KPNW RESEARCH COMPLIANCE COMMITTEE

Committee Sponsors:
Director, CHR and KPNW Vice President for Research
KPNW Vice President and Regional Compliance Officer

Chair: KPNW Research Compliance Manager

Committee Members / Areas of Representation:
- CHR IT Director and Information Security Officer
- CHR Research Data & Analysis
- KPNW Institutional Review Board
- CHR Researchers
- KPNW Delivery System Researchers
- Clinical Trials
- Privacy (Research)
- Financial Conflict of Interest (Research)

Staff Support:
Administrative Assistant

Purpose:

The purposes of the Research Compliance Committee (RCC) include:
- Ensuring that the research community maintains a significant presence within the research compliance decision-making process.
- Serving as an advisory board to the KPNW Research Compliance Manager in determining appropriate corrective action plans (CAPs), determining appropriate Financial Conflict of Interest (FCOI) mitigation strategies, responding to complaints, and handling similar issues.
- Establishing and maintaining policies and procedures to be followed by all personnel engaged in the conduct, support or oversight of research to effect compliance with applicable federal, state and local laws, and regulations.

The RCC is the final approval authority for all KPNW research compliance related policies and procedures. The RCC is responsible for maintaining a list of all research compliance policies and procedures, ensuring the timely update and revision of the policies, and communicating the policies and procedures to the research community.

Accountabilities:

The Research Compliance Committee is accountable for the following activities:
- Maintenance of the NW Region Research Compliance Management Plan
- Annual review and approval of the Research Compliance Committee Charter
- Approval of Research Compliance Committee minutes
- Approve and maintain research compliance policies and procedures with appropriate stakeholder input
- Periodic review of research compliance monitoring reports and action plans
- Responding to and tracking questions submitted to the CHR_Compliance email box, and periodic review of significant compliance issues
- Periodic review of conflict of interest disclosures
• Annual review of research compliance risk assessment results and work plan
• Review of regulatory and internal audit reports
• Review of regulatory enforcement actions

The Research Compliance Committee will provide the committee sponsors with copies of the meeting minutes once they have been approved by the committee.

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**Meeting Schedule:**

The Committee will meet no less than four times per year.

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**Voting Rules:**

• A vote is required for approval of policies, meeting minutes, FCOI management plans, and Corrective Action Plans that have been delegated to the RCC. Other decisions will be made by consensus.
• Decisions that require a vote are made by a simple majority.
• A quorum must be present in order for the committee to vote on an issue. A quorum equals half of committee voting membership plus one additional member.
• The voting members are the KPNW Chair and Committee members.
• Issues resulting in tied votes will be referred to the Committee Sponsors for decision.
• Committee members should contact Staff Support if they are unable to attend. If they are sending a delegate, they need to indicate if the delegate has proxy voting rights.
• Committee members, or their delegate with proxy rights, are eligible to vote.
• Members must be present (physically or electronically) at the meeting to vote.
• Meeting minutes and minor revisions or updates to policies, procedures, or other documents referred to the RCC may be approved by electronic vote. A Committee member’s lack of response after 5 business days will be considered an approval.

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**Policy Approval Process:**

The Research Compliance Committee follows NW.ECO.004, “Regional Policy Standards, Maintenance, and Oversight” in developing, maintaining, and approving policies. After an appropriate development and stakeholder review process, policies and procedures subject to oversight by the Research Compliance Committee will be approved as follows:

• The policy will be approved by a vote of the RCC.
• Once a policy has been approved by the RCC at a meeting, it will be sent to the RCC sponsors who have two weeks in which to exercise veto authority.
• When a policy is submitted for an electronic vote, the RCC sponsors will be included on the electronic request and may exercise their veto authority within the 5-day voting period. An additional veto period will not be provided.
• The Research Compliance Manager will maintain documentation of RCC approval.
• Approved policies will be uploaded to PolicyTech as the official system of record. The VP and Regional Compliance Officer is the PolicyTech signatory for research compliance policies.
• The Research Compliance Manager will ensure that policies potentially impacting individuals outside of KP are made available on the KPCHR public website.