INFORMED CONSENT DOCUMENT (ICD)
[Written subject information sheet & consent form]

Study Title:	Normal values of ambulatory 24-hour oesophageal pH-impedance monitoring in an Indian cohort of health volunteers
Language:	English

Subject Identification

Subject full name in BLOCK LETTERS:

Subject identification (ID) No: Date of Birth / Age at the time of consent:

Study Doctor

Name of the Investigator(s): **Email ID:**	Dr. Krithi Krishna Koduri drkrithivk@gmail.com
Name of the sub-investigator(s) / Guide: **Email ID:**	Dr. Aniruddha Pratap Singh draniruddhapratapsingh@gmail.com Dr. Rakesh Garlapati

Address(s) of the study site:

AIG Hospitals, No 136, Plot No 2/3/4/5 Survey, 1, Mindspace Rd, Gachibowli, Hyderabad, Telangana 500032.

Telephone: 040 4244 4222

1) **Participation.**

We are approaching you with a request to participate in this study as you are a healthy individual without any gastrointestinal symptoms, and we are seeking to establish normal values for acid exposure time through ambulatory 24-hour pH-impedance monitoring. Before you take part in this study, it is important that you understand what the study involves. Please read this information carefully and ask any questions that you might have. You will be included in the study only after you give consent to take part in the study.

2) **Purpose and Aim of the Study.**

The aim of this prospective study is to establish the normal Acid exposure times and 24-hour-ambulatory pH values in healthy Indian volunteers.

3) **The approximate number of participants and the expected duration of your participation in the study:**

There will be 50 healthy volunteers in this study. Your participation will last for a 24-hour period.

4) **What other treatment options do I have?**

Since this study is observational, there are no alternative treatments being tested.

5) **Study Procedure / Methodology.**

Participants will first go through a general health check-up, which includes a physical exam and lab tests. These tests will check things like their blood count, liver and kidney function, blood sugar levels, and thyroid health. If they agree, they may also have an endoscopy, which is a procedure where a doctor looks inside the stomach using a flexible tube. The doctor will also ask about any food allergies, heartburn (a burning feeling in the chest), or other digestive issues. They will also gather information about the person's daily habits, such as their eating patterns, sleep, and exercise routines.

After fasting for 8 hours (not eating or drinking), all participants will undergo a test called HRM (High-Resolution Manometry), which checks how well the muscles in the esophagus (the tube that carries food from the mouth to the stomach) are working. Participants will lie down on their back during the test. A small tube (called a catheter) will be placed in their throat, and after getting used to it, they will be asked not to swallow for 30 seconds. This will allow the doctors to measure how the muscles are at rest. Then, they will swallow small amounts of water (5 mL) every 30 seconds followed by 10 swallows of 5 mL every 30 seconds to acquire dynamic parameters. so doctors can measure how the muscles work when swallowing. The HRM system uses a special catheter with many sensors that measure pressure in the esophagus from the throat all the way to the lower part of the esophagus (near the stomach).

Another test will measure how food and liquids move through the esophagus and if there’s any acid, which can be important for checking for acid reflux (when stomach acid comes

back up into the esophagus). For this test, a small probe (tube) with sensors will be placed in the nose and passed into the esophagus. The probe has special electrodes that measure electrical signals to check for acid levels and the movement of food. The electrodes are placed at different points above the lower part of the esophagus to track the movement and acid levels in the area. Before starting, the electrodes will be tested and adjusted to ensure they are accurate.

The combined test will last for 24 hours. During this time, participants can continue with their usual daily activities, like eating, sleeping, and exercising. They will also be asked to record any symptoms they experience, such as heartburn, burping, or stomach upset, and press a button on a small device to mark when they eat, change positions, or feel any symptoms. This will help the doctors track how the body is reacting during normal daily life.

The procedure is non-invasive and aimed at understanding the normal reflux patterns in healthy individuals.

6) Role of the Patient:

Your role in this study is to allow for the placement of the pH-impedance monitoring probe and to carry out your daily activities During this time, you'll need to note any symptoms you might have (if any) and follow the instructions provided by the study staff.

7) Follow-up / Duration of the study.

The study requires one-time participation over 24 hours, and you will be required to attend the study site for the initial screening, probe placement, and data collection. There is no follow-up required after the study is completed.

8) What are the possible risks (adverse effects/advents events) and discomforts to you?

The procedure is generally safe; however, potential risks include minor discomfort from the placement of the nasal probe or irritation

9) What are the expected benefits of this study?

You may or may not benefit from participating in this study, but the knowledge gained may benefit others.

10) Adverse events and compensation.

You may experience discomfort from the probe in your nose, throat, or oesophagus.

11) Your responsibilities

Completely read the consent form and ask the Principal Investigator (PI) any questions you may have. You should understand what will happen to you during the study before you agree to participate. You should talk to the Principal Investigator (PI; the person in charge of the study) if you want to stop being part of the research study. You should report to the PI immediately about any problems you may be having with the study procedure/device.

You should fulfill the responsibilities of participation as described on the consent forms unless you are stopping your participation in the study. You can ask for the results of the study, if you want them. You should keep a copy of the consent form for your records

12) Voluntary Participation / Withdrawal from the Study

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. Even if you do decide to take part, you are free to leave the study at any time without giving a reason. This will not affect your future medical care in any way. Furthermore, your study doctor may withdraw you from the study if he/she feels this is in your best interest, or in case of stopping the study early. If you decide to withdraw your consent to participate in the study, your study doctor will ask your permission to perform the final evaluation and to collect the data through a report form. If you do not agree, no new data on you will be added to the database.

