CUNY HRPP Policy: Secondary Research Use of Identifiable Private Information and/or Identifiable Biospecimens

1. Purpose and Overview

The purpose of this policy is to provide mechanisms for secondary research use of identifiable private information and/or identifiable biospecimen, as defined in *CUNY HRPP Guidance: When is CUNY HRPP or IRB Review Required*? Secondary research refers to re-using identifiable information and/or identifiable biospecimens that are collected for some other primary or initial activity. Secondary research does not include any primary collections of either information or biospecimens.

2. Exempt research when consent is not required

Research involving the secondary use of identifiable private information and identifiable biospecimens that meets the criteria for exemption under 45 CFR 46.104(d)(4) may be conducted without obtaining informed consent.

3. Exempt storage or maintenance of identifiable private information or identifiable biospecimens for which broad consent is required

Storage or maintenance for secondary use of identifiable private information or identifiable biospecimens may qualify for an exemption under 45 CFR 46.104(d)(7) when broad consent is obtained. See CUNY HRPP Policy: Informed Consent Process and Documentation for more information on broad consent.

4. Secondary use of coded private information or coded biospecimens that is not deemed to involve human subjects

4.1. *Coded* means that: i) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e. the code); and ii) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

4.2. Research involving ONLY coded private information or specimens is NOT considered to involve human subjects, and therefore, does not require CUNY HRPP or IRB review, when BOTH of the following conditions are met:

4.2.1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; AND

4.2.2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example: i) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances,

until the individual(s) are deceased; ii) there is a CUNY UI-IRB approved protocol for a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individual(s) are deceased; or iii) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

5. **Non-exempt storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens using broad consent**
   An IRB may allow broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes), in accordance with Section Y of CUNY HRPP Policy: Informed Consent Process and Documentation.

6. **Non-exempt secondary research use of identifiable private information or identifiable biospecimens with an IRB granted Waiver of Informed Consent**
   An IRB may grant a waiver of informed consent for secondary research use of identifiable private information or identifiable biospecimens, in accordance with Section X of CUNY HRPP Policy: Informed Consent Process and Documentation.

   6.1.1. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB CANNOT waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

References

1. Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects

2. DHHS Guidance: Coded Private Information or Specimens Use in Research (2008)