

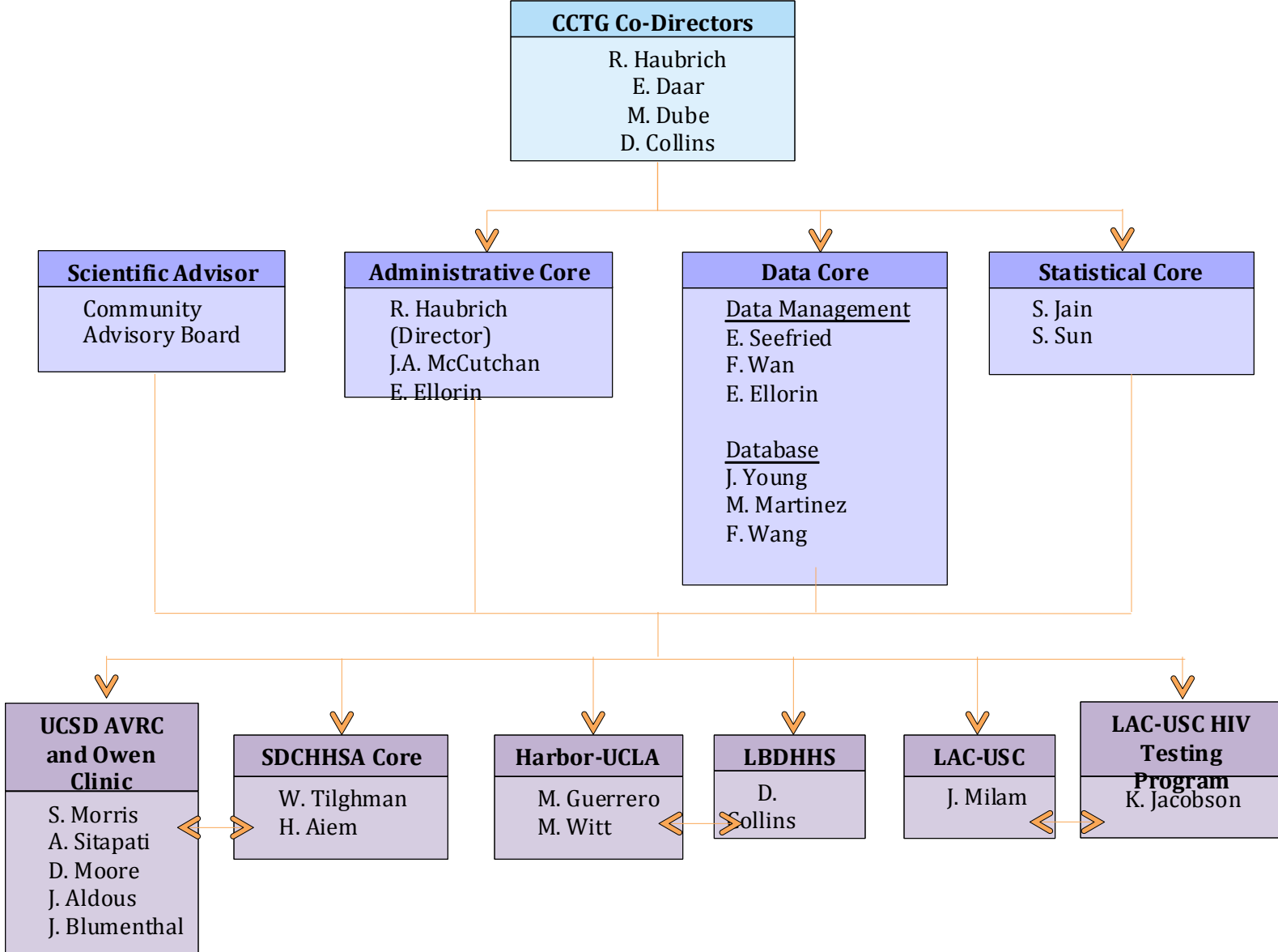
The California Collaborative Treatment Group



CCTG Goals

- **Build on the strengths of each collaborative site**
- **Address research questions of importance to HIV infected patients in California**
- **Provide access to research opportunities for underrepresented populations**
- **Collaborate with diverse disciplines (behavioral, basic science, pharmacology, microbiology)**
- **Mentor junior investigators to become the next generation of clinical investigators for the State of California**
- **Leverage funding from additional sources to build on the core funding from the CHRP**

CCTG Organizational Structure



CCTG Mentoring

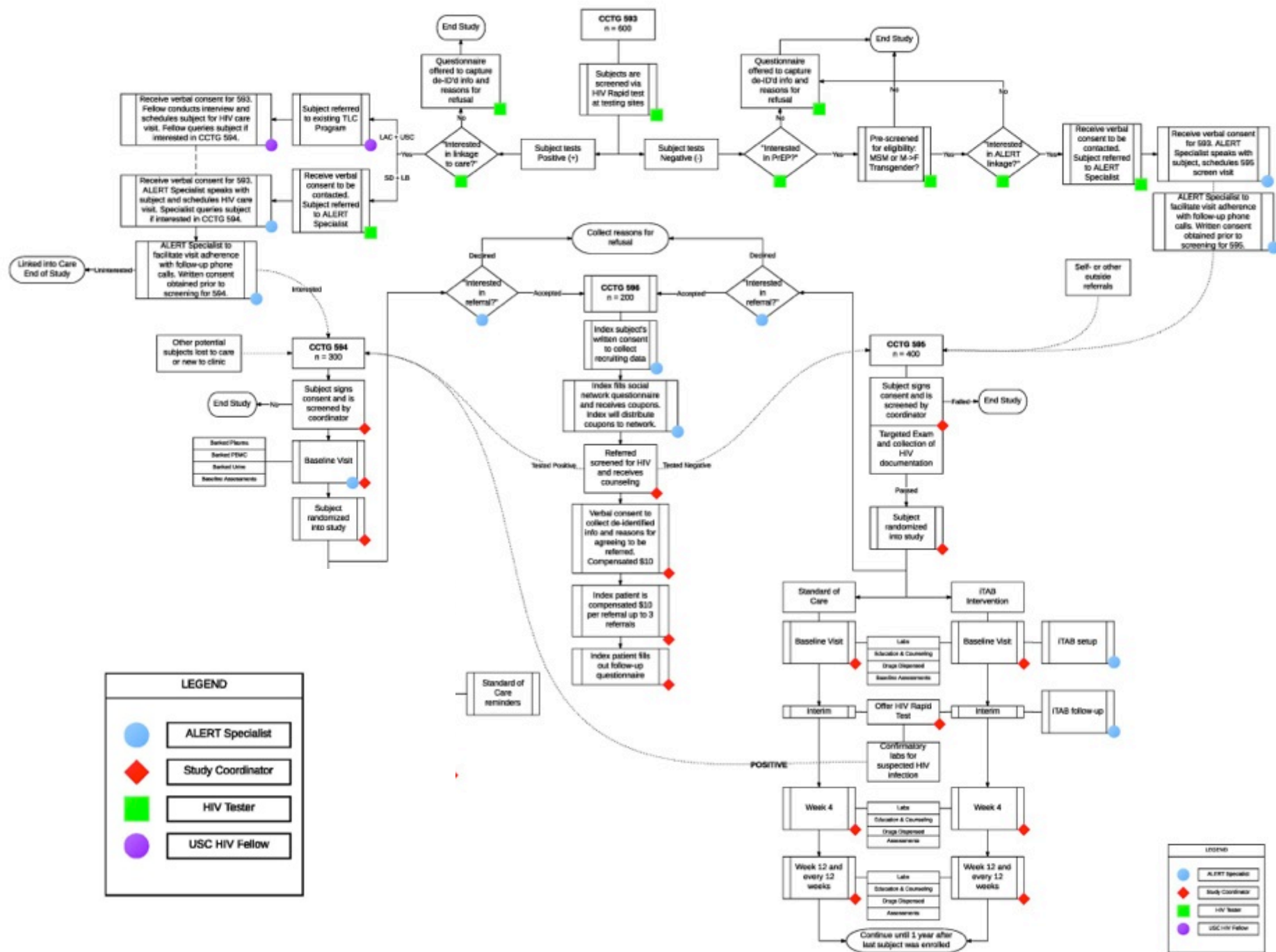
- **Objective:** Engage, enhance and enable success for new investigators in HIV clinical investigation
- **Design:**
 - Direct involvement with experienced HIV clinic researchers at each site
 - Involvement on protocol team at all stages of protocol development, study implementation, study conduct, analysis and presentation of results
 - Monthly meetings where junior investigators encouraged to be involved and take lead roles.

