Policy Title: Minimum Participation Requirements for Collaborative Research at KPSC	Policy Number: RRP.2011.01.03
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1.0 Policy Statement

KPSC encourages mutually beneficial research collaborations with outside organizations or entities; such collaborations can advance science and medicine, enhance the work experience of participating clinicians and lead to improved care for our members.

2.0 Purpose

When KPSC collaborates with outside organizations or entities on research studies involving KPSC members and/or their data, there is a minimum level of KPSC participation that is required. This policy outlines the minimum participation required at each stage of the research process. Its intent is to help investigators navigate the research process more smoothly and to facilitate mutually beneficial collaborations.

3.0 Scope/Coverage

This policy applies to all employees who are employed by the following entities (collectively referred to as "Kaiser Permanente"):

3.1 Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals (together, KFHP/H);

3.2 KFHP/H's subsidiaries;

3.3 Southern California Permanente Medical Group (SCPMG) (staff and physicians).

Because of the differences between clinical trials and other research, much of the information in this policy may not apply to a clinical trial.

4.0 Definitions

Biospecimen. Samples of human material such as urine, blood, tissue, cells, DNA and RNA.

Business Associate Agreement. A contract between two parties executed when KPSC discloses protected health information (PHI) to a Business Associate or when a Business Associate creates PHI on behalf of KP.

Confidentiality Agreement. A contract between KPSC and outside collaborator(s). Outlines confidential materials such as patient data that the parties wish to share with one another for certain purposes, but wish to restrict from generalized use.

Data Use Agreement (DUA). A contract required when a Limited Data Set (as defined by the HIPAA Privacy Rule) is used or disclosed in the context of research.

Indirect Cost. Costs that are incurred for common or joint objectives, and therefore, cannot be identified readily and specifically with a particular research project. Examples of indirect costs include the costs of operating and maintaining facilities, and general

administration and general expenses, such as the salaries and expenses of personnel administration and accounting.

Institutional Review Board (IRB). An independent committee constituted according to federal regulation (DHHS 45 CFR 46) for the purpose of reviewing and monitoring research, assuring that it is conducted so as to protect the safety, welfare and rights of research participants.

Limited Data Set. The HIPAA Privacy Rule makes provisions for and defines a "limited data set," authorized only for public health, research, and health care operations purposes. A limited data set must have all direct identifiers removed, including name and social security number; street address, e-mail address, telephone and fax numbers; certificate/license numbers; vehicle identifiers and serial numbers; URLs and IP addresses; full face photos and comparable images; medical record numbers, beneficiary numbers and other account numbers; device identifiers and serial numbers; and biometric identifiers, including finger and voice prints. A limited data set could include the following: admission, discharge, and service dates; dates of birth and death; age (including age 90 or over); and five-digit zip code or any other geographic subdivision, such as state, county, city, precinct and their equivalent geocodes (except street address).

Material Transfer Agreement. A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

Protected Health Information (PHI). Identifiable health information, including any demographic or other descriptive information that could link the identity of an individual to his/her health information. It includes information in paper medical records and in electronic databases or disease registries. It also includes identifiable information communicated verbally.

Principal Investigator (PI). The primary individual responsible for the scientific, technical, and administrative conduct of a research project. The PI is responsible for assuring that the research is conducted in compliance with federal regulations, and KPSC policies and procedures.

Sponsored Projects Administration (SPA) Unit. SPA provides dedicated finance staff, specially trained in research administration, to assist and coordinate in the pre-project administrative aspects required to conduct research.

5.0 Provisions

5.1 Developing the scientific question. It is *strongly encouraged* that KPSC collaborators provide input in the development process to ensure that the question asked is one that is scientifically sound, that will benefit KPSC members, and that KPSC can meaningfully participate in answering. Proposed projects in which KPSC's participation appears to be little more than providing access to our members and our data will not be approved. A KPSC investigator must be

actively integrated in conducting the research in cases where KPSC does not help develop the question. In all cases, there should be a KPSC author on manuscripts and abstracts based on the research.

