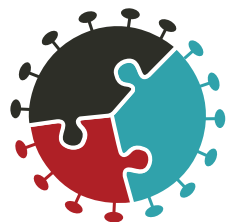
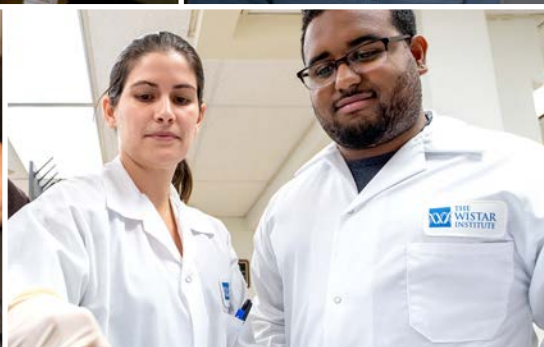




# JOINING FORCES TO ADVANCE HIV CURE RESEARCH

A POSITION PAPER ON CURE-DIRECTED CLINICAL RESEARCH AND ANALYTICAL TREATMENT INTERRUPTIONS, INCLUDING BILL OF RIGHTS AND RESPONSIBILITIES FOR PARTICIPANTS AND STUDY STAFF



**BEAT-HIV**  
DELANEY COLLABORATORY





**BEAT-HIV**  
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## THE BEAT-HIV COLLABORATORY

The Beyond Antiretroviral Therapy Martin Delaney Collaboratory to Cure HIV-1 Infection by Combination Immunotherapy (BEAT-HIV Delaney Collaboratory) is a United States-based consortium of HIV researchers and community stakeholders from leading academic research institutions working with the government, community-based organizations, industry partners, and communities of people living with HIV. The BEAT-HIV Collaboratory's objectives are to advance basic HIV cure-directed research and to conduct HIV-cure-directed clinical trials using immune-based therapies.

The BEAT-HIV Collaboratory is supported by the US National Institute of Allergy and Infectious Diseases, National Institute of Mental Health, National Institute of Drug Abuse and the Roberts I. Jacobs Fund of the Philadelphia Foundation.

Additional information can be found at <http://beat-hiv.org/>.

### WHY SEARCH FOR A CURE?



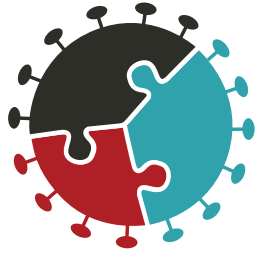
BEAT-HIV: Game Changers Trailer



THE WISTAR INSTITUTE



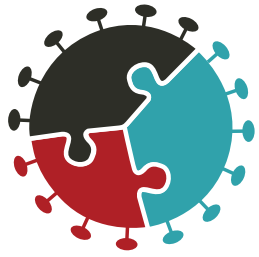
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## THE BEAT-HIV POSITION PAPER'S TOP TEN POINTS

1. Participation in a clinical study takes time and commitment. It is very important for potential participants to understand the time required for study visits and procedures and the length of the study. Joining a clinical trial may affect a participant's life schedule and may impact their relationship(s) or family, so it is important that when considering whether to join an HIV-cure directed study, potential participants discuss their decision with family and friends and their health care providers.
2. Both sex and gender matter in HIV cure-directed research. Study participant distribution must be sex and gender balanced, and data to be collected must address relevant emotional and social factors.
3. There are multiple barriers women face when participating in research, including competing life demands, i.e. scheduling, childcare, transportation, and access to information about HIV cure-directed clinical trials. Researchers should take these barriers into consideration as they design studies to facilitate the inclusion of women and meet women where they are in their lives.
4. Inclusion of cis- and trans-gender women is imperative for HIV-cure research so that when a cure is found, it will be both accessible and affirming for all people.
5. The informed consent process is one of the most important aspects of any clinical study. The informed consent process provides information about a research study, explains participants' rights and responsibilities in plain language, provides the space to raise any and all questions that potential participants may have about the study. The informed consent form should also clearly state that you participate only because you want to and that you are free to leave the study at any time.
6. Potential clinical study participants should understand that if they consent to enroll in a cure-directed study, the hope and the expectation is that they will be able to complete the study. However, this does not mean that they give up their right to stop participating in the study at any time without any consequences. Their ongoing participation in any clinical study is completely voluntary.
7. When reviewing the informed consent form, potential participants should pay special attention to who is sponsoring the study, what potential side effects could be expected and how those side effects will be addressed.
8. Analytic treatment interruption (ATI) is a closely monitored pause of antiretroviral therapy as part of a research study. The purpose of the pause in treatment is to determine the effect of the intervention on viral load compared to standard antiretroviral therapy.
9. ATIs remain the best way to evaluate HIV cure-directed strategies, particularly those that work with the immune system.
10. Any interruption of therapy may result in viral rebound, which must be carefully monitored. Viral rebound also carries risks of HIV transmission. Be sure to know how to protect your partner(s) and what laws cover the sexual transmission of HIV in the localities where you have sex. Remember study staff are there to help you answer any questions you have.



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## WELCOME: BEAT-HIV Community Advisory Board



Dear Readers,

We are the Community Advisory Board (CAB) of the BEAT-HIV Delaney Collaboratory. This Position Paper explains our perspectives and recommendations on HIV cure-directed clinical trials that include a closely monitored Analytical Treatment Interruption (ATI) phase. The Paper has been prepared by and for people living with HIV, researchers, and advocates. We have developed the Paper to answer frequently asked questions and provide recommendations for community members when considering joining a cure-directed clinical trial that features an analytical treatment interruption.

The membership of our CAB represents a broad spectrum of stakeholders who are united in the search for an HIV cure. We are people living with HIV. We are members of communities deeply affected by HIV and AIDS. We are allies united in advancing research towards an HIV cure.

Including perspectives of CAB members in the HIV cure-directed research agenda is a critical component of our work. Grounded in social justice and research equity, the BEAT-HIV CAB is action-oriented. Our membership is diverse and inclusive; many of us are long term survivors, come from different walks of life, represent communities disproportionately affected by HIV, and bring a range of perspectives and experiences to help inform our mission. We operate with the core principle that no matter where we come from or what our community of origin is, we all benefit by coming together as one cohesive unit to advance cure research. Many of us have years of experience in community and HIV activism, while others are new to this work. Together, with our researcher colleagues, we focus on the problem of how HIV persists in the body even with the successes of ART. We develop research questions that seek to create new strategies for HIV eradication in hopes of developing a cure for HIV.

The CAB's vision is to create a world where HIV and AIDS research meaningfully involves impacted and affected communities, is collaboratively created, and is openly shared. To advance this vision, our mission statement includes three core aims:

- **The CAB serves as a bridge community to provide input and feedback to investigators within the BEAT-HIV Collaboratory for HIV Cure Research in particular, but also to investigators from other Martin Delaney Collaboratories and other national and international groups working towards finding a cure for HIV infection.**
- **The CAB fosters and maintains communication and partnerships with project researchers in order to promote transparency and disseminate findings in HIV cure-directed research to our communities.**
- **The CAB integrates community involvement in HIV and AIDS cure-related research and clinical trials.**



Our CAB works in partnership with scientific and medical researchers at The Wistar Institute, the University of Pennsylvania, and the Philadelphia FIGHT Community Health Centers (FIGHT), who are conducting HIV cure-directed clinical studies in our communities. For 25 years, The Wistar Institute has partnered with Philadelphia FIGHT to provide access to clinical trials and to promote community health education. FIGHT is a well-known community-based organization (CBO) and pioneering federal qualified community health center (FQHC). Since 1990, they have provided primary care, community education, research, and advocacy for people living with HIV/AIDS and other affected communities in the greater Philadelphia area regardless of their ability to pay. This joint community-academic partnership, which we term the Community Engagement Group (CEG), seeks to foster and integrate robust community involvement in all areas of HIV cure-directed research and community health education. This innovative partnership of the CAB, Wistar, Penn, and FIGHT is unique and pioneering in the field of HIV cure-directed research. It brings together the diverse experiences and expertise of our CAB members, our project scientists, and our community-based (CBO) health partner, Philadelphia FIGHT, to advance research towards an HIV cure.

The Community Engagement Group (CEG) of the BEAT-HIV Delaney Collaboratory has established meaningful, bidirectional lines of communication between researchers and communities most affected by HIV. The primary objectives of our CEG strategy are to ensure that CAB objectives are achieved within a wider effort integrating research and long-standing community groups serving persons living with HIV. We also want to ensure that the community has a respected voice in communicating with the BEAT-HIV leadership and investigators regarding the unique ethical and practical aspects of cure-directed research. This is a particularly important objective for the Delaney BEAT-HIV collaboration given its emphasis on enrolling people living with HIV in cure-directed clinical trials.

Our research participation builds upon our individual strengths and expands personal knowledge of HIV research literacy, communicating with and informing partners about research participation, and engaging medical care teams about treatment and research activities. We believe that open dialogue among people living with HIV, their loved ones and friends, health care providers, and clinical researchers can lead to better communication and improved knowledge of HIV as well as diminish internalized stigma, reduce stereotypes. This open communication gives us the ability to speak our own truths and expand overall self-awareness. We recognize that being a part of a community advisory board and/or participating in research can help to normalize and destigmatize living with HIV. Our engagement in cure directed research – as members of communities affected by HIV and AIDS – furthers the collective contributions of people living with HIV and AIDS to society and science. Participating in research can further empower people living with HIV to actively contribute to the health and wellbeing of future generations.

Those of us who have been living with HIV for 20 or 30 years bear witness to research that has saved lives – our lives and the lives of our loved ones. We are grateful to all the advocates and clinical trial participants over the past 30 years whose efforts and endurance have gotten us so far in HIV treatment and care. BEAT-HIV Delaney Collaboratory research is focused on taking HIV research and treatment to the next level – the development of a cure for HIV. We hope our work and this document will advance HIV cure-directed research that recognizes the people who have come before us as well as the research volunteers and scientists who are conducting pioneering HIV research that advances of the science of HIV and gets us closer to a cure for all.

In health and solidarity,  
**The BEAT-HIV Community Advisory Board**

# Statement from Jane Shull, Chief Executive Officer, Philadelphia FIGHT Community Health Centers



On behalf of Philadelphia FIGHT, I am honored to be asked to contribute to this very important *Position Paper on Cure-Directed Clinical Research and Analytical Treatment Interruptions* developed as a team effort by the BEAT-HIV Delaney Collaboratory Community Engagement Group (CEG). In this Position Paper, the CEG has created a roadmap filled with vital information for anyone considering participating in an HIV cure-directed clinical trial.

At FIGHT, we strive always to recognize the contributions of people living with HIV/AIDS to the progress we have made in treating HIV. We have reached the point where HIV is a manageable, treatable condition for most people. There is a wide variety of effective drugs to control the virus, many of which only need to be taken once a day, and many of which have very minimal side effects. This, as readers will be well aware, represents enormous progress in a relatively short period of time. This progress was only made possible because of the courage of early HIV activists, the people who refused to lay down and die, and who instead educated themselves and their communities, became advocates and activists, who challenged scientists and government in the corridors of power, and in the course of this activism, changed the world. We all owe these early activists an enormous debt of gratitude.

But there is another group of people with HIV/AIDS whose contributions have been equally critical, but who receive relatively little attention. This group consists of people who from the earliest days of HIV, courageously participated in clinical trials – experiments with new drugs in people – that enabled researchers in the late 1980s and early 1990s to develop the first line of medications that has led to today’s effective treatments, which have turned HIV into a chronic but manageable disease for many. We are so used to witnessing the effectiveness of today’s available treatments that it is easy to forget these treatments weren’t always available, and that at the time of the first clinical studies, we weren’t sure if these treatments would work. Yet, people living with HIV and AIDS came forward, over and over again, to volunteer for clinical trials in the hopes that they would aid themselves and communities affected by HIV in the search for a cure. Because of these courageous clinical trial volunteers, people with HIV today have effective treatment and AIDS is no longer a death sentence.

One other task remains. That task is to not just treat HIV, but to cure it. In other words, to reach the point where we no longer talk of managing HIV, but where we can say to people living with HIV that there is a course of treatment after which they will no longer have HIV. This is similar to what has already happened with Hepatitis C, another disease that has taken many lives over the past decades. Hepatitis C is now curable. HIV can be too.

But, similar to how we got to Hepatitis C treatment and cure, these studies that we have embarked on will need volunteers to step forward, to be willing to take some risks – because these risks will turn out to have been worth it when we can cure HIV/AIDS. Although this collaboration has taken every possible step to keep every single study participant safe, we know it will still take courage to step up, courage to stay the course, and courage to face any possible side effects. Courage, however, sometimes needs a little help. This help can come through the support of family, friends, and the care team. Another way help can come is through information as provided here in this Position Paper. Throughout the AIDS epidemic, information put into the hands of people living with HIV/AIDS, has been crucial in advancing treatment and cure. Information on these trials, how they will work, the theory behind them, possible risks, and possible benefits, should be available to all, not hidden from patients, and discussed among study participants and researchers.

