



Dear Colleague,

December 2015

Alaska Premier Health has been selected to participate in a weight loss research study and is beginning the screening process for subjects. **OPTI-WIN** (Effectiveness of the **OPTI**fast® Program compared **With** a reduced-eNergy, food-based diet plan on body weight) is a 52 week open, randomized controlled trial comparing Optifast® with a modified Diabetes Prevention Program for the food-based control group. DPP is a recognized standard lifestyle intervention. In addition to the dietary interventions, both groups will participate in behavioral counseling sessions as well as a moderate exercise program.

Our team is seeking volunteers for this year-long study. It includes active weight loss as well as maintenance phases for both programs. Participation would include study related appointments, diagnostic testing and nutritional counseling specific to the assigned weight loss method. Subjects should be able to present to the clinic at least weekly during the trial. There is no cost to inquire about or to be included (if selected to participate) in the study.

**Inclusion Criteria:**

Ages 18-70  
BMI  $\geq 30$  and  $\leq 55$   
Non-smoker ( $> 6$  months)  
 $\leq 14$  alcoholic drinks/week  
Willing/able to give consent  
Read and speak English

**Exclusion Criteria:** (partial list)

Active weight loss participation in past 3 months  
Weight change  $> 5\%$  in past 3 months  
Optifast® participation within past 5 years  
No weight loss medication in past 3 months  
Bariatric procedures or liposuction  
Type I Diabetes or HgbA1C  $> 10$   
Cardiovascular disease/surgery within 6 months  
Surgery/physical limitation preventing regular physical activity  
Milk or soy food allergies  
Pregnancy/delivery/nursing within 6 months

If you know of anyone who might be interested in learning more, the enclosed announcement letter is IRB approved for distribution to potential subjects. It has our contact information. Anyone with questions or interested in being a participant is encouraged to call and speak with a member of our research team at (907) 561-3488.

You have been provided with a few of the announcements for distribution. Please contact Alaska Premier Health if you would like us to provide more copies. Our anticipated screening window is short—hopefully less than a month, as we would like to be able to randomize and initiate treatment as soon as possible.

We are excited and honored to have been included as a site for this clinical trial. Thank you for your time and assistance in achieving our full study subject goal.

Sincerely,

Sally L. Coburn, RN-BC, APRN-BC  
Principal Investigator