5.2 **Developing the study.** With rare exceptions approved by the KPSC Senior Director of Research, a KPSC investigator must be involved in developing the study design and protocol. If multiple KPSC sites are involved, it is ideal (but not required) that someone from each site participate. If all the data are to be collected at KPSC, a KPSC investigator must be the principal investigator (PI); only rarely will exceptions to this rule be granted. A data use agreement specifying how data may be shared with and used by outside collaborators must be in place before any data are shared with non-KPSC collaborators..

5.3 **Funding and budgets.** KPSC requires that all research-related expenses be paid by the research project. This includes collaborations that request limited KPSC involvement, such as using KPSC staff to recruit KPSC members.

5.3.1 KPSC researchers and collaborators should consult with Research & Evaluation's SPA unit as early as possible for guidance in developing budgets and statements of work.

5.3.2 The usual expectation is for the budget to cover at least 10% FTE effort for the KPSC PI.

5.3.3 Indirect costs are included in all KPSC research budgets.

5.3.4 Once funding has been secured, contracts between KPSC and collaborators must be executeded. This includes the contract specifying KPSC's role, responsibilities and budget. It may also include confidentiality or non-disclosure agreements, memoranda of understanding, or business associate agreements. The SPA Unit works with investigators to complete this paperwork.

5.4 **Study implementation.** Research conducted at KPSC facilities, or involving information or biospecimens of KPSC members, *must* be implemented by KPSC staff under the direction of a KPSC investigator. Such research must conform to all applicable KPSC policies.

5.4.1 **IRB Review.** Any research that includes sharing KPSC patient data or biospecimens with outside institutions, including other KP regions, must undergo KPSC IRB review and must be IRB-approved before research activities can begin. Similarly, research that includes another institution sharing their data with KPSC must also undergo KPSC IRB review. Any changes to study protocols must be approved by the IRB before they can be implemented. Any adverse events or protocol violations must be submitted to the KPSC IRB per IRB policy.

5.4.2 **Consent to Contact Patients.** Some collaborators may wish to recruit KPSC members to outside studies (e.g., not conducted at a KPSC facility, not requiring any KPSC resources, and not accessing any KPSC member data or biospecimens). Investigators interested in this type of

recruitment must contact the KPSC Senior Director of Research for consent to contact these patients. The determination of whether or not to give consent will be made after feedback is solicited from relevant clinical personnel. KPSC members' physicians of record are not authorized to provide this consent. KPSC IRB review is required for this type of project; no patient names or contact information may be released for research purposes without IRB approval and a Data Use Agreement (DUA) in place.

5.4.3 **Administration of Informed Consent.** For all research conducted at KPSC facilities that requires informed consent, KPSC staff (rather than collaborators' staff) must administer the consent and retain the fully executed informed consent form in the study participants' files. This file with the informed consent document must remain in the custody of KPSC. In rare circumstances, exceptions to these requirements may be granted by the KPSC Senior Director of Research.

5.4.4 **Data Collection.** For KPSC members participating in collaborative research, KPSC staff must collect and/or coordinate all biomedical information, surveys, or other data.

5.4.5 **Implementing Interventions.** Some research studies include medical and/or behavioral interventions. Unless the intervention requires a skill that KPSC staff do not possess and cannot reasonably be trained to carry out, all interventions should be implemented by KPSC personnel.

5.4.6 **Communications with Enrolled Participants.** Some research involves contacting participants after they have been enrolled; this may be to remind them of research appointments, to complete a questionnaire, or other reasons. In all cases, when KPSC members who are enrolled in a collaborative research study are to be contacted, this contact must be made by KPSC personnel.

5.4.7 **Use of Biospecimens.** Many studies involve biospecimens (existing specimens or new specimens collected specifically for research). If any biospecimens will be shared outside KPSC, specific guidelines must be followed. All KPSC biospecimens are owned and controlled by KPSC. Collaborating institutions must sign a Materials Transfer Agreement (MTA) defining the procedures for specimen access, tracking and return. No biospecimen transfer can take place until there is an MTA in place. Investigators whose research may involve biospecimens should confer with the KPSC Senior Director of Research.

