



**University of  
Nottingham**

UK | CHINA | MALAYSIA



**FEED1**


FLUIDS EXCLUSIVELY  
ENTERAL FROM DAY 1

# INSTRUCTIONS FOR USE OF THE SCREENING, ENROLMENT AND RANDOMISATION DATABASE

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## 1. LOGGING ONTO THE ENROLMENT AND RANDOMISATION DATABASE

Enter the below link to the FEED<sub>1</sub> trial enrolment and randomisation system into your internet browser. Please note, the database is designed to run using Internet Explorer .

<https://ctu2.nottingham.ac.uk/1704/>

You will be navigated to the login screen. Here you should enter the username and password provided to you by the FEED<sub>1</sub> trial management team. On your first login you will be prompted to change your password to something of your choice.

## Feed-1 trial randomisation system (CTU. 1704), login

User Name:

Password:

login

[Forgot password?](#)

Once you have entered your username and password you will be presented with a research site dropdown list. Here you will be able to select either your own research site or 'Site 99: Dummy Investigator'. You are encouraged to use Site 99 to familiarise yourself with the database and also to train new members of the research team. Please note, your own research site will only be visible after your site has been given the green light for recruitment to commence.

Once you have selected a site you will gain access to the main menu.

## 2. PARTICIPANT ENROLMENT

### 2.1. MOTHER ENROLMENT

Select 'Enrol a new mother'. This will bring up the new mother enrolment page where you enter the mother's NHS number. Then press submit to proceed to the enrolment form.

The screenshot shows the main menu of the Feed-1 trial randomisation system. At the top left is the Nottingham Clinical Trials Unit logo. At the top right are 'Log off' and 'Change password' buttons. Below the header, the user is logged in as 'Selected - Dummy investigator (Dummy Hospital 99)' with 'Mother : not selected'. The main menu is titled 'Feed-1 trial randomisation system (CTU. 1704), main menu' and includes the instruction 'Click on desired function's link'. The menu items are: 'Select a different site', 'User administration' (circled in blue), '5 week post EDD infant well being status check', 'Monthly Screening Entry - 1 month outstanding', 'Select existing mother', and 'Enrol a new mother' (circled in red).

## New mother enrolment (NHS number)

Mother's NHS Number	<input type="text"/>	<input type="text"/>	<input type="text"/>
	(999)	(999)	(9999)
Re-enter NHS Number	<input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="button" value="submit"/>		

On the enrolment page, use the drop down menus to state whether the woman has delivered, the type of consent, date of consent, expected date of delivery, mothers initials, mother's date of birth, whether it is a multiple pregnancy and the number of infants. When this page is complete, click the submit button.

**Please note: if 'oral assent' is indicated in this enrolment form, when written informed consent is obtained post randomisation, this must be entered onto the randomisation system. (Please refer to section 6.2 of this guide titled 'RECORDING CONSENT STATUS (POST RANDOMISATION)').**

## Mother

Please ensure mother's **EDD of 30-Oct-2019** is correct before proceeding  
With this EDD, infant(s) need to be born between these dates to be eligible

- › 21-Aug-2019 (30 weeks + 0 days) and
- › 10-Sep-2019 (32 weeks + 6 days)

Submitted data accepted

Enrolment	
Ref. No.	99069
NHS Number	451 876 9945
Has the woman delivered ?	yes ▾
Please specify the type of consent given	written informed consent ▾
Date of written consent/oral ascent (dd-mmm-yyyy)	09 ▾ Sep ▾ 2019 ▾
Expected date of delivery (EDD)? (dd-mmm-yyyy)	30 ▾ Oct ▾ 2019 ▾
Mothers Initials	P-O
Mother's Date of Birth (dd-mmm-yyyy)	09 ▾ Mar ▾ 1995 ▾
Is this a multiple pregnancy?	no ▾
	If yes, how many infants: ▾

If details are correct go to the next form to enter the infants eligibility details.

[next form](#)

### 3. INFANT ENROLMENT

Once the mother enrolment details have been submitted, the infant enrolment page will need to be completed.

#### 3.1. SINGLE BIRTH

To include the infant in the trial, click 'include in'. This will bring up a form to check the eligibility of the infant.

If you wish to exclude the infant from the trial, click 'exclude'.

