

## Section 10. Randomization

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This SSP section describes the randomization system and process for HPTN 074 including how to request a user account, how to randomize a participant, confirmation of randomization and how to access randomization system support.

### 10.1 Participant Randomization Overview

Randomization is the process whereby a participant is assigned to a study treatment arm. There are two main steps in the randomization process:

- Request randomization using the HPTN 074 Frontier Science & Technology Research Foundation (FSTRF) Randomization system.
- Receive and print randomization confirmation notice.

### 10.2 Requesting FSTRF User Accounts

Every staff member who intends on randomizing participants must have a FSTRF user account in order to access the system. To create an account, please follow the following steps:

- Go to the FSTRF Portal: <https://www.fstrf.org/apps/cfm/apps/common/Portal/index.cfm>
- Click on the link for “Register”
- Enter your information (e.g. first name, last name, institution, e-mail address)
  - If you are a staff member, for example the clinic coordinator, requesting an account for one of your staff, please enter your own information under “Person completing this form”. If you are entering information for yourself, you can check the box for “same as above”.
- Create a password
  - This is the password you will use to access the system moving forward once an account has been created.
- Click “Next”
- Chose the project “HPTN” from the drop down menu and click “Other- Non-Laboratory Staff” for your position from the menu. In the comments, please write the protocol number and your site.
- Click “Next”
- For “Web/Data Access for Lab(s)”, click “No”
- For “Randomization Access”, click “Yes”
- Click “Institution number not available”
- Click both “Access to Randomization Checklists” and “Access to Randomize Patients”
- Review your information and click “Submit”

**NOTE:** You will not be able to utilize the FSTRF system, even if you have an account, until your site has been activated for HPTN 074.

### 10.3 Requesting Participant Randomization Using the FSTRF System

The participant must meet all eligibility requirements before CRS staff request randomization for a participant via the HPTN 074 FSTRF web-based Randomization System.

If review of the criteria is complete and the volunteer meets eligibility criteria, RANDOMIZE.

In HPTN 074, randomization **MUST ONLY** occur once 1) the index participant has completed the screening procedures AND 2) has recruited a network partner that has also successfully completed the screening process.

Once you have an account and your site is activated, open the FSTRF system at [www.fstrf.org/Portal](http://www.fstrf.org/Portal) click on “Portal Log In” and log in using your FSTRF Randomization System username and password (**Figures 1 and 2**).

**Figure 1.** FSTRF Page

The screenshot shows the FSTRF website interface. The top left features the 'frontier science' logo. The top right has a 'Skip Links' link and the text 'Frontier Science & Technology Research Foundation, Inc. (FSTRF)'. A left-hand navigation menu lists various links, with 'Portal Log In' circled in red. The main content area is titled 'Research Collaborations' and lists numerous research groups and programs, each with a link to their respective page.

| Navigation Menu                            | Research Collaborations   |
|--|---|
| <a href="#">FSTRF Home</a>                 | <a href="#">ACTG</a> AIDS Clinical Trials Group<br><a href="#">Inventory Request for ACTG and IMPAACT Repository Specimens</a>  |
| <a href="#">About Frontier Science</a>     | <a href="#">CIPRA Haiti</a> CIPRA Haiti HT001 Data Management   |
| <a href="#">Contacts and Key Personnel</a> | <a href="#">CPQA</a> Clinical Pharmacology Quality Assurance Program<br><a href="#">CPQA Clinical Pharmacology Tutorial</a>   |
| <a href="#">European Affiliates</a>        | <a href="#">DENIMM</a> Dendritic Cell Immunization Project  |
| <a href="#">Laboratory Data Management</a> | <a href="#">IBCSG</a> International Breast Cancer Study Group   |
| <a href="#">New User Registration</a>      | <a href="#">IBSOS</a> Irritable Bowel Syndrome Study  |
| <a href="#">Portal Log In</a>              | <a href="#">IMPAACT</a> International Maternal Pediatric Adolescent AIDS Clinical Trials Group<br><a href="#">IMPAACT Pediatric/Maternal Diagnosis Appendix 40</a><br><a href="#">Inventory Request for ACTG and IMPAACT Repository Specimens</a> |
| <a href="#">Mail to Webmaster</a>          | <a href="#">IRC</a> Influenza Research Collaboration  |
| <b>Openings:</b>                           | <a href="#">LDMS</a> Laboratory Data Management System  |
| -Amherst, NY                               | <a href="#">LSOCA Group</a> Longitudinal Study of Ocular Complications of AIDS  |
| -Boston, MA                                | <a href="#">PHACS</a> Pediatric HIV/AIDS Cohort Study   |
| -Madison, WI                               | <a href="#">PRO 140</a> Progenics PRO 140 Study   |
|  | <a href="#">PROMISE IMPAACT</a> IMPAACT PROMISE Study   |
|  | <a href="#">VQA</a> Virology Quality Assessment Program   |
|  | <a href="#">Quality of Life</a> Quality of Life/Adherence Forms   |
|  | <a href="#">Related AIDS Sites</a> Links to other AIDS related WWW sites  |
|  | <a href="#">ECOG</a> Eastern Cooperative Oncology Group Page  |

