Informed Consent

GUIDANCE SHEET 4

Written informed consent **must** be obtained using the **MAMA In-person Consent Form** (for in-person consent) or the **MAMA Remote Consent Form** (for remote consent) before a woman can be randomised to MAMA or any study procedures take place.

After screening

When a woman has been identified as eligible for the MAMA trial provide the following documents:

MAMA Participant Information Leaflet (PIL)	To provide information on the MAMA Trial.
Infant Immune Response PIL	To provide information on the optional Infant Immune Response element of the trial.
Participant Information QR Card	QR code links to the MAMA website and Participant Information Video.

If the consent discussion takes place remotely, the woman should be provided with these documents either as a physical hard copy or as an electronic copy via an email or as a digital download.

Who can take consent?

Staff who have relevant GCP training, MAMA study training (documented on the **MAMA Training Log**), and are authorised by the Principal Investigator (PI) to 'Obtain informed consent' (documented on the **Site Delegation Log**). Please check for any other relevant trust requirements for obtaining consent.

Who can give consent?

Only the woman can give consent for her participation in the trial.

Infant Immune Response Consent

There is a separate, optional section of the consent form for women to agree to be contacted about their baby to taking part in the "Infant immune response" component of the MAMA study after their baby is born. This part of the trial is described in the **Can my baby take part?** Section of the **MAMA PIL** and in more detail in the **Infant Immune Response PIL**.

This part of the study involves 3 home visits to to take blood samples when the baby is 2 months, 5 months, and 13 months of age. Women do not have to agree to their baby having blood tests in order to take part in MAMA.

When to consent?

In order to take part in MAMA, consent must be given before 28 weeks' gestation.

How to consent?

Give the woman the opportunity to consider the information, and ask questions to decide whether they would like to participate in the trial.

Women should be aware that participation is voluntary and that they may change consent at any time without giving a reason, and without this affecting the quality of their or their child's care. If they choose to discontinue the trial allocation, they will be asked to continue providing data for the study – though they may choose to withdraw from this aspect too (see **Gudance Sheet: Change of consent**).

Completion of In-Person MAMA Consent Form

- Where in-person consent is possible the **MAMA Consent Form** must be signed and dated by the woman and the healthcare professional taking consent.
- Ensure that:
    - All boxes are **initialled and completed**.
    - The writing is clearly **legible**.
    - Details have transferred through **all three copies** of the form.
- Women should **initial (not tick)** each box before signing and dating the form (do not complete in advance).
- The dates for the participant and healthcare professional signatures must be the same. Women must not be given a consent form to sign at a later date.
- Any healthcare professional signing this form must be delegated by the PI to take
- consent on the MAMA Site Delegation Log.
- Any corrections on the consent form must be made in a GCP-compliant manner (for eg do not back date any corrections)

Optional section

- Points 8, 9, and 10 on the **MAMA Consent Form**, which relate to the infant immune response element of the trial, and whether there are any long term effects of taking biologics during pregnancy, are optional and whilst we would like women to agree due to their importance, they are not mandatory for taking part in MAMA.

GUIDANCE SHEET 4

MAMA Consent Form

Please complete in black ballpoint pen

The Monoclonal Antibody Medications in inflammatory Arthritis: stopping or continuing in pregnancy (MAMA) study

Hospital name: OUH NHS Foundation Trust

Study number: 2765

		PLEASE INITIAL
1.	I confirm that I have read the Participant Information Leaflet (version 1.0, dated 19/09/2024) for the above study. I have had the opportunity to consider the information, ask questions, and have these answered satisfactorily.	GC
2.	I understand that my participation is voluntary and that I am free to withdraw from any aspect of the study at any time without giving any reason, without my medical care or legal rights or those of my baby being affected.	GC
3.	I understand that relevant sections of mine and my baby's health records and data collected during the study may be looked at by the research team, and individuals from University of Oxford, University of Manchester, the Medicines and Healthcare products Regulatory Agency (MHRA), the MAMA Coordinating Centre or the host Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access these records.	GC
4.	I understand that both mine and my baby's personal identifiable information will be collected, stored and used by the MAMA Coordinating Centre at the University of Oxford to enable follow-up, for sending questionnaires, and to send study results and will be retained as explained in the Participant Information Leaflet.	GC
5.	I agree that personal identifiable information including my name and email address can be shared with the digital app supplier based at University of Oxford, Oxford Research Software Engineering Group (OxRSE) for the purposes of the MAMA app. I understand that any information will be treated confidentially.	GC
6.	I agree to my General Practitioner (GP) and rheumatologist being informed of my participation in this study.	GC
7.	I agree to take part in this study.	GC

