RESEARCH SUBJECT CONSENT FORM

TITLE:	Multi-Centre, Prospective, Consecutive, Paired Diagnosis, Diagnostic Performance Study of the EMVision emu™ Brain Scanner in the Detection of Intracranial Haemorrhage in Suspected Stroke Patients
PROTOCOL NO.:	EMV-CIP-03 WCG IRB Protocol #20250375
SPONSOR:	EMVision Medical Devices Ltd
INVESTIGATOR:	Name Address City, State, Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

In this consent form "you" generally refers to the research subject. If you are being asked as the legally authorized representative to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

How long will I be in this research?
We expect that your taking part in this research will last the length of your current hospital stay, but no longer than 28 days.

Why is this research being done?
The purpose of this research is to determine the accuracy of the EMVision emu Brain Scanner in the detection of hemorrhagic stroke (bleeding in the brain).

What happens to me if I agree to take part in this research?
The first thing that will happen is the doctor will read your medical history and examine you to see if the scanner would be a good fit for your head size. If the doctor believes that you meet the criteria, study assessments will be performed and you can then be scanned by the EMVision emu Brain Scanner.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include:

The risks involved in this study are expected to be minimal and may include discomfort from wearing the device. There are no known health risks from the exposure of ultra-high frequency radio signals of this type, particularly for the short exposure time that you will experience in this study. The scan procedure using the EMVision emu Brain Scanner is non-invasive and uses non-ionizing radiation to perform the scan.

Participation in this study would expose you to signal power intensities of no more than 10 mW. It is important to remember that mobile phones transmit between 600 mW to 2W of power so this is significantly less signal power (about 10%) than a mobile phone.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research. Information learned from this study may help other people in the future.

What other choices do I have besides taking part in this research?
You do not have to take part in this study to receive treatment at this hospital. The hospital will treat your condition per their standard of care whether or not you participate in this study.

What else should I know about this research?
While you are participating in this study, medical care will be exactly the same as if you were not in the study. This study does not involve treatment or diagnosis and will not interfere with your treatment or diagnosis during your hospitalization in any way.

Your information collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Why is this research being done?

The purpose of this research is to evaluate a new investigational device for the diagnosis of stroke, the EMVision emu Brain Scanner. Stroke is the result of a blood clot stopping the normal flow of blood in the brain (ischaemic stroke) or a breakage in a blood vessel causing bleeding in the brain (haemorrhagic stroke). Stroke is a medical emergency and must be quickly diagnosed and treated. Computed tomography (CT) or magnetic resonance imaging (MRI) scans are commonly used to diagnose stroke, but they are not always available.

The company EMVision has developed the emu Brain Scanner, a helmet-like device which scans the head using ultra-high frequency radio signals. It is portable and easy to use, making it more accessible than CT or MRI machines. It is hoped that easier access to the EMVision emu Brain Scanner will reduce the time taken to diagnose stroke, leading to faster treatment and better health outcomes.

The EMVision emu Brain Scanner is a new investigational device and its accuracy in detecting haemorrhagic stroke is currently unknown. A diagnostic device must be carefully studied to determine its accuracy before it is used broadly in hospitals, so that doctors know how likely it is that the diagnosis is correct. It is the purpose of this study to determine the accuracy of the EMVision emu Brain Scanner in the detection of haemorrhagic stroke.

Medical devices must be approved for use by the Food and Drug Administration (FDA). The EMVision emu Brain Scanner is an experimental device. This means that it is not an approved device to diagnose stroke in the USA.

This study is being conducted by EMVision Medical Devices Limited.

About 300 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last the length of your current hospital stay, but no longer than 28 days.

What happens to me if I agree to take part in this research?

If you decide to participate in this study, you will be asked to sign this consent form and will be enrolled in the study.

The hospital may have already taken a scan of your brain using CT as part of the hospital's process to diagnose your condition. Following the CT scan, the hospital will have a confirmed diagnosis of your condition.

Your study doctor will make sure you qualify to participate in the study. The first thing that will happen is the doctor will read your medical history and examine you to see if the scanner would be a good fit for your head size. If the doctor believes that you meet the criteria, study assessments will be performed and you can then be scanned by the EMVision emu Brain Scanner.

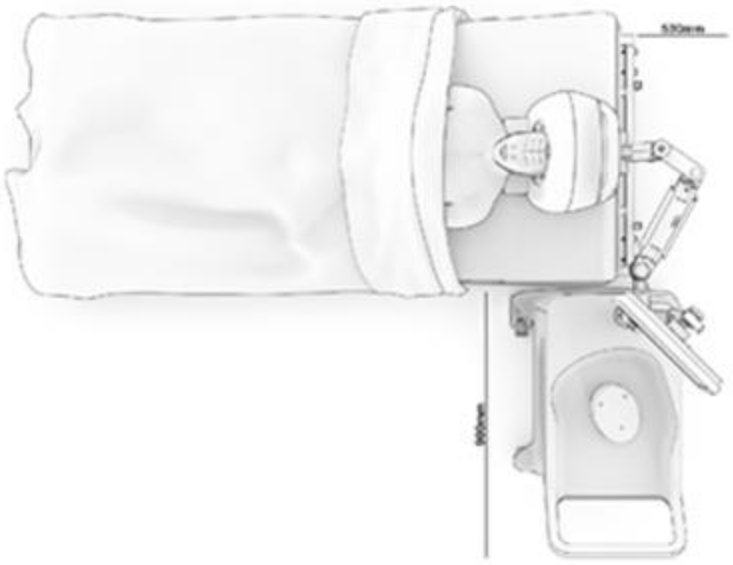
In cases where a signed consent is not possible due to a potential patient's condition or no legally authorized representative (LAR) is available, any data collected (anonymous) will not be entered to the study until you or your LAR are able to decide if you would like to participate and give consent (consent may be obtained up to 72 hours after arrival to the treating hospital).