#### Infant enrolment

Please ensure mother's **EDD of 30-Oct-2019** is correct before proceeding  
With this EDD, infant(s) need to be born between these dates to be eligible

- 21-Aug-2019 (30 weeks + 0 days) and
- 10-Sep-2019 (32 weeks + 6 days)

Single pregnancy specified on mother enrolment.


- If this is correct please include/exclude the infant(s) below
- Otherwise click previous to correct mothers enrolment details

[prev form](#)

	Infant	Infant I.D.	Included in trial?	Action
▶	Infant number 1			<a href="#">include in / or exclude from trial</a>

[prev form](#)

If an infant is selected to be included in the trial, this will be shown by a green tick.

	Infant (click link to select infant)	Infant I.D.	Included in trial?	Action
▶	Infant number 1	99072-1		<a href="#">exclude from trial</a>

Complete the eligibility form for the infant by clicking on Infant number 1:

<b>Infant</b> (click link to select infant)	
▶	<b>Infant number 1</b>

Using the drop down arrows, enter the infant's date of birth; time of birth; gestational age in weeks and days at birth; whether the infant has reversed end diastolic flow on Maternal Umbilical Artery Doppler; whether the infant had any IV fluids; whether the infant has a severe congenital anomaly and the infant's sex. Type the infant's birth weight into the box provided. All fields must be entered to submit data for randomisation.

### Infant enrolment

1 infant included in the trial.

- ▶ If this is correct please enter details for this infant to check eligibility. Please click on the submit button to save the data you have entered.
- ▶ Otherwise, include/exclude infants(s)

Infant	Infant I.D.	Included in trial?	Action
▶ <b>Infant number 1</b>	<b>99069-1</b>		<a href="#">exclude from trial</a>

[prev form](#)

Infant number 1 (first born)	
Infant's date of birth (dd-mmm-yyyy)	<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <span style="font-size: small;">[today's date?]</span>
Infant's time of birth (hh:mm)	hh: <input type="text" value=""/> mm: <input type="text" value=""/>
What was the infant's gestational age in weeks and days at birth?	Weeks: <input type="text" value=""/>
	Days: <input type="text" value=""/>
Infant's birth weight (g)	<input type="text"/>
Does this infant have reversed end diastolic flow on Maternal Doppler?	<input type="text" value=""/>
Has the infant had any IV fluids?	<input type="text" value=""/>
Does this infant have a severe congenital anomaly?	<input type="text" value=""/>
What's the infant's sex?	<input type="text" value=""/>
Infant number 1 (first born)	

Please click on the submit button to save the data you have entered.

[prev form](#)

After you have submitted the eligibility data and the infant is confirmed to be eligible, a live countdown will show the 3-hour eligibility expiry time. The eligible infant must be randomised within 3 hours of birth otherwise they will no longer be eligible.

Infant	Infant I.D.	Included in trial?	Eligibility confirmation	3 hour eligibility expiry
 Infant number 1	99069-1			1h 42m 8s

[prev form](#) | [randomise](#)

To proceed to the Infant Randomisation page, click randomise.

### 3.2. MULTIPLE BIRTHS

On the infant enrolment page, the table shows you how many infants have been delivered. Select include or exclude for each infant.

#### Infant enrolment

Please ensure mother's **EDD of 30-Oct-2019** is correct before proceeding


With this EDD, infant(s) need to be born between these dates to be eligible

- 21-Aug-2019 (30 weeks + 0 days) and
- 10-Sep-2019 (32 weeks + 6 days)

Multiple pregnancy specified on mother enrolment (2 babies).

- If this is correct please include/exclude the infant(s) below
- Otherwise click previous to correct mothers enrolment details

[prev form](#)

Infant (click link to select infant)	Infant I.D.	Included in trial?	Action
 Infant number 1			<a href="#">include</a> in / or <a href="#">exclude</a> from trial
Infant number 2			<a href="#">include</a> in / or <a href="#">exclude</a> from trial

[prev form](#)



If an infant is selected to be included in the trial, this will be shown by a green tick.

An infant I.D will be assigned to each included infant. Number of infant by birth order is indicated by the number after the initial part of the ID (e.g. 99030-1; 99030-2 etc.).

