

Children's Hospital, Boston  
300 Longwood Avenue  
Boston, MA 02115



## Children's Hospital

7/11/2001

Dear Coordinators,

This letter clarifies our commitments to you in your role as a Study Coordinator for the Maternal PKU Resource Mothers Program: A Clinical Trial. In addition, it specifies what we expect of the Study Coordinators as part of the project. As you know, the staff at Children's Hospital in Boston coordinates the study. This is a collaborative study, involving 8 metabolic centers in the United States. Each center has a Study Coordinator who enrolls subjects and oversees the Resource Mothers. The Study Coordinator communicates closely with Boston Children's Hospital. The study is federally funded in part by the National Institute of Child Health and Development (a part of the NIH) and in part by the Maternal and Child Health Bureau. The study began in 9/1/2000 and should continue through 2004.

### Our Commitments to You:

As part of the project, we will provide you with training, involving a workshop or conference in the next two years. We will reimburse you for your travel and pay you a \$300 stipend for attending the workshop.

We will provide you with a consultation, should you desire it, regarding any aspect of the study and any aspect of maternal PKU. We will send you information about other research and newly published educational materials. You are free to contact any of the study staff at Children's Hospital, Boston should you have any questions or concerns or a wish to discuss a specific case.

Once the study is over, we will provide you with a disc containing all of the data collected at your center. You are welcome to publish reports on this data. We will also provide you with a summary of the full data set and a summary of the study findings. Depending upon your involvement in contributing to the data set and your involvement in other aspects of data analyses and interpretation, you may also be listed as an author on publication derived from the study. If there is something specifically you wish to do, please let us know.

We have budgeted \$8,000 a year for you or your metabolic center (depending upon the arrangement that has been made), based upon on your following 10 maternal PKU cases.

### Expectations from the Coordinator:

We expect at least a one-year commitment and hope for a three-year commitment to the program. We also expect the Study Coordinators to attend the training session, if at all possible. If this is not possible, we expect the Study Coordinators to review the training materials and call the study personnel at Children's Hospital, Boston if there are any questions or concerns.

The Study Coordinators are expected to maintain close contact with the Resource Mothers in order to provide supervision. The supervision will occur at least three times for each

woman being followed by a Resource Mother, and more often if necessary. The supervision will usually occur in person, but can be done through other forms of communication if desired. Supervision will last 30 minutes to an hour.

Each study coordinator needs to document familiarity with human subject guidelines. This involves an understanding of the history of principles for conducting research with human subjects, the rules for confidentiality, and other important ethical considerations. In all probability, you have satisfied this requirement through your hospital. If not, you can take the test over the Internet that is being used by personnel in studies that are funded by the NIH. The website can be found at: [grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Study Coordinators are expected to follow the study protocol as outlined in the Resource Mother's Coordinator Manual. This includes enrollment of subjects, obtaining informed consent, accepting random assignment of subjects to either the Resource Mothers group or the group without a Resource Mother, data collection, and submission of data on the computerized data forms. Study Coordinators administer the questionnaires to the subjects in the group without a Resource Mother twice during the woman's pregnancy. They make sure that a recent maternal IQ score is available, and that developmental testing is performed when the offspring is one year old. (Study personnel in Boston will assist in locating a psychologist to perform the testing and will pay for the assessments).

We hope that this letter clarifies the aspects of the study. This center depends heavily on the Study Coordinators in each metabolic center. It simply could not be done without you! So, please do not hesitate to contact us if you have any questions, concerns or suggestions. Together, we believe that we can discover if the innovative Resource Mothers Program can truly make a difference.

Best wishes and thank you for your willingness to work on the Study.

Sincerely,

Susan E. Waisbren  
Principal Investigator



## **COORDINATOR RESPONSIBILITY CHECKLIST**

### **ENROLLMENT**

Informed Consent signed  
Informed Consent sent to coordinating center  
Background and registration form  
Intelligence testing

### **ASSIGNMENT of RESOURCE MOTHER**

Resource Mother contacted  
Case information communicated to RM

### **PRIOR to PREGNANCY**

Weekly blood phenylalanine and tyrosine  
Monthly nutrition assessments  
Monthly weights  
RM supervision if woman is in treatment group

### **DURING PREGNANCY**

Weekly blood phenylalanine and tyrosine  
Monthly nutrition assessments  
Monthly weights  
Per trimester - RM supervision if woman is in treatment group  
6 weeks gestation: metabolic visit and laboratory data including full amino acid profile  
12 weeks gestation: metabolic visit and laboratory data including full amino acid profile  
20 weeks gestation: metabolic visit and laboratory data including full amino acid profile  
20 weeks gestation: get medical release forms for obtaining birth information  
32 weeks gestation: metabolic visit and laboratory data including full amino acid profile  
32 weeks gestation: psychosocial questionnaires (to be administered by RM of woman is in the treatment group or by the coordinator if the woman is in the control)

### **BIRTH**

Pediatric exam  
Outcome of pregnancy

### **ONE YEAR**

Bayley Scales of Infant Development  
Offspring medical and support services during the first year of life