



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

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June 12, 2018

MEMORANDUM FOR CAPT JOHN GILSTAD, MC, USN, ARMED FORCES RADIOLOGY RESEARCH INSTITUTE

SUBJECT: USU Institutional Review Board (IRB) (FWA 00001628; DoD Assurance P60001)
Approval of Protocol CGHE-B1-9011 for Human Subjects Participation

Congratulations! The Initial Review for your No More than Minimal Risk human subjects research protocol CGHE-B1-9011, entitled "Comparing Hospital Hand Hygiene in Liberia: Soap, Alcohol, and Hypochlorite," was reviewed by the full Institutional Review Board on January 11, 2018 and approved with stipulations. The response to stipulations have been reviewed by a subcommittee of the IRB and approved by Edmund G. Howe, M.D., J.D., IRB Chair. The date of this approval is June 12, 2018. This approval will be reported to the USU IRB scheduled to meet on June 14, 2018.

The objectives of this multi-modal, multi-phase study is to (1) determine the most appropriate cleansing material for routine hand hygiene, and (2) determine how best to implement hand hygiene programs in Liberian health facilities. The specific aims of the study include (1) examining current hand hygiene infrastructure, practices, and barriers in health facilities in Lofa County and Bong County, Liberia (phase 1); (2) develop soap, alcohol, and chlorine-based hand hygiene interventions with key stakeholders (phase 2); (3) pilot soap, alcohol, and chlorine hand hygiene interventions for 8 months on wards (phase 3); and (4) test soap, alcohol, and chlorine hand hygiene interventions across entire hospitals for 12 months, evaluating implementation and effectiveness (phase 4).

This approval is limited to phase 1 of the study (exploratory phase involving qualitative interviews with hospital administrators and healthcare workers, quantitative spot check observations of existing hand hygiene infrastructure, and structured observations of hand hygiene actions by healthcare workers and family caregivers). For the observational aspect of phase 1, the full IRB waived the requirements for informed consent on May 30, 2018 pursuant to 32 CFR 219.116(d).

Note, this approval is contingent upon receipt of host country approval and subsequent Component level administrative review and approval. Research activities cannot commence until these approvals have been secured.

Authorization to conduct protocol CGHE-B1-9011 will automatically terminate on January 10, 2019. If you plan to continue data collection or analysis beyond this date, IRB approval for continuation is required. Please submit an application for continuing approval to the IRB Office 60 days prior to your termination date.



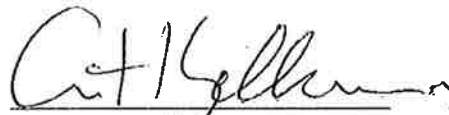
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You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding this IRB action or questions of a more general nature concerning human participation in research, please contact Micah Stretch at 301-295-0819 (micah.stretch@usuhs.edu) or Margaret Pickerel at 301-295-9813 or margaret.pickernel.ctr@usuhs.edu.

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Edmund G. Howe, M.D., J.D.,
Chair, IRB

 JUN 13 2018
Arthur L. Kellerman, MD, MPH Date
Professor and Dean, School of Medicine