

CHR POLICY ON RESEARCH ETHICS

The Center for Health Research (CHR) is dedicated to the search for knowledge for public benefit achieved through adherence to high ethical standards of research. In all aspects of their work and association with CHR, CHR staff and associates are expected to adhere to high standards of ethical conduct. This document does not attempt to identify all ethical standards that apply to the work of CHR and to its employees and associates. Rather, it seeks to make explicit certain behavioral expectations that, along with other policies and procedures of CHR, govern the conduct of research. This document summarizes CHR's requirements for research ethics and supports KP national policy on research misconduct: [Research Misconduct policy document](#)

As used in this document, "subject" refers to the person participating in the research as well as to the person legally responsible for that person if that person is a minor or legally incompetent. The use of headings is for convenience and clarity rather than to limit the applicability of the statements. From time to time this document will be reviewed to maintain currency.

A. Investigators

1. Investigators will not propose or engage in research in which (a) the probable risks to subjects are not identified and minimized to a reasonable extent, and (b) the risks are not reasonable in relation to the probable benefits to subjects and the importance of the knowledge to be gained.
2. Investigators will not knowingly use their research roles to obtain information from subjects for other than research purposes.
3. Investigators and CHR administration will honor commitments made to subjects as part of the actual or implied research contract with them.
4. Investigators will not make commitments to subjects that they cannot fulfill or that have not been agreed to by CHR and, if applicable, by KP.
5. Investigators will pursue research in an objective and scientifically disinterested manner. Any potential conflict of interest will be disclosed to the RSPO on the "Study Summary" form and to CHR's Chief Operating Officer prior to study commencement. More information on CHR and KP's conflict of interest policy may be found at:
http://kpnet.kp.org/national/compliance/principles/pract_conflicts.html
<http://centernet/centernet/LeadershipPolicies/conflict/default.aspx>
6. Investigators who serve as the principal investigator on a project (whether internally or externally funded) will act to ensure the integrity of project records and data during the life of the project. After project completion, project records and data will be archived. Principal investigators sign an assurance to this effect on the KPNW RSPO Initial Review Questionnaire. Source documents/records and basic computer data files will not be destroyed without the authorization of the investigator originating them, if available, and the CHR Director who will consult with the investigator group before authorizing their destruction. Privacy Rule / HIPAA documentation, as required by 45CFR164.316, will be retained for at least 6 years from the date of its creation or the date when it last was in effect,

whichever is later. And, other study documents must be retained for at least three years for federally-funded projects, per OMB circular A-110 statement “Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the Federal awarding agency.”.

The retention of documents and data will safeguard scientific access for replications of published analyses and for secondary use of project data and records consistent with standards for protection of human subjects. The investigator who is the primary author of a published paper or of a paper delivered (with a final written draft) at a scientific meeting will maintain records for a reasonable period of time documenting data and methods sufficient for replication or other scientific review.

7. Investigators who act as sponsors or primary coinvestigators on projects conducted through CHR, but directed by persons outside CHR, will be responsible for ensuring data integrity as described in paragraph no. 6, above.
8. Investigators will include in published research findings adequate caveats to alert readers to deficiencies of data, method, or project implementation as they may bear on reported findings.
9. Investigators will present their findings honestly; they will not knowingly distort or omit data that would significantly modify the interpretation of findings.
10. Investigators will make their own biases or values explicit whenever these might reasonably affect their interpretation of research findings.
11. Investigators will not misrepresent their abilities or qualifications in research applications.
12. In developing and pursuing research, investigators will respect the legitimate interests in data sets and research areas delineated by the research agenda of others.
13. When financial support for research has been accepted, the investigator will make every reasonable effort to carry out the research and to fulfill the reporting requirements of the funding source.
14. Investigators and CHR administration will ensure that all project and CHR staff are informed as to CHR policy on research ethics and confidentiality. Principal investigators sign an assurance to this effect on the KPNW RSPO Initial Review Questionnaire. The RSPO defines training criteria in Standard Operating Procedure 009 and provide training at:
<http://centernet/centernet/rspo/apps/cert/default.html>
15. Investigators serving as sponsors of research conducted by persons outside CHR will ensure that the research complies with CHR's procedures and policies, including those on confidentiality and ethics.
16. When serving as the principal investigator on a project, investigators will fulfill the principal investigator role as defined in grants or contracts accepted by CHR.

B. CHR Investigators, Other Employees, and Associates

(e.g., student trainees, visiting scholars, outside investigators)

1. All informed consent and confidentiality procedures as specified by the Kaiser Permanente Northwest Institutional Review Board, Kaiser Permanente organizational policy, and CHR will be followed.
2. Investigators and other employees/associates will adhere to the procedures and practices in effect at CHR for the collection, processing, and reporting of data.
3. CHR investigators and other employees/associates are required to comply with federal and KPNW regional policies on misconduct:

http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

http://kpnet.kp.org/national/compliance/principles/pract_busrecords.html.

CHR has policies and procedures for responding to allegations of research misconduct, and is committed to compliance with those policies and procedures.

