**PARTICIPANT INFORMATION AND INFORMED CONSENT DOCUMENT**

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| Trial Title: | Clinical validation of a novel, low-cost Spectral Artificial Visual Examination (SAVE) colposcope as a tool for the invasive, in situ dual screening of female genital schistosomiasis (FGS) and cervical cancer. |
| Trial Number: | DUALSAVE 001 |
| Name of Sponsor: | Oslo University Hospital, Norway |
| UKZN BREC Approval Date: | [Insert] |
| Study Doctor: | Dr Fezeka Gloria Wulana |
| Institution Name: | General Justice Gizenga Mpanza Regional Hospital |
| Site Address: | Department of Obstetrics and Gynaecology |
| 24-Hour Contact Number: | [Insert] |
| Participant Identifier / number: | [Insert] |
| Date: | [Insert] |

Good day,

My name is <Insert>. I work with scientists and research doctors from BRIGHT Academy and University of KwaZulu-Natal and others in the DUALSAVE-FGS project.

We are doing research on screening for two diseases:

1. Women’s schistosomiasis known as Bilharzia or FGS (Female Genital Schistosomiasis)
2. Cervical cancer

We are conducting research to find a diagnostic method that can differentiate between Bilharzia and cervical cancer in private parts of women. We want to find out if the method we are using is useful, practical, and comfortable. You are being invited to participate in a research study that involves an examination tool for this.

# WHY YOU ARE BEING ASKED TO PARTICIPATE?

We know that Bilharzia worms cause urinary problems, but we have also found that women get genital damages from Bilharzia. Previous research has shown that genital Bilharzia can be mistaken for a sexually transmitted disease or cancer. However, genital Bilharzia is only caused by touching infested water, which is found in this district. Every woman living near infested water bodies should be tested.

We ask you

* + because you may have had contact with the Bilharzia parasite in the water sometime in your life
  + because health professionals should be able to distinguish between the diseases and give correct treatment in the future
  + because we would like to invite you to be part of the following study.

# PROCESS AND EXPECTATIONS

Participating in this study means that:

* + You give voluntary permission to take part in the study by signing the informed consent form
  + You are invited here today for clinical investigation, including a gynaecological exam.
  + You will provide specimens for lab assessment.
  + Digital images will be taken using standard and new equipment.
  + If you allow, your samples will be tested for cervical cancer, Bilharzia infections, sexually transmitted infections (STI´s) and HIV after signing the HIV Informed Consent.
  + If there is reason to do other tests you will be asked for permission.
  + If you wish, you will receive treatment for Bilharzia, worms, or other diseases as recommended by the local health system.
  + If we discover special problems during the interview or the investigation, we will refer you for treatment with your permission.

# GYNAECOLOGICAL EXAMINATION

If you consent to be part of the study, a normal gynaecological investigation to look for genital Bilharzia and any other genital problems will be conducted today. The procedure may be uncomfortable especially if you are tense or nervous. It is best that you try to be relaxed. The examination will be done by a qualified nurse or doctor with an assistant present in the room who will ensure the investigation is carried out correctly. You will also have a female chaperone with you, who is fluent in your language. A normal gynaecological investigation means that the nurse or doctor will inspect both outside and inside of your private parts.

# QUESTIONNAIRE INTERVIEW

With your permission, you will be asked some questions about your health and medical history. If you are willing, you may be invited to a longer interview at a later date.

# STUDY VISIT (only today)

You will be asked to give written informed consent prior to any activity. If you agree, the following procedures will be performed:

* The trial staff will collect information such as age.
* The trial staff will perform a body weight assessment.
* The trial staff will ask about medical history, if you are currently taking any medication, if you have had some operations, or if you have allergies to any medication.
* An Adverse Events Assessment will be performed.
* If you are invited to the trial and agree, the following will be performed:
  + A normal gynaecological investigation.
  + During the examination, a new type of equipment will be used, the SAVE colposcope. This involves taking gynaecologic images that will be checked by a group of experts WITHOUT YOUR NAME. It will not be possible to recognize who the image belongs to.
  + Tests will be done to check gynaecological Bilharzia and sexually transmitted diseases (STIs). A cytology sample will be taken to screen for cervical cancer (a more advanced version of the pap-smear).
  + During the examination a cotton swab with acetic acid will be applied on the cervix, this is normal procedure for cancer screening.
  + A sample of your blood (a small amount, approximately 3 teaspoons) will be drawn for laboratory analyses.

