







#### The HPTN Scholars Program:

Enabling independent investigators in the HIV prevention research field.



Linda-Gail Bekker The Desmond Tutu HIV Centre UCT CTU, Cape Town.





Interest and investment





### Exciting clinical science attracts new young talent



"Fred, rumor has it you're closing in on some profound, elemental truths about the universe, and I wanted to remind you that our research funding specifically prohibits that!"

#### Odds of Success : first R01

#### The NIH's long tail

Although investigators aged 41–45 won more R01 and equivalent grants than did any other age group in 2016, the majority of awards go to researchers over the age of 45.





#### Desperate need for opportunities to :

- Participate in "interim" funding opportunities
- Less fiercely competitive
- Practice some skills
  - Grant writing, project management, budget management, manuscript writing.
- Develop a network
- Give a "leg up" to get pilot data
- Build CV

Without giving up the "day job"!



#### UCTCTU CRSs



#### Choic HPTN 067,

NX.





- More p AMP, 075, 076, let
- Choice persiste 082, 083, 084
- Allows
- Mimics what toolbox appr.

ral perspective –leads to better uptake and

n, including traditionally hard-to-reach populations prevention may be like.....





## So, you would like to be an HPTN scholar?

Making a successful application: Choosing a project Choosing a mentor Increasing the chances of success

#### Choosing a project

- Get to know what studies are "out there"
- Attend the HPTN meetings .....hear about the studies- understand the project objectives and get familiar with the protocol chairs, protocol numbers and protocol project support.
- Protocols are on the HPTN web sites
- Make contact with chair and discuss possibilities
- Think what interests you, what your capabilities are and when your "cycle" would be
- Consider projects that are
  - 1. recently finished
  - 2. will have data available in your cycle

#### Think about topics.....

- That are not the primary objectives protocol team has first tabs on those!
- Explore angles or ideas with existing data
  - Review exploratory objectives
- Explore sub-populations within the data
  - Particular age group, sub-population
- Use the data in new ways
  - Use the data in modeling study

#### Challenges

- Timing, timing, timing......
- Steer away from primary objectives and discuss secondary objectives- think about exploratory objectives.

#### Think about mentor....

- Where are they located?
  - Co-located, at another site, another time zone?
- What is their role on the parent study?
  - Will they be able to influence decisions and do they know the parent study?
- How available are they?
  - How busy? How expert? Able to offer mentorship?
  - May still need assistance in particular areas
- How supportive are they?
  - Willing to go out to bat for you?





# The case of Dr. Jesne Kistan and ADAPT/HPTN 067 in Cape Town

An International HPTN Scholar in Cycle 1.

A Phase II, Randomized, Open-label, Pharmacokinetic And Behavioral Study Of The Use Of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Preexposure Prophylaxis (Prep)

Alternative

Dosing

to Augment PrEP

Pill

Taking





#### **Overall Purpose:**

A **Behavioral study** to evaluate the feasibility of non daily PrEP regimens.

Recommendations for **intermittent usage**, compared with daily usage, to provide comparable **coverage** of risk exposures with preand post-exposure dosing, decreased **pill requirements**, and decreased **symptoms**.



#### **Overall PI: Robert Grant**



Harlem Prevention Centre 179 HIV-uninfected at risk MSM/TGW NYC (Harlem), USA Dec 2014 Silom Community Clinic 178 HIV-uninfected at risk MSM/TGW Bangkok, Thailand March 2014

Emavundleni Prevention Centre 179 HIV-uninfected at risk WSM Cape Town, South Africa June 2013



#### Primary Objective:

To test the hypothesis that recommending nondaily PrEP, compared with recommending daily usage, will be associated with:

- Equivalent coverage of sex events with pre- and post-exposure dosing
- Lower number of pills needed for coverage and fewer pills used
- Decreased self-reported symptoms/side effects
  (both severity and frequency) during 24 weeks of self-administered use



- To describe safety outcomes including adverse events among all participants and drug resistance and plasma HIV RNA levels among participants who seroconvert
- Assess differences between arms in the acceptability of different PrEP regimens and in perceptions of advantages and disadvantages of different regimens
- Assess differences by arm in adherence
- Develop objective measures of drug exposure by obtaining steady state pre-dose "trough" drug concentration in several biological matrices for participants during a lead-in period of weekly DOT
- Evaluate the potential influence of PrEP usage on:
  - changes in sexual behavior, planning for sex, prediction of risky situations, and recognition of possible HIV exposure from baseline to final on-drug assessment in relation to PrEP optimism

### HPTN 067 Design







#### **PrEP** for Younger Women? Jesne's question.....



 To assess differences in acceptability of PrEP between young African woman (age:18 -24) and older African woman (age: ≥ 25) within the different PrEP dosing regimens.

To assess differences in **adherence** between young African women (age:18-24) and older African woman (age≥ 25) within the different PrEP dosing regimens

ADAPT HPTN 067: An open label of oral PrEP use by 179 women in Cape Town, South Africa.

- **Majority of women** took oral PrEP when made available in open label.
- **Daily dosing** resulted in good adherence (higher drug levels) & better **coverage** of sex acts, compared to intermittent use.
- Daily dosing may foster better habit formation and provide the most forgiveness for missed doses at observed adherence levels.





#### Tips to a successful application

- Sit down with protocol chair and mentor preferably face to face....
- Consider feasibility, timing, scope
- Clarify which permissions, approvals will be needed and time line for these
- Start early to allow time for :
  - Initial drafting of proposal
  - Back and forth with mentor- use this feedback
  - Submission to protocol team see if mentor can endorse
  - Further potential back and forth using mentor support
  - Be politely persistent and engaged
  - Trouble shoot with mentor support if things get "stuck"

#### In the application, articulate

- How this proposal plays to your strengths and capabilities
- Make a compelling case for : Why this? Why you? Why now?
- How it will enhance the overall study, site, HPTN? Be honest about any risks and provide mitigating solutions
- In the mentorship plan: show feasibility, compatibility, realistic expectations

#### During the project

- Remain in touch and engaged with mentor
- Watch timelines carefully
- Be politely persistent and seek help early if things seem stuck
- Use networking opportunity to seek help in other quarters keeping mentor informed
- Try for F2F mentorship sessions where possible but skype and tele calls also ok
  - Long distance mentorship possible but more challenging
- Take responsibility: Remind mentor, others about timelines, tasks and milestones
- Give enough time for inputs, be responsive to guidance and apologise when timelines are tight!
- Leave sufficient time for report backs and manuscript writing

#### Good luck!!!!



#### Extraordinary opportunity....

### To make a difference and translate good ideas into great work .....and saved lives!



Your ordinary acts of love and hope point to the extraordinary promise that every human life is of inestimable value.





- The UCTCTU and its CRSs
- Giuseppe, Jill, Christie, Ntando, Lulu, Danielle, Zoh, the CRS leaders
- Other CTUs: PHRU, Aurum, CAPRISA

Kathy, Fatima, Glenda, Gavin

- The Networks and Core teams : HVTN, HPTN, MTN, INSIGHT, ACTG, IMPAACT
- Their support teams: LAB, SHARP, FHI
- The DAIDS, NIH program

COMMUNITIES OF VOLUNTEERS IN SOUTH AFRICA