



## **Informed consent for HIV phylogenetic research: A case study of urban individuals living with HIV approached for enrollment in an HIV study**

### *Consentimiento informado para la investigación filogenética del VIH: un estudio de caso sobre individuos que viven con el VIH en una zona urbana que fueron contactados para la participación en un estudio sobre el VIH*

Abby E. Rudolph (1), Omar Martinez (2), Robin Davison (2), Chineye Brenda Amuchi (3)

(1) Department of Epidemiology and Biostatistics, Temple University College of Public Health, Philadelphia, USA

(2) School of Social Work, Temple University College of Public Health, Philadelphia, USA

(3) Department of Epidemiology, Boston University School of Public Health, Boston, USA

**Abstract:** *Introduction:* Phylogenetic analyses can provide insights on HIV transmission dynamics. Country and state-level differences in HIV criminalization and disclosure laws and advances in next generation sequencing could impact perceived study risks. *Methods:* We present study opt-out rates and the reasons provided during enrollment for a study conducted in Boston (6/2017-8/2018). *Results:* Of 90 patients approached to participate, 45 did not consent to participate. Reasons for not participating included unwillingness to discuss their HIV status, privacy and confidentiality concerns, disinterest, and lack of time. *Conclusions:* Given low participation rates and concerns related to HIV disclosure, privacy, and confidentiality, these questions remain (1) should informed consent be required for all phylogenetic analyses, including de-identified and surveillance data? (2) what additional steps can researchers take to protect the privacy of individuals, particularly in contexts where HIV is criminalized or there have been civil/criminal cases investigating HIV transmission? And (3) what role can community members play to minimize the potential risks, particularly for those most marginalized? These questions require input from both researchers and community members living with HIV/AIDS.

**Keywords:** HIV epidemiology, Stigma, Informed consent, Disclosure, Phylogeny.

**Resumen:** *Introducción:* Los análisis filogenéticos pueden proporcionar información sobre la dinámica de transmisión del VIH. Las diferencias a nivel nacional y estatal en las leyes de criminalización y divulgación del VIH y los avances en la secuenciación de la próxima generación podrían afectar los riesgos percibidos del estudio. *Métodos:* Presentamos las tasas de exclusión voluntaria del estudio y las razones proveídas durante la inscripción para un estudio realizado en Boston (6/2017-8/2018). *Resultados:* De los 90 pacientes que se acercaron para participar, 45 no dieron su consentimiento para participar. Las razones para no participar incluyeron la falta de voluntad para discutir su estado en relación con el VIH, preocupaciones de privacidad y confidencialidad, desinterés y falta de tiempo. *Conclusiones:* Dadas las bajas tasas de participación y las preocupaciones relacionadas con la revelación del estado serológico con respecto al VIH, la privacidad y la confidencialidad, estas preguntas permanecen (1) ¿se debe requerir el consentimiento informado para todos los análisis filogenéticos, incluyendo la información anónima y datos de vigilancia? (2) ¿qué pasos adicionales pueden tomar los investigadores para proteger la privacidad de las personas, particularmente en contextos donde el VIH es criminalizado o ha habido casos civiles / criminales que investigan la transmisión del VIH? Y (3) ¿qué papel pueden desempeñar los miembros de la comunidad para minimizar los riesgos potenciales, particularmente para los más marginados? Estas preguntas requieren aportes tanto de investigadores como de miembros de la comunidad que viven con el VIH/SIDA.

**Palabras claves:** Epidemiología del VIH, estigma, consentimiento informado, divulgación, filogenia

Received: 11/11/2019 Reviewed: 07/06/2020 Accepted: 08/06/2020 Published: 07/07/2020

*Referencia normalizada:* Rudolph, A.E., Martínez, O., Davinson, R. & Amuchi, Ch.B. (2020). Informed consent for HIV phylogenetic research: A case study of urban individuals living with HIV approached for enrollment in an HIV study. *Ehquidad. International Welfare Policies and Social Work Journal*, 14, 129-144. Doi: 10.15257/ehquidad.2020.0015

*Correspondencia:* Abby E. Rudolph, PhD, MPH. Temple University College of Public Health. Department of Epidemiology and Biostatistics. Correo electrónico: [abby.rudolph@temple.edu](mailto:abby.rudolph@temple.edu)

**Conflict of Interest Statement:**

The authors report no conflict of interest.