Providing that information, interspersed with first person accounts from study participants reflecting on their experience with the topics covered in each section, is the core of the remarkable achievement of this Position Paper by BEAT-HIV Delaney Collaboratory’s Community Engagement Group. We at FIGHT are proud to be a partner in this effort, and we know this document will be very useful to anyone considering participating in a Cure-directed clinical trial.

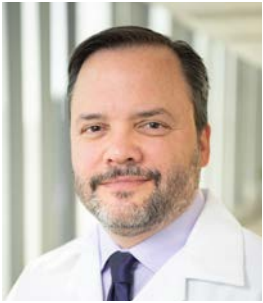
Jane Shull  
Executive Director, Philadelphia FIGHT



<https://fight.org>



# Statement from BEAT-HIV Collaboratory Principal Investigators



HIV cure research would not be possible without community volunteers who donate their time, their emotional resources, and their bodies to cure-directed clinical studies in hopes of moving us closer to a cure for HIV infection for all. We, the principal Investigators of the BEAT-HIV Collaboratory, thank community members and clinical trial participants for their support and collaboration. We affirm that clarity of purpose and transparency on how clinical research will impact study participants are central to the HIV cure research effort. It is this spirit of transparency and collaboration that we are excited to have participated in this

joint effort with our community to create the Position Paper on Cure-Directed Clinical Research and Analytical Treatment Interruptions. Our hope is that this Paper will increase community awareness and be a “starter” for ongoing dialogue by setting clear expectations of what may lay ahead for both clinical research scientists and persons considering entering a study directed towards getting us closer to an HIV cure.

Clinical researchers often struggle to communicate how HIV cure studies may impact participants because they often are not themselves persons living with HIV nor members of the communities asked to enroll in studies. This Position Paper now seeks to correct this imbalance. Here community members who have participated in HIV cure-directed studies, or are leaders in their respective communities, provide a discussion by and for the community. Topics addressed not only describe why participation in HIV cure-directed trials is important, but also why study designs include therapy interruptions, and what this may mean in terms of relationships, health, insurance, criminal laws, and mental health aspects. The discussion included in this Position Paper, together with personal stories, provide a level of information that is not available to clinical researchers or potential study participants anywhere else but here.

While a very limited number of individuals have been cured of HIV or achieved durable control in the absence of therapy, the path forward to eradicating HIV safely and routinely is unclear. Only through a strong partnership between researchers, clinicians, government, pharmaceutical companies and most importantly people living with HIV and their friends and family can progress be made. We are certain that this will become a must-read for anyone considering enrolling into a cure-directed clinical research study in the future. We thank you for supporting our shared goal to develop a cure for HIV infection in all people.

Luis J. Montaner, DPhil  
James L. Riley, PhD  
For the BEAT-HIV Collaboratory



PHOTO: NIH/NIAD

This collaborative funding initiative, sponsored by the National Institutes of Health, honors Martin Delaney (1945-2009), who was the Founding Director and public voice of Project Inform, one of the nation’s oldest and best-known non-profit foundations working in AIDS. An internationally recognized leader of efforts to provide experimental drugs to seriously ill people prior to FDA approval, his was a key voice in the development of the regulations that today allow accelerated FDA licensure of promising drugs.





## OVERVIEW: Audience of Interest and Objectives

This Position Paper has been written with the community in mind. It is meant to help clarify and demystify HIV cure-directed studies, especially those that employ an Analytical Treatment Interruption (ATI). As well, this Paper is directed to HIV researchers, health providers, funding agencies, and others looking to support HIV cure-directed research. We know that many of us have concerns about ATI studies and would like to learn more about HIV cure-directed research. This Paper aims to provide answers to some of the most common questions. The questions we answer here were raised by Community Advisory Board Members (CAB) and other questions that we and the Community Engagement Group (CEG) have received from community members, healthcare providers, and other stakeholders.

We offer this Paper as an opportunity to engage potential participants, their partners, spouses, friends, family, and their communities in conversations about the perceptions, understandings, and misunderstandings that surround ATI studies. The Paper seeks to engage and inform a diverse array of stakeholders and to advance HIV cure-directed research literacy for all. Our hope is that cure-directed research will bring us closer to finding a strategy that will free patients from having to take a daily regimen of HIV medications and that will provide relief to parts of our world where access to ART medications remains challenging.

This Paper is the product of a partnership between the BEAT-HIV Community Advisory Board, the BEAT-HIV Principal Investigators, clinical researchers, and Philadelphia FIGHT, a pioneering community health center. The CEG has undertaken the writing and distribution of this Position Paper, which builds upon the expertise and diversity of perspectives shared among the members of this partnership. This Paper benefits from the input we have solicited from our community-at-large during presentations at conferences and workshops in both local and national settings.

It is important to note that the recommendations and positions taken in the Paper are intended for communities in the United States. We hope all readers will be able to adapt and tailor the Paper's recommendations and lessons in ways that will be relevant in their local communities.

Throughout the development of this Position Paper, we have taken a **"trauma-informed approach"** to health education, medical care, and HIV cure-directed research. The term trauma denotes negative events and circumstances that produce psychological distress and may have adverse effects on the wellbeing of an individual. Trauma is an experience shared by many people living with HIV/AIDS (PLWHA) prior to and after diagnosis. As the U.S. HIV epidemic continues, it has increasingly become a public health crisis that disproportionately affects communities bearing the detrimental effects of systemic racism, homophobia, transphobia, **classism**, and **patriarchy**. PLWHA are impacted and burdened by lifetime individual-and community-level trauma. In the language we use and the recommendations we offer, we strive to advance positions that reduce trauma and advance **equity** and wellbeing.

The core content of this Paper is conveyed in the five Modules listed below. Of note, we include a module that specifically addresses the special considerations and stark disparities in the enrollment of cis-and trans-women in HIV cure-directed research and people of color who have under presented in health research.

- **Module 1: What is an Analytical Treatment Interruption (ATI)? Why are ATIs used in HIV cure-directed research?**
- **Module 2: Considerations for Participation in HIV Cure-directed Studies**
- **Module 3: Considerations for Navigating the Informed Consent Process in an HIV Cure-directed Study**
- **Module 4: Additional Social and Health Implications to Consider**
- **Module 5: Women and Cure-directed Clinical Research**

For each Module, we first summarize the most relevant points and then respond to these in a series of frequently asked questions and recommendations. Each Module ends with personal reflections from persons having direct experience with the topic discussed. These writers include past and current ATI study participants and those whose personal circumstances proved to be a barrier to study participation. These writers discuss their experiences and share their lessons. As an added resource to this Position Paper, we include information on the HIV Cure-directed Research Education Videos (available at [beat-hiv.org](http://beat-hiv.org)).

Following the Modules is a newly-created a Bill of Rights and Responsibilities for both potential participants and study teams in HIV cure-directed research trials involving ATIs. We have added a Glossary of words, phrases, and clinical terminology that are commonly used in an ATI study and in Informed Consent Documents. Throughout the Paper, terms defined and explored in Glossary have been **bolded**.

Our Paper concludes with a list of additional Resources and community organizations that provide information and support for clinical trial participants and for those considering participating in an HIV cure-directed clinical trial.

In conclusion, our main objective for this Position Paper is to help potential study participants and study personnel advocate for study practices that safeguard the rights and wellbeing of clinical trial participants and help to protect the interests of all who are involved in clinical research towards a cure for HIV. The science of HIV continues to evolve rapidly. This Position Paper will help advance our collective work to advance research literacy and the meaningful involvement of community stakeholders in the search for a cure to the global HIV pandemic.





## MODULE 1:

### What is an Analytical Treatment Interruption (ATI)? Why are they used in HIV cure-directed research?

#### SUMMARY POINTS

- ART interruption remains the best measure to evaluate HIV cure-directed investigational strategies, particularly those that work by an activation of the immune system towards control or eradication of HIV once ART is stopped.
- Closely monitored ART interruption as a component of a cure-directed study is justified if prior research has shown that the drug or curative strategy being studied has demonstrated, in laboratory settings, a potential efficacy justifying its testing in people living with HIV.
- The primary risks of a long-term interruption of ART are the onset of HIV viral rebound (i.e., HIV becomes detectable) and reduction in CD4 count (a type of immune cell).
- Additional risks of therapy interruption also include a) the potential for development of resistance against anti-HIV medicines, b) HIV disease progression, and c) the risk of HIV transmission to other people.
- Make sure you understand the study sequence (i.e., what will happen when), the Informed Consent documents, and discuss what personal issues you may need to consider.
- Discussing study participation with your significant other or partners, if warranted, should also be recommended as ATIs may present a transmission risk.
- Above all, ask questions, get informed, and only proceed when you (not just your provider) fully understand the risks and that participation is right for you.

Antiretroviral therapy (ART) should **ONLY** be interrupted in the context of a closely-monitored research study or as recommended by your physician.



## FREQUENTLY ASKED QUESTIONS

### What is therapy interruption or analytical treatment interruption (ATI) and why are ATIs needed?

ART interruption is a pre-determined, closely-monitored pause in taking antiretroviral medications. The reason HIV cure-directed studies include a therapy interruption or ATI is because there is currently no other way to see if the strategy being tested can delay or prevent a return of viral load (HIV rebound) after antiretroviral therapy (ART) is stopped. Right now, no laboratory test exists that will show whether a viral rebound will occur or not after ART interruption. Measuring viral rebound after ART is stopped remains the best and most definitive way to evaluate HIV cure-directed strategies.

### Are all ATI the same?

No, ATIs in HIV cure-directed studies are not the same.

An HIV cure-directed strategy may try to reduce HIV while you are on ART. If a reduction is achieved, it is expected to prolong the time to viral load rebound during an ATI. This is called a **time-to-rebound study**. On this type of HIV cure-directed study, the experimental drug or vaccine is started prior to the ATI period. The hope is that over the course of the trial, the experimental drug will reduce the level of HIV that was present in the participant prior to the start of the ATI. The goal is a longer period of time off HIV medication before any viral rebound.

An alternative HIV cure-directed strategy is to try to have your body respond to control HIV upon viral rebound. This is called a **rebound set point study**. On this type of HIV cure-directed study, a participant will also start to receive an experimental drug or vaccine prior to the ATI period. The hope is that when/if the virus rebounds during the ATI, the experimental drug that was started prior to the ATI will already be in place and “kick in” after the viral rebound to control the virus. In a rebound set point study, a participant may need to be viremic for a period of time to determine if the study drug is effective allowing the immune system to take over.

### When are ATIs appropriate?

Since ATIs are the current way to test a clinical strategy that is intended to control or eliminate HIV, they are used once there is a clear path showing that the strategy being tested has pre-existing data to support its potential success (Julg et al., 2019). ATIs are not appropriate as a first test to see if a strategy works, but rather as a final test after a pre-existing body of work already indicates anti-HIV activity. ATI testing is then the only way to see if the strategy is clinically useful. For example, data in laboratory experiments or in animal models should show activity of the strategy against HIV. All anticipated safety-related concerns should be addressed before the study and should be monitored throughout the study to ensure participant safety.

### What are the risks of an ATI?

- Health risks of long-term interruptions of ART are primarily associated with viral rebound (i.e.: HIV replication, increase in viral load), potential decrease in CD4 counts, and possible increase in inflammation. Additional concerns regarding how viral rebound may affect pre-existing heart conditions or **HIV-associated neurocognitive disorders** need to be discussed with your HIV care team.
- Viral rebound may also increase the possibility of developing resistance against one or more drugs (or class of drugs) in the previous ART regimen, so investigators should make sure there are comparable back-up ART regimens options available for all participants who undergo an ATI. While it is most likely, there is also no guarantee that participants will maintain a sustained undetectable status into the future. To date, prior ATI studies have shown that participants who experienced a viral rebound were able to successfully return to undetectable status after resuming their prior ART regimen.
- Finally, the possibility of viral rebound also introduces the risk of transmission if participants do not maintain an undetectable viral load status (or stable suppression state) during the ATI period.

### How are risks of an ATI best managed?

First, you must decide if study participation is right for you. Second, you are always free to restart ART and withdraw consent and your participation in a clinical study at any time. Study entry criteria is developed by researchers, with input from the community, and are intended to help participants minimize risks associated with the study. Common exclusion criteria to ATI studies includes (1) advanced disease before ART (example: CD4 count history of less than 200), (2) ongoing active diseases apart from HIV (example: heart, neurological or cancer conditions), and (3) low recovery of CD4 count after ART (example: CD4 count lower than 450 on ART) (Julg et al., 2019).

