



HOW TO COMPLETE THE CRF – OUTCOME DATA

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019


CONTENTS OF THE CRF BOOKLET

- Each participant will have a Case Report Form (CRF) booklet.
- A CRF booklet contains:
 - **Baseline Form**
 - **Outcome Form**
 - **Adverse Event Form**

This presentation will focus on the **Outcome Form** and the **Adverse Event Form**:

- Completion should start after the participant has been randomised.

COUNTRY		HOSPITAL NAME		SITE ID	
PATIENT INITIALS	First	Last	SCREENING ID NUMBER	Site ID #	Patient Screening #


woman²

Case Report Forms

FULL TITLE OF STUDY	Tranexamic acid for reducing postpartum bleeding in women with anaemia: an international, randomised, double-blind, placebo controlled trial
SHORT TITLE	World Maternal Antifibrinolytic Trial-2
TRIAL ACRONYM	WOMAN-2
PROTOCOL NUMBER	ISRCTN62396133
CLINICALTRIALS.GOV ID	NCT03475342

DO NOT REMOVE ANY PAGES FROM THIS BOOKLET

This booklet contains all case report forms (CRFs) needed for a trial participant:

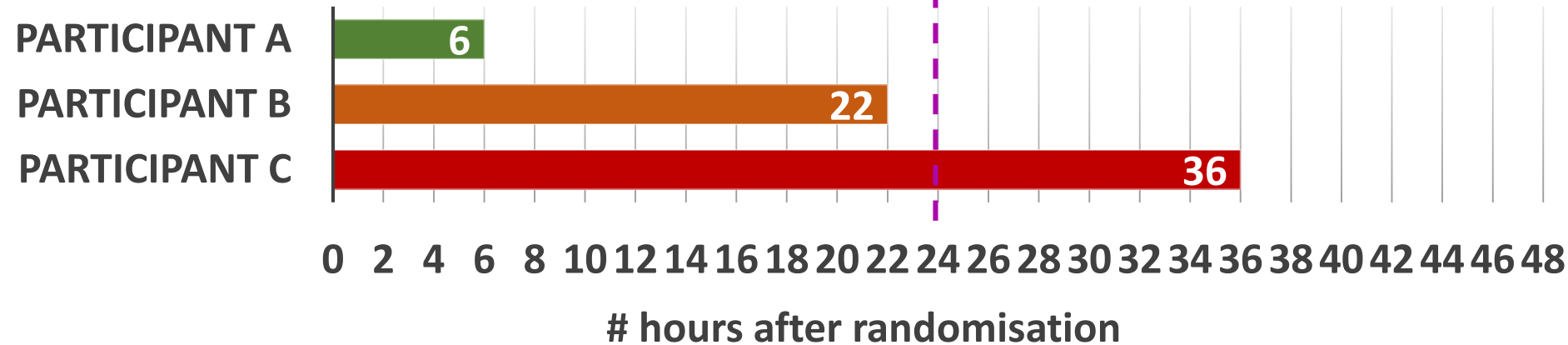
Form name
Baseline form
Outcome form
Adverse event form

OUTCOME DATA COLLECTION

What?	When
<p>Outcome form (Part 1): Sections A – C</p> <ul style="list-style-type: none"> • About the patient • Interventions given • Postpartum haemorrhage diagnosis 	<p>At 24 hours after randomisation, discharge from hospital or death – whichever occurs first</p>
<p>Outcome form (Part 2): Sections D – G</p> <ul style="list-style-type: none"> • Patient reported outcomes • Management • Complications • Status of baby/ies 	<p>At 42 days after randomisation, discharge from hospital or death – whichever occurs first</p>
<p>Adverse event form</p> <ul style="list-style-type: none"> • If in hospital: any <u>untoward</u> medical event that occurs up to 42 days after randomisation and is NOT collected on the outcome form • If discharged from hospital: any <u>untoward</u> medical event, which develops up to 42 days after randomisation (including those listed on the outcome forms) 	<p>Immediately any event that fulfils the Adverse Event definition as per the protocol, up to 42 days after randomisation</p>

WHEN TO COMPLETE THE OUTCOME FORMS – example scenarios

Discharged from hospital after randomisation



- **Example 1: Participant A** – If a woman is discharged at 6 hours (or anytime before 24 hours) after randomisation complete **all** of the outcome form (Parts 1 and 2) at the point of discharge
- **Example 2: Participant B** - dies 22 hours (or anytime before 24 hours) after randomisation - complete **all** of the outcome form at the point of death. Questionnaire and walk test not applicable
- **Example 3: Participant C** - discharged 36 hours (or anytime after 24 hours and up to day 42) after randomisation - complete **Part 1** at 24 hours after randomisation. Complete **Part 2** at point of discharge

