

Guidance on Requests for Student Involvement in Research or Scholarly Projects Kaiser Permanente Northern California

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Incorporates review comments from DMEs, RPMs and Doug Corley

This guidance is for physicians and personnel involved in Undergraduate and Graduate Medical Education (UME and GME and hereinafter may be referred to as GME), with the goal of recommending how to facilitate requests from physicians or students who seek arrangements for medical or undergraduate students to participate in research or scholarly projects.

This guidance does not apply to:

- Students from the Kaiser Permanente School of Medicine (KPSOM), who are handled via a different workflow. These can be facilitated by the Biostatistical Consulting Unit (BSCU), within the Division of Research. This support is available whether or not the student needs analytic support from the BSCU. Please contact the BSCU (BSCU@kp.org) for assistance.
- Medical, graduate, or undergraduate students selected for specific structured training programs approved for support by Medical Education. These programs already have specific onboarding processes. These include the:
 - [Public Health Research Internship Program](#) for undergraduate or graduate students, hosted by KP Napa-Solano
 - [UCSF/Kaiser Permanente Undergraduate Research Internship](#) for pre-medical students from underrepresented groups
 - [KP SCORE Program](#) providing medical students with summer clinical research opportunities in OB-gyn, otolaryngology, thoracic surgery, and emergency medicine, hosted by KP East Bay
 - If you have a specific structured training program approved for support by regional Medical Education that should be added to this list, please let us know by contacting the BSCU at BSCU@kp.org.

Principles

The opportunity to work with medical or undergraduate students has the potential to benefit individual attending physicians by offering avenues to mentor aspiring colleagues and enlist volunteer effort for projects the attending physician leads or supports. Mentoring students also can help build the pipeline of residents, fellows, and attendings and enhance national reputation for Kaiser Permanente as an organization. At the same time, making arrangements for students to have appropriate training and access to electronic health records requires effort from medical center-based UME, GME, and other personnel for logistics and for taking responsibility for mitigating data privacy and security risks.

This guidance is intended to support Kaiser Permanente attending physicians, including Directors of Medical Education and Program Directors, and personnel. It is meant to help those involved with such requests appraise the factors affecting tradeoffs between the benefits and costs of student involvement in projects. These recommendations were formulated based on input from the Directors of Medical Education (DMEs) and Research Project Managers (RPMs) with experience with such requests. This guidance was developed and will be maintained by the

Physician Advisor for Medical Education-Sponsored Research and the Managing Director of the BSCU, with oversight of the Institute for Medical Education leaders.

Workflow

In general, requests for students to be involved in research or scholarly projects need to be initiated by a sponsoring TPMG attending physician. Requests from students without a TPMG physician sponsor cannot be accommodated.

Students fall into one of four categories:

- A. At KPNC for a medical school clinical rotation currently or in the future
- B. In a specific structured training program approved by Medical Education (see list above)
- C. Has previously done a medical school-approved clinical rotation at KPNC
- D. None of the above – for example, a medical student who has never done a rotation with KPNC, or a college student

