

## Document Coversheet

Study Title: Culturally AdapTed Harm Reduction Intervention: Community Engaged  
InterVention for Black Adults that MisusE Opioids and Stimulants

Institution/Site:	University of Kentucky
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## Consent to Participate in a Research Study

IRB Approval  
7/16/2024  
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IRB3

### KEY INFORMATION FOR Mobile Applications for Preschool Parents (MAPP) Study

We are asking you to choose whether or not to 1) volunteer for a research study about mobile apps for parents/guardians of preschool aged children, and 2) allow your children to be part of the study through you, with you using the apps at home with your family and answering questions about your children. We are asking you because your family receives services at one of the partner community organizations.

This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

#### WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how effective 2 different mobile apps are for parents/guardians of preschool aged children:

- a. an app focused on family nutrition and wellness (CHEW app)
- b. an app focused on parents reading to their children (Beanstack app, or Bookroo app as an alternative)

We will let you know which app you will use first for 8 weeks. After that, you can start to use the other app.

You will take some online surveys about you and your children when you sign up and then again after the first 8 weeks. The study team will only interact with you. We will not interact directly with your children.

Your participation in this study will last up to around 5 hours and 15 minutes over the next 5 months (20 weeks).

#### WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The family health and wellness app might help you improve nutrition, physical activity, sleep, feeding children at mealtimes, and related topics for you, your preschool child, and your family.

The reading app might help you read more to your preschool child (and other children), which is good for child learning and development.

For a complete description of benefits, refer to the Detailed Consent.

#### WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might not want to sign up for the study if you don't want to take online surveys, use mobile apps as parents/guardians of preschool children while at home with your children, or answer questions about your children's behaviors. For a complete description of risks, refer to the Detailed Consent.

The alternative is to use other available mobile apps related to family health, wellness, or reading, or to not use any apps like this.

#### DO YOU OR YOUR CHILDREN HAVE TO TAKE PART IN THE STUDY?

No. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer yourself or not to answer questions about your children.

#### WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns about this study or you want to withdraw yourself or your children from the study, contact Pamela Hull, PhD, of the University of Kentucky, Department of Behavioral Science at [pam.hull@uky.edu](mailto:pam.hull@uky.edu) or 859-562-0292.

If you have any concerns or questions about your or your child's rights as volunteers in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

## DETAILED CONSENT:

### ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will not be able to be in this study if any of these apply to you:

- you are under 18 years of age
- you are not the parent or guardian of a 2-5 year-old child,
- you don't receive services at the partner community organization
- you don't speak and read English
- you don't own an Apple/iOS or Android mobile device (phone or tablet)
- you don't have internet access for the mobile device (data plan on device or in-home WiFi)
- or you are not able to load and access the assigned mobile app on your phone or tablet when you sign up

### WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

We will host an in-person information meeting at each partner community organization for interested parents to sign up. If you cannot go to this in-person meeting, the study team can do it with you over the phone or Zoom. The rest of the study you will do at home on your mobile phone or tablet with your family.

The total amount of time you and your children will be asked to volunteer for this study is up to around 5 hours and 15 minutes over the next 5 months (20 weeks).

### WHAT WILL YOU BE ASKED TO DO?

Below is a list of what we will ask you to do in the study. All of the parents/guardians in the study at your organization will use the same app for the first 8 weeks. Then we will let you know how to download the other app to your phone or tablet if you want to use it.

Our team will randomly pick which of the two mobile apps you will use first – either the CHEW app or the Beanstack app. "Randomly" means it will be picked by chance and that you will not get to choose which app you use first. If you cannot install Beanstack on your phone or tablet, the alternative app is Bookroo.

If you use the Beanstack or Bookroo app first, we will ask you to send us screenshots of your weekly reading logs.

For the CHEW app only, we will track how you use that app. This includes: time using the app, screens viewed, responses to questions, information you enter, rewards earned, age and dietary preferences for you and family members, selected language, and IP address of your phone.