Community members have expressed concern about potential transmission of HIV to partners during an ATI. Research staff address these concerns through (1) ongoing counseling and education on risks and what to avoid (i.e., pregnancy, sex without condoms, etc.), (2) providing information for sexual partners on how to access counseling for PrEP (pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) services to be used together with condoms for partners, (3) offering frequent monitoring for HIV viral load rebound and CD4 counts during an ATI, and (4) defining clear instructions and criteria for resuming ART (Dee, Boone, Palm, Campbell, & Dubé, 2019). More detailed discussions on reducing risk of HIV transmission can be found in our “Recommendations” below as well as in (a) Treatment Action Groups (TAG) Community Recommendations for Clinical Research Involving Antiretroviral Treatment Interruptions in Adults and (b) Peluso et al, 2020.

Community members have drawn our attention to the potential risk of increased anxiety, stress, and worry during a treatment interruption (Dee et al., 2019). These feelings and concerns are normal when participating in any research study and especially so when enrolled in a treatment interruption study. Participants in these trials are strongly encouraged to reach out to their study team and their care team if they are experiencing any of these emotional and/or mental health concerns. Study staff should be equipped to support participants through this process and to have resources available to participants.

### How do we meet participants “where they are”?

Clinical sites must provide **culturally competent**, trauma-informed, integrated, medical care and social services to our participants. Participants should feel free to question each step of the process. The study team must work to address the unique needs of each individual. Participants are encouraged to talk openly about fear and stigma that can be associated with trial participation. It is natural to be apprehensive, and participants are encouraged to express what they are feeling during or after appointments. Study teams should openly acknowledge the injustices perpetrated on communities of color in the past, while underscoring safety at every step.

By openly acknowledging that participants’ motivations for joining a study are not the same, a non-judgmental space is made for everyone regardless of what they tell us are motivating factors. Inclusivity and respect for the dignity of patients must remain at the center of study values.

### How do I know if a study with an ATI is appropriate for me?

Getting medical advice from HIV providers and HIV care teams (nurse, case manager, social worker, etc.) is important. If you consider participating in an HIV study, you should review the study plan to assess if your medical history, i.e. CD4 count before ART, ongoing health issues, or history of cardiovascular or neurological conditions might put you at greater risk than is acceptable to you.

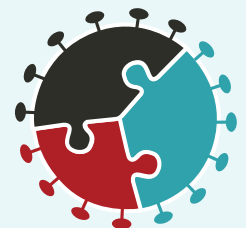
ATIs can increase your risk of transmitting HIV to your sexual partner(s). It is highly recommended that you talk with your significant other or sexual partner (or partners) to discuss this risk and the strategies you will use to manage it (e.g., condom use, PrEP use by partner, and/or avoiding pregnancy and sexually transmitted diseases). You may want to talk with your social worker or case manager to discuss any potential barriers you might encounter: caregiving obligations, transportation, scheduling, or **intimate partner violence (IPV)**. Work-arounds or other accommodations could be made with open dialogue with your care team as well as the study team. Finally, you should only participate if you feel confident with the study team and the informed consent process (with clearly stated contact information on how access assistance if needed), and when you (not just your provider) fully understand the risks and the plan to monitor your lab results during the ATI.

### What are acceptable ATI criteria for the BEAT-HIV study team?

Study entry criteria are designed to, among other things, minimize the risk incurred by an individual during an ATI, and are specific for each study. For example, our BEAT-HIV studies will recruit persons who are receiving ART and have been virally suppressed (i.e. have had consistently undetectable viral loads) for at least 6 months, have a current CD4 count > 450, and have never experienced CD4 counts below >200 (nadir CD4). We exclude individuals with diseases that may increase risk of an ATI, such as ongoing cardiac/autoimmune/neurological conditions, or cancer. Criteria for restarting ART during or at the end of an ATI depend on the study strategy being tested and there may be milestones such as the first confirmed measurement of a viral load >200 copies/mL, or the expiration of a 6-week period during which viral load remains >1000 copies/mL. In cases of prolonged periods of viremia, such as the latter example, usually additional safeguards should be in place (e.g. CD4 count should remain above 300 and there should be no evidence of disease progression).

## RECOMMENDATIONS

- Currently ATIs are considered the gold standard in evaluating whether the strategy under study shows efficacy in sustaining suppression of HIV in the absence of ART. As with all clinical trials, there are risks. We explore these issues in more detail in Modules 2, 3, and 4. The decision to participate in an HIV cure-directed clinical trial is yours; we recommend that you discuss the risks and benefits of the study and your individual medical history with your healthcare team and clinical trial study staff. We also draw your attention to the added resources included at the end of this document.
- Risks of potential HIV transmission during an ATI can be best addressed and reduced by implementing preventive and supportive steps during an ATI clinical trial (Peluso et al., 2020):
  - Participants should be encouraged to communicate with partners about their participation in an ATI study.
  - If agreeable to the participant, partners can be invited to accompany participants during their study visits.
  - Study staff should feel comfortable discussing HIV transmission issues with participants including prevention education and services, PrEP (pre-exposure prophylaxis), and PEP (post-exposure prophylaxis).
  - Participants should be aware that a sexually transmitted infection, if detected during an ATI, may increase risk of transmission.
  - We recommend that these conversations take place over the course of the study.
  - Participants and partners should be offered direct referrals to PrEP and PEP services. These referrals should be provided proactively and conducted in a “warm hand-off” fashion.



**BEAT-HIV**  
DELANEY COLLABORATORY



## Personal Reflection: Analytical Treatment Interruption



“ I am a 63-year old gay, white male, and a long-term survivor. I am in a long-term, committed relationship and have Medicare coverage as well as supplemental insurance. A more detailed description of my experience in a cure-directed study is available in an editorial that was published in the *Journal of Virus Eradication* in 2019 entitled, “From early AIDS vaccine to HIV cure research with analytical treatment trials: A study participant testimonial.”

*I tolerate my meds and I can manage my HIV. Stopping meds, even missing one day of meds, was something that was completely contrary to what I had thought, had been told, and had tried to adhere to, for the last 20 years or more. It was almost unthinkable. Compliance was the key to survival. Always have your meds with you. Make sure you have a valid prescription for refills.*

*Now, I had a whole room full of doctors, nurses and various other people in white coats, asking me to voluntarily stop my med as part of a cure-directed study. What a change. I had to admit that going off meds sounded attractive: they had no idea how many mornings I woke up and wanted to say “forget it” and just not take those pills.*

*The big question is how and why could this be safe? Would I undo any of the good I have done by starting on HIV meds as soon as they were available? What about resistance? Would I be able to go back on the same meds? How many others have done this, and avoided resistance? Was everything I had been told before about resistance not true?*

*About five months into my cure-directed study, I stopped taking my HIV meds. I was receiving an experimental drug, but not the HIV drugs I had been taking that had kept me undetectable for so long. U equals U [Undetectable = Untransmittable]. This could change. I knew that I could start having an increase in my viral load. I knew that I would be tested regularly. But I also knew that there could be a time lag between becoming detectable and getting a test result that showed it. This meant I could no longer rely on my “U” status. I had to worry about transmission.*

*I have been undetectable for so long that HIV transmission was not something that I worried about anymore. All of the sudden, it was back to the eighties and nineties again. If I became viremic after stopping meds the possibility of transmission was back. Every clinic appointment, for my study, even before going off my meds, included discussions about transmission and offers of condoms.*

*Now, I was no longer on meds. I wouldn't be tested for two weeks. On the one hand, I loved being off meds. But every day that passed, I had to think about the possibility of transmission.*

*After the first two weeks off meds, my blood test showed that I was detectable. I could transmit. As much as I was getting counseling about transmission from my study doctor, and even with what I knew from being positive for so long, it was still kind of scary. Fear is irrational. My viral load, while detectable, was still under 1,000. How high would it go? All of the sudden, I am thrown back in time. I am detectable.*

*I ended up being off my meds for 76 days. I have to say, I loved not taking pills every morning. A group of us used to make jokes about what all these drugs were doing to our insides. I always said that I was going to end up being nothing but dust inside. Now, after two and one half months of no drugs, I became detectable and would have to restart. I was able to just restart with my same meds. Within 27 days of restarting, I was back to undetectable. I have been undetectable ever since. For me, being on a cure-directed study and going off meds did not create any resistance issues for me.*

*Stopping meds takes a burden on partners/spouses, families and sex partners. But I still believe that with support from a study team the potential benefits outweigh any risks. ”*



## MODULE 2:

# Considerations for Participation in HIV Cure-directed Studies

### SUMMARY POINTS

- HIV cure-directed studies are conducted to achieve long-term suppression of HIV and maintenance of an undetectable viral load in the absence of ART therapy. Studies are also conducted to provide scientific information and clinical findings that will help us get closer to achieving a stable cure HIV.
- Cure-directed studies often include a period of time when a participant will pause their ART. During the pause of ART, a participant is likely to experience an increase of viral load or the return of HIV being detectable in the blood. During this interruption of ART therapy, a participant's viral load and T-cell CD4 counts are carefully and closely monitored; participants will be restarted on ART according to the study's procedures. Following re-initiation of ART, participants are monitored closely until the virus has been suppressed in the blood again.

Studies seek to achieve durable control without ART or a classic cure.
- Participants should be comfortable with all persons and organizations associated with the study.
- Understand that if you provide informed consent to enroll in an HIV cure-directed study, the hope and the expectation is that you will be able to complete the study; however, you are free to stop whenever you want.
- Clarify who will interact with you during a study and to what extent you will interact with doctors at the start of the study or if complications emerge.
- HIV cure-directed studies may ask you to provide informed consent to long-term storage of your samples after the study ends to allow for new analyses in the future as novel techniques and information changes.



## FREQUENTLY ASKED QUESTIONS

### Why participate in an HIV cure-directed study when my meds are working?

Research is the only way we will advance toward a cure. Indeed, current antiretroviral therapy was made possible because volunteers participated in HIV studies that tested how effective these therapies were when first introduced. Today, cure-directed research is a priority in the HIV research effort (OAR, 2020), since we now know of a limited number of cases have shown HIV can be cured. Although these selected cases were the result of cancer therapy (i.e. transplantation of stem cells) that carries a higher risk of death than current anti-HIV medicines. This strategy cannot be implemented in a large-scale fashion, but we now know it is possible to suppress HIV to undetectable levels for a significant amount of time, and potentially clear the virus from the body. Additional reasons for supporting HIV cure-directed research also include reducing social stigma associated with HIV, as well as removing lifelong dependency on ART, the economic burden of therapy administration world-wide, and the potential side effects associated with long-term ART into the future (Dubé et al., 2018; Simmons et al., 2017; Sylla et al., 2018).

Four decades into the global HIV epidemic, Timothy Ray Brown and Adam Castillejo remain the only two people determined to have been cured of HIV. Each had been diagnosed with cancer and received a stem cell transplant from donors with a naturally-occurring gene mutation that prevents HIV infection. Despite interrupting their HIV medications for 2+ years (Mr. Castillejo) and 10+ years (Mr. Brown), HIV cannot be detected in any of the samples tested to date.

### What steps are taken to protect my overall health?

All clinical trials should have been registered on [clinicaltrials.gov](https://clinicaltrials.gov) and have been carefully reviewed for safety by independent safety and review boards and the United States Food and Drug Administration (FDA - the agency that approves new medications) (if a new drug). For example, only persons who meet certain eligibility criteria are permitted to participate in studies that have added risks, such as a pause in ART. All known side effects associated with the study, which may affect your health, should be discussed with you before the study starts. Study staff should also discuss what steps will be taken to limit any long-term impacts of the study. Although there are always risks associated with ART interruption (see Module 1), an ATI is closely monitored, and ART restart has proven safe in several recent studies (Salantes et al., 2018). Study staff will always be ready to respond quickly to protect health and safety of study participants, and it is important that participants are given contact information where study staff can be reached 24/7.

### Will I still be able to see my primary care doctor? Will the study team share information with my primary care team?

Yes. Your primary care doctor and your study team should work together to ensure your wellbeing throughout the study. The study team should plan to convey routine lab results with your primary care team and if any medical issues arise. It is important to note that information will not be shared with your care team without consent.

### Am I going to experience an increase in viral load? How long will I be off antiretroviral meds? Will I get sick if I get off meds under a study?

