Change of consent

Once a woman has been randomised and a study number allocated, they are entered into the study. Women have the right to change their consent for the trial at any time.

If a woman wishes to change their consent, this should be recorded on the **MAMA Change of Consent Form**.

Women can opt to change their consent to the following aspects of the study:

- Completing follow-up questionnaires (this includes participant questionnaires on OpenClinica and reporting data through the MAMA app)
- Allowing for data to be collected from they and their infant's medical records
- Receiving study updates
- Sharing of data with national databases
- Being invited to take part in follow-up studies
- Being contacted about taking part in the immune response component of MAMA
- Taking part in the immune response component of MAMA

Data collected up to point of change of consent will be used in the trial.

It is important to notify the MAMA study team as soon as possible after becoming aware of any change of consent.

Key points:

- If there is a permanent or temporary discontinuation or interruption of the allocated trial pathway by the woman or her clinician this does not constitute a withdrawal or change of consent if they are not changing other aspects of consent (e.g. data collection).
- If a woman's infant dies, wherever possible, it should be discussed with the woman whether she wishes to continue with the trial. A change of consent form should be completed if required.
- If known, please include reason for change of consent. However, women should not feel pressured to give a reason for a change in consent or to discuss it more than they would like.
- A **Change of Consent Form** should be completed as soon as possible after a woman notifies the site team or MAMA study team so that any required changes can be made, for example planned messages to women for questionnaires. You can start completing the form even if you do not have all the information, additional information can be added at a later date (just close the form instead of marking as complete). The MAMA study team receive an automatic notification if a **Change of Consent Form** has been started. If you think there may be a delay in recording the necessary information on the **MAMA Change of Consent Form** please notify the MAMA study team of any change of consent by phone or email.

- If a woman notifies the MAMA study team directly that they wish to change their consent, the MAMA study team will notify the site team and ask the site to follow up with the woman if appropriate and complete the **MAMA Change of Consent Form**.

Process for Change of Consent

This process varies depending on the type of change of consent. Please use the flow diagram on the next page to confirm the right process. If you are unsure which process to use, contact the MAMA study team.

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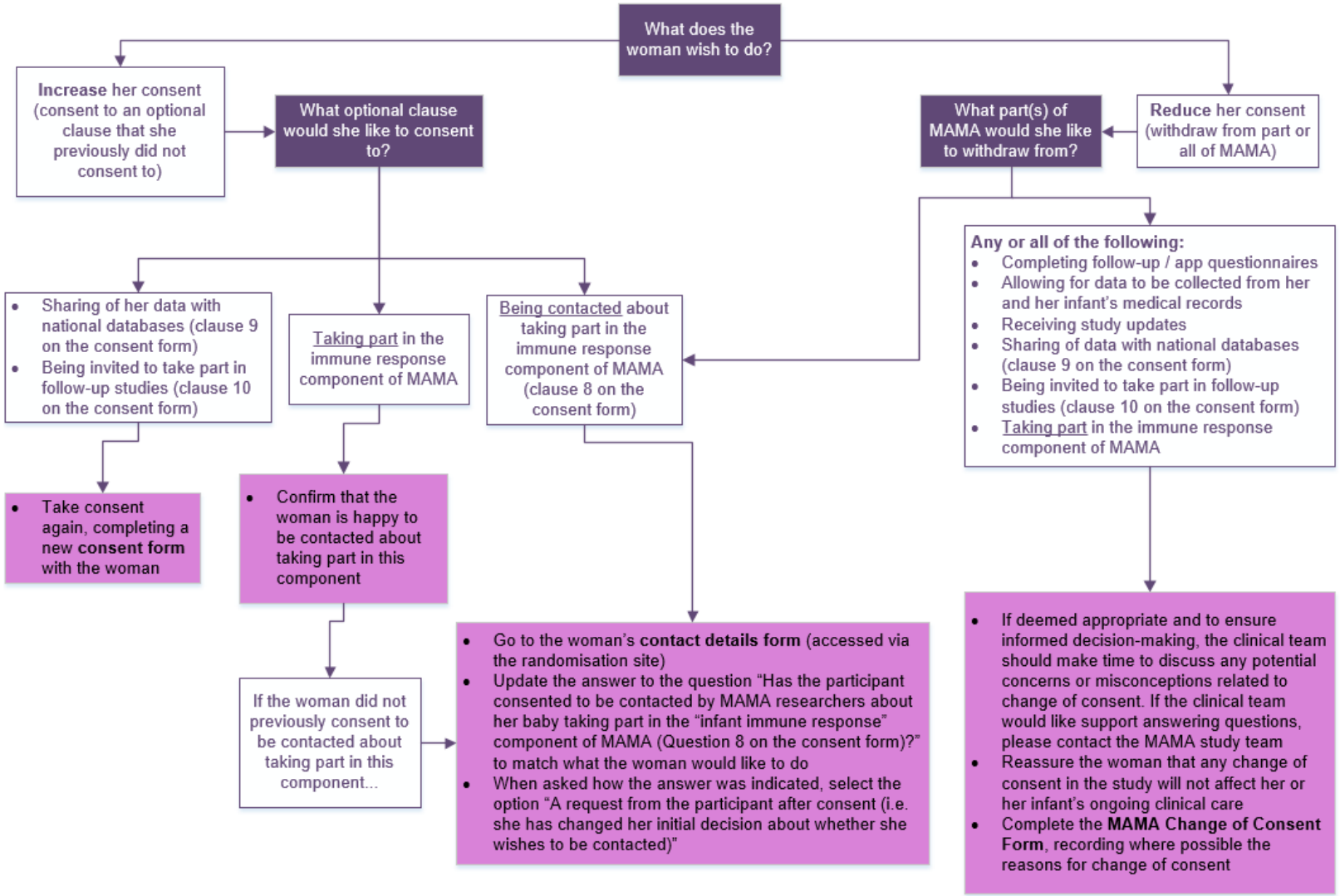
What does the woman wish to do?
Increase her consent (consent to an optional clause that she previously did not consent to)
What optional clause would she like to consent to?
Reduce her consent (withdraw from part or all of MAMA)
What part(s) of MAMA would she like to withdraw from?
Sharing of her data with national databases (clause 9 on the consent form)
Being invited to take part in follow-up studies (clause 10 on the consent form)
Taking part in the immune response component of MAMA
Being contacted about taking part in the immune response component of MAMA (clause 8 on the consent form)
Any or all of the following:
Completing follow-up / app questionnaires
Allowing for data to be collected from her and her infant's medical records
Receiving study updates
Sharing of data with national databases (clause 9 on the consent form)
Being invited to take part in follow-up studies (clause 10 on the consent form)
Taking part in the immune response component of MAMA
Take consent again, completing a new consent form with the woman
Confirm that the woman is happy to be contacted about taking part in this component
If the woman did not previously consent to be contacted about taking part in this component...
Go to the woman's contact details form (accessed via the randomisation site)
Update the answer to the question "Has the participant consented to be contacted by MAMA researchers about her baby taking part in the "infant immune response" component of MAMA (Question 8 on the consent form)?" to match what the woman would like to do
When asked how the answer was indicated, select the option "A request from the participant after consent (i.e. she has changed her initial decision about whether she wishes to be contacted)"
If deemed appropriate and to ensure informed decision-making, the clinical team should make time to discuss any potential concerns or misconceptions related to change of consent. If the clinical team would like support answering questions, please contact the MAMA study team
Reassure the woman that any change of consent in the study will not affect her or her infant's ongoing clinical care
Complete the MAMA Change of Consent Form, recording where possible the reasons for change of consent