you have about your rights as a research participant.

India: If you feel that your human rights are violated in the MindKind study, you can appeal to Dr. Deepa Paturkar, Member Secretary of the Institutional Review Board of Indian Law Society at deepapaturkar@ilslaw.in

South Africa: This study has been approved by the Committee for Human Research (CHR) at Walter Sisulu University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research. You can contact the Chairperson of the Committee for Human Research at Walter Sisulu University, Dr. Dan Mwesingwa-Kayongo at dkayongo@rtc.utr.ac.za.

The United Kingdom: This study has received ethical approval by Oxford University and Cambridge University. You can contact the Oxford committee at ethics@medsci.ox.ac.uk. You can contact Chair of the Cambridge committee, Dr. Rhys Morgan at researchintegrity@admin.cam.ac.uk.

In the USA, contact: Western IRB (WIRB) at help@WIRB.com.

If required by law, the study staff may give your contact information and identifiable study data to the appropriate legal entities (e.g ethics boards, oversight authorities, IRBs or CHRs). This is for auditing purposes, so they can monitor the safety, effectiveness, and conduct of our research.

Your personal information will be used to confirm your eligibility for this study, to assess the results of this study, and to meet legal and regulatory requirements.

You do not give up any of your rights by participating in this research. If you are a citizen or resident of the European Union, see the [GDPR addendum](#) for more information about your rights as a data subject.

Thank you for considering participating in the MindKind study.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. Here is a summary of the material I read today:

- The purpose of the **MindKind Study** is to understand whether, and how, young adults are willing to use a mobile App to self-manage and share their data regarding their mental health.
- I have a choice to participate or not. It is up to me. If I decide to participate, I can change my mind at any time for any reason. There is no penalty if I stop (withdraw)
- This is a research study. It is not for diagnosis or health care. My responses will not be monitored in real time. If I experience mental distress, I will contact a medical professional.
- I am not expected to personally benefit from the study. I will not be paid for the use of my information. My participation may help future generations.
- I will use the MindKind Study App to respond to questions about my mental health and wellbeing, and will contribute phone usage data, if I choose to do so.
- My information will be transferred to the United States and stored securely.
- Researchers will use my information for research. If I give my permission, they may share data with other researchers for future research.
- I have read and considered the risks of participating in this study. The most common risks of participating are emotional discomfort and risks to my privacy. There may be risks we do not yet know at this time.
- The Research Institution may contact me to update my research record or to invite me to participate in other studies.
- I can contact the study team with any questions or concerns related to the MindKind study.

I freely consent to be in this research study.

By signing this consent I have not given up any of my legal rights.

Name of adult participant: _____

Signature and Date: _____

EEA- General Data Protection Regulation Addendum

As required by the law of the European Union, and its member countries, additional information is being provided to you as a research participant.

For the purpose of EU law, particularly the General Data Protection Regulation (GDPR), the legal basis for the collection and use of your data is your consent as well as the public interest in the research being conducted.

If you are habitually located in the EEA, you have certain rights related to the processing of the information we collect from you. While some of these rights apply generally, certain rights apply only in certain limited circumstances. We will comply with your request to exercise your rights unless we have compelling legitimate grounds to deny your request or we cannot comply with your request for legal reasons. We will respond to your request within 1 month of receiving it.

- **You have the right to access your data.** You can write to us at any time asking to know what personal information is being held where and for what purpose.
- **You have the right to rectification.** If there is an error in the information we collect from you, you have the right to make a request to have it fixed. You can write to us to ask for any incorrect personal data about you to be corrected.
- **You have the right to erasure.** You may ask us to delete or remove some or all of your personal data at any time.
- **You have the right to restrict processing.** At any time, you can withdraw your consent to our processing of your Personal Data.
- **You have the right to data portability.** You can request a copy of your data in usable format.
- **You have the right to object.** You can withdraw from providing data to the App at any time.

If you have questions about your rights and choices or would like more information about your rights and choices, you can email privacyofficer@sagebionetworks.org.