**Authorship:**

A.E.R. and O.M. conceived the manuscript concept and drafted an initial outline together; A.E.R. took the lead on writing the manuscript with legal input from O.M. and R.D.; C.B.A. conducted participant interviews, drafted the initial study tran chart, and provided additional context for research findings; all authors provided critical feedback and approved a final transmi of the manuscript.

**Acknowledgements:**

This research was funded by NIH/NIAID grant number R21AI131979 (PI: Rudolph). The content is solely the responsibility of the authors and does not necessarily represent the transmi views of the NIH. All study materials and research protocols were reviewed and approved by the Institutional Review Board at Boston University Medical Center.

## 1. INTRODUCTION

HIV phylogenetic anaylisis involves sequencing the HIV viral genome, or specific regions of the genome, to identify putative transmission links and/or clusters of related infections based observed viral sequence similarities. Partial HIV-1 *pol* gene sequences obtained from routine genotypic tests of drug resistance, encode sufficient viral variation to infer putative HIV transmission linkages (suggestive of a common source of infection).(Hué, Clewley, Cane, & Pillay, 2004) The public health benefits of phylogenetic analyses have been profound. For example, phylogenetic analyses have revealed relevant information for transmission prevention programs (i.e., ongoing transmission of drug-resistance,(Chan et al., 2011; Grabowski & Redd, 2014) associations between demographic and behavioral characteristics and viral spread,(Chan et al., 2013; Grabowski & Redd, 2014) presence of sub-epidemics and their longitudinal dynamics within risk groups,(Chan et al., 2015; Hué et al., 2004) and the role that very late presenters,(Audelin et al., 2013) acute/chronic infections,(Dennis et al., 2014) undiagnosed infections,(Fisher et al., 2010) and migration(Frentz et al., 2013; Grabowski et al., 2014; Hué, Pillay, Clewley, & Pybus, 2005; Mehta et al., 2015; Wertheim et al., 2014) play in specific epidemics). HIV testing programs can also use information obtained from these analyses to target uninfected persons with geographic, risk behaviors, and demographic characteristics similar to those in HIV transmission clusters(Dennis et al., 2012).

Potential harms to the individual include the risk of HIV disclosure, loss of confidentiality, and legal consequences including criminal prosecution and civil liability. According to a report published in 2016, 72 countries (and 30 states within the United States) had adopted laws permitting the criminalization of HIV. (Coltart et al., 2018) Though there is variation among criminalized behaviors within the United States, twenty-four states require HIV positive individuals who are aware of their diagnosis to disclose their status to sexual partners and fourteen states require disclosure to needle-sharing partners. (Lazzarini et al., 2013) At the time the 2016 report was published, prosecutions for not disclosing one's HIV status, potential or perceived HIV exposure, and/or unintentional transmission had been reported in 61 countries. (Coltart et al., 2018) Although transmission between two individuals cannot be proven solely with phylogenetic analyses (i.e., similarity could also be due to a common source of infection or an unsampled intermediary), phylogenetic analysis has been presented in both criminal and civil cases as evidence to prove/disprove transmission between two parties (Abecasis, Pingarilho, & Vandamme, 2018).