Infant (click link to select infant)		Infant I.D.	Included in trial?	Action
▶	Infant number 1	99072-1	✓	<a href="#">exclude from trial</a>
	<a href="#">Infant number 2</a>	99072-2	✓	<a href="#">exclude from trial</a>

Complete the eligibility form for the first born infant by clicking on Infant number 1:

Infant (click link to select infant)	
▶	Infant number 1
	<a href="#">Infant number 2</a>

[prev form](#)

Using the drop down arrows, enter the infant's date of birth; time of birth; gestational age in weeks and days at birth; whether the infant has reversed end diastolic flow on Maternal Umbilical Artery Doppler; whether the infant had any IV fluids; whether the infant has a severe congenital anomaly and the infant's sex. Type the infant's birth weight into the box provided. All fields must be entered to submit data for randomisation. To save the data, click submit at the bottom of the form.

Infant number 1 (first born)	
Infant's date of birth (dd-mmm-yyyy)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> [today's date?]
Infant's time of birth (hh:mm)	hh: <input type="text"/> mm: <input type="text"/>
What was the infant's gestational age in weeks and days at birth?	Weeks: <input type="text"/>
	Days: <input type="text"/>
Infant's birth weight (g)	<input type="text"/>
Does this infant have reversed end diastolic flow on Maternal Umbilical Doppler?	<input type="text"/>
Has the infant had any IV fluids?	<input type="text"/>
Does this infant have a severe congenital anomaly?	<input type="text"/>
What's the infant's sex?	<input type="text"/>
Infant number 1 (first born)	

Please click on the submit button to save the data you have entered.

[prev form](#)

Then click the link for infant number 2 to open the eligibility form. Complete and submit forms for all other infants included in the trial.

Infant (click link to select infant)	
▶	<a href="#">Infant number 1</a>
	<a href="#">Infant number 2</a>

[prev form](#)

After you have submitted the eligibility data, a live countdown will show the 3-hour eligibility expiry time for the infants that are confirmed to be eligible. The eligible infant(s) must be randomised within 3 hours of birth otherwise they will no longer be eligible.

Infant (click link to select infant)	Infant I.D.	Included in trial?	Eligibility confirmation	3 hour eligibility expiry
<a href="#">Infant number 1</a>	99072-1	✓	✓	1h 47m 35s
▶ <a href="#">Infant number 2</a>	<a href="#">99072-2</a>	✓	✓	2h 47m 35s

When eligibility information has been entered for both infants, click randomise to proceed to the randomisation page.

[prev form](#)

If one or more infant(s) are ineligible to be included in the trial, this will be shown by a red ✗ cross. When you click randomise, only the eligible infant(s) will proceed to the infant randomisation page.

#### Infant enrolment

1 infant(s) confirmed as eligible. 1 infant(s) confirmed as ineligible.

- If this is correct please click [randomise](#) to proceed to randomisation.
- Otherwise edit infant details to check eligibility

Infant (click link to select infant)	Infant I.D.	Included in trial?	Eligibility confirmation	3 hour eligibility expiry
<a href="#">Infant number 1</a>	99070-1	✓	✓	1h 13m 55s
▶ <a href="#">Infant number 2</a>	<a href="#">99070-2</a>	✓	✗	n/a

[prev form](#) | [randomise](#)

## 4. INFANT RANDOMISATION

All that you are required to do here is to check the information that is presented to you. There are two checkboxes, one to confirm that the information presented is correct and another to confirm once again that the participant(s) meet the eligibility criteria for the trial. If you are happy that the answer to both of these questions is 'Yes', then tick both boxes and click on

Randomise

### INFANT RANDOMISATION

Mother	
Ref no.	99072
Initials	A-D
Date of Birth	10-Jul-1992
NHS No.	995 321 4484
Expected Date of Delivery	30-Oct-2019
Multiple pregnancy?	yes (2 babies)

2 eligible infants:									
Infant Number	I.D.	Birth date/time	Gestation age at birth	Weight (g)	Reversed end diastolic flow on Maternal Doppler	Had any IV fluids	Severe congenital anomaly	Sex	3 hour eligibility expiry
1	99072-1	09-Sep-2019 14:00	32 wks 5 days	700(<10th centile)	no	no	no	male	1h 43m 5s
2	99072-2	09-Sep-2019 15:00	32 wks 5 days	700(<10th centile)	no	no	no	female	2h 43m 5s

Please check each box to declare each statement as correct:

- the above information is correct
- the infant(s) meet the trial entry criteria (as per protocol)

Then click the button if you wish to randomise the patient on the [Feed-1](#) trial

[prev form](#)

**Please note: in emergency situations, an extra 30 minutes is available. You will need to have reached the infant randomisation page as above. The extra 30 minutes allows you to check the eligibility criteria. The extra time is not included in the countdown.**

Once you have clicked 'randomise', you will be presented with the 'randomisation completed' screen. This will show the treatment allocation for the infant(s). You can print this page if required by clicking [Print this page](#) at the bottom of the page.