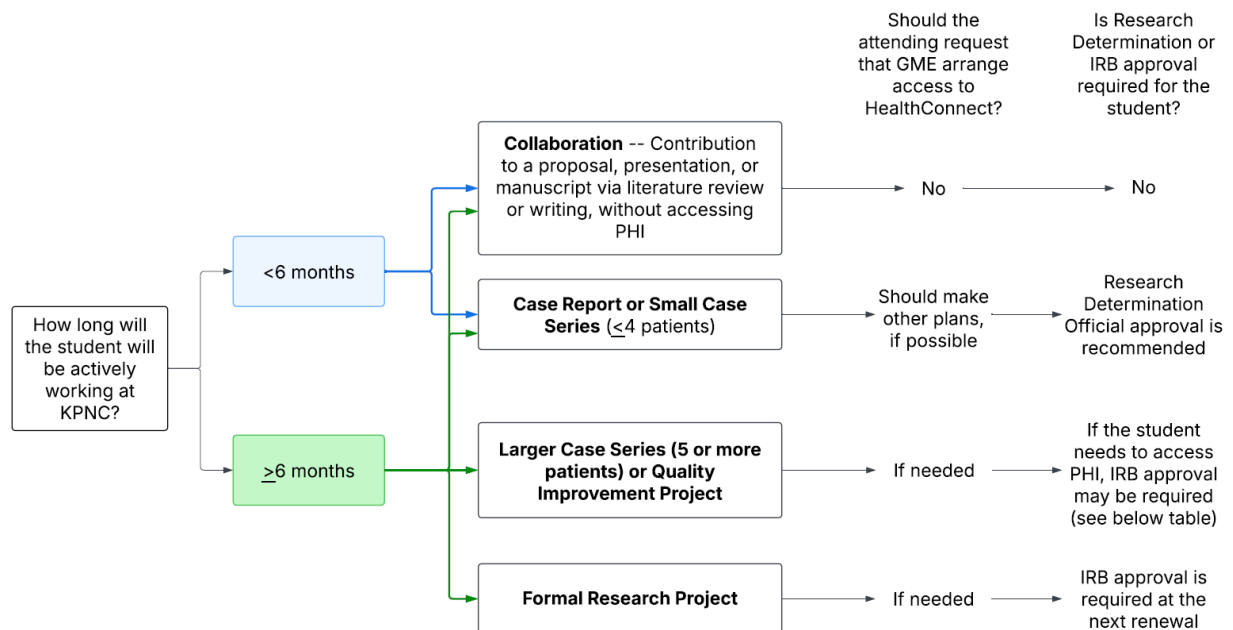
In general, students who are under the age of 18 are not eligible to participate in projects that require access to individual patient data.

1. For students in category A (at KPNC as part of a medical school clinical rotation), ask how long the student will actively be working with us at KPNC. “Actively” means that they are doing a clinical rotation that provides them with access to HealthConnect. Medical students who do clinical rotations at KPNC lose access to HealthConnect when their rotation(s) ends, and such access is not easy to extend.
2. Students in category C (who have previously done a medical school-approved clinical rotation with us) would need to be onboarded and given access to HealthConnect and/or other KPNC systems including an NUID and KP email. The attending physician who proposes to mentor the student should make a request of the DME at their medical center (see item 5 below). If a decision is made to onboard the student, the arrangement should follow their school’s formal affiliation agreement with KPNC. The ability to fulfill such requests is not guaranteed.
3. Students who will not be actively working with KPNC for at least 6 months should not be encouraged to participate in research or quality improvement (QI) projects that require access to individual patient data in HealthConnect. Such students should be encouraged to participate in (see **Table**):
 - Literature review, writing, or other aspects of scholarly projects that do not require handling individual patient data
 - Case reports
 - Case series (4 or fewer cases)

Note that for students working on case reports or case series, GME will generally not extend or re-establish their HC access after their clinical rotation at KPNC ends. If they are co-authoring such products, their TPMG attending should plan to make arrangements for them to participate without accessing HC after their clinical rotation. Ideally, the student should complete any chart review before finishing their clinical rotation; alternatively, the attending physician can complete the needed elements of chart review if the student no longer has HC access.

4. Students who will be supported by local GME leadership (the DME) to work actively with TPMG attendings and KPNC systems for 6 months or more are eligible to work with individual patient data during that period, provided they complete required training and agree to follow appropriate standards for data security. The 6 months is a rule of thumb and periods that are not consecutive but total 6 months may qualify.
 - The ability to handle individual patient data for 6 months or more makes a student eligible to work on additional types of projects, including (see **Figure**):
 - QI projects (these typically require Research Determination Official review, but often do not require IRB approval)
 - Formal research projects (these typically require IRB approval)

Figure. Workflow for planning student research or scholarly projects



See the **Appendix** for details and links to related guidance.

5. A TPMG attending physician who wishes to arrange for a student to access HealthConnect or other KPNC systems for a project may ask their DME whether such an arrangement is feasible. The DME has the authority and responsibility to decide whether their GME team has the resources to support such onboarding.

The ability to make such arrangements is not guaranteed and will depend on whether local resources are available. A DME who receives such a request should evaluate:

- a. Potential benefits of the arrangement for the attending
- b. Alignment with current GME programs (e.g., whether the attending or student are in a specialty for which KPNC has a residency or fellowship program)
- c. Whether the project idea or research question originated with the TPMG attending or with an outside physician or researcher
- d. Potential benefits of the project to KPNC as a learning health system

If the DME believes the project's benefits are compelling and that appropriate personnel have time available to make the needed arrangements, they can ask a medical center-based GME manager or administrator to arrange access to HealthConnect or other KPNC systems. The DME has the authority to make the decision and move forward without regional approval, but the regional team is available to provide consultation when requested (contact BSCU@kp.org). Research project managers (RPMs) are not able to arrange HealthConnect access for medical students, nor to extend existing HC access.

