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

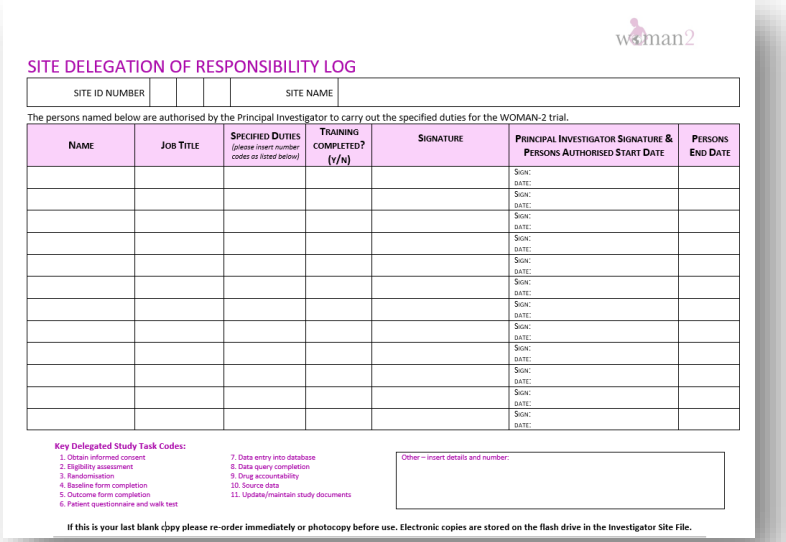
WHAT IS CAPACITY TO CONSENT?

- **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



woman2

SITE DELEGATION OF RESPONSIBILITY LOG

SITE ID NUMBER				SITE NAME	

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 (please insert number codes as listed below)	TRAINING COMPLETED? (Y/N)	SIGNATURE	PRINCIPAL INVESTIGATOR SIGNATURE & PERSONS AUTHORISED START DATE	PERSONS END DATE
					SIGN: DATE:	
					SIGN: DATE:	
					SIGN: DATE:	
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Key Delegated Study Task Codes:

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

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

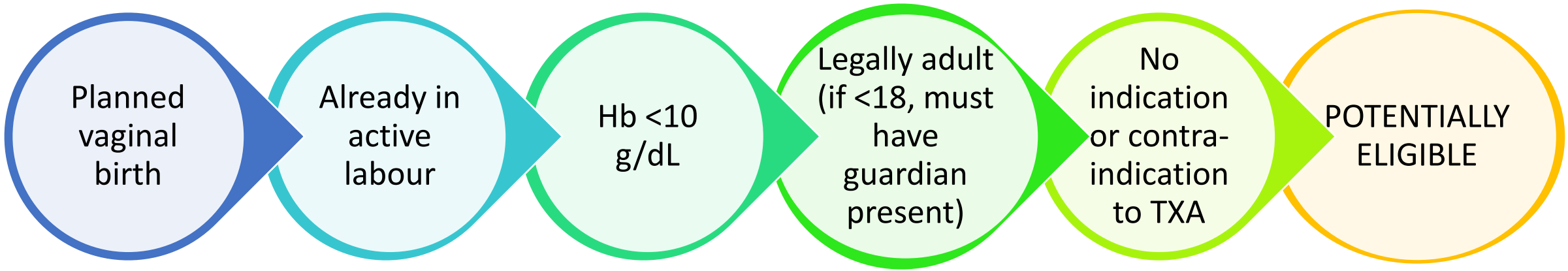
- **Please make these available at antenatal clinics and any other clinics where pregnant women attend.**
    - Information is also available on the trial website (woman2.lshtm.ac.uk)

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 women as 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 <u>capacity to consent:</u>