## INFANT RANDOMISATION

**Randomisation completed - email confirmation sent.**

Mother	
Ref no.	<a href="#">99072</a>
Initials	A-D
Date of Birth	10-Jul-1992
NHS No.	995 321 4484
Expected Date of Delivery	30-Oct-2019
Multiple pregnancy?	yes (2 babies)

2 randomised infants:								
Randomisation No.		<a href="#">R20057</a>						
Treatment allocation		<b>Full milk feeding from day one</b>						
Date of Randomisation		09-Sep-2019 15:23:18						
Randomisation by		Emily Wallbanks						
Infant Number	I.D.	Birth date/time	Gestation age at birth	Weight (g)	Reversed end diastolic flow on Maternal Doppler	Had any IV fluids	Severe congenital anomaly	Sex
1	<a href="#">99072-1</a>	09-Sep-2019 14:00	32 wks 5 days	700(<10th centile)	no	no	no	male
2	<a href="#">99072-2</a>	09-Sep-2019 15:00	32 wks 5 days	700(<10th centile)	no	no	no	female

[re-send email confirmation](#)

[prev form](#)

[Print this page](#)

[next form](#)

You will receive a confirmation email as reassurance that the randomisation was successful.

Click 'next form' to go to the Mother's Contact

[Print this page](#)

Details page.

## 5. MOTHER'S CONTACT DETAILS

The mother's contact details must be entered after infant randomisation. Here you should enter as much of the data as possible regarding the mother's contact details. Please note that fields marked with an orange box are mandatory.

### Mother's contact details

**Warning: some \*mandatory contact details are missing**

Nb - mandatory contact fields denoted like this

Mother's NHS Number <small>(999 999 9999)</small>	<input type="text"/> <input type="text"/> <input type="text"/>
Mother's first name	<input style="border: 1px solid orange;" type="text"/> *
Mother's last name	<input style="border: 1px solid orange;" type="text"/> *
<b>Primary contact details</b>	
Address	<input style="border: 1px solid orange;" type="text"/> * <i>property name or number</i> <input type="text"/> <i>road name</i> <input type="text"/> <i>town</i> <input type="text"/> <i>city</i> <input type="text"/> <i>county</i> <input style="border: 1px solid orange;" type="text"/> * <i>post code</i>
Mobile phone number	<input style="border: 1px solid orange;" type="text"/> or tick <input type="checkbox"/> if no mobile
Confirm mobile phone	<input type="text"/>
Home phone number	<input style="border: 1px solid orange;" type="text"/> or tick <input type="checkbox"/> if no home phone
Email address	<input style="border: 1px solid orange;" type="text"/>
Confirm email	<input type="text"/>
Questionnaire Type	<input type="text" value="v"/>
Has the participant withdrawn from further communication? (CTU only)	<input type="text" value="v"/>
<b>Secondary contact details</b>	
We need a secondary contact address (such as grandparent or any other family/friend where the mother is happy to receive correspondence) to ensure that we can maintain contact with families for long-term follow-up.	
Was the woman able/willing to provide secondary contact information in order to aid ongoing contact?	<input type="text" value="v"/>
Address	<input style="border: 1px solid orange;" type="text"/> <i>property name or number</i> <input type="text"/> <i>road name</i> <input type="text"/> <i>town</i> <input type="text"/> <i>city</i> <input type="text"/> <i>county</i> <input style="border: 1px solid orange;" type="text"/> <i>post code</i>

Click Submit to save any changes.  
[prev form](#)

Please enter whether the mother would like to complete the 6-week questionnaire via post or online using the drop down menu.

Click submit to save the data.

## 6. RECORDING ADDITIONAL MOTHER ENROLMENT DETAILS

### 6.1. DEMOGRAPHIC DETAILS

To enter additional demographic details, this must be done after randomisation. Click main menu at the top of the page and select 'Edit mother enrolment details'. Complete the section titled 'Demographics'. Using the drop down menus, state whether the mother received antenatal corticosteroids and magnesium sulphate and provide the mother's ethnicity.

