

Kaiser Permanente Medical Care Program	Standard Operating Procedure	KFRI
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Purpose

This Standard Operating Procedure (SOP) is to document the process for verifying whether research, evaluation and analysis activities conducted in Kaiser Permanente (KP) are exempt from Institutional Review Board (IRB) review. Research that is determined to be exempt from IRB review under the Common Rule may be subject to HIPAA Privacy Rule provisions. When Privacy Rule provisions apply, this SOP also documents the process for complying with these requirements.

This SOP is written to comply with the terms of Federal Policy for the Protection of Human Subjects (Common Rule) 45 CFR 46, the HIPAA Privacy Rule (45 CFR 160 and 164), the KP Federalwide Assurance (FWA) #00002344, and the KP Human Research Participant Protection Program (HRPPP).

Scope

This SOP applies to activities typically conducted at KP. It does **not** address activities within exempt categories that typically do not apply at KP, such as those conducted in educational settings and taste and food quality evaluations. However, if an activity in one of these exempt categories is conducted at KP, federal regulations must be followed. (See Appendix A, Categories of Exemption under 45 CFR 46, §46.101.)

Definitions

See Appendix B, Definitions.

Policies

See Appendix C, Common Rule Exemption and HIPAA Determination Decision Tree.

1. The KP IRB will follow applicable federal regulations (the Common Rule) when determining if research is exempt from IRB review.

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2. The KP IRB will follow applicable federal regulations (the Privacy Rule) when determining if research that is exempt from IRB review requires written authorization to use and/or disclose PHI or whether the research qualifies for a waiver or alteration of such authorization.
3. The KP IRB and/or Region will communicate the criteria for exemption from IRB review, the process for verifying exemption from IRB review, and the HIPAA Privacy Rule requirements for research to the community of individuals who will potentially conduct research activities in the Region.
4. Verification of exemption from IRB review will be made only by the IRB of the KP Region in which the activity is being conducted.
5. The KP IRB may establish criteria for determining exemption from IRB review that differ from the federal criteria as long as the IRB criteria do not conflict with the federal criteria. Such criteria will be documented in writing.
6. The KP Project Leader or Researcher will not make the final determination of exemption from IRB review.
 - 6.1 The KP Project Leader or Researcher may make a preliminary determination of exemption from IRB review based on information provided by the IRB or the Region. The Project Leader or Researcher will then submit a request for exemption (see Appendix D for a model Request for Exemption from IRB Review and Determination of Privacy Rule Requirements) or a research application to the IRB.
7. KP will not provide a retrospective verification of exemption from IRB review to research that has already been conducted.
8. When reviewing an activity for the purpose of verifying exemption, the KP IRB/reviewer will review the entire scope of the activity, not individual components of the activity.
9. The IRB Chair is authorized to verify exemptions from KP IRB review.
 - 9.1 The IRB Chair may delegate this authority in writing to another appropriately qualified IRB member or the IRB Administrator. See Appendix E for a model IRB Chair Delegation of Authority.

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- 9.2 The reviewer can defer the decision to the convened IRB or to an appropriately constituted subcommittee of the IRB.
10. The KP IRB or designated reviewers will review all requests for exemption from IRB review within a reasonable timeframe after receipt of the exemption request.
- 10.1 If the project is determined to be **not** exempt from IRB review, the IRB Administrator or his/her delegate will notify the Project Leader/Researcher in writing, and instruct the Project Leader/Researcher to submit a completed research application for IRB review.
11. If the project is determined to be exempt from IRB review, the reviewer will determine if the HIPAA Privacy Rule applies.
- 11.1 If protected health information (PHI) will not be used and/or disclosed, the HIPAA Privacy Rule does not apply.
- 11.2 If PHI will be used or disclosed, the Privacy Rule applies. The reviewer will determine whether the project/study requires:
- Written authorization from individuals whose PHI will be used, or
 - A waiver of authorization.
- 11.3 If PHI will be used, disclosed to and/or created by a KP Business Associate, a Business Associate Agreement will be required.
- 11.4 If a Limited Data Set will be used and/or disclosed, a Data Use Agreement will be required, and a HIPAA authorization or waiver of authorization will not be required.
- 11.5 Disclosure accounting rules will apply if PHI will be disclosed outside of KP, unless pursuant to a signed authorization or as a limited data set.
12. To determine whether the requirement to obtain a HIPAA Privacy Rule authorization may be waived, the reviewer must be a member of the KP IRB with authority to conduct expedited review, which must be delegated in writing by the IRB Chair.
- 12.1 If the IRB Chair has not delegated authority to conduct expedited review in writing to the reviewer, the project will be given to an IRB member who does have such authority.

