EPoS

Randomisation Guidelines

Version 1

24 March 2015

Randomisation

1.0. Before you start

The Subject Enrollment System is hosted on the Frontier Science (USA) website – www.fstrf.org/Portal. In order to enrol patients, individual users must have registered with the system (see instructions below) and have a website password as well as randomisation authorisation. There may be several users at each centre.

PLEASE BE SURE TO REGISTER WITH THE SYSTEM WELL AHEAD OF THE TIME WHEN YOU WANT TO ENTER THE FIRST PATIENT AS THE VERIFICATION PROCESS WILL TAKE UP TO 3 BUSINESS DAYS.

Registration
Please follow these steps to register for use of the website and for screening registration and randomisation:

Connect to the Frontier Science home page at www.fstrf.org

Select **New User Registration**

The registration form will appear as in Figure 1.0 and must be completed for every user of the system

New User Registration - General Information

Please note that all requests will be verified by FSTRF User Support before processing.

* Required Field

Registrant Information

* First Name:	
* Last Name:	
* Institution Name:	
* Phone Number:	ext.
* Email Address:	
Address 1:	
Address 2:	

Figure 1.0 – Frontier Science web password registration form

Ensure you select **EPOS** option in the project section. Ensure **Site Staff** in the positions field is ticked (**Figure 1.1**). Click **Next** to continue.

New User Registration - Project Selection

Please choose a project. If you need access to multiple projects, each project must be added one at a time. Project Selection screen.

* Required Field

Registrant Name: Kate Burrell

* Project: EPOS

* Position: ☑ Site Staff

Comments:

[< Back] [Reset] [Next >]

Figure 1.1 – Appropriate projects or affiliations

In the **Randomisation Access** section of the form enter your Institution number and select access to enroll patients (**Figure 1.2**).

Randomization Access

* Institution number: [   ]

Note: you may enter multiple Institution number values separated by commas.

☑ Access to enroll patients (?)

[< Back] [Reset] [Next >]

Figure 1.2 – Randomisation Access

You can move to the next screen by clicking **Next** or move back a screen by clicking **Back**. If you need to clear all the information and re-start from the beginning click **Reset.**

Once you have completed all the steps in the registration form you will be asked to review all the information that has been entered. Any errors can be corrected at this point. Once the information has been reviewed click **Submit**. A screen will appear confirming your request has been received and must be verified before it can be processed (**Figure 1.3**).

New User Registration - Request Form Submitted

Your request has been received and must be verified before it can be processed. Once verification is complete, your request will be processed within three business days. You will receive an email with login instructions when the request has been completed. If you have any questions, please contact Frontier Science User Support.

The information you submitted and a reference number appear below. Please print this page for your records.

Reference #: 4

Registrant Information

Registrant Name: Ann Lange
Institution: Frontier Science Scotland
Phone: +441540651000 ext.
Email: ann.lange@frontier-science.co.uk
Address 1:
Address 2:

Figure 1.3 – Request Form Submitted

You will receive two emails from User Support: the first email will acknowledge that you have submitted a request for a web password and that your account will be created within 3 business days; the second email will be sent to you once your account has been created and will detail your username and password. Keep your username and password safe. Please note: passwords must be changed every 90 days.

Before randomising a patient:

- You must have randomisation authorisation. If you do not have randomisation authorisation, see Section 1 above for instructions on how to register for website access and randomisation authorisation.
- Your site **must** be approved and activated for the study you select!
- The study you select must still be open to accrual.

1.1 Common Terms Used in Enrollment

Centre Number/ Site Code	The Centre Number/Site Code uniquely identifies each institution participating in the EPoS trial. The Randomisation System refers to this as the Site Code**.**
Subject Number/ Patient ID/ E-Code	When a patient is randomised, the system assigns a Subject Number/Patient ID. The Subject Numbers are composed of six digits, and are assigned sequentially for patients entered on the trial. The first patient will be 100001, the second 100002 etc. Alternative terms are Patient ID and Patient Identifier.
Output Page	The output page is displayed and emailed to the user after every attempt to enroll a subject.