When the Demographics form is completed, click submit.

Please note: if mother has initially provided oral assent, consent status form (section below) must be completed to submit the demographic details.

Demographics	
Did the Mother receive antenatal corticosteroids?	<input type="text" value="v"/>
Did the Mother receive Magnesium Sulphate?	<input type="text" value="v"/>
Ethnicity	<input type="text" value="v"/>
	If other, please specify <input type="text"/>

If details are correct go to the next form to enter the infants eligibility details.

[next form](#)

### 6.2. RECORDING CONSENT STATUS (POST RANDOMISATION)

If it is indicated that the mother has provided oral assent on enrolment, when written informed consent is given at a later time or date, this must be entered on the randomisation system.

Click main menu at the top of the page and select 'Edit mother enrolment details'. Complete section titled 'Consent Status (Post Randomisation)'. Use the drop down menus to select whether written informed consent has been obtained and provide the date of consent.

When the Consent Status form is complete, click submit. Please note: the Demographics section must also be completed in order to submit data.

Consent Status (Post Randomisation)	
Has written informed consent been obtained?	<input type="text" value="v"/>
Date of written consent (dd-mmm-yyyy)	<input type="text" value="v"/> <input type="text" value="v"/> <input type="text" value="v"/> <a href="#">[today's date?]</a>

If details are correct go to the next form to enter the infants eligibility details.

[next form](#)

### 6.3. UPLOADING WRITTEN CONSENT FORM

Once written consent has been obtained, this must be entered onto the randomisation system.

To do so, click on 'edit mother enrolment details' in the main menu.

#### Mother

Please upload consent form

Please complete outstanding Demographic details

Enrolment	
Ref. No.	99067
NHS Number	945 577 1454
Has the woman delivered ?	yes
Please specify the type of consent given	written informed consent
Date of written consent/oral ascent (dd-mmm-yyyy)	05-Sep-2019
Consent form	<p><b>✗ outstanding</b></p> <ul style="list-style-type: none"> <li><a href="#">upload consent form</a></li> </ul>

Click on 'upload consent form'.

## Upload consent forms

**Warning: consent form is outstanding.**

Consent form <b>✗ outstanding</b>
Enter file name of scanned consent form including path and click upload:
<input type="text"/> <input type="button" value="Browse..."/> <input type="button" value="upload"/>

Then click browse to select the document from the computer. Click upload to save the consent form.





Consent form	<b>✓ uploaded 16-Sep-2019 16:07:23</b>
	<ul style="list-style-type: none"><li><a href="#">download existing form</a></li></ul>
	<input type="button" value="Discard"/>

When the consent form is successfully uploaded, this will be shown by a green tick. To discard the current form, click discard. Complete the demographics section at the bottom of the page and when complete, click submit to save the data.

## 7. 5-WEEK WELLBEING REPORT

NCTU will be sending out follow-up questionnaires (by email or post) once infants reach 6 weeks corrected age. It is crucial that NCTU are aware of the wellbeing of infants to ensure that appropriate questions are included in the questionnaire and that accompanying letters include added sensitivities where necessary. Once an infant has reached 5 weeks corrected gestational age (i.e. term gestation + 5 weeks), the 5-week infant status report will need to be completed.

To access this report, click '5 week post EDD infant well being status check' on the Main Menu.

-  [Reports and trial manager's tools](#)
-  [User administration](#)
-  [Download study datasets](#)
-  [5 week post EDD infant well being status check](#)



**Feed-1 - 5 week post EDD infant well being status check**

**1 infant(s) confirmed as living have death log incorrectly completed in Macro - [click here for Macro login](#)**

Nb \* Status cannot be altered once 6 week questionnaire has been sent out

Site	Mother			Infant			Infant Check				
	Ref No	Ints/DOB	EDD	EDD +5 wks	Infant Ref.	Included in trial	Macro Discharge Date	Macro Death Date	Status *	Date	Checked by
Editing infant 99001-1											
				99001-1	yes	16-AUG-2019			TBC living died	17-Oct-2019 10:13	Chris Rumsey

Message from webpage



Sure you want to set status of 99003-1 to died?

OK

Cancel

To confirm the status of the infant(s), click 'TBC' on the status column and use the drop down menu to select whether the infant is living or dead. Then press OK in the message from webpage to save the status.

