Participant's Name: _____
Participant's Medical Record Number :_____

| Date : 13/6/2025 | IRB No : TH/IEC/BHR/ 0154/2025/ TNV/P1/V4 | Hospital Name: Tanvir Hospital |
|---|---|---|

# A New Red Flag Classification to Predict Vasovagal Syncope During Office Hysteroscopy: A Cross-Sectional Pilot Feasibility Study

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**Hospital/Institute Name: Tanvir Hospital**

**Research informed Consent Document**

**A New Red Flag Classification to Predict Vasovagal Syncope During Office Hysteroscopy: A Cross-Sectional Pilot Feasibility Study**

| **Principal Investigator:** | **Principal Investigator telephone number (available 24/7 and for emergencies): +91 9951911155** |
|---|---|
| **Sponsor:** None | **Other Study Contact Numbers:** +91 9849784915 |

| **Key Information Section** |
|---|
| You may be eligible to take part in this research study. Taking part in this study is completely voluntary.<br>This form contains information that will help you decide whether to take part. All of this information is important, but here are some key important points to keep in mind:<br>• It is completely up to you whether you take part in this study.<br>• Even if you decide to join the study, you are free to leave at any time if you change your mind.<br>• This is research; researchers do research to learn about many different things.<br>• This is research; medical scientists do research to learn about diseases or conditions and how to treat them.<br>• Research is different from regular medical care, which has already been tested in research<br>• The purpose of this study is to 1) to form a red flag classification of pain to predict vasovagal syncope 2) To reduce the prevalance of vaovagal syncome during office hysteoscopy 3) To improve procedural safety<br>•You will be in this study at the time of the hysteroscopy procedure<br>• The risks are those associated while introducing the hysteroscope through the cervical canal into the uterine cavity and while performing the procedure, that may cause mild discomfort or pain . If uncomfortable, the procedure can be stopped immediately.<br>• The possible benefits of this study are diagnosis and treatment of the condition in offfice without anaesthesia, allowing you to return back to daily activities/ work on the same day. |

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|---|---|---|

You are being asked to take part in this research study because you have abornormal uterine bleeding or infertility, and the investigator feels that you may benefit from the office hysteroscopy procedure.

The purpose of this document is to:
• Explain your rights and responsibilities
• Explain the purpose of the study
• Describe what will happen if you decide to take part in this study
• Explain the potential risks and benefits of taking part in the study

Participation in research studies is voluntary. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.

**Why is this study being done?**
Hysteroscopy (camera inserted into the uterus (womb), through the cervix to look inside the womb) +/- endometrial biopsy (a small sample of tissue taken from the lining of the womb) +/- removal of polyp(s)/ fibroid / septum, that may prevent an embryo from implanting properly. It is also done to treat abnormal uterine bleeding. The womb is filled withvfluid, which passes along the hysteroscope, to make it possible to see inside. You will be awake during the procedure. During the procedure, if you experience pain or dizziness, it may lead to fainting, also called vasovagal syncope. Vasovagal syncope is a condition when the heart rate and blood pressure drops suddenly. It is immediately corrected and usually not harmful. The risk of vasovagal syncope is very low, 0.21–1.85%. Through this study we plan to establish a predictive red flag classification system to help the surgeons reduce the chances of vasovagal syncope and improve procedural safety.

Approximately 1100 patients will be recruited in total from multiple centers from United States of America, South America and India.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.

**How long will I be in this study?**
If you agree to take part in this study, your involvement will last for the day of the procedure.

You can choose not to be in the study or stop participating at any time without penalty or loss of any rights or benefits you are entitled to. Please talk to the study staff first before you stop participating in the study.

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|---|---|---|

**What will happen to me in the study?**
The study is designed to collect information about your response to office hysteroscopy regarding the level of pain you feel as comparable to the menstrual cramps, i.e periods
Office hysteroscopy will be performed as the standard of care, and you will be awake all through the procedure. During hysteroscopy, you will be asked about the level of pain in comparison to the mestrual cramps while undergoing the procedure. You will be asked if the pain is less or equal to the menstruation or more than menstruation. A nurse will always be by your side and check your vitals such as pulse rate and blood pressure before, during and after the procedure.

