

# Section 6. Web Randomization

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This section provides information on the process for randomization to study group for MTN-027 study participants using the Frontier Science & Technology Research Foundation (FSTRF) randomization system.

## 6.1 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:

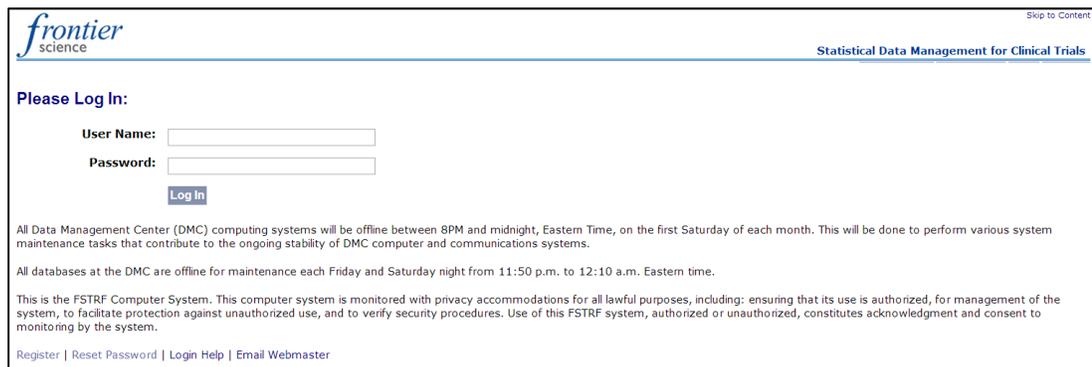
- request randomization using the MTN-027 Frontier Science & Technology Research Foundation (FSTRF) Randomization system
- receive and print randomization confirmation notice

## 6.2 Requesting FSRTF User Accounts

Staff must have FSTRF user account in order to access the system and randomize participants. Follow the below steps in order to create an account.

- Go to the FSTRF Portal:  
<https://www.fstrf.org/apps/cfm/apps/common/Portal/index.cfm>
- Click on the link for “Register”

**Figure 1.** Log in page of the FSTRF Randomization System



- Enter your information (e.g. first name, last name, institution, e-mail address)
- Create a password
  - **NOTE:** This is the password you will use to access the system moving forward once an account has been created.

- 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”.
- Click “Next”
- Choose the project “MTN” from the drop down menu and click “Other- Non-Laboratory Staff” for your position from the menu. In the comments, please enter “MTN-027” and your site name.
- 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 for accuracy and click “Submit”

**NOTE:** If you or your staff member already has a FSTRF account, for example, due to participation in another clinical trial, you must still request an account via the FSTRF Portal in order to randomize for MTN studies. Use the same e-mail and password of the existing account to request the MTN account.

### 6.3 Requesting Participant Randomization Using the FSRTF System

CRS staff will request randomization for a participant via the MTN-027 FSTRF web-based randomization system once the participant has met all eligibility requirements at the participant’s Enrollment Visit (Visit 2.0).

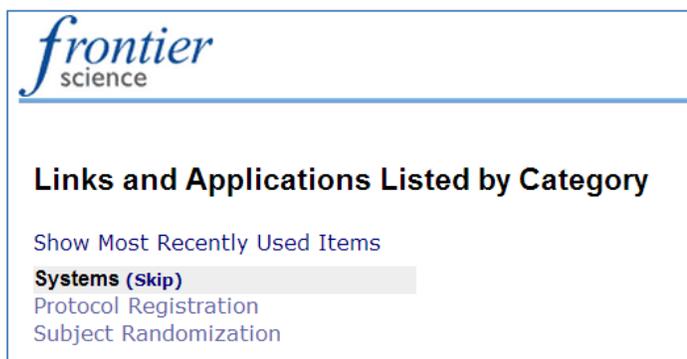
To request randomization for a participant:

1. Log onto the FSTRF system at [www.fstrf.org/Portal](http://www.fstrf.org/Portal) (see Figure 1) and log in using your FSTRF Randomization System username and password