Table 1: List of Procedures

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| Informed consent (this paper) |
| Recording of age |
| Short medical history |
| Inclusion/exclusion criteria |
| Normal gynae examination using standard equipment, including diagnostic images |
| Examination with new equipment (the SAVE colposcope), including diagnostic images |
| Cytology (similar to pap-smear) and cervical specimen swabs |
| Blood (for laboratory assessments) |
| HIV pre-test counselling, HIV rapid test, HIV post counselling |
| Adverse events and adverse device effects assessment |
| Dispensing of medication, if relevant. Referral, if relevant. |

# THE DURATION OF THE TRIAL

If you decide to participate in the trial, you will finish today but if you wish, we will contact you to give you results.

# RISKS

The risks and discomforts from procedures related to this research are minimal. Some may feel embarrassed and uncomfortable during the gynaecological investigation. The new equipment (the SAVE colposcope) does not require inserting through the skin or the body opening, therefore there is no risk directly related to the equipment. If you receive treatment for any infection we discover, these might have some side effects. Praziquantel (the tablets to treat Bilharzia) might give side effects such as feeling sick for a couple of days. Some people may get a rash, diarrhoea or vomit.

# BENEFITS

You will receive free referral to the ordinary health care system for any disease we discover. If you have signs of disease, you will be treated or referred to an expert. The extra trial procedures will not change the care you receive. In the future other women may benefit from the new knowledge coming from the trial.

# YOUR RIGHTS AS A PARTICIPANT IN THIS TRIAL

Your participation in this trial is entirely voluntary and you can refuse to participate, or you can stop at any time without giving any reason. Your refusal to participate or your withdrawal from this clinical trial will not affect your access to other medical care or remove your benefits.

The trial doctor may withdraw you from the trial if the doctor thinks it is best. If this happens, reasons will be provided to you, if you wish to know. Also, if we find out that you did not give accurate information, you may be withdrawn from the trial. This will not affect your access to other medical care.

# ORGANIZATIONAL AND TECHNICAL SECURITY MEASURES

The trial is funded by Oslo University Hospital, Norway (“Sponsor”). They are working together with University of KwaZulu-Natal, Durban University of Technology, BRIGHT and others. We have taken security measures to prevent loss of your personal information, unauthorized use or access, changes or disclosure. For example, your name and your medical information will be stored SEPARATELY. Personal information will be de-identified and coded before it is stored, analysed or transferred. The code will be kept under lock by the leader. This means that the medical information will be processed in a way that cannot be tracked directly back to you. Oslo University Hospital will notify you if there is a problem with this, if it is required by law to do so. We will follow strict procedures on this.

# POPI ACT - DATA PROTECTION (protection of your personal information)

Under South Africa data protection law ***“Protection of Personal Information Act 2013”*** your trial site and the Sponsor (Oslo University Hospital) will be jointly responsible as ‘controllers’ to ensure that your information is safeguarded. The information collected in this trial might be transferred to a country outside of South Africa. If your information is transferred outside South Africa the sponsor is responsible for protecting your information.

# CONSENT TO USE AND SHARE PERSONAL DATA

By signing this consent document, you consent to the use and sharing of your de-identified personal information (without your name) for the purposes of this clinical trial. You do not have to give this permission. However, if you do not consent, you will not be able to participate in the clinical trial.

# WILL YOUR CONSENT EVER EXPIRE?

This permission has no expiry date.

