



Place in Site Master File #9a

Instructions for the HOT-ICU trial - eCRF

The screening and randomisation procedure is described in the trial document 'Instruction for screening and randomisation'.

Log on

Please go to <http://www.cric.nu/hot-icu>.

Here you will find links to the data entry system (OpenClinica), the Medication dispensing system and the trial documents.



Handling Oxygenation Targets in the Intensive Care Unit



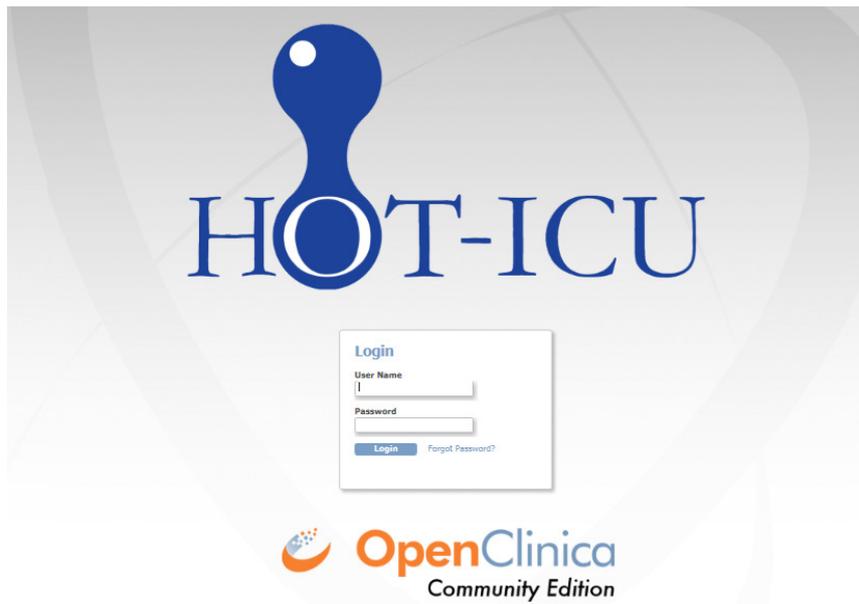
Screen, randomise, and enter data



Trial documents

Click the 'Screen, randomise and enter data' link.

If you have not received your login, please send an email to hot-icu@cric.nu



If your browser presents a warning about a certificate from an un-trusted source, please accept the connection and – if possible – install the certificate on your computer. The certificate is required to encrypt the connection between your computer and the server.

We recommend avoiding the use of Internet Explorer version 8 or older as browser when using this eCRF.

A quick tour through the eCRF

Participant list

After login in you will see the participant list.

(Screen shots below is from a demo version of the HOT-ICU eCRF)

Trial Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Daily Form	Discharge and readmission	Withdrawal	Follow-Up 90 days	Follow-Up 1 year	Actions
DK01021	Olav Test 10	D4444445555	04-06-2017	✔	📄	📄	📄	📄	📄	📄	Click here to enter data
DK01020	Olav Test9	D4545454545	04-06-2017	✔	📄	📄	📄	📄	📄	📄	Click here to enter data
DK01018	Gxgxgd	D1010101010	03-06-2017	✔	📄	📄 x2	📄	📄	📄	📄	Click here to enter data
DK01017	2222	D2222222222	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01016	aaa bbbbbb	D1111111111	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01014	Olav Test8	D1234567777	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01010	Testkåte	1504806666	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01009	Olav Test7	D7777777777	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01008	Olav Test7	D6666666666	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01007	Olav Test6	D5555555555	02-06-2017	✔	📄	📄 x3	📄	✔	📄	📄	Click here to enter data
DK01006	Janus #1	D3444444444	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data
DK01005	Olav test6	D4444444444	02-06-2017	✔	📄	📄 x3	📄	📄	📄	📄	Click here to enter data

Each trial participant has one row. In the first three columns you will find

- Trial participant ID – an automatically generated identifier number. Write this ID in your screening log and use it when communicating with the coordinating centre.
- National identification number (as described in the instruction for screening and randomisation)
- Name of the patient (as written in the screening procedure)
- Enrolment date

The next columns show the different trial events. The colours of the icons indicate the status of the event

- 📄 = not started, data entry not possible (Daily forms, follow-up form)
- 📄🕒 = the form is scheduled. In this state data entry is possible if necessary (discharge/withdrawal)
- 📄🟡 = data entry possible/started but incomplete
- ✔ = completed
- 📄🔴 = data has been entered, but not saved (appears when filling out forms in the eCRF)

New forms will be generated daily (maximum of 90 days). The colour of the icon in the column with Daily forms will turn green when all generated daily forms have been completed. When a new form is generated it will turn back to yellow until all forms have been completed. To see which Daily forms are incomplete you have to click on the participant (further information are provided below).

