THE FENWAY INSTITUTE

FENWAY HEALTH

Institutional Review Board
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DATE:	September 6, 2017
TO:	Sean Cahill, PhD
FROM:	Fenway Community Health IRB
PROJECT TITLE:	[919387-10] Developing HIV prevention strategies to engage adolescent MSM and transgender youth
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
APPROVAL DATE:	September 6, 2017
EXPIRATION DATE:	October 4, 2017
REVIEW TYPE:	Expedited Review

Thank you for your submission of Amendment/Modification materials for this project. The Fenway Community Health IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission included the following project documents:

- Abstract/Summary - Protocol Summary - TRACK CHANGES.doc (UPDATED: 09/5/2017)
- Abstract/Summary - Protocol Summary.doc (UPDATED: 09/5/2017)
- Advertisement - Att 5a. Focus Group Recruitment Ads - TRACK CHANGES.pptx (UPDATED: 09/5/2017)
- Advertisement - Att 5a. Focus Group Recruitment Ads.pptx (UPDATED: 09/5/2017)
- Application Form - Amendment Application - 9.5.17.docx (UPDATED: 09/5/2017)
- Consent Form - Att 4b. Informed Assent.docx (UPDATED: 09/6/2017)
- Consent Form - Att 4a. Informed Consent.docx (UPDATED: 09/6/2017)
- Consent Form - Att 4b. Informed Assent - TRACK CHANGES.docx (UPDATED: 09/6/2017)
- Consent Form - Att 4a. Informed Consent - TRACK CHANGES.docx (UPDATED: 09/6/2017)
- Other - Att 5b. Recruitment Language - TRACK CHANGES.docx (UPDATED: 09/5/2017)
- Other - Att 5b. Recruitment Language.docx (UPDATED: 09/5/2017)
- Other - Att 3b. AMSM Focus Group Guide.docx (UPDATED: 09/5/2017)
- Other - Att 3b. AMSM Focus Group Guide - TRACK CHANGES.docx (UPDATED: 09/5/2017)

- Protocol - Protocol.docx (UPDATED: 09/5/2017)
- Protocol - Protocol - TRACK CHANGES.docx (UPDATED: 09/5/2017)

This submission has received Expedited Review based on the applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All Unanticipated Problems, Serious Adverse Events, Major Protocol Violations and Research Related Incidents must be reported promptly in accordance with Fenway IRB reporting requirements. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee by October 4, 2017. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of October 4, 2017.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact the Manager of Research Integrity and Compliance at regulatory@fenwayhealth.org. Please include your project title and reference number in all correspondence with the regulatory office.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Fenway Community Health IRB's records.