Research Activities	Estimated Time
At the information meeting when you sign up for the study: <ul style="list-style-type: none"> <li>• You will fill out the Enrollment Form and take Part 1 of the baseline online survey (about 20 minutes)</li> <li>• We will tell you which one of the two apps to use first and how to download it to your phone or tablet.</li> </ul>	1 hour and 30 minutes
Next, when you are at home, you will take Part 2 of the baseline online survey.	10 minutes
All of the parents/guardians in the study at your organization will use the same app for 8 weeks.	3 to 5 minutes per day (2 to 3 hours total)
After the first 8 weeks, you will take a follow up online survey, both Part 1 (about 20 minutes) and Part 2 (about 10 minutes), while you are at home.	30 minutes
Then we will let you know how to download the other app to your phone or tablet if you want to use it.	5 minutes
We will track your use of the CHEW app through 20 weeks after the day you signed up for the study.	None
<b>Total Time</b>	<b>up to 5 hours and 15 minutes</b>

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks of using the mobile apps and taking the online surveys for the study are minimal.

Using mobile apps and taking online surveys have a small risk of disclosure of identity. The mobile apps are for educational purposes only and are not intended as medical or professional advice.

You may choose not to answer any survey questions that make you feel uncomfortable.

In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

## WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study.

The family health and wellness app might help you improve nutrition, physical activity, sleep, feeding children at mealtimes, and related topics for you, your preschool child, and your family.

The reading app might help you read more to your preschool child (and other children), which is good for child learning and development.

The information learned in this study may help other parents/guardians make informed decisions about which mobile apps they choose to use for their families.

## IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want you or your children to take part in the study, there are other choices such as using other commercially-available apps related to family health, wellness, or reading.

## WHAT WILL IT COST YOU TO PARTICIPATE?

It will not cost you anything to be in the study. The mobile apps used in the study are free to download from Apple and Google Play app stores.

The family nutrition and wellness app does not include any optional paid or premium features.

For the reading app, we ask you to use only the free features of the app for the study, not any optional paid or premium features in the app.

## WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

- We will assign you an anonymous study ID number.
- Only people in this study can use the family nutrition and wellness app, which was created by our team. After downloading it, we will give you an Access Code to unlock and use the app, and you will enter your Study ID number into the app.

You should know that in some cases we may have to show your information to other people. For example, the law may require or permit us to share your information with authorities, such as child or adult protective services, if you report information about a child or elder being abused.

To ensure the study is conducted properly, officials of the University of Kentucky and the U.S. Department of Agriculture may look at or copy pertinent portions of records that identify you.

We will use REDCap for the online surveys. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will use a secure web-based platform called Google Analytics to track how you use the family nutrition and wellness app, using your anonymous study ID number.

We will make every effort to safeguard your and your children's data in REDCap and Google Analytics. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet. Google Analytics may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

## **CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

## **WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive up to \$100 for taking part in this study. For each payment, we will give you either physical gift cards, e-gift cards, or a re-loadable plastic debit card.

The list below breaks down the payments for completing each part of the Baseline Survey and Follow Up Survey, plus an additional reward for using the assigned app during Weeks 1-8. For this additional reward, you can earn “coins” for using the assigned app regularly during the first 8 weeks. The coins are worth \$1 each, of up to \$30 as the maximum additional reward, paid at the end of the first 8 weeks. See the Appendix for details of the tasks that earn coins for each app.

### **Study Payment Amounts:**

Baseline Survey

- Part 1: \$25
- Part 2: \$10

Use of assigned app

- Weeks 1-8: up to \$30

Follow Up Survey

- Part 1: \$25
- Part 2: \$10

**Total: up to \$100**

## **WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?**

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

## **WHAT ELSE DO YOU NEED TO KNOW?**

If you volunteer for you and your children to take part in this study, you will be one of about 1,200 parents/guardians and children in Kentucky to do so.

The U.S. Department of Agriculture is providing financial support for this study.

The information that you are providing in the study will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of this clinical study will be available on <https://www.clinicaltrials.gov/>. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## **WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?**

All identifiable information (e.g., your name, physical address, cell phone number, email address, alternative phone numbers, county, child's first name, child's date of birth, and your date of birth) will be removed from the information or samples collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information or samples may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your and

your children's de-identified information stored, it will be available indefinitely and cannot be removed due to the inability to identify it.

If you choose to, you may continue using any of the apps after the study ends. We will not track CHEW app usage data after the study ends.