From the front page (participant list) you can proceed to:

1. Screening procedure
2. Site overview
3. Participant details (data entry)

Participant List for 4131 Rigshospitalet

For Screening click here: [Go to Patient Screening](#) For Site overview click here: [Site Overview](#)

Trial Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Daily Form	Discharge and readmission	Withdrawal	Follow-Up 90 days	Follow-Up 1 year	Actions
DK01021	Olav Test 10	D4444445555	04-06-2017	✔	🟡	🟡	🟡	🟡	🟡	🟡	Click here to enter data
DK01020	Olav Test9	D4545454545	04-06-2017	✔	🟡	🟡	🟡	🟡	🟡	🟡	Click here to enter data
DK01018	Gxgzxgd	D1010101010	03-06-2017	✔	🟡	🟡 x2	🟡	🟡	🟡	🟡	Click here to enter data
DK01017	2222	D2222222222	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data
DK01016	aaa bbbbbb	D1111111111	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data
DK01014	Olav Test8	D1234567777	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data
DK01010	Testkåte	1504806666	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data
DK01009	Olav Test7	D7777777777	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data
DK01008	Olav Test7	D6666666666	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data
DK01007	Olav Test6	D5555555555	02-06-2017	✔	🟡	🟡 x3	🟡	✔	🟡	🟡	Click here to enter data
DK01006	Janus #1	D3444444444	02-06-2017	✔	🟡	🟡 x3	🟡	🟡	🟡	🟡	Click here to enter data

Site overview

In the upper right corner (see screen shot above) you will find the 'Site overview' button. Clicking this button will give you a quick overview of your enrolled patients.

Site Overview

- AU01 ▾ [Click here to get back to Front page](#)
- Click "Participant ID" or "Name" to highlight row
 - Hover on Form status symbol to see start date and end date
 - Click Form status symbol to enter form data

Participant ID	Name	Screening	Baseline	DF 1	DF 2	DF 3	DF 4	DF 5	DF 6	DF 7	DF 8	DF 9	DF 10	DF 11	DF 12	DF 13	DF 14	DF 15	DF 16	DF 17
AU01001	Christian Petersen	✔	🟡	🟡	🟡	🟡														
AU01002	[Name unknown]	✔	✔	🟡	🟡	🟡														
AU01003	Lisa Thomsen	✔	🟡	🟡	🟡	🟡														
AU01004	John Thomas	✔	🟡																	
AU01005	Emma Jackson	✔	🟡																	

Point at 🟡 (without clicking) to see start and end date of the form.

Click the participant ID to highlight the row (green).

Click 🟡 to enter the incomplete form.

If icons are missing the forms have not yet been generated. If the patient has been discharged and readmitted, Daily forms during the period out of ICU will be empty and should not be completed.

Data entry – general information

After randomisation the following forms will be available:

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- Baseline form
- Daily form (1 per day when the patient is in the ICU with a maximum of 90 days)
- Discharge form (to be completed at discharge or death).
- Withdrawal form (to be completed if the patient is withdrawn from the trial because of SUSAR or withdrawal of consent)
- Follow-up 90 days (becomes active 90 days after randomisation). If the patient dies in the ICU and the discharge form is completed, the follow-up form will automatically be completed
- Follow-up 1 year (becomes active one year after randomisation).

To enter the forms (participant details) click the link '[Click here to enter data](#)'

Participant List for 4131 Rigshospitalet

For Screening click here: [Go to Patient Screening](#)

For Site overview click here: [Site Overview](#)

Trial Participant ID	Name	NIN	Enrolment Date	Screening	Baseline	Daily Form	Discharge and readmission	Withdrawal	Follow-Up 90 days	Follow-Up 1 year	Actions
DK01021	Olav Test 10	D44444445555	04-06-2017								Click here to enter data
DK01020	Olav Test9	D45454545454	04-06-2017								Click here to enter data
DK01018	Gxgzxgd	D101010101010	03-06-2017			x2					Click here to enter data
DK01017	2222	D222222222222	02-06-2017			x3					Click here to enter data
DK01016	aaa bbbbb	D111111111111	02-06-2017			x3					Click here to enter data
DK01014	Olav Test8	D1234567777	02-06-2017			x3					Click here to enter data
DK01010	Testkåte	1504806666	02-06-2017			x3					Click here to enter data
DK01009	Olav Test7	D777777777777	02-06-2017			x3					Click here to enter data
DK01008	Olav Test7	D666666666666	02-06-2017			x3					Click here to enter data
DK01007	Olav Test6	D555555555555	02-06-2017			x3					Click here to enter data
DK01006	Janus #1	D34444444444	02-06-2017			x3					Click here to enter data

