Application to Participate in a Medical Research Project:

2.0 MR-EYE
Towards a consensual Magnetic resonance Imaging protocol of the Human Eye

Dear Madam, Dear Sir,

We invite you to participate in our research project.

Your participation is entirely voluntary. All data collected in this project adhere to strict data protection standards.

The research project is led by Prof. Benedetta Franceschiello (HES-SO Valais-Wallis) and in collaboration with Prof. Dr. Med. Hendrik von Tengg-Kobligk, from the (Inselspital). The overall responsibility for this project lies with HES-SO Valais-Wallis (project sponsor). Should you be interested, we will provide you with the results.

During an interview, we will explain the main aspects and answer your questions. To give you an early insight into the project, here are the key points to consider. Further detailed information is provided below.

Why are we conducting this research project?

- MRI allows the properties of tissues to be measured while performing a task or at rest. However, the interpretation of MRI images is sometimes hampered by patient movement, especially related to organs that move involuntarily, such as the eyes.
- Our research project aims to develop a technique for acquiring images of the eyes without motion errors from MRI images.

What should I do if I agree to participate? – What will my involvement entail?

- Form of participation: If you agree to participate in our project, you will need to undergo an MRI scan at the CHUV imaging center or at the Translational Imaging Center Bern (Sitem) at Inselspital.

What are the benefits and risks associated with participating in the project?

Benefits

- Your participation in this research project will not bring you any direct benefits.
- By participating, you are contributing to helping future patients.

Risks and constraints

- The study is subject to strict data protection rules.

By signing at the end of the document, you confirm your understanding of its contents and willingly consent to be part of the project.

Detailed information

1. Objective of the project and selection of participants

In this information sheet, our research project is also simply referred to as *'the project'*. If you agree to participate, you will be referred to as a participant in the project.

This project aims to develop a technique for correcting eye movements in functional anatomical MRI images. We are reaching out to you because participation is open to all healthy volunteers. To participate, you must be between 18 and 45 years old, in good health without any current relevant somatic or psychiatric illnesses under treatment. You should not have any contraindications for magnetic resonance imaging (MRI), such as claustrophobia, metal implants or pacemakers, epilepsy, or pregnancy.

2. Project's general information

MRI is a non-invasive technique that enables to record the brain anatomy and neuronal activity while participants perform tasks or are at rest. However, MRI is susceptible to image errors caused by motion, which becomes particularly challenging in organs such as the eyes. Resembling the blurring effect in photographs resulting from subject motion, MRI cannot reliably measure brain anatomy or activity if the participant moves their eyes during scanning. In this project, we are developing a new technique, 2.0 MR-Eye, in healthy adult volunteers, within the goal of providing a method to correct these motion-related errors in moving organ imaging. Successfully correcting motion artifacts represents a groundbreaking advancement in this field.

If you participate in this project, you will undergo an anatomical and/or functional MRI, which will aid in the development of this motion correction technique.

This is a project conducted at CHUV and Inselspital, under the direction of an investigator from HES-SO Valais-Wallis. The project will last approximately 5 years, but participant recruitment will take place over about 12 months. Data acquisitions will be performed over a period of 4 years, and data analyses will start from the 18th month after the beginning of the study and continue until its end (5th year).
We intend to recruit 175 adult participants.

This project is conducted in compliance with Swiss legislation. We also adhere to all internationally recognized guidelines. The competent ethics committee has reviewed and approved this project.

3. Project procedure

If you participate in the project, you will be invited to undergo an MRI scan at the CHUV radiology department (Center for Biomedical Imaging) or at the Translational Imaging Center Bern (Sitem) at Inselspital. The members of the research team will explain the examination procedure and the safety measures to be taken (do not wear any metallic items). You will first fill out a safety questionnaire regarding the MRI (standard procedure).

You will then be placed in the MRI machine. Specifically, for the examination, you will lie on the machine's bed, and the antenna that acquires the MRI data will be placed above your head. During the scan, a distinct colored dot will be projected into your field of vision, representing a non-invasive visual stimulus. This dot may move within your visual field or remain static. Additionally, the interior of the dot may change contrast using a flashing display panel.

Your eye movements will be recorded using a camera (Eye Tracker).
In total, the expected duration is 1 hour, including setup and MRI image acquisition.

