

Application and Evaluation of Teledermatology In An Underserved Area of Honduras

Michael Ray Baze

Dissertation submitted to the Faculty of the Virginia Polytechnic Institute and State University in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

In

Curriculum & Instruction

H. Dean Sutphin, Chair
Richard K. Stratton
Kerry J. Redican
James R. Palmieri

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Blacksburg, Virginia

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Research and Graduate Affairs Institutional Review Board

Edward Via College of Osteopathic Medicine

Notice of Approval

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March 16, 2011

Michael Baze, DO
PhD Candidate

RE: IRB#2011/001, Application and Evaluation of Teledermatology in an Underserved area of Honduras

Dear Dr. Baze:

The proposed research is eligible for expedited review according to the specifications authorized by 45CFR 46.110 and 21 CFR 56.110. Your protocol has been reviewed via expedited procedure by two members of the VCOM IRB. Reviewer concerns and questions were addressed to you via email on March 4, 2011 and then again on March 15, 2011. Your responses and revised protocol have been reviewed and accepted by the reviewers and your project has been **approved**.

Please remember that as the PI, you are responsible for promptly reporting to the IRB any proposed changes in the research activity prior to being implemented. You are also responsible for promptly reporting any injuries or adverse events or unanticipated risks to subjects. If an adverse event that is both serious and unanticipated occurs, you must notify the IRB within 24 hours. In case of an adverse event that is serious but not unanticipated, you must notify the IRB within 5 working days. In case of an adverse event that is not serious, but is unanticipated, you must notify the IRB within 10 working days. If an unanticipated event involving risks to subjects or others (but not meeting the definition of an adverse event) occurs, the PI must notify the IRB within 10 working days.

Federal guidelines dictate that IRB-approved research must be reviewed no less than once a year. Note that your **continuation review will be March 16, 2012**. Approximately 30 days before this date, you will receive a Progress Report Form, Form D, from the IRB Coordinator. Please fill out this report and submit it to the IRB Coordinator at least two weeks prior to your review date. If re-approval is not obtained prior to the expiration date, all activities involving human subjects must cease immediately, except where necessary to eliminate immediate hazards to the subjects. If the study should close prior to the expiration date, please submit your report promptly using Form D, following closure of the study, to the IRB Coordinator.

Please be advised that the VCOM IRB will be conducting routine audits as a means of ensuring compliance with VCOM and federal policies in an effort to assure the protection of human subjects.

Your project may, at any time throughout the approval period, be subject to this type of monitoring.

Thank you for your cooperation. If you have any questions or concerns, please do not hesitate to contact the IRB Coordinator, Sharon Kauffman.

Sincerely,

A handwritten signature in black ink that reads "Hara P. Misra". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Hara P. Misra, DVM, PhD
Chairman, VCOM Institutional Review Board