# Randomisation

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Randomisation should occur as soon as possible after consent is obtained. This is to ensure that women do not become ineligible before they are randomised.

Prior to randomisation please ensure that:

- Eligibility has been confirmed by a delegated individual as recorded on the **MAMA Site Delegation Log** (see **Guidance Sheet – Screening and Eligibility**).
- Eligibility has been documented in the woman's medical records
- Written informed consent has been obtained using the **MAMA Consent Form** or the **MAMA Remote Consent Form** (see **Guidance Sheet – Informed Consent**).

Women will be randomised to either:

**The continuing group**
Women in this group will continue taking their biologic thoughout pregnancy.

**OR**

**The stopping group**
Women in this group will stop their biologics before the third trimester (28 weeks) of pregnancy, and restart no earlier than 2 weeks post-pregnancy.

**For both groups, all other aspects of clinical care are determined by the treating clinical team.**

## Who can randomise?

Randomisation can be completed by a member of staff who:

- has documented completion of MAMA randomisation training

AND

- has been authorised to undertake randomisation by the Principal Investigator (recorded on **MAMA Delegation Log**)

## Where to find the randomisation website?

- From a device with internet access, visit https://rct.npeu.ox.ac.uk and select the MAMA icon
- Altneratively, go to the MAMA website (https://www.npeu.ox.ac.uk/mama) and click 'Randomise to MAMA'.
- Login to the randomisation website using your individual login details.
  - Username = *ForenameSurname* (or you can use the email address associated with your account)
  - Password = You'll be asked to set a password when you first login. If you're unsure what your password is, select 'Forgot Password?' on the homepage
- Contact MAMA study team to request an account or if you have any issues logging in.

## How to randomise

- Once you have logged in select 'Randomise woman'
- Complete the eligibility criteria and select 'Continue'
- Check that all information has been entered correctly. The website will highlight any errors, correct these by clicking 'Amend' or, where needed, discuss with the delegated clinician who confirmed eligibility.

If unsure about eligibility please discuss with the local PI, and, if required, the MAMA Study Team, before randomising the woman.

- On the confirmation screen, the woman will be allocated a **MAMA Study ID**.
- Enter the **MAMA Study ID** immediately onto the completed **MAMA Consent Form** (In-person or Remote).

## Technical support

If you experience technical difficulties or require technical support, please contact the MAMA study team using the contact details below:

- During office hours, contact the MAMA Study Team on: **01865 743859**
- In the case of urgent out-of-hours queries, please phone **0800 1385451**

If you have tried to randomise a woman and are not sure if it has been successful, return to the home screen of the randomisation website. This will list the most recent randomisations at your site. Please check this before trying to randomise again

## Contact Details Form

After a woman has been randomised, click the '**Enter contact details**' button. This will open up a new window to enter contact details as required.

**Please enter the Contact Details information as soon as possible** – this is essential for the participant to be able to complete the Baseline Questionnaire and use the MAMA App and for the MAMA Study Team to send the GP Letter and Rheumatologist Letter. If you are unable to complete the contact details section immediately following randomisation, please return to the website as soon as possible to complete it.

To access the Contact Details Form:

- From the randomisation Menu, click on the '**Recruitment List**' link.
- On the Recruitment List screen locate the woman's study number, then click '**Edit**', in the '**Edit contact details**' column, adjacent to the required study number.

In the contact details section you will be asked to enter:

- The woman's name and NHS / CHI / healthcare number
- Mobile number, email address and postal address
- Details of the woman's GP and rheumatologist
- Where the woman is receiving obstetric care (if not at her recruiting site)

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- Whether consent was remote or in-person
- Whether the woman has consented to be contacted about the infant immune response component of MAMA (question 8 on the consent form)
- Whether the woman is able and willing to use the MAMA app
- Whether the are any potential issues regarding communication with the participant that we should be aware of (for instance, language barriers, oraccessibility requirements)?

If the woman is not able to use the MAMA app, there are two alternatives available:

- Completing scheduled questionnaires about her arthritis online (via a link to an OpenClinica questionnaire)
- Completing paper questionnaires

See **Guidance Sheet: Data Collection** for more information.

If you do not have all of the information for the contact details form available immediately, you can return to the form later.

**This is important so that the relevant processes can be put in place.**

**Once a woman has delivered her baby (or babies), please return to the contact details form and update it with the baby's name, NHS/CHI/healthcare number, and (if you have not already provided this via the Outcomes form) date of birth.**

## MAMA Welcome pack

Please provide the appropriate '**Welcome pack**' for the allocated intervention to women recruited in-person.

Include the following documents:

- MAMA Welcome Card
- Rheumatologists QR Card (allocation specific)
- MAMA Translation Supplement

For women recruited remotely the **Welcome Pack** will be sent out by the MAMA Coordinating Centre.

## Data Entry

Once the woman has been randomised, please ensure completion of the **Entry Form** on OpenClinica (Please refer to **Guidance Sheet: Data Collection)**



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