Online Consent Form Introduction

Hi there! Before you get started with the study, we'd like to share some important information about the study and obtain your consent to participate. The consent form contains information about:

- The purpose of the study
- What you'll be asked to do
- Potential risks & benefits of study participation
- Alternatives to participating in this study
- Your rights as a research participant

The major key points have been broken up for your convenience. At the end of certain sections, there will be corresponding comprehension questions. These will help to reinforce key points we'd like you to be aware of before consenting to participate in this research study.

If you still have questions about the study after you've gone through this consent form, you'll have an opportunity to ask a study staff member questions.

Title of Research Study: IntelliCare Study
Investigator: [redacted]
Supported By: Northwestern University

Why is this research being done?
This study is being conducted by [redacted] from the Northwestern University Department of Preventive Medicine at the Feinberg School of Medicine.

The purpose for this study is to evaluate IntelliCare, a suite of apps that teach people skills they can use to manage anxiety and depression, and to understand how such services can best be provided to people like yourself.

This study will give researchers the opportunity to explore the outcomes by testing slightly different versions of the main IntelliCare app called the IntelliCare Hub. Researchers will also look at how IntelliCare works for people who use the program independently, versus people who work with an IntelliCare coach while using the apps.

Why am I being asked to take part in this research study?
You are asked to take part in this study because you are 18 years of age* or older, are interested in using and providing feedback about a mobile phone intervention for depression and anxiety, and are currently experiencing some of these symptoms yourself.
* Note: Depending on which state you reside in, the age to consent to research may be 19 years of age.

How long will the research last?

Your participation in this study will last up to 8 months.

What should I know about participating in a research study?

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

Question:
My participation in this research study is voluntary.

Is this statement true or false? (True or False)
(A) True
(B) False

What happens if I say "Yes, I want to be in this research?"

Screening Assessment
Once you go through this consent form, and if you agree to participate, you will continue on to complete an online questionnaire as part of our screening assessment (~30 minutes to complete.) Then you may be contacted to complete a telephone-based interview (~90 minutes to complete.) Both of these assessments will include questions about your recent mood and mental health history.

Based upon information gathered during these screening assessments, a determination will be made as to whether you will be invited to continue in the study.

What happens if I'm NOT eligible to participate in the study?

If it is determined that you are NOT eligible to continue in the study after the screening assessment, study staff will send you a resource guide with information about organizations that may be able to provide you with mental health treatment. You will also be compensated up to $40 for the screening assessments that you completed.

What happens if I'm eligible to participate in the study?

IntelliCare Program

If it is determined that you are eligible to continue in the study, and you choose to participate, you will receive information about how to download the IntelliCare apps onto your personal Android smartphone. At that point, you will be asked to use the IntelliCare apps over the course of 8 weeks. Each app works a little bit differently, but they all are designed to:

1. Teach you skills to manage your mood, and provide you with interactive tools so that you can practice these skills;
2. Help you anticipate stressful times and create plans to effectively cope in difficult situations; and
3. Provide you with tools that you can use in-the-moment to help you manage symptoms of anxiety and sadness.

How does the IntelliCare experience differ for each participant?

The IntelliCare experience can differ for each participant in two ways, most notably in:

1. The version of the main IntelliCare app, called the Hub and;
2. The level of support from that of a human coach.

As a participant, you will be randomly assigned to use one of two versions of the main IntelliCare app, and randomly assigned to use the apps independently, or work with an IntelliCare coach who will support you remotely in using the IntelliCare apps.

1. <u>If you are randomly assigned to use the apps independently,</u> study staff will help you download the appropriate IntelliCare apps, and then you will be asked to use the apps for a few minutes every day on your own. Using these apps regularly will help you to get the most out of the program. You will be able to contact the study team if you run into technical issues when using the apps.