Mentoring

- Promotion of Sheldon Morris recommended by DOMCAP
- Eric Ellorin accepted to UCSD MAS program in clinical research
- Jason Young co-director of CFAR BIT core
- Jill Blumenthal received approval for provider attitudes/ barriers to PrEP (CCTG 598), funded by CCTG leveraged funds

Leveraged Studies and Funding

- Milam/ Morris- NIMH R21; CCTG 597: Risk compensation and PrEP use to prevent HIV infection
- Morris- R01 application submitted: The Rectal Mucosal Environment of Individuals on PrEP
- Morris/ Blumenthal: The Use of Dried Blood Spots to Measure Medication Adherence in Prep: (CCTG 595 Substudy)
- Morris: A Prospective Study of DTG to Reduce HIV Semen Shedding (ViiV)
- Blumenthal: PrEP Accessibility Research and Evaluation (PrEPARE) 2: HIV Risk Perception among Men who have Sex with Men
- Menchine/ Arora/ Jacobson: 4th generation Ag/Ab architect at ED testing program (Gilead)



CCTG 595: A Multicenter, Randomized Study of Text messaging to improve Adherence to *PrEP In Risky MSM (TAPIR)*

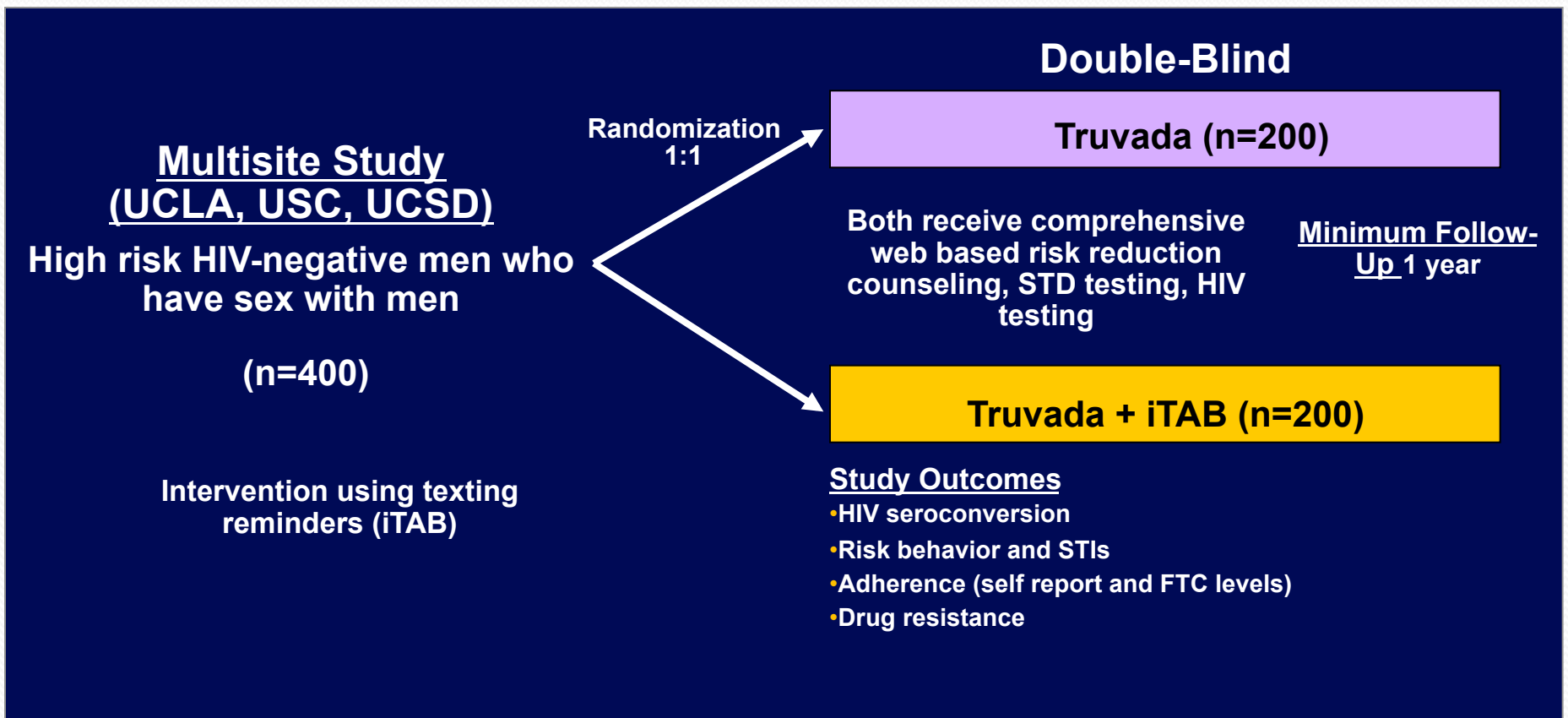
California Collaborative Treatment Group (CCTG)

Protocol Co-Chairs:
Sheldon Morris M.D., M.P.H.
David J. Moore, Ph.D.

Vice-Chairs:
Richard Haubrich M.D.

February 12, 2013
UCSD AVRC

CCTG 595 Study Schema

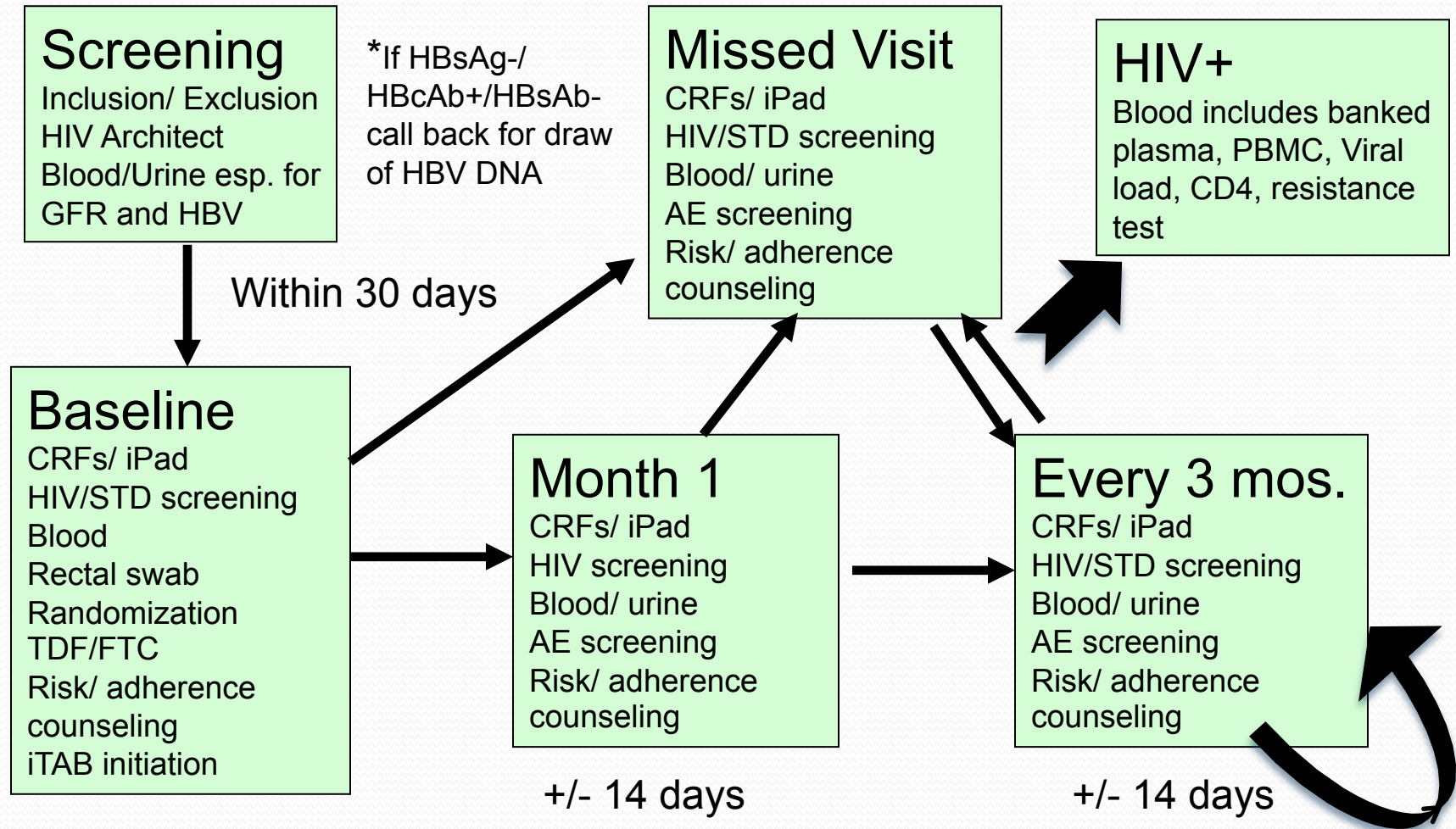


iTAB Intervention

- Texting reminders developed and chosen by participant that will be received daily
- If possible, participants use their own cell phone; otherwise receive study phone
- All participant go through process of reminder generation



