Chapter 14

Research using Retrospective Review of Existing Materials

Existing data can provide a rich source of information for the development and conduct of valuable research. Such research is also subject to the requirements of IRB review. This chapter provides and overview of the relevant regulations and resources available to support this type of research.

1. Regulations

a) Retrospective studies involve research conducted by reviewing materials (data, documents, records, specimens) collected in the past e.g., medical records, school records, or employment records, and existing at the time the research is proposed and initiated.

b) Such research may be exempt under Federal regulations at (45 CFR 46.104(4) if the identifiable private information or identifiable biospecimens if at least, one of the following criteria must be met:

i. The identifiable private information or identifiable 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 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 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those are defined at 45 CFR 164.501 and for "public health activities and purposes" as described under 45 CFR 164.512(b).
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 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, it all of the identifiable private information collected, used, or generated as part of the activity will be maintained in system of records in subject to the Privacy Act of 1974.

c) If not exempt, the IRB may review such research utilizing expedited procedures, provided that the research involved no more than minimal risk to subjects.

d) However, retrospective studies using existing materials occasionally present significant, greater that minimal risks and required review by the convened IRB. These situations may include highly sensitive information and the reviewer may have concerns about invasion of subjects' privacy and/or the adequacy of confidential protections proposed in the presented research.

2. Research Utilizing Large Existing Data Sets

a) Research often involves the use of large, existing data sets.

b) When the data sets are publicly available their use is exempt, even if they contain, sensitive, identifiable information.

c) The use of large, existing data sets requires IRB review when they contain identifiable private information about living individuals. In these cases, the IRB must determine whether the information can be used without additional informed consent from the participants.

d) The IRB should first examine the condition of informed consent under which the data were originally obtained. The proposed research is permissible under the original terms of consent.

e) If this is not the case, the IRB should consider whether it is permissible to wave the usual informed consent requirements in 45 CFR 46.116(b).

f) The IRB may determine that the research can proceed only if the investigator obtains and uses anonymized data through the services of an Honest Broker. Under this scenario, code and other identifiers are permanently removed from the data set before the data are sent to the investigator. Removal of identifiers is accomplished in such a manner that neither the investigator nor the source maintaining the data set can re-establish participants' identities.

g) "Honest Broker" being an individual that who is not engaged in the research and can remove all identifiers from the data prior to providing to the investigator.

h) Most established data and specimen repositories provide this service.

3. Research Using Data or Tissue Banks (Biorepositories)

a) Human data repositories collect, store, and distribute identifiable information about individual persons for research purposes. Human tissue repositories collect, store, and distribute identifiable human tissue materials for research purposes.

b) Tissue repository (tissue banks) involve three components:

i. The collectors of data or tissue samples,
ii. The bank/repository storage and data management function
iii. the recipient investigators.

Under a repository arrangement, the IRB formally oversees all elements of repository activity, setting the conditions for collection, secure storage, maintenance, and appropriate sharing of the data and/or tissues with external investigators. Specifically, the IRB determines the parameters for sharing data and/or tissues in a manner such that additional informed consent of participants is, or is not, required.

c) Typically, these parameters involve formal, written agreements stipulating conditions as follows:

i. The repository should not release any identifiers to the investigator,
ii. The investigator shall not attempt to recreate identifiers, identity subjects, or contact subjects,

iii. The investigator shall use the data only for the purposes and research specified,
iv. The investigator shall comply with any conditions determined by the repository IRB to be appropriate for the protection of participants.

4. Prisma Health Data Support Core

a) all studies that propose the use of data from Prisma Health Medical Records or other established data repositories must be submitted to and approved by the Data Support Core.

b) The Data Support Core will also assist in making determinations about requirements for any Data Use / Data Sharing agreements for transfer of data outside of Prisma Health Networks and protected systems.

c) https://academics.prismahealth.org/research-and-innovation/research-administration/research-data-services-and-data-support-core