6. A TPMG attending who is interested in mentoring a student in a scholarly project should be aware that they will be primarily responsible for supervising the student. They will need to guide the student through the process of project or study design, protocol writing, gaining any needed approvals from the Research Determination Office or Institutional Review Board, data collection, and preparation of presentations or manuscripts. RPMs are not able to take on this responsibility. The time commitment for case studies and case series is more modest than for QI or formal research projects. QI or research projects can require 10 to 20 hours or more from the mentor over the course of a 6 to 12-month period.
7. For research projects with IRB approval, whether a student needs to be added to the IRB application depends on their role. If the student is not handling any individual patient data, they do not need to be added to the IRB application.

As of 11/1/2025, if the student does need to be added to the IRB study team, a formal IRB modification is no longer required. They should be added to the team if creating a new IRB project or during the next the Continuing Review/Progress Report/Administrative check-in. PIs are required to obtain and keep IRB approvals and study records, and to make these approvals available upon request by the IRB or institutional officials.

Appendix. Descriptions of project types and links to related guidance

Table. Overview of project types feasible for medical or undergraduate students

Time period the student will be actively working with KPNC	Type of project that is feasible for this student	Will the student need HealthConnect access for this project type?	Will the student need to complete or be added to an IRB application for this project type?
Less than 6 months	Collaboration -- Contribute to a research proposal, manuscript, or presentation (e.g., conducting a literature review or completing a manuscript)	No	No
	Case report or small case series (4 or fewer patients)*	No, provided the attending physician can make needed information available after the student no longer has clinical access to HealthConnect	No, but we encourage PIs to obtain Research Determination Office (RDO) exemption and mention medical student involvement
6 months or more	All above types of projects		
	Larger case series (5 or more patients), quality improvement project , or research project that <u>does not</u> require access to PHI	No	No
	Larger case series (5 or more patients), quality improvement project , or research project that <u>does</u> require access to PHI	Yes	Yes; if the project is IRB approved, the student should be added to the IRB study team. They are considered internal while onsite in KPNC. If the student is not onsite and is accessing PHI, they are considered an “outside collaborator” which requires submitting “Appendix O” to the IRB form and possibly a data sharing agreement.

- **Case Reports and Series:** At KPNC, we define a case report as an assessment of one patient, and a case series as an evaluation of fewer than 5 patients. Refer to Case Report and Series Guidance* for detailed definitions and instructions. Visit the Research Determinations* webpage for instructions on how to submit a case report/series approval request.
 - [Research Determinations Request Form](#)*
 - [KPNC Case Reports Patient Consent Form](#)*
- **Operational or Quality Improvement (QI) Projects:** If your idea is operational in nature and aims to evaluate existing local practices with a goal of documenting and correcting deficiencies, your project may qualify for exemption from Institutional Review Board (IRB) review. Visit the [Research Determinations](#)* office webpage for instructions on how to submit an exemption request.
 - [Determining Whether a Project Involves Human Subjects Research that Requires IRB Review](#)*
 - [Research Determination Definitions](#)*
 - [Research Determinations Request Form](#)*
 - [KPNC Patient Consent Form](#)*
- **Clinical Research:** Studies involving human participants to evaluate treatments, interventions, diagnostics, or epidemiological patterns and determinants of health and disease in populations.
 - [KPNC Investigator Manual](#)*
 - [KPNC Representation of Activities Preparatory to Research \(RAPToR\) Form](#)*
 - List of required trainings to conduct KPNC research:
 - [Complete Required IRB Training](#)*
 - Complete the [CITI Training](#) and select Kaiser Permanente as your organization:
 - Human Subjects Protection Basic: Biomedical (Biomed) Comprehensive or Social-Behavioral-Educational (SBE) Comprehensive
 - Conflicts of Interest
 - HIPAA Basics for Healthcare Professionals
 - [Create an IRBNet Account](#)*
 - Link to [IRBNet](#) - After creating your IRBNet account, go to the **‘Other Tools: Forms and Templates’** section to download all required forms and templates.

**KP Network Required*