## Appendix: Rewards for Using Assigned App during Weeks 1-8

### Family Health and Wellness App: Rewards (Coins) during Weeks 1-8

Feature	Task	Max Coins
Your Profile	Add a photo/ avatar for parent/guardian <i>Limit: 1 coin</i>	1
Your Profile	Add dietary preferences for parent/guardian <i>Limit: 1 coin</i>	1
Family Member Profiles	Add a photo / avatar for family members <i>Limit: 1 coin per user</i>	3
Family Member Profiles	Add dietary preferences for family members <i>Limit: 1 coin per user</i>	3
Goal Setting	Set a new goal <i>Limit: 2 coins per week</i>	8
Goal Tracking	Track a goal for 7 days in a row <i>Limit: 2 coins per week</i>	8
Wellness Resources and Tips	Explore 5 wellness resources or tips links <i>Limit: 1 coin per week</i>	8
Recipes	Save 5 recipes as favorites <i>Limit: 1 coin per week</i>	8
Recipes	Save at least 1 recipe's ingredients to a shopping list <i>Limit: 1 coin per week</i>	8
Shopping List	Create a weekly shopping list <i>Limit: 1 coin per week</i>	8
Meal Planning	Add at least 3+ meals or snacks to your meal plan <i>Limit: 1 coin per week</i>	8
<b>Monetary Reward: \$1 per coin during weeks 1-8, earning up to maximum of \$30</b>		

### Reading App: Rewards (Coins) during Weeks 1-8

Category	Task	Max Coins
Log reading to child	Send screenshot of week's reading log to MAPP team <i>Limit: 1 coin per week</i>	8
# days read	Read to child for 10 minutes or long in one day <i>Reading must be noted in log sent to MAPP team</i> <i>Each day with 10+ minutes earns 1 coin</i>	32
<b>Monetary Reward: \$1 per coin during weeks 1-8, earning up to maximum of \$30</b>		



## INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix: Rewards for Using the Apps during Weeks 1-8**

**You will sign the informed consent form electronically online. You will enter your email address so that you can receive an electronic copy of the consent form after it has been signed electronically.**

Do you agree to participate in this research study?   ☐ Yes   ☐ No

How many of your children ages 2-5 will participate in 1 the study with you?

☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6 or more

List the names of your 2-5 year old children who will participate in the study with you.

Child 1: First and Last Name \_\_\_\_\_

What is your relationship to [this child]?

- ☐ Mother (biological, adopted or step)
- ☐ Father (biological, adopted or step)
- ☐ Legal Adult Guardian
- ☐ Other relationship
- ☐ None of the Above

Child 2: First and Last Name \_\_\_\_\_

What is your relationship to [this child]?

- ☐ Mother (biological, adopted or step)
- ☐ Father (biological, adopted or step)
- ☐ Legal Adult Guardian
- ☐ Other relationship
- ☐ None of the Above

Child 3: First and Last Name \_\_\_\_\_

What is your relationship to [this child]?

- ☐ Mother (biological, adopted or step)
- ☐ Father (biological, adopted or step)
- ☐ Legal Adult Guardian
- ☐ Other relationship
- ☐ None of the Above



Child 4: First and Last Name \_\_\_\_\_

What is your relationship to [this child]?

- ☐ Mother (biological, adopted or step)
- ☐ Father (biological, adopted or step)
- ☐ Legal Adult Guardian
- ☐ Other relationship
- ☐ None of the Above

Child 5: First and Last Name \_\_\_\_\_

What is your relationship to [this child]?

- ☐ Mother (biological, adopted or step)
- ☐ Father (biological, adopted or step)
- ☐ Legal Adult Guardian
- ☐ Other relationship
- ☐ None of the Above

Additional children ages 2-5: Enter their full names and your relationship to each one.

\_\_\_\_\_

Do you agree to allow these children to participate indirectly in this research study? ☐ Yes ☐ No

Sign the consent form using your finger (on a touchscreen) or mouse.

[Sign online version only]

On the next screen, you will enter your email address so that you can receive an electronic copy of the consent form after it has been signed electronically.

Enter the name of study staff assisting with consent form: \_\_\_\_\_