Visit Schedule

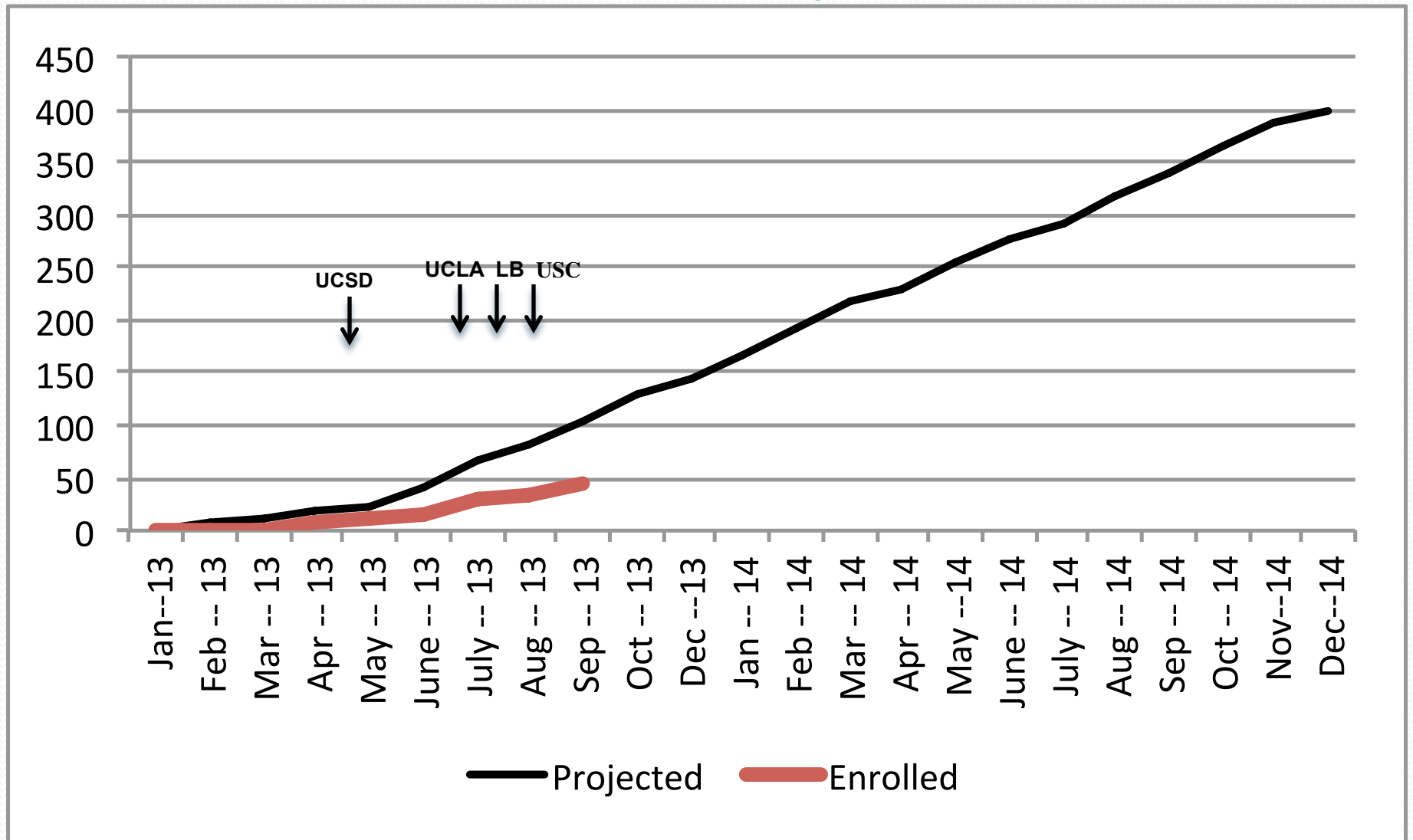


CCTG 595 Progress Updates

Current Enrollment: Randomized

	Number Randomized (%)
Gender:	
Male	41 (98%)
Transgender M to F	1 (2%)
Race:	
White Non-Hispanic	28 (67%)
Hispanic	8 (17%)
Black/Asian/Other	6 (16%)
Inclusion Risk Category:	
HIV serodiscordant partner	26 (62%)
Unprotected anal sex with >2 men	20 (48%)
Unprotected anal sex/recent STD	4 (10%)

Enrollment by Month



Visit and Safety Monitoring

Visit week:	
0	42/42 (100%)
4	31/31 (100%)
12	15/16 (94%)
24	1/1 (100%)
Safety Listing:	
Creatinine	2 x grade 1 elevation (1.1 and 1.2)
AST	1 x grade 2 (131) 1 x grade 1 (57)
ALT	3 x grade 1 (57, 58, and 75)
Glucose	1 x grade 3 (282)
Bilirubin	1 x grade 2 (1.7)
ANC	1 x grade 3 (702)

Recruitment - UCSD

what is PrEP?

Pre-exposure prophylaxis, or PrEP, has been added to existing strategies to prevent HIV infection. PrEP requires a person who is HIV-negative to take a pill daily to reduce their risk of HIV infection. Studies have shown that PrEP reduces risk of infection in men who have sex with men as well as in heterosexual men and women.

Daily PrEP, with regular condom use and other HIV prevention methods, reduces HIV infection risk by up to 90%.

In July 2012, the U.S. Food and Drug Administration approved the combination of FTC-TDF, or Truvada®, for use as PrEP among sexually active adults at risk for HIV infection.



Daily PrEP with condom use, and other HIV prevention methods, can reduce infection risk by up to 90%



PrEP research studies

PrEP, as part of a research study, is available to you at no cost at the UC San Diego AntiViral Research Center (AVRC) in Hillcrest.

There are eligibility requirements that you must meet to qualify to participate in one of our PrEP research studies. Not everyone interested in participating in a PrEP research study will be eligible.

Some eligible people may choose to participate in a research study that may be reimbursed.

For more information about a research study, contact the research coordinator.

info@chri.ucsd.edu



PrEP

the basics

quick facts

- PrEP uses Truvada® (FTC-TDF), an FDA-approved antiretroviral medication, to prevent HIV infection
- PrEP should only be taken by people who are HIV-negative
- Taking PrEP does not mean that you are 100% protected from getting infected with HIV
- PrEP should not replace other safer sex practices, such as condom use
- PrEP does not prevent other sexually transmitted infections
- PrEP should only be taken with the support of a health care provider
- Taking PrEP includes getting routine blood tests done
- You may have side effects from taking PrEP

before starting PrEP >>>

- Have a thorough and honest talk about your sexual activity and HIV risk with a health care provider
- Get an HIV test
- Test for hepatitis B, kidney function and sexually transmitted infections

what is Truvada®?

Truvada® is a pill made up of two HIV medications: FTC (emtricitabine) and Emtriva (emtricitabine). Currently, it is used to prevent HIV infection and hepatitis B. It is also used to treat HIV.

what are the side effects?

Truvada® is usually well tolerated, but some studies included headaches, weight loss, and nausea. We do not yet know about all long-term side effects from taking Truvada® for more than two years. It is known that Truvada® can cause side effects in some people. Those who use PrEP need to be aware of these side effects.

when is PrEP right for you?

If you're HIV-negative and are trying to prevent HIV, there are some questions for you to consider:

- Is your main sexual partner HIV-positive?
- Has a man – especially an HIV-positive man – penetrated you during anal sex?
- Have you been treated recently for HIV?
- Do you or your sex partner(s) use injection drugs?
- Do you or your sex partners(s) exchange sex for money or drugs?

where can i get PrEP?

PrEP must be prescribed by a medical professional. PrEP is covered by some insurance companies and some manufacturers.

A number of PrEP research studies are currently being conducted by the California HIV/AIDS Research Program (CHAMP) at the UC San Diego AntiViral Research Center (AVRC).



while taking PrEP, you should have >>>

- Doctor visits every 2-3 months
- HIV tests at least every 3 months
- Evaluations for side effects, adherence and risk

HIV Prevention Research Study

Are you a man who has sex with men?

Are you HIV-negative?

Are you interested in taking a medication that could reduce your risk of getting HIV?

If so, you may qualify for a study at the UC San Diego AntiViral Research Center (AVRC) that is looking at a method of reinforcing adherence to a medication recently approved by the FDA for preventing HIV infection. In this study, we hope to learn if text message reminders increase adherence to pre-exposure prophylaxis (PrEP).

