University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

APPROVAL OF SUBMISSION

July 13, 2018

Dear ANDREW TALAL:

On 7/13/2018, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	A prospective study showing the effect of video interactive education on medical decision making in patients on opiate replacement therapy (ORT) with a history of Hepatitis C.
Investigator:	ANDREW TALAL
IRB ID:	STUDY00002677
Funding:	Name: Merck Sharp & Dohme Corporation
Grant ID:	
IND, IDE, or HDE:	None
Documents Reviewed:	• Brochure 4, Category: Other; • data spreadsheet, Category: Other; • Brochure consent, Category: Consent Form; • Brochure 3, Category: Other; • video consent, Category: Consent Form; • Brochure 7, Category: Other; • poster 5, Category: Recruitment Materials; • poster 3, Category: Recruitment Materials; • poster 2, Category: Recruitment Materials; • poster 1, Category: Recruitment Materials; • demographic questionnaire, Category: Surveys/Questionnaires; • Brochure 1, Category: Other; • HCV pre and post test, Category: Surveys/Questionnaires; • REALM SF, Category: Other; • Brochure 6, Category: Other; • poster 4, Category: Recruitment Materials; • Brochure 5, Category: Other; • IRB MERCK07132018 with track changes (1).docx, Category: IRB Protocol; • AF_18104221.pdf, Category: Sponsor Attachment; • Brochure 2, Category: Other;

The IRB approved the study from 7/13/2018 to 7/12/2019 inclusive. The Initial study materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Non-committee Review. Before 7/12/2019 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review application with required explanations. You can submit a continuing review application by navigating to the active study in Click IRB and selecting 'Create Modification / CR'. Studies cannot be conducted beyond the expiration date without re-approval by the UBIRB.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

HIPAA Authorization combined with consent document

The consent form document includes the HIPAA authorization for use/disclosure of personal health information and has met the required elements of the federal regulations of HIPAA.

UBIRB approval is given with the understanding that the most recently approved procedures will be followed and the most recently approved consent documents will be used. If modifications are needed, those changes may not be initiated until such modifications have been submitted to the UBIRB for review and have been granted approval.

As principal investigator for this study involving human participants, you have responsibilities to the SUNY University at Buffalo IRB (UBIRB) as follows:

1. Ensuring that no subjects are enrolled prior to the IRB approval date.
2. Ensuring that the study is not conducted beyond the expiration date without re-approval by the UBIRB.
3. Ensuring that the UBIRB is notified of:
    - All reportable information in accordance with the New Information SOP (HRP-024).
    - Project closure/completion by submitting a Continuing Review/Modification submission.
4. Ensuring that the protocol is followed as approved by UBIRB unless a protocol amendment is prospectively approved.

5. Ensuring that changes in research procedures, recruitment or consent processes are not initiated without prior UBIRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. Ensuring that the study is conducted in compliance with all UBIRB decisions, conditions, and requirements.
7. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.
8. Bearing responsibility for securing any other required approvals before research begins.

If you have any questions, please contact the UBIRB at 716-888-4888 or ub-irb@buffalo.edu. Please include the project title and number in all correspondence with the UBIRB.