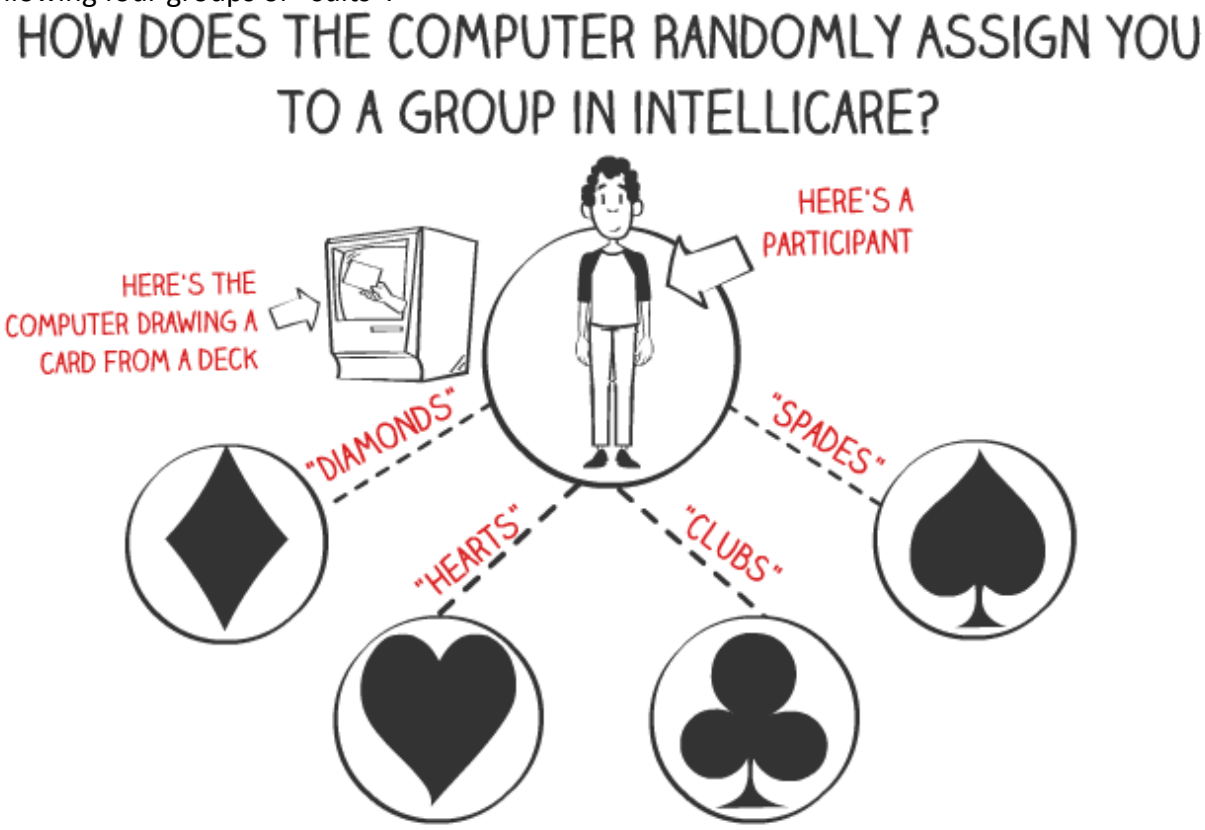
2. <u>If you are randomly assigned to work with an IntelliCare Coach</u>, your IntelliCare coach will help you decide how to use the apps and will help you learn how the skills and strategies from the apps can fit into your life. You may communicate with your coach a few times a week throughout the 8 weeks of the study, primarily via text messaging, and also via brief phone calls, as needed.

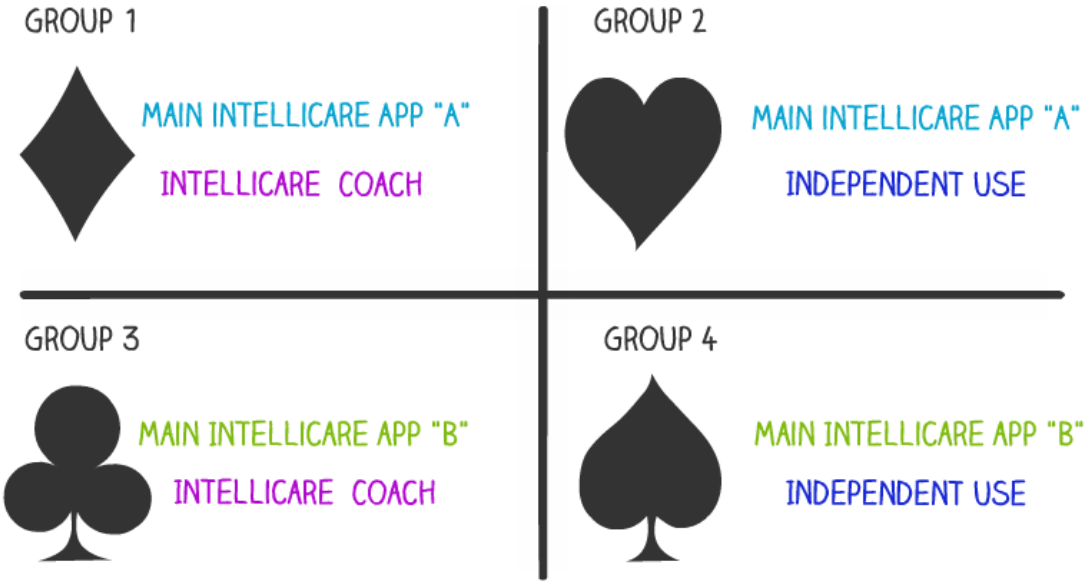
What does it mean to be "randomly assigned"?

