

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

Study Title:	EUS-Guided Attenuation Imaging and Shear Wave Elastography in Individuals With Normal FibroScan: Establishing Preliminary Reference Values in a Pilot Feasibility Study
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:	
Name of the sub-investigator(s) / Guide:	
Email ID:	

Address(s) of the study site:

Telephone:

1) Participation.

You are being invited to participate in a research study because you are undergoing an Endoscopic Ultrasound (EUS) examination and meet the eligibility criteria for this study. Before deciding whether to participate, please read the following information carefully. You may ask any questions regarding the study. Participation is completely voluntary.

2) Purpose and Aim of the Study.

The purpose of this study is to establish normal reference values for two liver assessment techniques called **Attenuation Imaging (ATI)** and **Shear Wave Elastography (SWE)** when performed during Endoscopic Ultrasound (EUS).

These techniques may help doctors assess liver fat content and liver stiffness more accurately in the future. Currently, normal values for these EUS-based measurements are not available.

3) Age Criteria, approximate number of participants at AIG and in total, the expected duration of the participant participation in the study:

Parameter	Details
Age Criteria	≥18 years
Total Participants at AIG	Approximately 100
Total Participants Overall	100
Study Design	Prospective observational study
Duration of Participation	Single study visit during scheduled EUS procedure
Study Duration	Until recruitment of all participants

4) What other treatment options do I have?

Participation in this study is optional. Your routine medical care and planned EUS procedure will continue whether or not you choose to participate. Refusal to participate will not affect your treatment in any way.

5) Study Procedure / Methodology.

If you agree to participate:

1. Your routine FibroScan results will be reviewed.
2. During your planned EUS procedure, additional measurements called ATI and SWE will be performed on your liver.
3. Measurements will be taken from both the right and left lobes of the liver.
4. No additional surgery, biopsy, medication, or treatment will be given as part of this study.
5. The procedure will be performed during the same EUS examination that is already planned for your clinical care.

Nothing in addition to the normal treatment is being done to you except recording these imaging measurements during the scheduled EUS examination.

6) Role of the Patient:

As a participant, you will:

- Provide informed consent.
- Allow collection of demographic, clinical, laboratory, FibroScan, and EUS data.
- Inform the investigator about any relevant medical conditions.
- Cooperate during the study procedure.
- Report any unexpected symptoms or concerns.

7) Follow-up / Duration of the study

This study does not require any additional follow-up visits beyond your routine clinical care. Data collection will occur during your scheduled EUS procedure.

8) What are the expected benefits of this study?

You may not receive any direct medical benefit from participating in this study.

However, the information obtained may help establish normal EUS-based liver measurement values and contribute to future research on liver diseases. **You may or may not benefit from participating in this study, but the knowledge gained may benefit others.**

9) Your responsibilities.

You are requested to:

- Read this consent document carefully.
- Ask questions if anything is unclear.
- Inform the study team about any medical conditions.
- Report any unexpected symptoms following the procedure.

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 PI if you want to stop being part of the study. You can ask for the results of the study if you wish.

10) 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.

11) 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.

12) 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:

Telephone:

(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 8712015028

(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.	
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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: _____