UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Research Involving the Use of Existing Data/Specimens

A. GENERAL INFORMATION

There are studies that involve the secondary use of existing data, either from public or private documents. For example, they may take the form of reviews of existing medical records, police reports, vital statistic records, student records, accessing computer databases that have been produced from previous studies, etc. The **secondary use of existing data requires IRB approval or Certification of Exemption from IRB review.** For the most part, these protocols will qualify for expedited review or exemption. However, there are occasions when they require full IRB review.

The main concern when doing research that involves the secondary use of existing records is that the **confidentiality** and **privacy** of the subjects **is protected**. If the investigator records the information in such a manner that subjects cannot be identified directly or through identifiers the research would most likely qualify for expedited review or exemption. If, however, such identifiers are to be recorded, the research may require full IRB review to ensure that, among other things, procedures for protecting privacy and confidentiality are adequate. Full IRB review would most likely be needed if the investigator proposes to contact the subjects, or family members to gather additional information. Please also see guidance on HIPAA regulations that may also apply to this type of research.

B. SUBMISSION PROCESS

For protocols that require expedited review, the standard Biomedical Studies application or Social and Behavioral Studies application must be submitted. For protocols that meet criteria for exemption from IRB review, the Exempt Status application must be used. When submitting a protocol for the secondary use of existing data to the IRB, investigators must ensure that adequate steps are being taken to preserve the confidentiality of the data they collect. The investigator must specify who will have access to the data, how, and at what point in the research personal information will be separated from other data, and whether the data will be retained at the conclusion of the study. If data is to be retained, the investigator must justify the anticipated risks and benefits with respect to retention. *Keep in mind that the secondary use of existing data is not limited merely to documents and records that may be used in social and behavioral research or medical research; it also applies to pathological specimens, and diagnostic specimens used in medical research.*

C. FURTHER INFORMATION

For further information about expedited review, please review SOPP, section 3.10, Expedited Review. For further information about exemption from IRB review, please review SOPP, section 3.9, Exemption from IRB Review. You may also contact the Human Research Protections Program at (858) 657-5100 or visit the HRPP website at https://irb.ucsd.edu/.