

eISF and Document Box

- The MAMA Investigator Site File will be provided **electronically**.
- Original paper copies of documents should be retained according to local site policy.
- Legible electronic copies of document should be uploaded to the MAMA Coordinating Centre via the **NPEU Upload Tool**.

The MAMA Document Box and contents should be kept in a suitable location where it is accessible to all relevant staff.

Electronic Investigator Site File (eISF)

The Investigator Site File (ISF) is stored electronically at site. The local team will agree a suitable file location during site initiation, and use the folder structure and contents provided by the NPEU. Original paper copies of documents such as Consent Forms, Incident Forms, and SAE Forms should be retained according to local site policy. Send legible electronic copies of Consent Forms, Incident Forms, and SAE Forms to the MAMA Coordinating Centre via the **NPEU Upload Tool**.

Document Box

The Document Box and contents will be provided to the site by NPEU. The local team agree a suitable location to keep the Document Box where it is accessible to all relevant staff. The Document Box contains recruitment documents, Guidance Sheets and other useful information. Participant data should not be stored in the Document Box.

Recruitment documents

Recruitment documents include the basic documents needed for one women to participate in MAMA:

MAMA Preconception Information Leaflet	To provide an introduction to the MAMA Trial for women who may be planning pregnancy or who are pregnant but have not yet been seen at a recruiting site. For use, for example, in rheumatology clinics or midwife booking appointments.
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.
MAMA In-person Consent Form	To document informed consent when this can be obtained in-person.
MAMA Remote Consent Form	To document informed consent when consent is obtained remotely.

MAMA Welcome Pack	To be provided to a woman at randomisation – will be posted to women recruited remotely by the MAMA Coordinating Centre.
- Welcome card	Thanks women for participating and includes an infographic showing when they will be contacted.
- Rheumatologist QR card (allocation specific)	For a woman to carry to show her allocation when at rheumatology appointments.

Data Collection Packs

For participants who indicate they would prefer not to use the MAMA App for data collection, paper versions of the participant facing MAMA CRFs can be provided. Data Collection Packs are individual folders containing paper versions of the Baseline form and MAMA Paper Diaries for recording arthritis activity.

The MAMA Coordinating Centre will send direct links and post paper questionnaires. We will also send reminders and make phone calls to women as required.

Reordering Documents

Request more documents by emailing mama@npeu.ox.ac.uk.

Amendments

NPEU sends any amendments to study documentation (once approved by the relevant regulatory bodies) to sites, with instructions for new and superseded documents.

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