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13. To determine if a waiver of authorization can be approved, the reviewer must find and document the following:
 - 13.1 The use and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
 - a. An adequate plan to protect the identifiers from improper use and disclosure;
 - b. An adequate plan to destroy the identifiers at the earliest opportunity unless there is a health, research, or legal justification for retaining the identifiers; and
 - c. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law;
 - 13.2 The research could not feasibly be conducted without the waiver; and
 - 13.3 The research could not feasibly be conducted without access to and use of the PHI, and that access to PHI will be the minimum necessary to conduct the research.
14. If a project meets the waiver of authorization criteria, the reviewer may approve the waiver. The IRB Administrator will notify the KP IRB and Project Leader/Researcher.
15. If the project does not meet the waiver of authorization criteria, an authorization form will be developed for participants to sign.
16. Completion of an IRB-approved "Request for Exemption from IRB Review" (this can be the IRB research application or an abbreviated form such as that in Appendix D) will be required for processing a request for exemption from IRB review.
 - 16.1 The reviewer may request additional information from the Project Leader/Researcher and may confer with the IRB Chair or others for assistance in making the determination regarding exemption from IRB review and/or applicability of the Privacy Rule.

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17. The KP IRB staff will file all information relating to all projects meeting exempt verification and Privacy Rule requirements, including the notice of exemption, in a file maintained by the IRB Administrator.
 - 17.1 It is strongly encouraged that the category of exemption be documented in the IRB records.
18. Research involving contact with children or prisoners does **not** qualify as exempt (e.g., for survey research that might otherwise be exempt).

Exemption Criteria

1. Projects typically conducted at KP are considered to be exempt from IRB review if **all** activities being conducted under the project meet the federal criteria listed in 1.1 and 1.2 below. See Appendix A, Categories of Exemption under 45 CFR 46, §46.101 for a complete description of federal exemption criteria.
 - 1.1 The project is limited to the collection or study of **existing** data, documents, records, or specimens that:
 - a. Are publicly available; or
 - b. The information will be recorded in such a manner that it cannot be linked directly or through identifiers to an individual member, physician, employee, or other individual.
 - 1.2 The project involves survey or interview procedures or observation of public behavior, **unless**:
 - a. The information obtained is recorded in a manner that people can be identified (directly or indirectly or by identifiers); **and**
 - b. Any disclosure of individuals' responses outside the research could reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.
2. The KP IRB may want to consider **additional** exemption criteria to include:
 - 2.1 No data collected or analyzed under a project that meets exemption

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criteria 1.2 or 1.3 above will be released outside KP, including to a collaborator affiliated with another institution, a Business Associate, a vendor, an independent contractor, or a research sponsor; **or**

- 2.2 The results of the analysis that meet exemption criteria 1.2 or 1.3 above will not be published, presented or otherwise placed in the public domain.
3. Some KP IRBs consider a single case study to be exempt from IRB review; however, a series of case studies could lead to generalizable knowledge and is, therefore, subject to prospective IRB review.
 - 3.1 Each KP IRB should develop guidelines on the number of case studies that are considered as research and require IRB review. This number should be no greater than six.

Appendices

Appendix A: Categories of Exemption under 45 CFR 46, §46.101

Appendix B: Definitions

Appendix C: Common Rule Exemption and HIPAA Determination Decision Tree

Appendix D: Model Request for Exemption from IRB Review and Determination of Privacy Rule Requirements, Form KP-003

Appendix E: Model IRB Chair Delegation of Authority, Form KP-027

Categories of Exemption under 45 CFR 46, §46.101**IRB review is required by federal regulations except for the following:**

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Definitions

Agreement: Any legally binding document between two parties. The term “agreement” can be used interchangeably with “contract” or “subcontract.”

Authorization: A written agreement by an individual to permit use and/or disclosure of his/her Protected Health Information (PHI) for a particular research project according to HIPAA Privacy Rule standards. This agreement is commonly incorporated as a separate section in the research consent form.

Business Associate: An entity or person, not a member of KP’s workforce and not a Researcher, who performs research support services on behalf of KP that involve the use or disclosure of PHI (e.g., if you are a researcher and hire a mailing vendor to support your study, giving them names and addresses of study participants, the vendor is considered to be a Business Associate).

