

Part 1 - Before experiment

Research Participant ID

Study day (A or B)

Date (dd-mm-yy) - -

Personal data

Age years

Sex ☐ male ☐ female

Pregnancy test result (if female) ☐ positive ☐ negative

Height cm

Weight kg

Checklist

Emergency bag ☐

Extra thermometer ☐

Informed consent

 Present ☐

 Signed ☐

Initial screening ☐

Self report form - General health ☐

Part 2 - Before cooling

Research Participant ID

Study day (A or B)

Checkliste

No concurrent illness

Light breakfast

No tobacco last 24 h

Last 24 h

No caffeine, alcohol or grapefruit

No hard physical exercise

Inclusion criteria achievedyesno

Exclusion criteria **not** achievedyesno

Tablet taken (hh:mm) :

Checkliste

Corpuls	Attached	Turned on	Comments
Esophageal probe			
BP Cuff			
SpO2			
ECG			
Venflon			
Skin temperature sensors (7 pcs)			
Chamber sensors	Present		
Temperature			
Humidity			

Part 3 - Baseline

Research Participant ID

Study day (A or B)

Time (hh:mm)

Corpuls

Esophageal temperature

°C

Heart rate

/min

BP Systolic

mmHg

BP Diastolic

mmHg

SpO2

%

Questionnaire

Subjective shivering (0-2)

Objective shivering (0-3)

RASS (-5-4)

Cold discomfort (0-10)

Pain (0-10)

Nausea

yes

no

If yes

mild

moderate

severe

Comments

Research participant ID

Study day (A or B)

Start cooling (hh:mm) :

	Klokkeslett (hh:mm)	Shivering		RASS	Discomfort		Nausea		
		subj (0-2)	obj (0-3)	(-5 - 4)	from cold (0-10)	pain (0-10)	yes	no	severity (1-3)
start									
00:20	:						☐	☐	
00:40	:						☐	☐	
01:00	:						☐	☐	
01:20	:						☐	☐	
01:40	:						☐	☐	
02:00	:						☐	☐	

Research Participant ID

11/11/2019

Study day (A or B)

11

Standard

<80?

>200?

Time (hh:mm)

start

00:20 :

Page 1 of 1

00:40

00:40 :

01:00

01:00 :

01:20

01:20 :

01:40

01:40 :

02:00

02:00 :

Safety measurement

<80?

sys

dia

>200?

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Part 5 - Transition

Research participant ID

Study day (A or B)

Cooling stopped

Time (hh:mm)

 :

Temperature at termination

 °C

Cause

☐

Temperature (35°C)

☐

Time (2 h)

☐

Participant withdrawal

☐

Technical issue

Rewarming

Time start (hh:mm)

 :

Adverse events to report?

☐

Yes

☐

No

(If yes - AE form)

Part 6 - During rewarming

Research participant ID

Study day (A or B)

Subjective scores

Time (hh:mm)	Shivering		RASS (-5 - 4)	Discomfort		Nausea		
	subj (0-2)	obj (0-3)		from cold (0-10)	Pain (0-10)	yes	no	severity (1-3)
start								
00:00								
00:20								
00:40								
01:00								

Objective scores

Blood pressure

Time (hh:mm)	Standard			Safety measurement		
	sys	dia	<80? >200?	sys	dia	<80? >200?
start						
00:00						
00:20						
00:40						
01:00						

Adverse events to report?

☐ Yes ☐ No (If yes - AE form)

Part 7 - After experiment

Research participant ID

Study day (A or B)

Checklist

Data transfer

Corpuls

☐

Sensor skin temperature

☐

Ambient temperature sensor

☐

Completed forms

☐

Adverse events to report?

☐

Yes

☐

No

(If yes - AE form)