

# Do you suffer from Gastroesophageal Reflux Disease (GERD) and Hiatal Hernia?

If you are 22 years old or older, this study may be for you.

<https://classic.clinicaltrials.gov/ct2/show/NCT04795934>

## Study for adults with GERD and Hiatal Hernia

The Digestive Health Clinic at Ascension Seton Medical Center Austin, is seeking people with **GERD** and **Hiatal Hernia** to participate in a research study, led by **Dr. Francis. P. Buckley III** designed to compare effectiveness between two approved approaches to treatment: Laparoscopic Nissen Fundoplication (LNF) and Transoral Incisionless Fundoplication (TIF).

After screening, subjects will be randomized in a 1:1 ratio, blinded at time of procedure of the procedure type, and will participate in 9 total follow-up visits over 5 years (4 in the first year and 5 annual questionnaires).

Participation is completely voluntary, and participants can withdraw at any time.

You will receive \$400 after the completion of all study questionnaires and attendance of all in person visits at the 12-month follow-up visit. You will receive \$100 annually for the remaining 4 years after completion of follow-up questionnaires. If you are able to complete the entire study, you will receive up to \$800.

## Location

The location of surgery will be in Ascension Seton Medical Center Austin, 1500 Red River St Austin, TX 78701

## Are you eligible?

1. 22-80 years of age
2. Have GERD with hiatal hernia < 5 cm, and Hill grade III or IV
3. Pathologic reflux while off Proton Pump Inhibitor(PPI) based on Lyon criteria by either of the following:
  - a. Conclusive evidence for pathologic reflux defined as acid exposure time (AET) > 6% or LA grade C or D esophagitis.
  - b. Borderline evidence of pathologic reflux defined as presence of one of the following parameters: AET 4-6%, LA grade A or B, and signed informed consent.
4. Commitment to long-term study
5. Ability to give consent individually or by a legally authorized representative



If you're unsure if you meet the requirements, or have any questions, please call **Digestive Health Clinic** to **book an appointment @**

**512-324-7831**