All generated forms will now be available. You have the opportunity to

1. Enter or edit data. If you want to edit data in a submitted form click 'Administrative edit'.
2. View data (read only)

Participant Details

DK01020
NIN: D4545454545
Name: Olav Test9

Event (Occurrence Number)	Start Date	End Date	CRFs (Status, Updated, Actions)			
Daily Form (1)	04-06-2017 07:16	04-06-2017 23:50		Click here to enter data	Click here to view data (read only)	(0)
Screening	04-06-2017 07:15	04-06-2017 07:16		Administrative edit	Click here to view data (read only)	04-06-2017 (o.schjoerring@rn.dk)
Baseline	04-06-2017 07:16			Click here to enter data	Click here to view data (read only)	(0)
Discharge and readmission	04-06-2017 07:16			Click here to enter data	Click here to view data (read only)	05-06-2017 (o.schjoerring@rn.dk)
Withdrawal	04-06-2017 07:16			Click here to enter data	Click here to view data (read only)	

In the forms:

Click on 'info' to see explanations and further information.

Please read this information carefully!

Date format is always **dd-mm-yyyy**. You can use the Calendar or enter the date directly

Time format is **24 hours hh:mm**

When answering some of the questions you will have the opportunity to check an 'Not Available' box.

Missing data will reduce the quality of data and we kindly ask you to confirm that the information requested is unobtainable before checking this box.

At the bottom of each form you will have the opportunity to:

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- **Exit (no save).** Use this bottom if you entered the form without changing data
- **Save.** This will only be an option when data has been entered
- **Submit form.** This will only be an option when the form is complete

Icons at the patient list and in the overview will turn green  when a complete form has been **submitted**.

If complete and only **saved**, the icon will be still be yellow .

Front page | Log Out Trial Participant ID

Participant Details

DK01002
NIN: D1205681245
Name: Michael Thomsom

Event (Occurrence Number)	Start Date	End Date 	CRFs (Status, Updated, Actions)
Screening	16-11-2015 08:42	16-11-2015 09:17	<div style="display: flex; align-items: center;">  16-11-2015 (userdk01) <div style="margin-left: 10px;"> <p>Administrative edit</p> <p>Click here to view data (read only)</p> </div> </div>
Baseline	16-11-2015 09:17		<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;"> <p>Click here to enter data</p> <p>Click here to view data (read only)</p> </div> </div>
Discharge and readmission	16-11-2015 09:17		<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;"> <p>Click here to enter data</p> <p>Click here to view data (read only)</p> </div> </div>
Withdrawal	16-11-2015 09:17		<div style="display: flex; align-items: center;">  <div style="margin-left: 10px;"> <p>Click here to enter data</p> <p>Click here to view data (read only)</p> </div> </div>

Specific forms in the eCRF

Baseline form

This is the most comprehensive form and will take 20-30 minutes to complete.

Please pay attention to the following:

- “Date and time of ICU and hospital admission”: if the patient has been transferred from another ICU/hospital please enter date and time of the first admission
- All data should represent the condition at the time of randomisation, relevant periods before randomisation are specified within the questions or ‘info’

Daily form

All days are defined as from 06:00 to 06:00 (24h time, local time zone). The first Daily form will be available on the first morning after randomisation at 06:00. The last day is from 06:00 until discharge or death.

Hence, in most cases the first and last day will not be 24 hours. Hereafter a Daily form is generated once a day at 06:00 with a maximum of 90 days. The first Daily form will be available the day after randomisation.

If a Daily form does not turn green despite it is complete, please make sure the form has been submitted (and not just saved).

Discharge/readmission

The discharge/readmission form is used to discharge and readmit the patient (available several times). Hence, this form will only turn green if the patient is registered dead in the ICU.

If a patient dies within the ICU, discharge the patient in the system by completing the discharge form. Completing this form will stop the generation of Daily forms.

TIP: If you enter data retrospectively and the patient has been discharged or is dead it may be advantageous to complete the discharge form before Daily forms, as the system will remove irrelevant Daily forms.

If the patient is readmitted to the ICU, go to the discharge/readmission form again and click ‘add’. This will generate a new row. Please complete date and time of readmission.

If an unnecessary row by accident is generated you have to delete it by clicking ‘X’ in the right side.