If the Randomisation is successful, the page will display the Subject Number, the EPoS trial, arm (group) allocation and the information entered by the user.

If Randomisation is unsuccessful, the output page will display an error message. The output pages should be retained in the site study records. Alternative terms are Results Page, Confirmation or Confirmation of Randomisation. |

1.2 Accessing and Running the Program

To access the Subject Enrollment System, use the following instructions:

Please ensure that java scripting is enabled.

Connect to the website at http://www.fstrf.org/Portal using Internet Explorer 8 or higher. A prompt asking for your username and password will appear. Enter your website username and password. If you do not have a website password, please see Section 1 above for instructions on how to register.

After entering the Subject Enrollment System, you will see the following page (**Figure 1.4**):

Frontier Science Registration and Randomisation System

Enter Institution Code and select a Study

☐ **Blank Eligibility Checklist**

Institution (for this enrollment) :
Please Select ▼

Study:
Please Select ▼

[Continue] [Reset]

Figure 1.4 - Subject Enrollment System main page

From here you may either obtain a blank eligibility checklist for the EPoS study or randomise a patient.

2.0 Using the Subject Enrollment System

2.1 Obtaining a Blank Eligibility Checklist

If you simply need to print or view a blank copy of the eligibility checklist for Randomisation, use the **Blank Eligibility Checklist** option. This option will bring up a copy of the randomisation checklist that can be printed or viewed, but not completed electronically if you select this option.

To obtain a blank randomisation checklist, use the following steps:
- Connect to the Subject Enrollment System using the instructions in Section 1.2 Accessing and Running the Program.
- On the Subject Enrollment System main page (**Figure 2.0**) click the checkbox next to **Blank Eligibility Checklist.**

Frontier Science Registration and Randomisation System

Enter Institution Code and select a Study

☑ **Blank Eligibility Checklist**

Institution (for this enrollment) :
Please Select ⌄

Study:
EPOS ⌄

Continue   Reset

Figure 2.0 Selecting a Blank Checklist

When selecting a **Blank Eligibility Checklist**, you are not required to select an **Institution**, so you may skip over this field.

In the **Study** field select **EPOS** from the drop-down menu.

Press the **Continue** button.

A window will pop up (**Figure 2.1**) to confirm that you would like a Blank Eligibility Checklist for the study you selected. If the correct study is displayed, press **OK** to move on to the next screen. If the displayed study is incorrect, press **Cancel** and make your changes.
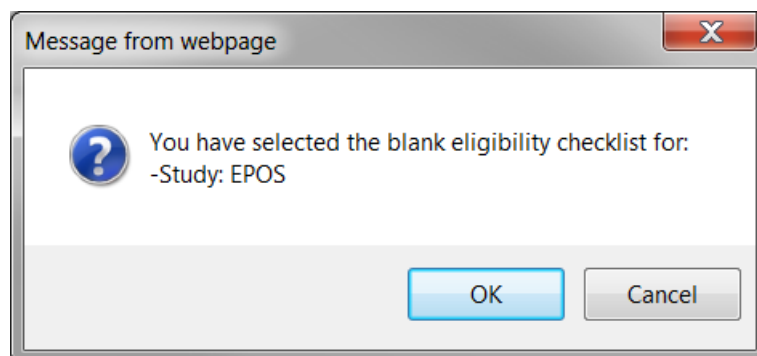
Message from webpage   X

You have selected the blank eligibility checklist for:
-Study: EPOS

OK   Cancel

Figure 2.1

The screen in **Figure 2.2** will appear. There is only one step for this study. Step 1 is the Randomisation step. Press the **Continue** button.