Many cure-directed studies include steps that will require you to stop your ART. As cure-directed studies look to reduce HIV or provide a more effective control mechanism, a direct test of how the strategy may affect HIV may depend on what happens once therapy is paused. Following therapy interruption, you will likely become viremic; in other words, the virus is likely to be detected in the blood again. Your viral load will be measured frequently during this time. The frequency of monitoring during a period of therapy interruption should not permit viral load to persist if you experience any HIV-related complication, such as a T-cell/CD4 count below 300. How long you will be off your meds may vary, depending on the ART restart criteria. A thorough review of your medical history, including access to complete medical history/records, is needed to ensure that any ongoing medical conditions are considered prior to enrollment and to make it is as safe as possible to participate.

### **Will I be able to go back to using the same meds? Will I be undetectable again?**

The informed consent form should state the criteria that will determine when you will pause your antiretroviral treatment and when you will resume taking your meds (see Module 3 for a more detailed description of Informed Consent). Although it is not guaranteed, prior research has demonstrated that you will be able to resume using your same HIV meds after an ATI, and that you will again achieve undetectable status. (For additional information, please refer to the summary points and Frequently Asked Questions in Module 3, “Considerations for Therapy Interruption in Cure-directed Studies.”)

### **Who will interact with me and what role does the researcher have? Will I see him/her?**

Depending on the way the study is organized, you may or may not regularly interact with the **Principal Investigator** listed on the Informed Consent Form. When joining a study, you should clarify what interactions you will have with the researcher or doctor in charge. Research studies have several team members each with different responsibilities. Your main contact is most likely to be a study nurse or coordinator. There may be studies where your interaction with the Principal Investigator may be limited to the beginning and thereafter only if any complications arise. If you feel that you need more interaction with the study researcher, you should feel free to request them.

### **Who pays for study tests and other procedures?**

Clinical studies should cover all added tests that go beyond your insurance coverage as part of the study costs. Note that it is not uncommon that clinical studies incorporate routine tests you would normally have covered into study plan, such as CD4 count and viral load. You should ask if there will be any instances where your insurance will be billed outside of what is covered by the study. The Informed Consent document should describe what happens with any costs incurred if complications emerge during the study. Study staff are available to answer questions.

### **Why do studies often ask for my samples to be stored long after study is over?**

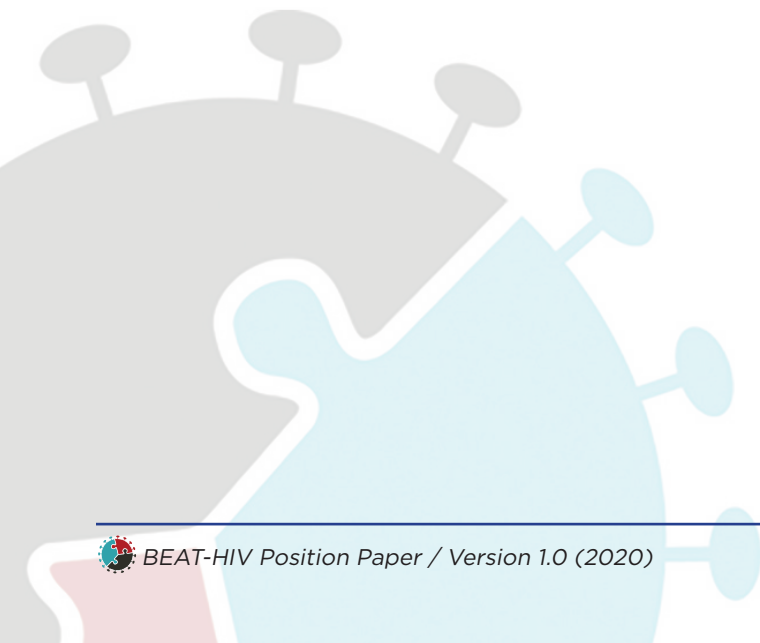
The research questions to be answered by your participation are based on the most current information and tests available to the study team. However, as new information emerges, there could be new research efforts that your samples may usefully contribute to. In other words, study samples are often kept beyond the original dates of the study (and sometimes shared with other institutions), so that after a study ends investigators can learn even more from your participation. It is important to read and understand this authorization to store your samples prior to signing it. The authorization to store samples is part of the Informed Consent form. A decision not to give consent to long-term storage of your samples should not prevent you from participating in the study.

### **Does it matter if I withdraw from a HIV cure-directed study?**

Agreeing to participate on a study is an important decision. Even though you signed an informed consent form, you can still change your mind and decide to end your participation at any time. **This is your right as a study volunteer.** It is important to note that if you start a study, whatever you do afterwards becomes the outcome of the study itself. The study team cannot replace your slot for another. Clinical studies often take more than 3+ years to plan, require large investments of time and resources, and do not allow your slot be given to another person. Therefore, your participation should be carefully considered. Keep in mind that your participation is always voluntary, and that study staff will respect your autonomy and the personal choices that you have for participating or withdrawing from a study.

## RECOMMENDATIONS

- Choosing whether or not to participate in a clinical trial is an important and meaningful decision for all people. We recommend that potential participants consider their personal reasons for participating and do so in consultation with their healthcare providers, study staff, friends and family.
- It is important for potential participants to be aware of the aims and procedures of a clinical study and to feel comfortable asking study staff any questions before joining a study.
- Potential participants should be aware of the people and organizations associated with the study and should feel comfortable asking study staff any and all questions about the study, its procedures and protocols, potential side effects, and the role of individuals and organizations in the research project.
- Participants should be aware that their primary care doctor remains an integral member of their healthcare team whether an individual chooses to join a clinical study or not. Participants should be aware that they are able consult with their personal healthcare providers over the course of the study.
- Since cure-directed studies often include a period of time when a participant will pause their antiretroviral medications (ART), we recommend that participants discuss any and all concerns about the analytical treatment interruption and potential return of the virus with study staff and their own personal healthcare provider.



**BEAT-HIV**  
DELANEY COLLABORATORY



## Personal Reflection #1: Cure-directed Study Participation

“ I am a 54-year old African American male and a long-term survivor (1994). I am in a long-term, committed relationship and have full health care coverage provided by my employer. I recovered from having a T-Cell count of 15 in 2001 and am currently undetectable with minimal adverse health issues from my formal hospitalization. This was my first participation in a cure-directed study.

*I made a conscious decision to participate in the study because it was the first time since my diagnosis that I felt that I could do something to change the outcome for those affected by HIV/AIDS. I was happy to be a part of the study because the treatment available to me brought me from the brink of death to it being a manageable condition. And the thought of suspending my treatment to see how my immune system would respond also intrigued me.*

*I received information about the study and the blood work that would be required along with the injections that I would have to have administered. All this was new to me, but I was anxious to start. The first weeks of the study went well, and the team at the clinical site made sure that I was well informed about my lab results, and potential side effects and the next steps in the process. After I suspended my HIV drug regimen as a part of the study, issues with my white blood cell level began to make the researchers take more attention to monitoring me.*

*I was required to make additional visits and to take added measures (more injections) to ensure that my white blood cell levels remained at an acceptable level. I did endure side effects and there were times when I didn't feel well. But, I didn't mind the extra effort that I had to make because I wanted to be a test case for patients with similar issues. I was committed to continue as long as I could.*

*About a month and a half into my HIV drug suspension or ATI, my viral load began to rebound so I had to restart my medications. I was very disappointed because I hoped that I would be able to stop taking my meds for a longer length of time. The research team provided support and encouraged me to not be too disappointed and to continue to be a part of this significant study.*

*Upon completion, I honestly walked away proud that I was a part of it. And knowing that the next generation of long-term survivors will benefit from my involvement and hopefully do the same until HIV/AIDS no longer exists. ”*

## Personal Reflection #2: Cure-directed Study Participation



“ I was diagnosed with HIV in 2007 and ever since, it has been my mission to give back to the community. I became a member of Positive Women’s Network over 10 years ago and began HIV-advocacy upon graduating the Treatment, Education, Activist Combating HIV (TEACH) program at Philadelphia FIGHT. I currently sit on the Philadelphia FIGHT Ambassador CAB, as well as the PeopleHood and Positive Community Committees. I volunteer for the Prison Health News, a publication produced and distributed to people who are incarcerated, and I am working for Vote Positive PA.

I participated in a study to help find a cure for HIV/AIDS. I didn’t think about the possibility of my medications not working when I needed to restart them. I wanted to help newly diagnosed patients get the help they need by coping with their HIV/AIDS statistic. I know that one day there will be a cure. If doing this research can help others, then I will keep doing this research. I want to do all that I can to help others. I feel helping others is helping me. This was a great experience for me. I would do it again.

I never thought about not completing this study. I never thought it was a contract either. When I agreed to do the study, I also knew what I was getting into. Nobody made me or coerced me to do this research. I wanted to help. ”



## MODULE 3:

# Considerations for Navigating the Informed Consent Process in an HIV Cure-directed Study

### SUMMARY POINTS

- The informed consent process is intended to provide you with information about a research study, to explain your rights and responsibilities in language that you understand, and to provide the space for you to raise any questions that you have about the study.
- The informed consent form should clearly state that you participate only because you want to.
- You should feel comfortable to review the informed consent form with whomever you want.
- When reviewing the informed consent form, pay special attention to who is sponsoring the study, what side effects to expect, and how will they be addressed.
- Although the informed consent process takes place at the beginning of your participation in the study, you should feel free, and have the right, to review and discuss the informed consent form and process with study staff at any time during your participation.
- An ATI study may have different **study arms (or treatment groups)**, and it is important to understand the differences between the arms of a clinical study.

The informed consent process is one of the most important aspects of any clinical study.



## FREQUENTLY ASKED QUESTIONS

### **What are the essential aspects and points that should be covered in an Informed Consent Form?**

The informed consent form should fully explain what the research is all about (in other words, the who, what, where, why, and how). It should describe in detail what is expected from you (how many visits, what types of samples will be gathered, what dates you are expected to visit the clinical site, where the study visits will occur, and how long each visit will last.). The informed consent form must state that your participation is voluntary and that you can leave the study at any time. The informed consent form will also explain how you will be reimbursed for expenses and your time. Potential participants should always be encouraged to ask for clarifications, details, explanations, summaries, tables/graphics, or whatever helps them understand the study's purposes, procedures, risks and benefits. See additional information in the Resources section.

### **Who will discuss the Informed Consent with me?**

Each study team defines their own informed consent process, which may be carried out by a study nurse or research assistant. Some states, however, require that a physician review the informed consent documents during the enrollment process. It is important to know that you have the right at any time during a study to ask to review and discuss the informed consent Form and study procedures with staff. You may have questions that develop over the course of the study, and you are entitled to have the informed consent form reviewed and your questions answered at any time.

### **If English is not my first language, can I ask for a translation or for a bilingual speaker to help me?**

Yes. Understanding the informed consent document is very important as each word in the informed consent form is intended to give you information that you need to know. If you are not comfortable with your understanding of the informed consent form or have difficulties understanding any aspect of the study - you should not sign the form and instead ask for assistance. You can ask for a translation of the informed consent form, and you have the right to have a trusted person or persons review with the informed consent form with you and to have them come with you during study appointments.

### **If the informed consent document states that I will get paid during the study, is my participation like being “hired” for a job?**

No. Your participation remains voluntary at all times. Any payment provided is to reimburse you for time and travel. There is no expectation that you need to stay in a study because you already have received a payment.

### **Does the informed consent form need to state what happens if I get injured in study?**

Yes. The informed consent form should describe how you will be taken care of if you get injured and what aspects of any medical care you need will be covered by the study or your personal insurance provider.

### **Should the informed consent form make clear how my confidentiality will be protected?**

Yes. The informed consent form must explain how your personal information will be kept confidential. The form will provide a description of who will have access to your medical records, who will have access to study records and personal information, and whether any of your data will be kept on clinical site electronic medical records. All clinical trial participants are entitled to confidentiality, and study staff have the responsibility to ensure that your participation in the study and medical information remain confidential.

### **If I sign an informed consent form, am I done with providing consent until the study ends?**

Even after you sign the initial study informed consent form, you may be asked to sign additional updated informed consent forms. Any additional informed consent forms may describe specific clinical procedures that have been added or changed. Forms may also explain if the study timeline has changed because new information has become available. Do not sign any updated informed consent form until you fully understand what new information has been added. You should feel free to ask questions about the study at any time, and you are entitled to discuss your participation with the study team at any time. Since you have the option to withdraw from the study at any time, each time you come to a study visit or procedure, you are basically reconfirming that you agree to continue your participation.