For more information, contact

619-226-9269

avrc.ucsd.edu | 619-543-8080

UC San Diego
SCHOOL OF MEDICINE
AntiViral Research Center

Recruitment – LA / Long Beach



LABioMed

Los Angeles Biomedical
Research Institute
at Harbor-UCLA Medical Center

Research Study Information

Are you a man interested in taking medication that could reduce your risk of getting HIV (Pre-exposure Prophylaxis, otherwise known as PrEP)?

Are you HIV-negative or know of someone who is HIV-negative?

Are you sexually active w

Are you at ongoing risk fr

If so, you may qualify for LABioMed at Harbor-UCLA Health Department if text messaging remind the study medication acc

If you are interested on p study, call Angela at (31



LABioMed

Los Angeles Biomedical
Research Institute
at Harbor-UCLA Medical Center

Estudio de Investigación

Es usted un Hombre interesado en tomar medicina que le reduzca el riesgo de adquirir VIH (Profilaxis para evitar infección de VIH, también llamado PrEP)?

Es usted VIH-negativo o conoce a alguien que es VIH-negativo?



PrEP: A method for HIV prevention

Quick Facts:

- ✓ PrEP uses Truvada (FTC-TDF), an approved antiretroviral medication to prevent HIV infection
- ✓ PrEP should only be taken by people who are HIV negative
- ✓ Taking PrEP does not mean that you are 100% protected from getting HIV
- ✓ PrEP should not replace other safer sex strategies, such as condoms
- ✓ PrEP does not prevent other sexually transmitted infections
- ✓ PrEP should only be taken with the support of a health care provider
- ✓ Taking PrEP includes getting routine blood tests done
- ✓ You may have side effects from taking PrEP

PrEP, as part of a study will be available at no cost to you at Los Angeles Biomedical Research Institute at Harbo-UCLA Medical Center (LABioMed) and at the Long Beach Department of Health and Human services clinic (LBDHHS)

For more information or how to access PrEP contact the following PrEP sites:

LABIOMED 310-232-3849 ASK FOR ANGELA
1134 WEST CARSON ST. TORRANCE, CA 90503

LBDHHS 562-570-4125 ASK FOR MICHAEL
2525 GRAND AVENUE, LONG BEACH, CA 90815

PrEP is not just about taking a daily pill. Before you start PrEP, the following tests and exams should be done:

- ✓ A thorough and honest talk about your sexual activity and HIV risk
- ✓ An HIV antibody test and possibly a test to detect HIV directly
- ✓ Test for hepatitis B, kidney function and sexually transmitted infections

While you're taking PrEP, the following should be done:

- ✓ Doctor visits every 2-3 months
- ✓ HIV tests at least every 3 months
- ✓ Evaluation for side effects.

Daily PrEP with condom use (and other HIV prevention methods) can reduce infection risk by up to 90%.



PrEP

Pre Exposure
Prophylaxis

what you
need to
know...



PrEP: A new method for HIV prevention

What is PrEP?

Pre exposure prophylaxis or PrEP is a new HIV prevention method in which people who don't have HIV infection take a pill daily to reduce their risk of infection. Studies have shown that PrEP reduces risk of infection in men who have sex with men as well as in heterosexual men and women.

Daily PrEP with regular condom use (and other HIV prevention methods) reduces infection risk by up to 90%.

In July 2012 the U.S. Food and Drug Administration approved the combination medication FTC-TDF or Truvada for use as PrEP among sexually active adults at risk for HIV infection.



What is Truvada?

Truvada is a pill made up of two HIV meds — Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine). Currently, it is commonly used together with other meds to treat HIV infection and for the treatment of hepatitis B.

What are Truvada's side effects?

Truvada is usually well tolerated, but short-term side effects that were seen in PrEP studies included headaches, weight loss, nausea, diarrhea and stomach pain. We do not yet know about all long-term side effects since PrEP studies only followed people for less than two years, but it is known that Truvada can cause bone loss and can damage the kidneys in some people. Those who use PrEP need to be monitored closely.

When is PrEP right for you?

If you're HIV-negative and are trying to stay that way, then PrEP might be right for you.

Here are some questions to consider

- ✓ Is your main sexual partner HIV-positive?
- ✓ Has a man — especially an HIV-positive man or a man whose HIV status you are not sure about —

penetrated you during anal sex ("topped" you) without a condom recently?

- ✓ Have you been treated recently for a sexually Transmitted disease?
- ✓ Do you or your sex partner(s) use alcohol and/or drugs heavily?
- ✓ Do you or your sex partner(s) exchange sex for money, housing or other needs?

Where do you get PrEP?

PrEP must be prescribed by a medical provider. The cost is covered by some insurance companies and may be available for some through the manufacturer.

A number of PrEP demonstration projects are being launched in the U.S., including some funded by the California HIV/AIDS Research Program of the University of California. Our team is part of this effort and as part of a study will provide PrEP as well as behavioral counseling and other services to eligible men who have sex with men and transgenders in the Long Beach and South Bay area for free at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center and at the Long Beach Department of Health and Human Services clinic.





Added Value

Milam/ Morris- NIMH R21 funded; CCTG 597: Risk compensation and pre-exposure prophylaxis use to prevent HIV infection

Morris- R01 application submitted: The Rectal Mucosal Environment of Individuals on Pre-Exposure Prophylaxis

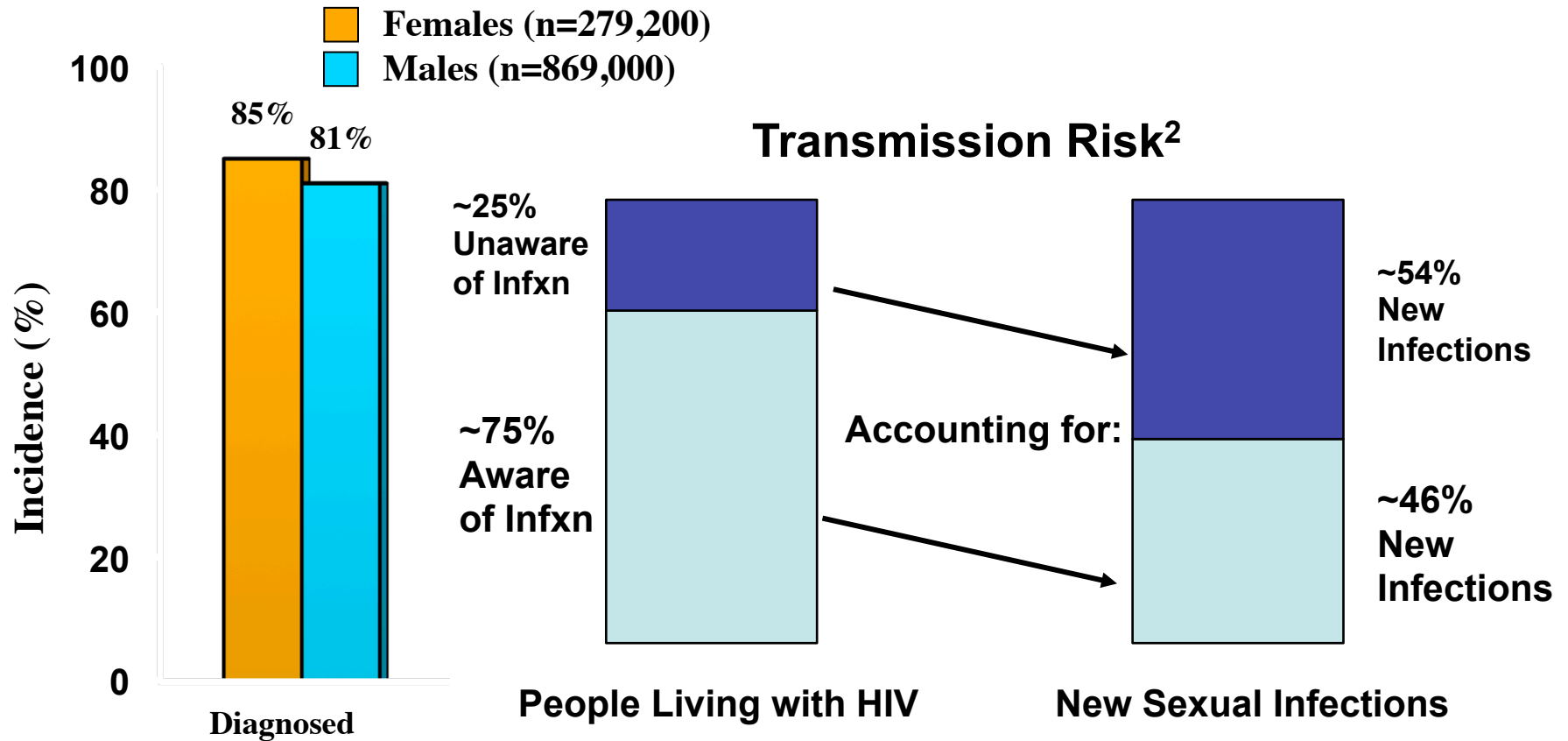
Morris/ Blumenthal: The Use of Dried Blood Spots to Measure Medication Adherence in CCTG 595

CCTG 594: Engagement and Retention in Care for HIV+

Protocol Co-chairs:	Amy M. Sitapati, M.D. Jeannette Aldous, M.D.
Protocol Vice-chairs:	Eric Daar, M.D. Joel Milam, Ph.D
Co-Investigators:	Katya Calvo, M.D. Michael Dube, M.D.
CTS:	Eric Ellorin
Biostatistician:	Sonya Jain, Ph.D.
Study Monitor/Data Unit:	Fang Wan, M.S. Edward Seefried, R.N.