**Figure 2.** Log in view of the FSTRF Randomization System

frontier science

Skip to Content

Statistical Data Management for Clinical Trials

Please Log In:

User Name:

Password:

Log In

All Data Management Center (DMC) computing systems will be offline between 8PM and midnight, Eastern Time, on the first Saturday of each month. This will be done to perform various system maintenance tasks that contribute to the ongoing stability of DMC computer and communications systems.

All databases at the DMC are offline for maintenance each Friday and Saturday night from 11:50 p.m. to 12:10 a.m. Eastern time.

This is the FSTRF Computer System. This computer system is monitored with privacy accommodations for all lawful purposes, including: ensuring that its use is authorized, for management of the system, to facilitate protection against unauthorized use, and to verify security procedures. Use of this FSTRF system, authorized or unauthorized, constitutes acknowledgment and consent to monitoring by the system.

[Register](#) | [Reset Password](#) | [Login Help](#) | [Email Webmaster](#)

Once logged in, you will see the Projects screen (**Figure 3**), You may need to select the HPTN Project tab.

Under “Systems”, click on “Subject Randomization”

**Figure 3.** Links and Applications Listed by Category

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Change Selected Project

Skip Project Links

All HPTN HVTN

Links and Applications Listed by Category

Show Most Recently Used Items

Systems (Skip)

Protocol Registration

Subject Randomization

On the next screen, use the drop down menus provided to select your institution and study, click “Continue” (**Figure 4**). Disregard (i.e., do not check) the box for “Blank Eligibility Checklist” as it is not required and is not referring to the protocol eligibility criteria. On the next view, Click “OK” in the confirmation pop-up box (**Figure 5**).

**Figure 4.** Chose Institution and Study

The screenshot shows the 'HPTN Subject Randomization System' interface. At the top, it says 'Enter Institution Code and select a Study'. There are two sections, each with a 'Blank Eligibility Checklist' checkbox. The first section shows a dropdown menu for 'Institution ( for this enrollment ) :'. The menu is open, showing a list of institutions with '251 Kiev, Ukraine' selected and circled in red. A red arrow points to the dropdown arrow. Below the list are contact details for the selected institution. The second section shows the 'Institution' dropdown set to '251 Kiev, Ukraine'. Below it, the 'Study:' dropdown is open, showing a list of studies with '074 (HPTN 074)' selected and circled in red. A red arrow points to the dropdown arrow.

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## HPTN Subject Randomization System

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Enter Institution Code and select a Study

**Blank Eligibility Checklist**

**Institution ( for this enrollment ) :**

- 251 Kiev, Ukraine
- Please Select
- 250 Jakarta, Indonesia
- 251 Kiev, Ukraine
- 252 Thai Nguyen, Vietnam
- 253 Bronx Prevention Center
- 254 New Jersey Medical School
- 255 Emayundleni, Cape Town
- 256 Spilhaus, Harare
- 257 Chapel Hill
- 258 Los Angeles
- 259 San Francisco
- 260 Washington DC
- 261 Soweto
- 262 Durban
- 263 Lilongwe
- 264 Rio de Janeiro
- TEST TEST SITE

Fax +1 716 832-8437  
Help [Online Help \(.pdf\)](#)

**Blank Eligibility Checklist**

**Institution ( for this enrollment ) :**

251 Kiev, Ukraine

**Study:**

- Please Select
- Please Select
- 074 (HPTN 074)
- 076 (HPTN 076)
- 077 (HPTN 077)