# CAN YOU WITHDRAW YOUR CONSENT?

Participation in the trial is entirely voluntary and you may withdraw at any time. You have the right to withdraw your consent at any time by informing a member of the trial team on site or at:

Site: Bright Academy

Site Tel: 087 150 2794

Site email address: brightresearch.cbthr@gmail.com

# WHAT HAPPENS IF YOU LEAVE THE CLINICAL TRIAL?

# Your decision to participate in this trial is voluntary. If for any reason you end your participation in the trial, site staff will inform the Sponsor that you are doing so. Any information collected about you prior to your withdrawal may be used and shared in accordance with this participant informed consent document. However, you may request that the information must be deleted (in terms of Section 24 (1) of POPIA).

The sponsor and / or the clinical trial site will keep your personal information for 10 years after the investigation has ended. After this 10-year period the information will be destroyed.

# HOW YOUR SAMPLES AND PERSONAL DATA ARE TAKEN CARE OF

Your name and your medical information will be stored SEPARATELY. Personal information will be de-identified and coded before it is stored, analysed or transferred. The code will be kept under lock by the leader. No one outside the investigation room will ever know about your personal information. Samples, medical images and the interview will be analysed and stored *without* your name on it. The specimens and images, without your name, will be investigated in the best laboratories for parasites, viruses and bacteria and cancer. Samples, medical images and the interview without your name, might be sent to other countries for analysis by experts. No one will be able to recognise you from this. If you agree to participate in the trial, you also give permission for this.

All information will be stored securely. The samples and information will only be used to study Bilharzia, women’s diseases, human papillomavirus (HPV) and screening for cervical cancer. You may, at any time, request that your samples, medical images and the interview are destroyed. The research leader and the doctors of the trial are formally responsible for the security. These have access to the code list with name and address file. If important health information is discovered during the trial, we will make sure that you are informed, if you wish.

# CONTACT DETAILS FOR ADDITIONAL INFORMATION

Today, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the trial such as:

* A research-related injury or illness.
* Payment or compensation for being in the trial.
* Your responsibilities as a research participant.
* Eligibility to participate in the trial.
* The trial doctor’s or trial site’s decision to exclude you from participation.
* Results of tests and/or procedures.

Please contact the 24-hour telephone number through which you can reach your trial doctor or another authorised trial site staff.

Site: Bright Academy

Site Tel: 087 150 2794

Site email address: brightresearch.cbthr@gmail.com

# WHO APPROVED THE PROJECT?

The trial has been approved by both the **University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC)** <Insert Approval Number> and **South African Health Products Regulatory Authority (SAHPRA)** for compliance with medical and ethical standards.

The trial has been structured in accordance with:

* the Guidelines on Clinical Trials and Ethics in Health Research, published by the Department of Health, South Africa.
* the Declaration of Helsinki adopted by the World medical Association (WMA)

These documents give recommendations to researchers and doctors in biomedical research involving human patients. Copies of these documents may be obtained from the trial doctor should you wish to review it.

The Biomedical Research Ethics Committee (BREC), which is an independent committee, is established to help protect the rights of research participants. If you have any questions about your rights as a research participant, or if you have concerns and / or complaints regarding this research trial, please contact:

# BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus Govan Mbeki Building

Private Bag X 54001 Durban, 4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2602486 - Fax: 27 31 2604609

Email: [BREC@ukzn.ac.za](mailto:BREC@ukzn.ac.za)

If you have questions about this trial, you should first discuss them with your trial doctor or the ethics committee (information above). After you have consulted your doctor or the ethics committee and they have not provided you with answers to your satisfaction, you should write to the National Health Research Ethics Council or the South African Health Products Regulatory Authority (SAHPRA) at:

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| The Chief Executive Officer  **South African Health Products Regulatory Authority (SAHPRA)**  Loftus Park, Building A 402 Kirkness Street,  Arcadia, Pretoria, 0083  Tel: +27 (0)12 501 0300  Fax: +27 (0)12 395 9201  Email:  [Boitumelo.Semete@sahpra.org.za](mailto:%20Boitumelo.Semete@sahpra.org.za) | The Chair  **National Health Research Ethics Council**  c/o Directorate: Health Research, Secretariat for NHREC  Private Bag X 828 Pretoria, 0001  Tel: +27 (012) 395 8113  Fax: +27 (012) 3958467  E-mail: [nhrec@health.gov.za](mailto:nhrec@health.gov.za) |

# COSTS AND FINANCIAL ARRANGEMENTS

You will not be expected to pay for any trial medication, the trial related visit or procedures.

# COMPENSATION FOR PARTICIPANTS

You will not be paid for participation in this trial. However, **R400.00** will be paid to cover your travel expenses.

# INSURANCE

If you become ill or are injured during trial day, you will get the medical care that you need right away. If you tell the trial staff that you think you have been injured, then they will help you get the care you need.

If you are injured as a result of procedures done for the purpose of this trial, we will pay for medical expenses necessary to treat your injury that are not covered by your medical scheme or any other third-party coverage. This only applies if the injury is directly due to a trial procedure.

During the trial you are insured for compensation as required by local regulations, if injury to your health occurs. If you suspect that your health was injured or if you have an existing condition not related to your participation in this clinical trial, you must notify the trial doctor immediately. If you directly notify the insurer, please inform your trial doctor as well. Your trial doctor may support you in notifying the insurance in a case of suspected, trial-related health damage.

We ask for your cooperation to uncover the cause and extent of the damage and to minimize the damage. During the trial day, you must not undergo any other medical treatment unless you consult the trial doctor first – except emergencies - but you must immediately notify your trial doctor of any emergency treatments that you had.

The insurer will pay for all reasonable medical costs required to treat your bodily injury, in accordance with the **SA Good Clinical Practice Guidelines (2020 or third version)**, which are based on the **Association of the British Pharmaceutical Industry (ABPI)** Guidelines. You may request a copy of these guidelines from the trial doctor.

**The insurance company is:** (Insert Insurance details)

**Your Policy number is:** (Insert Insurance nr)

**Contact details of the insurance company:** (Insert Insurance details)

The insurer will pay without you having to prove that the research was responsible for your bodily injury.

The insurer will not pay for harm if, during the trial you:

* Do not follow the trial doctor’s instructions.
* Suffer an injury arising from negligence on your part or do not take reasonable care of yourself.

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes or malpractice.

If you belong to a private medical scheme, you should inform them that you are participating in a research trial.

# CONFIDENTIALITY

All information obtained during this trial is strictly confidential and will be maintained as such. Information that may be reported for example in scientific journals will not include any details that identifies you as a participant in this trial. The results of this research trial may be presented at meetings or in publications. However, you will not be personally identified in any presentations or publications.

In connection with this trial, it might be important for domestic regulatory health authorities, such as the Department of Health (DOH), the National Health Research Ethics Council (NHREC), the Biomedical Research Ethics Committee (BREC), the South African Health Products Regulatory Authority (SAHPRA), as well as authorised persons on behalf of the Sponsor, to be able to review your medical records related to this trial.

Therefore, by signing this document, you authorise your trial doctor to release your medical records in appropriate circumstances to the Sponsor, its employees or agents, domestic and foreign regulatory health authorities, the SAHPRA and BREC. You understand that these records will be utilised within reason by them only in connection with carrying out their legal obligations relating to this clinical trial.

Any information uncovered regarding your test results or state of health as a result of your participation in this trial will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this trial, but this information will not be told or shown to any other than those mentioned above without your written permission. The only exception to this rule will be in cases where we are obliged by law to report incidences of communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorised state agency.

The information collected during this trial may be added to research databases and used in the future by the Oslo University Hospital to develop a better understanding of the diseases or improve the efficiency, design and study methods of future research or patient management. Such information will not identify you by name.

