Georgetown University Institutional Review Board

Date:	5/6/2016
To:	Mark Mattar
From:	Amy Harchelroad Institutional Review Board
IRB #:	2016-0200
Title:	Post Endoscopic Procedure Satisfaction Scores
Approval Date:	5/2/2016
Expiration Date:	5/1/2017
Action:	Initial Review - Expedited

Attachments being reviewed: **4** documents were reviewed as part of this submission:

Document	Version
No Consent	0.01
HIPPA Waiver form	0.01
Protocol	0.02
Sample Post Procedure Call Survey	0.01

Stamped Documents: 2016-0200 Study Stamped HIPAA Waiver.pdf

The above-referenced protocol and consent form were approved through expedited review by the IRB Chair or a designee on 5/2/2016. The IRB has determined that the research involves no greater than minimal risk and falls under the following expedited review category:

5. Research involving materials (data, documents, records, or specimens) that:
(a) have already been collected for some other purpose, **OR**
(b) will be collected for non-research purposes (such as medical treatment or diagnosis).
7. Research on:
(a) individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), **OR**
(b) research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

This is to inform you that you may commence your project. Please note that this approval is granted through 5/1/2017.

This study will automatically become inactive when its approval expires on 5/1/2017 *unless* a continuing review submission is approved by the IRB before that date. The IRB requires that you submit an application for annual renewal at the end of each approval period and/or at study completion. It is the principal investigator's responsibility to submit the annual renewal application at least one month before the expiration date.

Any investigator whose project is externally funded must submit the applicable sponsor grant or contract for review and approval by the appropriate sponsored research office of the recipient institution (GU or MHRI). The project cannot proceed without the approval of the sponsored research office.

The International Committee of Medical Journal Editors (ICMJE) has established a requirement for registration of clinical trials in a public registry prior to enrollment as a condition of consideration for publication. Georgetown University has established a central registration process through the National Library of Medicine's Clinical Trials Protocol Registration System (PRS) known as ClinicalTrials.gov. Please contact the GU PRS administrator, Patricia Mazar, by e-mail at mazarp@georgetown.edu to set up a PRS user account to register clinical trials. The e-mail should contain the principal investigator's full name, department, phone number, and e-mail address.
Additional information may be found at http://ora.georgetown.edu, http://clinicaltrials.gov/, and at http://www.icmje.org/clin_trialup.htm.

For all Department of Defense (DoD) sponsored research, please note that you must obtain approval from the DoD human subjects committee as well as the local IRB before commencing this project.

** If promotional advertisements will be used for patient recruitment, they must be submitted for IRB review and approval prior to their use.

** Any incentives for participation in research are subject to IRB review and approval as well.

Please remember to:

1. Seek and obtain prior approval for any modifications to the approved protocol.
2. Promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the IRB within seven (7) calendar days. This includes information obtained from sources outside GU or MHRI that reveals previously unknown risks from the procedures, drugs, or devices used in this study.

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