



University of Nevada, Reno

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DATE: December 21, 2017
TO: Eric Osgard, MD
FROM: University of Nevada, Reno Institutional Review Board (IRB)

PROJECT TITLE: [1139179-2] Simethicone pretreatment with low-volume Polyethylene Glycol-3350 and Bisacodyl in an effort to improve bowel wall visualization

REFERENCE #: Biomedical

SUBMISSION TYPE: Response/Follow-Up

ACTION: APPROVED

APPROVAL DATE: December 21, 2017

EXPIRATION DATE: December 21, 2018

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review # 1a and 7

The above-referenced protocol was reviewed and approved by the UNR IRB in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56). This approval is based on assessment that the research met all applicable regulatory criteria. The research must be conducted in accordance with this approved submission. This submission has received Expedited Review based on applicable federal regulations.

Please prepare your continuing review form at least 4 weeks prior to your expiration date using IRBNet. <https://www.irbnet.org>. Our office will send you a courtesy reminder to that effect. Unless renewed, the IRB only has authority under the federal regulations to allow a study to be open 12 months or less. There is no grace period. The study will be closed on the above stated expiration date unless the IRB receives and approves a continuing review report.

Instructions on preparing a modification or submitting your renewal is located on our web site at <http://www.unr.edu/research-integrity/human-research/irbnet>. Call our office if you have any questions or problems with use of IRBNet software.

Approved Documents

- Application Form - Research Drugs Biologicals Dietary Supplements(revision) 031017 (1).docx (UPDATED: 12/19/2017)
- Application Form - 1_Part II Application BIO 031017 (revision)(9)-2.docx (UPDATED: 12/19/2017)
- Consent Form - Consent Form BIO(revision) 051216(1).doc (UPDATED: 12/19/2017)
- HIPAA Consent/Authorization - HIPAA Authorization -- PHI not at UNR (revision)103017.docx (UPDATED: 12/19/2017)
- Letter - Revision letter.docx (UPDATED: 12/19/2017)
- Protocol - Narrative Study Protocol Template 07.06.17-1.docx (UPDATED: 12/19/2017)
- CV/Resume - CV - Manasewitsch.pdf (UPDATED: 11/16/2017)
- CV/Resume - CV Svendsen.docx (UPDATED: 11/16/2017)
- CV/Resume - CV Rishi.docx (UPDATED: 11/16/2017)
- CV/Resume - CV Kaur.docx (UPDATED: 11/16/2017)

- CV/Resume - CV Osgard.doc (UPDATED: 11/16/2017)
- CV/Resume - CV Doyle.pdf (UPDATED: 11/16/2017)
- CV/Resume - CV Abubaker.pdf (UPDATED: 11/16/2017)
- Investigator Agreement - Dr. Osgard PI form.pdf (UPDATED: 11/16/2017)
- Letter - Site permission.pdf (UPDATED: 11/16/2017)
- Other - Product label.jpg (UPDATED: 11/17/2017)
- Training/Certification - CITI Manasewitsch.pdf (UPDATED: 11/16/2017)
- Training/Certification - CITI Svendsen.pdf (UPDATED: 11/16/2017)
- Training/Certification - CITI Rishi.pdf (UPDATED: 11/16/2017)
- Training/Certification - CITI Kaur.pdf (UPDATED: 11/16/2017)
- Training/Certification - CITI Osgard.pdf (UPDATED: 11/16/2017)
- Training/Certification - CITI Doyle.pdf (UPDATED: 11/16/2017)
- Training/Certification - CITI Abubaker.pdf (UPDATED: 11/16/2017)
- University of Nevada, Reno - Part I, Cover Sheet - University of Nevada, Reno - Part I, Cover Sheet (UPDATED: 11/6/2017)

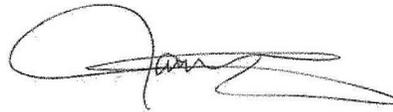
If you have any questions, please contact Valerie Smith at 775.327.2370 or at valeries@unr.edu.

NOTE for VA Researchers: You are not approved to begin this research until you receive an approval letter from the VASNHCS Associate Chief of Staff for Research stating that your research has been approved by the Research and Development Committee.

Sincerely,



Richard Bjur, PhD
Co-Chair, UNR IRB
University of Nevada Reno



Janet Usinger, PhD
Co-Chair, UNR IRB
University of Nevada Reno

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Nevada, Reno IRB's record.