

D2d Collaborating Clinical Site Budget Justification

Site Name:

A. Senior/ Key Persons

Consortium Principal Investigator:

Sangeeta Kashyap, MD is an endocrinologist and expert in insulin resistance, obesity and type 2 diabetes. She has a long history of NIH and foundation grants, including projects directly examining a variety of clinical outcomes in persons with type 2 diabetes. For the proposed study, Dr. Kashyap will oversee all aspects of the study at Cleveland Clinic. She will serve as the key through her leadership role in the Endocrinology Institute; she will also direct recruitment activities of study team members.

Co-Investigator:

Betul Hatipoglu, MD (5% effort, no salary request) is an endocrinologist. Dr. Hatipoglu will assist Dr. Kashyap with the recruitment activities for this study.

Anita Misra-Herbert, MD (5% effort, no salary request) is a staff within the Medicine Institute. Her interest includes preventative medicine. Dr. Misra-Herbert will assist Dr. Kashyap with the recruitment activities for this study.

B. Study Personnel

Research Coordinator:

Robert McCoy, RN is the research coordinator for all diabetes trial within the Endocrinology and Metabolism Institute. He participated as a coordinator for multi-center industry sponsored trial and NIH sponsored trial. Robert will support Dr. Kashyap with the day to day study activities specifically with recruitment, enrollment, participant visits, participant follow-up and coordination efforts with the coordinating center.

Research Assistant(s):

TBD (50% effort in Yr 2,4 &5, 75% effort in Yr 3)
The Research Assistant will support the research coordinator with day to day study activities specifically with study start up, scheduling the participants' visits, calling the participant to remind them of their visits and data entry. The Research Assistant will be responsible for all IRB submissions and regulatory maintenance of the study.

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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.

Office supplies including postage, paper, pens, binders and folders.

2. Publications Costs – not applicable

3. Consultant Services – not applicable

4. ADP/Computer Services (site dependent, generally 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

Participant Recruitment

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Site Name:

Participant Stipends and Transportation Costs

\$75 participant stipends for visits conducted on site: screening, baseline, randomization, month 3, month 6, semi-annual visits, annual visits and end of study visit.

Use of Clinical Research Units

Laboratory Supplies

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

Basic lab supplies including gloves, masks and sharps container.
Phlebotomy supplies including vacutainer tubes, vacutainer barrels, needles, bandaid and alcohol pads.
Dry Ice
Glucose Tolerance Test Beverage
Urine Collection Container and Wipe

Pharmacy Fees (generally waived for NIH studies)

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IRB Fees (generally waived for NIH studies)

Other Direct Costs

Lab start up fee for the special labs to process the study samples according to the lab manual and packaged to be sent to the central lab for analysis.

Patient Care Charges include: physical exam, CBC, serum pregnancy test, HbA1c, FGP, CMP, lifestyle counseling.