

SOP: Randomisation

Version	Author(s)	Date	Changes	Approved by
1.0	Janus Engstrøm Anne Mette Plomgaard	29.05.12	Initial Version	Gorm Greisen
1.1	Janus Engstrøm Anne Mette Plomgaard	03.07.12	Minor changes	Gorm Greisen
1.2	Janus Engstrøm Anne Mette Plomgaard	11.07.12	Minor changes	Gorm Greisen
1.3	Janus Engstrøm Anne Mette Plomgaard	25.10.12	Minor changes and Emergency randomisation	Gorm Greisen
1.4	Berit Grevstad	21.01.13	Updated email address for data manager	Gorm Greisen
1.5	Janus Engstrøm	27.02.13	Updated randomisation procedure and phone number for data manager	Gorm Greisen

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Before randomising the child/children always make sure that the parent(s) are informed and that the informed consent is signed.

1.0 How do I give the child/children a study-ID?

- Find the “Patient Inclusion List”
- *Note the Personal Identification Number of the child or the mother of the child in the first available row.*
- The child is given the study-id left to the Personal Identification Number
- Use the study-id when randomising the child

When creating the profile in the eCRF use the study-id.

1.1 What if it is twins?

Twins are always randomized *in bloc!*

- *Note the Personal Identification Number of both children or the mother of the children in the first available row.*
- The children are given the study-id left to the Personal Identification Number
- Use only this one study-id when randomising the twins

When creating the profiles in the eCRF use '*study-id*'a for twin A and '*study-id*'b for twin B

Example:

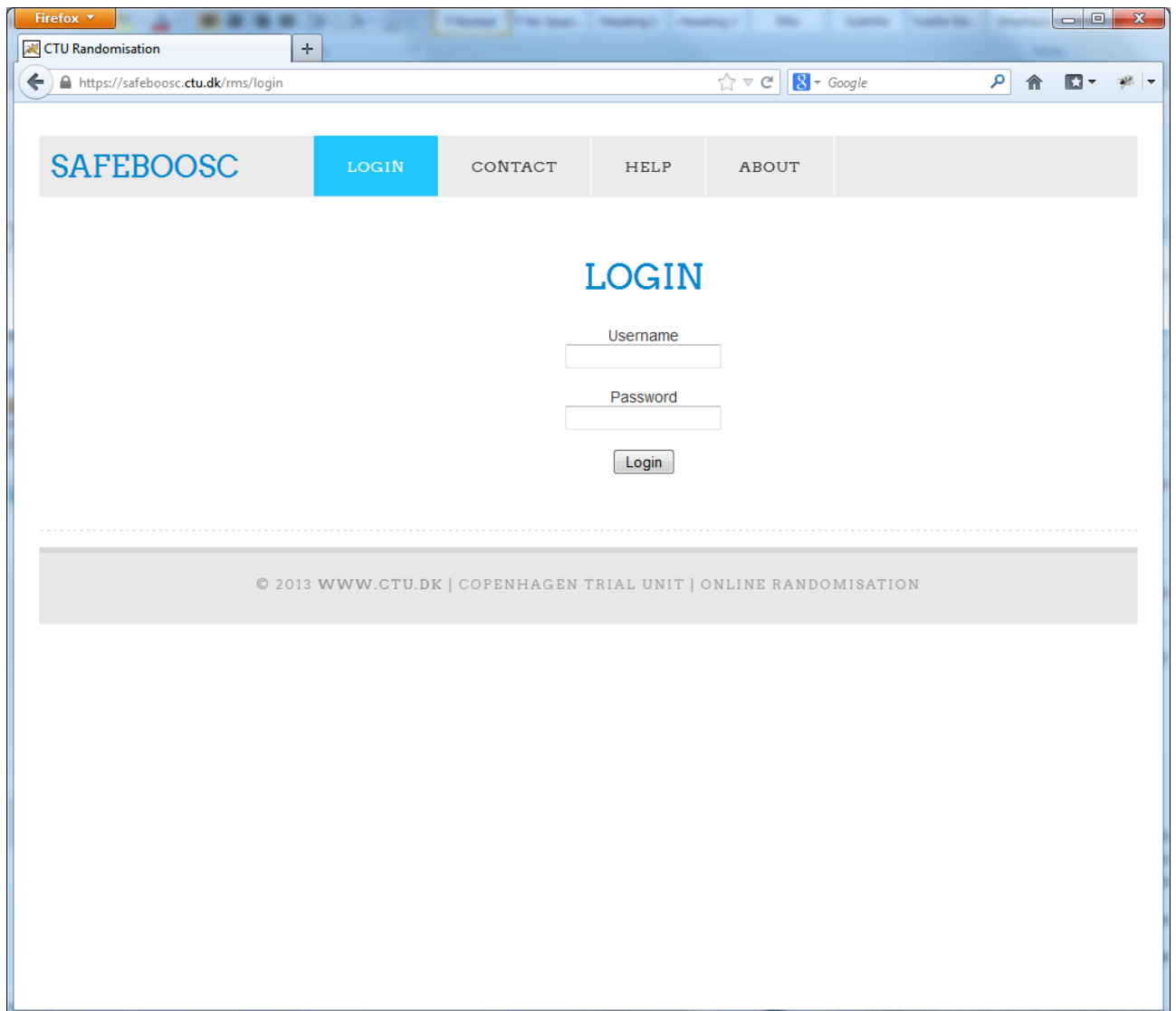
Profile for Study-ID DK9999 becomes **DK9999a** and **DK9999b** in the eCRF.