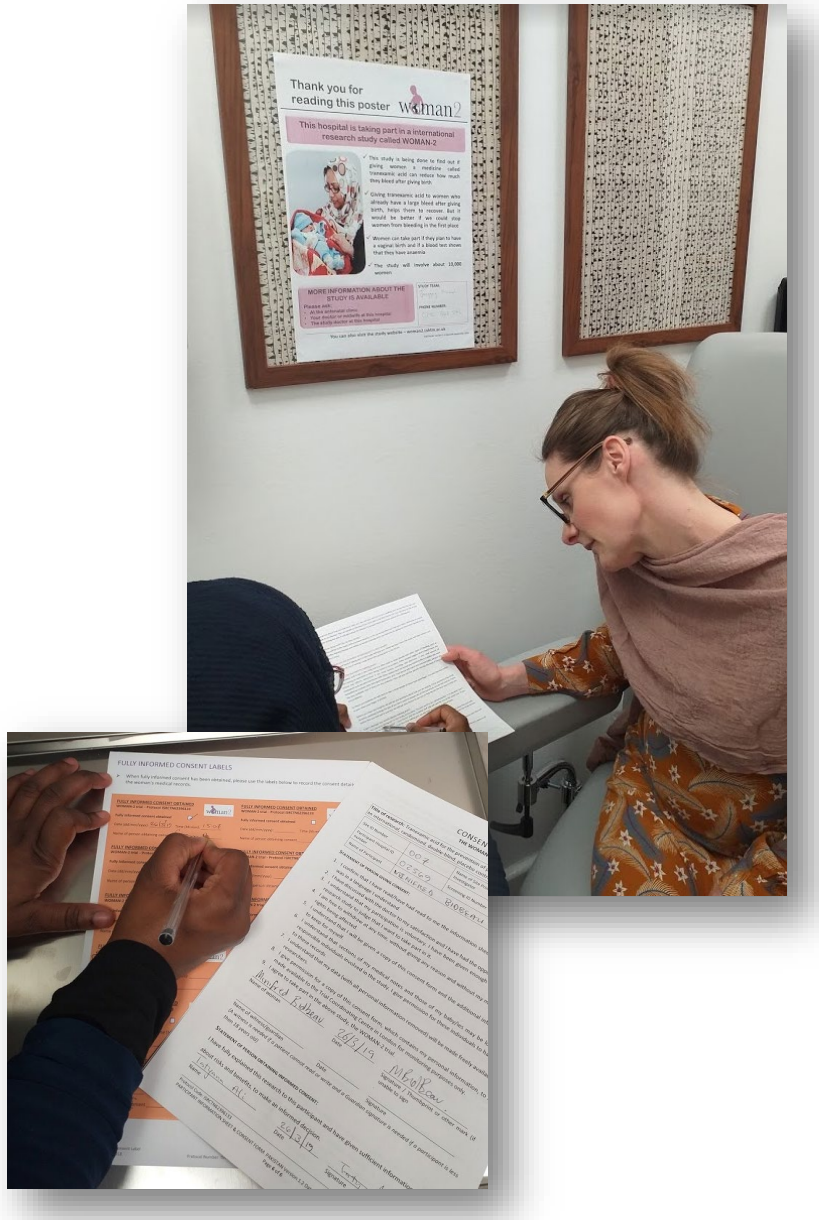
- Give the woman the participant information sheet and discuss the trial with her in a language she understands

- 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 <u>does not have full capacity to consent</u>:

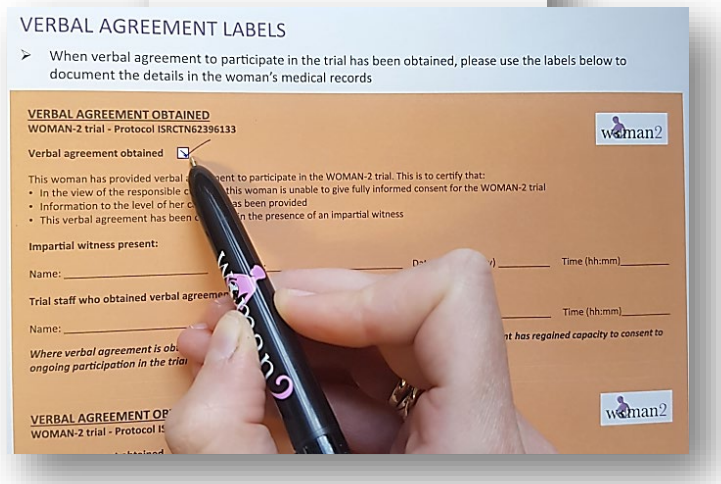
- If willing, give brief information and obtain verbal agreement
  - ➢ *An impartial witness must be present (i.e. not named on the Delegation Log)*
  - ➢ *If <18 years old, guardian should be present*

- 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



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**

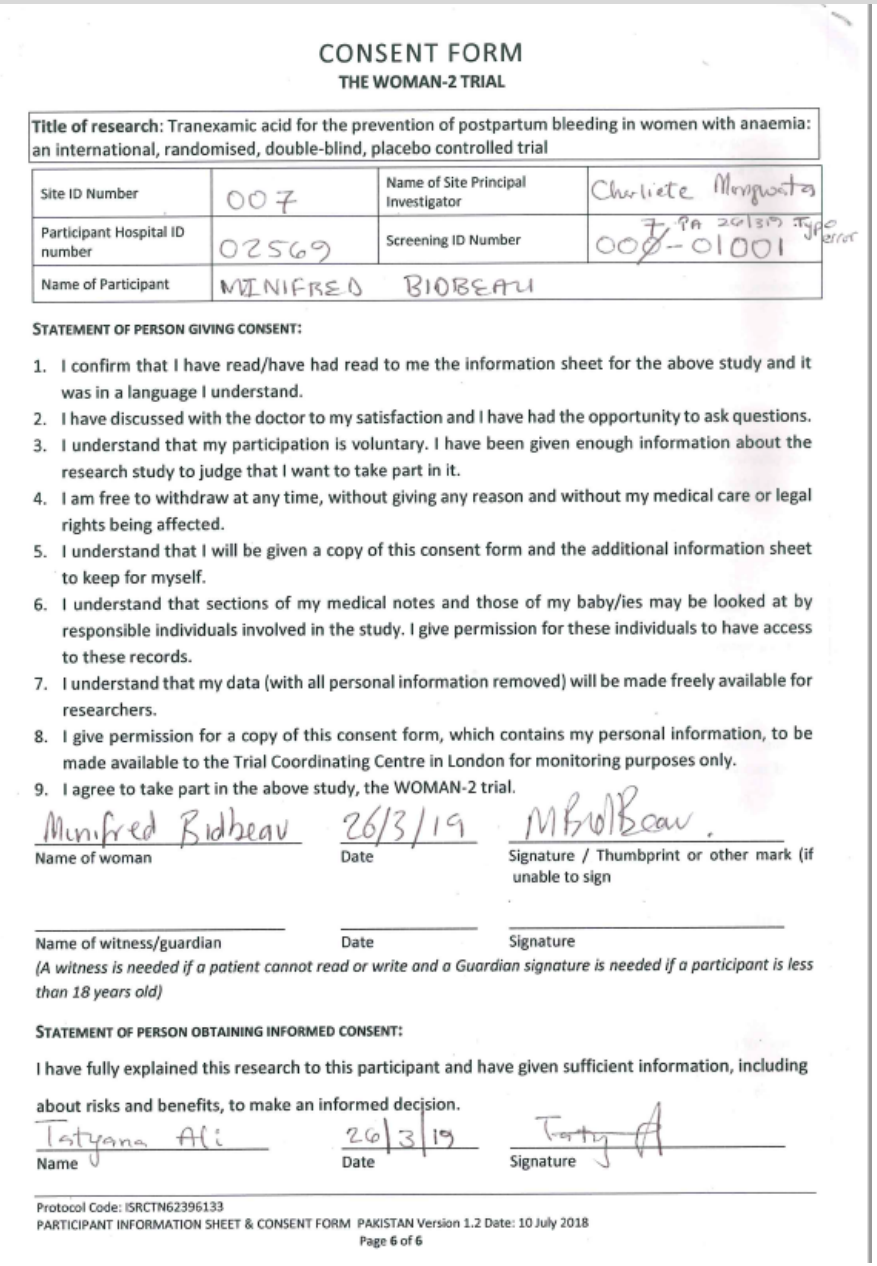
Fully informed consent, or verbal agreement, must be obtained before baseline data collection and randomisation

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	Charlotte Mongwatsa
Participant Hospital ID number	02569	Screening ID Number	007-01001
Name of Participant	MINIFRED 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.

Minifred Bidbeau — Name of woman; 26/3/19 — Date; Minifred Bidbeau. — 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 — Name; 26/3/19 — Date; Signature

