

The Steps to Conducting Clinical Research*

**Experts at CHR can help you through each of these steps.*

A. Generation of Research Idea

1. Physician-initiated research
2. Approached about academic or industry trial research

B. Idea Refinement

1. Does the research apply to just KPNW or to all researchers or clinicians?
2. Is it Research or a Quality Initiative? These two things have different funding sources, and Quality Initiatives do not require IRB oversight (D).

Research

- A systematic study intended to increase knowledge of a subject; to apply new knowledge to meet a recognized need; or to produce useful materials, devices, systems, or methods.
- Research produces knowledge that is generalizable, such as results to be published in a scientific manuscript or presented at a conference.

Quality Initiative

- An initiative to change operations, the implementation of a new process to improve quality, or an analysis of how a new clinical or operational process has affected outcomes.
- Quality Initiatives produce non-generalizable knowledge and could be funded through internal KPNW resources instead of grants.

C. Funding Plan

1. What resources do you need?
2. Who is going to fund you?
3. Can the research be done with CHR or KP internal resources?
4. Is the research appropriate for industry funding or federal grant funding?

D. Approval for Protection of Research Participants

Just as a medical ethics board reviews medical care, the KPNW Institutional Review Board (IRB) reviews and approves all regional research and protects the rights and welfare of human research study participants (e.g., our KPNW members).

E. Organizational Review, Signoff

Everyone affected in the medical practice (e.g., dept. chief, patient-care manager) reviews and signs off on the research or quality initiative. This ensures that the department can accommodate the study.

F. Implementation, Training, & Oversight

It can be tricky to implement a research trial within a clinical environment and ensure that the data collected are of research quality. For example, if four different people collect data, they must collect it in precisely the same way.