MEMO

To: Julie Wise, OIRA Desk Officer

Through: Project Clearance Branch, HHS

From: Simone Glynn, Branch Chief, NHLBI

Subject: Change Request for Prevalence, Incidence, Epidemiology and Molecular Variants of

HIV in Blood Donors in Brazil, OMB Control Number, 0925-0597, Expiration

Date: July 31, 2015.

We would like to modify the existing OMB approved HIV risk behavior questionnaire. We have identified a few areas that can be improved. These areas include providing a specific definition of the sexual behaviors we are interested in during the risk factor interview, adding addition response options for transgender responses, and adding questions on the age of sexual debut. The proposed changes will not alter the respondent burden because only two questions (E3 and E5) for each person who completes the questionnaire are new. The remaining changes are clarifications and addition of more answer options.

Definition of Sex.

We would like to include the following more explicit definitions of sex in the instructions of Sections E and F as follows:

Please note: For the next few questions the terms sexual contact and sex refer to any of the following activities, whether or not a condom or other protection was used: Vaginal sex (contact between penis and vagina), Oral sex (mouth or tongue on someone's vagina, penis, or anus), Anal sex (contact between penis and anus).

Justification: These are the definitions of sex that have been adopted by the American Association of Blood Banks. In addition, these are the definitions of sex we are using in the currently approved US blood donor risk factor study ("Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance (NHLBI)." OMB Control Number: 0925-0630, Expiration Date: April 30, 2014).

Age of Sexual Debut.

E3. (Ask of Men Only) How old were you when you had sex with a woman for the first time?

9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

E5. (Ask of Men Only) How old were you when you had sex with a man for the first time?

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9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

E7. (Ask of Women Only) How old were you when you had sex with a man for the first time?

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9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

E9. (Ask of Women Only) How old were you when you had sex with a woman for the first time?

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9997 Don't Know

9998 Refuse to Answer

9999 Not Applicable

Justification: Adding these questions will help establish the age of opposite sex and same sex debut if persons have answered yes to the previous questions about having had opposite or same sex sexual relations. Early sexual debut has been associated with drug use and sexual risk behaviors, including number of sexual partners and sexual activity under influence of substances (1).

Reference:

(1) Long-term health correlates of timing of sexual debut: results from a national US study. Sandfort TG, Orr M, Hirsch JS, Santelli J. Am J Public Health. 2008 Jan;98(1):155-61.

Addition of Transgender Answer Options.

- E1. What do you consider yourself to be? (Choose one)
 - 1 Straight/heterosexual
 - 2 Bisexual
 - 3 Gay/homosexual
 - 4 Transgender
 - 7 Don't Know

8 Refuse to Answer G2. What is Partner 1's gender? 1 Male 2 Female Transgender 7 Don't Know 8 Refuse to Answer G19. What is Partner 2's gender? 1 Male 2 Female 3 Transgender 7 Don't Know 8 Refuse to Answer G36. What is Partner 3's gender? 1 Male 2 Female Transgender 7 Don't Know 8 Refuse to Answer G53. What is Partner 4's gender? 1 Male 2 Female Transgender 7 Don't Know 8 Refuse to Answer What is Partner 5's gender? G70. 1 Male 2 Female 3 Transgender 7 Don't Know

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Refuse to Answer

Justification: Although this is a sensitive topic, adding this answer option in the ACASI interview for the HIV case study will provide some insight for the HIV epidemiology among blood donors in Brazil. Studies

have demonstrated that transgender populations especially male to female (MFT) are more likely to report risky behaviors activities (2). Also previous reports on health of transgender suggest this community is disproportionately affected by HIV and other sexually transmitted infections (3,4). A recent survey among 575 MSM in a city in Sao Paulo state, Brazil has revealed that 85% classified themselves as men, and 15% as transgender. In addition, 32% reported childhood experiences with older partner (5). Blood centers in Brazil usually don't ask sex with transgender questions during the donor health screening questionnaire.

References:

- (2) Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepaz N. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review.; HIV/AIDS Prevention Research Synthesis Team. AIDS Behav. 2008 Jan;12(1):1-17.
- (3) Bauer GR, Travers R, Kyle Scanlon K, Coleman TA. High heterogeneity of HIV-related sexual risk among transgender people in Ontario, Canada: a province-wide respondent-driven sampling survey. BMC Public Health. 2012;12:292
- (4) Clements-Nolle K, Marx R, Guzman R, Katz M.HIV prevalence, risk behaviors, health care use, and mental health status of transgender persons: implications for public health intervention. Am J Public Health. 2001;91:915–921.
- (5) Alex A Carballo-Diéguez, Ivan I Balan, Curtis C Dolezal, Maeve B MB Mello. Recalled sexual experiences in childhood with older partners: a study of Brazilian men who have sex with men and male-to-female transgender persons. Arch Sex Behav **41**(2):363-76 (2012).