Retrospective and Prospective Record Review: IRB implications

The method used in conducting record reviews for human research studies has implications related to the type of IRB review and informed consent requirements.

Review Type

Secondary research involves research use of material collected for some other primary or initial activity. Several factors are involved in determining whether secondary research requires IRB review, and if so the appropriate review type. If you are conducting a review with identifiable private records, the records meet the definition of human subject and IRB review is required. **A record review involving little to no risk to subjects may be eligible for Exempt Review** or Expedited Review. **Both permit secondary use of material retrospectively or prospectively collected.**

- **Retrospective record review:** evaluates data that is existing at the time the protocol issubmitted to the IRB for initial approval.
- **Prospective record review:** evaluates data that **does not yet exist** at the time theprotocol is submitted to the IRB for initial review.

For help determining which review is needed, see the criteria below or link to the ORI Interactive Secondary Research Tool.

Exempt Category 4 (2019) *Secondary research for which consent is not required: Use of identifiable private information or identifiable biospecimens that have been or will be collected for some other "primary" or "initial activity," if at least one of the following criteria is met:*

i. *The identifiable private information/biospecimens are publicly available*

ii. *Information, which may include information about biospecimens, 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 notcontact 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 careoperations" 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); 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 non-research 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 section 20B(b) of the E-Government Act of 2002, 44 U.S.C. 3501.*

Expedited Category 5 *Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis) or material obtained for research purposes, as long as the material was not collected for the currently proposed research. The objectives may be the same or similar to the original research and the use should be consistent with the terms and promises set forth in the informed consent for which the material were originally obtained.*

> Note: The expedited review procedure may not be used where identification of the subjects and/or their responses/information would reasonably place them at risk of criminal or civil liabilityor be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, *unless* reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Additional information regarding IRB review type may be found at https://www.research.uky.edu/office-research-integrity/irb-review-types

Informed Consent

The UK IRB generally requires **informed consent** (or waiver/alteration of consent) regardless of the type of review utilized by the IRB. The ethical principle of Respect for Persons mandates that subjects enter into research voluntarily and with adequate information. Informed consent may only be waived or altered in specific circumstances where the regulatory criteria and ethical considerations are met.

In order for the IRB to approve a waiver of consent process, the IRB must be satisfied that all of the following criteria are met:

A. The research involves no more than minimal risk to the subjects;
B. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
C. The research could not practicably be carried out without the waiver or alteration; and
D. Whenever appropriate, the subjects or legally authorized representatives will be provided withadditional pertinent information after participation.
E. If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practically be carries out without using such informationor biospecimens in an identifiable format.

The IRB may determine that obtaining informed consent is required if the investigator is unable to justify why it's impracticable to conduct the research without a waiver. For **prospective record reviews**, most investigators are likely to have access and opportunity to complete an informed consent process with prospective subjects.

For non-FDA-regulated research, Common Rule regulations also provide a mechanism to waive documentation of informed consent. The only element waived in this case is the requirement for a signed consent document. To learn about the options and differences in these two regulatory provisions, see the brief Waiver of Consent vs. Waiver of Documentation of Consent video.

Research subject to HIPAA regulations must also either obtain a HIPAA Authorization from the subjects or qualify for a HIPAA Waiver of Authorization. Note: a HIPAA Waiver of Authorization does not mean the research is exempt from all of HIPAA's privacy regulations. It only means that a signed HIPAA Authorization form is not required because specific waiver criteria have been met. HIPAA is designed to protect the use and disclosure of individually identifiable healthinformation (also defined as Protected Health Information or PHI).

See the following links in the IRB Survival Handbook for additional information on Informed Consent https://www.research.uky.edu/office-research-integrity/informed-consentassent and HIPAA in research https://www.research.uky.edu/office-research-integrity/hipaa-human-research