PARTICIPANT CONSENT FORM AND INFORMATION SHEET FOR THE STROKE RISKOMETER E-HEALTH RESEARCH PROJECT (RIBURST)

Study Background
People who use the Stroke Riskometer app are invited to be part of an international study called "Stroke Riskometer E-health Research Project".

About us
We are a research team at the National Institute for Stroke and Applied Neurosciences (NISAN) based at Auckland University of Technology, Auckland, New Zealand. Our Institute conducts studies on the impact of neurological disorders including stroke and aims to find ways to prevent these disorders.

Stroke is one of the biggest causes of death and disability in the world today. It carries an enormous emotional and socioeconomic impact on patients, families, and health services. However, many strokes are preventable, and you could reduce your risk of having a stroke simply by being aware of, and controlling, certain lifestyle factors.

Invitation to participate
You are invited to take part in a research study titled “Stroke Riskometer E-health Research Project” that aims to better understand the risk factors associated with stroke and to assess how much influence each risk factor has on the likelihood of having a stroke in the future. You will only be required to complete the Stroke Riskometer now, and once in every 12 months over a 5-year study period to track the changes to your potential risk factors and monitor any changes in health outcomes.

Your participation in this research is completely voluntary. Your explicit consent to participate in this research will be indicated by your accepting the terms and conditions of the study. We will not collect any information about you if you decline participation.

What is the purpose of the study?
The purpose of this study is to investigate the relationship between an individual’s risk factors for stroke and their related health outcomes over time.

Who can participate in the study?
Everyone over the age of 20 that downloads the latest version of the Stroke Riskometer App will be asked if they wish to participate in the study.

What happens during the study?
If you agree to participate, you will be asked to enter some additional contact details after completing the Stroke Riskometer so we can contact you by e-mail and push notifications to remind you of follow up assessments.

Approximately 12 months from the date you first entered your data and once every 12 months thereafter over a 5-year period, you will be asked to complete the Stroke Riskometer questionnaire again – you will be sent a reminder prior to that time. At that stage you will be asked to complete the same questions that were completed by you in the Stroke Riskometer App in order to link your initial stroke risk with any relevant health outcomes.

How was I identified as a potential participant?
You were identified as a potential participant after downloading and using the Stroke Riskometer App.

How much time will the study tasks take?
The questionnaire will take approximately 3-5 minutes to complete.

Can I withdraw from the study?
Taking part in this study is completely voluntary and you are not under any obligation to consent to complete the questionnaire or your individual information. You can withdraw at any time after submitting your completed questionnaire. You can do this by choosing the "Withdraw from study" under the Study tab of the App. If you would like to withdraw from the study, please send the Researcher an e-mail.

What are the discomforts and risks?
There are no known discomforts or risks to you as a participant of this study. You do not have to answer any question that you feel uncomfortable with. If, for any reason, you feel discomfort, you can withdraw from the study at any time. If you require further information about the study or the questions, you will be able to contact the researcher by email. The contact details are provided at the end of this form.

What are the benefits?
The main benefit for you will be the ability to learn more about your individual stroke risk. In addition, participants in this study will be offered an opportunity to save their stroke risk profile and monitor changes in their stroke risk over time. Overall, the information gained from this research has the potential to develop the Stroke Riskometer App to more accurately identify, and enable individuals to manage, the modifiable risk factors associated with stroke and other disorders, such as heart disease, dementia and diabetes. A lay summary of the research findings and any feedback on the study will be disseminated on the website of our research institute at http://www.nisan.aut.ac.nz

Who will my information be shared with?
Although NISAN will not disclose your name and e-mail to any other party, NISAN may share elements of your personal data with approval of the Study Steering Committee, including with researchers from other academic institutions working in conjunction with researchers at NISAN. Where this happens, all appropriate technical, organisational and contractual safeguards will be in place to ensure the protection of your personal data. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

What are the costs of participating?
The App can be downloaded for free. After downloading the app there are no further costs involved. You may also wish to download premium content and features for free by sharing the link to the Stroke Riskometer app with just four other people.

Can I tell other people about the study?
Yes. This study is a part of the World Stroke Organization educational campaign. If you share the link to the Stroke Riskometer with just four other people, you will get the premium content.

Participant concerns
You may wish to consult your doctor before participating in the study or if you are concerned about your stroke risk. If you have any questions about the study, please feel free to contact the Researcher at the contact details provided below.

Researcher Contact Details:
Email: stroke.riskometer@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee 24/02/2020 - AUTEC Reference number 14/201.

