

Instructions for Letter of Intent 2015

Effect of Dietary Interventions in Prader-Willi Syndrome

SUBMISSION DEADLINE: September 1, 2015 at 5 pm Eastern Time

The Foundation for Prader-Willi Research (FPWR) seeks to stimulate research that will improve the lives of individuals with PWS in the near term. We are particularly supportive of research developing and evaluating new therapeutic approaches to PWS. We also are interested in supporting innovative research that will lead to significant advances in our understanding of this disorder.

Prader-Willi Syndrome (PWS) is a multi-faceted disorder causing developmental disability, hyperphagia usually with obesity, behavioral problems and an increased incidence of psychiatric illness. Parents are typically counseled to provide a low-calorie (typically low fat) diet, adjusted for the age and activity level of the child. There is little guidance provided to families or nutrition specialists on the optimal amounts of macronutrients (carbohydrate, fat and protein) in the diets of children with PWS, aside from the importance of meeting minimum requirements for vitamins and minerals and limiting foods with low nutritional value.

FPWR is now requesting letters of interest from researchers interested in studying the effect of dietary interventions in PWS. We are particularly interested in applications from teams who have previously studied or applied dietary interventions in children with developmental disabilities. Dietary interventions can include but are not limited to a ketogenic or modified ketogenic diet, or a low glycemic index diet. The successful team will include a clinician familiar with health issues that could arise more frequently in the PWS population during the intervention. Outcomes will include (but are not limited to) changes in weight, body composition, hyperphagia questionnaire scores, behavioral assessments from parents and caregivers, and plasma markers (e.g. insulin) as appropriate. FPWR will assist with recruiting of participants through the newly launched Global PWS Registry, upon approval of the Registry Advisory Board.

Budget – A detailed budget will be requested during the full application process. The maximum budget will be \$100,000 in direct costs, plus indirect costs of up to 8% of direct costs, to be spent over 1 year. Higher budgets may be considered depending on the scope of the project, and projects with lower budgets are also welcome.

Preliminary inquiries about the suitability of proposed experiments and other questions regarding the grant application and review procedures can be sent to Jessica Bohonowych, Associate Director of Research Programs Jessica.Bohonowych@fpwr.org, or Theresa Strong, Grants Program Director grants@fpwr.org or by contacting FPWR (contact information at www.fpwr.org). Applications will be submitted through ProposalCentral (<https://proposalcentral.altum.com/>). Please contact Jessica Bohonowych to express interest in submitting an application and to request access to the submission portal.

1. Face Page

The face page should include the following information:

- * Title of the Project
 - * Principal Investigator
 - * Principal Investigator Contact Information: Mailing Address; Phone Number; Fax Number; e-mail address
- The study must be approved by an Institutional Review Board before release of funding.

2. Qualifications of the Investigators (5 page limit per person)

Biographical sketches (NIH-style biosketch) or short CVs of the principal investigator and key personnel should be included. The information provided should include the applicant's previous experience with dietary interventions and any publications or presentations relevant to the project*.

3. Research Plan (2 page limit)

Format:

1. Aim, Background and Rationale: State the goal of the project. Explain the rationale for the approach proposed for the dietary study, and how this approach could be well suited for individuals with PWS.

2. Previous Studies: Describe previous studies performed by yourself or others that support the feasibility of the study and its potential for adaptation to dietary management in PWS.

3. Experimental Design and Methods: Provide a general overview of the study design and discuss how the dietary intervention would be implemented[#].

4. Impact. Outline the potential benefits of wider implementation of the dietary intervention in individuals with PWS, and possible complications that may make the intervention difficult to adapt to PWS.

***In the full application,** the final team will include a clinician familiar with the PWS phenotype and potential PWS-specific complications. FPWR can facilitate recruiting such a person to the team if the applicant requests this assistance.

[#]In the full application, applicants will be asked to provide details for study design, recruiting, criteria for selection of participants, numbers of clinic visits, study length and proposed outcome measurements. They will provide the number of participants and the reasons why that number would be sufficient to detect changes in one or more of the outcomes measures. They will discuss how the dietary intervention will be provided to the participants and how the participants would be advised on dietary content. They will discuss possible reasons that participants may withdraw from the study.

Thank you for your interest in PWS research!