DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
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FCMR-UWZ (1oo) 27 January 2022

MEMORANDUM FOR All Personnel, Walter Reed Army Institute of Research (WRAIR)

SUBJECT: WRAIR Policy #62, Laboratory Notebook Control and Management

1. References.

a. Army Regulation (AR) 380-5 (Army Information Security Program).

b. AR 27-60 (Intellectual Property).

c. AR 70-57 (Army Technology Transfer).

d. AR 25-400-2 (The Army Records Information Management System [ARIMS]).

e. National Institutes of Health (NIH), Office of the Director (Guidelines for Scientific Record Keeping in the Intramural Research Program at the NIH), December 2008.

f. WRAIR Policy #52 (Records Management).

2. History. This version of the policy revises and supersedes the previous version, which was issued 3 May 2018. This version of the policy is effective upon signature and will remain in effect until amended or rescinded.

3. Purpose. This policy establishes guidelines and procedures for the creation, maintenance, and control of laboratory notebooks at WRAIR and its Directorates.

4. Definitions.

a. Conception and reduction to practice: The two steps required for determining when an invention occurred, who invented it, and who might have rights in the invention. See Appendix A, Conception and Reduction to Practice.

b. Laboratory notebook: An organized, contemporaneous record of essential activities that occur in a research and development effort in a laboratory setting, including experiments performed, steps taken to test a hypothesis, and experimental results obtained.

c. WRAIR personnel: All U.S. Military and Civilian employees, Foreign Service Nationals/Locally Employed Staff, contractors, cooperative agreement personnel, guest researchers, special government employees, volunteers, fellows, students, and trainees

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****This supersedes WRAIR Command Memorandum 2018-16, dtd 3 May 2018.**

of WRAIR or its Directorates.

d. WRAIR Science Archivist: An individual responsible for the archival, control, storage, transfer, and destruction of all scientific records at WRAIR and its Directorates, including laboratory notebooks.

5. Background. Complete, accurate, and understandable record keeping is essential to the integrity of scientific research. The laboratory notebook is a time-tested tool for documenting research, replicating and validating results, and securing proper recognition for Army scientific accomplishments. Laboratory notebooks also serve important legal purposes, as they are primary documents used to support patent positions in courts or administrative proceedings, and can be used in drafting patent applications, resolving issues of inventorship, and establishing ownership of an invention and dates of invention, among other purposes. This policy is intended to ensure that researchers at WRAIR and its Directorates follow laboratory notebook practices that align with Department of the Army requirements and intellectual property standards.

6. Applicability and Scope. This policy applies to all WRAIR personnel who are engaged in research and development efforts that occur in a laboratory setting. The primary purpose of this policy is to ensure compliance with Department of the Army records management and intellectual property requirements.

7. Policy.

a. Information about essential activities that occur in a research and development effort in a laboratory setting, including, but not limited to, experiments performed, steps taken to test a hypothesis, and experimental results obtained, must be properly recorded in a laboratory notebook. The information recorded in laboratory notebooks must have sufficient specificity and detail to:

(1) Ensure that subsequent WRAIR personnel can continue research efforts without unnecessarily duplicating potentially costly or time-consuming activities;

(2) Ensure that subsequent WRAIR personnel can access previously collected data that may be useful for answering new research questions; and

(3) Satisfy the requirements for evidence in legal proceedings to establish the dates of conception and reduction to practice of each invention, who conceived of each invention, who reduced each invention to practice, and iterative steps therein. By following section 9, Guidance, the requirements for evidence in a legal proceeding will be assumed to be fulfilled. See Appendix A, Conception and Reduction to Practice.

b. Laboratory notebook entries must be handled and classified (if necessary) in

accordance with Army Regulation 380-5. Laboratory notebooks must be classified and controlled according to the most highly classified information they contain.

c. Disposition of laboratory notebooks must be in accordance with Army Regulation 25-400-2, 372 Chapter 7. All laboratory notebooks and associated data are government property and must be secured when not in use. Laboratory notebooks, whether physical or electronic, must not be removed from WRAIR or its Directorates without appropriate authorization.

d. A laboratory notebook may be any suitable commercially available bound paper notebook, commercially available electronic laboratory notebook system, custom-designed electronic laboratory notebook system, or a hybrid notebook consisting of a combination of paper and electronic records.

e. Because it is often not feasible to record large datasets in laboratory notebooks, data for laboratory research and development projects may be stored in a separate, secure location, such as physical binders or electronic databases. Laboratory notebooks must clearly indicate the location, date of creation, and mode of access for such data.

8. Responsibilities.

a. Commander.

(1) Provides the resources to administer, control, and archive laboratory notebooks in accordance with this policy.

(2) Appoints an investigating officer when information indicates that laboratory notebooks or associated binders may have been lost, significantly damaged, compromised, or otherwise improperly controlled.

b. Branch/Organizational Equivalent Directors.

(1) Ensures all personnel within the Branch/Organizational Equivalent utilize laboratory notebooks to record essential information about laboratory research and development efforts in accordance with this policy.

(2) Ensures laboratory notebooks are reviewed and assigned a classification in accordance with Army Regulation 380-5.

(3) Ensures the Branch/Organizational Equivalent has adequate procedures for distributing, tracking, storing, and retiring laboratory notebooks in accordance with Army Regulation 25-400-2 and WRAIR Policy #52 (Records Management).

