

Red Ribbon Registry Clinical Data Transfer and Use Agreement

This Data Transfer and Use Agreement governs an arrangement through which the data described below is made available to you. The data derives from the NIAID HIV Clinical Trials Networks protocol “Red Ribbon Registry: A database of people interested in HIV clinical trials,” and is designed to create a database of people interested in participating in NIAID-funded HIV clinical trials conducted by the ACTG, HPTN, HVTN and IMPAACT networks. The HIV Clinical Trials Volunteer Screening Registry, named the Red Ribbon Registry (R3) will collect preliminary data from these volunteers to categorize their potential for participation in a diverse set of HIV clinical trials conducted by the networks as described above. Data will be made available to the clinical trials site(s) in the vicinity of the participant’s residence for outreach and recruitment into appropriate HIV clinical trials.

The Data Set will contain individual identifiers as set forth in 45 CFR 164.514(e)(2). The “Data Set” refers collectively to all downloads or volunteer data obtained from the registry. Individual identifiers will be provided to you under the following data use conditions:

Use of Data Set

Use of Data Set. You will use the Data Set only for purposes of identifying potential volunteers to participate in HIV Clinical Trials conducted in collaboration with the NIAID HIV Clinical Trials Networks (the “Purpose”) and for no other use.

Permitted Users. The Data Set will be used solely by you. You will restrict access to the Data Set and prevent unauthorized users from using or accessing it.

No Transfer. You will not distribute or transfer the Data Set to any unauthorized person or any third party for any reason.

No Unapproved or Commercial Use. You will not use the Data Set for any purpose other than the Purpose. You will not use the Data Set in any research that is subject to consulting or licensing obligations to any for-profit organizations.

Use under Suitable Containment. You agree to store, transfer, and use the Data Set under suitable containment conditions pursuant to the HIPAA Security Rule described in 45 CFR Part 160 and Subparts A and C of 45 CFR Part 164. Under no circumstances may the Data Set be emailed or transferred via mobile storage devices.

Confidentiality of the Data Set. You agree to maintain the confidentiality of the Data Set. You agree not to disclose any of the Data Set in any form other than to authorized users. You will not use the Data Set for publication.

No Warranties. The Data Set is provided “as is” without any express or implied warranties of any kind.

Unique Identifiers. You agree to retain unique identifiers provided for each volunteer and to transmit any status updates solely using these identifiers.

Breach Notification. You agree to notify Fred Hutch immediately upon becoming aware of any data security breach. Notices should be directed to generalcounsel@fredhutch.org with a copy to jkublin@fredhutch.org.

Compliance. You agree to utilize the Data Set in accordance with all applicable laws, including but not limited to the Health Insurance Portability and Accountability Act of 1996, as amended, and all applicable organizational guidelines and policies. By accessing the Data Set, you represent that you have all applicable approvals in place that are necessary to use and access the Data Set for the Purpose, including but not limited to approval by an Institutional Review Board.

Deletion of Data Set. You agree to delete the Data Set from your device and servers upon the first of

the following to occur: (a) completion of enrollment by your organization for the particular clinical trial for which the Data Set was downloaded; or (b) completion or termination of the Purpose.