PRIVACY NOTICE

We care about your privacy and want to be open with you about what we do with your personal information. This privacy notice describes how we collect, use and share personal information and explains your rights in relation to those activities. We must comply with the Privacy Act 1993 and if you are in the European Union, the General Data Protection Regulation (GDPR).

What kind of information is collected and why?
If you consent to participate in the study, all the information you entered into the app will be collected. All this electronic information will be encrypted and stored securely at the Auckland University of Technology in New Zealand and destroyed after 15 years. You will be asked to provide alternative contact details (such as the e-mail address of a close family member) in case we do not receive a response from you at the 12-month follow-up. However, you are under no obligation to provide an alternative contact. Not providing an alternative contact does not affect your participation in the study.

How is my privacy and my personal data protected?
We take the protection of your personal data very seriously and protect any personal data accordingly. Your data will be kept in a secure database located on the premises of AUT in New Zealand; a country which the European Union Commission has deemed as having an adequate level of data protection. All communication between the Stroke Riskometer App and the data collection services will be encrypted. The data will be preserved by technical, physical and administrative measures from loss, unauthorised disclosure or change.

Who will my information be shared with?
Although NISAN will not disclose your name and e-mail to any other party, NISAN may share elements of your personal data with approval of the Study Steering Committee, including with researchers from other academic institutions working in conjunction with researchers at NISAN. Where this happens, all appropriate technical, organisational and contractual safeguards will be in place to ensure the protection of your personal data. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

How long will my information be kept?
The data will be stored securely and destroyed after 15 years.

What are my rights?
The right to be informed
We have published this information sheet to keep you informed as to what we do with your personal information. We strive to be transparent about how we use your personal information.

The right to access
You have the right to access your information and to check that we are lawfully processing it. Please email the Researcher if you want to access the personal information we hold about you.

The right to correction
If the information we hold about you is inaccurate or not complete, you have the right to ask us to rectify it. You can correct your information by emailing the Researcher.

The right to deletion
This is sometimes called ‘the right to be forgotten’. If you want us to delete all your personal information, please email the Researcher.

The right to restrict processing
You have the right to ask us to restrict how we process your personal information. This means we are permitted to store the data but not further process it. If you want us to restrict processing of your information, please email the Researcher.

The right to data portability
We will allow you to obtain and reuse your personal information for your own purposes across services in a safe and secure way. Please email the Researcher if you wish to export your information.

The right to object
You have the right to object to how we process your personal information. If you wish to object, please email the Researcher.

The right to withdraw consent
You have the right to withdraw your consent to participate in the study at any time. If you choose to withdraw your consent, the research performed on your data before withdrawal will not be affected. If you want to withdraw your consent, please email the Researcher.

The right to complain to a Supervisory Authority including the New Zealand Privacy Commissioner
You have the right to complain to the Auckland University of Technology Ethics Committee (AUTEC) Executive Secretary. If you are a New Zealand study participant, then you also have the right to complain to the New Zealand Privacy Commissioner if you feel that we have not responded to your requests to solve a problem.

How can you lodge a complaint?
There a few ways to lodge a complaint:

- With us directly: National Institute for Stroke and Applied Neurosciences at 90 Akoranga Drive, Northcote, 0627 Auckland, New Zealand (Private Bag 92006, Auckland 1142)
  E-mail: stroke.riskometer@aut.ac.nz
- With the Auckland University of Technology Ethics Committee (AUTEC). Information about how to lodge a complaint is available on the AUTEC website.
- With the New Zealand Office of the Privacy Commissioner (only for New Zealand study participants).
  Information about how to lodge a complaint is available on the Privacy Commissioner's website.

CONSENT FORM

I consent to participate in the research project titled “Stroke Riskometer E-health Research Project”, using the Stroke Riskometer App.

In giving my consent I acknowledge that I am 20 years or older and that:

1. I have read the Participant Information Sheet and understand what this research involves for me.

2. I have read the Participant Privacy Notice and understand how my personal information will be handled.

3. I understand that my involvement is strictly confidential. I understand that any research data gathered from the results of the study may be published however no information about me will be used in any way that is identifiable. Therefore, I consent to you collecting, through the Stroke Riskometer app, information regarding my health, and contacting me for follow-ups and future health-related studies.

4. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

5. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) now or in the future.

6. I have been given the opportunity to discuss the information and my involvement in the project with the researcher/s using the contact information provided in this form.

7. I will be asked to provide alternative contact details, but I am under no obligation to do so, and that not providing an alternative contact does not affect my participation in the study. I understand that I may be contacted via e-mail to see if I am interested in any future follow-up studies, and that I am under no obligation to participate in these.