



Title:	Research Using Existing Data & Materials		
SOP Number:	4201	Effective Date:	June 2, 2017
Previous Version Dates:			

## 1 Research using existing data and materials

Each separate human subjects research study requires IRB review and approval of the specific proposed study, regardless of whether the data set or research materials have been previously compiled.

Research involving the use of data meeting any one of the conditions below is not considered human subjects research and does not require approval by the IRB:

- Data on decedents;
- Data that have been stripped of all identifiers that could link that data to living persons
- Data coded in such a way that the present investigators cannot identify individual subjects (e.g., access to linkage codes is prohibited through an agreement with the custodian).

Under federal regulations, research utilizing only the types of data described above is not considered human subjects research and need not be approved by the IRB, although IRB review may be needed to make this determination.

Research involving the use of data meeting one of the conditions below is eligible for IRB exemption from continuing review:

- If the sources of data are publicly available; (45 CFR 46.101(b)(4))
- 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. (45 CFR 46.101(b)(4))

When existing data sets contain identifiable private information about living individuals and these sets are not publicly available, IRB review and approval is required before research can proceed. The IRB must determine whether the information can be used without obtaining additional informed consent. As such, the IRB should first examine the conditions of informed consent under which the data were originally obtained. It may be that the proposed research is permissible under the conditions under which the data were obtained, including contracts, informed consent or a HIPAA authorization.

If this is not the case, the IRB should consider whether it is appropriate to waive the informed consent requirements in accordance with 45 CFR 46.116(d). In many cases, a waiver of consent will be appropriate. In other cases, the IRB may determine that the research can only proceed if the investigator obtains data with codes and identifiers removed in such a way as to preclude the investigator or the source maintaining the data set from establishing subjects' identities. If the proposed data set includes PHI the IRB must determine whether the original HIPAA

authorization will cover the use of the data, whether the IRB can waive authorization or whether additional consent/authorization is required.

Prospective studies using materials (e.g., data, documents, records, specimens) that will be collected for some purpose unrelated to the research do not qualify for exemption. The IRB may use expedited procedures to review research that proposes to use materials (e.g., data, documents, records, specimens) that will be collected in the future for non-research purposes.

The IRB review should include review of the terms and conditions under which the data or materials were originally obtained and released to the investigator. The purpose of this review is to make sure that the proposed new use is not incongruent with original purposes, permissions, or approvals.