

Memorandum

To: Study Sponsors

From: Paul Newton, JD, CIP – Legacy Research Institute

Date: 2015

Re: Institutional Review Board

The Legacy IRB maintains a Federal Wide Assurance with the Department of Health and Human Services' (DHHS) Office of Human Research Protections (OHRP). The assurance number is FWA00001280. That assurance dictates that the Legacy IRB is governed according to NIH regulations 45CFR46, as well as the Food and Drug Administration regulations, 21CFR56, and meets the International Conference for Harmonization's Good Clinical Practice Standards. If you have any questions concerning the membership of the Legacy IRB please contact OHRP.

The Legacy IRB is composed of two separate committees. IRB-01 is chaired by Carl Heisel, RPH and IRB-02 is chaired by Kathy Stoner, PharmD.

Legacy IRB is authorized to approve research studies for all of the Legacy Health System including Legacy Good Samaritan Medical Center, Legacy Emanuel Medical Center, Legacy Meridian Park Medical Center, Legacy Mount Hood Medical Center, Legacy Salmon Creek Medical Center and the Legacy Research Institute.

The Research Regulatory Specialist is authorized to sign documents representing decisions made by the full board. Research activities which may be reviewed through expedited procedures (as specified by 45CFR46) will be signed by a chair, vice-chair, or other members of the IRB as appropriate.

IRB-01 meets on the second Tuesday of each month, while IRB-02 meets on the fourth Tuesday of each month.

The administrative offices for the Legacy IRB are located at:

Legacy Research Institute
1225 NE 2nd Ave., 4th Floor
Portland, OR 97232