Record Reviews

Record reviews are a type of secondary research. Secondary research involves research use of material collected for some other primary or initial activity.

The specifics of the record review will determine whether IRB review is needed and if so, what type of review is applicable. The ORI Interactive Secondary Research Tool provides guidance on need for and level of review that may apply to your research.

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 review types permit secondary use of material retrospectively and/or prospectively collected.

- Retrospective record reviews evaluate data that is in existence at the time of IRB approval.
- Prospective record reviews evaluate data that does not yet exist at the time of IRB approval.

In your IRB application, indicate if collection will include review of records generated after IRB approval (i.e., prospective record review). You may also include a date range for records you will review or include in data pulls. For instance, the beginning date would be the date the earliest record was generated. The end date would be the date the most recent record was generated. The end date could be the same as the study closure date.

Informed Consent Implication:

Human subject research requires informed consent or an IRB approval to waive or alter informed consent. For **prospective record reviews**, the IRB would consider if the investigators are likely to have access and opportunity to complete an informed consent process with prospective subjects or if it is impracticable to conduct the research without a waiver. In other words, impracticable means the research could not be conducted if informed consent were required.

Informed consent may only be waived or altered in specific circumstances where the regulatory criteria below and ethical considerations are met.

Criteria for waiver or alteration of informed consent:

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.

Research subject to HIPAA regulations must also either obtain a HIPAA Authorization from the subjects or qualify for a HIPAA Waiver of Authorization.