

**SCIENTIFIC RECORDS AND RESEARCH DATA (INCLUDING RESEARCH-RELATED BIOLOGICAL MATERIALS)
[UMDNJ Office of Academic Affairs]**

III. SCIENTIFIC RECORDS AND RESEARCH DATA* (INCLUDING RESEARCH-RELATED BIOLOGICAL MATERIALS)

The goal of scientific record-keeping is to provide sufficient information so that research procedures, results and analyses can be repeated by another investigator who is experienced in the area of research, and so that questions arising after publication can be answered. Investigators are obligated to record and preserve data in a form that allows future scrutiny and evaluation. The retention of accurately recorded, well-organized and complete original research data and results (including unique reagents and research-related biological materials) also provides the most effective response to questions that may arise about the propriety of the conduct of the research. Inability to produce well-kept original research data may place the integrity of the research itself into question.

Because of the complexity, diversity and changing technology of modern research, no single method of data recording can be advocated. Each researcher should consider how best to meet the goals of record-keeping with regard to his/her type of research.

Unless impractical for certain types of data or for certain disciplines, scientific notes are best kept in bound notebooks with numbered pages and made in permanent ink on the day the studies are performed. Entries should contain the time and date and be signed. Depending on the type of data and research, entries may consist of printouts affixed to the notebook rather than handwritten notes. Computer technology has changed the concept of handwritten laboratory notebooks, but even with computer-generated and/or computer-stored data, it is important that descriptions of what was done and titles of computer runs be recorded. Hard-copy printouts of computer-stored data should be generated on a regular basis and bound into the notebook. If

* "Research data" can include tangible and physical representations of experimental findings; in addition to sets of numbers, "data" can be unique reagents, tissue samples, cell lines, clones, other biological preparations, software, slides, videotapes, sound/voice recordings, photographs, etc.

data are in a form that cannot be recorded in or affixed to a notebook, notebooks can still record descriptions and chronologies of the experiments performed, descriptions of the instrumentation used, and the location and form of the data.

Logbooks or inventories for radioactive substances, organic compounds, dangerous chemicals and biologicals are essential.

All data, unique reagents and research-related biological materials resulting from a research project should be continuously available to all personnel working or collaborating on the project (except, of course, during periods of investigator “blinding”). Data should eventually be communicated to the external research community to facilitate use of the information gained. Individual research groups should establish policies for the internal and external sharing of research data and research materials within the limits of fairness to all parties and within any constraints put forward by funding agencies. Research data and any unique research materials such as recombinant DNA, DNA sequences, DNA or RNA constructions, antibodies, purified enzymes, receptors, etc. should be made available, if possible and appropriate, to other responsible researchers and collaborators.

Original research data, including “raw” (primary) data, must be retained for no less than five years after the termination of the grant under which the research was performed or after the publication of the research results, whichever is later, and preferably indefinitely. Where questions or allegations have been raised regarding the validity of the data or appropriate conduct of the research, all of the original research data must be preserved at least until such questions or allegations have been completely resolved. Absence of original data may create the presumption of misconduct or questionable research practices in the event of an allegation of misconduct. At present, there is no statute of limitations on misconduct-in-science allegations. Therefore indefinite retention of data may be in the researcher’s best interests.

All original research data and materials should ordinarily be retained by the research unit of origin at the University or by the University department so that: (1) they can be made available to individuals involved in the research within the research group; (2) they are available for other

investigators if the original work needs to be repeated or if questions arise (including questions about the propriety of the conduct of the research); and (3) the University can fulfill its institutional responsibilities and the requirements of any applicable laws and governmental regulations. Arrangements should be made to ensure that any investigator (faculty, non-faculty staff, student, postdoctoral fellow) who leaves the research group or laboratory will have access to the original data and materials from his/her research performed in that group or laboratory, and will be given copies of such data or samples of research-related materials if requested and if feasible. In those cases in which the principal investigator or laboratory head is leaving the institution and wants to retain the original research data or research materials, or when making copies or giving samples is impractical because of the nature or form of the data, the department chair (or dean if the investigator is a chair) must be informed of this in writing. This written notice must contain an itemized description of the original data or materials to be removed, and must give their future location and an assurance that the University will be given access to the data if there is a need to review it or if questions or allegations of misconduct in science should arise. Non-faculty staff and trainees who leave the laboratory, the research group or the institution must get written permission from the principal investigator or laboratory head to retain original data or research materials in lieu of copies. In some research projects, availability of research data, records or materials may be restricted by laws, by the requirement for confidentiality or for investigator blinding, by governmental regulations and/or by contractual provisions with some sponsors.

Each research group or laboratory is encouraged to establish specific procedures regarding availability of and access to original research data and materials. These procedures should be consistent with these Guidelines and must conform to existing University policies including those on patents, copyrights, and the sale or transfer of materials. Disagreements among individual researchers or between research groups or laboratories concerning issues of access to and use of research data and materials which cannot be amicably resolved should be discussed with appropriate administrative officers, such as the department chair, the research dean, an identified school ombudsperson and/or the dean.

The University has developed policies regarding patents, copyrights, and the sale or transfer of materials which have their own requirements for compliance.

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