5.4.8 **Sharing Data.** Collaborators must safeguard protected health information shared by KPSC. KPSC can share de-identified or limited data. Federal law – HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH Act) – regulates what data may be shared and how it may be shared.

5.4.8.1 De-identified data must exclude 18 specific identifiers. De-identified data may be shared without the execution of a DUA because such data cannot be used to identify the individual.

5.4.8.2 When the research requires sharing some limited identifying information, such as birth dates or zip codes, limited data sets may be used. Limited data sets exclude 16 specific identifiers that could link an individual with his or her information, but can include dates, five-digit zip codes, state, county, city and precinct. Because limited data sets include some PHI, KPSC will only share them when a DUA has been executed. KPSC requires DUAs for limited data sets even if the research is exempt from IRB review.

5.4.9 **Use of Biohazardous Agents, Toxins and Genetic Material.** Human subjects research conducted within KPSC involving biohazardous agents, select agents and toxins, recombinant DNA, gene transfer and gene therapy is subject to SOP KP-200 and must be reviewed and approved by a KPSC Regional Research Committee on Biosafety or the Institutional Biosafety Committee.

5.4.10 **Intellectual Property.** It is Kaiser Permanente's policy, subject to certain exceptions, that KPSC claims the exclusive right to all intellectual property arising from KPSC research. If KPSC's rights are shared with other institutions, organizations or program collaborators, or when such entities agree to contribute to the evaluation, development or exploitation of intellectual property, KPSC may elect to enter into separate agreements to establish the means by which intellectual property rights will be protected and royalties distributed.

5.5 Interpreting and reporting results. The development of study protocols should also include at least preliminary data analysis plans. Data analysis may be carried out by KPSC or by the collaborating institution; in either case, there should be communication regarding the analysis process and findings as it is underway.

5.5.1 Some analysis and the interpretation of some results should be guided by the intricacies of KPSC data. For example, an increase in the incidence rate of a given condition among KPSC patients may reflect a true increase in the disease, or it may reflect increased surveillance or a change in how cases are defined. Discussion and interpretation of KPSC clinical results in a manuscript or other forum must be drafted and approved by a KPSC author.

5.5.2 When reporting research results in any forum, all collaborators--including KPSC--should be acknowledged. For manuscripts submitted to scientific conferences or for publication in scientific journals, there must be a KPSC author if research was conducted at KPSC. The order of authorship should be defined by the role played in planning the study design,

collecting and interpreting data, and writing the manuscript. Which researchers should be listed as authors, and the order of authorship, should be guided by the Uniform Requirements of the International Committee of Medical Journal Editors. Honorary authorship to content experts or others who did not contribute meaningfully to the manuscript is not permitted.

6.0 References/Appendices

6.1 Health Insurance Portability and Accountability Act of 1996 (HIPAA):

6.1.1 U.S. Department of Health and Human Services. 45 Code of Federal Regulations Parts 160, 162, and 164; Health Insurance Reform: Security Standard, Final Rule (February 20, 2003).

6.1.2 U.S. Department of Health and Human Services. 45 Code of Federal Regulations Parts 160, 162, and 164; Standards for Privacy of Individually Identifiable Health Information; Final Rule (August 14, 2002).

6.2 Subtitle D of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009, addresses the privacy and security concerns associated with the electronic transmission of health information.

6.3 KP SCAL Data Security Principles for Collaborative Research http://kpnet.kp.org/ncal/researchsupport/documents/kfri_data_security_principles.doc.

6.4 KP Security Policy, SCAL-SEC-014 *Use of Data in Computing Environments*.

6.5 SOP KP-200

6.6 Uniform Requirements of the International Committee of Medical Journal Editors: http://www.icmje.org/#author.

6.7 Appendix A: Collaborative Research Flow Chart

7.0 Approval

This policy was approved by the following representative of the Department of Research & Evaluation

Steven J. Jacobsen
Senior Director of Research
Research & Evaluation

_Signed_____09/16/2015_____
Signature Date

Policy Life History

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APPENDIX A: COLLABORATIVE RESEARCH FLOW CHART