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April 23, 2014

Erin LeBlanc, MD, MPH
Kaiser Permanente Center for Health Research
3800 North Interstate Avenue
Portland, OR 97227

RE: D2d clinical trial

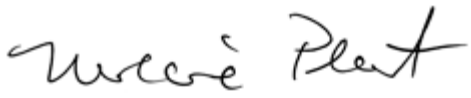
Dear Dr. LeBlanc:

On April 15, we spoke about the Kaiser Permanente NW Center for Health Research's application to become a clinical site for the D2d clinical trial. The Kaiser Permanente Northwest Institutional Review Board (KPNW IRB) meets monthly to review new studies and I would expect that the review of this trial could be conducted swiftly by our monthly review.

You propose to use KPNW electronic medical records (EMR) to identify potential participants. This is a common method used to identify potential eligible participants among KPNW members to recruit for our IRB approved studies. Therefore, I do not anticipate concerns about using the KPNW EMR to identify potential participants for your proposed trial.

Finally, a waiver of signed consent to have laboratory testing done at KPNW labs for screening is something we have approved for some prior studies, and our IRB would also be open to reviewing a request for a waiver of signed consent for your initial screening to confirm eligibility by glucose testing (by fasting plasma glucose and/or HbA1c). Obviously signed written consent would be required for eligible participants to be randomized to Vitamin D vs. placebo.

If you should have any questions regarding this notice, please feel free to contact me at the address provided below.



Melanie Plaut, MD, CIP
Chair
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