Your participation in the project may end prematurely if the MRI scan cannot be successfully completed.

4. Benefits

Your participation in the project will not bring you any direct benefit. However, the project results could lead to the development of a new technique for correcting motion during MRI scans, which could benefit future patients.

5. Voluntary participation and obligations

Your participation is entirely voluntary. If you choose not to participate or if you decide to participate and later change your mind during the project, you do not need to provide justification.

If you choose to participate in this research project, you will be required to:

- follow the instructions and fulfill the requirements outlined in the research protocol.
- inform the project leader of your current health status, which may potentially contraindicate your participation.

6. Risks and constraints

There is no apparent risk associated with participating in the study. MRI is a safe and non-invasive examination. However, due to physiological changes related to pregnancy that can alter visual perception, pregnant women will be excluded. This means that a woman cannot participate in the study if she is pregnant or if there is a possibility that she might be pregnant, and for this reason, pregnancy tests will be provided to participants before the study.

7. Alternatives

If you do not wish to participate in this research project but remain open to the possibility of participating in other projects, please inform the investigators.

8. Results

The project yields various results:

- Individual results that directly concern you, individual results discovered incidentally (known as incidental findings).
- The final objective results of the project as a whole. Following the project's completion, the project leader can send you a summary of the overarching results, should you wish to receive it.

1. The physician-investigator will inform you during the project of any significant new discovery concerning you. You will be informed verbally and in writing; thereafter, you can decide again whether you wish to continue your participation in the project.

2. Incidental findings are considered "concomitant results," meaning results that were not explicitly sought but were obtained by chance. This is particularly the case with MRI scans. You will be informed of incidental findings if they have an impact on your health. This means that such findings will be communicated to you if a previously unknown condition is accidentally discovered, or if preventive measures can be taken to prevent the onset of a disease. However, there will be no systematic review of the scans by a

radiologist: the technician or the principal investigator conducting the scan will consult a physician if there is any doubt.

3. The physician-investigator can send you a summary of the overall results at the end of the project.

9. Confidentiality of data and samples

9.1. Data processing and coding

As part of this research project, data regarding you and your health are collected and processed, partly in an automated manner. These details are coded at the point of collection. Coding means that all identifying information (name, date of birth, etc.) is replaced with a code. It is not possible to link the data back to you without this code, which will be always kept securely within the hospital.
Only a limited number of individuals may access your uncoded data, exclusively to perform necessary project-related tasks. These individuals are bound by confidentiality agreements. As a participant, you have the right to access your data at any time.

9.2. Data protection

We rigorously adhere to data protection directives. It is possible that your data may need to be transmitted in coded form, for example for publication purposes, and made available to other researchers. When health data or biological samples are stored on site, they form a research database.
As the project involves collaboration between three Swiss institutions (HES-SO Valais-Wallis, CHUV and Inselspital), a data transfer agreement is established, allowing imaging data to be shared in coded form as part of this project.

9.3. Data protection in the event of re-use

Scientific journals and funding organizations may request the sharing of the data underlying publications on a dedicated site ('Open Data'). This data-sharing approach allows for the validation of published results (reproducibility), the aggregation of data from different studies, and more generally, the use of the data by other researchers. In the case of such sharing, your data will always be de-identified so that it is not possible to trace it back to your identity. If you withdraw your consent to participate in this project, the data already shared cannot be removed. You must agree to this if you participate in the study.

9.4. Right to access during inspections

The project may be subject to inspections, which may be conducted by the competent ethics committee. The project leader must then disclose your data as required for these inspections. All individuals involved are bound by strict confidentiality.

10. Withdrawal from the project

You are free to withdraw from the project at any time. However, the medical and MRI data collected up to that point may still be analyzed in coded form.
Upon withdrawal, your data will remain coded in the project documents primarily to maintain the scientific integrity of the project. Therefore, you must agree to this before giving your consent.

11. Compensation

You will receive a compensation of 25.- CHF for your participation in this one-hour research project. Reimbursement of transportation expenses is also available upon request. Your participation will have no financial implications for you or your health insurance.

12. Responsibility
HES-SO, which initiated and is responsible for conducting the research project, is liable for any damages you may incur in connection with the project. The terms and procedures are defined by law.

