Title of research study: A Multidimensional Digital Approach to Address Vaccine Hesitancy and Increase COVID-19 Vaccine Uptake among African American Young Adults in the South (Tough Talks COVID)

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Permission to Take Part in a Human Research Study

Title of research study: *A Multidimensional Digital Approach to Address Vaccine Hesitancy and Increase COVID-19 Vaccine Uptake among African American Young Adults in the South (Tough Talks COVID)*

Investigators: *Lisa Hightow-Weidman, MD MPH and Henna Budhwani, PhD MPH*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an African American young adult between the ages of 18 and 29 living in North Carolina, Georgia, or Alabama and are not fully vaccinated against COVID-19.

What should I know about a research study?

- Someone will explain this research study to you.
- 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.
- You can ask all the questions you want before you decide.

Why is this research being done?

Making a decision about the COVID vaccine can be a difficult one. The purpose of this research study is to help African American youth make a decision about taking a COVID vaccine. We are testing our mobile app to find out if it helps African American youth make a decision about taking a COVID vaccine.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 3 months.

You will be asked to use our study app to complete the intervention in one month (if randomized to that group). All participants will be asked to complete surveys at baseline, 1 and 3-month time points.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

The greatest risks include feeling uncomfortable when asked personal questions or others finding out information you report. While it is helpful to the study if you share as much information as you can, you do not have to share any information that you do not want to, and study staff will make every effort to protect your privacy.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

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Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the development a mobile app that aims to improve COVID-19 vaccine uptake amongst African American young adults and their social networks, thus reducing COVID morbidity and mortality within this population.

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

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

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Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ToughTalksCOVID@nursing.fsu.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.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 subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 360 people will be in this research study nationally.

What happens if I say "yes" to being in this research?

If you choose to be in the study, you will be asked to sign this consent form electronically before you begin. After you provide your consent, you will be asked to verify your contact information for the study staff with contacts such as your email address and phone number, as well as the phone number of a relative or friend who knows how to get in contact with you. Study staff will not leave phone messages unless you give permission. The study staff will also not tell your relative or friend anything about this study or about you being in the study or give any information about you unless you give permission. You also can choose not to give any information that you do not want to give. However, we ask that you give the study staff at least one form of communication to contact you.

If you volunteer to be in this part of the study, you will be one of about 360 people who participates in the study. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. One group will get the app and the other group will not receive the app but will get written materials. If randomized to the mobile app arm of the study, you will be asked to complete the intervention materials within one month.

After signing this consent form, you will be asked to complete the baseline survey and afterwards will be sorted into one of two groups. After one month, everyone will be asked to complete the one-month follow-up survey (30-45 minutes) which will be emailed to you. After three months, you will be emailed the three-month follow-up survey (30-45 minutes). If you do not get sorted into the app group and have not made a decision about the COVID vaccine or booster at the end of study, you may choose to accept the app and complete the intervention on your own time. After three months, you may also be asked to complete an exit interview to tell us more about your experience using the mobile app. You will also be given the opportunity to complete an optional set of questions about Monkeypox immediately following the baseline survey.

Your participation will be entirely virtual. You will sign this consent form electronically and receive communication from study staff via email or text.

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What are my responsibilities if I take part in this research?

If you take part in this research and are randomized to the mobile app arm of the study, you will be responsible to complete the intervention materials within one month.

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

You can leave the research at any time it will not be held against you. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped. If you withdraw or are withdrawn from this study, all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Is there any way being in this study could be bad for me? (Detailed Risks)

This study is focused on COVID vaccine hesitancy and uptake, including issues like medical mistrust and racial discrimination, which may be difficult or uncomfortable topic at times. There is some risk of feeling uncomfortable, embarrassed, or upset during your participation in this study. You do not have to share any information that you do not want to. You may stop at any point if you do not wish to continue with the study. It is unlikely you will be at risk of physical harm as a result of study participation.

The other risk involved in this study involves your privacy and confidentiality, as there is the potential for information about you to become known to others outside of the research team.

The information you provide will be kept confidential and stored securely. Your study ID number will only be linked to your name and contact information within the study's secure enrollment database. This database will not be linked to any of your other study records or data you provide during the study. Only approved research staff members at FSU and research staff members at RTI International can access this database using a secure server, password, and cell phone confirmation. Research staff members involved in this study are required to sign a form stating that they will protect and keep private all information on every person in the study.

You will be informed if the study staff learns of any new risks.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information. However, we cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Your confidentiality and privacy are our top priorities. All the information we collect for this research study will be stored in locked file cabinets and/or kept in secure computer files. We will also create a unique study code for the research information we collect about you so identifying information will not remain with the data and, whenever possible, will be kept separately from your name. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used.

The study team would like to message you by text messaging and/or e-mail that are not protected; however, you may say "no" to receiving these unprotected messages and you may still participate in this study. If you say "yes," messages may contain personal information about you and may be sent or

received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team. You will be asked at the end of this consent form to indicate your choice.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving un-protected communication, you will no longer receive un-encrypted (unprotected) messages specific to this study.

At the end of the study, all your information from the study will be coded and stored at Florida State University.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, FSU will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of Florida State University, research sponsors, or government agencies for purposes such as quality control or safety.

This study is collecting data from you. We would like to share your data with other researchers so that future studies may be done. Those studies may be done by researchers here or at other places. Those studies may be about health or other conditions like those in this study, or different conditions. Before we share data, your name and other information that might identify you will be removed. Also, before we share your data, other researchers must promise that any shared data will only be used for genuine research purposes. These researchers must also agree not to try to identify you.

If you later change your mind and no longer wish to have us share your data, contact the investigator. We will do our best to honor your request and to retrieve any data that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data we will not be able to retrieve the shared data. In addition, if the shared data have already been used for new research, the information from that research may still be used.

We will do our best to protect your data when the data are shared. However, even if we remove any information that may identify you, such as your name, there is a possibility that someone could or might try to identify you. There is also the possibility that unauthorized people might try to access your data. In either case, we cannot reduce the risk to zero. Also, you will not receive any direct benefit from sharing your data. However, sharing your data may be used in future research that could help others.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions, undermining the right or privacy of another participant, or because the entire study has been stopped.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institutes of Health.

If you agree to take part in this research study, you will be provided with up to $360 for your time and effort. All participants will receive $50 for completing the baseline survey, $50 for the one-month follow up survey, and $50 for the three-month follow up survey. If you receive the app and complete at least 75% of the app activities, you will receive an additional $50 completion incentive. If you complete an exit interview, you will receive $50 for your participation in the interview. All participants also have the opportunity to complete an optional set of questions about Monkeypox for an additional $10. Standard of Care participants who choose to access the Tough Talks COIVD app at the end of the study will be asked to complete a survey at 1- and 3-months after initiation and will receive $50 each for completion of those surveys.

It will not cost you anything to be in this study.

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Your signature documents your permission to take part in this research.

Signature of subject	Date

Printed name of subject