THE FOLLOWING ARE OPTIONAL		PLEASE INITIAL
	They relate to measuring infant immune response and whether there are any long term effects of taking biologics during pregnancy	
8.	I agree to be contacted by researchers from the MAMA Coordinating Centre about my baby to taking part in the "infant immune response" component of the MAMA study. I understand that agreeing to be contacted does not oblige me or my baby to participate in this part of the study.	GC
9.	I agree that the MAMA coordinating centre can keep mine and my child's personal identifying information and share them with external organisations such as NHS England or equivalent UK NHS bodies, the Department for Education and the Office for National Statistics in order to access routinely collected information about my child's health or school attainment, and special educational needs via databases such as the National Pupil Database at school age.	
10.	I agree to researcher teams at the University of Oxford, and the University of Manchester keeping and using my personal details to contact me so that they can invite me and my child to take part in future follow up studies looking at the long term effects of biologics. I understand that I can decline for me and my child to take part in a follow up study if I do not want them to. Future studies will require additional ethical approval.	GC

Full name (CAPITALS) GEMMA COLLIER	Signature GCollier	16/04/25
Name of person taking consent ROSE SMITH	Signature RSmith	16/04/25

The MAMA Coordinating Centre
NPEU Clinical Trials Unit, National Perinatal Epidemiology Unit (NPEU)
Nuffield Department of Population Health, University of Oxford,
Old Road Campus, Oxford OX3 7LF
T: 01865 743859 E: mama@npeu.ox.ac.uk W: www.npeu.ox.ac.uk/mama

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When completed: 1 copy to MAMA coordinating centre; 1 copy for participant; 1 for Site File (original); 1 copy in participant's medical notes

Write the name of hospital clearly here.

After consent, obtain a study number from the Randomisation website and write study number here.

Boxes must be initialled and not ticked.

This section is optional and is not mandatory for participipants' to complete.This section can be left blank

The participant providing consent and the health professional taking consent must sign the consent form and date the form on the same date.

GUIDANCE SHEET 4

Remote consent – MAMA Remote Consent Form

Consent may be obtained remotely (via telephone or video call) in order to facilitate the extended time that might be required for a woman to decide to participate, to give potentially eligible women identified outside the recruiting site e.g. in a rheumatology clinic an opportunity to be in the trial, and to maximise the ease of recruitment for the women who may only visit the maternal medicine service infrequently. This will also facilitate consent for women who may require support for consent, such as language interpretation, or for those with visual impairment.

Remote consent should be of the same standard as in-person consent as outlined above.

ID checks

- The health professional taking remote consent must complete the identity checks and confirm the woman's name and address.
- It must be documented in the woman's medical notes that the woman consented to the ID checks during the consent process.

Remote consent form completion

- Complete the consent form in **BLOCK CAPITALS**.
- The health care professional must ensure that the participant has verbally agreed to each consent item **by initialling the boxes with their own initials** (not the woman's initials).
- Ensure that:
    - All boxes are **initialled and completed**.
    - The writing is clearly **legible**.
    - Details have transferred through **all three copies** of the form.
    - Each box has been initialled (not ticked) before signing and dating the form (do not complete in advance).
- Any healthcare professional signing this form must be delegated by the PI to take consent on the **MAMA Site Delegation Log**
- Any corrections on the consent form must be made in a GCP-compliant manner (for eg do not back date any corrections)

Optional section

- Points 8, 9, and 10 on the **MAMA Consent Form**, which relate to the infant immune response element of the trial, and whether there are any long term effects of taking biologics during pregnancy, are optional and whilst we would like women to agree due to their importance, they are not mandatory for taking part in MAMA.

GUIDANCE SHEET 4

MAMA Remote Consent Form

Please complete in black ballpoint pen

The Monoclonal Antibody Medications in inflammatory Arthritis: stopping or continuing in pregnancy (MAMA) study

Hospital name: OUH Foundation Trust **Study number:** 2765

Participant's first name (BLOCK CAPITALS): GEMMA

Participant's last name (BLOCK CAPITALS): COLLIER

Healthcare Professional Declaration: I confirm that I have undertaken participant identity checks (including name, date of birth and address) and I have confirmed the identity of the participant.

