



Institutional Review Board Notice of Approval

Principal Investigator/Project Director: Jane Fox

Project Title: Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) Recipient Data (Chart Abstraction)

Sponsor Agency: DHHS/HRSA

Abt IRB #: 2004

Protocol Approval Date: 4/22/2019

Review Type: Expedited per 45CFR46.110 (Category 5)

Type of Approval: Full Implementation

The Abt IRB approved a waiver of consent per 45CFR46.116(f) and has determined that the waiver of HIPAA authorization satisfies the three criteria in the Privacy Rule per 45CFR164.512(i):

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

- (1) An adequate plan to protect the identifiers from improper use and disclosure;
- (2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- (3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information described in the protocol including: medical chart data of Ryan White HIV/AIDS Program (RWHAP) clients

Please note the following requirements:

Problems or adverse reactions: If any problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson or IRB Administrator immediately.

Renewal: You are required to apply for renewal of approval at least annually for as long as the study is active. Your next review date should be on or before **4/21/2020**.

A handwritten signature in black ink, appearing to read "Tenzin Dorkan". The signature is written in a cursive, flowing style.

Teresa Doksum, Ph.D., M.P.H.
IRB Chair
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138
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617-349-2896

Date: 4/22/2019

Cc: Katie Speanburg, IRB Administrator



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Project Title: Chart Abstraction of Ryan White HIV/AIDS Program (RWHAP) Recipient Data (Chart Abstraction)

Sponsor Agency: HRSA

Abt IRB #: 2004

Review Type: Expedited

Approval Date September 16, 2019

Type of Approval: Study Modification

Modification Number: Submitted 9/10/2019 re: expanding eligibility criteria

Please note the following requirements:

The Board's approval of this modification does not alter your responsibilities for the project's continuing review.

Problems or adverse reactions: If any problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson or IRB Administrator immediately.

Consent forms: In the event the approved study includes procedures for written informed consent, you only may use consent forms that bear the Abt Associates Inc. (or local) IRB approval stamp.

Renewal: You are required to apply for renewal of approval at least annually for as long as the study is active. Your next review date should be on or before **April 21, 2020**.

IRB Chair
Teresa Doksum
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Date
October 9, 2019

Cc: Cicely Wanska