Enter all outcome data into the trial database within 24 hrs of both forms being completed

OUTCOME FORM (Part 1): SECTIONS A - C

WHEN: At 24 hours following randomisation, discharge or death – whichever comes first

- **Complete Section A:**
 - Using the HemoCue analyser provided, carry out a haemoglobin test:
 - Take a drop of blood from the participant's finger, fill the microcuvette, put it in the HemoCue holder, close and wait for 15 - 60 seconds for the results.
- **Complete Sections B:**
 - Includes information about interventions given during delivery.
- **Complete Section C:**
 - Includes information on postpartum haemorrhage (PPH) diagnosis.
- Obtain data from medical records where possible, otherwise speak to clinical team.



Once all sections are completed, sign and date where indicated on CRF page 20

OUTCOME FORM (Part 2): SECTIONS D – G

WHEN: At 42 days following randomisation, discharge or death – whichever comes first

- Complete **Sections D – G:**
 - Section D: Patient outcome
 - Section E: Patient Management
 - Section F: Complications
 - Section G: Status of baby/ies
- Obtain data from medical records.

The image displays three overlapping copies of the 'woman2' Outcome Form (Part 2). The top form shows Section D (Patient Outcome) and Section E (Management). The middle form shows Section F (Complications) with a hand writing on it. The bottom form shows Section G (Status of Baby/ies) and Section H (Person Completing Details). The forms include various tables and checkboxes for recording patient outcomes, management, complications, and baby status.

Baby number (in order of delivery)	Status – after randomisation (circle one)	Cause of death (if applicable)	Any thromboembolic event in baby? (circle one)	Was baby breastfed? (circle one)	Supplemented feeding? (circle one)
1	Alive	Died after randomisation	YES NO	YES NO	YES NO
2	Alive	Died after randomisation	YES NO	YES NO	YES NO
3	Alive	Died after randomisation	YES NO	YES NO	YES NO

66. Completed by (first name/last name)	Print name clearly				
67. Date completed	day	month	year	68. Time completed (24-hour clock)	hours minutes
69. Signature (person completing form)					

Once all sections are completed, sign and date where indicated on CRF page 30

OUTCOME FORM (Part 2): SECTION H

WHEN: At 42 days following randomisation, discharge or death – whichever comes **first**

Patient Reported Outcomes (PRO)

- **Complete Sections H:**
 - Observe the patient:
 - Are they short of breath?
 - Are they able to complete a questionnaire and/or 6 minute walk test?
 - If answer to **H2** is 'a' or 'b', begin the PRO questionnaire (sections I – K)

wman2

SCREENING ID NUMBER

OUTCOME FORM (2)
PARTICIPANT REPORTED OUTCOMES
COMPLETE SECTIONS 'H TO M' AT DISCHARGE FROM HOSPITAL OR DAY 42, WHICHEVER OCCURS FIRST
SECTION H - OBSERVATIONS

Please look at the participant and record your observations before starting this questionnaire:

H1. Observe participant for any respiratory difficulty (circle one which best describes the participant)

a. Not short of breath	
b. Mildly short of breath (but able to speak)	
c. Moderately short of breath (some difficulty with speaking)	
d. Severely short of breath (a lot of difficulty with speaking)	
e. Very severely short of breath (air hunger- unable to speak)	
f. Other (describe)	e.g. patient is on a ventilator

H2. Observe participant and check with the participant or caregiver and circle one response which best describes participant's current physical ability (circle one which best describes the participant)

a. Able to complete the questionnaire and walk test	
b. Able to complete questionnaire but not the walk test. Please give reason below why participant is unable to do the walk test	e.g. S...
Reason:	
c. Unable to complete questionnaire or the walk test. Please give reason:	e...
Reason:	

H3. Record interview start time

hours	minutes
-------	---------

If patient able to complete questionnaire: Interviewer please say the following to participant
I am going to read some statements to you that describe how people sometimes feel. Each possible answers. Please tell me which answer best describes how you feel since having you.
I will give you an example:
I will say "I feel hungry right now" and I want you to tell me which of the following answers best describes how you feel right now. The options are Not at all, a little, moderately, quite a bit, extremely.
What answer would you give? (allow the patient to answer)
In the same way, I will say a statement and give you the same possible answers. Please tell me which you best.
[PLEASE CIRCLE RESPONSE GIVEN]

OUTCOME FORM (Part 2): SECTIONS I - K

WHEN: At 42 days following randomisation, discharge or death – whichever comes first

Patient Reported Outcomes (PRO): questionnaire

What is the PRO questionnaire?