## **Why are there different arms on my study? Can I choose which arm I want to be on?**

### **What does this mean for me?**

Many studies investigating the effects of new medications and treatment strategies, not just HIV studies, have multiple arms (or different subgroups of participants) in the study. The term arm refers to a treatment condition or group within a research study. Including different arms in a clinical study is important for better isolating and learning about the specific ways each drug or curative study works. In an ATI study, there may be two (or more) arms. For example, one arm where a participant receives the drug and has an ATI, and the other arm where a participant does not receive a study-related drug or curative strategy nor experience a pause in antiretroviral therapy. This allows the research team to focus on how a specific drug or strategy works by comparing the study strategy with current standards of HIV care. Both arms are equally important and necessary for the study. The Informed Consent you are provided before enrolling will detail and explain if your study has multiple arms. If the study you are participating in includes more than one arm, you may be randomly assigned to one of the arms. If randomly assigned, you will not be able to decide what arm you are participating in. This procedure is known as the gold standard in clinical research: the **randomized-controlled trial**.

## **Should the informed consent state clearly who is funding the study and who is providing study medications or curative strategies?**

Yes. The team, people, and organizations behind a study are just as important as the study question itself. You are entitled to know: who is funding the study, who is providing the study medication, who is overseeing the study, who are the principal investigators or researchers, who is making sure the study is conducted and monitored, and who is the person who will interact with you as a participant. If this information has not been provided or if you are unsure of any of these aspects, you are entitled to have the study staff explain this information to you. You should also confirm that the study team and their objectives are listed on respected websites such as [aidsinfo.nih.gov](http://aidsinfo.nih.gov) and [clinicaltrials.gov](http://clinicaltrials.gov). You should also seek input from local community-based organizations for their collective experience with the team or organizations sponsoring the study.

## **Will the informed consent form state how any findings from the study will be communicated to me?**

### **Where will I be able to find out what the main outcomes of the study were?**

Not all Informed Consent forms state what will happen after all data have been collected and analyzed. Clinical trials take many years, and it could be months (or years) after the final study visit of the last participant in a study before the findings of the study are known and communicated. If you would like to learn about the results of the study, make sure to (1) reconfirm the contact information of who you can contact for information about the study after your participation has ended and make sure to obtain their contact information and (2) ask what is the anticipated end date of the study is so that you can time your future communication. We strongly recommend that study teams communicate any findings to participants. Consent for future contact should be documented and contact information should be securely stored.

## **What aspects are often not in the informed consent form but I should ask about anyway?**

- Is there a person I can call 24/7 for added support or questions?
- When will I see the study doctor during the study?
- Will my insurance be expected to cover any aspect of the study plan?
- Is there a plan to archive unused biological specimens?
- How do I find out the results of the study, will I be contacted?
- What if I get worried about being off my meds? Is there someone I can talk to?

## **What if I need to contact study staff in the future?**

Study staff and/or the principal investigator should remain available to previous participants, no matter how much time has passed from the conclusion of the study until you have a follow up question. The study principal investigator should be listed on the informed consent document. If you cannot locate your consent documents, [clinicaltrials.gov](http://clinicaltrials.gov) may be helpful in “tracking down” staff from previous clinical trials.

## RECOMMENDATIONS

- All informed consent forms must contain a statement that participation is voluntary.
- All informed consent forms must explain that the study involves research to get us closer to a cure but not indicate that an HIV cure will occur.
- Consent forms should state: the purpose of the study, the duration, the procedures, the risks and benefits of participation, any alternatives to participation, description of confidentiality of records and identifying personal information, compensation associated with participation, and whom to contact if you have any questions.
- The informed consent forms and process should be explained with plain, simple terminology and using the language that you are most comfortable with.
- We recommend that you take the informed consent form home and spend time with it, discuss it with your healthcare team and other trusted advisors, discuss questions about the study, and ensure that you fully understand the study procedures and what is being asked of you before you sign the form and commit to volunteering in a study.
- The informed consent process is an ongoing practice. You have the right at any time to ask questions about the informed consent form and your ongoing participation in the study. Study staff should include regular check-ins about the informed consent forms at important time-points during the study.
- Reimbursements and payments during the study should be clearly explained.
- Study teams should proactively communicate findings and results of the study to all participants.



**BEAT-HIV**  
DELANEY COLLABORATORY



## Personal Reflection: Informed Consent Process



“ I am a Field Coordinator for NHBS [National Health Behavior Survey] and COVID-19 contact tracer for the Philadelphia Health Department and Proprietor of “Prim and Proper Mobile Beauty Salon” and Lamour Productions – Entertainment Group”. I am a Licensed Beauty Stylist/Business Owner, Entertainer, Hostess/MC, Community Trans-Activist, and Mother of Face and Grace with a willingness to help anyone. In a career spanning 35 years, my only mission has been to make a difference by being an example. Showing the world that by giving of myself and consenting to be in studies and medical research. For others to trust the process, I show how trustworthy the consent process is, which makes the final analysis more precise. I live to help.

When Philadelphia FIGHT first called me for the study, I went to the office, and they had this big pile of papers. And of course, I am looking at this stack of papers thinking what did I get myself into? Then the study coordinator told me to ignore the papers and just look her in the eyes. Which I thought was pleasantly different, because she wanted to make sure that she had my attention, and that’s when she verbally explained to me what to expect during the study, what is going to be happening when, the increments of time it would be happening, and the different phases of the study. As she started breaking it all down, all of the fear I had – little by little – started disappearing.

All of these questions were rattling off in my head, and the biggest fear was cancer, which runs in my family, and interferon. Does interferon cause cancer or is it used to treat cancer?

As a trans woman, we question everything – the pink elephant. All I was thinking about was the pink elephant in the room, and I was thinking about Tuskegee.

This is about more than just a little bit of coin. Am I really helping to accomplish something to participate? When I do a study... God has blessed me so many ways, I’m not rich... but he always takes care of my needs, so I’m not worried about the money.

My thing is – will the information that has been gained [from the study] save someone else? When we get done – are you [the researchers] going to let people see the results and have a glimmer of hope?

*Because I want that 17-year old Andrea to know how to protect herself or if she comes in danger of certain diseases or drugs – I want to show her that she is not doomed, that she can make it. That is all that I want.*

*And that's when the study coordinator broke it down to me that interferon was a start. She broke the study down, what interferon does, the side effects, what I need to look out for and if I did get a side effect, what to do, who to call. Another good thing, my provider at FIGHT, she is my friend and is in PWN (Positive Women's Network) with me – she is friend enough that if I got scared, she would take my call – help me if I was feeling some type of way. She did not miss a beat. All of her explanations turned out exactly like she said.*

*The way they do informed consent at FIGHT – the research team and your providers meet with you to explain the research being done. They talk about the study and answer any questions. They were already answering my questions before I asked them or opened my mouth.*

*Especially as a trans woman, being on hormones, the big question was is the interferon going to interfere with my hormones? Are my levels of drug going to go down because of my Hep C, HIV? They answered all of my questions.*

*At first, they were offering all of this information so freely, and seeing all of the papers, giving me all of the negative information, and I was getting nervous. I thought is this going to be bearable or permanent? I was a little scared. And that's when they, the research team and doctors at FIGHT, explained that they wanted to be straight with me and not sugar coat anything, so that I knew when I said yes – I would be okay. And if I said no – that would also be okay too. Their willingness to explain made me more willing to participate. ”*



## MODULE 4:

### Additional Social and Health Implications to Consider

#### SUMMARY POINTS

- Participating in ATI trials may cause anxiety. Mental health support should be described in the informed consent form.
- If the participant's virus remains suppressed during the ATI, additional monitoring may be described in the informed consent form.
- There no direct benefits from study participation. However, previous participants have expressed feelings of giving back and hope for future generations.
- Stigma regarding HIV, both internalized and externally driven, still exists. How will a participant handle this?
- Some states have laws regarding the criminalization of HIV transmission. Prior to enrollment in an ATI study, participants should be aware of these laws in their specific location and where they might have sex, as well as understand their rights and the rights of their sexual partners.
- Participation in an HIV cure-directed study may have implications for the ability to participate in other studies.

Study participants may need to consider the potential for HIV transmission.



## FREQUENTLY ASKED QUESTIONS

### **If I need mental health support during the study, will that be provided?**

Participation in any study can cause worry and concern. Participation in an ATI can also cause anxiety. If, as a study participant, you experience anxiety or any mental health issues or concerns, you should immediately make the study team aware of this. You may be directed to local support groups and/or an individual care provider, counselor, or health psychologist. We recommend that the study team assist you in locating and receiving proper mental health support during the study.

### **What happens if the study intervention is successful and I remain virally suppressed?**

#### **Will I keep receiving the study drug or curative strategy?**

A study is for a predetermined amount of time, as specified in the informed consent form. The period of time during which a participant will experience a pause in antiretroviral therapy (ART) is set in advance and informed by how the study has been designed. This length of this period should be stated and described in the informed consent form. When you enroll in a study, you will be asked to follow the study procedures. In some cases, you may be followed after the official end of the study. Note that studies often have an option to extend monitoring beyond the anticipated study end, if you achieve long-term control of virus without ART.

### **Will the study team follow me after my participation ends?**

The informed consent form should state how long the study team will follow your progress after you complete the study in case long-term monitoring is included in the study plan.

### **What are the perceived benefits to participating in a cure-directed study?**

There are no direct anticipated clinical benefits from participating in an HIV cure-directed clinical study. Every participant has their own reasons for enrolling in a study. These may include access to medical care or increased access to medical care. Some participants may feel that the study doctors have more knowledge about HIV treatment. Some see study participation as a fast track to new and better HIV treatments. It is important for participants to understand that HIV cure-directed clinical studies are investigational and not therapeutic or providing “a cure”, therefore they may have no direct benefit to participants. It is highly unlikely that participants will be cured of HIV. It is important for the research team to address these feelings and reasons that potential participants may express during study visits. Some see participation in altruistic terms – a way to give back to those who participated in the early studies that were groundbreaking in HIV research and/or a way to give back to the community now and in the future. Each participant has their own reasons for participating in a clinical trial and their own personal thoughts on potential benefits (K. Dubé et al., 2020; Sylla et al., 2018; Yang & Underhill, 2018).

### **Does my state criminalize HIV transmission? How do I find this out, and how will this affect me during my study?**

The first step is knowledge. Laws regarding HIV transmission and criminality vary from state to state and you need to know the law where you live (and where you might have sex). We recommend that you contact any of the HIV legal services in the “References” section of this paper to learn your state’s laws.

During an ATI, there is the potential of becoming viremic and thus able to transmit the virus. The study will provide regular HIV tests to help you monitor your status. If you are detectable, you may reduce or eliminate the risk of transmission by engaging in lower risk activities, consistent and correct condom use, and/or asking sexual partners to use PrEP.

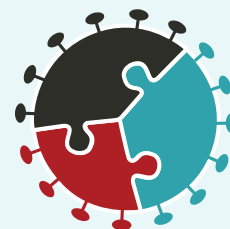
## Given that I can remain undetectable under ART, why should I risk losing this status?

### How can I justify this to myself?

The only way to determine with certainty if an HIV cure-directed strategy is effective is to stop taking ART for a defined period, while under close supervision on a study. The current standard of care for HIV is ART. Stopping this treatment may seem unreasonable, but a closely monitored analytical treatment interruption is currently the best way we have for studying whether an experimental strategy shows promise. It is important that a participant understand the reason for pausing ART and feels comfortable communicating their reasons with their family, friends, and partners (see Module 1). Without people willing to take part in clinical studies, we will not be able to make progress in our search for an HIV cure. Like those who took part in early clinical trials in the 1980s and 1990s that demonstrated the lifesaving effect of combination antiretroviral therapies – participants in HIV cure-related clinical trials are trailblazers and heroes.

## RECOMMENDATIONS

- The design, procedures, and steps in a clinical study must be explained carefully and comprehensively to participants. Participants must be informed that they may be assigned to a specific group or “arm” of a study.
- The study team should be attentive to the mental health of study participants. Study staff should assist participants in locating and receiving proper mental health support during the study if needed.
- Criminalization of HIV transmission is an important concern for people living with HIV. We recommend that study staff work with their respective HIV law offices to learn about HIV criminalization laws in their local regions and become familiar with legal services in their communities. We also recommend that participants make themselves aware if any of the laws exist in your communities and how to protect sexual partners. We have provided information about community legal service organization in our “Resources” section.
- Participants should ask if participating in this clinical trial will exclude them from participating in other clinical trials, either at the same time or in the future.
- Participants should ask study personnel whether they will receive continued monitoring if a study is successful and they remain without a viral rebound during or after the ATI.



**BEAT-HIV**  
DELANEY COLLABORATORY

## Personal Reflection: Self-empowerment and Gratitude



“ I serve on HIV Prevention Trials Network (HPTN) community advisory boards for both George Washington University/Milken School of Public Health and Whitman-Walker Health in the District of Columbia; on the Virginia Community HIV Planning Group; as a Community Engagement Ambassador for the BELIEVE Martin Delaney Collaboratory for HIV Cure Research; on the Convening Group for the HIV 50+ National Advocacy Network; and as co-founder of Impacto LGBT, a nonprofit community-based organization serving the LGBT Latinx community of Northern Virginia.