**NOTE:** You must request a FSTRF user account – see above section 6.2

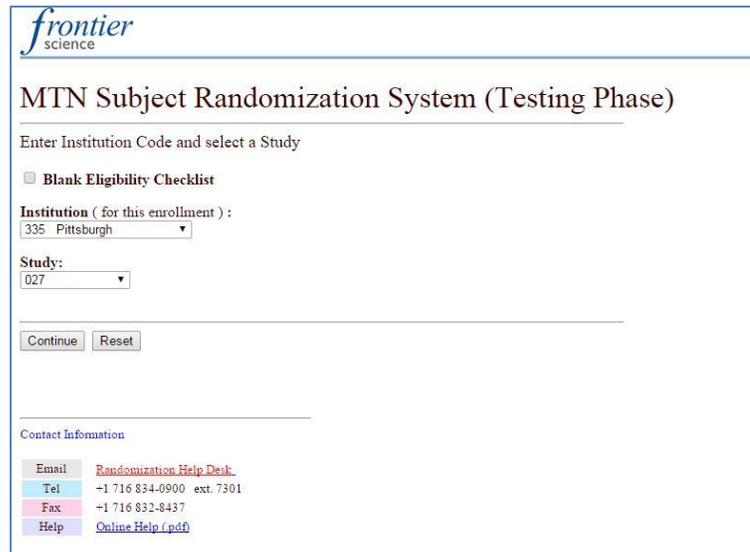
2. Once logged on, you will arrive at the welcome page (see Figure 2). From the welcome screen, click on “Subject Randomization”

**Figure 2.** Links and Applications Listed by Category Page of the FSTRF Randomization System



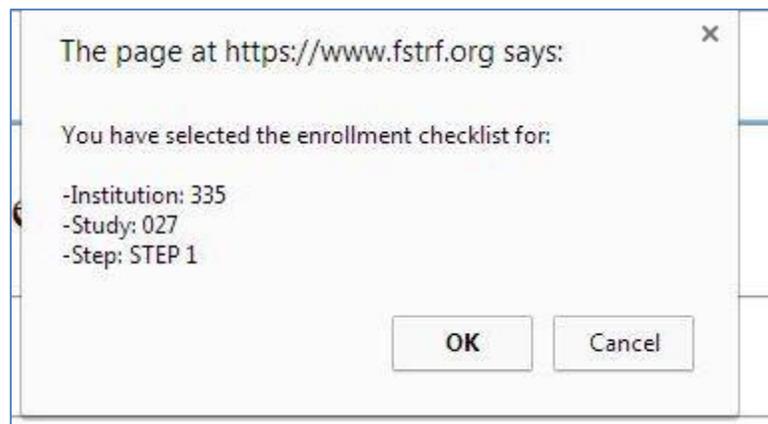
3. From the Randomization Screen, use the drop down menus provided to select your institution and study, then click “Continue” (see Figure 3a). You can disregard (e.g., leave blank) the check box for “Blank Eligibility Checklist”, since it does not apply to MTN-027. Click “OK” in the confirmation pop-up box (see Figure 3b).

**Figure 3a.** FSTRF MTN Subject Randomization System Part 1



The screenshot shows a web form titled "frontier science MTN Subject Randomization System (Testing Phase)". The form includes a header with the "frontier science" logo. Below the header, the text "Enter Institution Code and select a Study" is displayed. There is a checkbox labeled "Blank Eligibility Checklist" which is unchecked. Below this, the "Institution (for this enrollment) :" field is set to "335 Pittsburgh" and the "Study:" field is set to "027". At the bottom of the form, there are "Continue" and "Reset" buttons. A "Contact Information" section is located at the bottom of the page, listing contact details for Email, Tel, Fax, and Help.

**Figure 3b.** FSTRF MTN Subject Randomization System Part 1 Pop-up Box



The screenshot shows a confirmation pop-up box with a close button (X) in the top right corner. The text inside the box reads: "The page at https://www.fstrf.org says: You have selected the enrollment checklist for: -Institution: 335 -Study: 027 -Step: STEP 1". At the bottom of the box, there are "OK" and "Cancel" buttons.