Infected and Unaware

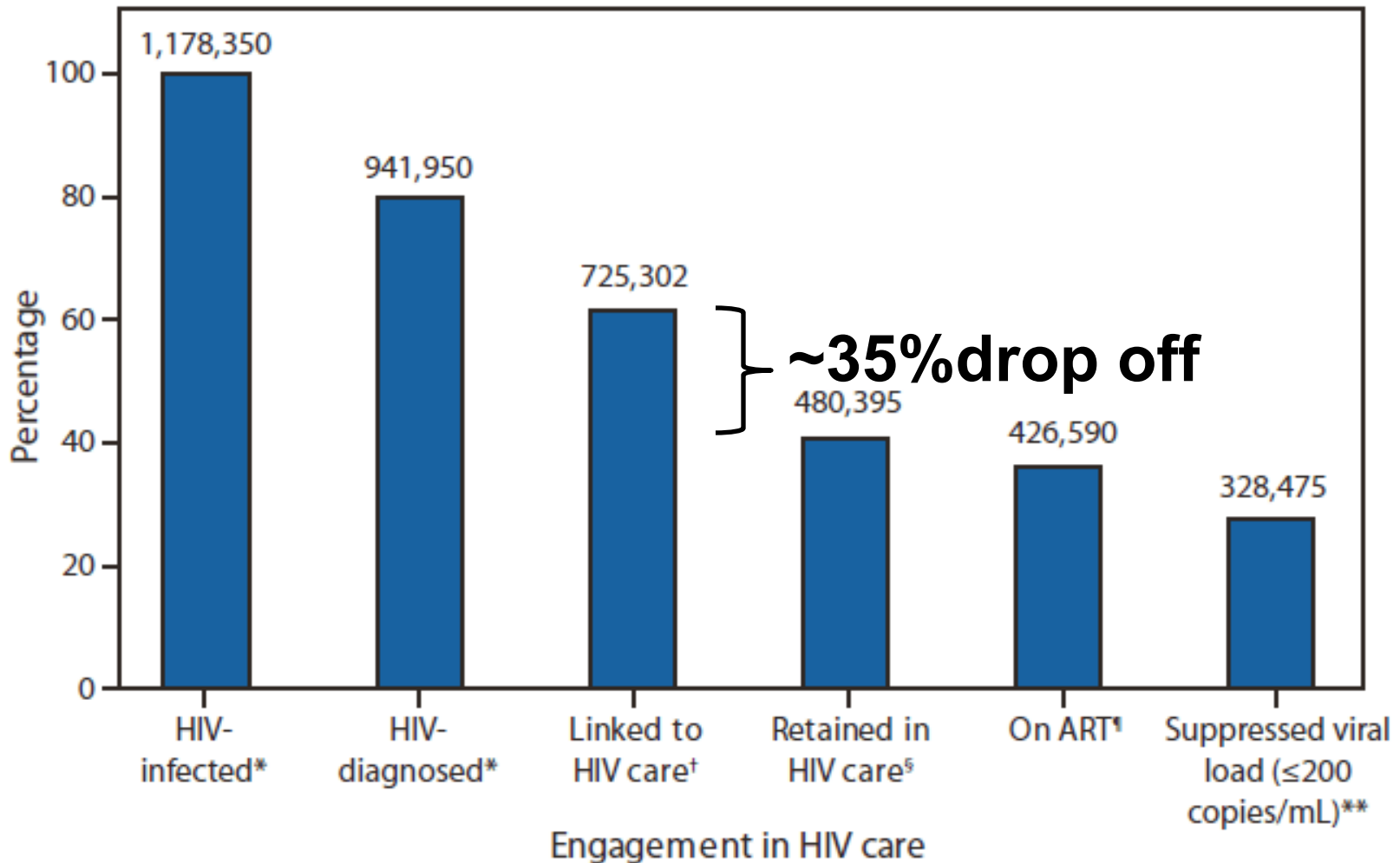
CDC and Prevention National HIV Surveillance System¹



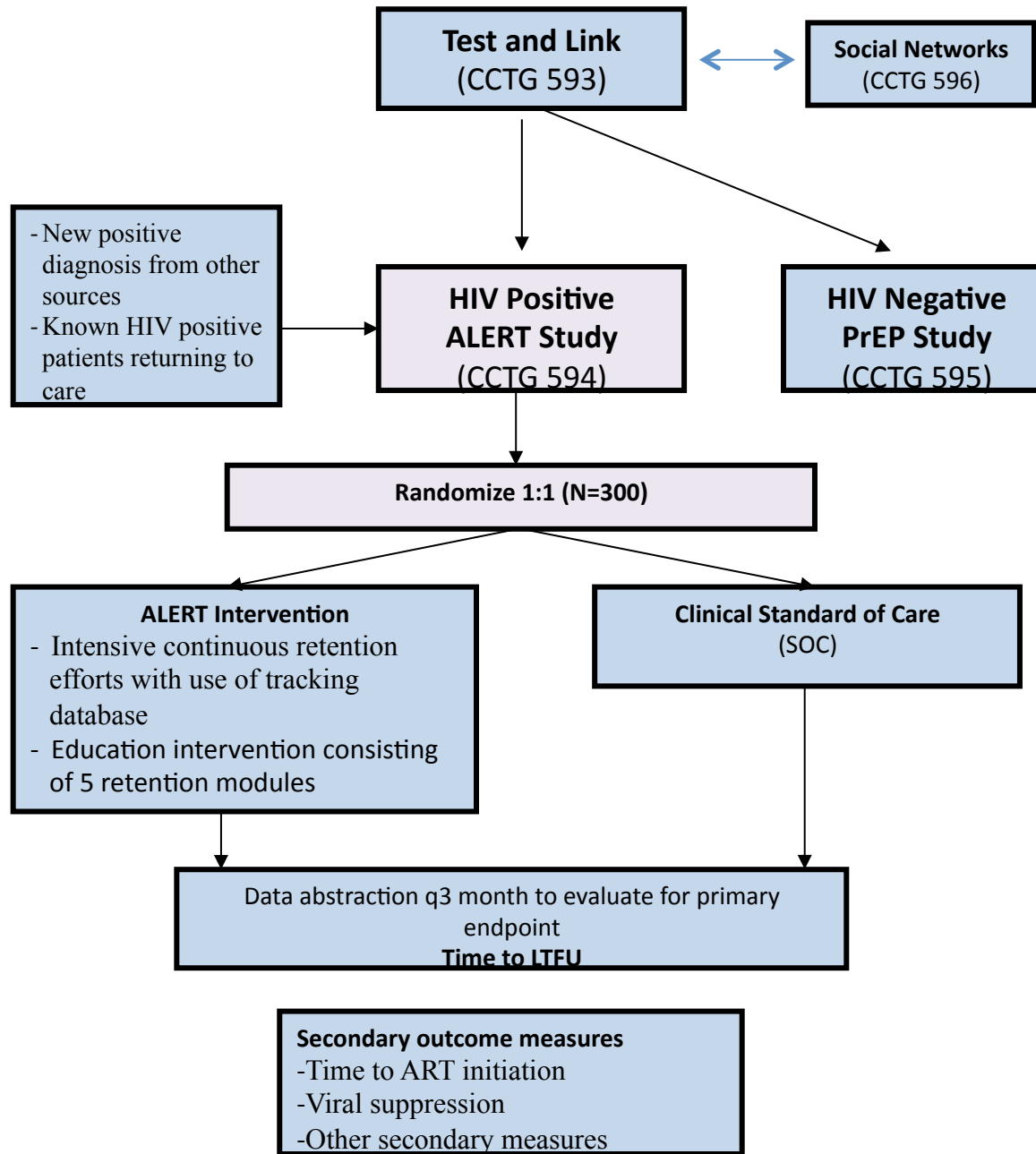
n= 1,148,200 HIV-infected persons, 18% of whom are unaware of their infection.

1. Hall HI, et al. 19th IAC. Washington, DC, 2012. Abstract FrLBX05.
2. Marks et al. AIDS 2006; 20:1447

HIV Cascade



On November 29, 2011, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).