Dischar...(8/14)

Title: Discharge and readmission

Exit (no save)

DISCHARGE AND READMISSION FORM

Date of ICU readmission (dd-mm-yyyy)	Time of ICU readmission (hh:mm, 24 hours format)	Date of ICU discharge (dd-mm-yyyy)	Time of ICU discharge (hh:mm, 24 hours format)	Patient discharged to [info]	Has the patient been enrolled in other interventional trials during this ICU admission	Patient transferred to site Id	
		<input type="text" value="04-06-2017"/>	<input type="text" value="23:50"/>	<input checked="" type="radio"/> General Ward <input type="radio"/> ICU participating in HOT-ICU trial <input type="radio"/> ICU not participating in HOT-ICU trial <input type="radio"/> Home (including nursing homes and similar) <input type="radio"/> Dead	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="text" value="N/A"/>	
<input type="text" value="05-06-2017"/>	<input type="text" value="12:00"/>					<input type="text" value="DK01"/>	
		<input type="text"/>	<input type="text"/>	<input type="radio"/> General Ward <input type="radio"/> ICU participating in HOT-ICU trial <input type="radio"/> ICU not participating in HOT-ICU trial <input type="radio"/> Home (including nursing homes and similar) <input type="radio"/> Dead	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>	<input type="button" value="X"/>

Return to top Exit (no save)

After completing the discharge/readmission form, Daily forms will again be generated.

Patients transferred from/to other ICUs

ICUs **not** participating in HOT-ICU:

If a patient is transferred to your ICU please screen the patient for inclusion in HOT-ICU.

If you transfer a patient to another ICU **not** participating in HOT-ICU the patient will be regarded discharged from ICU. Please complete the discharge form. Follow-up 90 days and follow-up one year still have to be completed.

ICUs participating in HOT-ICU:

If a patient is transferred from your ICU to an ICU participating in HOT-ICU, complete the discharge form and choose the centre at the list. In the electronic system, the patient will be transferred to a 'transferral site' accessible by you and the receiving department. Please complete all forms as soon as possible.

Hereafter the patient will be transferred to the receiving department. **Please inform the receiving department that the patient is enrolled in the HOT-ICU trial.**

If a patient is transferred to your ICU and has not been transferred in the electronic system, please contact the coordinating centre soon as possible.

Withdrawal

The patient can be withdrawn from the trial for the following reasons:

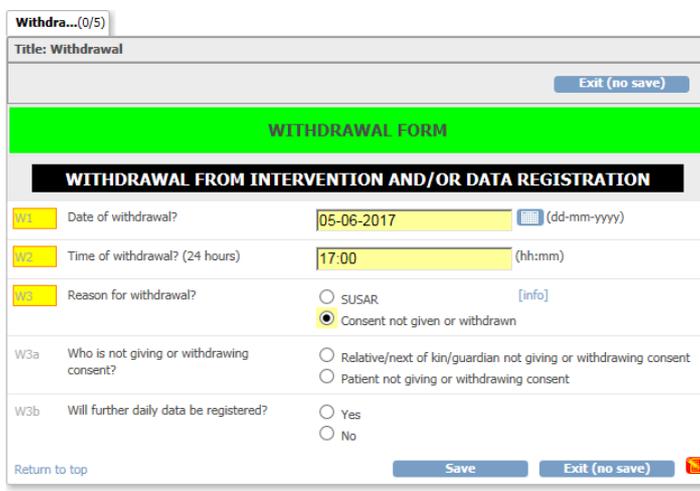
1. SUSAR
2. Consent not given or withdrawn

Please complete the withdrawal form.

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Please continue completing Daily forms unless consent to do this has been withdrawn.

Withdrawal  **DK01009**
NIN: D777777777
Name: Olav Test7



WITHDRAWAL FORM	
WITHDRAWAL FROM INTERVENTION AND/OR DATA REGISTRATION	
W1	Date of withdrawal? <input type="text" value="05-06-2017"/> (dd-mm-yyyy)
W2	Time of withdrawal? (24 hours) <input type="text" value="17:00"/> (hh:mm)
W3	Reason for withdrawal? <input type="radio"/> SUSAR [info] <input checked="" type="radio"/> Consent not given or withdrawn
W3a	Who is not giving or withdrawing consent? <input type="radio"/> Relative/next of kin/guardian not giving or withdrawing consent <input type="radio"/> Patient not giving or withdrawing consent
W3b	Will further daily data be registered? <input type="radio"/> Yes <input type="radio"/> No

Will only be shown if 'Consent not given or withdrawn' has been marked in W3

Follow-up

Ninety days and one year after randomisation, the relevant follow-up forms will be activated respectively, please fulfil these.

If the patient dies within the ICU and this is marked in the discharge form, date of death will automatically be fulfilled in the 90 days follow-up form. However, the form still has to be fulfilled, as other questions need answering.

If the patient dies within the ICU and this is marked in the discharge form, the one-year follow-up form will automatically be completed and will thus not appear.