See: [Research Misconduct policy document](#)

Types of research misconduct prohibited at CHR are: fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
 - Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.
4. Investigators and other employees/associates who have access to privileged or confidential information because of their employment at the Center for Health Research or their involvement in a research project will not exploit that information for their own or another's private, financial, or other interests.
 5. Investigators and other employees/associates who become aware of any breach of research ethics described in this document or in the confidentiality of patient and study participant data will report the breach to their supervisor, the CHR Research Integrity Office (Don Freel, COO), or the [Compliance Hotline](#) 1-888-774-9100. Kaiser Permanente's "Principles of Responsibility" emphasizes that it is all KP employees' responsibility to maintain an environment in which we can speak candidly about our concerns and report suspected noncompliance without fear of retaliation. Managers and supervisors have additional responsibilities to promote this kind of environment. Kaiser Permanente does not tolerate retaliation against individuals who:
 - report illegal, unethical, or otherwise inappropriate acts,
 - refuse to participate in wrongdoing, or
 - cooperate with government investigations.

Anyone who retaliates against individuals who report or refuse to participate in violations of law, regulations, policies, or the Principles of Responsibility is subject to disciplinary action up to and including termination. Furthermore, according to federal guidelines that CHR must follow (42 CFR 93.108), the disclosure of the identity of complainants (those who alert their supervisor and CHR Director) in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law.

C. Data

1. All data pertaining to research subjects will be handled and maintained in conformity with CHR and KPNW policies and procedures on confidentiality:
 - <http://www.kpchr.org/public/spo/hipaa.htm>
 - <http://centernet/centernet/LeadershipPolicies/HIPAA/default.htm>
 - <http://www.kprchr.org/public/rspo/confidentiality.htm>
 - http://kpnet.kp.org/national/compliance/principles/pract_respecting.html
 - http://kpnet.kp.org/hipaa/regional_info/nw_region.html
 - http://internal.or.kp.org/ice/policies_procedures/hipaa_privacy_policies/14_HIPAA_PRIV_kp_Minimum_Necessary_NW.pdf
2. Data collection procedures will conform to scientifically accepted standards to assure the integrity of the data.
3. When an investigator(s) proposes to use data for a project or a presentation or publication that were produced for other purposes by another investigator(s), the latter will be invited to participate as co-investigator(s) or co-author(s) if that investigator is still affiliated with CHR.
4. Acknowledgment of the contribution of the investigator(s) who produced the data used by another will be made when the former elects not to participate as co-investigator(s) or co-author(s) or is no longer affiliated with CHR.
5. Data obtained through CHR are the property of CHR, although investigators are guaranteed access to those data requisite to their research as long as they are affiliated with CHR, and as long as there are appropriate IRB approvals and access is in accordance with Privacy Rule / HIPAA requirements.
6. Investigators terminating employment or association with CHR will continue to have access to those data necessary for the completion of work in progress unless termination is for violation of ethics or confidentiality.
7. Records/documents and data files can be removed from CHR only with authorization of the CHR Director and only under the conditions specified by the Director. See:
 - <http://centernet/comptech/apps/documents/getdoc.aspx?docid=53e83eba-5b67-4a42-82ed-b0e905472c1f>
 - <http://centernet/comptech/apps/documents/getdoc.aspx?docid=02e80c21-d1c1-4782-b7b6-eea6557a59a0>
 - http://centernet/centernet/documents/getdocbypath.aspx?path=Documents/Centernet/LeadershipPolicies/TDATA_TRANS.pdf

- <http://centernet/centernet/documents/getdocbypath.aspx?path=Documents/CenterNet/leadershipPolicies/movingdata.pdf>

D. Funding and Funding Sources

1. Funding will not be sought or accepted for research that appears likely to violate the research ethics of CHR.
2. Sources of financial support for research will be acknowledged in reports and publications of the research unless the funding source requests that acknowledgment not be given.
3. Funding for research will be accepted only where findings can be made a part of the public domain, except that CHR may engage in limited research for the exclusive benefit of its host organization, Kaiser Permanente.

E. Authorship/Acknowledgments

1. The author(s) of reports, papers, and publications will be responsible for the content of these documents, which includes but is not limited to the scientific quality of the work exhibited in the document.
2. Authorship and the order listed on reports, papers, and publications will accurately reflect the investigators' professional contribution and responsibility for the data, findings, and reporting of the research.
3. Persons who play a leading administrative or creative role in the design or implementation of a demonstration project or intervention program will be appropriately recognized through authorship or acknowledgment.
4. The lead author on a publication, report, or presentation will be responsible for the designation of persons for authorship, order of authorship, and acknowledgment.
5. With their permission, acknowledgment will be made in the reports, papers, and publications of those whose assistance was in some way special but not sufficient for authorship.
6. Researchers using CHR's core data systems such as the inpatient and outpatient information systems will acknowledge CHR's development and maintenance of those systems in their reports and publications.

F. Publications

1. CHR will ensure the right as well as the responsibility of researchers to publish the results of their research.
2. Investigators will not engage in research where the contractor or granting agency reserves the right to withhold the publication of research findings with the exception that research performed for the benefit of Kaiser Permanente may be withheld from publication when agreed to in writing in advance of performing the research.
3. Publications will acknowledge or identify CHR and, if applicable, the source of funding.
4. Official publication of research results will be through scholarly or scientifically recognized organizations or publishers.
5. The news media will not be used to release research results prior to publication or presentation at a scientific meeting or other outside peer review, with the

exception of public policy research funded by an agency that might elect to release findings in this or alternate ways.

Document Approval

This policy, version 2.0, was reviewed and approved by CHR's Compliance Committee on April 18, 2007.