Manual M-3, Research and Development in Medicine. Part I, General

Chapter 5, Research and Development Support
(Paragraphs 5.01 through 5.05)

Revises Chapter 5 dated March 5, 1985

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Research and Development in Medicine
General

M-3, Part I
March 5, 1985

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Department of Medicine and Surgery
Veterans Administration
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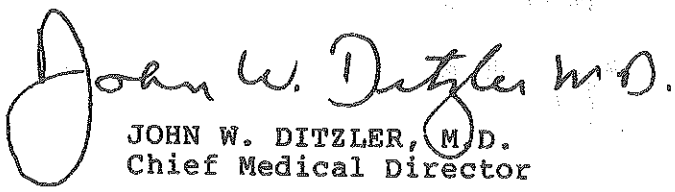
March 5, 1985

Part I, "General," VA Department of Medicine and Surgery Manual M-3, "Research and Development in Medicine," is published for the compliance of all concerned.



JOHN W. DITZLER, M.D.
Chief Medical Director

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FOREWORD

VA (Department of Veterans Affairs) Veterans Health Administration Manual M-3, "Research and Development in Medicine," Part I, "General," April 27, 1982, has been completely rewritten to incorporate all policy and procedural changes arid additions in the administration of research and development since that date. Parts II, III, and IV have also been completely rewritten to provide a convenient, readable set of documents for clear communication and effective administration of research and development. Similar reissuances are planned at 2-year intervals in the future.

The Research and Development Manual covers all three Research and Development Services and is organized as follows:

Part I ..... General
Part II ..... Medical Research Program
Part III ..... Health Services Research and Development Program
Part IV ..... Rehabilitation Research and Development Program

The provisions of this manual apply to all medical, rehabilitation and health services research conducted in VA medical centers, both locally and centrally reviewed.

RESCISSIONS

The following material is rescinded:

1. COMPLETE RESCISSIONS

a. Manuals

M-3, part I, chapter 9, dated March 5, 1985, and change 3 dated January 6, 1988
M-3, part I, chapter 12, dated January 31, 1989

b. Interim Issues

II 10-68-2
II 10-68-3
II 10-69-14
II 10-81-44

c. Circulars

10-84-75
10-84-198 and Supplement No. 1
10-85-128
10-87-27 and Supplement No. 1
10-87-53 and Supplement No. 1
10-87-110 and Supplement No. 1
10-89-034 and Supplement No. 1
10-89-131 and Supplement No. 1
10-90-044 and Supplement No. 1
10-90-046 and Supplement No. 1
10-90-052 and Supplement No. 1
10-90-069 and Supplement No. 1
10-90-115

rescinded by VHA Dir 1200 dtd 11/01/01

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CHAPTER 5. RESEARCH AND DEVELOPMENT SUPPORT

5.01 INTRAMURAL PROGRAMS

a. Intramural R&D (research and development) is fmanced in several ways:

(1) Institutional VA funds for research and development allocated as recommended by the R&D Committee.

(2) Centrally administered VA funds, for example, in support of a cooperative clinical study, allocated for programs recommended by the R&D Committee.

(3) Gifts or donations received for research in the General Post Fund with the approval of the facility's R&D Committee and the facility Director. These include donations of equipment or supplies, as well as funding by nonprofit foundations, private donors, and companies. The Research General Post Fund is discussed in detail in paragraph 5.05.

(4) Grants, contracts, gifts, or donations to other than the General Post Fund which have been approved by the R&D Committee and the facility Director.

b. The funding must be administered by one or more of the following:

(1) The VA health care facility using appropriate VA funds including the General Post Fund. (See MP-4, pt. V; and DM&S Supplement to MP-4, pt. VII, ch. 4.)

(2) An affiliated school or university.

(3) A not-for-profit fund, foundation, corporation, etc., outside the VA and affiliated institutions, approved by the R&D
Committee and the facility Director to receive and administer R&D funds for one or more investigators. Such arrangements should be reserved for exceptional circumstances.

c. The ACOS/R&D (Associate Chief of Staff for Research and Development) is responsible for assurance that an audit was conducted for each non-VA entity administering R&D funds used within the VA facility or arranging an audit of the financial statement. Ehis is a necessary requirement for continuing acceptance of the funding by VA investigators from that non-VA entity.

d. **VA R&D Funding Terms and Divisions**

(1) **Funding Program.** A major division of VA funding, of which there are three: 821, 822, and 824.

(2) **CC (Cost Center).** A division of VA Program 821 funding: funding in Programs 822 and 824 are not divided into cost
centers.

(3) **Common Resource.** A facility, function, or equipment shared commonly by investigators at a medical center. Common resources are funded under cost centers 10 1, 102, and I 05.

(4) **Category.** A division of cost center 102.