Frontier Science Registration and Randomisation System

Institution:
Protocol: EPOS

Please select a step:

◉ STEP 1 Randomisation

[Continue]   [Reset]

Figure 2.2 – The step selection page

You will see a confirmation screen – **Figure 2.3**

Message from webpage

You have selected the enrollment checklist for:

-Study: EPOS
-Step: STEP 1 Randomisation

[OK]   [Cancel]
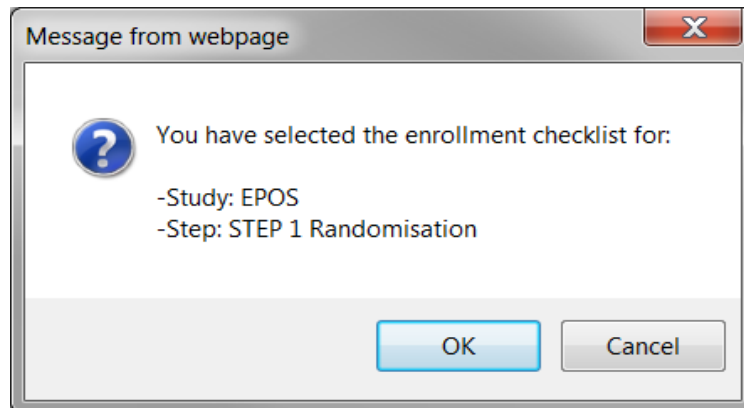
Figure 2.3

After confirming the study and step the Randomisation Checklist will appear (**Figure 2.4**). You may print the checklists or simply view them, but you will not be able to fill them in, nor submit it online.

Frontier Science Registration and Randomisation System

Institution:
Protocol: EPOS
Step 1:   Randomisation

Blank Eligibility Checklist:

Q0010

    Protocol EPoS

    Checklist Date: 10 March 2015

    ☐ Click here to continue!

Figure 2.4 – The first section of the blank eligibility checklist

To download a copy of the checklists and store them on your computer for future use, scroll to the end of the checklist and select **Download Blank Checklist** (**Figure 2.5**).

Additional Information:

Comments:

Signed: _____   Date: _____

Download Blank Checklist

Calculate Time Between Dates

Return To Main Menu

Figure 2.5 – Bottom of blank eligibility checklist

Follow the instructions to save the file on your computer. To return to the main page of the Subject Enrollment System, either click the **Back** button twice or click on the **Return To Main Menu** link at the bottom of the checklist (**Figure 2.5**).

2.2 Enrolling a Subject

Before accessing the randomisation system, it is recommended that you complete paper copies of Randomisation Eligibility checklist for the patient so that you can be sure that all the necessary information is available.

To enroll a subject to EPoS, connect to the Subject Enrollment System using the instructions in **Section 1.2** Accessing and Running the Program.

Frontier Science Registration and Randomisation System

Enter Institution Code and select a Study

☐ **Blank Eligibility Checklist**

Institution (for this enrollment) :
NN-001-NN   Test Institution NN Oslo ∨

Study:
EPOS   ∨

[Continue] [Reset]

Figure 2.6 Subject enrollment main page

When enrolling patients, make sure that the checkbox next to Blank Eligibility Checklist is **not** checked (**Figure 2.6**).

In the **Institution** field, select the **centre number** for your site/institution from the drop-down menu.

In the **Study** field select EPOS from the drop-down menu.

Press the **Continue** button.

