

Notification of Exempt Determination

Date: February 22, 2021

Principal Investigator: david lounsbury, PhD

Study Title: Provider-targeted communications strategies to reduce stigma and promote PrEP uptake

IRB #: 2020-12407

Reference #: 070180

Type of Submission: Submission Response for Initial Review Submission form

Determination Date: 02/22/2021

Expiration Date: 02/21/2024

Exempt Category

- Exempt 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

HIPAA Determination

- HIPAA does not apply to this study.

This study is consenting participants and therefore the study must be activated in the Velos system. Please be sure that either you or your coordinator are trained and certified in use of the Velos system and that your study is activated in Velos before any participants are recruited to your study.

To request access for Velos/EPIC Training, please contact the Montefiore IT help desk via email (itservicedesk@montefiore.org) or (914) 881-4554 requesting instructions on how to sign up for Velos/EPIC Training.

PIs Only: Please email veloshelp@montefiore.org to request the PI online training link.

Data Use Agreements: If you are releasing data to an external site/entity/collaborator, you are required to obtain a DUA (Data Use Agreement). This may be obtained through the Research Agreement Request Portal (https://einsteinmed.co1.qualtrics.com/jfe/form/SV_8fgVaus0Bpcpeux).

Re-review by the IRB will be required if any substantive change is made in the protocol during the course of the study, to determine whether or not the study still qualifies as Exempt Research.

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

Reviewed Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

Expiration Notice: Institutional approval for this study is limited to the period specified above. In order to gain re-approval, you must submit a Progress Report by 01/21/2024. To facilitate this, iRIS will send an email reminder 60 days prior to the due date. When this project is completed, submit a final Progress Report to close the file.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.