- The PRO questionnaire is a quality of life assessment tool.
- Each statement describes how people sometimes feel.
 - For each statement, the participant should say which answer best describes how they feel since giving birth.
- There are five possible answers to each statement

'Not at all'

'A little'

'Moderately'



'Extremely'

'Quite a bit'

OUTCOME FORM (Part 2): SECTIONS I - K

BEFORE STARTING THE QUESTIONNAIRE

- Check the participant's medical records:
 - *to determine whether question K8 is relevant (e.g. baby could have been a stillbirth or is requiring hospitalisation)*
- Complete question H1 (this has to be completed before disturbing woman) then complete question H2
- Find a suitable location to administer the questionnaire
 - E.g. Somewhere reasonably quiet and where the woman would be comfortable
- Give some background information on the PRO (guidance available on CRF pg 31 and 32)

OUTCOME FORM (Part 2): SECTIONS I - K

ADMINISTERING THE QUESTIONNAIRE

- Ask the questions exactly as they appear in the CRF
- Always ask questions in a sensitive manner
- Do not provide your own examples for questions.
 - If a participant finds it difficult to understand a question, try to explain the concept of the question being asked. If the participant has provided examples, you may use these examples to help elicit an answer to the question
- Do not change answers to previously asked questions



OUTCOME FORM (Part 2): SECTIONS L - M

WHEN: At 42 days following randomisation, discharge or death – whichever comes first

Patient Reported Outcomes (PRO): 6 minute walk test

What is the 6 minute walk-test?

- The 6 minute walk test is an assessment of exercise tolerance.
- Participants will be asked to walk between 2 cones, as many times as they can, for a period of 6 minutes.

Why the walk test for WOMAN-2?

- The walk test will show the impact of blood loss and give an indication of the woman's ability to carry out her daily physical activities after giving birth.

What will you need?

- 2 cones
- Tape Measure
- 1 or 2 chairs
- Blood Pressure Monitor
- Stopwatch



OUTCOME FORM (Part 2): SECTIONS L - M

WALK TEST - SET UP (1)

- Identify a **straight** area of walkway (e.g. a quiet corridor)
- Measure a distance between 10-30 metres and put the cones at either end as turning points
- The longer the distance the better to avoid participants having to make too many turns to minimise dizziness
- Have a chair (or 2) available to be given to the participant if she needs to stop and rest
- Ensure baby/(ies) is safely with family members, ward staff or in a cot where the mother can see him/her during the test
- Have water/other drinking fluid available
- Ensure help is available if needed during the walk test



OUTCOME FORM (Part 2): SECTIONS L - M

WALK TEST - SET UP (2)

- Check the woman's medical records and confirm with her:

Do not carry out the walk test if the woman has:

- A history of angina
- Had a myocardial infarction during the previous month

- Ensure appropriate pain relief has been given if required
- If participant uses walking aids (e.g. walking stick), have aid available
- If possible, use a wheelchair to bring the participant to the walk test area
- Complete **Section L** (*participants perceived breathlessness*)
- Complete **Section M1** (*blood pressure, heart rate and respiratory rate*)

A second person should be present during the walk test if the woman has a:

- Resting heart rate of greater than 120 bpm
- Systolic blood pressure of greater than 180 mmHg
- Diastolic blood pressure of greater than 100 mmHg

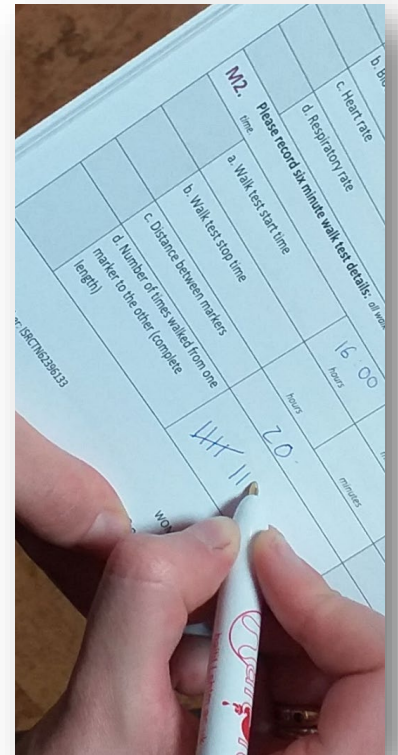
- Read the script on page 36 of the CRF
- Provide a demonstration of the walk test



