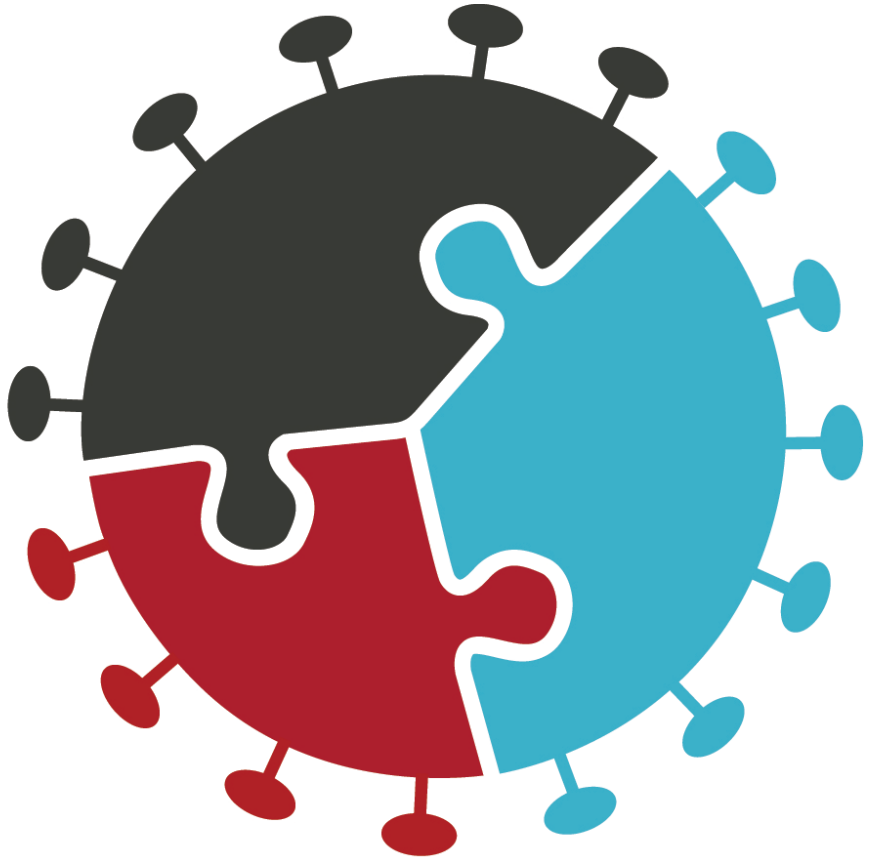

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BEAT-HIV ATI Position Paper: Perspectives and Discussion

Bill Freshwater
Beth Peterson
Chris Roebuck

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Outline of Presentation

- BEAT-HIV CAB – Who we are
- Why is this ATI Position Paper important and Who is our audience?
- Development of Position Paper
  - Process and Timeline
- Description of Document:
  - Five Modules (questions and reflections)
- Participant & Staff Bill of Rights and Responsibilities
- Appendixes:
  - Glossary
  - Resources
- **Discussion & Input**

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BEAT-HIV CAB

Vision Statement

A world where HIV and AIDS research *meaningfully involves* impacted communities, is *collaboratively created,* and *openly shared*.

Mission Statement

As a Philadelphia based HIV Cure Research Community Advisory Board our Mission is to:

- Integrate community involvement in HIV and AIDS cure related research and clinical trials;
- Serve as a bridge community to provide input and feedback to BEAT HIV projects;
- Foster and maintain communication and partnerships with project researchers in order to promote transparency and to disseminate findings in HIV cure research to our communities.