A window will pop up and confirm your institution and the study selected (**Figure 2.7**). If the institution and study are correct, press **OK** to move to on to the next screen. If you need to change anything, press **Cancel** and make your changes.
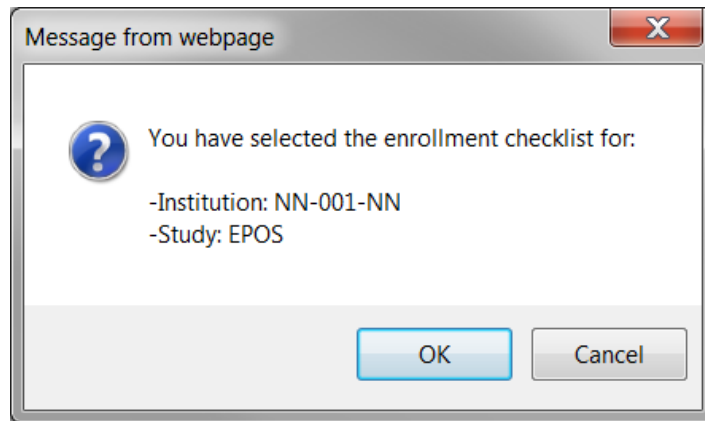
Figure 2.7

The screen in **Figure 2.8** will appear. There is only one step for this study. Step 1 is the Randomisation step.

Press the **Continue** button.

Figure 2.8 – The step selection page

A window will pop up to confirm the selected institution, study and step (**Figure 2.9**). If the information is correct, press **OK** to move to on to the next screen. If you need to change anything, press **Cancel** and make your changes.
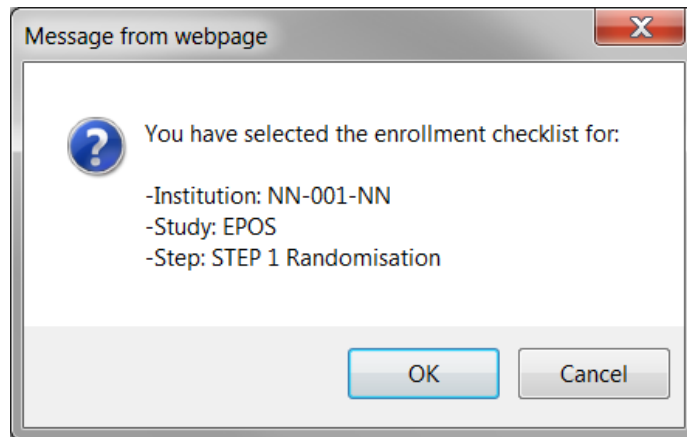
Figure 2.9

After confirming the institution, study, and step you will move on to the Randomisation checklist for the study, as shown in **Figure 2.10**.

Frontier Science Registration and Randomisation System

Institution: NN-001-NN
Protocol: EPOS
Step 1: Randomisation

Eligibility Checklist:

Q0010

Protocol EPoS

Checklist Date: 10 March 2015

☐ Click here to continue!

Figure 2.10 – The eligibility checklist

Note: Before completing the checklist, check the institution and protocol information at the top of the page to ensure it is correct.

If you are using a paper copy of the checklist as a pre-enrollment check, ensure the Eligibility Checklist Date on the paper copy is the same as the most recent version on the system. This will ensure you are not using an old version of the checklist.

To access the randomisation checklist click in the checkbox labelled **Click here to continue.**

To complete the checklist follow the guidelines in section **3.0 Completing the Eligibility Checklist.**

Once you have answered all required questions, you will be informed that all criteria have been met. Click **OK** (**Figure 2.11**).
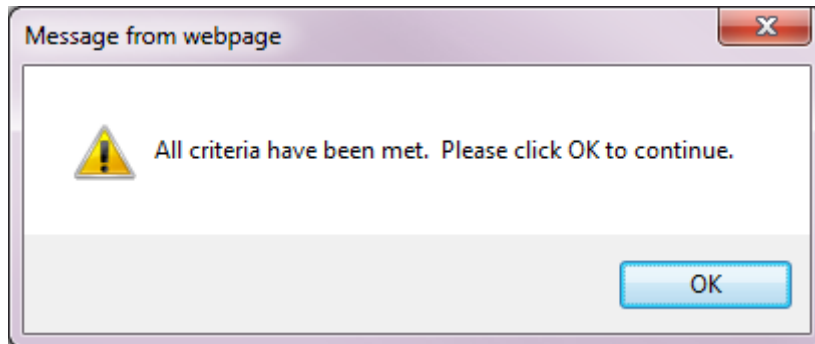

<div align="center">**Figure 2.11**</div>

The **Additional Information** section of the checklist will now be displayed as shown in **Figure 2.12**.

