Does Your Study Require IRB Review?

Note that the PDPH IRB requires review of some studies that are exempt from review per federal regulation. These are noted below. Please contact our office (IRB_submission@phila.gov) if you have questions.

Submission of request for Determination. Complete an application through the OneAegis system (https://pdph.oneaegis.com/Login.aspx) at any time if you believe your study does not require IRB review. Do not wait for an IRB submission deadline. If the study is determined to require IRB review, or if waiver of HIPAA authorization is required, be prepared to submit materials for full IRB review.

Your study may not require IRB review in the following circumstances (references are to the applicable federal regulations):

Not research per federal regulations

- The study is not a systematic investigation designed to develop or contribute to generalizable knowledge. 45CFR46.102(l)
- The study is restricted to scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected. 45CFR46.102(l)(1)
- The study is a public health surveillance activity conducted by a public health authority that is specifically authorized by law to collect or receive such information for the purpose of preventing or controlling disease. Note that this PDPH policy is more restrictive than the exemption at 45CFR46.102(l)(2)
- The study is collection and analysis … by or for a criminal justice agency solely for criminal justice or criminal investigative purposes. 45CFR46.102(l)(3)
- The study is limited to authorized operational activities … in support of …national security missions. 45CFR46.102(l)(4)

Not human subjects research per federal regulations

- The study does not involve living individuals about whom you: (1) Obtain information or biospecimens through intervention or interaction with the individual; or (2) Obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens. 45CFR46.102(e)

Exempt per federal regulations (not applicable to studies involving prisoners; numbers 1-5 do not apply to FDA-regulated studies)

The study is limited to the following:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction
(2) Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner

that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; 45CFR46.104(d)(2)(i) (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. 45CFR46.104(d)(2)(ii) Note that studies exempt with limited review under 45CFR46.104(d)(2)(iii) are not exempt from review per PDPH policy.

(3) Research involving benign behavioral interventions 45CFR46.104(d)(3): Research involving interventions is not eligible for exemption from review by the PDPH IRB.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met 45CFR46.104(d)(4):
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under [HIPAA] 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations'' or "research'' as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes'' as described under 45 CFR 164.512(b); Use of this exemption means that the use or disclosure of data meets all HIPAA requirements. Unless HIPAA authorization for research has been provided by the subjects, a waiver of HIPAA authorization will be required.
or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with regulations specified in 45CFR46(104)(d)(4)(iv) You must document that the study procedures meet the specific regulatory criteria in category 4(iv) in order to claim this exemptions.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs... (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing

the research involving human subjects. 45CFR46.104(d)(5) You must document that the study meets the specific regulatory criteria in category 5 in order to claim this exemption.

(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. 45CFR46.104(d)(6)

PDPH IRB requires review by the full Board of studies eligible for limited review under federal regulations 45CFR46(104)(2), 45CFR46(104)(3), 45CFR46(104)(7) and 45CFR46(104)(8)