Principal Investigator Notification:

From: Mayo Clinic IRB

To: Christopher Aakre

CC: Christopher Aakre
Mikhail Dziadzko
Vitaly Herasevich

Re: **IRB Application #:** 15-009228

Title: Evaluation of Clinical Score Usefulness and Feasibility of Integration into Electronic Health Record Interfaces

IRBe Protocol Version: 0.03
IRBe Version Date: 1/7/2016 12:18 PM

IRB Approval Date: 1/11/2016
IRB Expiration Date: 1/10/2017

The above referenced application is approved by expedited review procedures (45 CFR 46.110, items 5 and 7). This approval is valid for a period of 1 year. The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111.

The Reviewer noted that oral consent without HIPAA authorization is appropriate for the provider cohort of this study. The oral consent and E-mail script were reviewed and approved as written. The Reviewer approved waiver of the requirement for the Investigator to obtain a signed consent form in accordance with 45 CFR 46.117 as justified by the Investigator. As protected health information is not being requested from this subject group, HIPAA authorization is not required in accordance with 45 CFR 160.103. The surveys were reviewed and approved as written.

For the patient chart review cohort, the Reviewer approved waiver of the requirement to obtain informed consent in accordance with 45 CFR 46.116 as justified by the Investigator, and waiver of HIPAA authorization in accordance with applicable HIPAA regulations.

The Reviewer noted the Conflict of Interest (COI) Review Board determination related to Dr. Vitaly Herasevich. The Reviewer accepted the COI Review Board determination confirming conflict of interest. The Reviewer accepted the COI Review Board management plan.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.

3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO).
4) Compliance with Mayo Clinic Institutional Policies.
okay

Mayo Clinic Institutional Reviewer

From: Sveen Ziebell, Monica M., M.B.A.
Sent: Monday, March 14, 2016 8:08 PM
To: Aakre, Christopher A. (Chris), M.D.
Cc: Herasevich, Vitaly, M.D., Ph.D.
Subject: RE: Question about COI review recommendations for IRB # 15-009228

Disclosure would only be required for the survey related to AWARE.

Monica

Monica Sveen-Ziebell, M.B.A.
Administrator
Office of Medical-Industry Relations and
Conflict of Interest Review
Phone: (507) 538-8288
email: sveenziebell.monica@mayo.edu

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Mayo Clinic
200 SW 1st Street
Rochester, MN 55905
www.mayoclinic.org

From: Aakre, Christopher A. (Chris), M.D.
Sent: Monday, March 14, 2016 10:39 AM
To: Sveen Ziebell, Monica M., M.B.A.
Cc: Herasevich, Vitaly, M.D., Ph.D.
Subject: Question about COI review recommendations for IRB # 15-009228

Mrs. Sveen Ziebell,

Dr. Herasevich and I have a question about the recommended COI management strategy #4 for IRB #15-009228, where disclosure was recommended in the participant survey that:

> "One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research."

The study is performing two participant surveys; We are contacting you to clarify which survey requires this disclosure (one or both).

Survey #1 – Multi-specialty survey on clinical score usefulness. This survey is not related to AWARE.
Survey #2 – Usability assessment of a module integrated into AWARE that automatically calculates a specific clinical score.

We are assuming the second survey requires the disclosure because it involves AWARE. However, the first survey is not related to AWARE. Does the first survey also require the disclosure?

Thank you for your time.

Sincerely,
Chris Aakre