<div align="center">**Figure 2.12 – The Additional Information section of the checklist**</div>

Enter any relevant additional information in the **Comments** field.

To enroll the subject, click on the **Enroll** button and then click **OK** when prompted if you'd like to enroll (**Figure 2.13**).
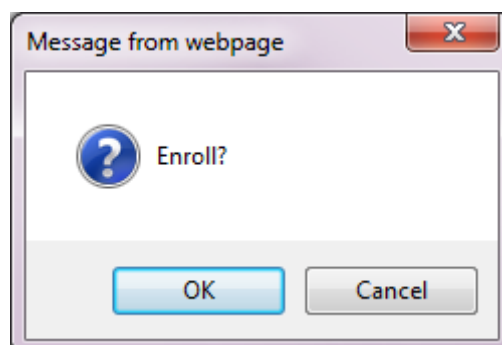

<div align="center">**Figure 2.13**</div>

At this point the Subject Enrollment System Result page will be displayed, with either a **successful** or **unsuccessful** message (**Section 2.2.1 and 2.2.2**).

2.2.1 Successful Enrollment

If the enrollment to the randomisation step was successful, the result page will look similar to the screen shown in **Figure 2.14.**

Frontier Science Registration and Randomisation System Result:

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

PRS Date & Time: [19 March 2015 12:01:16 (GMT-04:00) US Eastern Time]

Enrolling as: [burrell.kate]

Site Number: [NN-001-NN]  Study: [EPOS]  Step: [1]

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

PRESCRIPTION:
  - EPoS II  Group 1:  3 year and 5 year and 10 year surveillance
    colonoscopy

Subject Number: [100047]   Tracking Number: [1074]

Stratum string: [222]  Balancing: [yes]  Balancing ID key: [NN-001-NN]  IBG key: [02]
******************************************************************************
```

Figure 2.14

The following information will be displayed:

- The institution (NN-001-NN in the example), study (EPOS), and step (Step 1) to which the subject has been enrolled
- The Subject Number (100047)
- The EPoS study allocation
- The arm (group 1 or 2) within the allocated study
- The completed randomisation eligibility checklist, with all questions and answers.

The result page will also be sent in email as an HTML attachment to the user who enrolled the subject. If this causes a problem at your site or if you need a different format, please email epos.rando@frontier-science.co.uk

2.2.2 Unsuccessful Enrollment

If enrollment was unsuccessful, the result page will display an error message indicating the problem or asking you to contact the Randomisation Helpdesk (see **Figure 2.15** below)

Possible errors include:
- A different site code has been entered from that selected in the drop down menu
- The user is not approved to enroll subjects
- Patient is ineligible
- Study is not open
- Patient is already enrolled to the study
- An accrual limit has been reached and the study is not open to any new patients

Frontier Science Registration and Randomisation System Result:

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

PRS Date & Time: [23 February 2015 10:47:40 (GMT-05:00) US Eastern Time]

Enrolling as: [burrell.kate]

Site Number: [NN-001-NN]   Study: [EPOS]   Step: [1]


*** THE SITE CODE SELECTED FROM THE DROP-DOWN MENU DOES NOT MATCH THE SITE CODE ENTERED IN Q0040 ***

(M101) SQIRL LIMIT HAS BEEN REACHED [sqirl]


(M001) *** PATIENT RECORD REJECTED -- PATIENT NOT ENROLLED ***

Subject Number: [** NOT ASSIGNED **]   Tracking Number: [** NOT ASSIGNED **]

Stratum string: [122]   Balancing: [none]
********************************************************************************
```

Figure 2.15 – Unsuccessful Enrollment

If an error message is received within the Results page, the subject will not have been enrolled to the study. The error message and completed eligibility checklist will be emailed to you as an HTML attachment and you should contact the EPoS helpdesk at epos.rando@frontier-science.co.uk for advice.