Every participant has an equal chance of receiving one or the other version of the IntelliCare app, as well as receiving or not receiving coaching.

A computer program will randomly assign you to the version of the main IntelliCare app that you will get to use. In addition, the computer program will randomly assign half of the participants to use the IntelliCare apps independently without coaching, and the other half to interact with a human coach. Ultimately, there will be four separate group assignments.

It may be helpful to think of your assignment like picking a card with a certain suit from a deck of cards--when you pick a card, the probability of getting a card with a suit of hearts, diamonds, clubs or spades is the same. Thus, you have the same chance of being assigned to one of the following four groups or “suits”:





You will not be able to pick which group you end up in, nor will the study staff get to choose. Your group assignment is made by the computer and it is entirely up to chance. This method helps ensure the research study is fair.

Question:
How is my study group assignment determined? (Multiple choice)

(A) I get to choose which group I'd like to be in
(B) I am randomly assigned by a computer
(C) Study staff choose my group assignment
(D) None of the above choices

Will I receive payment by participating in this research?

As a study participant, you will have the opportunity to earn up to $160 in total. You will not be compensated for using the IntelliCare apps themselves, but you will receive compensation for completing the following research assessments:

By going through this consent process and fully completing the following screening questionnaire, you will receive $10.

If you are still eligible after that point, a study staff member will schedule an eligibility interview with you. Once you go through an eligibility phone interview, you'll earn $30.

If you are enrolled in the study, you will be asked to complete up to 4 additional online assessments at the following time points:

- At Week 4 and Week 8 in the IntelliCare program; and
- At 3 and 6 months after you end the study program.

You'll receive $30 for completing each assessment.

Research Study Payment Schedule

Time point	Steps	Compensation Amount
Screening Assessment: Before study enrollment	Complete consent process and follow-up questionnaire. (~Approximately 30 minutes to complete.)	**$10**
Screening Assessment: Before study enrollment	Complete phone eligibility interview. (~Approximately 90 minutes to complete.)	**$30**
Evaluation 1: Week 4, about halfway through program	Complete questionnaire online. (~Approximately 30 minutes to complete.)	**$30**
Evaluation 2: Week 8, when program ends	Complete questionnaire online. (~Approximately 30 minutes to complete.)	**$30**
Evaluation 3: 3 months after program completion	Complete questionnaire online. (~Approximately 30 minutes to complete.)	**$30**
Evaluation 4: 6 months after program completion	Complete questionnaire online. (~Approximately 30 minutes to complete.)	**$30**

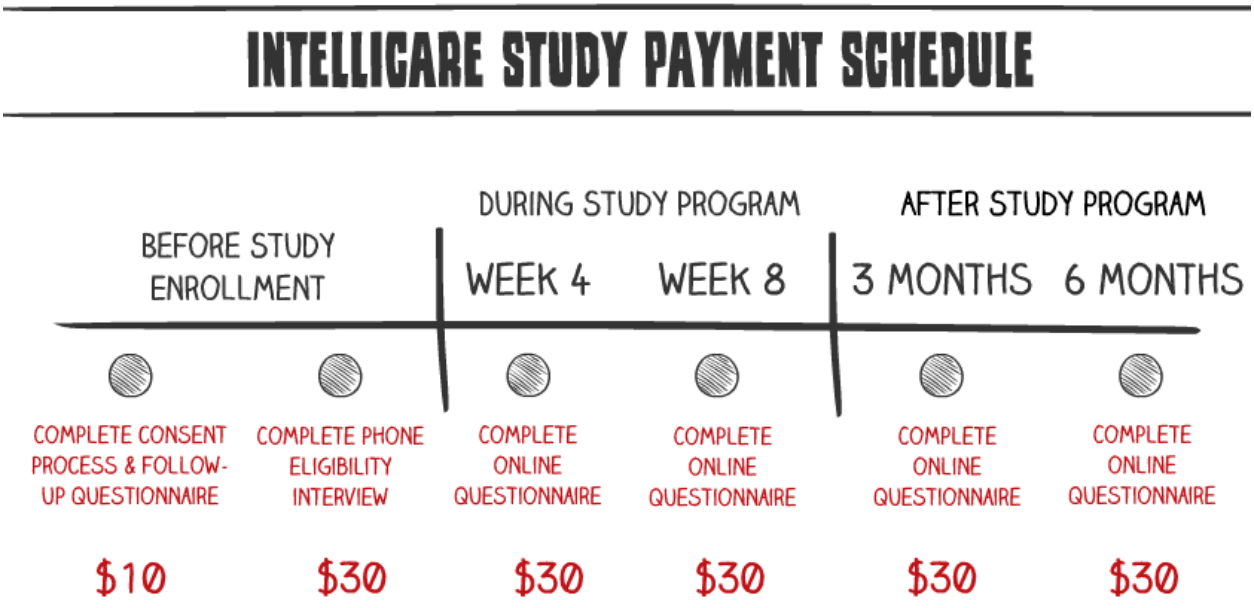
How will I be paid?