# HPTN Subject Randomization System

Enter Institution Code and select a Study

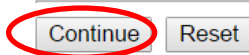
**Blank Eligibility Checklist**

**Institution ( for this enrollment ) :**

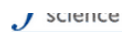
251 Kiev, Ukraine ▼

**Study:**

074 (HPTN 074) ▼



**Figure 5.** Eligibility checklist pop-up confirmation box

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# HPTN Subject Randomization System

Enter Institution Code and select a Study

**Blank Eligibility Checklist**

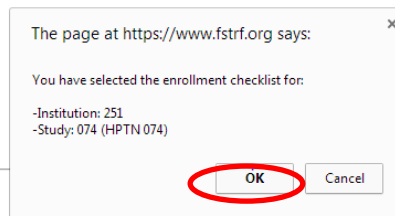
**Institution ( for this enrollment ) :**

251 Kiev, Ukraine ▼

**Study:**

074 (HPTN 074) ▼

Continue Reset



The next screen is pre-filled and does not require any action from your part. Click “Continue” (**Figure 6**) to proceed.

**Figure 6.**

The screenshot shows the 'frontier science' logo at the top left. Below it is the title 'HPTN Subject Randomization System'. Underneath the title, there are two lines of text: 'Institution: 251' and 'Protocol: 074'. Below that is a section titled 'Please select a step:' with a radio button selected next to 'STEP 1'. At the bottom of the form, there are two buttons: 'Continue' (which is circled in red) and 'Reset'.

Click “OK” in the confirmation pop-up box of the next screen (**Figure 7**).

**Figure 7.**

This screenshot is similar to Figure 6, but it includes a confirmation pop-up box. The pop-up box has a title bar that says 'The page at https://www.fstrf.org says:'. The main text inside the box reads: 'You have selected the enrollment checklist for:'. Below this text, there is a list of three items: '-Institution: 251', '-Study: 074', and '-Step: STEP 1'. At the bottom of the pop-up box, there are two buttons: 'OK' and 'Cancel'. The background interface is the same as in Figure 6, but the 'Continue' button is no longer circled.

On the next screen, select the box by “Click here to continue!” Enter the participant’s ID Number (PTID), without dashes, in the space provided and select your site and select the site you are randomizing for. (**Figure 8**).

**NOTE:** You must enter a valid PTID to proceed, if you enter an invalid PTID, an error pop-up box will notify you that a valid PTID is required.

Figure 8.



## HPTN Subject Randomization System

Institution: 251  
Protocol: 074  
Step 1:

### Eligibility Checklist:

Q0001

Protocol HPTN 074

Integrated treatment and prevention for people who inject drugs: A vanguard study for a network-based randomized HIV prevention trial comparing an integrated intervention including supported antiretroviral therapy to the standard of care

Eligibility Checklist Date: February 11, 2015

[Click here to continue!](#)

Q0002

Enter the participant's Patient Number.



Q0003

Select your site.

- Jakarta, Indonesia [[Eligible](#)]
- Kiev, Ukraine [[Eligible](#)]
- Thai Nguyen, Vietnam [[Eligible](#)]



On the next screen, click “OK” to confirm that all criteria have been met (**Figure 9**).

**Figure 9.**

The screenshot displays the 'frontier science' logo at the top left. Below it, the text 'HPTN Subject Randomization System' is visible. The interface shows the following details:

- Institution: 253
- Protocol: 076
- Step 1:

An 'Eligibility Checklist:' section contains the following information:

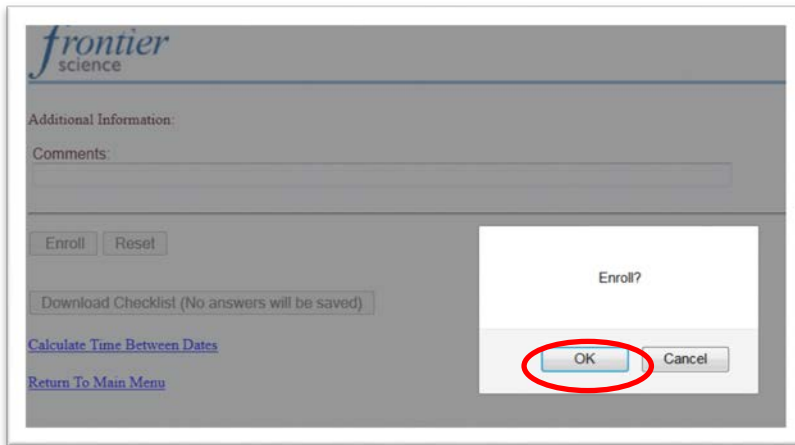
- Q0001**  
Protocol HPTN 076  
Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre-Exposure Prophylaxis (PrEP)  
Eligibility Checklist Date: September 17, 2014  
 Click here to continue!
- Q0002**  
Enter the participant's ID number.  
222222224
- Q0003**  
Select your site.
  - Bronx Prevention Ctr, USA [Eligible]
  - New Jersey Medical School, USA [Eligible]
  - Emavundleni, Cape Town, SA [Eligible]
  - Spilhaus, Harare, Zimbabwe [Eligible]