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BEAT-HIV CAB

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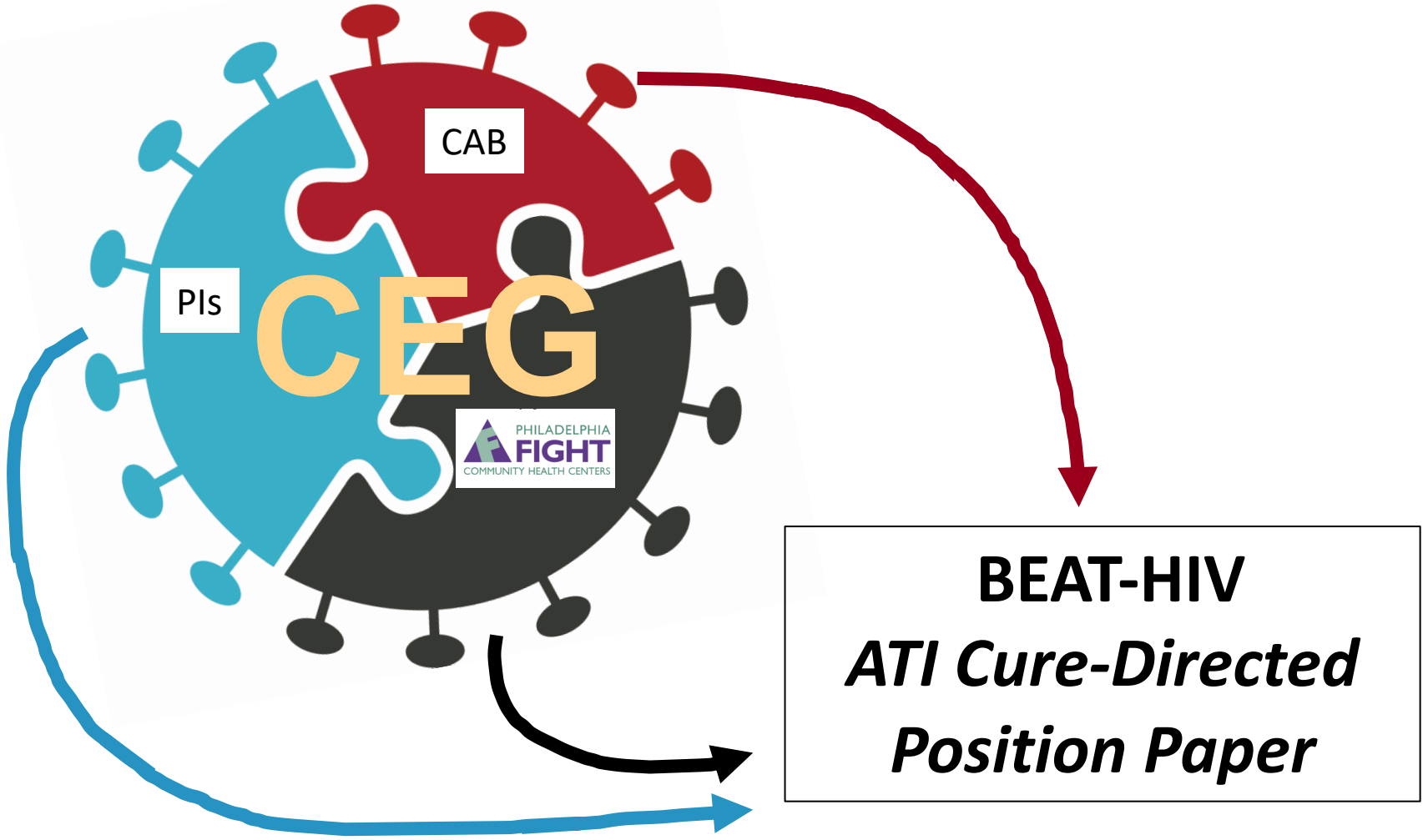
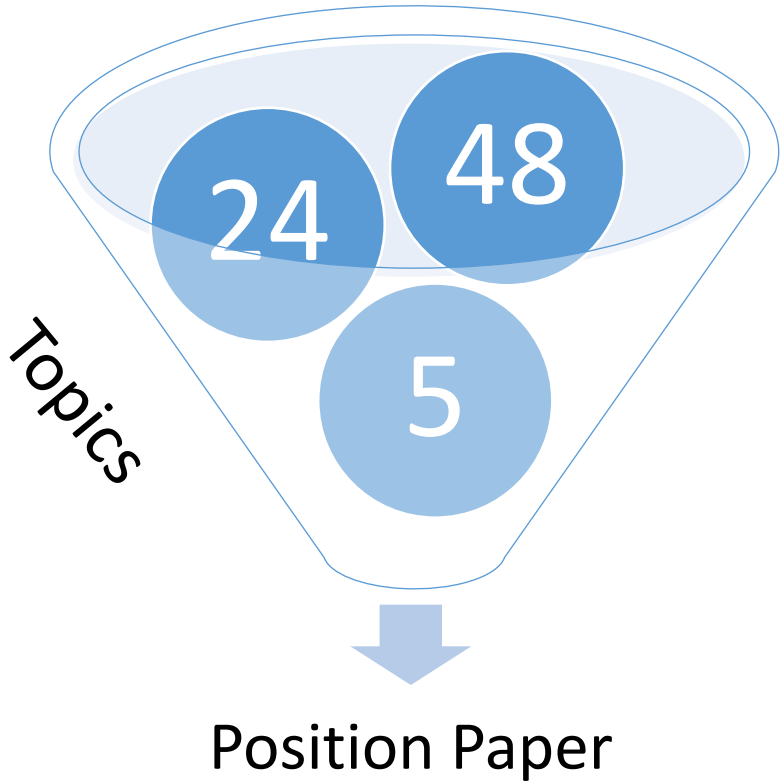
BEAT-HIV MODEL: Community Engagement Group