Depending on Northwestern University payment guidelines and availability at the time of your participation, payments to participants will be issued in one of the following ways:

- Amazon.com credits (click here for terms and conditions).
- By check
- Through Northwestern University Payroll (if you are Northwestern University employee)
- Through PayPal (this payment option is only available to Focus Pointe Global panelists)

The Amazon.com credits can be used for making online purchases through the Amazon.com website and there are no fees associated with this type of payment.

Hard copy checks and PayPal payments typically take 3-4 weeks to process and subsequently, for participants paid with these methods, the two $30 payments associated with evaluations at Weeks 4 and 8 will be combined into one lump sum after the Wk8 assessment is completed.



Is there any way being in this study could be bad for me?

The risks from being in this study are minimal, but it is possible that you may experience emotional discomfort or increased anxiety as a result of answering questions about your mental health or from reactions to the study materials.

If you do not wish to answer a question, you may skip it and go to the next question. You also have the option of stopping at any time.

If you do experience any emotional discomfort during a study assessment, we ask that you notify a study staff member.

If you experience an emergency, such as thoughts of harming yourself or someone else, please call 911, or 1-800-SUICIDE immediately for assistance. These services are available to you 24 hours a day, 7 days a week.

What are the benefits of my participation in this study?

Researchers hope that people will use the apps to better manage their symptoms and improve their quality of life. Potential benefits gained by your study participation include possible improvements in your mood and quality of life. You're also helping researchers better understand how to treat depression and anxiety. Moreover, even after your participation in the study is complete, you may continue to use your Intellicare apps independently, at your own discretion.

Are there any financial costs to being in this study?

There will be no costs to you for being in this study.

However, participants will be asked to download the IntelliCare apps onto their personal smartphones and may interact with a study coach via text message; therefore, study participation will require use of personal text and data plans. Participants who have a limited monthly data and/or text messaging package will be responsible for monitoring their usage per their smartphone plans and will be responsible for paying any overage fees incurred as a result of exceeding their monthly plans. The research study is not responsible for any overages and in no way endorses or expects participants to surpass their monthly plan limits.

What happens if I do not want to be in this research study?

You do not have to take part in this study, and it will not be held against you.

What other procedures or courses of treatment might be available to me?
Instead of being in this research study, you have the choice to: download the Intellicare apps from the Google Play Store without study involvement, or seek care from a therapist or physician in your community.

What happens if I say "Yes," but I change my mind later?

You can leave the research study at any time and it will not be held against you. To do so, simply inform a study staff member of your decision. We also want you to know that your discontinuation of participation in the study would not result in any penalty against you.

It's also important to note that your participation in this study may be discontinued by the investigator without your consent if we believe that your continued participation may be a danger to your health or well-being. If this occurs, we will provide you with appropriate referrals for your care. If we believe you are at imminent risk of harming yourself or someone else, we will contact emergency services to locate you and ensure the safety of you and others.

Question:
Should you choose to discontinue your study participation, when could you do so? (Multiple choice)

- **(A) At any point in time**
- **(B) Only at the end of the study**
- **(C) Only after the half-way point of the study**
- **(D) None of the above choices**

What information will be collected for the research?

Study data will include information that you provide through study assessments, interactions with study staff (via phone, email, and text message), and your app usage. Please note that study assessments and other interactions with study staff may be audio recorded, and the audio recordings will be included as study data.