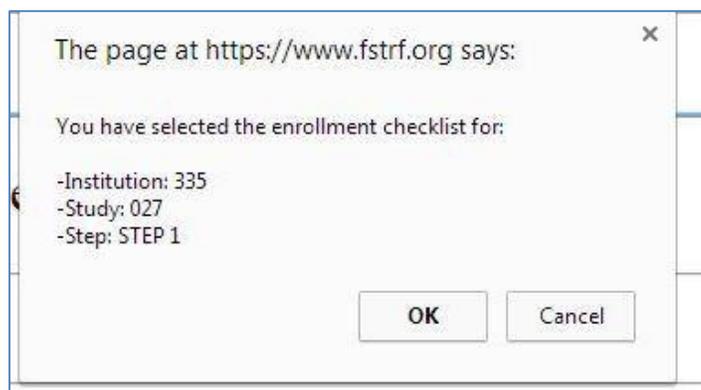
4. The next page is pre-filled so you do not need to edit or complete anything on this page. Click “Continue” (Figure 4a). Click “OK” in the confirmation pop-up box (see Figure 4b).

**Figure 4a.** FSTRF MTN Subject Randomization System Part 2

The screenshot shows the 'frontier science' logo at the top left. Below it is the title 'MTN Subject Randomization System (Testing Phase)'. The interface displays 'Institution: 335' and 'Protocol: 027'. A section titled 'Please select a step:' contains a radio button selected next to 'STEP 1'. Below this are 'Continue' and 'Reset' buttons. At the bottom, there is a 'Contact Information' section with a table of contact details:

Contact Information	
Email	<a href="#">Randomization Help Desk</a>
Tel	+1 716 834-0900 ext. 7301
Fax	+1 716 832-8437
Help	<a href="#">Online Help (.pdf)</a>

**Figure 4b.** FSTRF MTN Subject Randomization System part 2. Pop-up Box



5. On the next screen, select the box for “Click here to continue!” Enter the participant’s Participant ID Number (e.g. PTID), without dashes, in the space provided and hit the “Enter” key on your keyboard. You must enter a valid PTID to proceed (See Figure 5a). Click “OK” in the confirmation pop-up box (figure 5b).

**Figure 5a.** FSTRF MTN Subject Randomization System Randomization Page

frontier  
science

**MTN Subject Randomization System**

Institution: 335  
Protocol: 027  
Step 1:

Eligibility Checklist:

Q0001  
Protocol MTN 027  
A Phase 1 Safety and Pharmacokinetics Study of MK-2048/Vicriviroc (MK-4176)/MK-2048A Intravaginal Rings  
Eligibility Checklist Date: February 27, 2015  
 Click here to continue!

Q0002  
Enter the participant's Patient Number.

Q0003  
Select your site.  
 Alabama Microbicide [Eligible]  
 Pittsburgh [Eligible]

Additional Information:  
Comments:

**Figure 5b.** FSTRF MTN Subject Enrollment System Randomization Page Pop-up Box

The page at https://www.fstrf.org says:

All criteria have been met. Please click OK to continue.

6. Click “Enroll” at the bottom of the page and “OK” in the confirmation pop-up box (See Figures 6a and 6b). This will confirm the request to randomize the participant.

**Figure 6a.** FSTRF MTN Subject Enrollment System Randomization Page

frontier  
science

Q0002  
Enter the participant's Patient Number.  
777777774

Q0003  
Select your site.  
 Alabama Microbicide [Eligible]  
 Pittsburgh [Eligible]

Additional Information:  
Comments:

Enroll | Reset

Download Checklist (No answers will be saved)

[Calculate Time Between Dates](#)

[Return To Main Menu](#)

**Figure 6b.** FSTRF MTN Subject Enrollment System Randomization Page

frontier  
science

The page at https://www.fstrf.org says:  
Enroll?  
OK | Cancel

Q0002  
Enter the participant's Patient Number.  
777777774

Q0003  
Select your site.  
 Alabama Microbicide [Eligible]  
 Pittsburgh [Eligible]

Additional Information:  
Comments:

Enroll | Reset

Download Checklist (No answers will be saved)

[Calculate Time Between Dates](#)

[Return To Main Menu](#)

Contact Information  
Email: [Randomization Help Desk](#)  
Tel: +1 716 834-0900 ext. 7301  
Fax: +1 716 832-8437  
Help: [Online Help \(.pdf\)](#)

## 6.4 Randomization Confirmation Notices

When a participant has been successfully randomized, you will see the following web message (Figure 7). A notification of randomization will also be sent via e-mail to:

- CRS Clinic Coordinator and CRS Pharmacist aliases
- Randomization confirmation notices will include date of randomization, CRS clinic staff member name, DataFax site number (Inst.), study number, PTID, site location, and the randomization number (Code).
- The Eligibility Checklist Date on the confirmation notice refers to the date that this item was last modified by FSTRF when configuring the web randomization interface. This date does not signify the date that each participant’s eligibility for the study was confirmed. Rather, the date provided on the MTN-027 Eligibility Checklist word document should be used as the date that each participant’s eligibility was confirmed.
- Once the randomization confirmation notice is received, CRF staff must complete the following steps:
  1. Write the randomization number (code) on the MTN-027 prescription before sending to the pharmacy.

**NOTE:** The randomization number (Code) provided by FSTRF will be displayed as a 4-digit number with a leading 0, while the randomization number provided by SCHARP will be a 3-digit code. When transcribing the randomization number onto the MTN-027 Prescription and Enrollment (ENR-1) CRF, the leading “0” should not be transcribed. For example, if the FSTRF randomization code provided is “0201”, drop the leading 0 and enter “201” as the randomization number on the MTN027 Prescription and on the Enrollment CRF.

**NOTE:** The randomization time within this confirmation email is provided in Eastern Standard Time (EST). When completing item 5 on the Enrollment CRF, convert the time of randomization according to each site’s local standard time zone, as needed.

2. Print two copies of the randomization confirmation email – one to keep in the participant’s study binder and the second to send with the study prescription to the pharmacy.
3. All randomization notices should be kept in a secure location
4. Please refer to SSP Section 7 for additional guidance on study product dispensation considerations for clinic staff.

**Figure 7. FSTRF MTN Randomization Notice**

**frontier**  
science

## MTN Subject Randomization System (Testing Phase) Result:

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SES (rando 3.46.1.0)  
Copyright 2002 FSTRF

PRS Date & Time: [04 March 2015 12:18:04 (GMT-05:00) US Eastern Time]

Enrolling as: [berthiaume.jennifer]

Inst.: [335] Study: [027] Step: [1]

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

PTID: [111111111] Code: [0201]

Stratum string: [2] Balancing: [none]

\*\*\*\*\*

Eligibility Questions and Answers:

Q0001 A  
Protocol MTN 027

A Phase 1 Safety and Pharmacokinetics Study of MK-2048/Vicriviroc  
(MK-4176)/MK-2048A Intravaginal Rings

Eligibility Checklist Date: February 27, 2015

Q0002 N  
Enter the participant's Patient Number. |

Your answer is: 111111111,

Q0003 C  
Select your site. |

1. Alabama Microbicide [END]  
2. Pittsburgh [END]  
Your answer is: PITTSBURGH

## 6.5 Randomization Codes

Randomization confirmation notices will include 4-digit randomization number (codes). The 3-digit randomization number (with the leading “0” deleted) will be used by the pharmacist to identify which study product sub-lot code should be dispensed. Randomization numbers (codes) will appear on confirmation notices that are sent to both CRS Pharmacists and Clinic Coordinators.

## 6.6 Logging Out

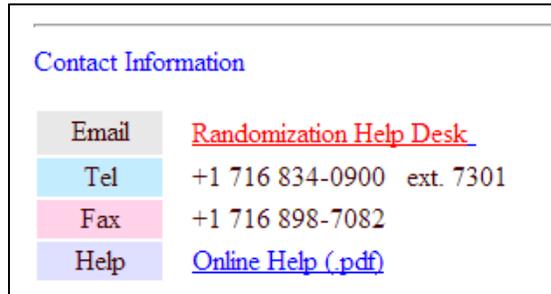
To log out of the FSTRF system, click on “skip to content” in the upper right corner of the screen. This will reveal a menu bar with a logout option (see Figure 8).

**Figure 8.** Signing out of FSTRF



## 6.7 Randomization Technical Support

In circumstances where CRS staff need to randomize a participant, but are unable to access the FSTRF system due to technical problems, have any issues with the FSTRF randomization, or do not receive the randomization confirmation email, the CRS staff should contact FSTRF via the contact information provided at the bottom of the portal.



For operational issues, contact the MTN-027 SCHARP Project Manager and the Statistical Research Associate.