OUTCOME FORM (Part 2): Section M

CARRYING OUT THE WALK TEST

- Use the stop watch to time 6 minutes
- If a participant usually uses a walking aid, they should use it for the walk test
- To encourage the participant, after each minute, tell the participant the following:
 - After the first minute, *"You are doing well. You have 5 minutes to go."*
 - After two minutes, *"Keep up the good work. You have 4 minutes to go."*
 - After three minutes, *"You are doing well. You are halfway done."*
 - After four minutes, *"Keep up the good work. You have only 2 minutes left."*
 - After five minutes, *"You are doing well. You have only 1 minute to go."*
- Do not use any other words of encouragement (or body language, to speed the participant up)
- Keep a tally of :
 - the number of times walked from one marker to the other
 - the number of times the participant stops to rest
- The walk test is for 6 minutes in total, even if the participant rests for most of the time
- When a participant stops to rest, please remind them at 1 minute intervals to continue walking if they can



OUTCOME FORM (Part 2): Section M

IMMEDIATELY AT THE END OF 6 MINUTES

- Ask the participant to stop and stand still.
- Provide a chair if necessary
- If an incomplete length has been walked, mark where the participant stopped
- Complete **Sections M3 and M6 immediately** after walk test (Bp, HR, RR and breathlessness score)
- Complete the remainder of **Section M**

The image shows two pages of the WOMAN-2 CRF form, Section M, used for data entry after a walk test. The left page (Page 38 of 43) contains instructions and tables for recording vital signs (Blood pressure, Heart rate, Respiratory rate) and walk test details (start/stop time, distance, number of markers). The right page (Page 39 of 43) contains a table for recording the number of steps walked and a 'PERCEIVED BREATHLESSNESS POST TEST' section with a Likert scale from 0 to 6. A hand is shown writing the number '6' in the 'Moderately' column.

PERCEIVED BREATHLESSNESS POST TEST	Not at all	A little	Moderately	Quite a bit	Extremely
M6. I have difficulty in breathing right now.	0	1	6		

If you have any concerns about the well-being of a participant, refer her back the treating clinician for further assessment and ongoing care


ADVERSE EVENT FORM

(1) While participant is in hospital: record any untoward medical event that occurs **up to 42 days** after randomisation and is **NOT** collected on the outcome form

(2) After participant has been discharged from hospital: record any untoward medical event, which **develops up to 42 days** after randomisation (including those listed on the outcome forms)

- Record any Adverse Event immediately when it occurs (see Protocol for definition) on the Adverse Event CRF
- Complete all columns of each row
- Column B: SERIOUSNESS** - if any Adverse Event fulfils one or more of the 'seriousness' criteria, a Serious Adverse Event form (found in Investigator Study File, section 4) must also be completed

All adverse events must be uploaded to the trial database **within 24 hours of occurrence**

 SCREENING ID
NUMBER

ADVERSE EVENTS

Use this form to record any Adverse Event reported (and not already collected as an outcome). See Protocol section 3.15 and guidance in the ISF

A. IS THE EVENT DUE TO PROGRESSION OF UNDERLYING ILLNESS?	B. SERIOUSNESS	C. RELATIONSHIP TO TRIAL INTERVENTION (causality)	D. IF NOT SUSPECTED (2) AT C, POSSIBLE ALTERNATIVE CAUSE:	E. OUTCOME*					
1. Yes 2. No	1. Non-serious 2. Serious 3. Patient died 4. Involved or prolonged in-patient hospitalisation 5. Results in persistent or significant disability/incapacity 6. Life-threatening 7. Other, medically important	1. Suspected to be related – if yes, provide reason why 2. Not suspected to be related	1. Basic disease/pre-existing condition 2. Intercurrent disease 3. Concomitant medication 4. Non-drug therapy/intervention 5. Prior to randomisation 6. Other non-drug cause, specify	1. Recovered 2. Recovered with sequelae 3. Condition improving 4. Condition still present and unchanged 5. Condition deteriorated 6. Death					
If 2-6 selected, complete SAE form									
AE ID	Adverse Event	A	B	C	D	E	Date of outcome (if ongoing, leave blank) (dd/mm/yyyy)	Date reported (dd/mm/yyyy)	Person reporting (full name)
1									
2									
3									
4									
5									
6									