[Scientists+CBO+CAB]



Process towards Modules



- CAB-led project; identification and consolidation of topics for inclusion and prioritization
  - Collaborate with our partners, PIs and Philadelphia FIGHT: **Community Engagement Group (CEG)**

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Timeline

December 2017
Proposal at CAB

Jan'18-Jun'18	Sept '18	Oct '18	April '19	May '19	Oct. '19	CROI
					Sep'19	

- Topics
- Format of paper
- Module assignments
- Info gathering
- BRR
- Review other position papers
- Personal reflections
- Module 1
- Module 2
- Module 3
- BRR draft
- Module 4
- Module 5

***BEAT-HIV Videos Started** → **June '19**

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Why is this important?

Essential information that we want the BEAT-HIV community members to know about participation in cure-directed studies, *with special attention to studies including therapy interruption*.

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Audience

- Paper written at an 8th grade level
- Directed to Western Society audiences
- Directed to Adults
- Primarily directed to participants and interested persons; secondary audience includes scientific or medical professionals
- Intended to complement BEAT-HIV study documents

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Outline of Document

- **Introduction**
- **Modules**
  - Module 1: What and why are ATI interruptions in HIV cure-directed studies?
  - Module 2: Considerations for participation in cure-directed studies
  - Module 3: Navigating the informed consent process
  - Module 4: Social implications to consider when enrolling in an ATI studies
  - Module 5: Women in HIV Cure-Directed Research
- **Participant & Staff Bill of Rights and Responsibilities**
- **Appendixes**
  - Glossary
  - Added Resources

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Format of Each Module

- Summary Points
- Frequently asked questions
- Personal reflections

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Module 1 – What and why are ATI interruptions in HIV cure-directed studies

- **What is a therapy interruption or analytical treatment interruption (ATI) and why are they needed?**
- **Are all ATI the same?**
- **When are ATIs appropriate?**
- **What are the risks of an ATI?**
- **How are risks of an ATI best managed?**
- **How do I know if a study with an ATI is appropriate for me?**
- **What are acceptable ATI criteria for the BEAT-HIV study team?**

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Module 2 – Personal considerations for participation in cure-directed studies

- **Why participate in an HIV cure-directed study when my meds are working?**
- **Will the intervention hurt, affect or change my general health?**
- **Does it matter if I withdraw from a cure-directed study?**
- **Am I going to be viremic? How long will I be off meds? Will I get sick if I get off meds under a study?**
- **Will I be able to go back to using the same meds? Will I be undetectable again?**
- **Who will interact with me and what role does the researcher have? Will I see him/her?**
- **Are study activities and tests to be covered by my insurance?**
- **Why do studies often ask for my samples to be stored long after study is over?**

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Module 3 – Navigating the informed consent process

- **What are the essential points to an informed consent form?**
- **Is the named researcher on the informed consent the one that should be consenting me?**
- **If English is not my first language, can I ask for a translation or for a native-speaker to help me?**
- **If the informed consent states that I will get paid during study, is my participation like being "hired" for a job?**
- **Does the informed consent need to state what happens if I get injured in study?**
- **Should the consent make clear how my confidentiality will be guarded?**
- **If I sign an informed consent form, am I done with consenting until the study ends?**
- **What aspects are often not in the informed consent but I should ask about anyway?**
- **Should the informed consent state clearly who is sponsoring this study?**

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Module 4 – Social implications to consider when enrolling in an ATI study

- **Given that I can remain undetectable under ART, why should I risk losing this status and possibly be stigmatized by the community? How can I justify this to myself?**
- **Why are there different arms on my study? Can I choose which arm I want to be on? What does this mean for me?**
- **If I need mental health support during the study, will that be provided?**
- **Does my state criminalize HIV transmission? How do I find this out, and how will this affect me during my study?**
- **What happens if it works? and I remain virally suppressed. Will I keep receiving the study treatment? How long will you follow me?**
- **What are some benefits to participating in an ATI study?**

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Module 5 – Why is the participation of Women important in advancing HIV cure research?

- **Why is gender equity important in HIV cure-directed research?**
- **What are the biological differences in women that matter?**
- **Why is it harder to recruit women?**
- **What are concerns that are particular to women in HIV cure-directed research?**
- **What motivates women to participate in HIV cure-directed research?**

Module 5 – Why is the participation of Women important in advancing HIV cure research?

- Providers must support the autonomy of their female patients by offering opportunities to engage in HIV cure-directed research
- Community education and engagement that meets women where they are
- Flexible and mindful scheduling (early morning, late evening, weekends)
- Provide additional honorarium sufficient to cover the cost of childcare for study visits
- Provide supervised play area for children during study visit
- 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
- In studies where investigators are concerned with blood draws and anemia, provide iron supplement
- Offer birth control for women of reproductive age (two methods of contraception if study so stipulates in the informed consent form)

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Module 5 – Why is the participation of Women important in advancing HIV cure research?

- Provide rest area for longer or more invasive visits
- Provide children's books (for children to take home)
- Ensure study team and environment is safe and welcoming for all women
- Screening process should include a trauma-informed assessment to evaluate potential participants' needs in the context of the study
- Engage the potential participant's case management team at to address social issues that could interfere with study completion, for instance, does she have a safe place to live
- Funding agencies mandates for clinical trial enrollment that reflects the epidemic

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Bill of Rights and Responsibilities for Participants and Staff

- 22 Participant Rights
- 13 Participant Responsibilities
- 11 Staff and Study Team Responsibilities

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Appendices

- Glossary of key terms

- Resources
  - TAG Cure-Related Resources (Richard Jefferys)
  - Local resources (Ex. AIDS Law Project, Bebashi, Mazzoni Center, Philadelphia FIGHT)
  - Bibliography – key articles and papers

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The BEAT-HIV Delaney Collaboratory would like to offer special thanks to the following individuals for their time, expertise, and generosity.

- Bill Freshwater
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- Dave Metzger
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- Chris Roebuck
- Teresa Sullivan
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- Will Carter

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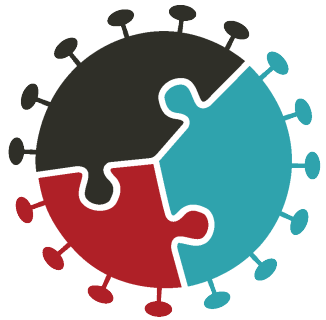
The Wistar Institute

PHILADELPHIA FIGHT COMMUNITY HEALTH CENTERS

Penn University of Pennsylvania

PHILADELPHIA FOUNDATION



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The BEAT-HIV Delaney Collaboratory is supported by NIH grant number UM1AI126620 co-funded by NIAID, NIMH, NINDS, NIDA and the Office of AIDS Research.

Questions for Discussion

What are your thoughts on the topics we covered?

What did we miss?

Thank you for your interest and support!

Contact: freshwaterwilliam@gmail.com

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Module 1 – What and why are ATI interruptions in HIV cure-directed studies

- Therapy interruption remains the best measure to evaluate HIV cure-directed strategies, particularly those that work with the immune system.
- Therapy interruption studies are only appropriate if other research has already shown that the treatment to be added has the potential to be effective .
- Risks of long-term interruptions of ART are primarily associated with the onset of a future viral rebound.
- Main risks upon therapy interruption are the potential for development of resistance against anti-HIV medicines, disease progression, and the risk of transmission.
- Make sure you understand the study sequence (i.e., what will happen when) and the informed consent and have discussed what individual 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.

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Module 2 – Considerations for participation in cure-directed studies

- HIV Cure-directed studies are conducted to achieve either a long-term remission of ART therapy, or to get closer to achieving a stable cure for HIV.
- You need to be comfortable with all persons and organizations associated with the study.
- Determine what aspects of the study design depend on your insurance versus covered by study. This is important with respect to complications if encountered.
- Understand that if you consent to enroll in a cure-directed study, the hope and the expectation is that you will be able to complete the study.
- Cure-directed studies often include therapy interruption periods that will result in periods of viremia (even if carefully monitored).
- 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.
- Cure-directed studies may ask you to consent to long-term storage of your samples after the study ends in order to allow for new analysis in future as novel techniques and information changes.

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Module 3 – Navigating the informed consent process

- The informed consent process is intended to provide you with information in an easy to understand format.
- The informed consent form should clearly state that you participate only because you want to.
- You should take the informed consent form home and spend time with it, ask questions, and ensure that you fully understand it before you sign it. YOU SHOULD FEEL COMFORTABLE TO REVIEW THE INFORMED CONSENT FORM WITH WHOMEVER YOU WANT.
- Pay special attention to who is sponsoring study, what are the side effects expected and how will they be addressed.

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