

RANDOMIZATION

Once the informed consent has been signed, contact the study coordinator in Boston (Fran Rohr) and let her know whether the woman with PKU began the diet before or during pregnancy. The woman will then be assigned to the treatment group (Resource Mothers) or the control group (no Resource Mothers).

The study coordinator will usually be able to let you know the randomization within a day. If the study coordinator will be away for more than a day, she will email the contributing coordinators at each clinic and let them know whom to call in her absence.

ASSIGNMENT OF RESOURCE MOTHERS

If the woman with PKU is assigned a Resource Mother, the coordinator at the contributing center will determine who the Resource Mother will be. This is generally a matter of which Resource Mother is the closest geographically, though other factors, such as whether or not the Resource Mother has another case, may be considered.

The contributing center coordinator will provide information about the woman with PKU to the Resource Mother, including contact information, basic background information, and the diet that has been prescribed. The Case Information Form may be used for this purpose.

If the woman with PKU is pregnant at the time of enrollment, the Resource Mother should make the first visit within a week. If the woman with PKU is planning a pregnancy, the Resource Mother should make the first visit within 2-3 weeks, but should call the woman with PKU as soon as possible to establish contact.

Let the study coordinator know who the Resource mother will be so that Dianne Sullivan can be contacted. Dianne Sullivan will call the Resource Mother prior to the initial visit to offer support.

Frequency of RM Visits

The RM should visit a maximum of 20 times during the pregnancy. A log for keeping track of visitation is included in this packet. If the woman with PKU is already pregnant, the visits will occur approximately every other week. If the woman with PKU needs more frequent help in the beginning of the pregnancy, more visits may be scheduled early in the pregnancy, and less frequent ones near the end.

If the woman with PKU is planning a pregnancy, the RM should visit initially one or two times, and then determine with the clinic coordinator how frequently subsequent visits are needed, keeping in mind that the model for this program dictates a maximum of 20 visits. There is much flexibility in this aspect of the study – some women need more help as they attempt to resume diet.