AMERICAN DENTAL HYGIENISTS' ASSOCIATION
GUIDELINES ON RESEARCH MANAGEMENT

Introduction

American Dental Hygienists' Association has both rights and responsibilities toward scientific data generated by research conducted based on association data and information. Data produced from federally sponsored research are subject to federal policies regarding maintenance, retention and dissemination. Similarly, research that is regulated by specific governmental entities, such as clinical investigation overseen by the Food and Drug Administration (FDA), may be subject to more specific data management requirements. In addition, increased mobility of researchers in recent years has changed the continuity of scientific research necessitating the development of institutional policies on data access, retention, and transfer.

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 also includes 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, electronic storage, photographs, slides, negatives, films, scans, images, autoradiograms, electrophysiological recordings, gels, blots, spectra, cell lines, reagents, modified organisms, specimens, IRB consent forms, case report forms, drilling cores, collected organisms, and other materials that are relevant to the research project.

Data Recording and Retention

The retention of accurately recorded and retrievable research data is of utmost importance for the progress of scientific integrity. The investigator has a clearly defined responsibility for recording in, retaining, and storing research data. These records should include sufficient detail to permit examination for the purpose of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions, including sufficient data to substantiate the date of conception of any invention made in the course of the research.

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 (which should include all co-investigators), and the study hypothesis, the experimental notebook should include detailed information on the equipment and materials used, sources of the materials,

experimental methodology, statistical treatments, results and conclusions, and the time and conditions of the work 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, possible in more than one laboratory, it is recommended that the principal investigator maintain a master of 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.

Many investigators are replacing the written record of a notebook with an electronic notebook, which is a computer-based system to record and store research results. Electronic notebook programs must contain all the information described above for the experimental notebook. Electronic notebooks should provide for encryption of data, and must have the ability to both track any changes made to data that have been entered, and permit the user to lock down the data to prevent subsequent data manipulations. Electronic notebooks or systems used in FDA-subject clinical investigations must also comply with the requirements of 21 CFR Part 11 (for drug studies) and 21 CFR Part 280 (for device testing).

There are governmental guidelines prescribing the length of time researchers must maintain the original data, and these requirements, which vary depending on the funding source for the research and the type of research conducted, are listed below. In accordance with these guidelines, the ADHA requires that research records be archived for a minimum of seven years after final reporting or publication of a project. 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, as required by an external governmental or commercial funding source, or as needed in connection with pending or reasonably anticipated litigation. If any questions regarding the research, including but not limited to research integrity allegations, are raised during the seven-year retention period, the records should be kept until such questions are fully resolved. The principal investigator should determine that their data collection systems meet any applicable standards.

Some specific retention requirements that may exceed the seven-year minimum include the following:

> For research supporting a drug-marketing application to the FDA, "an investigator shall retain records… for a period of two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified." (21CFR312.62)
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> For research supporting a device-marketing application to the FDA, "an investigator or sponsor shall maintain the records for a period of two years after the latter of the following two dates: the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol." (21CFR812.140)
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> For research involving children, records shall be retained at least until the pediatric subject reaches the age of 23.

Data Ownership and Access to Data

Both the principal investigator and the ADHA have responsibilities, and hence rights, concerning access to, use of, and maintenance of original research data. Research data belongs to both the institution, which can be held accountable for the integrity of the data even after the researchers have left the institution. Although the primary data should remain in the laboratory where it originated, consistent with the precepts of academic freedom and intellectual integrity an investigator not part of the originating laboratory may be allowed to retain copies of the research records and portions of materials created by him/her in the course of the research. Copies of intangible data created by an investigator may be taken with the investigator if he/she leaves the institution. Samples of tangible materials created or collected in the course of the research, may be transferred to another institution, if sufficient samples exist, and if the samples can be easily split at a minimal cost. In all cases, the transfer shall be subject to the terms of a material transfer agreement negotiated by the original institution and the recipient institution. These rights to access data also apply to trainees and students who are an integral part of the research project.

Extramural sponsors providing support for research may also have the right to review the data and records resulting from that extramural support.

Sharing of Data

Published primary research data and unique materials collected or created in the process of research developed with federal funds should be shared on request by other researchers in accordance with the general spirit of colleagueship within the scientific and medical community. All research requests submitted to the ADHA must include a completed Shared Data Agreement Form.

Reviewed and approved by:

Ann Battrell

Executive Director, ADHA

Text adapted from the University of Pittsburgh: http://www.provost.pitt.edu/documents/RDM_Guidelines.pdf.