*Only complete Column E and Date of outcome on final review of patient/event

Additional pages available in the Investigator Site File if needed

ALERT CARD

- All participants should be given an **ALERT CARD at discharge** which contains information on who to contact if they develop any problems

PRINCIPAL INVESTIGATOR: Before discharge please fill in the details below and to the right, and then give this card to the woman or her relative.	
Name of participant	
Randomisation number	
Date of randomisation	


THIS WOMAN WAS RANDOMISED INTO THE WOMAN-2 TRIAL. Please inform the Doctor or trial team member named below if she develops any medical problems within six weeks of date of randomisation.	
Doctor's name	
Telephone	
Trial team contact	
Telephone	
Hospital	
Address	

The trial is sponsored and coordinated by a team at the University of London

Clinical Trials Unit,
London School of Hygiene & Tropical Medicine,
Keppel Street, London WC1E 7HT, UK

WOMAN2@LSHTM.AC.UK

Protocol number ISRCTN62396133
Version 1.1 : Date 30 April 2018

ALERT CARD	
-------------------	---

Please keep this card with you and show to anyone giving you medical treatment.

If you require any medical treatment within six weeks of having your baby, the doctor named overleaf must be informed.

GENERAL GUIDANCE ON COMPLETING THE CRF BOOKLET

- All data contained in the CRF booklet must be recorded in the medical records
 - If trial data is *not* available in the medical records but has been obtained by speaking with the trial participant or the clinical team, record this in the medical records if allowed.
 - Otherwise, record this data in the WOMAN-2 communication logbook
- CRF completion and database entry can be delegated to a trained trial team member by the Principal Investigator (PI). The PI retains overall responsibility
- The PI should review and sign each **completed** CRF booklet

woman2
WOMAN-2: COMMUNICATION LOGBOOK

Principal Investigator's Name
Full Hospital Name
Site ID

This logbook consists of two sections:
SECTION 1: (pages 1 - 20) is to record key participant information
SECTION 2: (pages 21 - 58) is to record general trial information

Start a new Logbook when one section has been fully completed.
File completed logbooks in the Investigator Site File.

IF FOUND, PLEASE RETURN TO:
Book Number:

woman2
SCREENING ID NUMBER

PRINCIPAL INVESTIGATOR CERTIFICATION
Please review CRF Booklet and complete below once all data has been entered

I certify, as Principal Investigator, that all information present in this CRF booklet accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified

a) PI Full Name	b) PI Signature	c) Date
-----------------	-----------------	---------

GENERAL GUIDANCE ON COMPLETING THE CRF BOOKLET

- Each page in the CRF booklet has guidance for completion. Review this guidance carefully
- Use black or blue ink pen with clear, legible handwriting throughout
- Ensure all applicable fields have been completed

IF YOU ENTER AN INCORRECT VALUE ON THE FORM:

- Do NOT use correction fluid
- Cross out the incorrect value so it is still visible
- Enter the correct value alongside
- Date and initial and provide a reason for **each** change