Business Associate Agreement: A legally binding agreement between KP and its Business Associate.

Common Rule: Federal regulations with which most federal agencies agree to comply in order to assure consistency in the standards and mechanisms for the protection of human research participants. The Common Rule is summarized in DHHS regulations 45 CFR 46, Subpart A.

Covered Entity: A health care provider, health plan, or health care clearinghouse that is required to comply with HIPAA Privacy Rule regulations. For the purposes of research, the KP Region functions as a covered entity, although it is technically an Organized Health Care Arrangement (OHCA), a type of covered entity under the HIPAA Privacy Rule.

Data Use Agreement: A legally binding document required when Limited Data Sets are used or disclosed in the context of research.

Department of Health and Human Services (DHHS): The cabinet-level department of the U.S. government that promulgates regulations to protect human research participants.

Disclosure: Releasing, transferring, providing access to, or divulging PHI outside KP and/or between KP Regions. This includes situations in which an individual, not in KP’s workforce, has access to PHI on KP premises (e.g. clinical trials monitor).

Exempt: Does not require KP IRB review or monitoring or compliance with 45 CFR 46 requirements for informed consent, etc.

Existing Data or Specimens: Data or specimens in existence prior to implementation of the research project or activity.

Expedited Review: A review of a study or study-related document or change that is conducted by the IRB Chair or by one or more appropriately qualified reviewers designated by the Chair from among the members of the IRB. To qualify for expedited review, the study or study-related item must be determined to be minimal risk and meet additional criteria as defined by federal regulation and IRB policies. Privacy Rule waivers, alterations, and authorizations may be approved using an expedited review procedure.

Federalwide Assurance (FWA): An agreement between a research institution and the Office for Human Research Protections (OHRP), stipulating terms by which the institution will protect the safety, welfare and rights of research participants in accordance with federal regulations (45 CFR 46). KP's FWA stipulates that 45 CFR 46 will apply to all research conducted in KP, regardless of sponsor.

Health Insurance Portability and Accountability Act (HIPAA): The Health Insurance Portability and Accountability Act was passed by the U.S. Congress in 1996. New regulations have been promulgated by the Department of Health and Human Services (DHHS) under the law, which are known as the "Privacy Rule."

Human Research Participant Protection Program (HRPPP): A systematic and comprehensive program to assure compliance with applicable federal regulations and the protection of research participants. KP's HRPPP covers the following compliance areas: Human Subjects, Conflicts of Interest, Research Misconduct, HIPAA, and Clinical Trials.

Institutional Review Board (IRB): An independent and formal committee comprised of scientific and non-scientific members with authority and responsibility to determine if research can be conducted under its jurisdiction and under what conditions. IRBs are responsible for monitoring research until it is complete.

Kaiser Permanente Medical Care Program (KP): The national health care program comprised of several corporate entities including Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, and eight Permanente Medical Groups.

Limited Data Set: Information that can include specific identifiers and must exclude others considered to be PHI. A Limited Data Set may **include**:

1. Dates (e.g. admission, discharge, and service dates, dates of birth and death); and
2. Five-digit zip codes and state, county, city, and precinct, but not any other postal address information.

A Limited Data Set must **exclude** all of the following identifiers:

1. Names;

2. Street addresses;
3. Telephone numbers;
4. Fax numbers;
5. E-mail addresses;
6. Social Security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Other account numbers;
10. Certificate and license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URL)
14. Internet Protocol (IP) addresses;
15. Biometric identifiers, including finger and voice prints; and
16. Full-face photos and any other comparable images.

Linked: It is possible to connect information about or relating to an individual to the identity of that individual, including by a code maintained by the Principal Investigator (PI) or other, that could be used to make such a connection.

Minimum Necessary: Reasonable efforts are made to limit the use or disclosure of PHI to only that which is necessary to accomplish the intended purpose.

Office for Civil Rights (OCR): A federal regulatory office within DHHS which has enforcement authority of the HIPAA Privacy Rule.

Office for Human Research Protections (OHRP): A federal regulatory office within DHHS responsible for compliance with 45 CFR 46.

Privacy Rule: A comprehensive federal regulation which provide protection for identifiable health information referred to in the regulation as protected health information (PHI). The Privacy Rule establishes the conditions under which PHI may be used and/or disclosed by health care organizations that qualify as covered entities (CEs), such as KP.

Project Leader/Researcher: The KP individual responsible for the research or research-related activities being reviewed for exemption from IRB review.