Hypotheses

Primary hypothesis

- Subjects randomized to the ALERT specialist arm will have higher levels of “retention in care,” defined as maintaining at least one visit with a prescribing HIV provider within 180 days, compared to subjects in the SOC arm

Secondary hypotheses

- Subjects randomized to the ALERT specialist arm will have higher ART uptake compared to subjects in the SOC arm
- Use of detailed assessments at study entry will allow for the identification of covariates associated with poor retention and initiation of ART
- Use of an ALERT specialist and a structured retention module intervention will modify the impact of covariates on retention and initiation of ART

Primary/Secondary Objectives

Primary Objective:

- To evaluate the effect of an ALERT specialist on retention in care, based on time to LTFU

Secondary Objectives:

- To evaluate the effect of an ALERT worker on the time to initiation of ART per DHHS guidelines
- To assess factors predictive of loss to care, such as demographic, socioeconomic, and psychosocial factors, risk behavior, substance use and psychiatric illness
- To assess if the ALERT intervention mitigates the impact of psychosocial barriers on retention in care and initiation of ART

Secondary Objectives

Additional secondary objectives:

- To compare in the intervention vs. SOC arm (assessed at 12 month intervals)
- Baseline and annual scores on standardized assessments of HIV literacy, disclosure and social support, perception of stigma, barriers to care, ART adherence and Intention to Adhere, Beck Depression Index, substance use evaluations, HIV high-risk transmission behaviors, and measures of self-efficacy
- Number of visits per year with HIV prescribing provider per year
- HIV RNA < 50 and 200 copies/mL at 12 months and every 12 months thereafter
- CD4 cell counts and changes from baseline in CD4 at 12 months and every 12 months thereafter
- Time to AIDS diagnosis or death

The ALERT Worker Intervention

- ALERT worker introduces self to patient
- Intervention arm
 - ALERT specialist tracks on-going engagement, appointments and educational modules
 - Missed appointment results in outreach to reschedule, using tracking database collected at enrollment if necessary
 - Educational modules (~monthly)
 - HIV literacy
 - HIV health systems
 - HIV disclosure
 - Medication adherence and continuation with care
 - Self-efficacy
- Standard of care arm
 - Outreach as described above for those who reach primary endpoint

Module 1: HIV Literacy

- Objectives: To enhance understanding of HIV disease and how it affects the body.
- Introduction: Find out existing knowledge base regarding HIV and note gaps in knowledge
- Educational material to review with patient
 - What is HIV
 - HIV Transmission
 - “What are some of the ways that HIV can be spread to another person?”
 - “What are ways that HIV is not spread to another person?”
 - “Is it safe to have oral sex with the use of condoms if you are on HIV medication?”
 - People who continue to use needles or syringes should never share needles or borrow from someone else.
 - HIV Treatment
 - HIV and how you fell
 - Summarize

Module 3: Social Support and Disclosure

- Objectives: To identify social support networks, provide guidance on disclosure and encourage engagement of support network in HIV care
- Interaction
 - Identify goals for social support
 - “What kind of help or support do you think you will need to successfully stay in HIV care?”
 - Identify members of social support network
 - Identify members of the network most likely to be helpful in reaching the listed goals for social support
 - Assess comfort with disclosure and identify
 - Establish a plan

CCTG 594 Protocol Status

- RCT to evaluate the effectiveness of a clinic-based HIV Active Linkage, Engagement, and Retention to Treatment (ALERT) specialist on improving endpoints of retention in care and maintenance of antiretroviral therapy (ART) as compared to SOC in HIV primary care clinics (n=300)
 - Inclusion of those new to care or LTFU (>180 days out of care)
 - Primary endpoint is Time to LTFU (no visit in last 180 days)
- Protocol Version 1.0- May 10, 2013
- IRB approved UCSD and Harbor-UCLA, under submission at USC
- Start-up meeting- June 11, 2013
- ALERT working training- July 19, 2013

eCRF Examples

Inclusion and Exclusion Criteria



Search Site
 only in current section

- Home
- Harbor-UCLA
- Long Beach
- UCSD
- USC
- iTab
- CCTG Studies**
- CCTG Documents

- CCTG eCRFs
- PHI eCRFs
- Harbor-UCLA
- Long Beach
- UCSD
- USC
- 593
- 594
- 595
- 596 Index
- 596 Network

You are here: Home > CCTG Studies > CCTG eCRFs > Inclusion and Exclusion Criteria - 594

Inclusion and Exclusion Criteria - 594 -- Published 2013-06-03

Is there a signed IRB-approved consent form in the source document? ■

- Yes
- No

Was an exemption requested and obtained for this subject? ■

- Yes
- No

If Yes, reason:

— Inclusion Criteria —

HIV-1 infection, as documented by any licensed screening antibody test, such as ELISA, and confirmed by a second antibody test, such as Western blot, or detectable plasma HIV-1 RNA at any time prior to study entry. If an ELISA or Western blot is not available, HIV infection must be documented by two HIV RNA values ≥ 2000 copies/mL, drawn at least 24 hours apart. The RNA assays must have been run at a CLIA-approved laboratory or equivalent. ■

eCRF Examples

Demographics

Current State:

- pending-entry

Collection Date ■

9/18/2013

Month of Birth ■

select a value ...

Year of Birth ■

(yyyy)

Gender ■

- Male
- Female
- Male to Female
- Female to Male

Ethnicity ■

Check only one category

- Hispanic or Latino
- Not Hispanic or Latino
- Subject does not want to report
- Subject does not know
- Ethnicity not available

Race ■

Check all that apply

Retention Module

You are here: [Home](#) > [CCTG Studies](#) > [CCTG eCRFs](#) > [Retention Module](#)

Retention Module -- Published 2013-07-25

Which Module was completed on this date? ■

- Module 1 - HIV Literacy
- Module 2 - HIV Health Systems
- Module 3 - Social Support and Disclosure
- Module 4 - Medication Adherence and Continuation with Care
- Module 5 - Self-Efficacy

How was the Module conducted? ■

If Over the phone, detail specifics in Call Log.

- In person
- Over the phone

Time Taken ■

(ex. 1.5 hours)

Percent completed ■

- Complete (>90%)
- Partial (>=50%)
- Not Completed (<50%)

Was adherence discussed? ■

- Yes
- No

Completion Date ■

(mm/dd/yyyy)

CCTG 593

Testing and Linkage to Care

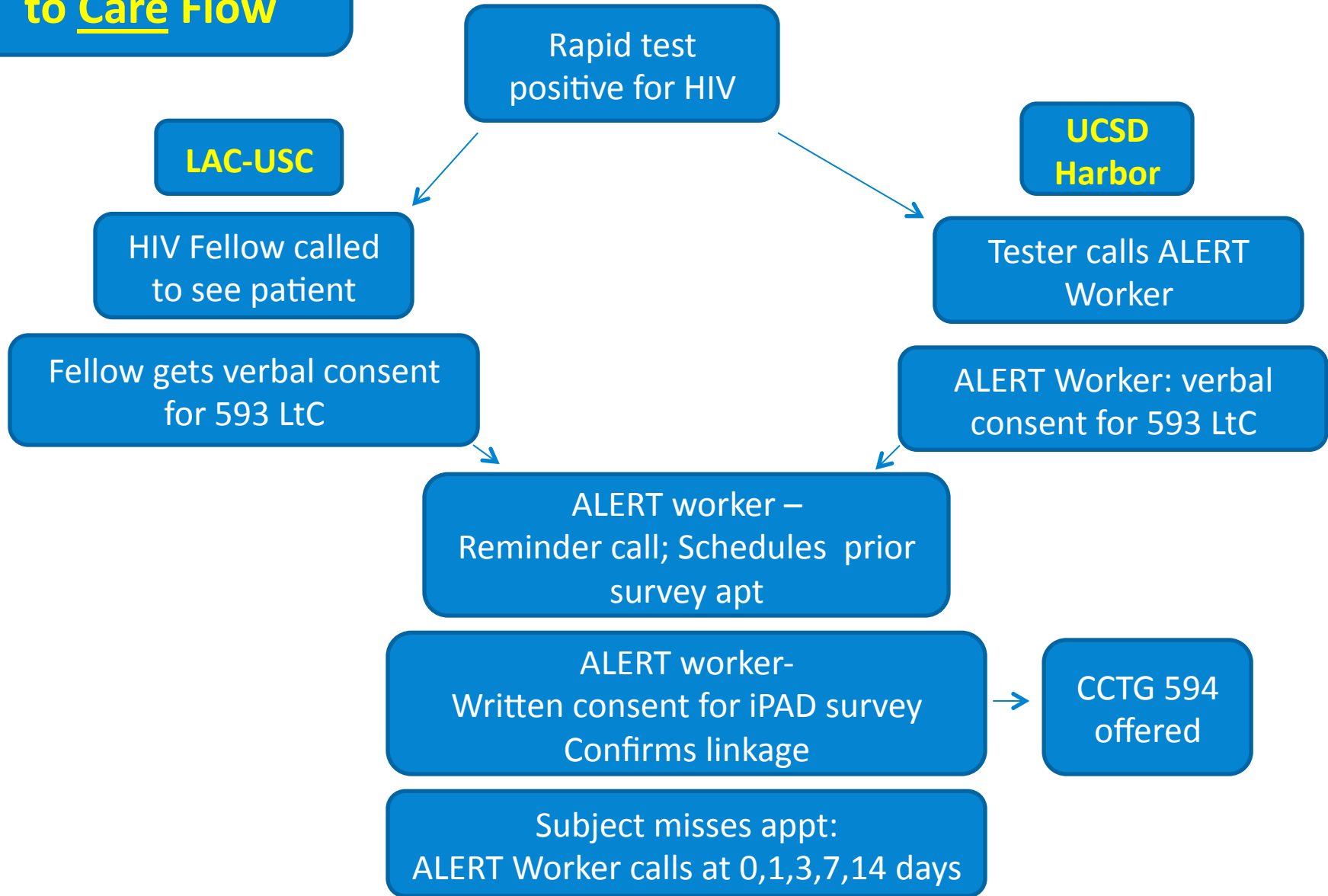
**A Multicenter Demonstration Project of the
California Collaborative Treatment Group (CCTG)**

