



INFORMATION AND OBTAINING CONSENT

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

PRESENTATION OVERVIEW

- What is informed consent?
- What is capacity to consent?
- What is valid consent?
- Consent in the WOMAN-2 trial:
 - Giving prior information about the trial to the woman and her family
 - Eligibility
 - Fully informed consent
 - Verbal agreement
 - Tips for completing the consent form and common consent form completion errors

WHAT IS INFORMED CONSENT?

- Informed consent is based on respect for the individual and in particular the individual's autonomy/capacity and right to define his or her own goals and make choices designed to achieve those goals for his/her own life
- Informed consent in research means **more than simply obtaining the signature** of the potential research participant *on a consent form*
- **It is a process that involves:**
 - conveying accurate and relevant information about the study and its purpose
 - disclosing known risks, benefits, alternatives and procedures
 - answering questions
 - enabling the potential participant to make an informed decision about whether to participate

WHAT IS VALID INFORMED CONSENT?

In order for consent to be valid it should be based on the following 6 critical elements:

- 1. Full capacity:** The participant must have the capacity to begin the informed consent process
- 2. Fully informed:** The research team must disclose all relevant information to the potential participant. The minimum information for a valid informed consent is the approved version of the Participant Information Sheet and Consent form
- 3. Understanding:** The participant must comprehend the information. The research team must evaluate the potential participant's ability to understand the proposed intervention in the study
- 4. Agree:** The participant must agree to the proposed intervention in the research study
- 5. Voluntary:** The participant's agreement must be voluntary and free from coercion
- 6. Freedom to withdraw:** Participants can withdraw consent at any time

Consider if this can be achieved if the women is in pain and/or due to give birth imminently


WHAT IS CAPACITY TO CONSENT?

- **Capable adult:** Adults have the capacity to consent when they:
 - possess sufficient mental capability to understand the information provided
 - appreciate how it is relevant to their circumstances
 - are able to make a reasoned decision about whether or not to participate in a particular study (bearing in mind the need for urgent treatment in the critical situation)
- **Minor:** In some countries those under 18 years of age do not have the legal capacity to provide their own consent. In such cases, a guardian must be present to witness the consent process and countersign the consent form
- **Emancipated adults:** In some countries those 14 years and above with responsibility for their own household are considered to be emancipated adults and can consent for themselves
- **Who can assess capacity?:** The treating clinician can assess the woman's capacity to give fully informed consent

CONSENT IN THE WOMAN-2 TRIAL

A woman's capacity to consent may be impaired due to analgesia, pain, other medication or the urgency of the situation.

- The consent procedure for WOMAN-2 can be adapted depending on the clinical situation and the capacity of each woman
- Clinical assessment of capacity to consent is needed
- Permission from woman's treating clinician is needed to approach eligible women
- Only those trial team members who have been trained on the consent procedure and delegated this task on the *delegation of responsibility log* can obtain consent



SITE DELEGATION OF RESPONSIBILITY LOG

SITE ID NUMBER						SITE NAME	
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The persons named below are authorised by the Principal Investigator to carry out the specified duties for the WOMAN-2 trial.

NAME	JOB TITLE	SPECIFIED DUTIES <small>(please insert number codes as listed below)</small>	TRAINING COMPLETED? <small>(Y/N)</small>	SIGNATURE	PRINCIPAL INVESTIGATOR SIGNATURE & PERSONS AUTHORISED START DATE	PERSONS END DATE
					SIGN: DATE:	
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Key Delegated Study Task Codes:

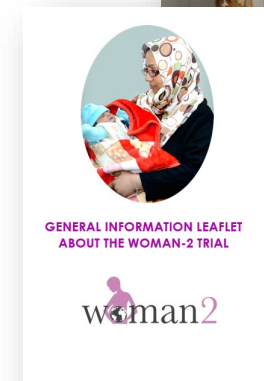
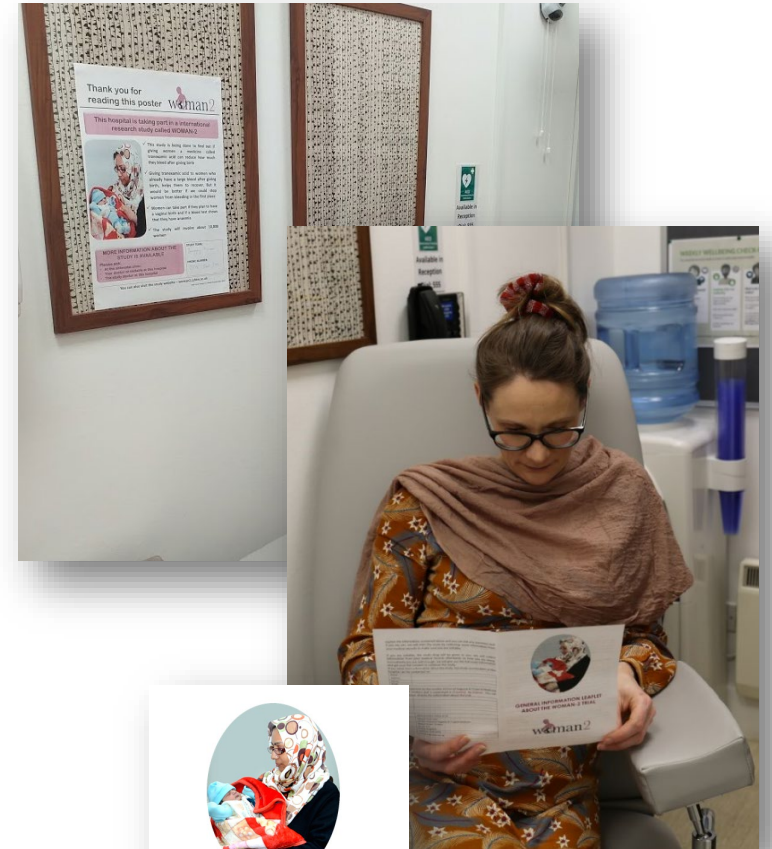
1. Obtain informed consent	7. Data entry into database
2. Eligibility assessment	8. Data query completion
3. Randomisation	9. Drug accountability
4. Baseline form completion	10. Source data
5. Outcome form completion	11. Update/maintain study documents
6. Patient questionnaire and walk test	

Other - insert details and number:

If this is your last blank copy please re-order immediately or photocopy before use. Electronic copies are stored on the flash drive in the Investigator Site file.

GIVING PRIOR INFORMATION

- Information about the trial should be made available to pregnant women and their families where possible:
 - Wall Posters
 - Brief information leaflets
- **Please make these available at antenatal clinics and any other clinics where pregnant women attend.**
 - Information is also available on the trial website (woman2.lshtm.ac.uk)

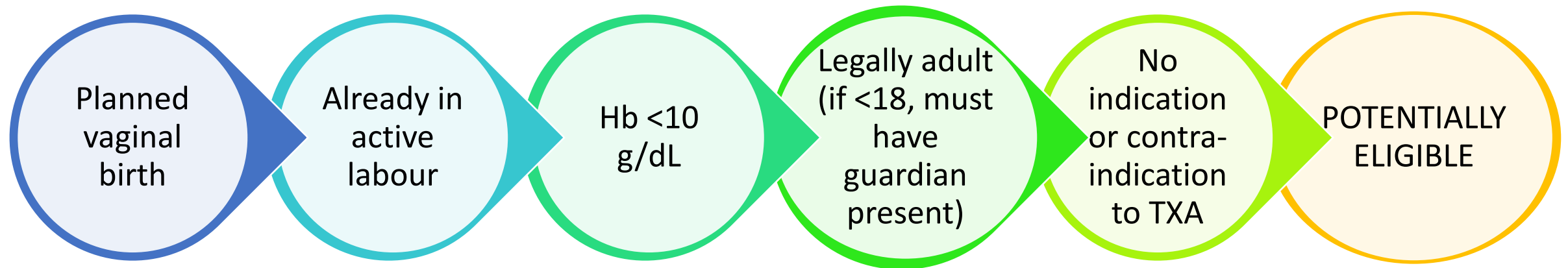


If a woman indicates that she does not want to be considered for inclusion in the trial, please respect her wishes and document this clearly in her medical records

ELIGIBILITY

After a woman has been admitted to hospital in active labour, an **initial assessment of eligibility** should be carried out

Review the woman's medical records and check the woman has/is:



If eligible, follow appropriate consent procedure

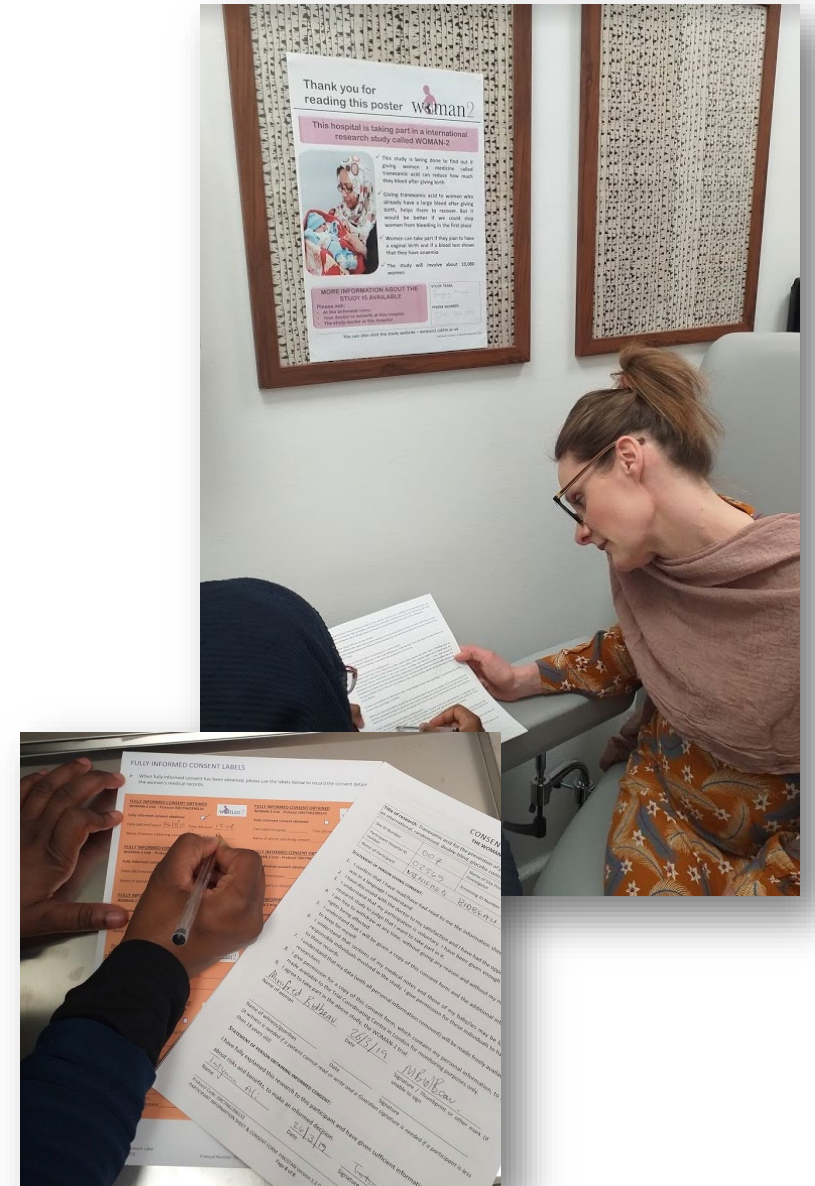
FULLY INFORMED CONSENT

If woman is judged to have capacity to consent:

- Give the woman the participant information sheet and discuss the trial with her in a language she understands
- If she agrees to take part, her written consent must be obtained using the WOMAN-2 Consent Form

NOTE:

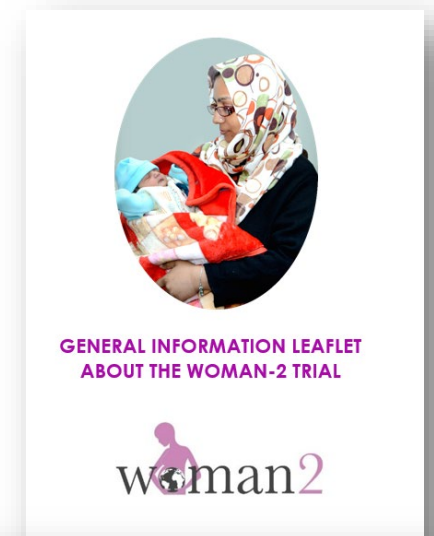
- *If woman is <18 years old, guardian should be present*
 - *If woman is unable to read and write, impartial witness should be present*
 - *In Uganda, those 14 years and older are emancipated adults and can consent for themselves*
- Document the consent process in the woman's medical records. WOMAN-2 labels are available



VERBAL AGREEMENT

If woman does not have full capacity to consent:

- If willing, give brief information and obtain verbal agreement
 - *An impartial witness must be present (i.e. not named on the Delegation Log)*
 - *If <18 years old, guardian should be present*
- Document the verbal agreement in medical records. WOMAN-2 labels are available
- When women regains capacity, fully informed consent should be obtained for continuing in the study
 - If a woman is discharged before fully informed consent is obtained
→ continue to seek consent up to 42 days post randomisation (i.e. until the period for Adverse Event Reporting ends)
- Record all attempts to assess capacity and obtain fully informed consent in the woman's medical records



VERBAL AGREEMENT LABELS

➤ When verbal agreement to participate in the trial has been obtained, please use the labels below to document the details in the woman's medical records

VERBAL AGREEMENT OBTAINED
WOMAN-2 trial - Protocol ISRCTN62396133

Verbal agreement obtained

This woman has provided verbal agreement to participate in the WOMAN-2 trial. This is to certify that:

- In the view of the responsible clinician, this woman is unable to give fully informed consent for the WOMAN-2 trial
- Information to the level of her capacity has been provided
- This verbal agreement has been obtained in the presence of an impartial witness

Impartial witness present:
Name: _____ Date: _____ Time (hh:mm) _____

Trial staff who obtained verbal agreement:
Name: _____ Date: _____ Time (hh:mm) _____

Where verbal agreement is obtained, the woman has regained capacity to consent to ongoing participation in the trial

VERBAL AGREEMENT OBTAINED
WOMAN-2 trial - Protocol ISRCTN62396133

A hand is shown holding a black pen with a pink decorative swirl, writing on the form. The "woman2" logo is visible in the top right and bottom right corners of the form.

CONSENT

If woman is <18 years old:

- **Consent must be witnessed by a guardian.** A guardian is an appropriate responsible adult (e.g. her parents, husband, partner or other family member) who must also counter sign the form

If woman is unable to read or write:

- Explain trial in the presence of an **impartial witness** who must counter sign the consent form.
 - **an impartial witness** cannot be a trial team member and must be able to read and write. An impartial witness is someone independent from the trial, i.e. not named on the Delegation Log. E.g. hospital staff member, or an adult accompanying the woman at hospital
- Obtain mark (e.g. thumbprint) in place of a signature if woman is unable to write.

Documenting consent:

- A copy of PIS and signed ICF to should be given to the woman,
- A copy should be put in the medical records
- The **original should be stored in the Investigator Site File (ISF), box file 2**

Fully informed consent, or verbal agreement, must be obtained before baseline data collection and randomisation

TIPS FOR COMPLETING THE CONSENT FORM

The top section (Header) should be completed by the trial team member obtaining consent

- The Screening ID Number is the number assigned to the woman at Initial Assessment of Eligibility. The number comprises the Site ID Number and the Participant Screening Number

Ensure that the woman understand all consent statements

CONSENT FORM THE WOMAN-2 TRIAL

Title of research: Tranexamic acid for the prevention of postpartum bleeding in women with anaemia: an international, randomised, double-blind, placebo controlled trial

Site ID Number	007	Name of Site Principal Investigator	Charlote Mungwa
Participant Hospital ID number	02569	Screening ID Number	007-01001
Name of Participant	MUNIFRED BIDBEAU		

STATEMENT OF PERSON GIVING CONSENT:

1. I confirm that I have read/have had read to me the information sheet for the above study and it was in a language I understand.
2. I have discussed with the doctor to my satisfaction and I have had the opportunity to ask questions.
3. I understand that my participation is voluntary. I have been given enough information about the research study to judge that I want to take part in it.
4. I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
5. I understand that I will be given a copy of this consent form and the additional information sheet to keep for myself.
6. I understand that sections of my medical notes and those of my baby/ies may be looked at by responsible individuals involved in the study. I give permission for these individuals to have access to these records.
7. I understand that my data (with all personal information removed) will be made freely available for researchers.
8. I give permission for a copy of this consent form, which contains my personal information, to be made available to the Trial Coordinating Centre in London for monitoring purposes only.
9. I agree to take part in the above study, the WOMAN-2 trial.

Munifred Bidbeau 26/3/19 MBidBeau
Name of woman Date Signature / Thumbprint or other mark (if unable to sign)

Name of witness/guardian Date Signature
(A witness is needed if a patient cannot read or write and a Guardian signature is needed if a participant is less than 18 years old)

STATEMENT OF PERSON OBTAINING INFORMED CONSENT:

I have fully explained this research to this participant and have given sufficient information, including about risks and benefits, to make an informed decision.

Tatyana Ali 26/3/19 Tatyana A
Name Date Signature

TIPS FOR COMPLETING THE CONSENT FORM

Women should add their name, date and signature or thumbprint here (if unable to write).

Where a witness/guardian is needed they must countersign the consent form here.

The trial team member obtaining consent must provide their name, date and signature here.

CONSENT FORM THE WOMAN-2 TRIAL

Title of research: Tranexamic acid for the prevention of postpartum bleeding in women with anaemia: an international, randomised, double-blind, placebo controlled trial

Site ID Number	007	Name of Site Principal Investigator	Charlotte Mungwaza
Participant Hospital ID number	02569	Screening ID Number	7 PA 20130 007-01001 error
Name of Participant	MINIFRED BIOBEAU		

STATEMENT OF PERSON GIVING CONSENT:

1. I confirm that I have read/have had read to me the information sheet for the above study and it was in a language I understand.
2. I have discussed with the doctor to my satisfaction and I have had the opportunity to ask questions.
3. I understand that my participation is voluntary. I have been given enough information about the research study to judge that I want to take part in it.
4. I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
5. I understand that I will be given a copy of this consent form and the additional information sheet to keep for myself.
6. I understand that sections of my medical notes and those of my baby/ies may be looked at by responsible individuals involved in the study. I give permission for these individuals to have access to these records.
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8. I give permission for a copy of this consent form, which contains my personal information, to be made available to the Trial Coordinating Centre in London for monitoring purposes only.
9. I agree to take part in the above study, the WOMAN-2 trial.

Minifred Bidbeau 26/3/19 M Bidbeau
Name of woman Date Signature / Thumbprint or other mark (if unable to sign)

Name of witness/guardian Date Signature
(A witness is needed if a patient cannot read or write and a Guardian signature is needed if a participant is less than 18 years old)

STATEMENT OF PERSON OBTAINING INFORMED CONSENT:

I have fully explained this research to this participant and have given sufficient information, including about risks and benefits, to make an informed decision.

Istiyana Ali 26/3/19 Istiyana A
Name Date Signature

TIPS FOR COMPLETING THE CONSENT FORM

To make a correction to the consent form:

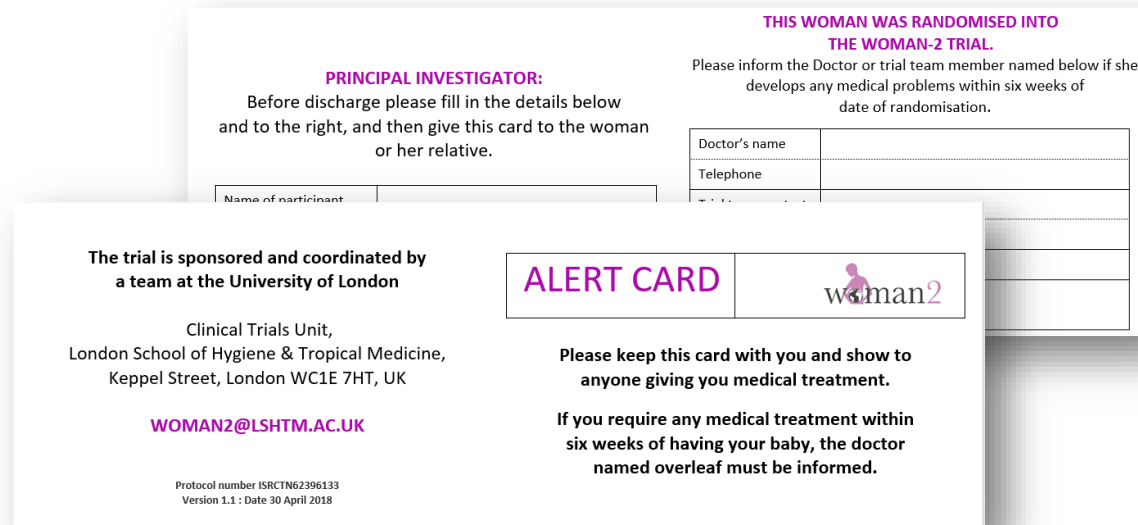
- draw a line through the error,
- write the correct information nearby,
- provide a reason for the change,
- initial and date the correction.

Screening ID Number	000-01001 7 PA 20/3/19 Type error
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WITHDRAWAL OF CONSENT

A participant is free to withdraw her consent at any time:

- Record withdrawal in medical records
- Inform CTU - email woman2@lshtm.ac.uk
- Give a WOMAN-2 Alert Card and ask her to carry it for at least 6 weeks after her entry to the trial (the date should be written inside the card)
- All data collected up to the point of withdrawal must be submitted to the trial database



The image shows two overlapping forms. The top form is a 'Principal Investigator' form with a header 'THIS WOMAN WAS RANDOMISED INTO THE WOMAN-2 TRIAL.' and instructions to fill in details before discharge. It includes a table for 'Doctor's name' and 'Telephone'. The bottom form is the 'ALERT CARD' with the WOMAN-2 logo. It contains contact information for the Clinical Trials Unit at the University of London, the email WOMAN2@LSHTM.AC.UK, and the protocol number ISRCTN62396133. It also includes instructions to keep the card and show it to medical treatment providers.

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.

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	

Name of participant

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.

FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 6.3:

- Information giving and obtaining informed consent, guidance number 6.3

The collage consists of several overlapping documents:

- WOMAN-2 Guidance Number 6.3: Information Giving and Obtaining Informed Consent** (Page 3 of 3). This document provides detailed instructions on giving prior information, obtaining informed consent (for women with and without full capacity), and consent withdrawal. It includes a table for recording consent status.
- WOMAN-2 Consent Form** (Page 3 of 3). This form includes sections for 'Obtaining Appropriate Consent' and 'Ensuring the Consent Form is Completed Correctly'. It features a 'Consent Labels and Verbal Agreement Labels' table and a 'Consent Form' section with fields for name, date, and signature.
- Common Errors When Completing the Consent Form**. A checklist of errors to avoid, such as incomplete header information, missing names/dates, and improper corrections.
- Consent Labels and Verbal Agreement Labels** table. A table with columns for 'Consent Labels and Verbal Agreement Labels' and 'Consent Labels and Verbal Agreement Labels'.
- Consent Form** section. A form with fields for 'Consent Labels and Verbal Agreement Labels' and 'Consent Form'.
- Ensuring the Consent Form is Completed Correctly** section. A section with instructions on how to complete the consent form correctly, including a table for recording consent status.



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HYGIENE
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MEDICINE