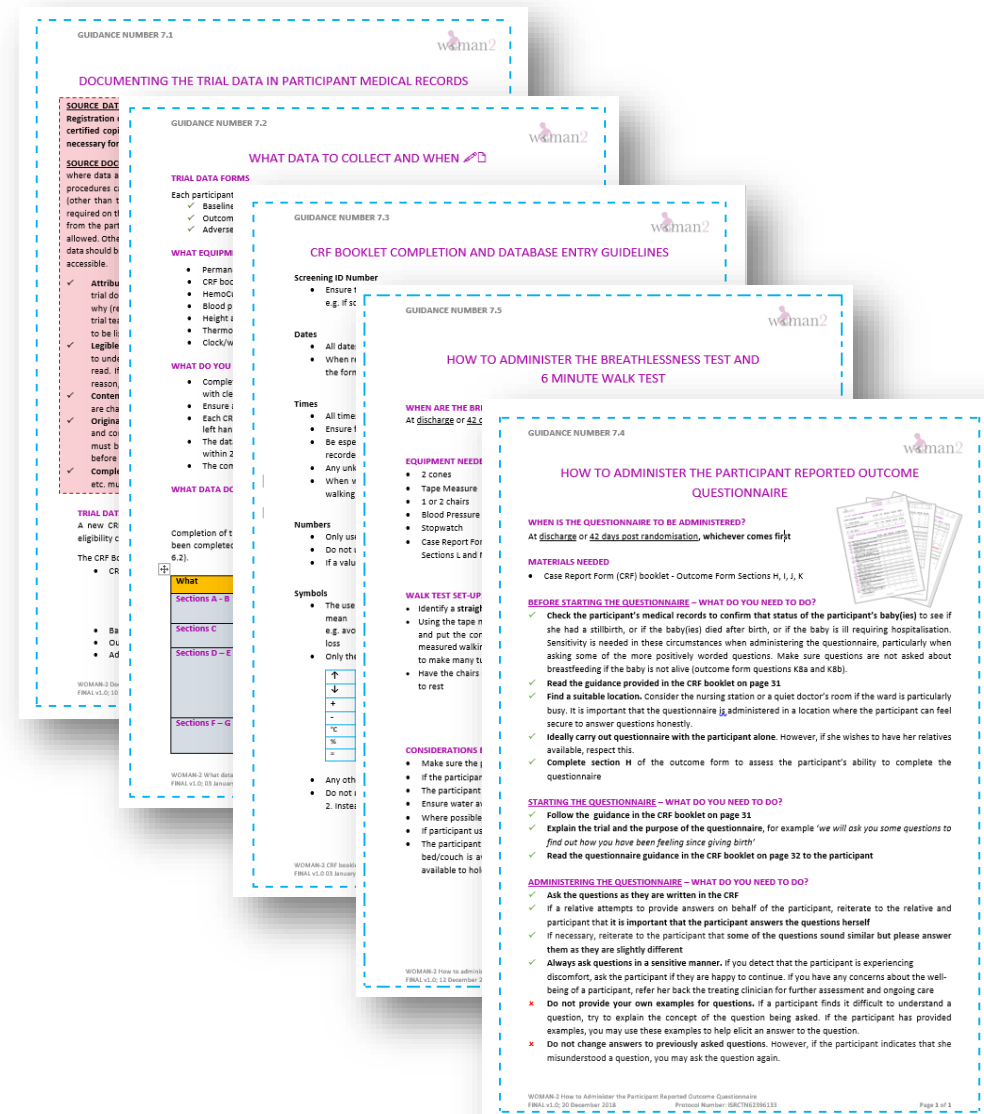
The image shows a page from a CRF booklet. At the top right, there is a 'SCREENING ID NUMBER' field with a grid for entering digits. Below this, the page is divided into two main sections: 'BASELINE FORM' and 'GUIDANCE PAGE'. The 'GUIDANCE PAGE' contains instructions: 'QUESTIONS 1 – 26 MUST BE COMPLETED BEFORE RANDOMISATION', 'QUESTIONS 27 – 34 MUST BE COMPLETED AT RANDOMISATION', and 'QUESTIONS 35 – 60 SHOULD BE COMPLETED BEFORE RANDOMISATION IF TIME ALLOWS, OTHERWISE COMPLETE AS SOON AS POSSIBLE'. Below the instructions, there are two questions: 'Q8a Provide haemoglobin level in g/dL. Q8b Provide the packed cell volume in % – only ONE field is required. Haemoglobin/PCV test must be done on arrival to hospital in active labour.' The main body of the page is 'SECTION B – MEASUREMENTS', which contains two conversion charts: 'Weight Conversion Chart' and 'Height Conversion Chart'. Each chart has columns for 'Imperial' and 'Metric' units. Below the charts, there are instructions: 'Record height in metres', 'Record weight in kilograms', 'Use conversion tables provided above if needed. N.B If weight is above that on scale, determine metric amount by adding together component parts e.g. for 20 stone, add kilogram values for 15 and 5 stone', and 'If woman cannot be weighed for clinical reasons, use best estimates'.

A close-up of a form field labeled 'Hospital code (in your study file)'. The original handwritten value '121' is crossed out with a diagonal line. Next to it, the corrected value '122' is written. To the right of the correction, there is a handwritten note: 'DP 6/12/18 Correction - error on entry'.

FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 7:

- 7.1 - Documenting trial data in participant medical records
- 7.2 - What data to collect and when
- 7.3 - CRF completion and database entry guidelines
- 7.4 - How to administer the Participant Reported Outcome Questionnaire
- 7.5 - How to administer the breathlessness test and 6 minute walk test





Clinical Trials Unit
London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

Tel: +44(0)20 7299 4684
Email: woman2@Lshtm.ac.uk
Website: woman2.Lshtm.ac.uk



LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE

