FENWAY COMMUNITY HEALTH IRB
Waiver or Alteration of Informed Consent

Protocol Title:	Developing HIV prevention strategies to engage adolescent MSM and transgender youth
IRBNet Number:	919387-1
Protocol Version/Date:	V1.0 08-17-16
Principal Investigator:	Sean Cahill, PhD (TFI)
Co-Investigators:	Kerith Conron, ScD, MPH and Holly Fontenot, PhD, RN, WHNP-BC
Study Coordinator	Sophia Geffen
Sponsor:	CDC Division of Adolescent and School Health, National Opinion Resource Center

Use section A of this form to request Fenway IRB review if you propose to obtain informed consent for the research activity without also obtaining the participant's signature on the consent form. Note: If the IRB grants this waiver, the investigator will still be required to provide information about the research to each potential participant, but the participant's signature on the form will not be required. A written script of the information that will be read or given to potential participant must be provided for IRB review with this submission. In addition to describing the study, the script must contain the basic elements of informed consent, as referenced in 45CFR46.116(a) and 21CFR50.25. If the study will collect protected health information (PHI), the script must also present the core elements of authorization, as referenced in 45CFR164.508(c). A request for waiver or alteration of HIPAA authorization, found on IRBNet website within forms and templates, must also be submitted.
Use section B of this form to request Fenway IRB review if you propose to waive or alter all or some of the elements of consent or the consent process for the research activity. Note if the research activity plans to collect protected health information (PHI), you will need to submit a request for a waiver or alteration of HIPAA authorization. Section B applies only to research that is subject to Department of Health and Human Services (HHS) regulations. It does not apply to research that is subject to Food and Drug Administration (FDA) regulations.

Please select one:

☒ Waiver of written informed consent (i.e., waiver of the signature) (complete Section A)

☐ Waiver or alteration of required elements of informed consent process (complete Section B)

Section A

45 CFR 46. 117 (c) states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
Please check the type of waiver you are requesting.

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☒ (1) A waiver of written informed consent because the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality.

> ***This applies only to research that is subject to Department of Health and Human Services (HHS) regulations. It does not apply to research that is subject to Food and Drug Administration (FDA) regulations.***

(For example, the only record of the name or other identifying information of the subject would be the signed consent form and knowledge of an individual's participation or information provided could lead to potential legal, social, or physical harm.)

Describe how the proposed research meets the condition outlined above:

1. The research involves no more than minimal risk to the subjects.

It is unlikely that participants will be at any risk for harm as a result of study participation. No identifiers or contact information will be collected as a part of the focus groups, thus, obtaining a signature as a part of the informed consent process would increase risk for participants. Further, no other identifiers are necessary since participants will not be followed after the focus groups and there is no need for locator forms or any other collection of identifying information.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

The waiver of each participant's signature will not affect the standard and reasonable protections afforded all TFI research participants. Participation in the focus groups is completely voluntary. Participants may decide not to take part or to withdraw from participation at any time without penalty or loss of any benefit to which they are otherwise entitled. The specific names of participants will not be recorded or made public at any time during the study, including publication of findings. None of the information will become part of any medical record, and all study records will be strictly maintained according to current legal requirements.

3. The research could not practicably be carried out without the waiver or alteration.

Because we do not collect identifying information as a part of the focus groups, a written consent would require additional identifying information that could potentially link subjects to their participation in the study.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

For study-related questions or concerns, information to contact TFI study staff, the TFI Coordinator of Research Compliance and the TFI Institutional Review Board will be made available to the focus group participants. Additionally, all

results from this study will be published in academic journals which are accessible to members of the public, including those who participated in the study.

☐ 45 CFR 46.117 (c) ; 21 CFR 56.109 (c)
(2) Waiver of written informed consent because the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

This applies to research that is subject to either HHS regulations or FDA regulations.

(For example, no questions are being asked that could result in potential embarrassment, personally or professionally.)

Describe how the proposed research meets the condition outlined above:

_____

When waiving the requirement for written consent, the FCH IRB requires that you submit a script or letter to participants that addresses the eight required elements of consent as stated in 45 CFR 46.116 (a)(1-8).

To document the explanation and review of the informed consent process with the participant an investigator can use an oral consent or an informational sheet.

Oral consent ☒ **(include oral consent script in submission)**
Information sheet ☒ **(include information sheet in submission)**

Section B

45 CFR 46 116 (d) allows an IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that all of the following criteria are met:
Provide supporting information for each criterion.

This applies only to research that is subject to Department of Health and Human Services (HHS) regulations. It does not apply to research that is subject to Food and Drug Administration (FDA) regulations.

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(1) The research involves no more than minimal risk to the subjects;
_____

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
_____

(3) The research could not practicably be carried out without the waiver or alteration; and
_____

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (If yes, include copy of debriefing statement)
_____