CHI Institute for Research and Innovation

FWA Number: FWA 00019514
OHRP IRB Number: IRB00009715

DATE: April 23, 2019

TO: David Pruitt, MD

PROJECT TITLE: [1146402-3] SMAP-AV: Saving Mucosa with Prophylactic Aloe Vera Therapy
SUBMISSION TYPE: Amendment/Modification

ACTION: AMENDMENT APPROVAL
DECISION DATE: April 23, 2019
REVIEW TYPE: Expedited Review

Thank you for your submission to the Catholic Health Initiatives Institute for Research and Innovation Institutional Review Board (CHIRB). The CHIRB has APPROVED your amendment submission. All research must be conducted in accordance with this approved submission. The following documents have been approved or noted as part of this approval:

- Amendment/Modification - CHIRB Amendment-Modification Request Form.pdf (UPLOADED: 04/23/2019)
- Consent Form - 1146402 CHIRB INFORMED CONSENT Template v 21 AUG 2017 - Tracked-CHIRB Revised.docx (UPLOADED: 04/23/2019)
- Consent Form - Consent Form Clean - Please Use to Edit Future Submissions (UPLOADED: 04/23/2019)
- Other - PI Attestation form.pdf (UPLOADED: 04/18/2019)
- Protocol - Protocol Clean - Please Use to Edit Future Submissions (UPLOADED: 04/23/2019)
- Protocol - 1146402 SMAP - AV sent to FDA v2. v3, v4 2.22.19 - TRACKED Protocol - CHIRB Suggested Changes.docx (UPLOADED: 04/23/2019)

The following documents have been reviewed and revised as part of this approval and are required to be used for the conduct of this research going forward.

- Stamped Document [APPROVED FOR USE - Consent Form (Most Recently Approved)]

This revised consent form can be found under the "Reviews" tab in IRBNet. If you would like to make further changes to the consent form, please submit an Amendment/Modification through IRBNet.

**Please note that it is your responsibility to obtain any additional local institutional or departmental required approvals prior to initiating your study.**

If you have any questions at any time, please feel free to contact the CHIRB at 1-844-626-2299 or CHIRB@CatholicHealth.net. Please include your project title and reference number in all correspondence with the CHIRB so that we can best assist you.

Thank you.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Catholic Health Initiatives Institute for Research and Innovation Institutional Review Board (CHIRB)'s records.

The CHIRB requires prompt reporting (within 10 business days of discovery) of events that are Unanticipated Problems regardless of whether the event occurred at the local study site (internal UAP) or at another participating study site (external UAP). Unanticipated Problems are 1) unanticipated AND 2) serious or life-threatening or potential for increased risk AND 3) possibly or definitely related to the protocol, as determined by the investigator. Unanticipated deaths that meet these 3 criteria must be reported to the CHIRB within 24 hours of discovery. Events that are not Unanticipated Problems may be reported to the CHIRB in summary form at the time of continuing review. All FDA and sponsor reporting requirements should also be followed.

All major protocol departures regarding this study must also be reported within 10 business days to this office. Major protocol departures are events that impact the risk and benefit of the research; may impact subject safety, affect the integrity of research data and/or affect a subject's willingness to participate in the research. All minor protocol departures can be reported at the time of continuing review.

Please submit your continuing review through IRBNet, and use the appropriate forms. Your documentation for continuing review must be received with sufficient time for the CHIRB to review and to issue approval. **Your study expires on March 5, 2020, and your continuing review should be submitted to the CHIRB 45 days prior to this expiration date.** The CHIRB will send reminder emails prior to study expiration, but it is the responsibility of the investigator to provide continuing review documentation to the CHIRB for continued approval of this study.

Please note that all research records must be retained for a minimum of three years after the completion of the project. Consent forms, including those for optional procedures, or other study documents pertaining to HIPAA, must be maintained for at least 6 years after the end of the study.

The following documents have been approved or noted as part of this approval:

- CHI - Research Application - CHI - Research Application (UPLOADED: 04/1/2019)
- Protocol - Protocol (Clean) (UPLOADED: 03/18/2019)
- Letter - SMAP-AV Protocol Modifications for CHIRB.pdf (UPLOADED: 03/14/2019)
- Letter - FDA approval to proceed with trial.pdf (UPLOADED: 02/22/2019)
- Letter - Cover letter for CHIRB 2019.docx (UPLOADED: 02/22/2019)
- **NOT APPROVED FOR USE** - Consent Form - Tracked changes to informed consent 2019.pdf (UPLOADED: 03/13/2019)
- **NOT APPROVED FOR USE** - Consent Form - revised informed consent 2019.pdf (UPLOADED: 03/13/2019)

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