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 maintained in paper medical records and in electronic databases or disease registries. It also includes identifiable information communicated verbally.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The term “study” is used interchangeably with “research.”

Researcher: In the context of this SOP, researcher is an individual or a team that performs one or more of the following functions in support of a research project: study design; data analysis or interpretation; or reporting of research findings.

Unlinked: It is impossible by any means to connect information about or relating to an individual to the identity of that individual.

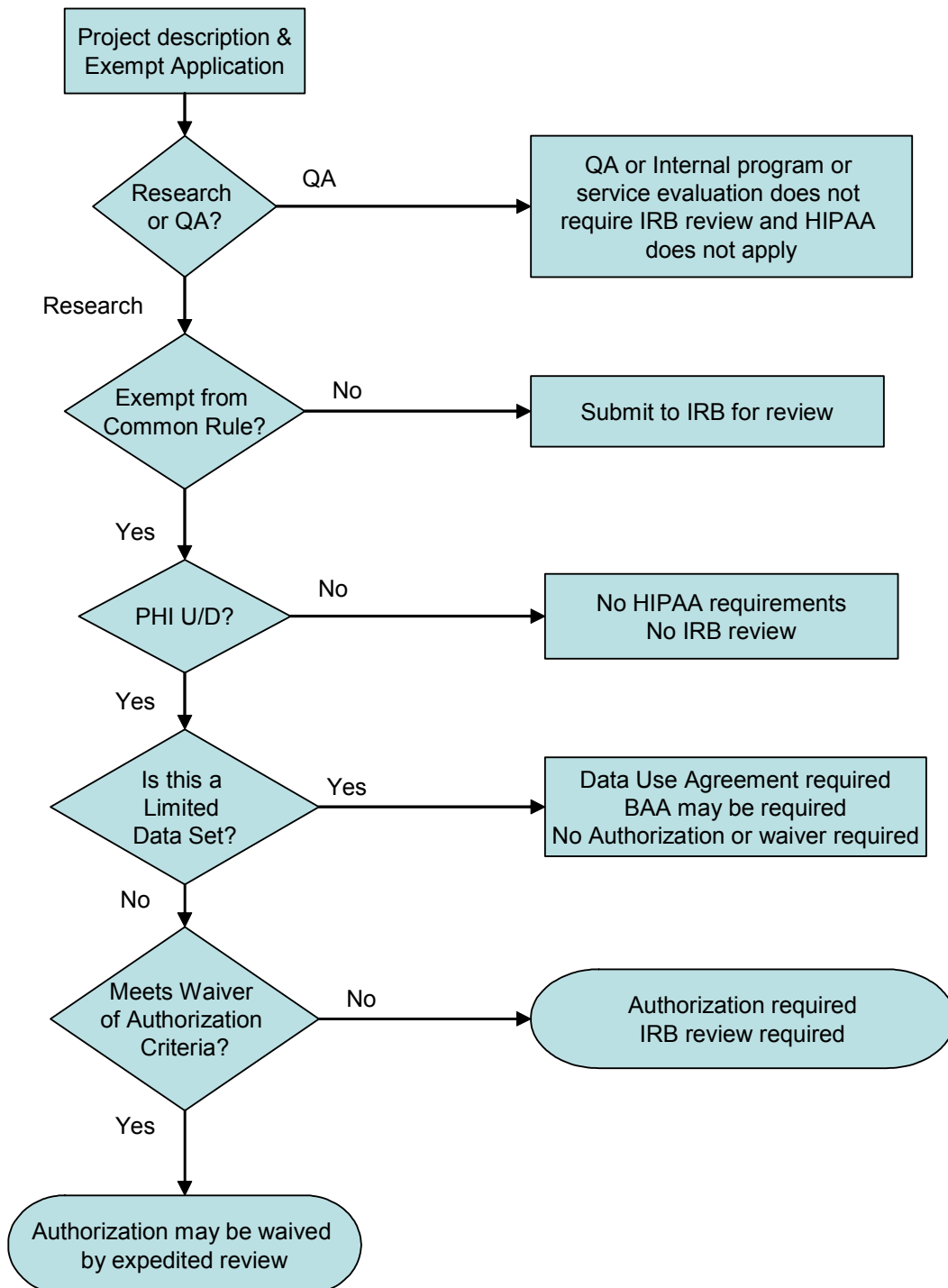
Use: Sharing, using, applying, examining, or analyzing PHI within a KP Region.