3.0 Completing the Eligibility Checklist

3.1 Errors

If you enter a date or other value that is out of range or invalid, the Subject Enrollment System will display an error message and then take you back to the field containing the error. You will not be able to proceed until a valid value has been entered. Sample error messages are shown in **Figure 3.0**.
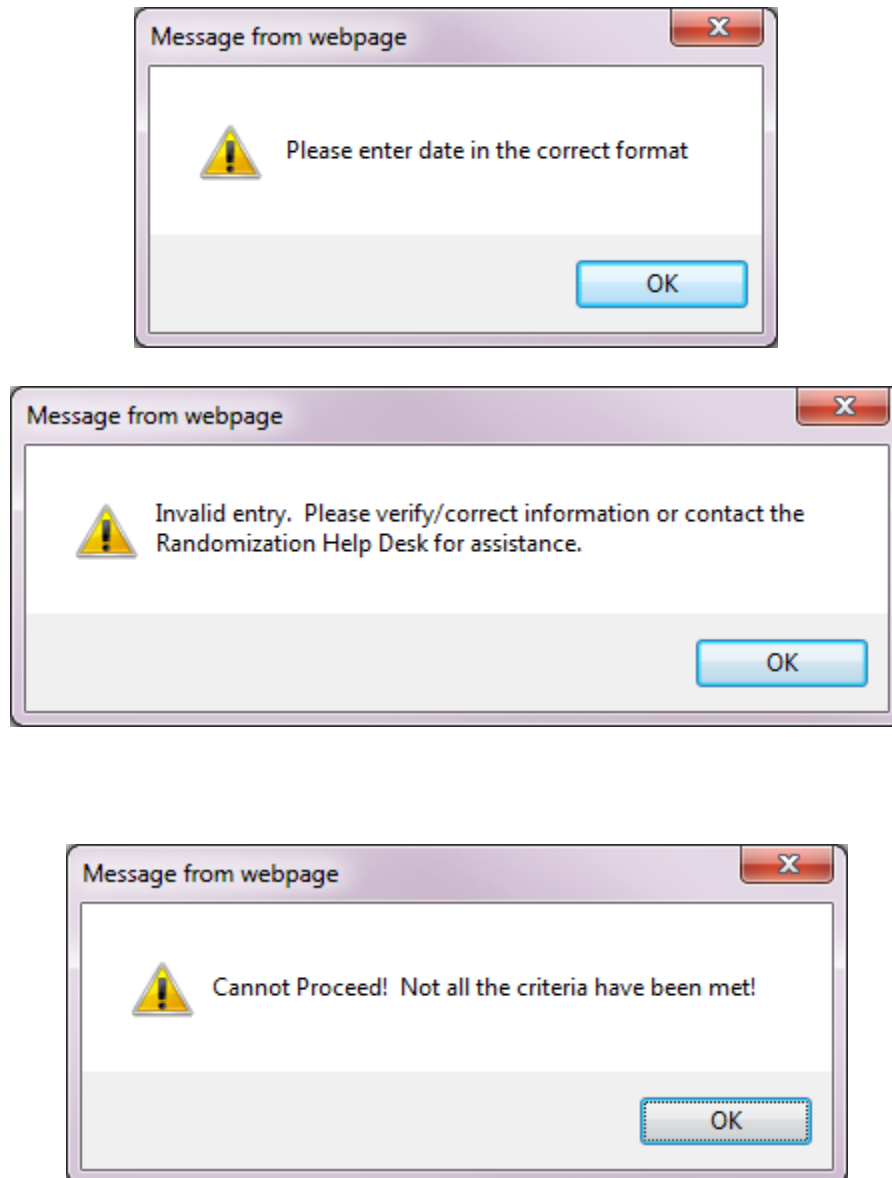

Figure 3.0 – Error Messages

Note: For this trial, all dates in the checklist are in the format dd/mmm/yyyy e.g 12/feb/2007

3.2 Moving around the Checklist

Use either the **Mouse** or the **Tab** key to scroll down to the next question.