A description of this trial will be available on the South African National Clinical Study Register website: [https://sanctr.samrc.ac.za](https://sanctr.samrc.ac.za/). This web sites will not include information that can identify you. At most, the Web sites will include a summary of the results. You can search this web site at any time.

**DECLARATION OF CONSENT**

**By signing below, I agree that:**

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| **Consent Statement** | **Participant**  **Initial** |
| I have read or had read to me the information sheet and consent form, for this trial. |  |
| I understand that this trial is investigational and what is means. |  |
| The purpose, treatment and procedures of this trial have been explained to me and I understand them. |  |
| I understand my responsibilities as a trial participant. |  |
| I understand that participation in the trial is entirely voluntary and that I can refuse to participate or withdraw at any time, without it affecting my ongoing care. |  |
| I have been informed of the possible risks, harm, and inconvenience of participating. |  |
| I am not pregnant or trying to fall pregnant. |  |
| If breastfeeding, I have been explained that examination might be uncomfortable, and still consent to the procedure |  |
| I have been informed of the expected benefits of the trial. |  |
| I have been informed of the compensation and treatment that would be available to me in the event of a trial-related injury. |  |
| I have been informed of the reimbursement I may receive. |  |
| I have had sufficient time to ask questions and they were answered to my satisfaction. |  |
| I have been given time decide whether or not to take part. |  |
| I am aware that the results of the trial, including my personal information may be disclosed to the sponsor, regulatory authorities, and research ethics committees, if required by law. |  |
| I have received a signed and dated copy of this informed consent form. |  |
| I agree to participate in this trial. |  |
| If I have any further questions/concerns or queries related to the trial, I understand that I may contact the researchers. |  |

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| **PARTICIPANT** | |
| I herewith confirm that I have been informed fully about the nature, conduct and risks of the above  trial. | |
| FULL NAME (capital letters) |  |
| DATE (DD-MMM-YYYY) |  |
| TIME (HH:MM) |  |
| SIGNATURE |  |

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| **IMPARTIAL WITNESS** | |
| I hereby verify that verbal consent was obtained from the above participant. The participant has been informed about the risks and the benefits of the research, understands such risks and benefits and is able to give consent to participate, without coercion, undue influence or inappropriate incentive. | |
| FULL NAME (capital letters) |  |
| DATE (DD-MMM-YYYY) |  |
| TIME (HH:MM) |  |
| SIGNATURE |  |

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| **TRANSLATOR** | |
| FULL NAME (capital letters) |  |
| DATE (DD-MMM-YYYY) |  |
| TIME (HH:MM) |  |
| SIGNATURE |  |

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| **VERBAL PARTICIPANT INFORMED CONSENT**  (This section is applicable when participants cannot read or write and should replace the previous Informed Consent section) | |
| I, the undersigned hereby confirm that:   * I have read and explained fully, to the participant, as well as the witness with the consent of the participant, the content of this document, indicating the nature and purpose of the trial in which I have asked the participant to participate. * I have explained both the possible risks and benefits of the trial and the alternative treatments available for her illness. * The participant has indicated that she understands the contents of the document and that she will be free to withdraw from the trial at any time without giving any reason or jeopardising her subsequent treatment. * I have informed the participant on the existence of relevant compensation arrangements in case of an injury attributable to the equipment used in the clinical trial, to which she agrees. * The participant has had sufficient opportunity to ask questions. * The participant has voluntarily agreed to participate in this trial. | |
| FULL NAME (capital letters) |  |
| DATE (DD-MMM-YYYY) |  |
| TIME (HH:MM) |  |
| SIGNATURE |  |

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| **PRINCIPAL INVESTIGATOR** | |
| I herewith confirm that the above has been informed fully about the nature, conduct and risks of the  above trial. | |
| FULL NAME (capital letters) |  |
| DATE (DD-MMM-YYYY) |  |
| TIME (HH:MM) |  |
| SIGNATURE |  |