2.0 How do I randomise the child/children?

1. Open a web browser and go to the following webpage:

<https://safeboosc.ctu.dk/rms>

SafeBoosC phase II - SOP - Randomisation



The screenshot shows a web browser window with the address bar displaying "https://safeboosc.ctu.dk/rms/login". The page features a navigation menu with "SAFEBOOSC", "LOGIN", "CONTACT", "HELP", and "ABOUT". The "LOGIN" button is highlighted in blue. Below the menu, the word "LOGIN" is displayed in large blue letters. There are two input fields: "Username" and "Password", each with a corresponding label above it. A "Login" button is positioned below the password field. At the bottom of the page, a grey footer bar contains the text "© 2013 WWW.CTU.DK | COPENHAGEN TRIAL UNIT | ONLINE RANDOMISATION".

2. Login using your site credentials
3. You are now presented with the randomisation screen:

RANDOMISATION

Please fill in all fields below and press Randomise

INVESTIGATOR

Your name

Test Testing

1

PARTICIPANT INFO

Study Subject ID

dk1247

2

Study Subject type

Twins

STRATIFICATION

Gestational age

26 weeks or more

3

Before pressing "Randomise" please verify that the entered data is correct.

Randomise

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1: Enter your full name here.

2: Study Subject ID (you just found it in the Patient Inclusion List) is the identifier of the child/children within the OpenClinica system for collecting study data. **(Remember: twins are randomized in bloc).**

Next, choose whether you are about to randomise a Singleton or a pair of Twins.

3: Choose the gestational age. Options are: less than 26 weeks and 26 weeks or more.

4: After **carefully reviewing** the above entered data, press the button to perform the randomisation.

After pressing the Randomise button, you are presented with a summary and the randomisation outcome.

RESULT

STUDY SUBJECT

Study Subject ID: **DK1247A and DK1247B**
Study Subject type: **Twins**

STRATIFICATION

Stratification: **26 weeks or more**

RANDOMISATION ALLOCATION

NIRS oximeter reading NOT visible

[Click here to Logout](#)

Carefully note the randomisation outcome before logging out of the randomisation system.

If you have performed a randomisation with incorrect stratification parameters, you should NOT perform the randomisation again, but use the given randomisation allocation. Next, contact CTU.

In case of questions or other problems, please contact CTU.

Telephone number +45 3545 7161 (daytime), ask for Janus Engstroem or send an e-mail: janus.engstroem@ctu.dk

3.0 Emergency randomisation

If you are unable to randomise online –
Please call Professor Gorm Greisen +45 4046 0747

He will need to know:

Your name
Study site
Study ID
Gestational age of the child

He will tell you which group the child is randomised to.