Verification: The process by which the KP IRB reviews a preliminary determination of exemption and officially determines and documents that the activity is or is not exempt from IRB review.

Waiver of Authorization: A waiver of the requirement for a written agreement by an individual, permitting the use and/or disclosure of PHI, as approved by the IRB.



Common Rule Exemption and HIPAA Determination Decision Tree





Request for Exemption from IRB Review and Determination of Privacy Rule Requirements (model form)

Complete this questionnaire for all projects for which you request exemption from IRB review. If you are completing this form in Word, type in the shaded text box, as appropriate.

Project Title:		
Kaiser Permanente Project Leader		
Name (Print)	Phone	Fax
Facility	Dept	E-mail
Signature (Not required if sent by e-mail)		

1. Does this project involve any prospective clinical intervention that differs from standard care?

Yes No
2. Is this project being conducted for internal quality assessment purposes only?

Yes No
3. If existing data, documents, records, or specimens will be used, are they ALL publicly available?

Yes Not all publicly available No existing data will be used
4. If this project involves a case study methodology, how many cases will be analyzed?

Not a case study Number of cases to be analyzed is:
5. Does this project involve survey, interview, observation, or any other prospective data collection?

Yes No
6. Will information collected or obtained under this activity be recorded in such a way that it can be linked directly or indirectly to any individual (including by an identifier, such as a code for which someone maintains a link)?

Yes, individuals could be identified* No
7. Could any disclosure of individuals' responses to survey or other data collection activities place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation?

Yes No

8. Will information collected or analyzed under the project be released outside KP, including to a collaborator affiliated with another institution, a business associate, an independent contractor, or a research sponsor?
- Yes No
9. Are there additional activities in this project that are not covered within the scope of questions 3 to 8?
- No Yes (briefly describe):
10. Will this project involve any increase in risk to participants (including risk to privacy, safety, welfare, or rights) beyond that normally encountered in everyday life?
- No Yes (briefly describe):
11. Will anyone working on the project have access to Protected Health Information (PHI) as defined under the HIPAA Privacy Rule?
- No Yes
- If yes, are all of these individuals on KP's workforce?
- No Yes
12. Will any PHI be released outside the KP Region and, if so, to whom?
- No PHI will be released
 PHI will be released to outside researcher(s) or collaborating research institution(s) including collaborators or coordinating centers (name):
 PHI will be released to research sponsors or pass-through grantors (name):
 PHI will be released to non-KP service vendors such as mailing services, survey services, web hosting, data/specimen storage services, laboratory or radiology services (name):
 PHI will be released to others (name):
13. If PHI will be released outside the KP Region, choose one:
- PHI will be released on fewer than 50 individuals, or
 PHI will be released on 50 or more individuals
14. Is the PHI to be used in KP or released outside KP the minimum necessary to conduct the project?
- Yes No
15. Do you assure that PHI to be used or released will not be reused or re-released to any other person or entity other than those listed in questions 11 and 12 above?
- Yes No
16. Describe your plan to protect the PHI from improper use or disclosure:
17. Describe your plan to destroy PHI at the earliest opportunity or provide a rationale for not destroying it:
18. Describe why you cannot feasibly conduct this project without access to this PHI:

19. Describe why the project could not feasibly be conducted if written authorization from all individuals whose PHI will be used were required:
20. Will videotapes, audiotapes, or photographs be made in which individuals may be identified?
 Yes No
21. Is this study being used to satisfy an academic degree requirement?
 Yes No
22. Please provide a one-paragraph summary description of the proposed project:

Submit this completed form to: (add Region-specific information)
E-mail submission to: (IRB Administrator)

IRB Chair Delegation of Authority (model form)

Name of IRB:

Name of IRB Chair:

Date:

I delegate authority to verify exemption from IRB review to the following IRB members or individuals:

- 1.
- 2.
- 3.

I delegate authority to conduct expedited review to the following IRB members:

- 1.
- 2.
- 3.

I delegate authority to sign IRB meeting minutes after IRB approval to the following IRB members:

- 1.
- 2.
- 3.

I delegate authority to sign or send correspondence on behalf of the IRB to the following IRB members:

- 1.
- 2.
- 3.

I delegate authority to act as Chair in my absence to the following IRB members:

- 1.
- 2.
- 3.

I delegate authority to conduct facilitated review on studies reviewed by the CIRB to the following IRB members:

- 1.
- 2.
- 3.

Signature of IRB Chair

Date