**What are the risks of being in this study?**
As a result of your participation in this study, you may experience the following side effects.

More likely :
While passing the telescope through the entrance( cervix) of the uterus, you may experince some discomfort or pain.

Less likely :
Sometimes the surgeon may fail to gain entry in the uterine cavity in office, thus requiring hysteroscopy under anaesthesia.
Infection
Bleeding

Rare, but serious :
Fainting, i.e vasovagal syncope.
The complications during surgery such as perforation or injury to bowel, bladder or major blood vessels is very uncommon.

You should discuss these with the study doctor and your regular health care provider if you choose to do so.
There may be more risks that are not known or not expected.
The study staff will tell you about any new information that may affect your health, welfare, or willingness to continue in this study.
With any research study, there is a potential for your confidentiality to be breeched. We estimate the risk will be minimal due to data security measures.

**Will I benefit from this study?**
The possible benefits of this study is better prediction and prevention of pain and vasovagal syncope. However, it is possible that other patients and the scientific community may gain from the results of this study. There is no placebo arm in this study and all patients will receive Office Hysterosocpy (standard).

**Who will see my study information?**
Study team members, will be able to see your study information. Your records will be checked by the reviewers may include the Institutional Review Board (the committee who oversees safety of volunteers in research studies), institutional officials.

**How will you keep my study information confidential?**

Study records that identify you will be kept confidential except as required by law. You will not be identified in study records or publications disclosed outside Tanvir Hospital.

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**What will happen to my identifiable private information once collected?**
Identifiers might be removed from your identifiable private information collected as a part of this research. After such removal, the information could be used for future research studies or be distributed to another investigator for future research studies without getting additional informed consent from you or your legally authorized representative.

**What are my costs (what will it cost me) for taking part in the study?**
If you agree to participate in this study, you are still responsible for paying for the usual care you would normally receive for the treatment of your health. You will be responsible for all co-pays, deductibles and denied claims.

**Will I be paid for participation in this study?**
This study involves a standard of care procedure, where the findings are being observed and recorded, hence it does not involve any payment.

**What happens if I am injured or hurt because I took part in this study?**
If you think that you have suffered a research related injury, seek medical care right away and contact the study team as soon as possible at +919951911155.

**Who can answer my questions about this study?**
You can ask questions about this study at any time. Please contact the study staff listed on page 1 of this document if you have questions about:

- Study procedures
- Reporting an illness, injury or other problem
- Leaving the study before it is finished
- Expressing a concern about the study
- Any other questions you may have about the study

**Can I be removed from the study?**
Yes, you may be removed from the study if:

- The study doctor decides to stop the study.
- The study doctor stops your taking part in the study for your safety.
- You are not eligible to take part in the study.

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**Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study**

If you sign this document, you give permission to Tanvir Hospital and their Affiliates to use or disclose your health information that identifies you for the study described earlier in this document.

The health information Tanvir Hospital and their Affiliates may use or disclose for this study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition and the procedure.

The health information listed above may be used by and/or disclosed to the following, as applicable:

- Researchers and their staff;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Clinical staff not involved in the study whom may become involved if it is relevant
- The Institutional Review Board (IRB) overseeing this study;

Tanvir Hospital and their Affiliates are required by law to protect your health information. By signing this document, you authorize Tanvir Hospital and their Affiliates to use and/or disclose your health information for this research.

**Signature**

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form. If I sign this form and agree to be part in the study I can not sue the doctor or the hospital if something goes wrong.

**BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE** 118 **STUDY DESCRIBED IN THIS CONSENT FORM**

**Name of Subject**_____

**Signature of Subject**_____**Date/Time**_____

**If signed by Legal Representative, the Relationship to subject**_____

I have explained the treatment to the subject or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
**Name of Study Staff Member Administering Consent**

_____ _____
**Signature of Study Staff Member Administering Consent** **Date/Time**