Title of research study: Development of a database to assess stroke symptoms in a stroke-affected population and non-stroke-affected population

Investigator: Dr. Michale Lakes

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 we want to collect information about people who have deficits from stroke and about people who have never had a stroke.

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?

Strokes affect many patients and can leave patients with life-long complications. We hope to develop a digital app that doctors can use to examine stroke symptoms. This may help patients get better treatment more quickly.

The researcher has partnered with a development team to develop this app.

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

We expect that it will take between 30 minutes to 1 hour to collect digital measurements. There are no planned follow up visits.

Using a secure device, similar to a cell phone or digital camera, the following information will be recorded:

- digital images of your face. This image will be converted into a digital representation of your features; the actual image will not be saved or used long term.
- measurements about your arm strength. You may be asked to hold the device at shoulder height for approximately 1 minute or just hold your arms out for 1 minute.
- your voice and speech patterns. You will also be asked to repeat some common phrases and words. This will be converted into a digital file so your actual voice will not be saved or used long term.

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?

There is a possibility that the data collection will be similar to the stroke assessments that were done when a patient was having a stroke. Both stroke survivors and non-stroke-affected individuals may experience some psychological distress if testing reminds them of having a stroke (either themselves or watching others).

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)"***

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include providing the necessary foundation to develop an application that could help future stroke survivors receive the best possible treatment.

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.

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 *Michael.Lakes@ketteringhealth.org or* 937-723-3507

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (937) 395-8401 or cheryl.rotterman@ketteringhealth.org 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 500 people will be in this research study.

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

A study team member will collect information about you using a cell-phone like device. You will be asked to perform the activities listed below:

- Stand in front of a plain background and to smile, frown, and raise your eyebrows.
- Repeat some common phrases and words.
- Hold the device in your hand and raise your arm to shoulder level. You will be asked to hold the device or arms out at shoulder level for approximately up to 1 minute.

These measurements will be taken after consent is signed. The total time for these measurements should not take longer than one hour.

If any measurement is not collected or is unable to be used, you may be contacted to have the measurements repeated at a future visit at your convenience.

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

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, contact the investigator. No future attempts to contact you will occur.

If you stop being in the research, already collected and analyzed data may not be able to be removed from the study database. If you agree, this data will be handled the same as research data.

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

- Physical risks
    - You may develop slight arm fatigue (tiredness) from holding the device or just holding your arms out.

- Psychological risks
    - Individuals may have some psychological distress if testing reminds them of having a stroke (either themselves or watching others).
- Privacy risks
    - Although data will be converted to digital de-identified files, breach of confidentiality is possible. The development team will only receive digital de-identified files. The study team will maintain a database of patient names. These will be stored on password protected servers. All attempts will be made to maintain patient privacy.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. If an app is able to be developed, the FDA may also oversee and regulate any future research.

The development team will retain digital images and data files to be used in possible future research on strokes or other similar conditions. Only de-identified data will be maintained. Although an exact time frame for data storage is not known at this time, it is likely the files will be maintained for at least 10 years.

What else do I need to know?

Your de-identified digital files may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Signature Block for Capable Adult

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

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	May 18, 2023 IRB Approval Date

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject	
Signature of legally authorized representative	Date
Printed name of legally authorized representative	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	May 18, 2023 IRB Approval Date

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.