*I am on effective combination antiretroviral therapy (cART) that enables me to maintain an undetectable viral load. I have participated during the past ten years in a dozen HIV-related clinical studies, two of which are ongoing. One of these two active studies is an HIV cure-directed clinical trial that involves analytical treatment interruptions (ATI). The first ATI, completed last fall, lasted a total of six weeks and went smoothly. I started the second ATI two weeks ago and will continue for as long as my immune system controls viremia, and I stay within the study safety limits as monitored via physical examination and laboratory testing every two weeks.*

*I participate in clinical research for a number of reasons. Participation does involve costs: a significant commitment of time, occasional discomfort, and for studies involving ATIs, a certain degree of risk (that I find reasonable). However, I benefit from participation in many ways. First and foremost, participation permits me to express gratitude to the many selfless people whose participation in clinical trials in years past led to the treatments that enable us PLWHA to live long and healthy lives today. I get the chance to say “thank you” to those who came before me while also “paying it forward” to benefit the next generation.*

*Research participation also empowers me in two distinct ways. First, I benefit from ongoing opportunities to learn with and from leading experts about HIV, various related illnesses/conditions, and how best to manage my health. I ask questions, learn something new during every clinic visit, and use this information to prepare for visits with my HIV doctors. Participation also empowers me to take charge of my situation by putting my virus to work. I didn't ask for the virus, but since I have to live with HIV, it will need to work as hard as I do.*

*Research participation provides the opportunity to serve. In all honesty, I never expected to focus on HIV. In fact I spent years trying to limit the degree to which HIV played any role in my life aside from daily medications, regular visits to my doctor and routine lab work. I now have the chance to advance the science of HIV and contribute in a small but essential way to development of cure strategies. I use my experience as a research participant to inform my work on community advisory boards, HIV care services planning groups, and advocacy on behalf of our community.*

*I am fortunate to have health insurance and access to quality healthcare services through the Maryland Medical Assistance program and expect no direct clinical benefit from participating in research. However, I received an unexpected benefit during the first ATI of my current clinical trial during which I experienced a marked decrease in the level of chronic fatigue that had plagued me for the past two years. I discussed this welcome reprieve with my HIV doctors and my study doctors, and we decided together to switch me to a new HIV medication when I resumed treatment. My HIV viral load was reduced within a month to an undetectable level. I continue to benefit from reduced fatigue and am now able to increase my level of physical activity to rebuild my stamina and energy reserves. What a welcome surprise!*

*Many clinical studies provide volunteers a modest stipend to reimburse direct costs of participation such as transportation, time, etc. This is a vital measure to expand access to participate to all interested volunteers regardless of their financial situation.*

*In summary, I benefit from participating in clinical studies in many ways, the most important of which include self-empowerment, a sense of purpose, and the opportunity to express gratitude to the many selfless volunteers and dedicated researchers whose work brought us to the promising place we are today in which HIV is a chronic but manageable condition, we are working to end the epidemic, and steady progress is being made towards effective cure strategies. ”*





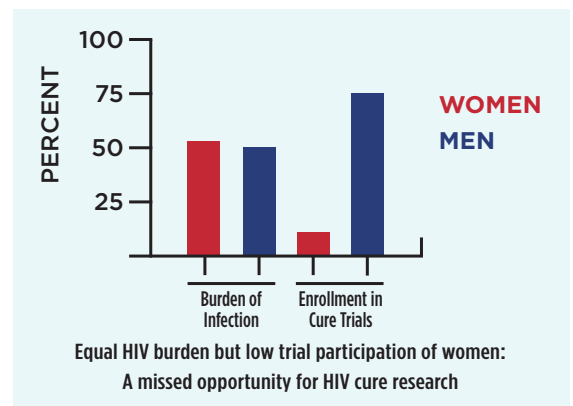
## MODULE 5:

### Women and HIV Cure-directed Clinical Research

#### SUMMARY POINTS

- In this module we conceptualize gender and sex on a spectrum. We employ the term women to represent and respect the entire spectrum, including trans- and cis-gender women and non-binary people of trans experience.

Women account for more than 50% of those living with HIV around the world, yet women represent only 11% of those participating in clinical trials.



*Johnston and Heitzeg, AIDS Res and Human Retroviruses, 2015*

- The glaring research disparity created by a lack of women participants must be addressed and rectified as the search for an HIV cure continues.
- **Both gender and sex matter in HIV cure-directed research.** There are gender- and sex-specific biological, emotional, and social factors and concerns that must be addressed in cure-directed research, ranging from how individuals are engaged and supported as they participate in cure-directed research to how the concerns and needs of women are addressed by study staff to how potential cure-related strategies may interact with hormones to how data are reported in research findings.
- There are multiple barriers that women face when participating in research, including scheduling, child-care, transportation, and access to information about HIV cure-directed clinical trials.

- Researchers have multiple opportunities to make participation of women easier such as increasing outreach and education for women, providing transit and childcare support, and being flexible in scheduling appointment times or extending “standard” operating hours.
- Inclusion of cis-and trans-gender women is imperative for HIV-cure research so that when a cure strategy is found, it will be both accessible and affirming for all people.
- We hope this module will provide all women with information to make informed and empowered decisions regarding their interest and participation in cure-directed clinical research.

**TRANSGENDER** (adjective). Trans comes from Latin, meaning “on the other side.” Transgender refers to a person whose gender identity is different from the sex and gender assigned at birth. Some people use the label trans to identify themselves; others may use a range of terms from queer to non-binary to feminine identifying.

**CISGENDER** (adjective). Cis comes from Latin, meaning “on the same side.” Cisgender refers to a person who identifies with the sex and gender they were assigned at birth.

The BEAT-HIV CAB, along with other health advocates, is committed to making space for voices to be heard and attention to be given to people who have been historically underrepresented in not only cure-directed clinical studies but HIV research more broadly (D. Chung et al., 2014; Goldstein & Walensky, 2019; Julg et al., 2019). This module exists because there are special considerations and stark disparities that remain unaddressed in current enrollment of women in HIV cure-directed research, as well as in how data on gender and sex are collected and reported. Women represent 52% of adults living with HIV globally (WHO, 2018). In the United States, women account for 19% of new HIV diagnoses and of those, African American women account for 57% of new infections (CDC, 2018). **However, women are consistently underrepresented in clinical trials, including HIV cure clinical trials where only 11% of enrolled participants are women (Johnston, 2015).** Put another way, in order to determine if a curative strategy being tested works as well in women as it does in men, it is critical to include a more representative number of women (and gender minorities) in the data analysis of HIV cure-directed clinical trials.

The FDA has issued guidelines to advance gender equity in clinical trial enrollment. The FDA advocates that enrollment of participants should be consistent with “... sex-specific prevalence of the disease or condition intended for treatment or diagnosis ...” and that researchers should be proactive in their efforts to enroll and maintain accrual of women in clinical trials (FDA, 2014). Further, it is important to collect and report complete enrollment data, i.e. demographic data that includes sex, gender, race, and ethnicity. The scientific community cannot address the **health disparities** long associated with HIV infection and lack of inclusion of women in HIV research studies without a complete understanding of who enrolls in cure-directed trials and how specific patterns of enrollment may vary across regions/cities/sites. Until enrollment data by gender and sex are widely reported as standard practice, we will never be able assess if a cure strategy will be effective in more than half of the people living with HIV.

## FREQUENTLY ASKED QUESTIONS

### Let's start with the basics. What is sex at birth? What is gender? Identity? Expression? Orientation?

Below we offer definitions to these terms since they often come up in our conversations about women and research. It is important for all to understand the meanings of these terms because they matter in HIV-cure directed (and other) research.

**Sex:** Sometimes this term is referred to as biological sex. We recommend using the term, “sex assigned at birth.” It refers to the assignment and classification of people as female, male, intersex, or another sex based on a combination of anatomy, chromosomes, and hormones. Sex assigned at birth can also be understood as a spectrum. There is no reason for sex and gender identity to be the same.

**Gender:** We recommend using the term, **gender identity**. Everyone has a gender identity, which refers to one’s internal sense of being female, male, both of these, neither of these, or another gender or genders.

**Gender expression or presentation:** These terms refer to the way a person presents herself to the world (or himself or theirself). Sometimes these terms refer to physical and social manifestation of one’s gender identity through clothing, voice, hairstyle, body shape, etc. Like sex and gender, gender expression is a spectrum and refers to a diverse range of expressions and presentations of what is commonly referred to as masculinity and femininity.

**Sexual orientation:** The term often refers to physical and sexual attraction. Sexual orientation may have little to do with how someone expresses their gender or the gender or sex of their physical and/or romantic partner(s). Sexual orientation lies along a spectrum as well.

### Why is sex and gender equity important in HIV cure-directed research?

The balance of women (cis- or trans-) and men (cis- or trans-), is important in HIV-cure directed research because women and men experience HIV differently. Biological factors, **pharmacokinetics** (PK) of ART (how drugs move within the body), and social factors experienced by women living with HIV could alter how different cure strategies impact a woman’s body or could render a treatment more or less effective. Depending on how a particular cure strategy is delivered and due to the historical systemic economic oppression of women, access may be limited for large segments of the population of PLWHA. Recall the global and national statistics of HIV, that across the world, women represent 52% of adults living with HIV (WHO, 2018). In the US, women make up 19% of new HIV diagnoses; of those, African American women account for 57% of new infections (CDC, 2018). These factors must be taken into account as studies and trials are developed, so that all women benefit when a cure strategy is developed.

We know that HIV affects the cis-female body differently than the male body (Scully, 2018), and, it is only recently that studies that have begun exploring the effects of HIV and HIV treatments in trans people (C. Chung, Kalra, McBride, Roebuck, & Sprague, 2016; C. Chung, Kalra, Sprague, & Campbell, 2016; Herbst et al., 2008; Klein, Psihopaidas, Xavier, & Cohen, 2020; Wansom, Guadamuz, & Vasan, 2016). Studies to date have shown several biological differences of HIV in the cis-female body:

1. Anatomical
2. Genetic and Hormonal (This is mainly related to the X chromosome, and estrogen being predominant in women.)

3. **Immune system** function (This refers to the different ways our bodies fight disease and infections.)
4. **HIV Latency** on ART (cis-gender women may have a smaller HIV reservoir)
5. T-cell or CD4 counts (women have been found to have lower T-cell or CD4 counts than men when on successful ART)
6. Microbiome (This refers to the small organisms living in a person's body. The way they influence health and medical treatments are just being understood.)

The reasons for these differences are not clear, nor are the pathways through which these differences impact long-term health. But what is clear is that sex and gender differences exist, and *that is why it's important to enroll more women in HIV research studies.*

Let's look at one example of these six biological differences.

Estrogen, commonly referred to as the “female sex hormone,” plays a key role in women's immune systems. It is important to underscore that people of all sexes and genders have various levels of estrogen in their bodies and that those levels change over the life course. Studies have shown that HIV interacts differently in female bodies (or in people assigned female at birth), and this may have to do with the influence of estrogen and its potential interactions with specific medications (Scully, 2018). For instance, women experience fewer symptoms during the early stages of infection and because of this, may be diagnosed later (Gianella, Tsibris, Barr, & Godfrey, 2016). At the same time, women tend to have higher CD4 counts and lower viral loads, but experience AIDS-related conditions faster than men with the same viral loads (Curno et al., 2016). Differences in body size, absorption, and clearance of antiretroviral therapy may also affect how cure-directed strategies may work in the female body (Curno et al., 2016). Researchers have shown that the HIV **reservoir** (persistent HIV that remains after ART) is smaller in women than in men, which is an important consideration when developing curative strategies (Das et al., 2018).

It is vitally important that transgender people are represented in HIV cure-directed research, so that we (investigators, clinicians, and the community) understand how hormones and cure treatments interact, in order for any cure strategy to be both effective and **affirming**.

### **What are some of the major barriers to participating in a clinical trial that women face?**

The easy answer, and one commonly heard at HIV science conferences among researchers, is that women “have more to do.”

True, women are primary caregivers for children and family members and are often the only wage earner in a home. However, the HIV cure landscape is more complex than simply saying women are busier than their male counterparts and then accepting that as the reason women are not participating in clinical trials. We can and should do better.

For women with children or families to take care of, participating in a complex clinical trial means adding another thing to manage in an already overburdened schedule. Flexibility is key to increasing the number of women in clinical trials. This may mean having earlier (or later) clinic appointments or extending visit windows to accommodate work or family care schedules. Flexibility may also mean providing additional study-related compensation for individuals with caregiving obligations. Examining the flow of the traditional study timeline may highlight opportunities to better respond to the needs of cis- and trans-women.