If there are multiple births, confirm the status of all infants born to a particular mother (this includes infants who were not randomised).

If for any reason you are unable to complete the well-being report please notify the trial management team by email.

## 8. ENTERING MONTHLY SCREENING

Each month, complete the monthly screening form. Enter the values into the boxes. If there is nothing to report, enter zero '0' into the boxes. To save the data, press submit at the bottom of the page.

### Monthly screening (version 3)

Please enter a value for all fields (enter zero if there is nothing to report)

JAN-2022	
Total number of infants born within gestation	<input type="text"/>
Number of infants whose mother was consented (antenatally or postnatally) <i>(please only record the consents for babies that have been born this month)</i>	<input type="text"/>
Reasons for non-consent - please state the MAIN reason using codes A to L below: <ul style="list-style-type: none"> <li>o for multiple births please record a reason for each infant, even if this reason was the same for each</li> <li>o if a mother was approached antenatally and did not consent, please check the medical records to ascertain the reason</li> </ul>	
A) Mother not approached because of lack of appropriate staff	<input type="text"/>
B) Mother not approached as missed by research staff	<input type="text"/>
C) Mother not approached because infant considered unsuitable for FEED-1 (clinical team not in equipoise)	<input type="text"/>
D) Infant >3h old at time of possible approach	<input type="text"/>
E) Infant not eligible: known congenital abnormality of the gastrointestinal tract or other congenital condition(s) that make enteral feeding unsafe	<input type="text"/>
F) Infant not eligible: small for gestational age AND evidence of reversed end-diastolic flow	<input type="text"/>
G) Infant not eligible: mother participated in trial previously	<input type="text"/>
H) Infant not eligible: mother younger than 14 years or 14-16 years old and not able to provide informed consent	<input type="text"/>
I) Mother approached but refused to participate	<input type="text"/>
J) Mother is participating in another trial and co-enrolment is unsuitable	<input type="text"/>
K) Mother unable to give consent	<input type="text"/>
L) Other	<input type="text"/>
<i>(please state)</i> <input style="width: 100%; height: 20px;" type="text"/>	

Please click on the submit button to save the data you have entered.

## 9. SELECTING EXISTING PARTICIPANTS

When you log into the randomisation database, in the main menu, click 'select existing mother'.

If you already have a participant selected and want to open a different participant, in the main menu, click 'select a different existing mother'

Then, to select the required participant, click on the correct Ref.No. You can also filter the participants by Ref.No, Initials, DOB, NHS Number, Number of Infants, whether they have been randomised and current gestation age.

#### Existing mother selection

Ref. No.	Initials	DOB dd-mmm-yyyy	NHS Number	Number of infants	Randomised?	Current gestation age	Action
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="filter"/>
99074	P-O	10-Apr-1992	898 471 5875	1	no	33 wks, 0 days	<a href="#">select</a>

Please note: If a mother is returning to you, with a second pregnancy, and has NOT previously been randomised, you can use the same Ref.No. as previously. You will need to re-consent, amend the date of consent, and upload the new consent form.

## 10. SITE SUPER USER


Selected site members will be granted 'site super' access to the RANDO system. This will enable them to grant RANDO and MACRO system access to other members of the team at their site so that they can become a site user.


### Feed-1 trial randomisation system (CTU. 1704), main menu

Click on desired function's link

 [Select a different site](#)

 [Reports and trial manager's tools](#)

 [User administration](#)

 [Download study datasets](#)

To do so, select 'User administration' in the main menu. Then select 'add new user profile'.

#### Enter new randomisation user profile

User Id:	<input type="text"/>
Full name:	<input type="text"/>
Email address:	<input type="text"/>
User type:	<input type="text"/>

Create a User Id using first initial and surname, with no gap in between, e.g. 'jsmith'. Enter the full name and email address and select 'site' in the user type drop down menu.

Click submit. This will take you to the Edit user randomisation profile page. To grant randomisation system access to an individual at your site, select your site on the Trial PI site drop down and click 'grant'. Access can be granted to site 99 (Dummy Hospital) to allow the user to become familiar with using the system.

**Reset / email user's password**

reset

**Grant/revoke user study access:**

Trial PI site	PI	Action
Site 99 : Dummy investigator (Dummy Hospital 99) - Active		grant

To receive the new user log in details, click 'reset'. This will send an email to the super user's email address, and the login details should be forwarded to the appropriate user.