

CONSENT TO TAKE PART IN RESEARCH

*Department of XXXX
XXXX*

*Study title: XXXX
Principal Investigator: XXXX; XXX-XXX-XXXX
Sponsor: XXXX*

Individual Session Consent

You are being asked to take part in a research study. Taking part in research is voluntary.

Your decision whether or not to take part will have no effect on your participation in the services or activities of any agency. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of this study is to test a smartphone “app” that will help people receiving supported employment services stay on the job.

Will you benefit from taking part in this study?

There is little chance you will benefit from being in this research study other than to have the opportunity to talk with other individuals about ways in which a smartphone app should be designed to help them. We hope to gather information that may help people in the future.

What does this study involve?

Your participation in this study involves an individual session that will last about 1 hour. You will be asked to talk about ways a smartphone app might be useful to you on the job. At the session, we will describe the study to you, provide you opportunity to ask questions, and confirm that you are capable of giving informed consent. We will show you examples of technology, have you try them out, and ask about things you would find most helpful and least helpful. We will take notes during the session, but these notes will not include your name. You will be asked to complete a Usability Questionnaire at the end of the session to provide information on your background and experiences using technology tools and the Internet, and your opinions of the examples we have shown you.

We will ask your permission to audio-record the session. We do this to keep a record of the session to compare with our written notes. We will destroy the audiotapes at the end of the study. If you do not agree to audio-recording, we will not record the session.

What are the options if you do not want to take part in this study?

Your participation is completely voluntary. You may choose not to participate in this study at any time. You may leave the session to take a break, if you'd like, and return when you are ready. Your decision to not participate and/or to withdraw from the study at any time will have no effect on the services provided to you by any agency.

If you take part in this study, what activities will be done only for research purposes?

You will complete the survey and participate in the session for research purposes, to explore the ways in which individuals might use the smartphone app and to provide recommendations for technology developments that may help individuals in the future.

What are the risks involved with being enrolled in this study?

There is very little chance of any harm to you from taking part in this study. If you become frustrated or in any way uncomfortable in the session, a member of the research team is available to talk with you. In our previous research, this is very rare.

Loss of confidentiality is the other possible risk in this study. Even though we will not be asking for sensitive personal information, we are very careful to protect your privacy. It is also possible that another person in the focus group may talk about the focus group outside the group, after the focus group session. We will discuss this at the beginning of the group and ask everyone to agree keep everything private and not discuss details outside of the focus group. We will emphasize that this is for everyone's protection, so that people feel totally comfortable sharing their honest opinions.

Other important items you should know:

- **Leaving the study:** You may choose to stop taking part in this study at any time. If you decide to stop taking part, it will have no effect on any services you may receive at any agency. You will not lose any benefits to which you are entitled. You will not be penalized in any way.
- **Number of people in this study:** We expect XX people to enroll in this study.
- **Funding:** The XXXX provides funding to XXXX for this research.
- **Product Development:** If the results of this research are used to develop a product sold for a profit, you will not share in the profit. You will not receive money from the profits.

How will your privacy be protected?

The information collected as data for this study includes:

- Background information such as your age, gender, education and family circumstances.

- Your report of mental health diagnosis.
- Information about technology tools you use, like computers, the Internet, a tablet (iPad) or cell phone.
- Ways you think tools like this might be helpful to individuals at work.
- Your answers on the survey at the end of the individual session.
- Audio-recordings and the notes taken by researchers.

We will collect this information in a brief questionnaire and in notes we take during the session. In addition, if you agree, we will record the session. Your name will not appear on the survey or in the notes. The audio-recordings will be kept in locked filing cabinets and will also be labeled only with your study number.

We are careful to protect the identities of people in this study. We will make every effort to keep the data in this study private. The informed consent form is the only written document that will contain your personally identifiable information. There will be no way to connect your consent form to your survey responses or your participation. We will keep the signed consent forms in a separate place from the data, so names can never be connected with any data. Both will be kept in locked storage. We will not use your name in any reports written from this study. Some study data will be kept on computers. These files will be password-protected. They will be kept on computers used only by the research team. Audio-recordings will be destroyed when all study activities are done.

There are some times when we cannot keep all of your information private. These include:

- If we believe you are going to harm yourself or someone else;
- If we believe that a child or adult who is unable to take care for him/herself is being abused or neglected;
- If you sign a paper giving us permission to release your information.

We will keep the data from this study until we are done working with it. When the study is completed, the data will be shredded or deleted.

The information collected for this study will be used only for purposes of research as stated earlier in this form.

Who may use or see your health information?

Some of the information we collect in this study has to do with your health. By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the Principal Investigator plus others working on this study at XXXX.

The information collected for this study may be used by researchers or officials of the following institutions.

- XXXX
- XXXX
- XXXX
- XXXX

During this study, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study. If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

What about the costs of this study?

There will be no cost to you for taking part in this study.

Will you be paid to take part in this study?

You will be paid \$XX for taking part in the individual session.

Whom should you call with questions about this study?

If you have questions about this study, you can call the research director, XXX, at (XXX) XXX-XXXX during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at XXXX, you may call the Office of the Committee for the Protection of Human Subjects at XXXX at (XXX) XXX-XXXX during normal business hours.

If you have questions, concerns, complaints or suggestions about human research at XXXX, you may call XXX, at (XXX) XXX-XXXX

CONSENT

I have read the above information about "XXXX" and have been given time to ask questions. I agree to take part in this study and I have been given a copy of this signed consent form.

My participation is completely voluntary. True False

My participation does not affect any of my mental health services. True False

If I withdraw from the study, none of my services will be affected. True False

Permission for Audio-Recording:

I agree to have the session audio-recorded.

I DO NOT agree to have the session audio-Recorded.

Participant's Signature and Date

PRINTED NAME

Determination of Competence

I, the representative of the Investigator and staff member of the research project, acknowledge that this study participant understands the research project and what is involved in participating. The participant asked questions as desired, and answered questions about each section as the informed consent was explained. Further I attest that the individual agreed to participate voluntarily.

Researcher or Designee Signature and Date

PRINTED NAME