Transportation may also be a barrier to enrolling women in HIV cure-directed clinical trials. In urban settings with mass transit, women with small children may find it challenging to navigate taking public transport with children in tow or having to take children with them to early morning appointments when that also involves getting children “ready to go” at an earlier hour than usual. In rural areas, it may not be possible for women to participate if they do not have access to a vehicle or if a bus/subway does not reach their location. Employing remote health or telemedicine or at-home study visits may address these obstacles.

Recruiting women into HIV cure-directed trials may require different strategies than are used for recruiting men, so traditional techniques to meet enrollment goals may be inadequate for increasing female participation.

Women typically earn less than men, making it more difficult to take time off from work. Frequently, women are employed in shift work, making it more difficult for them to participate in lengthy study visits. As well, strict window visits may be especially challenging for women with small children (Gianella et al., 2016).

There is also evidence to showing that provider bias plays a negative role in female participation in clinical trials and not just HIV cure trials. What does that mean? It means that doctors and other healthcare providers may not even mention research opportunities to their female patients. This silence effectively eliminates the opportunity for women to even consider joining a trial (Gianella et al., 2016; Grewe, Ma, Gilbertson, Rennie, & Tucker, 2016; Johnston & Heitzeg, 2015). This is especially relevant and problematic for communities that have been traditionally marginalized by medical and healthcare systems or excluded from research altogether. We know, and research has shown, that people want to participate in clinical studies. People have stated that they want to be able to contribute towards future treatments or cures for diseases and/or have expressed that they think being in a study might help their health. Women WANT to participate. Scientists just aren’t asking them! (Gianella et al., 2016).

Intimate partner violence (IPV) cannot be overlooked as a barrier for both cis-women and transgender women living with HIV who are interested in participating in HIV cure-directed clinical trials. Women experiencing IPV are cut off from social activities and from engaging in healthcare, regardless of clinical trial participation. IPV is about power and control of another human being; women in such relationships tend to self-isolate, have less control of their daily lives, and may be less able to make informed decisions to improve their lives. Additional barriers beyond those described above may exist, and this list is not intended to be all-inclusive.

### **What are concerns that are particular to women in HIV cure-directed research?**

Stigma and the fear of being discovered as a person living with HIV remains a significant concern for women considering participation in HIV cure-directed clinical trials (Dubé, 2019). When surveyed, women have responded that personal concerns include, but are not limited to, increases in viral load, long-term health, pelvic examinations, large blood draws, and intersectional stigma (K. Dubé et al., 2020; Gianella et al., 2016). Intersectional theory asserts that people are often disadvantaged by multiple sources of oppression: race, class, gender identity, sexual orientation, religion, and/or other identity markers.

### **What motivates women to participate in HIV cure-directed research?**

Factors motivating women to participate are not that different from those influencing men. Altruism, or wanting to help others, is a key motivator for women participating in cure clinical trials, as well as hope, access to treatment, improving personal knowledge about health and increasing the number of women in HIV cure-directed trials (K. Dubé et al., 2020; K Dubé et al., 2020; Sylla et al., 2018). The role of compensation cannot be overlooked, though investigators must be cautious of study payments that may be considered coercive. Compensation is perceived as a benefit for study participation (Sylla et al., 2018),

and therefore, may allow volunteers to have some measure of flexibility within their budgets to have funds not otherwise possible. For women experiencing abuse, access to social supports, study staff, and compensation may be a life-line for themselves and their families.

## RECOMMENDATIONS

In order to support the participation of cis- and trans-women in HIV cure-directed clinical trials, the BEAT-HIV Community Engagement Group offers the following recommendations. They are directed primarily to investigators, providers, and funding agencies:

### Foundational Principles

- Providers must support the self-determination and autonomy of their female patients by offering opportunities to engage in HIV cure-directed research.
- Ensure that community education and engagement activities meet women where they are.
- Develop study protocols that reflect the gender dynamics of the local epidemic, i.e. including a representative percentage of female participants in each arm and provide adequate time to meet recruitment targets.

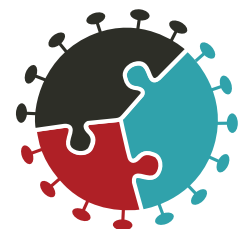
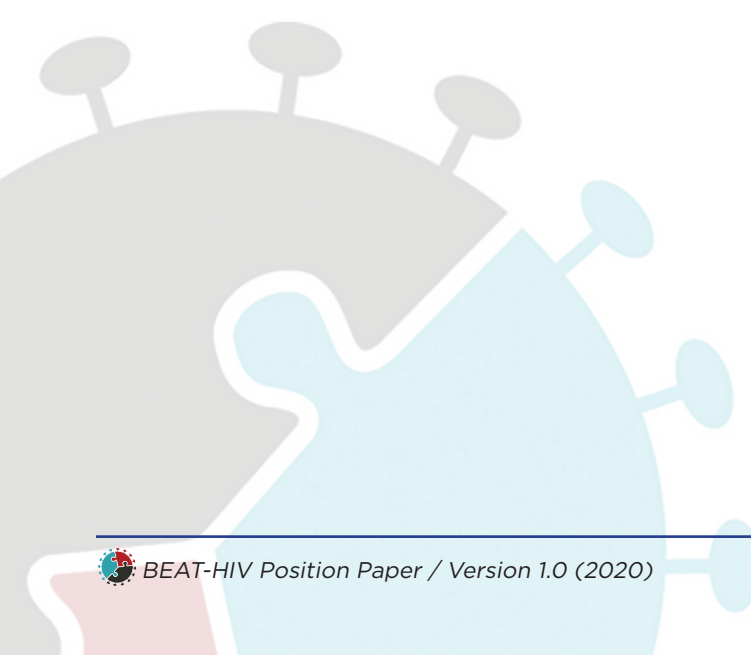
### Study Design and Operational Recommendations

- Ensure the study team and the research environment is safe and welcoming for all women.
- Offer birth control to sexually active women of reproductive age (two methods of contraception if study so stipulates in the informed consent form).
- Extend the upper age limit so that post-menopausal women can participate in HIV-cure directed research (and increase the potential participant pool).

### Social and Accessibility Implications and Recommendations

- Flexible scheduling (early morning, late evening, weekends).
- Remote/telehealth study visits or at-home visits, when possible.
- Provide additional honorarium sufficient to cover the cost of childcare for study visits.
- Provide supervised children's activity area for use during study visit and children's take home items, such as books.
- Provide transportation support via car sharing to make it easier for women to attend visits, especially for those with children (taxi, Lyft or Uber).
- Provide a meal or snacks at the study site and work with women to help with family meal preparation.

- Provide rest area for longer or more invasive visits.
- Engage the potential participant's case management team to address social issues that could interfere with study completion, for instance, having a safe place to live.
- Screening process should include a trauma-informed care assessment to evaluate potential participants' needs in the context of the study.
- Engage with advocacy groups focused on supporting and empowering cis and transgender women living with HIV.



**BEAT-HIV**  
DELANEY COLLABORATORY

## Personal Reflection: Barriers Preventing Women from Cure-directed Studies



“ I am a white, 50-year old, engaged heterosexual female who is a peer educator with Philadelphia FIGHT. I am living in gratitude for the opportunities to provide education to women and other people living with HIV.

*I found out that I was HIV positive almost 20 years ago. This was in the early 2000s before there were any 1-pill medications. At the time, I was living in an abusive relationship. I received my HIV care at a local clinic, and they wanted me and my partner to participate in a study to find out why I was positive, and he was not. He did not want me to do the research or the study because he was embarrassed. I think a lot of women want to participate. Some of those women, like me, are living with or have lived with domestic abuse and listened to everything that my partner told me to do or I would get beaten up. I was also in a drug addiction where he could use me as a puppet, so I did pretty much anything he said. I wanted to do the study trial. They weren't just looking for couples who are negative and positive, they were looking for better medications too, and at the time, I was taking 12 pills a day. Being in an abusive relationship, you get very sheltered and scared for yourself and your children. One of the other reasons why I did not participate in any studies was due to lack of childcare. At the time of the study that I wanted to participate in, I was in my 20s-30s and had small children. Back then, there was no place to take care of my children if I was in a study because the appointments were every day and sometimes the visits were long. If on-site childcare had been available, I might have been able to participate. I had no vehicle, so I would have had to take my kids on the bus and then the El into Center City to get to Jefferson. That would have been a lot to deal with. Another thing was that in those days, there were no support groups for women living with HIV, maybe living with domestic abuse and kids. People were afraid that the State would get involved if word got out that I was participating in research, why I was doing that, or that I was living with HIV. I was scared of DHS finding out, because people would tell your business. I also believe that many women are afraid that other people will find out what they are doing. Another thing that I was afraid of had to do with people finding out about my status and the research, because there was so much stigma. Sometimes my family and friends would find out and make my kids leave because they found about my status. Basically, the less information that is out there about you, the better. That is how it was back then. But in the future, studies should offer childcare and other help to women, so that we can join a study. ”*



# BILL OF RIGHTS AND RESPONSIBILITIES: CURE-DIRECTED RESEARCH TRIALS

*This document provides a short list of the rights and responsibilities you have while you participate in a BEAT-HIV research study. It also describes the rights and responsibilities of those who run HIV-cure related research studies. The purpose of the Bill of Rights and Responsibilities is to help research participants act on their own behalf and in partnership with study staff. It is our hope that this document helps research participants have more agency in their research participation, AND that it can help researchers design processes and procedures to best support participants. Please see the study Informed Consent form for more information.*

## **PARTICIPANT RIGHTS**

As a participant in a BEAT-HIV research study you have the right to:

- Know that your participation is voluntary.
- Know who is sponsoring the study.
- Have all known information, including potential risks and benefits of study participation, presented to you in a way you can understand.
- Have all questions answered to your satisfaction.
- Refuse to join the study or decide to leave the study at any time. You can also refuse to join any follow-up studies you are told about. Refusing to join any study has no impact on other clinical care you receive.
- Know if there are costs associated with participation and whether you will be compensated for your participation.
- Have clear information regarding any aspect of the study that may relate to your personal insurance.
- A discrimination-free study environment. Your personal choices, values, beliefs, and cultural context will be respected by the people conducting the study.
- Ask for assistance resolving study-related social problems and/or discrimination. Study personnel or other personal advocates should be available and open to talking more about your participation in the study.
- Referral to available counseling or other medical and treatment support services for issues.
- Have detailed information on how you will be contacted if ART needs to be reinitiated.
- Access to regular testing of viral load and CD4 counts during study and duration of a study ATI.
- Have information provided to you and your partners about how to prevent HIV transmission and how to access free HIV testing services. Condoms and HIV education should be provided to you and your partners. Information on how to access PrEP (Pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) services should be provided. Study staff should be available to provide “hands-on” and direct referrals to these services as requested.
- Assistance in meeting study commitments.
- Confidentiality. Communications and records about you and your participation in the study will be shared only as needed to conduct the study, or as required by law. See your study site’s informed consent form for more information.
- Maintain your legal rights. As a trial participant, you are not waiving any of your rights.
- Learn final study results from study team before any public announcement.

## PARTICIPANT RESPONSIBILITIES

As a participant in a BEAT-HIV research study, you have the responsibility to:

- Review and demonstrate an understanding of all the materials given to you, including the informed consent documents. Ask for explanation about any information you do not understand before you agree to participate in the study. You can also ask questions anytime during the study.
- Make an informed decision about whether to participate in this study after weighing the risks and benefits. It is important to know what the study is about, including possible risks and/or benefits. The staff will assist you in this. If it helps you to make a decision, talk to people you trust and respect about whether joining the study is right for you.
- Treat study staff with respect.
- Follow the instructions of the study staff to the best of your ability. Work together with the study staff to maintain your health and safety during the trial.
- Tell study staff as soon as possible if you experience discrimination and/or social harm that you think may be related to your trial participation.
- Keep your study appointments. Tell study staff as soon as possible if you need to reschedule an appointment.
- Give the study staff complete and accurate study-related information. Make sure the study staff has current and up-to-date contact information, such as telephone and email. Tell the study staff about any changes in your contact information or health information.
- Keep confidential the participation of others in the study.
- Tell study staff as soon as possible if you are unable to continue or if you decide to stop your study participation.