## **2. HIV DISCLOSURE LAWS AND IMPLICATIONS FOR INFORMED CONSENT FOR PHYLOGENETIC RESEARCH**

While thirteen states (Idaho, Kansas, Missouri, Nevada, New Jersey, North Dakota, South Dakota, South Carolina, Tennessee, Utah, Vermont, Wyoming) and the District of Columbia have no laws governing informed consent, there is significant variation among informed consent laws in the other states. For example, in Massachusetts, the state in which the current study was conducted, written informed consent is required prior to disclosing test results to a third party (i.e., researchers) and before disclosing the identity of the tested individual. The written consent form must state the purpose for the requested information, separate from the written consent for the release of any other medical information. To meet the requirements of written informed consent, an individual must sign a specific release authorizing the health care provider to test for HIV and/or disclose the results of an HIV test. A general release to a

health care provider authorizing the disclosure of medical records and information is insufficient. ("HIV test; informed consent; disclosure of results or identity of subject of test," ; The 191st General Court of the Commonwealth of Massachusetts) It is important to note that these restrictions only prohibit the disclosure of HIV status by health care providers. It is not a violation of informed consent laws for a physician, health care provider/institution or laboratory to disclose positive HIV test results to the department of public health. In fact, physicians and laboratories in Massachusetts, as in every state and the District of Columbia, are required to report all newly diagnosed cases of HIV to local or state health departments. (Forbes, 1996) However, state laws and policies do not always address the issue of research use of public health surveillance data. Data collected under public health authority does not require informed consent for the disclosure of this data for research purposes. Further, written informed consent to use phylogenetic sequences (originally collected as part of surveillance activities or research studies) in future large-scale phylogenetic analyses is not routinely obtained. (Coltart et al., 2018) In other instances, consent may also have been given for the collection of samples for storage and future research, without specific consent for the use of these data for the current study aims (Coltart et al., 2018).

### **3. RISK/BENEFIT RATIO FOR PUBLIC HEALTH RESEARCH**

In public health research, it is necessary to weigh the public health benefits of the research against the potential individual harms. Due to considerable variation between countries and among states within the United States with respect to HIV disclosure laws and consequently whether and under which circumstances this research can be conducted with/without written informed consent, the potential individual harms and the risk-benefit ratio vary depending on where the research is being conducted. Although the public health benefits and potential individual harms of phylogenetic research have been discussed by others (Coltart et al., 2018; Mutenherwa, Wassenaar, & de Oliveira, 2018), few studies have reported refusal rates for participation in such research and

reasons for refusal. This case study provides data on willingness to participate in research when written informed consent was required to conduct phylogenetic analyses and link phylogenetic data with data from their medical record.

#### **4. MATERIALS AND METHODS**

Between June 2017 and August 2018, 45 participants were enrolled in a study, which aimed to combine social network, spatial, and phylogenetic analyses to permit a more comprehensive understanding of HIV transmission in Boston, Massachusetts. Two types of participants were enrolled: (1) index participants (n=29), who completed an interviewer-administered survey (median = 24 minutes) and provided written informed consent to link their survey, electronic medical record (EMR), and phylogenetic data for combined analyses; and (2) phylogenetic participants (n=16), who provided written informed consent to link their EMR and phylogenetic data for analyses, but did not complete a survey. Only index participants received \$35 for their time spent completing the survey. Those eligible to participate as index participants included HIV patients who were diagnosed with HIV within the past six months or those who had been diagnosed over six months ago who (a) had missed taking prescribed HIV medications in the past 90 days, (b) were not virally suppressed, (c) engaged in higher risk drug use or sexual practices in the past 90 days, (d) had no HIV medical care visits in the last six months and were returning to the clinic for care, or (e) went more than six months without seeing a doctor for HIV care in the past 2 years. Of note, those who were not willing to take part in the survey portion of the study had the option to participate as a phylogenetic participant, instead.