**Sponsored by:
The California HIV/AIDS Research Program (CHRP)**

**Vice Chair: Mike Dube MD
Co Chairs: Kathleen Jacobson MD and Mike Menchine MD MPH**

**Co-Investigators:
Katya Calvo, MD and Jill Blumenthal, MD**

CCTG 593 Linkage to Care Flow



CCTG 593 Linkage to PrEP Flow

LAC-USC Harbor

Tester asks “interested in a study to connect you to a study to get meds to prevent HIV?”

Tester asks if MSM

Tester calls ALERT Worker

Rapid test negative for HIV

UCSD

CCTG 595 flyer available w/ ALERT Worker phone #

Patient calls ALERT worker

ALERT Worker confirms MSM and gets verbal consent for 593

ALERT worker: Reminder call Schedules prior survey appt

CCTG 595 offered

ALERT worker: Written consent for iPad survey, confirms linkage

Subject misses appt.
ALERT Worker calls at 0,1,3,7,14 days

Sample Size and Study Population

- **Sample Size**
- **Up to 600 subjects** will be tested and offered linkage across all CCTG sites (LAC +USC, LB, SD)
- **Study Population**
- Eligible subjects will include **any persons 18 years of age or older who have been tested for HIV at one of the CCTG testing sites**

Outcomes

- **Primary Outcome**
- **Effectiveness of the linkage program** - defined as the proportion of individuals who, after testing
 - a) HIV positive- will successfully be linked to care, or
 - b) HIV antibody negative- will successfully be linked to PrEP services, by the ALERT specialist
 - within 60 days of enrollment
- **Secondary Outcome**
- **Measure the acceptance of the linkage program**, which is defined as those individuals who, after testing HIV antibody negative, will agree to contact (UCSD) or be contacted by the ALERT specialist for linkage to PrEP.

Evaluation and Endpoints

- ***Outcome Measure of Linkage to Care***
 - Historic rate of successful linkage to care of **67%**
 - Target goal for successful linkage as at least **85%**
 - **50 subjects provides 80% power to detect 18%[↑]** of linkage compared to historical data
 - Phone survey for those who fail linkage
- ***Outcome Measure of Linkage to PrEP***
 - We estimate 50% of those offered linkage to PrEP will attend a PrEP clinic visit (800 screened/400 evaluated)
 - The proportion and 95% CI of those who are referred for linkage to PrEP who complete a PrEP evaluation visit will be calculated to provide a well-defined estimate of the rate of attending a PrEP visit (eg, 50% ± 4%)
 - Refusal survey finalized for all testing sites

Status of 593 at Parent Site (LAC-USC)

- ALERT workers hired Feb 1, 2013
- IRB Approval-
- Start Up meeting June 15, 2013
- Enrollment for Linkage to Care opened June 18, 2013
 - 7 enrollees as of September 7, 2013
 - Troubleshooting of MOPs to accomplish survey
- Enrollment for Linkage to PrEP from LAC-USC ED opened June 24, 2013
 - 1 enrollee
 - Screening ~ **150** HIV tested patients/week

Status at UCSD and Harbor UCLA

- **UCSD**

- IRB Approved
- ALERT Worker hired 7-15-13
- SDPH meeting 9-12-13
 - Necessary secondary review by SDPH regulatory board
- Enrollment to begin w/in weeks

- **Harbor UCLA**

- ALERT workers hired 2-1-13
- IRB submission in process

593 Refusal Survey

CCTG 596

Incentivized Social Network Recruitment for HIV Case Finding

**A Multicenter Demonstration Project of the California
Collaborative Treatment Group (CCTG)**

**Sponsored by:
The California HIV/AIDS Research Program (CHRP)**

Co Chairs: Sanjay Arora and Kathleen Jacobson

Vice Chair: Ricky Bluthenthal

**Co Investigators: Michael Dube, Sheldon Morris, Katya
Calvo**

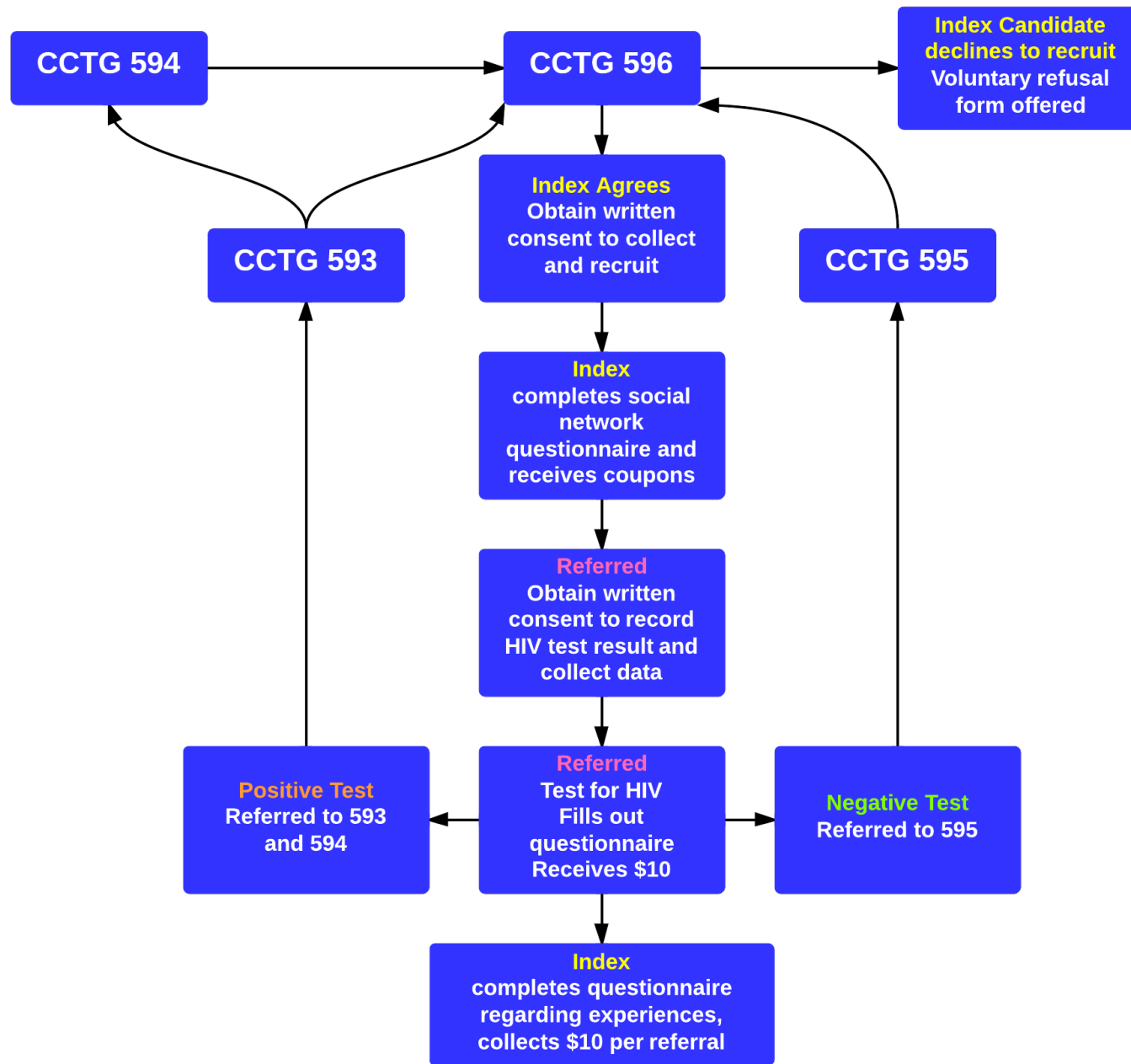
Design

- **Design**
- Financial incentive to recruit individuals (n=400) from the social networks of subjects enrolled in CCTG 593, 594, and 595 for HIV testing.
- **Duration**
- 30 days from the time of enrollment to 596.
- After 30 days, referred individuals can still receive HIV testing but neither the index case nor the referred individual will receive a financial incentive for the referral.