What happens to the information collected for the research?

Part 1: Privacy & Confidentiality
We take your privacy very seriously. As part of our commitment to your privacy, you have been assigned a unique study ID that will follow you throughout the course of the study.

Any study data containing your name or other information that could directly identify you is kept in secure, password protected, and locked files.

Once you download the IntelliCare apps, your mobile phone will collect and transmit data on your app usage. This information is also stored in a format that contains no identifying information about you, and the information is stored on secure servers for your protection.

While we take measures to protect your confidentiality, we may be required to break confidentiality if you were to tell us something that leads us to believe that you may be a danger to yourself or to others, or share information suggesting abuse or neglect of a minor, elderly person, or disabled individual. In those instances,we may need to disclose that information to keep everyone safe. Additionally, if your records were to be subpoenaed by the court, we would be obligated to share that information.

Question:
When would the research study staff have to break confidentiality? (Multiple choice)

- **(A) If I mention information about the abuse or neglect of a minor, elderly person, or disabled individual**
- **(B) If I disclose information about being in imminent danger of harming myself or others**
- **(C) If my records were to be subpoenaed by the court**
- **(D) All of the above choices**

Part 2: Data Sharing

You have the right to decide if we can use and share information gathered about you through this research study with others. By signing this consent form, you will give us permission to share some of your information with people other than the researchers at Northwestern University who are conducting this study. Personally unidentified study data used, created, or collected in the research study and information that describes but does not directly identify you (like age, gender, race, state, or zip code) may be shared with the following people:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study.)
- Other researchers and contractors working on this study and other studies who are collaborating to further research and agree to protect the data.
- Study monitors and auditors, for example from funding agencies, who make sure that the study is conducted properly.
- Readers and reviewers of scientific journals that may publish the results of this and other studies that involve your data.

The information that we share about you with with the people mentioned above will not include direct identifiers like your name, address, or telephone number. We would, however, like to ask for your permission to share audio recordings of study phone calls with researchers at other institutions with whom we collaborate, for example to look at how voice quality might be related to mood. While we will not provide identifiers like your name or address to any research collaborators, we do want to inform you that your voice print is unique, and is therefore considered an identifying piece of information. You will be provided an opportunity at the end of this consent form to indicate if you do not want us to to share audio recordings of your interactions with other researchers for scientific study.

The consent to share your information will not expire, unless it is revoked by you.

Question:
Once I sign the consent form, the study's researchers may share information collected about me to study staff, collaborators, and others. This information will NOT include direct personal identifiers like my name, address, or telephone number. I will be given an opportunity at the end of this consent form to indicate if I do not want audio recordings of my interactions with study staff to be shared with others.

Is this statement true or false? (True or False)
(A) True
(B) False

Who can I talk to?

If you have questions, concerns, or complaints, you can call [redacted] the research project coordinator at [redacted] Monday-Friday, 9am-5pm CST. You can also call the principal investigator on this study, [redacted] at [redacted] Monday-Friday, 9am-5pm CST.

If you're interested in receiving a paper copy of this consent form, you may request one from any of the study staff members that you've been in contact with already.

You may also reach out to Northwestern University's Institutional Review Board ("IRB") who has reviewed and approved this research, at (312) 503-9333, or irb@northwestern.edu, if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Permission to use anonymous comments and feedback

_____ I provide permission for the study team to use anonymous portions of my expressed opinions and impressions of the apps. These may be used in the design of future versions of digital interventions, promotional recruitment materials, the Center for Behavioral Intervention Technologies website, research papers, and presentations. My name or identifying information will never be associated with these opinions or impressions.

_____ I DO NOT provide permission for the study team to use anonymous portions of my expressed opinions and impressions of the apps.

Opt out of share audio recordings with other researchers

_____ Please initial here only if you DO NOT provide permission for the study team to share audio recordings of your interactions with other researchers who agree to protect your data are collaborating to further research.

Consent Summary:
I have read this consent form and I understand the research study. I have been told whom to contact if I have more questions. I can request that a copy of this consent form be emailed to me for my records.
If you wish to participate, please click the "I Agree" button. If you do not wish to participate in this study, please select "I Disagree."

_____I Agree
_____I Disagree

- I'd like to speak with a study representative before signing the consent form
- I have concerns about the study
    - Privacy
    - Time commitment
    - Other, plese specify:
- Other, please specify:

Subject's Name: _____
Subject's Signature: _____
Date: _____