

ELIGIBILITY AND INFORMED CONSENT

ELIGIBILITY

Any woman with phenylketonuria (PKU) who states she is planning to become pregnant or is already pregnant. Her blood phenylalanine level (when not treated) must be >6 mg/dl.

By agreeing to participate in the study and signing the informed consent, the woman agrees to being randomly assigned to the treatment group or the control group.

INFORMED CONSENT

The informed consent for each institution must be read to the potential enrollee. A copy of the signed informed consent should be sent to the coordinating center.

A summary of what participation in the study involves (both with and without a Resource Mother) is included in your packet.

QUESTIONS/ANSWERS

1. Does the Resource Mother have to come to my home?
The RM can usually help the most if she visits your home, where questions about food are easily addressed and cooking demonstrations can easily take place. We would prefer that a RM visit your home. However, if you do not wish the RM to come to your home, you can meet at another location (a park, library, restaurant, etc). Often, the RM will be in touch via phone or email. Visits usually last about an hour.
2. Why do I need an IQ test?
First, it will tell us what your learning strengths are. This will help the clinical staff present information in the best possible manner for you to learn—there is a lot to learn when returning to the diet! Secondly, there are many people who think that how well you do on diet depends on your IQ. We do not think this is necessarily true. We believe there are other factors, such as how much support you have and your attitudes toward the diet, which are more important than IQ.
3. What if I don't like my Resource Mother?
We have every reason to believe that you will. The RM's are women who are interested in helping other women with PKU. However, if a problem arises, please speak to the study coordinator for your clinic.