(5) **Program 821**: **Medical Research Service**

(a) CC 101-Administration

(b) CC 102-Common Research Support

(c) CC 103-Merit Reviewed Medical Research

(d) CC 104-Investigators' Salaries

(e) CC 105-Animal Research Facilities

(f) CC 106-Centrally Directed Priority Areas

(g) CC 107-Cooperative Studies

(h) CC 108-Career Development

(i) CC 109-Other Designated Research

(j) CC I 1 O-Research Career Scientist

(6) **Program 822. Rehabilitation Research and Development**

(7) **Program 824. Health Services Research and Development**

(8) **Category Codes for CC 102**

(a) 01 = **General Clerical Support.** All general clerical support not covered by cost center 101. Cost of manuscript preparation
is not included, nor are clerical costs attributable to individual R&D programs.

(b) 02 = **Animal Research.** Facilities and services pertaining to animal surgery shared by investigators as a common resource. Does not include animal surgical facilities integral to individual R&D programs. This does not include veterinary medical officer consultants, who are to be reported in cost center 105.

(c) 03 = **Consultants.** This category covers the cost of all consultants shared as a common resource in the R&D programs of the health care facility. The cost of consultants to individual R&D programs is to be placed in the cost center for each program. Does not include veterinary medical officer consultants. They are reported in cost center 105.

(d) 04 = **Core Chemistry/Biochemistry Laboratories.** Includes all costs (including personnel) of chemistry and biochemistry labs that are shared as a common resource by the R&D programs at the facility. Where such a lab is an integral part of an individual investigator's program, the cost should be placed in the cost center for each program.

(e) 05 = **Core Histology/Histopathology Laboratories.** Includes all costs (including personnel) of histology and histopathology labs that are shared as a common resource. Where such a lab is integral to an individual R&D program, the cost should be placed in the cost center for each program.

(f) 06 = **Common Resource Radioisotope Laboratories:** Covers all costs (including personnel) of radioisotope labs that are shared as a common resource. Radioisotope labs that are integral to individual R&D programs are to be placed in the cost center for each program.

(g) 07 = **Electron Miscroscope Laboratories.** Includes all common resource costs related to an electron microscopy service. Individual program costs in using the electron miscroscope are to be placed in the cost center for each using investigator's program.

(h) 08 = **Reproduction and Copying.** This category includes all common resource costs related to reproduction and copying. Commonly shared photocopying and printing costs are to be included. Costs associated with manuscript preparation are not to be placed in this category.

(i) 09 = **Manuscript Preparation and Editing.** All commonly shared costs of manuscript preparation and editing, including manuscript typing, are to be included in this category. Cost of obtaining reprints is not to be included, but should be placed in the cost center for each investigator's program.

(j) 10 = **Medical Illustration and Photography.** Includes all costs for medical illustration and photography services shared as a common resource. Where such costs are integral to an individual R&D program, they should be placed in the appropriate cost center.

(k) 11 = **Instrument and Equipment.** The costs of all equipment and instrumentation shared as a common resource are to be included in this category. Office equipment is not to be included in this category but should be placed in cost center 101. Development, maintenance, and repair costs are to be reported in Category 12..

(1) 12 = **Biomedical Engineering, Maintenance, and Repair.** This category is intended to cover all common resource costs related to the development, installation, maintenance, and repair of instrumentation. Salaries of biomedical engineers, BMETS (biomedical equipment technicians), electronics laboratories are to be included. Where any of these functions or facilities are a part of an individual R&D program, however, their costs should be placed in the cost center for that progrwn. Service contracts are to be covered in Category 13.

(m) 13 = **Service Contracts.** This category is to include the costs of all service contracts for equipment and instrumentation shared as a common resource. Service contracts in support of individual R&D programs are to be funded directly from those programs. A leased word processor would be included here.

(n) 14 = **Common Resource Glassware Preparation.** All costs associated with the preparation and washing of glassware where used as a common resource are to be covered by this category. Salaries and equipment costs are to be included.

(o) 16 = **Common Resource Computers, Data Processing and Statistical Services.** This category covers the costs of computers, programmers, computer specialists and statisticians used as a common resource. Where these services are integral to an investigator's individual program, they should be placed in the appropriate cost center.

5.02 EXTRAMURAL PROGRAMS

a. Contracts may be awarded within Research and Development. Some examples of activities to be achieved by contract are fabrication of prostheses; written consultative opinions, reviews, and critiques of R&D proposals or ongoing projects; statistical analyses and tabulations and laboratory tests for the conduct of testing and evaluation of medical devices and a report of same. The limits of the authority for contracting are outlined in 38 U.S.C. 4101(c). VA facilities shall award contracts only when necessary to accomplish specific goals such as those listed above, and these will be of limited scope and duration. Such contracts must be approved by the R&D Committee as well as by the facility Director. Larger contracts are negotiated and approved in VA Central Office although the ACOS/R&D may assist in their management. (See par. 3.02h.)

