

SOUTHWESTERN OKLAHOMA STATE UNIVERSITY

Weatherford and Sayre Campuses

GUIDELINES ON DATA AND RECORD RETENTION FOR EXTERNALLY SPONSORED PROGRAMS

1.0 Introduction

Southwestern Oklahoma State University has both rights and responsibilities toward scientific data generated by research or projects at the University. Data produced from federally sponsored research or other funded projects are increasingly subject to requirements of the Federal Freedom of Information Act (FOIA) and private sponsorships often generate potential conflicts of interest and litigation over ownership of research/project data. In addition, increased mobility of University researchers in recent years has changed the continuity of scientific research necessitating the development of institutional policies on data access, retention of records and transfer of records.

2.0 Definition of Data

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes computer software (computer programs, computer databases, and documentation thereof), and records of scientific or technical nature. The term does not include information incidental to award administration, such as financial, administrative, cost or pricing, or management information. In practice, scientific data include both intangible data (statistics, findings, conclusions, etc.) and tangible data. Tangible data include, but are not limited to notebooks, printouts, computer disks, photographs, slides, negatives, films, scans, images, autoradiograms, electrophysiological recordings, gels, blots, spectra, samples, specimens, IRB consent forms, and other materials that are relevant to the research or other funded projects.

3.0 Excluded Data

Certain data are explicitly excluded including preliminary analyses, communications with colleagues, and plans for future research. Additionally, data which would violate personal privacy (medical records, human subject information) or which must be held confidential for commercial necessity are excluded.

4.0 Data Retention

The retention of accurately recorded and retrievable research/project data is of utmost importance for the progress of scientific integrity. The investigator must have clearly defined responsibility for recording, retaining, and storing research/project data. These

records should include sufficient detail to permit examination for the purpose of replicating the research/project, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions.

The experimental notebook is the most common medium for documentation of experiments and its proper maintenance is of utmost importance. In addition to the study title, the investigators' names, and the study hypotheses, the experimental notebook should include detailed information on the materials used, sources of the materials, experimental methodology, statistical treatments, results and conclusions so as to enable replication of the experiments by others at any time. Bound notebooks with consecutively numbered pages are recommended for data recording and maintenance. Whenever possible, raw data should be stored together with the experimental notebook. In the event that this is not possible, explicit instructions as to where the data can be found (e.g., location of disks, samples, specimens, etc.) should be included in the notebook. For studies involving several investigators/collaborators, possibly in more than one laboratory, it is recommended that the principal investigator maintain a master log that catalogues the experiments of the whole study and provides the location of other experimental notebooks, data, and relevant materials stored in other laboratories or locations.

There are some governmental guidelines prescribing the length of time researchers must maintain the original data. The times required to retain data vary from three to seven years depending on the federal or state governmental organization. **In accordance with these guidelines, Southwestern Oklahoma State University requires that research records or other funded project records be archived for a minimum of five years after final reporting or publication of research/project or longer if so specified by the funding agency. The archived records should be the originals whenever possible. In addition, the records should be kept for as long as may be required to protect any patents resulting from this work or as required by an external funding source. If any questions regarding the research/project are raised during the mandated retention period, the records should be kept until such questions are fully resolved. Where no final report is required, the University shall retain the data for a minimum of five years after its public release or longer if so specified by the funding agency.**

5.0 Data Ownership and Access to Data

Both the principal investigator and the University have responsibilities, and hence, rights concerning access to, use of, and maintenance of original research/project data. Research/Project data belongs to Southwestern Oklahoma State University, which can be held accountable for the integrity of the data even after the researchers have left the University. Although the primary data should remain in the laboratory where it originated (and hence at the University), consistent with the precepts of academic freedom and intellectual integrity, the investigator may be allowed to retain the research/project records and materials created by him/her. In the event that the investigator leaves the University, an Agreement on Disposition of Research/Project Data and Records may be negotiated by the investigator and the Office of Sponsored Programs to allow transfer of research/project

records. However, consistent with the same precepts, it should be specified in the agreement that the University has the right of access to all research/project records and materials for a reasonable cause after reasonable prior notice regardless of the location of the responsible investigator. The University is ultimately responsible for producing original records in case of allegations of misconduct or fraud against its researchers and protecting research integrity and/or project fidelity.

Some circumstances may warrant an exception, requiring that the primary data and records be retained by the University. In the case of multi-institutional studies, the institution of the primary study director is responsible for retention and access to original data. Extramural sponsors providing support for research may also have the right to review the data and records resulting from that extramural support. When the data are used for a patent application filed by the University, it may be necessary for the original data to be kept at the University. Patient medical records also may not be removed from the University. Primary research/project data and unique materials (such as DNA, cell lines and genetic mapping information) developed with funds from the Public Health Service (PHS), of which the National Institutes of Health form a component) would be accessible to the research community after publication.

6.0 Split of Collaborative Team

When a collaborative team is dissolved, Southwestern Oklahoma State University policy states that each member of the team should have continuing access to the data and materials with which he/she had been working, unless some other agreement was established at the outset. The unique materials prepared in the course of the research/project should be available/accessible under negotiated terms of a transfer agreement.

7.0 Co-Investigators, Trainees, and Students

The original data must be retained by the senior investigator and co-investigators. Trainees and students who are an integral part of the research/project should be allowed continued access to all records and data, which pertain to their part of that project.

Note: These guidelines have been developed based on similar policies now being implemented at other universities.

Adopted: February 11, 2004