
Protocol Title: 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).

Protocol Status: APPROVED

Date Submitted: 07/14/2014

Approval Period: 07/14/2014-07/16/2015

Important Note: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

* * * Continuing Review * * *

Continuing Review Request

WHAT TO UPLOAD WITH YOUR CONTINUING REVIEW APPLICATION

For studies where research activities are limited to data analysis, upload subject safety information and publications (e.g., manuscripts, abstracts) since the last IRB approval, if applicable.

NOTE: if activities are limited to data analysis of de-identified/anonymous data (data that can no longer be linked to subject identifiers directly or through use of a code with master list kept), the study can likely be closed via the Final Report Form. See the SLU IRB Guidance for Closure of Human Subjects Research Studies.

For all other studies, upload:

- Subject safety information including the most current Serious Adverse Event (SAE) cumulative table and data safety monitoring reports since the last IRB approval, if applicable.
- Any publications (e.g., manuscripts, abstracts) since the last IRB approval.

Any changes, updated and/or new study materials should be uploaded and questions 19 - 24 of this form should be completed.

1. **Please indicate the status of the study:**

a) The study has not started but will become active.
Please explain why the study has not started.

b) X The study is ACTIVE (please check the appropriate box below):
Study is open to accrual.
Study is on hold or halted.
Please explain what needs to occur before accrual can resume.

X Study is permanently closed to accrual.

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i.	Y	Have all subjects completed all research related activities/interventions?
ii.	N	Will the research only remain active for long-term follow-up of subjects?
iii.	Y	Are remaining research activities limited to data analysis only? (See instructions above).
iv.	N	For studies that are closed to subject accrual, do any subjects need to be re-consented (to inform them about changes to study procedures, study risks, study personnel, etc.)? If yes, please submit a clean copy of consent/addendum consent for IRB review.

For IRB office use: * may qualify for expedited review

c) **The study has expired and needs to be re-initiated.**
Explain any research activities occurring during lapse in IRB approval.

2.	**Date the study was initially approved by the IRB:**	07/17/2012
3.	**Approval date of previous continuing review:**	07/08/2013
4.	**Total number of participants/records/specimens approved to date.**	150
5.	**Total number of subjects that have given consent (verbal or written) to date.**	25
6.	**Total number of subjects that failed screening (if not applicable, state N/A).**	N/A
7.	**Total number of participants accrued since the beginning of the project.**	25
8.	**For multi-center studies, number of subjects approved for accrual study-wide (SLU site plus all other sites).**	N/A
9.	**For multi-center studies, number of subjects enrolled study-wide (SLU site plus other sites).**	N/A

10. **Number of withdrawals from the research (since last approval date) and explanation/reasons for withdrawals.**

N/A

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11. Description and number of:

a) Reportable Protocol Deviations/Violations since the last approval date:

N/A

b) Unanticipated Problems (UPs) since the last approval date:

N/A

c) Serious Adverse Events (SAEs) since the last approval date:

N/A

12. Have there been any complaints about the research during the last year? N

If yes, please describe.

13. Briefly describe the progress of the study to date.

Patient recruitment completed. Now analyzing data.

14. Is there a Data Safety Monitoring (DSM) plan for this study?

Y No

Yes, a copy of the DSM report(s) for the last approval period is attached.

Yes, but a copy of the DSM reports(s) for the last approval period is not attached. Please explain below.

15. FDA Regulated Studies

Is this a Food and Drug Administration (FDA) Regulated Study, (i.e., involves drugs, devices, biologics)? If yes, please answer the following questions: Y

a) Have there been any changes in the FDA status of any drug or device used in the study? N

If yes, please explain:

b) Have any of the investigational drugs or devices used in this study received FDA approval? N

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If yes, please explain:

c) Have any new alternative drugs or devices been approved for treatment of the study condition that may affect subjects willingness to participate? N

If yes, please explain:

Have current subjects been notified? Please explain:

d) Has there been a change in the standard care that may be considered as an alternative to the investigational drug or device or that would affect the original study design? N

If yes, please explain:

Have current subjects been notified? Please explain:

e) Is there any new information that might affect the risk/benefit ratio and the willingness of current study subjects to participate or to continue to participate in the research? N

If yes, please explain:

Have current subjects been notified? Please explain:

f) Does the study include an investigator's brochure (IB)? N

If yes, what is the current version date?

(If study has multiple IBs, attach current versions in Attachments section (#16))

16. Provide a summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.

Nothing to report at this time.

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17. Have there been any significant amendments or revisions to the protocol during the past approval period? (Significant amendments include changes in study design or risk level including those that resulted in a change in consent). N

If yes, please briefly summarize the changes:

18. Y The consent materials attached to this eIRB application (including consent documents, assent documents, recruitment statements or other materials used to obtain consent) are the versions being used in the conduct of this study and all enrolled subjects have signed consent forms on file, if required. (If the requirement to obtain consent was waived or if no participants have enrolled since last continuing review, check N/A).

NOTE: The IRB routinely monitors consent document usage and may request copies of redacted participant consent forms.

19. Are any changes (amendments) requested with this Continuing Review?

Y Yes, please complete the remainder of this form.

No, form is complete. Please submit.

20. Summarize the proposed changes to the protocol in lay terms, including the type of change AND what the change involves. * If this is a change in PI a new Department Chair review is required. Please upload signed document in the Attachments section.

Change PI to Harsh Parikh, M.D.

21. Provide justification/explanation for the proposed changes.

Dr. Hussan completed the fellowship program.

22. Will currently accrued subjects need to be notified of changes? N

If no, please justify why not.

All subjects have completed the study.

If yes, please explain how AND when notification or re-consenting will occur.

23. Does the SLU IRB Protocol need to be modified? Y

24. Are consent documents modified? N

Proceed to the appropriate section(s) of the protocol and make your changes. Also make necessary changes in

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the Consent Form(s), Assent Form(s), Recruitment Statement, Questionnaire, or other attachments, as applicable. Upload any revised IRB materials. Please provide the entire revised document (not just revised pages). Use track changes or highlight (in yellow) changes to documents being revised. Please upload a tracked/highlighted copy of each revised document to be stamped upon IRB approval. NOTE: Upload a clean copy (changes or highlights removed) of documents in file formats other than Microsoft Word (i.e., the IRB will remove the tracked changes/highlights on uploaded Word documents).

NOTE: Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects.

Sponsored Studies: Remember to update the Sponsor's Protocol version number and date in the Funding section of the protocol (this information will appear on the approval letter).

List of changed sections:
Personnel Information
Subject Population 8(a-g)
Subject Population 8(h-k)
Risks (9)
Attachments (16)
