

SOP 008: SOP for Review of Research Using Patients Stored Data and Specimens

Purpose

To describe and document the procedure for reviewing research that is going to utilize patients' stored data and/or biological specimens

Scope

Applies to research that involves use of patients' stored data and specimens

Responsible Persons

HAUREC chairperson, HAUREC administrative team, HAUREC members, investigators, and custodians of the data and/or the specimens.

Background

Often, human biological specimens or data are obtained from patients during clinical practice or from targeted groups of research participants during prospective studies designed to observe outcomes or events. Such specimens and data are stored in repositories. These are available at the time research is proposed or initiated and may remain after the study has ended.

Procedures

This SOP is intended to aid ethical review of research that shall involve reviewing data, documents, records, or biological specimens collected in the past. These may include medical records, school records, employment records or biological specimens that are in existence at the time the research is proposed and initiated. Such research may be retrospective record reviews or studies that look at stored biological samples.

- a. Such research may be exempt if the information is publicly available or if the information is recorded in such a manner that participants cannot be identified, either directly or through identifiers linked to the participants.
- b. If not exempt, the HAUREC may review such research utilizing expedited procedures, provided that the research involves no more than minimal risk to participants and communities. (Refer to SOP 003).
- c. However, retrospective studies using existing materials occasionally entail significant greater than minimal risks and require review by the convened HAUREC meeting (e.g., where the research reveals previously undisclosed illicit behavior such as prostitution, drug abuse or where the expedited

review had concerns about infringement of subjects' privacy and/or the adequacy of confidentiality protections proposed by the investigators).

Research Utilizing Existing Data Sets

When the data sets are publicly available, their use is exempt. But if the existing data contains identifiable private information about a living individual, the research will require HAUREC review. In cases of identifiable private information, HAUREC must determine whether the information can be used without additional informed consent from the participants.

- I. In making this determination, the HAUREC shall 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 original terms of informed consent.
- II. If this is not the case, then the HAUREC will consider whether it is permissible to waive the usual informed consent requirements in accordance to stipulated guidelines. Many times, a waiver of consent will be appropriate.
- III. In other cases, the HAUREC may determine that the research can proceed only if the investigator obtains and uses "anonymized" data. Under this scenario, codes and other identifiers are permanently removed from the data set before the data are sent to the investigator, and the removal is accomplished in such a manner that neither the investigator nor the source maintaining the data set can re-establish participants' identities.

Research Using Data or Tissue Banks (also called Repositories)

Human data and tissue repositories collect, store, and distribute identifiable information and human materials respectively about individual persons either for research purposes or for clinical care.

Whereas there is no institutional policy at the School of Hospice Africa Uganda regarding banking of human research subject specimens as well as clinical data collected as part of research or clinical care, sites that collaborate with Hospice Africa Uganda are expected to have policy regarding the same.

The policy is supposed to cover the following components of Tissue Bank activities:

- a. Identity of the collectors of data or tissue samples;
- b. The bank/repository storage and data management center; and

- c. The sharing of data i.e. recipients of the data.
- d. Considerations of Intellectual Property Rights

HAUREC, with the guidance of UNCST, shall oversee all the activities involved in the above elements such as; setting the conditions for collection, secure storage, maintenance, and appropriate sharing of the data and/or tissues, or intellectual property with external investigators.

HAUREC after consulting with the site policy on data/specimen repositories shall evaluate the proposal using the following criteria;

- I. Determine whether the informed consent under which the specimens or data was collected is adequate to cover their use in the proposed study
- II. Determine whether the donors of the specimen are traceable/identifiable
- III. Determine whether the repository administrators can effectively anonymize the specimens/data before sending them to the investigators, and indeed, if the data the investigator is to receive is effectively anonymized.
- IV. Determine whether use of the specimens will offer extra risk to specimen donors.
- V. Determine if the proposed study involves genetic studies
- VI. Determine whether it is possible to carry out the research without waiving the informed consent.