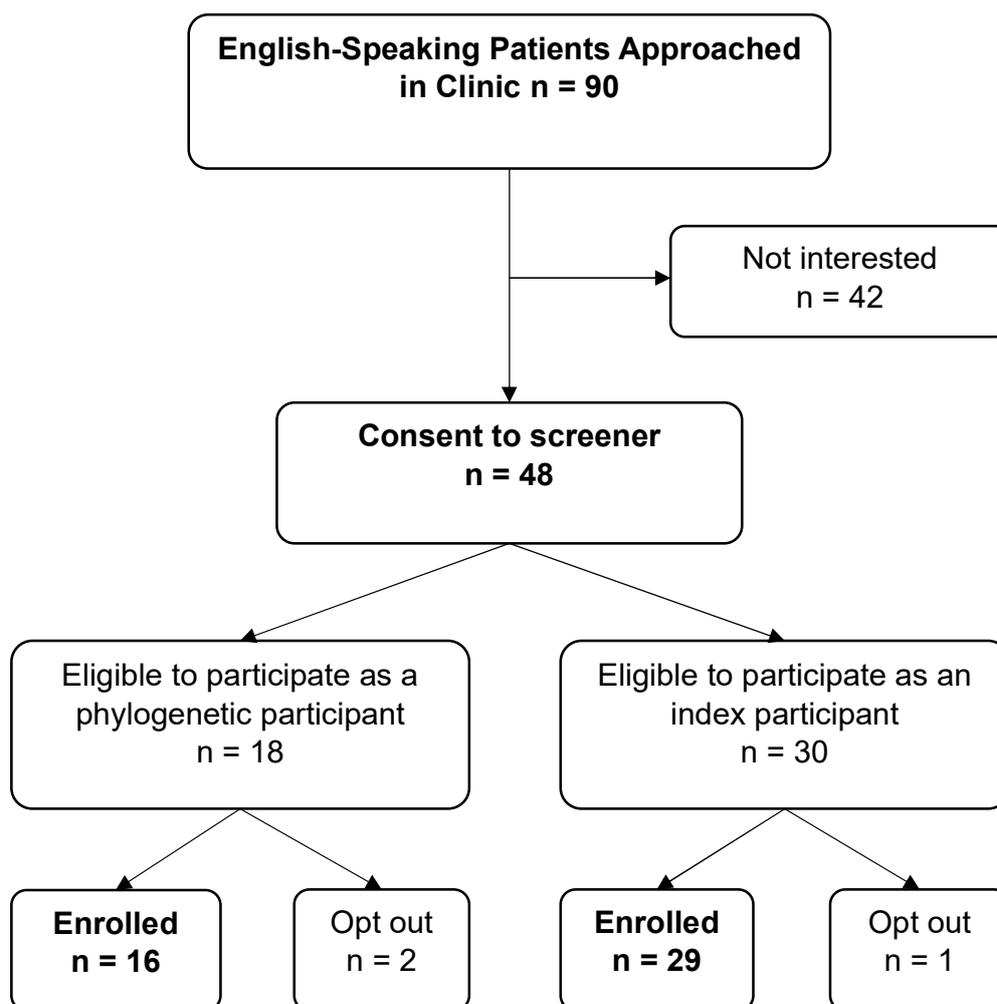
All research staff involved in participant recruitment and enrollment activities completed HIPAA, GCP, and CITI ethics training, signed a Confidentiality Pledge, and participated in an unconscious bias training workshop. The research protocol and all study materials were approved by the Boston University Medical

Campus Institutional Review Board. We also obtained a Certificate of Confidentiality from the National Institutes of Health.

Prior to study enrollment, 322 HIV patients at Boston Medical Center received a letter from their doctor that described the study and provided information about how they could learn more about the study and/or opt-out (see language in Table 1). Three individuals called the study number after receiving this letter to opt-out of the research (Figure 1). Over the 11-month enrollment period, 90 English-speaking HIV patients attending medical appointments at the Infectious Disease Clinic were approached. After their appointments, their doctors provided the patient with a flyer to introduce the study briefly (see language in Table 1) and asked the patient if they would be interested in learning more about the study from a research staff member. If the patient agreed, an introduction was made (i.e., a warm hand-off). Prior to screening for eligibility, the clinical research assistant briefly described the study to each potential study participant (see language in Table 1). After this brief description, 42 declined to participate further and 48 agreed to complete the screener to determine their eligibility as an index or phylogenetic participant (see Figure 1). Two individuals who were not eligible to participate as index participants declined to participate further due to the lack of study incentive. One index-eligible participant opted out while reviewing the consent form.

**Figure 1. Recruitment**

Flow-Chart of Study Recruitment, Including Those who Opt-Out and Enroll



Informed consent for HIV phylogenetic research: A case study of urban individuals living with HIV approached for enrolment in an HIV study

**Table 1. Relevant sections of study materials with the language used**

Domain	Study language	Study material
Data elements	The study would involve completing a 30-40 minute survey with a member of our study team and the use of some information from your medical records for research purposes.	Opt-out letter and study flyer provided to the patient by the clinician
Overview of study	The overall goals of this project are to learn how we can (1) reduce the number of people who become infected with HIV and (2) diagnose people sooner and provide treatment earlier so that they have a better prognosis. You should know that participation in research is totally separate from the care you are receiving at Boston Medical Center. Further, whether or not you decide to participate in this study won't affect your care in any way. With your approval, I would like to go through the consent form with you. It should take no more than 5 minutes of your time. Would that be okay with you?	RA introduction
Description of phylogenetic research	This study involves comparing your HIV virus with other HIV viruses to determine how similar they are to one another. This is also known as phylogenetics. To do this, we will look at changes present in your virus and compare them with changes present in other people's viruses to see if they are the same or different. Please note that these changes are part of the HIV virus found in your blood. They do not reveal anything about your personal genetic information (your DNA). Information about your HIV virus is already part of your medical record. When you were first diagnosed with HIV at BMC, your doctor ordered a test to determine which medications your virus would be resistant to. The changes present in your HIV virus help the doctor know which medications will not work to treat your HIV infection. To better understand why some viruses are more similar to one another than they are to other viruses, we would like to link this information with other information in your medical record. This information includes your demographic characteristics (e.g., age, gender, race/ethnicity, educational attainment, employment status, insurance type, birth place, housing status), drug use and sexual risk behaviors, CD4 count, the amount of HIV virus in your blood, and other infections you may have.	Consent form
Risks and discomforts	There is a risk of breach of confidentiality in this study if the data we collect about you is seen by anyone outside the study team. There are procedures in place to protect against such disclosure. These are detailed in the Confidentiality section.	Consent form
Potential benefits	There are no direct benefits to you for participating in this research study. However, the information collected could benefit others in the future through the development of HIV prevention interventions guided by our findings.	Consent form
Certificate of confidentiality	To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should know that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure of child abuse or threats of harm to self or others to state or local authorities.	Consent form
De-identification procedures	Your name will not be directly connected with your responses to the interview or to other data we collect about you. Instead of your name, we will use a study ID number. This means that the survey data that the interviewer collects will only include a study ID number. This study ID number will only be linked to your name in a separate encrypted file located in an encrypted folder on an encrypted drive in the PIs office. Only the PI and Research Coordinator will be able to access this file.	Consent form - confidentiality section
Confidentiality pledge	Every member of the research team has been educated on the importance of keeping your information confidential and has taken training on research ethics. Team members have also signed a statement saying that he/she will keep the information learned confidential	Consent form
Use and disclosure of your health information	Health information that might be used during this research includes: -Information from your hospital or office health records at Boston Medical Center and from any lab used by Boston Medical Center for HIV testing. This applies to information that is reasonably related to the aims, conduct, and oversight of the research study. Health information from your doctors or hospitals outside of Boston Medical Center will not be requested for use in this research. - New health information from tests, procedures, or visits between your study visit today and the end of this research study.	Consent form

## **5. RESULTS**

In this study, where patients were recruited in an infectious disease clinic and written informed consent was required to conduct phylogenetic analyses, as many people opted out of participating in the research as opted in. While we did not have IRB approval to examine the differences between those who enrolled and those who opted out, the research assistant noted refusals that were related to privacy/confidentiality concerns (n= 2), unwillingness to discuss their HIV status (n=1), and disinterest in being included in research (n=6). Most others only indicated that they were not interested or did not have time to participate.