EMVision emu Brain Scan Procedure

As soon as practical and medically appropriate, the EMVision emu Brain Scanner will be used to scan your head - not more than 30 minutes before or after your CT scan but before you undergo any treatment.

The operator will try to make sure that you are comfortable and at ease throughout the whole procedure.

The following picture shows how the EMVision emu Brain Scanner is set up. You will be lying down comfortably and the machine will be wheeled to the bedside. A sticker will be put on your forehead which will be used by the operator to help position the EMVision Brain Scanner when it is on your head. Then a disposable cap will be placed on your head. The back of your neck will be comfortably supported and the scanner headset will be placed on your head from next to the bed.



Once the headset is on your head, a fluid filled bladder will be inflated slowly so that it fits snugly against your head. The bladder is made of silicon and will feel cool against your skin. Once snug, the scan will take place. The entire set up and scanning process including fitting of the headset will take less than 15 minutes.

If you want to stop at any time, you can tell the person operating the scanner and they will remove the headset from your head and take the scanner away from the bedside.

All the study visits and procedures would be completed in the hospital during your current admission. There are no additional visits to the hospital required as part of this study. You will not be required to undress or perform any other physical activities.

The scan information from the EMVision emu Brain Scanner is saved as digital files and sent to the research team for analysis. No identifying information will be included with the data sent to the research team. The scan information from the EMVision emu Brain Scanner will be compared with your CT/MRI images by the research team.

There are no additional costs associated with participating in this study, nor will there be any payment to participate. The procedures in this study will take place while you are being treated at the hospital.

There are no additional restrictions involved when participating in this study.

EMVision emu™ Brain Scanner is investigational, which means that it is not approved by the Food and Drug Administration (FDA).

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

If you decide to participate in this study, your involvement is to have the scan procedure with the EMVision emu Brain Scanner, if your study doctor thinks you are clinically well enough to do so.

It is important that you inform the hospital staff and your study doctor/researchers if you do not want an EMVision emu Brain Scanner scan or if you experience any adverse effects from having a scan.

Could being in this research hurt me?

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

[START]

Your doctor will be looking out for side effects.

The risks involved in this study are expected to be minimal and may include discomfort from wearing the device. There are no known health risks from the exposure of ultra-high frequency radio signals of this type, particularly for the short exposure time that you will experience in this study. The scan procedure using the EMVision emu Brain Scanner is non-invasive and uses non-ionizing radiation to perform the scan.

Participation in this study would expose you to signal power intensities of no more than 10 mW. It is important to remember that mobile phones transmit between 600 mW to 2W of power so this is significantly less signal power (about 10%) than a mobile phone.

There may be risks that are unknown at this time.

The effects of the EMVision Brain Scanner on the unborn child and on the newborn baby are not known. Because of this, it is important that you are not pregnant or breast-feeding while you are participating in this study.

[END]

A specialist will look at the hospital's standard of care scans (CT/MRI) for features relevant to the study. On rare occasions, the specialist may find an unusual feature that could have significant risk to your health. If this happens, it will be discussed with you and appropriate action taken if required. We cannot guarantee that we will find any/all unusual features. In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

You will not be charged for the research involved in this study. Routine medical care to treat your condition (care you would have received whether or not you were in the study) will be part of your hospital bill. Your or your insurance company will be billed for the cost of usual medical care procedures and tests for patients with your disease or condition. This includes the CT scans

or MRIs, your hospital stay, any medication you are given, care before and after your procedure, and the costs associated with your procedure. If you have any questions about what your costs will be, ask the study doctor.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for costs for care you receive as part of a research study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. The Hospital and the sponsor will not pay for these costs. You may want to ask your insurance company about what costs they will pay for.

Will being in this research benefit me?

There are no expected benefits to the patient from participation in this study. Information gained from this study may be of benefit to other persons with the same medical condition.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Other researchers and centers that are a part of this study.
- The Institutional Review Board (IRB)
- Government agencies that regulate the research including: Office for Human Research Protections (OHRP); Food and Drug Administration (FDA); Veterans Administration (VA).
- Public health agencies.
- Research monitors and reviewer.
- Accreditation agencies.
- Imaging lab reviewing study imaging

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

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed in this document.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- The research is canceled by the FDA or the sponsor

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

What happens if I agree to be in this research, but I change my mind later?

If you decide to withdraw from this study, please notify the study doctor or a member of the hospital study staff before withdrawal.

If you do withdraw consent during the study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected by the Sponsor (EMVision) up to the time you withdraw will form part of the study results. If you do not want them to do this, you should not join the study.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

Statement of Consent:

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

Signature of subject capable of consent	Date
Signature of person obtaining consent	Date

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted
- If assent is obtained, have the person obtaining assent document assent on the consent form

Signature of subject's legally authorized representative	Date

I confirm I have explained the study to the extent compatible with the subject's capability, and the subject has either agreed to be in the study, or is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining consent/assent	Date

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.
- Medical imaging associated with your treatment and care

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB).
- The sponsor conducting this study and their business partners
- Auditor that may inspect the study from the sponsor or business partners

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject	**Date**
Signature of subject/legally authorized representative	**Date**