Use either the **Mouse** or press the **Shift** and **Tab** keys simultaneously to scroll up to the previous field.

3.3 Completing the Checklist

Capitalisation does not matter.

If you change an answer that was previously entered, you will have to re-enter all the questions following the question that was changed.

Do **NOT** press the Enter/Return key at any time during completion of eligibility information, as this will attempt to process the randomisation/enrollment and will show the following error message
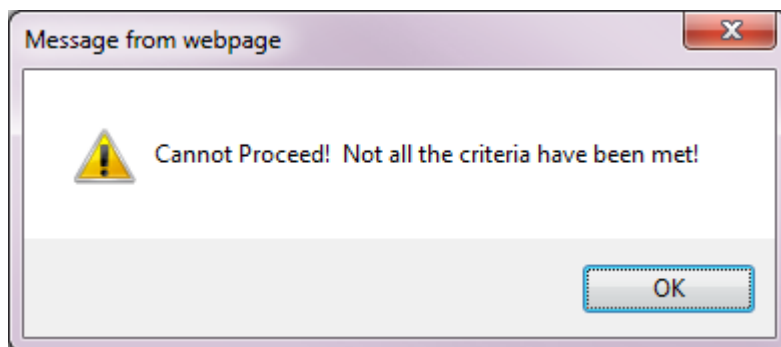
3.4 Entering Dates

Dates must be entered in the format indicated on the checklist, for example: dd/mmm/yyyy. If '/' is indicated in the format, then it must be included e.g. 12/jan/2007

The abbreviation **mmm** indicates that the first three letters of the month must be entered, using the following abbreviations:

Jan   January.
Feb   February
Mar   March
Apr   April
May   May
Jun   June
Jul   July
Aug   August
Sep   September

Oct   October
Nov   November
Dec   December

The first letter does not need to be capitalised.

3.5 Other Tips

In order to select a specific section of a drop-down menu, for example when selecting a **study** or **institution** on the main page, click on the **menu** and type the first letter or number of the section you wish to select. For example, to select the protocol, press **E** to select all studies beginning with E scroll until you find **EPOS**. The up and down arrow keys can also be used to scroll through the list.

The Subject Enrollment System is a web-based program, which means the **Back** button can be used to move around the program if necessary. For example, if you select the wrong study and move on to the step selection page or the eligibility checklist, you may still use the **Back** button to move back a page and select a different step.

4.0 Exiting the Program

To exit the Subject Enrollment System at any time click **Logout** in the top right hand corner and then you may close your browser window or go to a different web page. **You will lose any information on your screen at that time**. If you have not finished the checklist and you would like to come back to it at a later time, you can simply leave the web browser window open and return to it when you wish.

5.0 Contacts

All questions should be directed to the EPoS Randomisation Helpdesk by emailing the address below.

Helpdesk email: epos.rando@frontier-science.co.uk

Problems with Internet Access

If you have a question, or cannot access the internet (either temporarily or permanently) and wish to screen or randomise a patient, please email the user group epos.rando@frontier-science.co.uk. Include your name, your telephone and fax numbers and the nature of the question (e.g. 'I have a question about the eligibility criteria' or 'I would like to randomise a subject, but I cannot get on the internet'). If you want to screen or randomise a subject, you will be asked to fax or scan a completed paper checklist to the hub, so please be sure that this is printed out and completed by hand.

If you have no email access or you need to speak to someone about the randomisation system, call the number below.

Opening hours and telephone numbers

Scotland – 7.30am-to 5.30PM

Telephone   +44 1540 651000

Facsimile   +44 1540 651007

 or email epos.rando@frontier-science.co.uk