(4) Ensures that necessary trainings on this policy and periodic reviews of laboratory notebooks for research activities in the Branch/Organizational Equivalent are conducted to promote alignment with this policy.

c. WRAIR Science Archivist.

(1) Coordinates with Branch/Organizational Equivalent Directors to review and transfer laboratory notebooks to local WRAIR or Directorate archives and to long-term record storage as required.

(2) Ensures laboratory notebooks (ARIMS file number 27-60tt) are maintained for 30 years from the date of creation, either by archiving in secure storage facilities (for physical laboratory notebooks) or by electronic preservation in accordance with electronic records management regulations (for electronic laboratory notebooks).

(3) If and for as long as the Science Archivist position remains unfilled, the above responsibilities will transfer to the WRAIR Records Management Officer or designee.

9. Guidance.

a. WRAIR Branches/Organizational equivalents should develop written Standard Operating Procedures (SOPs) for the management and control of laboratory notebooks in accordance with this policy. These SOPs should include standards for the distribution, tracking, storing, and retiring of laboratory notebooks, as well as standards for contents and formats as appropriate.

b. When feasible, WRAIR personnel engaged in research and development efforts in a laboratory setting should use individual notebooks to record information from their own research work.

c. Laboratory notebooks in all formats should:

(1) Have unique identifiers;

(2) Be linked to specific research personnel;

(3) Be maintained in accordance with laboratory SOPs and best scientific practices;

(4) Be secured when not in use; and

(5) Be turned over to the WRAIR Science Archivist when they are no longer required for ongoing research and development efforts.

d. Laboratory notebook entries should:

(1) Be concise;

(2) Contain all pertinent facts;

(3) Include all negative, positive, and neutral findings;

(4) Be made soon after the time of the activity;

(5) Be signed and dated by the person who wrote the entry; and

(6) Be corrected by striking out the incorrect information and adding the initials of the person who made the correction, the reason for the correction, and the date of correction.

e. Physical laboratory notebooks should have:

(1) A permanent binding;

(2) All pages consecutively numbered prior to use (both sides of page may be used);

(3) No pages removed;

(4) All blank pages and empty space crossed out with a diagonal line;

(5) All markings made in black or blue indelible ink (other colors may be used for graphs);

(6) All incorporated documents (for example, supplementary reports, memoranda, photographs, and scans) permanently affixed to notebook pages, with date and signature visible over the tape and onto the page to which the document is affixed; or included in an associated binder with a cross reference to the binder number and page number recorded in the notebook; and

(7) All sheets containing potentially patentable material, including supplementary reports or memoranda, be signed by two witnesses who fully understand the entry (note: joint inventors cannot be used as witnesses).

f. Electronic laboratory notebooks should:

(1) Be created and maintained with systems that employ procedures and controls designed to ensure the authenticity, integrity, and confidentiality of electronic records;

(2) Have secure, system-generated, time-stamped audit histories to independently record the date and time of researcher entries and actions that access, create, modify, save, or delete electronic records;

(3) Never have changes obscure or eliminate previously recorded information;

(4) Be able to generate accurate and complete copies of records in both human readable and digital or electronic form suitable for inspection, review, copying, and printing;

(5) When feasible, authenticate researcher entries and witness attestation utilizing verifiable electronic signatures and time-stamping; and

(6) When feasible, approximate the features of physical laboratory notebooks that satisfy the requirements for evidence in legal proceedings to establish the dates of conception and reduction to practice of inventions.

10. Points of contact for this memorandum are:

a. For concerns about records maintenance, [redacted], Records Management Specialist/WRAIR Records Management Officer (FCMR-UWZ-IM), at [redacted] or [redacted];

b. For concerns about intellectual property requirements, [redacted], Chief, WRAIR Technology Transfer Office (FCMR-UWS), at [redacted] or [redacted].

c. For concerns about research integrity, [redacted], Research Integrity Officer (FCMR-UWS), at [redacted] or [redacted].

SIGNATURE ON FILE

CHAD A. KOENIG
COL, SP
Commanding

ENCL:
Appendix A:
Conception and Reduction to Practice

Appendix A: Conception and Reduction to Practice

Conception and reduction to practice are the two steps required for determining when invention occurred, who invented it, and who might have rights in the invention.

Conception has been described as the formation in the mind of a definite and permanent idea of the complete invention as it would be applied in practice. The idea should be a specific, settled idea, and a particular solution to the problem at hand, not merely a general goal or research plan. Conception is proven by corroborating evidence such as contemporaneous documentation (for example, details of the conception recorded in a laboratory notebook).

Reduction to practice is when an embodiment is constructed (for example, a prototype) or performed (for example, an experiment) that meets all of the limitations of the invention and determines that the invention works for its intended purpose. Ideally, enough embodiments are performed to demonstrate that the inventors possessed all embodiments of what they claim and that no undue experimentation is required across those embodiments.

As an alternative to actual reduction to practice, there can be what is called "constructive reduction to practice," where the invention is described in writing or otherwise recorded in sufficient detail to demonstrate what the actual reduction to practice would be. A patent application drafted directly from the inventor's conception is an example of constructive reduction to practice.

Between conception and reduction to practice there can be intermediary steps or milestone details, such as an improvement to the initial invention or additional species in the genus of the invention, or a finding of unexpected results over prior work. Questions about conception, reduction to practice, intermediary steps or milestones, species within a genus, or unexpected results may be directed to the Intellectual Property Division of the Office of the Staff Judge Advocate of the U.S. Army Medical Research and Development Command.