## **6. DISCUSSION**

Within this study, only 50% of those approached for study enrollment agreed to participate. Of note, 94% of those who agreed to review the consent form did enroll in the study. The high opt-out rates and concerns about discussing one's HIV status reflect to some extent the stigma surrounding HIV in Boston. To provide additional context for these findings, we provide data from index participants who completed the survey on HIV disclosure to network members and perceptions about HIV stigma in the community. According to surveyed participants, the average person disclosed their HIV status to 58.8% of the network members listed in their survey and 69% of study participants felt that people in their community were stigmatized because of their HIV status. In our sample, 37.8% reported being born outside of the United States and those not born in the United States were more likely to report perceived HIV stigma in their community than those born in the United States (83.3% vs. 58.8%, respectively). Compared with the HIV/AIDS patient demographics reported by the Massachusetts Department of Public Health in 2015, our sample had a greater proportion of patients who were born in the United States (62.2% in our sample vs. 52.5%). These data suggest a high burden of stigma related to HIV among those who agreed to participate in this study (and potentially more perceived stigma among those who opted out).

It is important to note that this study applied for and obtained an NIH-issued Certificate of Confidentiality; however, as of October 1, 2017, NIH automatically issues this certificate to all federally funded projects, which plan to collect or use identifiable, sensitive data. Thus, all NIH-funded projects moving forward should automatically be granted this protection without having to apply for it. Certificates of Confidentiality, which protect the privacy of individuals who participate in research studies, prohibit the disclosure of identifiable information to anyone who is not associated with the research (Wolf et al., 2012). There are limited exceptions, including the individual's consent to disclosure. To date, there have been a few legal cases that have challenged a Certificate of Confidentiality, though none of the decisions have provided significant insight into the scope or strength of the certificate (Wolf et al., 2012). According to one study, although two thirds of the twenty-four lawyers interviewed reported receiving legal demands for data protected by a Certificate of Confidentiality, most were resolved without the requested disclosure (Wolf et al., 2012). In most cases, the attorneys were able to avoid producing the requested information by citing the existence of the Certificate (Wolf et al., 2012).

Given (1) the number of participants who opted out of study participation before reviewing the consent form and (2) concerns specifically related to privacy, confidentiality, and HIV disclosure, the following questions remain: (1) Should informed consent be required for all phylogenetic analyses, even those using de-identified data or conducted as part of surveillance activities? (2) As new methods for analyzing these data emerge, should researchers be able to use data in ways not specifically articulated in the consent form, but which become possible with further innovation? (3) What steps should researchers take to protect the privacy of individuals, particularly in contexts where HIV is criminalized or there have been civil or criminal cases investigating HIV transmission? (4) Should guidelines be established that outline how this research and all of the potential risks (including legal) are explained to participants in the consent form? (5) How can

community members be involved in this process to minimize the potential risks, particularly for those who are most marginalized? These questions require input from both researchers and community members living with HIV/AIDS.

## **7. LIMITATIONS**

Because we did not systematically collect reasons for opting out of the research, the inferences we can make from these notes are limited. For example, individuals could have opted out for a number of reasons other than privacy and confidentiality related to the use of phylogenetic or medical record data. For example, recruitment activities took place within an infectious disease clinic at a Hospital. Because patients come to the clinic for medical care, participating in a study may not be a priority. Many patients also schedule multiple appointments with different providers on the same day, which restricts patient availability to participate in research on the days that they visit the clinic. Further, patients are living with other co-morbidities (i.e., substance use disorders, mental health conditions, and other chronic illnesses) and are struggling with a myriad of other issues (i.e., food insecurity, housing stability, immigration status), which may be of greater importance to them than their HIV status. Research fatigue is another potential explanation, as patients seeking care in a research hospital are frequently approached to participate in research studies.

