DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER
NATIONAL NAVAL MEDICAL CENTER
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IN REPLY REFER TO:
NAVMEDRSCHCENTERINST 5212
CCR

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NAVMEDRSCHCENTER INSTRUCTION 5212

From: Commanding Officer
To: Distribution

Subj: STANDARD OPERATING PROCEDURES AND PROVISIONS FOR COMMAND RESEARCH RECORDS AND ARCHIVES

Ref: (a) SECNAVINST 3900.39B
(b) SECNAVINST 5212.5C
(c) SECNAVINST 5430.20D
(d) OCNRINST 5210.2A
(e) BUMEDINST 5721.3
(f) NAVMEDRSCHDEVCOMINST 3900.2
(g) NAVMEDRSCHDEVCOMINST 5870.4
(h) NAVMEDRSCHINSTITUTEINST 3900.6D

1. Purpose. This instruction establishes standard operating procedures and provisions for all unclassified research records and archives generated within all Naval Medical Research Center (NAVMEDRSCHCENTER) departments, offices and programs. These procedures and provisions are effective immediately. This instruction will remain in effect until the issuance of a formal inter-service instruction for the relocation to Forest Glen. Joint concepts of operations efforts are in progress.

2. Background. The ethical conduct of scientific research, research administration, and laboratory support services is ultimately the responsibility of the Commanding Officer, Naval Medical Research Center (NAVMEDRSCHCENTER). This instruction is implemented to meet the requirements of higher authorities as found in references (a) through (h), and respecting the successful example of peer activities in university and private agencies.

3. Responsibilities

a. A centralized research records and archives area has been established in the basement of Building 18. Relevant research records and archives will be collected and stored in this area, unless otherwise specified, until relocation of the same materials is finalized at the new facility at Forest Glen.

b. The Office of Research Administration (00R) is mandated with design, implementation and oversight of the Command records and archives system; its physical space and resource materials; and all records and archives holdings. 00R personnel will collaborate with transition personnel in finalizing the inter-service instruction and arrangements for records and archives at the Forest Glen location. 00R personnel will seek the advice of the Office of Technology Transfer (00T), Office of Counsel (00L), higher authorities, universities and relevant extramural federal and private agencies regarding retention requirements and proprieties, electronic research administration services, and the appropriate transfer of records to federal File Retention Centers (FRC) and/or the National Archives and Record Administration (NARA). Transfer of records to FRCs and/or NARA will occur when permitted under the law but only when scientific, academic and management integrity no longer necessitates proximate location of records and archives for retrieval and reference. 00R will be responsible for the transfer of records when required or judged appropriate, and with administrative assistance from 00T, 00L, the Director for Administration (DFA), the Office of the Comptroller (00C), and the Command Master Chief (CMC).

c. Naval Medical Research Center Detachment (NAMRC DET) personnel are to implement similar provisions for the central maintenance of all records and archives at their own location [illegible] practices developed at NAVMEDRSCHCEN and as [illegible] consistent with [illegible]

(1) **Formal and informal laboratory notebooks:** All Command research data is the property of the government, therefore, special care is to be taken regarding formal and informal laboratory notebooks.

(a) It is the responsibility of each department and program to issue, maintain and reissue laboratory notebooks and all scientific materials related to work units and research efforts that are in progress.

(b) Departments and programs should retain and reissue formal and informal laboratory notebooks when the scientific research data contained therein is being transitioned to new work units and/or to a new laboratory. Department or program personnel may elect to submit such materials to the Command records and archives area.

(c) When laboratory efforts (work units etc.) are completed without transition plans for follow-on research efforts, formal and informal laboratory notebooks, not being re-issued, must be submitted to the central records and archives area. This includes notebooks and all related materials from existing programs and departments scheduled to be closed without a designated successor.

(d) In the event of programmatic or departmental reorganizations, it is imperative to safeguard the government's rights by transferring laboratory notebooks and similar materials to the de-structured program's or department's organizational successor. In the event that no scientific successor has been designated for a program or department being closed, all laboratory notebooks and similar or related materials are to be submitted to the Command records and archives area.

(e) Personnel may make permissible copies of all materials with the concurrence of departmental and program leaders.

(f) Formal and informal notebooks (and related materials) submitted to the records and archives area must be clearly identified for cataloguing. Identifiers are to include

full work unit numbers, names of investigators, names of programs and/or departments, dates of performance, etc.

(2) **Work Unit Files and Research Records**: From initiation of research planning to completion of laboratory efforts, OOR is responsible for oversight of Command files of all documents and materials related to scientific work units.

(a) Investigators are required to keep OOR work unit files current through submission of various materials. Such items must include: work unit information system (WUIS) data; protocols or project applications being submitted to research sponsors; protocol amendments or modification documents; all annual and other reports, copies of technology transfer and intellectual property items; publication reprints or manuscript copies; and all other materials related to the scientific progress or success of the scope of work etc.

(b) Copies of human subject or animal research protocol approval, review, and reporting documents must be submitted to OOR for work unit files by the Recording Secretaries of the Committee for the Protection of Human Subjects (CPHS) and the Institutional Animal Care and Use Committee (IACUC)

(c) Upon completion of a work unit, investigators must ensure that copies of all major data related to reported scientific accomplishments are submitted to OOR for inclusion in Command work unit files. Submission of these items ensures proper scientific crediting for work units and the maintenance of accurate Command research histories.

