EAST TENNESSEE STATE
UNIVERSITY

Office for the Protection of Human Research Subjects • Box 70565 • Johnson City, Tennessee 37614-1707

Phone: (423) 439-6053

IRB APPROVAL – Initial Expedited Review

January 29, 2018

To : VA R&D

RE: James Swenson, MD

Re: Evaluating Predictors and Consequences of Incomplete Capsule Endoscopy Examinations
IRB#: 0118.25sw
ORSPA #:

The following items were reviewed and approved by an expedited process:

- New protocol submission xform, CV of PI, HIPAA waiver and addendum, abstract, data collection sheet

On January 29, 2018, a final approval was granted for a period not to exceed 12 months and will expire on January 28, 2019. The expedited approval of the study will be reported to the convened board on the next agenda.

The IRB Vice Chair has granted a HIPAA Waiver for this project.

Study has been granted a Waiver or Alteration of Informed Consent by Jonathan Moorman, M.D, Vice Chair, ETSU/VA IRB, under category:

45 CFR 46.116(d)

The research involves no more than minimal risk to the participants as there is no interaction with the subjects as this is a chart review only with retrospective start date to begin at the time of study approval. The waiver or alteration will not adversely affect the rights and welfare of the subjects as the study is a chart review with no direct interaction with subjects that would put their rights/welfare at risk. The research could not practicably be carried out without the waiver or alteration as there are far too many subjects to attempt to contact practicably for consent. The researchers will need to review the charts of all people who meet the inclusion criteria if they are to achieve scientific validity and maintain scientific integrity. Providing participants additional

pertinent information after participation is not appropriate as there is no relevance to the subjects that have participated in this retrospective chart review.
This study was approved under expedited category: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Projects involving VA patients, facilities or employees must also be approved by the VA Research & Development Committee prior to initiating the study.

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 5 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 5 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,

J Moorman, m.d., PhD

Jonathan Moorman, M.D.
Vice-Chair, ETSU/VA IRB

cc: Joseph Wilkerson