



SAINT LOUIS
UNIVERSITY

GASTROENTEROLOGY & HEPATOLOGY CLINICAL RESEARCH UNIT

SAINT LOUIS UNIVERSITY HIPAA Authorization Form Privacy Protection for Research Volunteers

Participant	_____	IRB Number	_____ 22080
Principal Investigator (PI)	Hisham Hussan, MD	PI's Phone Number	_____ 314-890-2875
	<small>First Last Credentials</small>		
Title of Project:	The accuracy of I-Scan mode of imaging versus white light imaging as compared to CD31, CD34, CD61 stains (Standard of care) in differentiating Gastric Antral Vascular Ectasia (GAVE) from portal hypertensive gastropathy (PHT Gastropathy).		

Saint Louis University requires that private information about you be protected. This is especially true for your personal health information. Protected Health Information (PHI) is any health information that identifies you. To take part in this research, you must give the research team permission to use and share your PHI. The research team will only use and/or share your information as listed below.

Health information about you that may be used or shared for this research study includes:

The PHI kept by the study staff and doctor includes your name, address, date of birth contact information and medical record numbers. This information will not be shared outside of this institution. Additional PHI that will be collected includes your medical history, hospital, physician or clinic medical records, previous laboratory results, biological samples, pathology and/or radiology reports, interviews or questionnaires/health histories, data previously collected for research purposes.

To ensure the scientific integrity of the study, you may not be able to review some of your records related to the study until after the study has been completed.

The researchers may use or share your health information with:

- The Saint Louis University Institutional Review Board in order to provide research oversight
- Saint Louis University Hospital in order to provide research oversight
- Federal or state government representatives, when required by law
- Your primary physician will be contacted if the research team in the course of this research learns of a medical condition that needs immediate attention
- U.S. Food and Drug Administration

The researchers at Saint Louis University agree to protect your health information by using and/or disclosing it only as you authorize. However, if your PHI is shared with someone outside of the Saint Louis University research team and/or if you choose to share this information with others outside of this study, your health information may no longer be protected by HIPAA.

Your permission to use and/or share your PHI does not have an expiration date. There is no pressure on you to sign this form. However, if you choose not to sign this form, you may not take part in this research study. It will not affect your standard medical treatment, payment or enrollment in any health plans or affect your eligibility for benefits

If you choose to sign this form:

- You can change your mind and not allow the researcher use and/or share your PHI (revoke your authorization).
- If you revoke your authorization, you must send a written letter to: Dr. Hisham Hussan, 3545 Lafayette Ave. 2nd Floor, St. Louis, MO 63104, to inform him of your decision.
- If you revoke your authorization, researchers may only use and/or share your PHI already collected for this research study.
- If you revoke your authorization, your PHI may still be used and/or shared should you have an adverse event (a bad effect).
- If you revoke your authorization, your PHI may still be used and/or shared by the study doctor in order to preserve the scientific integrity of the study.
- If you withdraw your authorization, you will not be allowed to continue in the study.

If you have questions or concerns regarding your privacy and the use of your personal health information, please contact the University Privacy Officer at (314) 977-5545. You will also be given a copy of the Notice of Privacy Practices (a separate document). You will receive a signed copy of this Authorization form for your records.

Signature of Research Participant

Date

Print Name of Participant

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #22080

Approved: 09/17/12

Board #3

Saint Louis University



Signature of Principal Investigator
or Research Team Member

Date

Print Name of Principal Investigator or
Research Team Member