(d) Personnel may retain copies of all materials as permissible with the concurrence of program and department leaders.

(3) **Human Subject Research/Animal Research**: Due to high sensitivity, all original in-progress documents, data related to the submission, review, continuing approvals, to these research efforts must be kept current and maintained in assigned CPHS and IACUC areas.

(a) In-progress human subject or animal research protocol files are the responsibility of CPHS and IACUC. In addition, CPHS and IACUC are to retain all files of completed protocols for the periods of time specified by regulations.

(b) For files of completed protocols which have met required maximum retention time periods, CPHS and IACUC are to work with OOR to integrate such human subject or animal research protocol files for retention in the central records and archives area. It is the responsibility of the CPHS and IACUC Chairpersons to inform OOR when specific protocol files are to be transferred to FRCs or NARA.

(c) The CPHS and IACUC Recording Secretaries are to submit copies of approval letters, annual reviews or continuation reports, and required final summations to OOR for inclusion in work unit files. Since original protocol materials are required to be kept in CPHS and IACUC areas, copies of the same materials are not required to be submitted to OOR for work unit files.

(d) Upon completion of human subject and animal research protocols, investigators are to submit copies of all relevant research data and documents to the CPHS and IACUC Recording Secretaries for inclusion in official files.

(e) Upon completion of a protocol all original signed consent forms and related materials (e.g. questionnaires) must be submitted immediately to OOR for the Command records and archives area. Submitted materials will be treated with the same level of confidentiality required for hospital or clinic medical records. Such materials must be organized appropriately into files. Each file is to be marked clearly with DOD Protocol number (for protocols from FY94 onward), NMRI investigator(s) name(s), protocol title, protocol dates, number of records included, complete work unit number, and other appropriate identifiers. Original signed consent forms and related materials will be permanently retrievable. For original consent forms (and related materials) being kept in the program or department area with OOR review and prior approval, investigators are to submit identifying information and enrollee registry information for inclusion in archive records. Archival recording of these items will identify the internal program location of these records.

(f) To facilitate retrieval of original signed consent forms and related materials, 00R will develop an electronic dbase catalogue of consent form files according to protocol and a linked electronic dbase registry for individual consent form materials. The consent form and registry dbases will be protected with the same level of confidentiality required for hospital or clinic medical records.

(4) **Intellectual Property and Technology Transfer:** Signed originals of all items related to intellectual property and technology transfer are to be retained only by 00T and/or 00L. Such items include patent applications, invention disclosures, Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs) etc.

(a) Signed originals may not be kept in local areas or files. However, copies of all items may be retained.

(b) Signed originals of items still retained in local areas are to be submitted to 00T immediately. For each item submitted to 00T, investigators are to include full work unit number and program/department and investigator names. 00T is to submit one (1) copy of each of these submissions, with full work unit number and other identifiers, to 00RA for work unit files.

(c) Investigators are required to submit copies with authorizing signatures of new intellectual property and technology transfer items to 00RA for Command work unit files. Submissions must include full work unit number for inclusion in work unit files.

(5) **Publications/Presentations:** Investigators and other Command personnel must submit all items for publication clearance and publication reprints to the Command Editor as required.

(a) Investigators are required to submit copies of published manuscripts, or publication reprints to 00R for inclusion in Command work unit files.

(b) At their own discretion, investigators are encouraged to submit to 00R copies of abstracts or special presentation materials for inclusion in work unit files.

(6) **Memoranda of Understanding/Memoranda of Agreement (MOU/MOA)**: The Office of the Comptroller (00C) is responsible for the oversight and discharge of MOUs/MOAs. Signed originals of all such documents are to be retained only by 00C.

(a) Investigators are required to submit to 00RA copies of MOUs/MOAs directly related to one or more work unit files for Command work unit files.

(b) Copies may be maintained in local files or by individuals.

(c) To provide for various research administration or legal needs, 00C is to collaborate with OTT, 00L and 00R to establish clear and easy access procedures for MOU/MOA documents.

(7) **Research-Related Command Documents**: DFA is responsible for the oversight and retention of in-progress, research-related Command documents not delineated in paragraphs (a) through (g). DFA will submit to 00R completed research-related documents for integration into the central records and archives.

(8) **Electronic/Digital Records**: 00R will design, develop, implement and oversee an electronic/digital records and archives system for all research records and archives. 00R will work with Command administration to obtain essential acquisitions.

(a) The system will include digitized copies of all research records and archives in the Command and the system will be developed for multi-platform user access.

(b) Where permissible hard copies will be substituted with digital/electronic copies once required retention time periods have expired.

(c) In the case of signed consent forms and related materials (e.g. questionnaires) for human subjects research efforts, originals must be maintained in perpetuity. Digitized/electronic copies of original consent form materials

may be produced and maintained as long as they are held under appropriate levels of confidentiality and as long as these computerized formats are never substituted for original consent forms and related materials.

THOMAS J. CONTRERAS, JR.

Distribution:
List(s)
A, B, C, & D