FRED HUTCH
Institutional Review Board

Research Modification Form

Date:	03MAY22	**IR File #:**	10869
RG #:	RG1122194	**Sponsor's Protocol #** *(if applicable)*:	
Modification Version #:			

This box is for IRO only

IRO received 05/04/22

Date Received: _____

Principal Investigator:	James G. Kublin, MD, MPH	**Email:**	jkublin@fredhutch.org	**Phone:**	(206) 667-1970
Contact Person:	Caitie Hawley/Laurie Rinn	**Email:**	chawley@fredhutch.org	**Phone:**	419-371-1643
Study Title:	Red Ribbon Registry: A database of people interested in HIV clinical trials.				

Have you consulted with anyone in the IRO about this Modification? Who and when? No

1. What is being modified? Describe all changes, paying special attention to the boxes checked in Question 2, and provide a rationale for each. (Include at least a brief summary here; in addition, you may submit a separate memo with additional details if necessary.)

From the time this project was initially submitted to the IRB back on 28JAN22, several other aspects of the project have been developed for which we are seeking IRB approval. These include the following:

1. Text that will appear on the registry landing page ("Welcome" text that is mostly derived from the study ICF), the "Thank you" text that will appear on a page once a volunteer submits their survey, as well as opt out text for if a volunteer decides they no longer want to receive communications that are not related to joining a specific study.
2. We developed a set of emails that will be automatically generated by the Registry when a volunteer completes certain milestones:
   a. When a volunteer creates a new registration
   b. When someone has not completed a survey (reminder to finish)
   c. When a volunteer requests to be removed from the registry
   d. When a volunteer updates their registration
3. Text and graphical layout for the page on our public-facing website that pertains to the Red Ribbon Registry
4. Spanish translations and certificates of translation for the following items listed below. Please note, that in order to expedite this process, we obtained translations in advance of IRB approval. If there are any requested changes to

This box is for IRO only

Reviewing Committee (Reg ID): ☐ A (0021) ☐ B (0022) ☐ C (5619) ☒ D (9831)

Assurance #: FWA00001920

Review Type - ☐ Full ☒ Expedited ☐ Exempt/Admin

Agenda Date: 6/1/2022

Revision/Modification: M220503

Stacey Cohen
Digitally signed by Stacey Cohen
Date: 2022.05.05 12:51:51 -07'00'

Approval Signature, Chair or Designee

5/5/2022
Date

Stacey Cohen
Printed Name

****VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED****

DISTRIBUTION: ORIGINAL – IR File COPIES to: Investigator, Contact Person

For Review Type Expedited, the "Agenda Date" above is the date the expedited approval gets reported to the convened IRB.