D2d Collaborating Clinical Site Budget Justification

Site Name: Washington State University

A. Senior/ Key Persons

Consortium Principal Investigator:

Carol Wysham, M.D., Principal Investigator (effort = 1.2 calendar months for years 1 - 4)

Dr. Wysham will be responsible for trial over site and supervision of all trial aspects. This will include the recruitment phase, screening, physical exams, lab review, participant safety, and finalization of the trial and over site of the study staff.

Co-Investigator:

Lisa Woodard, PharmD, Co-Principal Investigator (effort = 1.2 calendar months for years 1-4)

Dr. Woodard will be responsible for the recruitment, screening, inclusion/exclusion of the participants. She will serve as the trial pharmacist. Her connections with the community will further enhance the recruitment phase, along with her enthusiasm in the area of diabetes prevention and pre diabetes.
Dr. Woodard will also serve as the leadership for the two educational events offered to the participants yearly.
Dr. Woodard is looking forward to collaborating on scientific committees and paper submissions.

B. Study Personnel

Research Coordinator:

Debra K. Weeks, LPN, CCRC, Research Coordinator (effort = 12 calendar months years 1, 2, 3 and 4
Debbie will be responsible for the overall participant management of the trial including recruitment, screening, lab draws, processing, shipping, source documents, mental assessments, drug accountability, clinic visits, participant retention, participant satisfaction, and training of other staff members.
We are asking for increased funding for year 4 from 75% to 100% for the research coordinator due to the exiting process for the trial participants, increased scheduling, data cleanup, IRB closeout and archiving of all records.

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Research Assistant(s):

Research Assistant TBD (effort = 12 calendar months years 1, 2 & 3 and 9 calendar months year 4)

We are asking for increased funding for this position from 50% to 100% for the first year. This position will spend time reviewing the data base at Rockwood Clinic for potential participants, send out letters of interest, follow-up phone calls for scheduling if applicable and do data entry. They would room patients, maintain medical supplies, and do office duties such as make appointments, reschedule, and make reminder calls. This is due to the shorter enrollment time as an add-on site.

C. Equipment – not applicable

D. Travel – not applicable

F. Other Direct Costs

1. Materials and Supplies
e.g. expenses for laboratory measurements, day-to-day office supplies, participant group meetings, etc.

PAML (local lab) charges for estimated **200** screenings, and estimated processing of serum calcium and creatinine during the study. 2 events per year providing light refreshment, Nutrition and Physiology demonstration, and Pharmacy presentation for 150 participants and spouses. Costs incurred for distribution of newsletters and study materials, include postage, printer paper, copier costs.
This cost analysis was gathered from page 6 of 12 of the D2d Collaborating Clinical Site Budget Version 3.1. Stating that the site is responsible for the screening CBC, AST/ALT, Alk.phosphatase, total bilirubin, S.creatinine, S. calcium, urine calcium-cr.ratio, FBG, A1c, 2hr GTT, and pregnancy testing if applicable. **Dependent on Screening**

2. Publications Costs – not applicable

3. Consultant Services – not applicable

4. ADP/Computer Services (site dependent, generally not applicable) – **Not applicable**

5. Subawards/Consortium/Contractual Costs – not applicable

6. Equipment or Facility Rental / User Fees – not applicable

7. Alterations and Renovations – not applicable

8. Other

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Participant Recruitment

We are requesting funds to cover costs of generating and distributing recruitment letters, nutritional baskets for organizations who have agreed to hand out our informational pamphlets, and advertising costs in The Inlander news magazine.
We have eighteen months to recruit and will be making every effort to hit all avenues.

Participant Stipends and Transportation Costs

We are requesting funds to cover participant stipends and transportation costs of $50.00 per patient per on site visit for 10 patient visits beginning at visit randomization.

Use of Clinical Research Units – Not applicable.

Laboratory Supplies
e.g. Phlebotomy fee, vacutainer tubes, etc.

We are requesting funding to cover costs associated with drawing blood such as alcohol wipes, butterflies, needles, vacutainer tubes and the cost of hazardous waste disposal.

Pharmacy Fees (generally waived for NIH studies) – **Not applicable.**

IRB Fees (generally waived for NIH studies) – **Not applicable.**

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Other Direct Costs

Our participant event costs are to include spouses, significant others or a friend. We found this most beneficial during the ACCORD and AIM-HIGH Trials. Diabetes is not a singular disease and affects the family of those affected. We had greater turnout at our events when some food items were served, education was offered to not only the participant but also some other family member or friend, the participants were more likely to come.
We realize the submitted budget is contingent on enrollment but we are committed as a site to enroll this trial as well or better than we did the ACCORD Trial.