

Resource Mother's Randomized Clinical Trial Coordinator's Manual



OVERVIEW: CONTRIBUTING CLINIC COORDINATOR

1. Letter of Understanding
2. Coordinator Responsibility Checklist



Section 1: Organization and Contact Information

1. Organizational Chart
2. List of Resource Mothers
3. List of Coordinators
4. Communication with Coordinating Center



SECTION 2: ENROLLMENT PROCEDURE

1. Eligibility and Informed Consent
2. Treatment Plan with a Resource Mother
3. Treatment Plan without a Resource Mother
4. Randomization and Assignment of a Resource Mother



SECTION 3: DATA COLLECTION

1. Data Collection Schedule
2. Request for Payment (Testing)
3. Sample Letter to Mother Regarding Testing
4. Sample Letter to Psychologist Regarding Testing
5. Filling Out Forms Online
6. Hard Copies of Forms
 - a. Registration and Background
 - b. Blood Phenylalanine Log
 - c. Nutrition Assessment
 - d. Weight Record
 - e. Appointments
 - f. Outcome
 - g. Newborn Pediatric Evaluation
 - h. Offspring One-Year Evaluation
 - i. Offspring Medical and Support Services
 - j. Resource Mother Contact Log
7. Psychosocial Questionnaires
 - a. Social Support Questionnaire
 - b. Knowledge of Maternal PKU
 - c. How Do You Feel About Yourself
 - d. Opinion Questionnaire
 - e. Home Organization Scale
 - f. Life Stress Questionnaire

- g. Attitude About Treatment



SECTION 4: OTHER INFORMATION FOR COORDINATORS

- 1. Psychological Testing
- 2. Supervision of Resource Mothers



SECTION 5: PACKET FOR THE RESOURCE MOTHERS

- 1. Case Information Form
- 2. Resource Mother's Visit Log
- 3. Resource Mother's Visit Summary
- 4. Request for Payment
- 5. Optional Questionnaires
 - a. How Am I Doing Now?
 - b. Diet Goals Worksheet
 - c. Initial Diet Checklist
 - d. Assessing Food Preferences
 - e. Module Assessment
 - f. Cooking Experience



OTHER MATERIALS

- 1. Protocol for Nutritional Support of Maternal PKU