A white confirmation pop-up box is overlaid on the right side of the screen, containing the text: 'All criteria have been met. Please click OK to continue.' The 'OK' button in this box is circled in red.

On the next screen, click “Enroll” and then click “OK” in the confirmation pop-up box of the following screen. (**Figure 10**).



**Figure 10.**



This will confirm the request to randomize the participant.

Once a participant has been successfully randomized, you will see the Randomization System Result message (**Figure 11**). A notification of randomization will also be sent via e-mail.

**Figure 11.** FSTRF Randomization Notice (Sample)

# HPTN Subject Randomization System Result:

```
*****
SES (rando 3.46.1.0)
Copyright 2002 FSTRF

PRS Date & Time: [12 February 2015 10:44:58 (GMT-05:00) US Eastern Time]

Enrolling as: [kassab.garrick]

Inst.: [TEST] Study: [074] Step: [1]

(M000) *** PATIENT SUCCESSFULLY ENROLLED ***

Intervention ————— Intervention/Control

PTID: [292929290]

Stratum string: [2] Balancing: [none]
*****
```

Randomization  
Confirmation Notice  
and  
Intervention/Control

## Eligibility Questions and Answers:

Q0001 A  
Protocol HPTN 074 ————— Protocol number and title

Integrated treatment and prevention for people who inject drugs: A vanguard study for a network-based randomized HIV prevention trial comparing an integrated intervention including supported antiretroviral therapy to the standard of care

Eligibility Checklist Date: February 11, 2015|

Q0002 N  
Enter the participant's Patient Number.|

Your answer is: 292929290, ————— Participant ID

Q0003 C  
Select your site.|

1. Jakarta, Indonesia [END]  
2. Kiev, Ukraine [END]  
3. Thai Nguyen, Vietnam [END]  
Your answer is: Kiev, Ukraine ————— Site confirmation

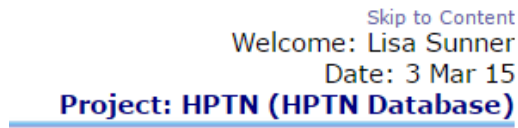
## Additional Information:

Comments:

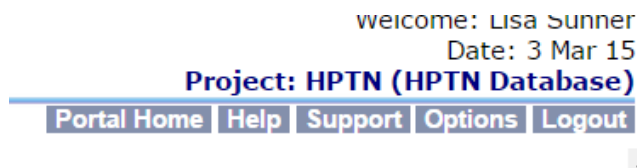
## 10.4 Log Out of FSTRF

To log out of the FSTRF system, click on “skip to content” in the upper right corner of the interface (see **figure 12**). This will reveal a menu bar with a logout option (see **figure 13**).

**Figure 12.** Signing out of FSTRF

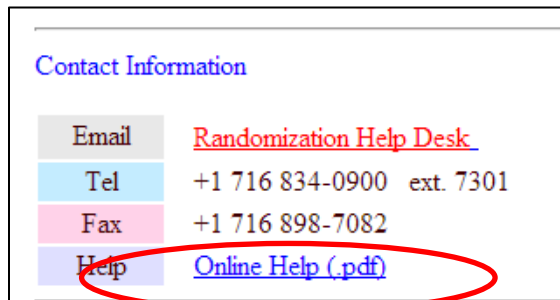


**Figure 13.** Signing out of FSTRF- Logout



## 10.5 Randomization Technical and Operational Support

If you encounter technical problems in accessing, or completing a randomization on, the FSTRF system, contact FSTRF via the contact information provided at the bottom of the portal webpage. Also note the “Online Help”



For operational issues, contact the HPTN 074 SCHARP PM.