Even though we relied on peer-navigator input to guide the procedures used for approaching patients about study participation (i.e., when, where, and how), three individuals opted out after receiving a letter that was mailed to them and 47% of those who agreed to speak with a research assistant about the study opted out prior to reviewing the consent form. The high opt-out rates prior to reviewing the informed consent document suggest that we might have benefited further from assembling a community advisory board to inform strategies to better convey the purpose of the research in a way that was more sensitive to the concerns of those involved, particularly to those sub-groups that are most vulnerable.

## 8. CONCLUSIONS

Given that these data are particularly sensitive and the procedures used to analyze the data are complex and constantly evolving, future directions for this research should include more involvement of community members in developing protocols and language for approaching patients for involvement in this research, for explaining what phylogenetic research is in lay terms, and to best convey the foreseeable risks and alleviate potential concerns. Engaged scholarship in public health and biomedical research is grounded in an ethos of social justice and a common goal: to address the health concerns of populations living in underserved, economically constrained, or minority communities. Drawing from our findings and existing literature on engaged scholarship ethics framework, we propose employing the engaged stakeholders' framework, upon which policies, research, and best practices can be established to address the concerns related to privacy and confidentiality arising from phylogenetic research (Corbie-Smith et al., 2018).

## 9. REFERENCES

- Abecasis, A. B., Pingarilho, M., & Vandamme, A.-M. (2018). Phylogenetic analysis as a forensic tool in HIV transmission investigations. *Aids*, *32*(5), 543-554.
- Audelin, A. M., Cowan, S. A., Obel, N., Nielsen, C., Jørgensen, L. B., & Gerstoft, J. (2013). Phylogenetics of the Danish HIV epidemic: the role of very late presenters in sustaining the epidemic. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, *62*(1), 102-108.
- Chan, P. A., Hogan, J. W., Huang, A., DeLong, A., Salemi, M., Mayer, K. H., & Kantor, R. (2015). Phylogenetic Investigation of a Statewide HIV-1 Epidemic Reveals Ongoing and Active Transmission Networks Among Men Who Have Sex With Men. *JaidS- Journal of Acquired Immune Deficiency Syndromes*, *70*(4), 428-435. Retrieved from <Go to ISI>://WOS:000364316300014
- Chan, P. A., Kazi, S., Rana, A., Blazar, I., Dejong, C. C., Mayer, K. H., . . . Kantor, R. (2013). Short communication: new HIV infections at Southern New England academic institutions: implications for prevention. *AIDS Res Hum Retroviruses*, *29*(1), 25-29. doi:10.1089/AID.2012.0130