## STUDY STAFF RESPONSIBILITIES

The BEAT-HIV study staff, including the Principal Investigator (PI), has the responsibility to:

- Treat study participants with dignity and respect, and as true partners in the research project. Maintain open lines of communication with participants. Respect the personal choices, values, beliefs, and cultural context of participants.
- Ensure all study participants are aware of any new information that may impact their safety in the study. This includes an ongoing review of all prescription and nonprescription medications used by a participant to determine any adverse or potential interactions with study medications.
- Provide accessible contact information and the means to be reached 24/7.
- Promptly answer any calls for added information or requests for call backs from participants.
- Consult the Community Advisory Board (CAB) and other local community stakeholders on research related issues and ensure the fair representation of participants in the clinical trial.
- Ensure informed consent is conducted in a manner that is understandable to each participant. Make sure that informed consent is received from participants for all-research related activities or interventions at all clinical visits. If there are significant study changes, consent from current participants will be obtained again. Consent should be an ongoing process.
- Conduct the study in an ethical manner, including protecting the rights, confidentiality and well-being of participants in the research study. At the end of the study, the study staff has the responsibility to inform participants which product they were receiving as well as share research study results with participants and the community in terms that are understandable.
- Provide appropriate referrals to participants and their partners for counseling and HIV prevention services, referrals for HIV treatment services, such as PrEP (Pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) and/or psychosocial services if needed during the study. Offer study participants and their partners information about and materials to prevent HIV transmission and how to access free HIV testing services. Provide “hands-on” and direct referrals to these services as requested.
- Respond to all questions and concerns, including the desire to quit the study in a timely manner.
- Communicate final study results to participants before any public announcement.

*This Bill of Rights and Responsibilities was created by the BEAT-HIV Community Engagement Group (CEG) inclusive of the Community Advisory Board (CAB), Community Partner organization (Philadelphia FIGHT) and BEAT-HIV research faculty team. The membership of the CAB represents a broad spectrum of stakeholders who are united in the search for an HIV cure. We are people living with HIV. We are members of communities deeply affected by HIV and AIDS. We are basic and clinical researchers. We are care givers. We are allies united in advancing research towards an HIV cure. Our Bill of Rights and Responsibilities has been adapted and revised from similar documents, including the “HIV Vaccine Trials Network and HIV Prevention Trials Network Bill of Rights and Responsibilities.” It was also developed in concert with HANC: HIV/AIDS Network Coordination’s Bill of Rights and Responsibilities Working Group.*

# BEAT-HIV CURE RESEARCH EDUCATION VIDEO SERIES

The HIV Cure Research Education Video Series is a first of its kind view of the people in Philadelphia moving toward an HIV Cure. Awareness of and interest in the HIV cure research agenda are growing, and this video project tells the story from the perspectives of PLWHA, researchers/providers, and key stakeholders involved in advancing the search for a cure. The series features those on the front lines and aims to demystify the process of HIV cure-directed research. It stresses the critical importance of an **equal partnership** between people living with HIV, researchers, and providers and was created using the community engagement group (CEG) model, a unique partnership among the BEAT-HIV CAB, Philadelphia FIGHT, and Wistar Institute/University of Pennsylvania. Key goals of the CEG include developing meaningful and relevant community education tools and advancing community engagement in HIV cure research.

Find the videos at <https://beat-hiv.org/hiv-cure-education-series/>

## VIDEO DESCRIPTIVE SUMMARIES:



### THE TOP TEN.

Reviews the top 10 items you should be aware of (and ask about) if considering joining a cure-directed study.



### GAME CHANGERS.

Describes who and what is behind an HIV cure-directed study. Community, providers, case managers, and researchers come together to explain what to expect.



### Time. Commitment.

Researchers and persons who have participated in recent studies discuss what it takes to finish a clinical trial.



### The Art of A.T.I.

Discusses what is an analytical treatment interruption (ATI) and why it is included in cure-directed studies.



# RESOURCES

*We have compiled a short list of Philadelphia area and national resources where you can learn more about HIV research and community organizations that provide support and advocacy.*

## ORGANIZATIONS

- **AIDS Clinical Trials Group (ACTG)**

The ACTG is the world's largest and longest running HIV clinical trials network. Information on clinical trials and community friendly fact sheets are provided at their website. <https://actgnetwork.org/>

- **AIDS Law Project of Pennsylvania**

The AIDS Law Project of Pennsylvania provides free legal services to Pennsylvanians and South Jerseyans living with HIV. <https://www.aidslawpa.org/>

- **ACT UP Philadelphia**

The AIDS Coalition to Unleash Power (ACT UP) Philadelphia is a group of individuals united in anger and committed to ending the AIDS crisis through direct action. They continue to strive to end the AIDS crisis within the context/through a lens of ending health disparities that are a clear result of inequality and injustice. <http://www.actupphilly.org/>

- **BEAT-HIV Delaney Collaboratory**

BEAT-HIV is consortium of more than 60 top HIV researchers from leading academic research institutions working with government, nonprofit organizations, community stakeholders, and industry partners to test combinations of several novel immunotherapies under new preclinical research and clinical trials.

<https://beat-hiv.org/>

- o Community Voices features stakeholder testimonials presented during BEAT-HIV Annual Meetings. <https://beat-hiv.org/community-voices-hiv-cure/>

- o The HIV Cure Research Education Video Series is a first of its kind view of the people in Philadelphia moving toward an HIV Cure. Find the videos at <https://beat-hiv.org/hiv-cure-education-series/>

- **Philadelphia FIGHT**

Philadelphia FIGHT is an AIDS service organization that provides primary care, consumer education, advocacy and research. FIGHT also offers a wide array of community support programs and behavioral mental health services. <https://fight.org/>

- **The Positive Man**

The Positive Man is a support group for HIV positive men who self-identify as being straight. We empower and encourage men to know that they are one of a kind and have something great to offer this world.

Contact info: **215-525-0460 ext.417** or [stjohnson@fight.org](mailto:stjohnson@fight.org).

- **Positive Women’s Network – USA (PWN)**

PWN is a national membership body of women living with HIV and allies that informs and mobilizes women living with HIV to advocate for changes that improve lives and uphold rights. <https://www.pwn-usa.org/>

- **Sero-Project**

Sero centers PLWHA leadership to end HIV criminalization, mass incarceration, racism and social justice by supporting inclusive PLWHA networks to improve policy outcomes, advance human rights, and promote healing justice. <https://www.seroproject.com/>

- **Transgender Law Center (TLC)**

TLC is the largest national trans-led organization advocating for a world in which all people are free to define themselves and their futures. Grounded in legal expertise and committed to racial justice, TLC employs a variety of community-driven strategies to keep transgender and gender nonconforming people alive, thriving, and fighting for liberation. <https://transgenderlawcenter.org/>

- **Treatment Action Group (TAG)**

TAG is an independent activist, and community-based research and policy organization fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus. <https://www.treatmentactiongroup.org/>

## OTHER RESOURCES

AVAC CUREiculum - <https://www.avac.org/cureiculum>

AVAC Good Participatory Practice - <https://www.avac.org/good-participatory-practice>

NIH Office of Human Research Protections – Informed Consent - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

US Department of Health and Human Services - [aidsinfo.nih.gov](https://aidsinfo.nih.gov)

US National Library of Medicine - [clinicaltrials.gov](https://clinicaltrials.gov)



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# GLOSSARY

**Affirming:** means to respect the identity, experiences, and self-determination of people and to provide support and validation to them.

**Analytical Treatment Interruption or ATI:** is a clinically monitored pause of antiretroviral therapy as part of a research study. Researchers and clinicians carry out the close monitoring of the treatment interruption in the context of a clinical study. The purpose of the pause in treatment is to determine the effect of the intervention versus standard antiretroviral therapy.

**Animal Models:** Animal models, such as non-human primates (NHP) or humanized mice, are particularly useful in HIV cure-directed research and biological research in general, because they have been shown to mimic aspects of the human response.

**ART Suppressed:** refers to the status of a patient undergoing antiretroviral therapy (ART) whose HIV viral load has been reduced to the level of undetectable.

**Auto-Immune:** relating to disease caused by antibodies or lymphocytes produced against substances naturally present in the body.

**Cis-gender:** a person whose sense of personal identity and gender corresponds with their assigned sex at birth.

**Classism:** prejudice against or in favor of people belonging to a particular social class.

**Clinical Strategy:** the development, plan or theory of a research study and how this is outlined for participants and study staff members.

**Culturally Competent:** refers to the ability to understand, communicate with, and effectively interact with people across cultures. To be culturally competent entails a basic understanding of one's own culture and an openness to be critical of perceived notions, beliefs, and norms; a willingness to learn about the cultural practices and worldviews of others; and a positive attitude toward cultural differences with a readiness to accept and respect those differences.

**Equity:** is defined as "the state, quality, or ideal of being just, impartial, and fair." To be achieved, equity needs to be recognized as an ongoing process on a variety of scales, ranging from the interpersonal to the systemic and societal.

**Gender Identity:** an individual's personal sense of having a particular gender.

**Health Disparities:** refer to differences in health status and health care between groups and where these differences are closely linked to social, economic, and/or environmental inequalities and disadvantages.

**HIV-Associated Neurocognitive Disorder (HAND):** HIV disorder that can cause issues with the brain and one's cognition

**HIV Criminalization:** the use of criminal law to penalize alleged, perceived, or potential HIV exposure. Many of these cases are based in the alleged non-disclosure of HIV status to an HIV negative partner. These laws vary state-by-state; most were passed in the 1980s and are often based in irrational fears of HIV (and people living with HIV) and outdated medical science.

**HIV Curative Strategy:** an approach to achieve one or more long-term goals in finding a cure for disease – either complete elimination of HIV from the body or a sustained or durable ART-free virologic control.

**HIV Cure-directed Study:** a study whose focus is to reduce levels of HIV in the blood beyond current therapies and/or to maintain HIV undetectable status without the use of antiretroviral medications.

**HIV Latency:** cells infected with HIV that do not actively produce copies of HIV and therefore become invisible to the immune system.

**Homophobia:** is the fear, hatred, discomfort with, or mistrust of people who are gay, lesbian, or bisexual.

**Immune System:** the immune system is a complex network of cells, tissues, and organs. Together they help the body fight infections and other diseases.

**Informed Consent Form:** a document in a research study that explains the research to be done, the study participant's role in the study, and the effects of the research on the participant. Informed consent is an ongoing process during a research study when participant's rights and responsibilities are explained and discussed with study staff. From the American Medical Association: "Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."

**Intimate Partner Violence (IPV):** physical, emotional, or sexual abusive behavior that is specifically violent and aggressive towards their partner (i.e. spouse or significant other). IPV may imply the need for trauma-informed care or trauma-informed research.

**Non-Binary:** having a gender identity outside the gender binary of man or woman, or male or female.

**Patriarchy:** a social system in which men hold primary power to the exclusion of women and predominate in roles of political leadership, social privilege, and control of property and money.

**Pharmacokinetics:** study of how drugs are maintained and removed from the body.

**Principal Investigator (PI):** the lead researcher(s) for a scientific study or clinical trial. Being in charge of the research study, PIs prepare and carry out all areas of the research protocol (plan for a study), and delegates responsibilities.

**Randomized Controlled Trial:** a study designed that randomly assigns participants into an experimental group or control group.



**Rebound Set Point Study:** when a participant stops their HIV medication to see when and at what level (or set-point) the viral load will be at as a consequence of having started an experimental drug while still taking HIV medication and/or starting the experimental drug at the time of stopping their HIV medication.

**Resistance:** lack of response and sensitivity to an anti-HIV drug, especially because of genetic change in HIV.

**Reservoir:** a group of cells in the body that are infected with HIV but are not actively producing new copies of HIV. Although antiretroviral therapy can reduce the level of HIV in the blood, latent reservoirs continue to survive. When a latent infected cell becomes reactivated it can begin to produce copies of HIV again.

**Time to Rebound Study:** when a participant starts an experimental drug while still taking HIV medication and/or at the time of stopping their HIV medication to see at what time their viral load will be detectable again.

**Transmission:** act of pathogenic microorganisms passing from one being to another.

**Transphobia:** is the fear, hatred, discomfort with, or mistrust of people who are transgender and/or gender non-binary and/or gender non-conforming.

**Trauma Informed Approach:** provides a framework for health and healing that recognizes that many people have a history of traumatic experiences in their lives. Trauma informed approaches to medical care and research and health care seek to promote a culture of safety, empowerment, and healing.

**Undetectable Viral Loads:** refers to the suppression of the amount of HIV in the blood with the use of antiretroviral therapy to a level that is not able to be detected by laboratory tests for at least six months. For most tests used in clinical settings today, this means fewer than 50 copies of HIV per milliliter of blood.

**Viral Load:** refers to how many copies of HIV are present in a milliliter of a sample of blood.

**Viral Rebound:** having a detectable HIV viral load – after being undetectable – is referred to as a “viral rebound.”



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