13. Funding
The project is primarily funded by a research fund (Swiss National Science Foundation).

14. Contact
You are welcome to inquire about the project at any time. Should you have any uncertainties during or after the project, please feel free to reach out to:

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Site Sitem Inselspital
Prof. Dr. Med. Hendrik, von Tengg-Kobligk
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Consent Declaration

Written Consent Declaration for Participation in a Research Project
Please read this form carefully. Feel free to ask questions if there is anything you do not understand or if you need clarification. Your written consent is required to participate in the project.

BASEC project number (after submission to the competent ethics committee):	2024-00165
Title **(scientific and common):**	2.0 MR-EYE Towards a consensual Magnetic resonance Imaging protocol of the Human Eye
Institution in charge **(project leader and complete address):**	Prof. Benedetta Franceschiello School of Engineering Institute of Systems Engineering HES-SO Valais-Wallis Route de l'Industrie 23 1950 Sion
Location of implementation:	CHUV and Inselspital
Responsable du projet sur le site CHUV: Nom et prénom en caractères d'imprimerie :	Prof. Benedetta Franceschiello
Project Leader at the site Sitem Inselspital: Last name and first name in printed script:	Prof. Dr. Med. Hendrik, von Tengg-Kobligk
Participant: Last name and first name in printed script: Date of birth:	

- I declare that I have been informed, both verbally and in writing, by the undersigned project leader, about the objectives and procedures of the research project, as well as the potential benefits, drawbacks, and possible risks.
- I participate in this project voluntarily and accept the contents of the information sheet provided to me regarding the aforementioned project. I have had sufficient time to make my decision.
- I have received answers to the questions I posed regarding participation in this project. I will keep the information sheet and receive a copy of my consent statement.
- I agree that competent specialists from the project management and the relevant ethics committee may access my uncoded data for the purpose of conducting checks and inspections, provided that the confidentiality of this data is strictly maintained.
- I will be informed of the results and of any incidental findings that directly affect my health.
- I am aware that my personal data and health information may be transmitted for research purposes within the scope of this project, solely in coded form. The sponsor ensures data protection compliant with Swiss standards and requirements.
- I can withdraw my consent to participate in the project at any time and without having to provide justification. This decision will not have any negative consequences on my ongoing

care. However, data collected up to the withdrawal will still be analyzed as part of the project.

- I am informed that HES-SO is responsible for any potential damages attributable to the project.
- I am aware that the obligations mentioned in the information sheet for participants must be adhered to throughout the duration of the project. The investigating physician may exclude me from the project at any time in the interest of my health.

Place, date	Signature of the participant

Certification by the Investigator: I hereby attest that I have explained to the participant the nature, importance, and scope of the project. I declare that I fulfill all obligations related to this project in accordance with current Swiss law. Should I become aware of any information during the project that may affect the participant's consent to participate, I undertake to inform them immediately.

Place, date	Investigator's last name and first name in printed script Signature of the investigator

Written Consent Declaration for the Dissemination of Data to Public Databases and the Reuse of Data in Coded Form

BASEC project number (after submission to the competent ethics committee):	2024-00165
Title **(scientific and common):**	2.0 MR-EYE Towards a consensual Magnetic resonance Imaging protocol of the Human Eye
Participant: **Last name and first name in printed script:** **Date of birth:**	

I agree that my data obtained as part of this project may be disseminated on public databases in coded form and reused for medical research purposes in coded form. This means that the data will be stored in a public database and subsequently used for an indefinite period within the framework of future research projects.

I am aware that my data is stored in coded form and that the identification list is kept in a secure place. The data may be published and sent for analysis to another database located in Switzerland or abroad, provided that it adheres to standards and requirements at least equivalent to Swiss standards and requirements. All legal provisions regarding data protection are respected.

I give my consent voluntarily and can withdraw my decision at any time before participating in the study. I do not need to justify my decision.

Generally, the data is used in an aggregated manner, and the results are published in a summarized form. I may be contacted if the data analysis reveals a finding relevant to my health.

I agree that my data will be de-identified for reuse in another research project, and I understand that I will not be able to withdraw my consent later.

I waive all commercial exploitation rights over my data.

Place, date	Signature of the participant

Certification by the Investigator: I hereby attest that I have explained to the participant the nature, importance, and scope of the publication and reuse of the imaging data.

Place, date	Investigator's last name and first name in printed script Signature of the investigator