- Chan, P. A., Tashima, K., Cartwright, C. P., Gillani, F. S., Mintz, O., Zeller, K., & Kantor, R. (2011). Short communication: Transmitted drug resistance and molecular epidemiology in antiretroviral naive HIV type 1-infected patients in Rhode Island. *AIDS Res Hum Retroviruses*, *27*(3), 275-281. doi:10.1089/aid.2010.0198
- Coltart, C. E. M., Hoppe, A., Parker, M., Dawson, L., Amon, J. J., Simwinga, M., . . . Ethics in, H. I. V. P. W. G. (2018). Ethical considerations in global HIV phylogenetic research. *Lancet HIV*, *5*(11), e656-e666. doi:10.1016/S2352-3018(18)30134-6
- Corbie-Smith, G., Wynn, M., Richmond, A., Rennie, S., Green, M., Hoover, S. M., . . . Nisbeth, K. S. (2018). Stakeholder-driven, consensus development methods to design an ethical framework and guidelines for engaged research. *PLoS ONE*, *13*(6), 1-12. doi:10.1371/journal.pone.0199451
- Dennis, A. M., Herbeck, J. T., Brown, A. L., Kellam, P., de Oliveira, T., Pillay, D., . . . Cohen, M. S. (2014). Phylogenetic studies of transmission dynamics in generalized HIV epidemics: An essential tool where the burden is greatest? *JAIDS Journal of Acquired Immune Deficiency Syndromes*, *67*(2), 181-195.
- Dennis, A. M., Hué, S., Hurt, C. B., Napravnik, S., Sebastian, J., Pillay, D., & Eron, J. J. (2012). Phylogenetic insights into regional HIV transmission. *AIDS (London, England)*, *26*(14), 1813.
- Fisher, M., Pao, D., Brown, A. E., Sudarshi, D., Gill, O. N., Cane, P., . . . Sabin, C. (2010). Determinants of HIV-1 transmission in men who have sex with men: a combined clinical, epidemiological and phylogenetic approach. *Aids*, *24*(11), 1739-1747.
- Forbes, A. (1996). Mandatory name-based reporting: impact and alternatives. *AIDS Policy Law, Bonus Report*, 1-4. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/11654491>
- Frentz, D., Wensing, A. M., Albert, J., Paraskevis, D., Abecasis, A. B., Hamouda, O., . . . Schmit, J.-C. (2013). Limited cross-border infections in patients newly diagnosed with HIV in Europe. *Retrovirology*, *10*(1), 36.
- Grabowski, M. K., Lessler, J., Redd, A. D., Kagaayi, J., Laeyendecker, O., Ndyanabo, A., . . . Mueller, A. C. (2014). The role of viral introductions in sustaining community-based HIV epidemics in rural Uganda: evidence from spatial clustering, phylogenetics, and egocentric transmission models. *PLoS medicine*, *11*(3), e1001610.
- Grabowski, M. K., & Redd, A. D. (2014). Molecular tools for studying HIV transmission in sexual networks. *Current Opinion in HIV and AIDS*, *9*(2), 126-133.

HIV test; informed consent; disclosure of results or identity of subject of test, Chapter 111 C.F.R.

HIV test; informed consent; disclosure of results or identity of subject of test, § 70F.

Hué, S., Clewley, J. P., Cane, P. A., & Pillay, D. (2004). HIV-1 pol gene variation is sufficient for reconstruction of transmissions in the era of antiretroviral therapy. *Aids*, *18*(5), 719-728.

Hué, S., Pillay, D., Clewley, J. P., & Pybus, O. G. (2005). Genetic analysis reveals the complex structure of HIV-1 transmission within defined risk groups. *Proceedings of the National Academy of Sciences of the United States of America*, *102*(12), 4425-4429.

Lazzarini, Z., Galletly, C. L., Mykhalovskiy, E., Harsono, D., O'keefe, E., Singer, M., & Levine, R. J. J. A. j. o. p. h. (2013). Criminalization of HIV transmission and exposure: research and policy agenda. *103*(8), 1350-1353.

Mehta, S. R., Wertheim, J. O., Brouwer, K. C., Wagner, K. D., Chaillon, A., Strathdee, S., . . . Murrell, B. (2015). HIV Transmission Networks in the San Diego–Tijuana Border Region. *EBioMedicine*, *2*(10), 1456-1463.

Mutenherwa, F., Wassenaar, D. R., & de Oliveira, T. J. D. w. b. (2018). *Ethical issues associated with HIV phylogenetics in HIV transmission dynamics research: A review of the literature using the Emanuel Framework*.

Wertheim, J. O., Brown, A. J. L., Hepler, N. L., Mehta, S. R., Richman, D. D., Smith, D. M., & Pond, S. L. K. (2014). The global transmission network of HIV-1. *Journal of Infectious Diseases*, *209*(2), 304-313.

Wolf, L. E., Dame, L. A., Patel, M. J., Williams, B. A., Austin, J. A., & Beskow, L. M. (2012). Certificates of confidentiality: legal counsels' experiences with and perspectives on legal demands for research data. *J Empir Res Hum Res Ethics*, *7*(4), 1-9. doi:10.1525/jer.2012.7.4.1

Abby E. Rudolph, Omar Martínez, Robin Davinson y Chineye Brenda Amuchi