FENWAY COMMUNITY HEALTH IRB
Waiver of Parental Permission

Protocol Title:	Developing HIV prevention strategies to engage adolescent MSM and transgender youth
IRBNet Number:	919387-1
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Principal Investigator:	Sean Cahill, PhD
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

The IRB may waive the requirement for obtaining permission (consent) from a parent or legal guardian for research that is not FDA-regulated if both of the following are true: the research meets the provisions for waiver in 45 CFR 46.116(d)(1-4); or the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), and an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and that the waiver is not inconsistent with Federal State or local law.

Section A: Waiver of Parental Permission (consent)

For non-FDA-regulated studies, waiver of parental/guardian permission is possible under 45 CFR 46.408(c) if the Fenway IRB finds one of the following (select appropriate waiver justification):

☒ **The waiver meets the provisions set forth in 45 CFR 46.116, Subpart A:**

- Research involves no more than minimal risk;
- Waiver will not adversely affect rights and welfare of the subjects;
- Research could not practicably be carried out without waiver; and
- Whenever appropriate, subjects will be given additional information after participation.

Provide explanation of why study meets above bulleted criteria for waiver of parental permission (consent):

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 parental permission 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 minor's parental permission 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.

Contacting a parent/legal guardian could constitute a breach of confidentiality for sexually active, young men, transgender women or transgender men who have sex with men and could potentially put some sexual and/or gender minority-identified youth at risk for abuse or ousting from the home if parents/legal guardians are not aware of their sexual orientation, gender identity or sexual behaviors.

It is expected that there will be parents/legal guardians who will not be aware of the subject's gender identity, sexual orientation or risk behaviors. A requirement for parental permission in this type of study could not only affect a person's willingness to participate, but could also potentially impact the ability of researchers to engage in this type of HIV-related research with adolescent MSM and transgender youth.

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.

Adequate protection has been substituted by the mechanisms in place to protect the privacy and confidentiality of subjects and by the treatment referrals offered if needed.

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☐ **Parental permission is not a reasonable requirement.**

- Permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children); and
  - An appropriate mechanism for protecting the children in the research is substituted; and
  - The waiver is not inconsistent with Federal, State, or local law.

Provide explanation of why study meets above bulleted criteria for waiver of parental permission (consent):