Your doctor, the sponsor of the study or designee, may end your participation in this study at any time without your consent. The possible reasons for ending your participation: if the study treatment offers you little or no future benefits or if you develop severe or life-threatening side effects. You will be discontinued from the study if you fail to follow directions for participating in the study.

13) Permission for Review of Records, Confidentiality and Access to Records

After seeking permission from you, the study doctor or research staff will collect information about you. This information called data will be entered without your name, on a report form. In all these report forms a code will replace your name. All the data collected will be kept confidential. Authorized personnel will enter the data into the investigator's / sponsor's case report form or computer database. The data collected will be used for the evaluation of the study and may be used in the future in related or other studies. This data may also be used for the purpose of publication and presentations at Scientific platforms.

The data may be submitted to health authorities for registration purposes. Health authorities, Indian Council of Medical Research (ICMR) and like, Institutional Ethics Committee (IEC) / Institutional Review Board (IRB) or other persons required by law may review the data provided.

To make sure that the data collected from you is correct, it is necessary for the sponsor or national / international authorities to directly compare them with your medical record. Such checks will only be done by qualified and authorized personnel. While all reasonable efforts will be made to keep the data confidential, absolute confidentiality cannot be guaranteed.

14) Questions/Information.

(i) If you or your representative(s) have any questions regarding the study or in case of study related injuries, you should contact your study doctor.

Name of the investigator/study doctor: Dr. Krithi Krishna koduri
Telephone: +91 9182645727

(ii) If you or your representative(s) have any questions regarding your subject rights as they relate to the study, you should contact the following personnel as allowed by local regulation and IRB/IEC policy,

Name of the IEC Personnel: Dr. Deepa Shukla
Telephone: +91 9953900117

(iii) If you seek emergency care, or if hospitalization is required, please inform the treating doctor that you are participating in a clinical trial.
(iv) If any new information becomes available during the study that may affect your willingness to participate, you will be informed.

Informed Consent Declaration

Date: _____

Subject Name: _____ **Sex:** _____

S/o, W/o., D/o: _____

Subject ID: _____

Date of birth/Age at the time of consent: _____

Address of the subject: _____

_____

Subject contact number:_____

Qualification: _____

Occupation: Student / Self-employed / Service / Housewife / Other **(Tick as appropriate)**

If other, kindly mention: _____

- I have been provided with the details of the known or foreseeable side effects and risks of the research medication and study procedures that I may receive.

- I understand I am free to accept or refuse my participation at any time without giving a reason. My decision to accept or refuse my participation will have no effect on my continuing treatment. I understand that I am free to discontinue my participation at any time without giving a reason. My decision to discontinue my participation will have no effect on my continuing treatment. I will keep all my rights to treatment and alternative therapy.

- I agree that data collected for the study will be used for the purpose described above, including transferring data to the case report form or database and processing and archiving by AIG in a coded form with respect to the confidentiality of my data.

- I agree that direct access to my medical records may be given to authorized persons representing national and international authorities. These authorities may include the local regulatory authorities or Institutional Ethics Committee (IEC)/Institutional Review Boards (IRB's).

- I understand that my study records can be forwarded to my primary physician if I request my study doctor to do so.

- I will not lose any rights that I have under the law by signing and dating this form.

- I have read and understood the information presented in this informed consent form. I have been given the opportunity to ask questions, and they have been answered.

- I will receive a signed and dated copy of this Informed Consent Form.

Serial No.	Particulars	Initial in box
1.	I confirm that I have read and understood the information sheet dated _____ (dd/mm/yyyy) for the above study and had the opportunity to ask questions. My questions have been answered satisfactorily.	
2.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that the ethics committee and the regulatory authorities will not need any permission to look at my health records both in respect of the present study or any further research that may be conducted in relation to it even if I withdraw from the trial. I agree with this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	
4.	I agree not to restrict the use of any data or result that arises from this study provided such use is only for the scientific purpose(s).	
5.	I agree to take part in the above study, allow access to my data in the study, and I agree to co-operate and inform unexpected or unusual symptoms experienced during the study. For the duration of the study, I will notify the investigator of any other medical treatments that may be necessary to undergo. I received a copy of this consent form.	
6.	All the above has been explained to me in a language I know and I understand.	

Name of the subject	Signature /thumb impression of the subject	Date (DD/MM/YYYY)
Name of the legally acceptable representative (Mention relationship with the subject)	Signature/thumb impression of the legally acceptable representative	Date (DD/MM/YYYY)
Name of the investigator	Signature of the investigator	Date (DD/MM/YYYY)

If the subject / legally acceptable representative cannot read:

Name of impartial witness 1	Signature of the impartial witness 1	Date (DD/MM/YYYY)
Name of impartial witness 2	Signature of the impartial witness 2	Date (DD/MM/YYYY)

Nominee(s):

Name: _____

Address_____

Telephone if any: _____

Legally accepted representative (LAR) [in case of signature obtained from LAR]:

Name: _____

Address_____

Telephone if any: _____

Impartial witness(es) if any:

Name: _____

Address_____

Telephone if any: _____