

CRITERIA FOR APPROVAL OF RESEARCH ACTIVITIES BY CPMG PHYSICIANS NOT IN THE INSTITUTE FOR HEALTH RESEARCH (IHR), AND PROCESS FOR CONDUCTING RESEARCH, DEFINITIONS included

Guidelines Statement

These guidelines describe requirements and processes to be followed for CPMG physicians not in the Institute for Health Research (IHR <http://kpc-co-ih-r.org/index.html>) to engage or participate in human subjects research.

Scope

These guidelines apply to any CPMG physician with a defined role of any kind on a research project other than as a research subject. This includes, but is not limited to, the conduct of or consultation on a research project from conceptualization to closure.

Research Activities

- Research activities include activities that meet the definition of “engaged in research” as described in the definitions section on page 5.

Guidelines

1. Approvals Must Be Obtained Prior to the Engagement in Research.

1.1. For CPMG physicians who will be “engaged in research” the following approvals are required prior to the engagement in research.

- 1.1.1. Clinical Department Chief and Regional Medical Director. If the physician is not in a clinical department, then approval may be obtained from his/her supervisor.
- 1.1.2. Health Plan Leadership of the Medical Office or Specialty Care Department if the proposed research may impact clinic flow, and/or utilize clinic space, clinic staff or other clinic resources.
- 1.1.3. Executive Director of the KPCO Institute for Health Research (IHR) or his/her designee.
- 1.1.4. KPCO Institutional Review Board (IRB) approval or approval to cede IRB review and oversight to another IRB.

2. If the proposed research will require .05 or less of the CPMG physician’s FTE, decision to support the physician’s FTE at \leq .05 would be made by Colorado Permanente Executive Team (CPET).

3. If the proposed research will require greater than .05 of the CPMG physician’s FTE, or the research will need additional support from the IHR (for example staffing and data access), the research will need funding.

3.1. Potentially acceptable sources of Research funding include the following:

- 3.1.1. External funding from federal, state, local government, university, industry, or foundation sources

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3.1.2. Internal KPCO or CPMG department funding

3.1.3.3.1.3. Internal funding from KP national or program office

3.2. Minimum funding requirements:

3.2.1. CPMG physicians “engaged in research” as part of their CPMG FTE must have internal or external funding to cover the costs of their time and effort for the research activity.

3.2.2. Each Research project must have a specific budget documenting the time and effort commitment for any participating physician and additional research staff along with the associated salary and fringe benefit expenses for that employee.

3.3. Management of Research budgets and funding (when using IHR staff and resources).

3.3.1. Research project budgets may be developed in conjunction with the IHR Sponsored Projects team.

3.3.2. Internally funded projects require a signed recharge agreement. This recharge agreement is developed and administered by the IHR Finance Administration team.

3.3.3. Externally funded projects require fully executed contracts with the funder.

3.3.4. Budgets, contracts, and financial administration of externally funded projects must be coordinated through the IHR Finance Administration team.

4. Research compliance

4.1. Any CPMG physician engaging in research activities must complete KPCO Regional and KP National Research Conflict of Interest disclosures.

4.2. Any CPMG employee engaging in research activities must submit a research application to the KPCO IRB: <http://www.insidekpcoco.net/irb>
http://www.kpcolorado.net/sites/default/files/sop_kp-012_initial_review.pdf

4.3. CPMG employees engaged or participating in research activities are required to complete training in the following areas: (<http://www.insidekpcoco.net/cpmg/irb/node/1165>)

4.3.1. Conflicts of interest

4.3.2. Human subjects protection

4.3.3. HIPAA for researchers

4.3.4. If the Research Activity is a Clinical Investigation or Clinical Trial as defined above, the employee is also required to complete training on Good Clinical Practice (GCP)

4.4. All projects and activities are subject to inspection by CPMG, KPCO, and Kaiser Foundation Research Institute (KFRI).

4.5. All CPMG employees participating in research are expected to follow all applicable federal, state, and local laws and regulations and organizational policies pertaining to research.

5. Research publications

5.1. Publication of potentially sensitive findings from any source or project must be discussed with the CPMG Vice President and Chief Quality Officer with shared oversight of the IHR prior to submission for publication.

6. Research process guidelines

The general research process guidelines are described below. To work through this process and assure necessary documentation, regulatory compliance and contracting is completed expeditiously and correctly, please contact one of the individuals listed as Key Contacts at the bottom of the page for assistance.

Outline of the pre-award process (prior to receiving funding from internal or external sources)

- Identify a site Principal Investigator who will be responsible for all project activities involving KPCO.
- Engage a research Project Manager within the IHR for preparation of the project approval request to be submitted to the IHR Executive Director.
- Complete project approval request form and submit to IHR Executive Director or designee.
- Obtain necessary CPMG and IHR approvals prior to seeking project funding
- Develop a full research protocol (Aims, background, methods, expected results and applications of results) consistent with the requirements of the proposed funder.
- Develop a project budget in conjunction with research project management and IHR sponsored projects staff.
 - Ensure that all necessary project staff are covered by budgeted funds.
- Submit proposal for funding through IHR Sponsored Projects Office according to previously established timeline. Obtain approvals from KFRI, if applicable, prior to submission to sponsor.

Process – Post Award

- Confirm Site Principal Investigator
- Engage research Project Manager for all aspects of study implementation management
- Prepare IRB documents, obtain IRB approval, and comply with IRB regulations
- Review budget and staffing needs with IHR Operations Management team
- Obtain project department ID/project ID for all project charges
- Conduct project in compliance with all relevant federal, KP national, KPCO, and IHR policies and procedures

Key Contacts:

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Reference: Research -Physicians not in Institute of Health Research (IHR)

Policy No. PR.006 and other applicable policies.

Definitions

Human Subject

- As defined by Health and Human Services (HHS): “Human Subject” is a living individual about whom an investigator conducting research:
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Federal Policy for the Protection of Human Subjects, 82 FR 7149 (January 19, 2017). *Federal Register: The Daily Journal of the United States.*
- As defined by the Food and Drug Administration (FDA): “Human Subject” is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. 21 C.F.R. § 50 (2016).

Research

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Federal Policy for the Protection of Human Subjects, 82 FR 7149 (January 19, 2017). *Federal Register: The Daily Journal of the United States.*

Clinical Investigation

- Means any experiment that involves a test article and one or more Human Subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, as amended, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. 21 C.F.R. § 50 (2016).

Clinical Trial

- A research study in which one or more Human Subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes. Federal Policy for the Protection of Human Subjects, 82 FR 7149 (January 19, 2017). *Federal Register: The Daily Journal of the United States.*

Human Subjects Research

- A project that meets the definition of Research and involves one or more Human Subjects.

Engagement in Research

- In general, a CPMG physician is considered *engaged* in a particular Human Subjects Research, Clinical Trial, or Clinical Investigation when the physician, for the purposes of the Research, Clinical Trial, or Clinical Investigation, obtains: (1) data about the Human Subjects through intervention or interaction with them; (2) identifiable private information about the Human Subjects of the Research; or (3) the informed consent of Human Subjects for the Research.
- KPCO and CPMG utilize the Department of Health and Human Services’ Office of Human Research Protection’s “Engagement of Institutions in Human Subjects Research” (2008) document as a guide for determining whether an activity constitutes “engagement in research.”