Name of health professional taking consent	Signature	Date
ROSE SMITH	RSmith	16 / 04 / 25

		PLEASE INITIAL
1.	I confirm that I have read the Participant Information Leaflet (version 1.0, dated 19/09/2024) for the above study. I have had the opportunity to consider the information, ask questions, and have these answered satisfactorily.	GC
2.	I understand that my participation is voluntary and that I am free to withdraw from any aspect of the study at any time without giving any reason, without my medical care or legal rights or those of my baby being affected.	GC
3.	I understand that relevant sections of mine and my baby's health records and data collected during the study may be looked at by the research team, and individuals from University of Oxford, University of Manchester, the Medicines and Healthcare products Regulatory Agency (MHRA), the MAMA Coordinating Centre or the host Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access these records.	GC
4.	I understand that both mine and my baby's personal identifiable information will be collected, stored and used by the MAMA Coordinating Centre at the University of Oxford to enable follow-up, for sending questionnaires, and to send study results and will be retained as explained in the Participant Information Leaflet.	GC
5.	I agree that personal identifiable information including my name and email address can be shared with the digital app supplier based at University of Oxford, Oxford Research Software Engineering Group (OxRSE) for the purposes of the MAMA app. I understand that any information will be treated confidentially.	GC
6.	I agree to my General Practitioner (GP) and rheumatologist being informed of my participation in this study.	GC
7.	I agree to take part in this study.	GC

THE FOLLOWING ARE OPTIONAL		PLEASE INITIAL
	They relate to measuring infant immune response and whether there are any long term effects of taking biologics during pregnancy	
8.	I agree to be contacted by researchers from the MAMA Coordinating Centre about my baby to taking part in the "infant immune response" component of the MAMA study. I understand that agreeing to be contacted does not oblige me or my baby to participate in this part of the study.	
9.	I agree that the MAMA coordinating centre can keep mine and my child's personal identifying information and share them with external organisations such as NHS England or equivalent UK NHS bodies, the Department for Education and the Office for National Statistics in order to access routinely collected information about my child's health or school attainment, and special educational needs via databases such as the National Pupil Database at school age.	GC
10.	I agree to researcher teams at the University of Oxford, and the University of Manchester' keeping and using my personal details to contact me so that they can invite me and my child to take part in future follow up studies looking at the long term effects of biologics. I understand that I can decline for me and my child to take part in a follow up study if I do not want them to. Future studies will require additional ethical approval.	

Healthcare Professional Declaration: I confirm that I have read all of the statements above to the participant and that the participant has verbally confirmed their consent to take part in the study. I have indicated this by providing my initials next to the relevant statements where the participant has provided their consent.

Name of health professional taking consent	Signature	Date
ROSE SMITH	RSmith	16 / 04 / 25

The MAMA Coordinating Centre

NPEU Clinical Trials Unit, National Perinatal Epidemiology Unit (NPEU)
Nuffield Department of Population Health, University of Oxford,
Old Road Campus, Oxford OX3 7LF

T: 01865 743859 E: mama@npeu.ox.ac.uk W: www.npeu.ox.ac.uk/mama

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When completed: 1 copy to MAMA coordinating centre; 1 copy for participant; 1 for Site File (original); 1 copy in participant's medical notes

Write the name of hospital clearly here. After consent, obtain a study number from the Randomisation website and write study number here.

Healthcare professional should sign here to confirm they have undertaken participant identity checks and confirm the identity of the participant.

Boxes must be initialled using participant's initial and not ticked.

This section is optional and is not mandatory for women to comple. This section can be left blank.

Only the health professional taking consent must sign the consent form. Countersignature from the participant is not required.

GUIDANCE SHEET 4

Filing Documentation

After randomisation please add the participant study ID to the consent form.

There will be three carbon copies of the completed consent form.

- The original paper copy should be retained in the site folder and an electronic copy saved to the electronic Investigator Site File (eISF).
- One copy should be provided to the woman, either as hard copy or electronically via email.
- One copy should be filed in the woman's medical notes.

Once complete, a clear scanned copy of the original should be sent to the MAMA Coordinating Centre via the **NPEU Upload Tool**. Training and access to this system will be provided to sites as required.

Change of Consent

If a participant wishes to change their consent to any or all parts of data collection for the trial, this should be recorded on the **MAMA Change of Consent Form**. See **Guidance Sheet: Change of Consent**.

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.