Protocol Code: ISRCTN62396133

PARTICIPANT INFORMATION SHEET & CONSENT FORM PAKISTAN Version 1.2 Date: 10 July 2018

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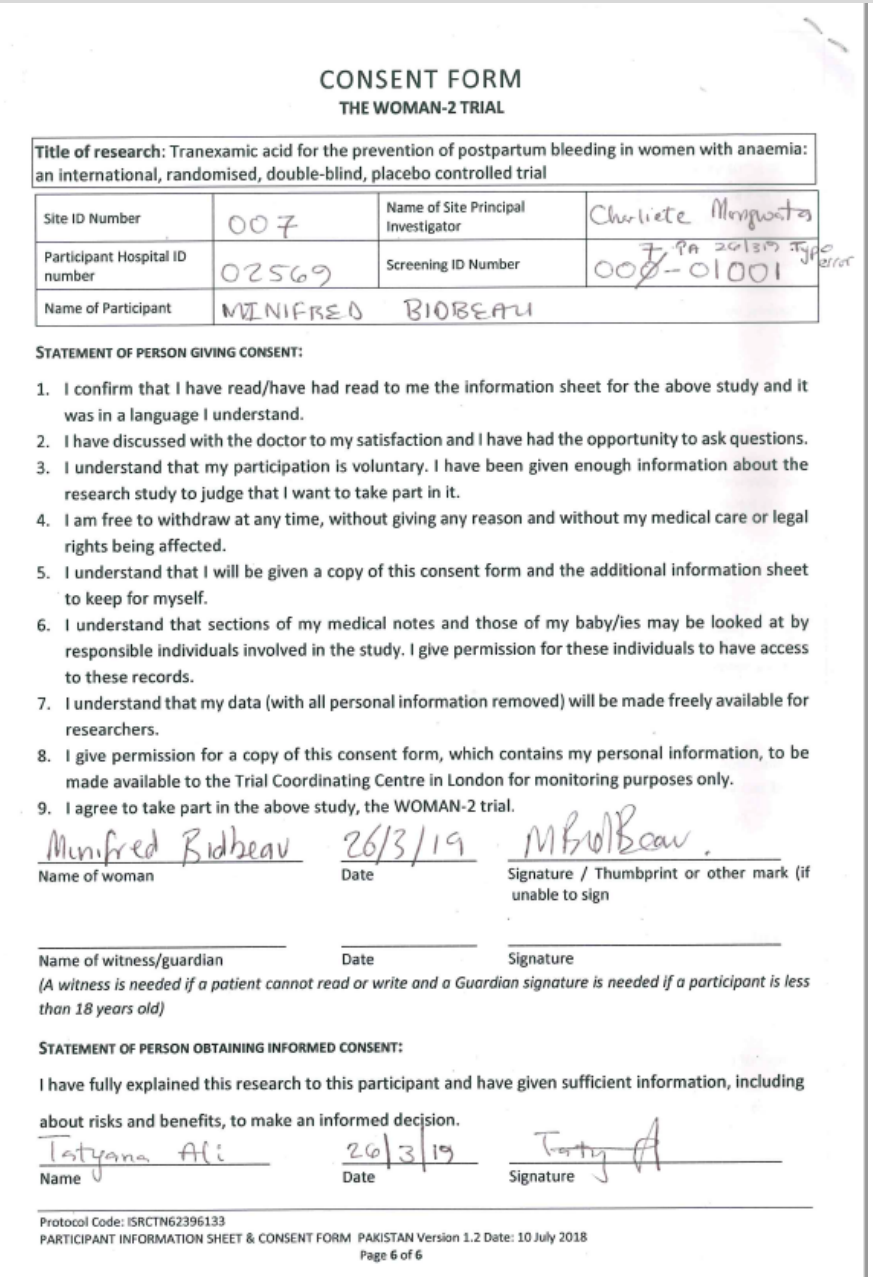
TIPS FOR COMPLETING THE CONSENT FORM

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.



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Participant Hospital ID number	02569	Screening ID Number	007-01001 PA 26/3/19 Type error
Name of Participant	MINIFRED BIDBEAU		

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TIPS FOR COMPLETING THE CONSENT FORM

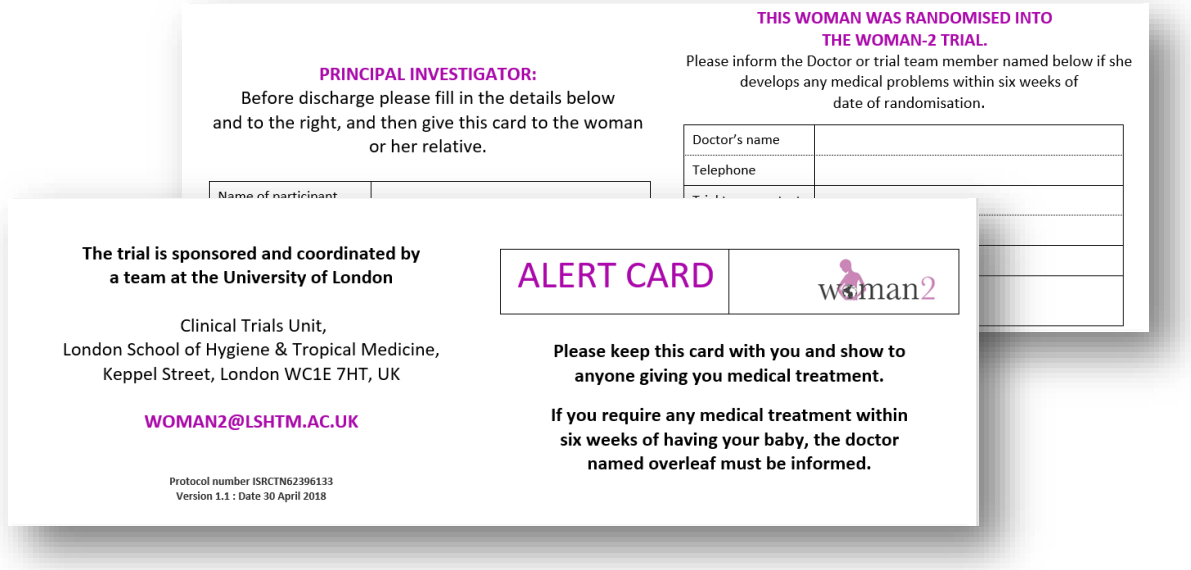
To make a correction to the consent form:

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

WITHDRAWAL OF CONSENT

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

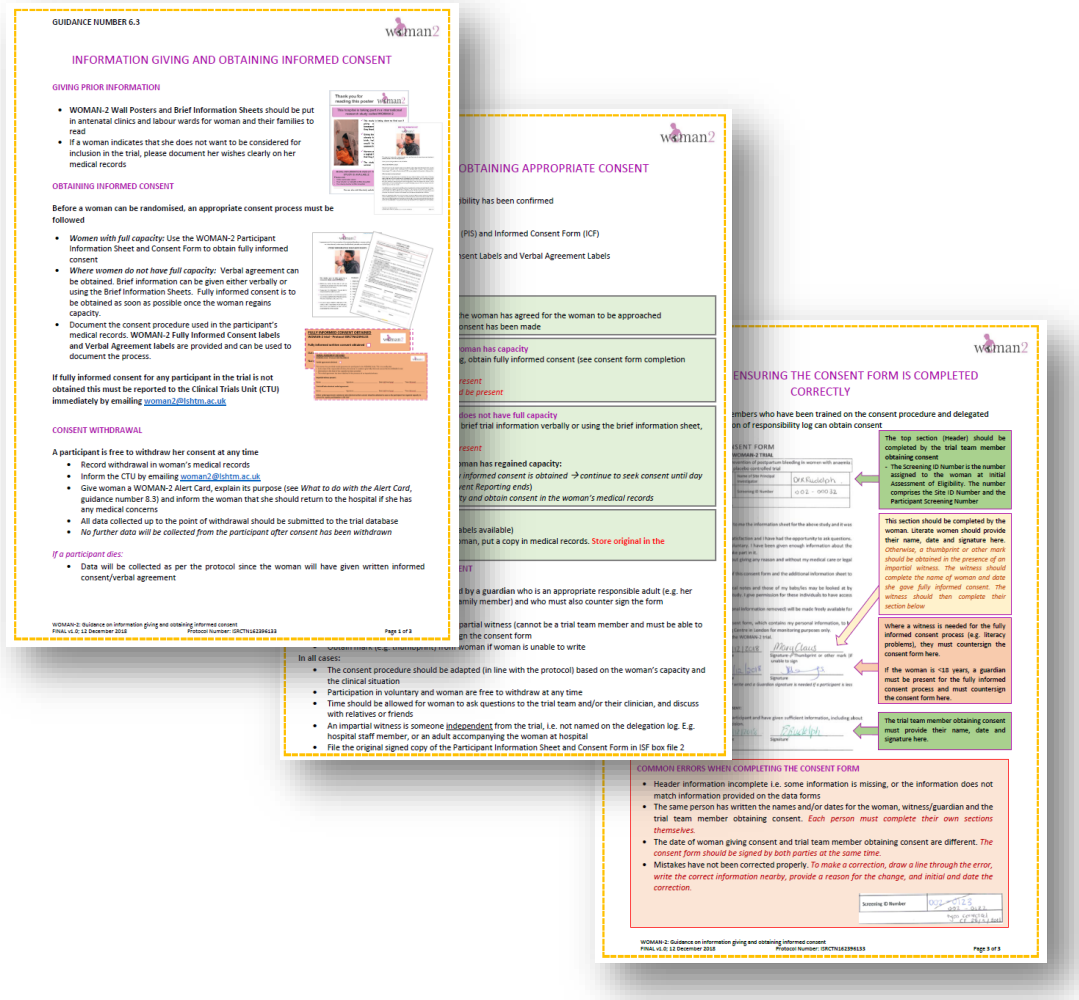
- Record withdrawal in medical records
- Inform CTU - email woman2@lshtm.ac.uk
- Give a WOMAN-2 Alert Card and ask her to carry it for at least 6 weeks after her entry to the trial (the date should be written inside the card)
- All data collected up to the point of withdrawal must be submitted to the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



FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 6.3:

- Information giving and obtaining informed consent, guidance number 6.3



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