Elements of Comprehensive Participant Readiness and Resilience Framework – A journey approach to HIV cure research

Creating a framework that supports study participants throughout their experience—and beyond

Before ATIs

Reframe the approach to informed consent to a person-centered framework (e.g., decision support around ATI trial participation, availability of peer navigators for decision support).

Enhance the informed consent process (e.g., multi-media/multi-modal informed consent process to accommodate disparate learning styles, literacy levels and cultural, linguistic and socieconomic backgrounds of prospective participants).

Provide clear information about known and potential risks of ATIs (based on previous trials), risks of experimental interventions and risks of monitoring procedures.

Explain to prospective participants the legal liabilities that may result from not disclosing their HIV status to sex partners during an ATI.

Discuss the potential long-term adverse events that can result from an ATI.

Ensure that treatment costs for adverse events due to the ATI are not borne by the participant.

Conduct pre-ATI assessments to determine a prospective participant's understanding and psychosocial readiness.

Plan and provide support around partner protection measures (for HIV-serodifferent relationships).

Multi-center trials must have a single lead institutional review board; there should be only one informed consent for the participant to sign.

During ATIs

Conduct close monitoring without overburdening trial participants.

Build support around partner protection measures.

Understand and consider the relationship dynamics and potential risks, including the risk for intimate partner violence.

Conduct psychosocial and mental health assessments and support—particularly addressing anxiety around being off HIV treatment.

Assess the impact of ATI participation on other people in participants' immediate social circles.

Develop and provide home-based viral load testing to self-assess transmissibility potential.

In case of unexpected intercurrent events (e.g., COVID-19, mpox pandemics), establish a mechanism for consultation with ATI participants, participant-centered communications, mental health safety screening and guidance to reduce risks to trial participants.

After ATIs

Conduct a mental health follow-up after the ATI period and study have ended.

Establish regular check-ins with participants following an ATI or the study's completion every six months.

Monitor for potential long-term effects of ATIs.

Provide ART resistance testing and assistance with ART regimen change if needed.

Disseminate research outcomes to participants in a way that is accessible to them.

Provide medical journals and other publications in which the study's findings appear free of charge to study participants.

Continue to check in with participants who have resumed ART after an ATI period has ended.

For participants who are post-intervention controllers, provide continued psychosocial support around being off ART and provide partner protection support.

For participants who are cured, provide psychosocial support around the anxiety of potentially having to relive the experience of an HIV diagnosis if they are no longer cured; offer support systems to maintain the social benefits they had received during the time they were living with HIV (e.g., housing benefits) and offer guidance around PrEP uptake if needed.

ATI support program goals

Provide high-quality research and patient/participant involvement in ATI trial designs.

Study designs should take into account other circulating endemic viruses such as new COVID-19 variants and/or seasonal flu, and how they may impact HIV viral load during an ATI.

Establish mechanisms to better understand research attitudes and perceptions around ATI trials.

Develop greater support services for ATI trial participants and partners—mental health services, access to pre-exposure prophylaxis (PrEP), referral to a support hotline.

Create an ATI participant experience database and research hub.

Offer professional development opportunities for community advisory board (CAB) members or former trial participants (e.g., certified peer navigators).

View behavioral and social sciences research as a gateway to ATI research participation.

Examine how the arts can be used to inform, engage and build trust among members of community groups underrepresented in HIV cure research (with approaches to measure effectiveness of community engagement).

Create and expand programs that encourage support of and participation in HIV cure research (e.g., HIV cure research ambassadors).

Use person-centered language—e.g., *participants* instead of *subjects*.

Develop community-centered education materials around ATI trials.

Provide adequate compensation to trial participants and CAB members for their participation expenses.

It is essential to involve primary care physicians during the entire research participation; this includes referrals to independent counselling and other support mechanisms during and after ATI periods.