Study Population

- **Eligible subjects to be “Index” *Peer Recruiter* Cases**
 - 593 - newly diagnosed HIV positive
 - 594 - recently or chronically HIV infected
 - 595 - high risk HIV negative individuals
- **Eligible subjects for incentivized HIV testing**
 - Individuals recruited from the index subject’s social network by index peer recruiter
- Enrollment will be controlled so that 50% offered network recruitment will be African American subjects.

- **Primary Outcome - Identification of new HIV infections**
- **Secondary Outcomes**
 - Feasibility of compensated social network referral for HIV testing
 - Description of the social networks of
 - Newly diagnosed HIV positive
 - Chronically HIV infected, unengaged individuals
 - High risk HIV negative individuals
 - Number of index cases that are willing to refer any contacts
 - Proportion of referred contacts that come in for HIV testing versus total number referred
 - Unintended consequences related to participation (index or referred)
- **Exploratory analyses**
 - Factors associated with index willingness to refer
 - Comparison of social network characteristics across studies



Incentivized Social Network Recruitment for HIV Case Finding
A Multicenter Trial of the California Collaborative Treatment Group
Funded by the California HIV/AIDS Research Program

Please return to Daisy Villafuerte or Janisse Mercado for HIV screening test
You may receive \$10 compensation for taking the HIV screening test

Research Study Sites:
Los Angeles County + University of Southern California
University of California San Diego
Harbor + University of California Los Angeles

LAC+USC
HEALTHCARE NETWORK



USC IRB: HS-13-00374

For more information, call us at:
323-343-8284

Open 9 am to 4 pm
Monday through Friday

ID #XXX-X-X

Activation Date: _____

Expiration Date: _____

Coupon is invalid if lost or tampered with



USC IRB: HS-13-00374

Entry points from 593-595 studies

- **593 - Linkage to Medical Care Visit**
 - following 593 survey
- **594 - Module 3 – “Disclosure“**
- **595 - 4 Week Visit**
- 594 and 595 may offer 596 at other times

Evaluation

- Greater than 99% power to detect a statistically significant difference from a historical rates of HIV positivity in the individual groups
- Examine factors associated with willingness to refer among subjects from CCTG 593, 594, and 595, using data from the Social Network Referral Survey form and Refusal forms
- Basic descriptive statistics will be used to examine demographic, health status, and attitudinal differences between those who refer and those who decline to refer.
- Descriptive statistics will be used to examine unintended consequences of referring/being referred to HIV testing
- Social network characteristics will be assessed for size and homophily using basic descriptive statistical techniques

Status of 596

- **USC – Parent site-approved and enrollment begun**
 - 593 connecting w/ subjects challenging
 - 594 pending
 - 595 will offer at 4 week visit which is pending
- **UCSD - IRB approval pending**
- **Harbor UCLA - preparing to submit to IRB**



Recruitment and Outreach

CCTG 595

AntiViral Research Center

UC San Diego
SCHOOL OF MEDICINE

HIV Testing Clinics and Sites

- Lobby
 - Business cards
 - Informational brochures
 - PrEP FAQ signage
- Exam Rooms
 - Flyer with tear-off tabs



Community Outreach

- Health Fairs
- LGBT Community Events
- LGBT and HIV/AIDS Service Agencies



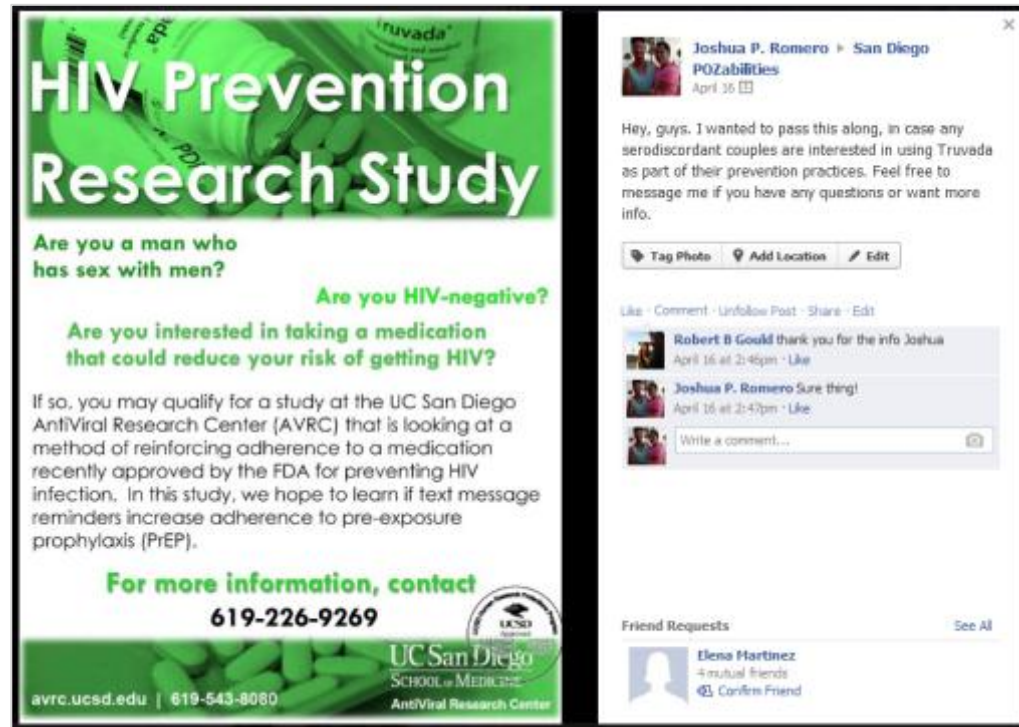
AntiViral Research Center

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Social Media

- Posting Information on HIV/AIDS and LGBT Agencies' Social Media Pages
- Interacting with Users of HIV/AIDS and LGBT Agencies' Social Media Pages
- Paid advertising on Facebook

** Staffing limitations do not support the implementation and management of unique social media pages for CCTG 595*



Social Media Interaction: Real World Example

Hello guys. [redacted] joined the group. [redacted] coming into [redacted] bother me. [redacted] type measu [redacted] a committer [redacted] about it, he [redacted] sex. I was a [redacted] think I'm go [redacted] same of a s

So my ques [redacted] anyone rec [redacted] and look th [redacted] Thanks guy

Joshua P. Romero All good advice. ^ If you have trouble finding a good doctor, there is a study at UC San Diego AntiViral Research Center that provides free Truvada for eligible participants. You can call this number for more info:



PrEP research study

- >>> Are you a man who has sex with men?
- >>> Are you HIV-negative?
- >>> Are you interested in taking a daily medication that could reduce your risk of getting HIV?

call us for more information 619-226-9269

August 22 at 4:07pm · Like · 3

Like · Comment · Unfollow Post · August 22 at 10:45am near San Diego

Study Blog-Based Website

- URL
 - TBD – Need suggestions for a .com or .org
- Content
 - Information from PrEP brochure
 - Contact info for each site
 - Web resources on PrEP
 - Articles about PrEP
 - Staff blog
- Mobility
 - Mobile-friendly design
- Blog
 - Brief articles by staff to help boost search engine rankings
 - First-hand, “things we’re learning about PrEP in the community” perspective

Mobile Application Advertising

- Grindr
 - Broadcast Message
 - Pops up when users sign in to app
 - Lots of text
 - Links from app to website
 - Runs in 24-hour blocks
 - Banner Ads
 - Displayed at bottom of app
 - Links from app to website
 - Sold in blocks of 1,000 impressions



MSM Social/Sexual Networking Sites

- Craigslist
 - Free ads
 - Localized to geographic area and municipal regions
- Adam4Adam, MANHUNT, Gay.com
 - Paid ads
 - Localized to geographic area



Local LGBT Publication Advertising

- Reach
 - Targets MSM population
 - Some publications circulate paid advertisements in e-mails and e-newsletters
- Rates
 - Often cheaper than mainstream local publications
 - Offer non-profit advertising rates