(1) Contracts must be in compliance with Federal and VA Acquisition Regulations.

(2) Unless otherwise directed by responsible authority, all contract negotiations by a VA health care facility are handled by the Supply Service of the facility. Only a contracting officer is empowered by law to execute the contract. There must be technical or scientific assistance, however, from the principal investigator or from a contract coordinator designated by the relevant R&D service in Central Office. No contract will be written for a period exceeding 1 year and each will specifically contain the following:

(a) A statement of the specific objectives with as much technical detail of the objectives as possible;

(b) A series of achievement dates or milestones of accomplishments for the contract period, which will allow coordination of accomplishments or progress to payment of vouchers;

(c) Specific instructions on voucher submissions for services performed; i.e., vouchers will contain work hours, work weeks, or work months for personal services expended on the contract, other labor charges, overhead materials, travel, and miscellaneous items in sufficient detail to verify services rendered and permit cost accounting;

(d) A timetable for delivery of the final products, and, in case of devices, a method of testing acceptability prior to final voucher payment;

(e) A reporting schedule that includes brief quarterly reports that highlight significant achievements or problems and a fmal report that includes engineering drawings, schematics, and sufficient detail to allow production of prototypes where desired, as well as any other products stipulated in the contract;

(f) Requirement of a termination report when an incompleted contract is discontinued, including a summary of results obtained and the reasons for termination; and

(g) Designation of a VA employee as contract coordinator. The contract coordinator is responsible for: (1) day-to-day liaison with the contractor on scientific or technical coordination or instructions and (2) verification of services rendered by the contractor; and

(h) Requirement that VA support be recognized in publications. (See par. 8.04.)

(3) Commercially available supplies, devices, and services can be obtained within the allowed dollar limits by local contract for use in an approved project.

(4) Contracts, modifications, or renewals submitted to VA Central Office as well as contracts requiring signature of the Chief Medical Director or the Administrator of Veterans Affairs must be accompanied by a briefing document containing the following items:

(a) **Contractor,** if known or proposed, Corporate name, and subdivision where needed. An individual can be named if appropriate.

(b) **Contract.** Name, number, and/or other identification of contract.

(c) **R&D Contact.** Name or position of person within VA having detailed information about the contract. Ordinarily this will be the contract coordinator.

(d) **Purpose.** Purpose or objective of the contract. This shall clearly place the proposed work in its overall technical or scientific context. It shall not exceed 200 words.

(e) **History.** The history of the contract will differ depending on whether it is an initial contract, a renewal, or a modification. It should not exceed 200 words.

1. **For Initial Contract:** List any preceding or concurrent closely related contracts with the same contractor. Note any prior unsuccessful attempts to obtain the same product.

2. **For Renewal or Modification:** Identify the extant contract if the designation differs. Provide an evaluation of the performance under the extant contract including whether the current target is being met and explain any deviation.

(f) **Justification.** The justification for an initial, renewal, or modified contract must cover, in order, three topics. It should not exceed a total of 200 words.

1. Need for, or intended use of, the product.

2. Reason for using the contract rather than an intramural or other mechanism.

3. Reason for selecting the specific contractor.

(g) **Costs and Schedules.** In simple tabular form, give the actual and estimated dollar costs and times for:

1. Past contract to the point of the current proposal.

2. Current proposal.

3. Future anticipated extension or continuation of the contract to the fmal product.

4. Totals

Example:	**Past**	**Current**	**Future**	**Total**	
FY					yrs.
COSTS	$	$	$	$	

(h) **Comments.** Additional comments are brief statements used to clarify obscure points in the contract, to meet likely objections or to explain specific difficulties. In total, they rarely should exceed 200 words.

b. The VA may enter into agreements with other Federal agencies under the provisions of 31 U.S.C. 1535. Such an agreement provides a means by which one agency with authority to conduct a certain activity contracts with another agency or department, which has the capability to perform it. These interagency agreements are agreements by which the VA may fund research and development performed by others or to perform research and development paid for by other agencies. In general, the agreements are negotiated and executed by VA Central Office but projects conducted under them must be proposed, reviewed, monitored, and reported as are other research programs. Agreements with non-Federal organizations are processed through other contractual mechanisms.

c. Grants, i.e., unencumbered funding in support of research and development, are not made by VA facilities or by VA Central Office.

d. In the case of consultant services, controls as outlined in VA Acquisition Regulations (subpt. 837.2) may apply. Any questions as to applicability should be directed to a duly appointed contracting officer or to District Counsel.

5.03 CONSULTANTS AND EXPERT REVIEWERS

a. All contracts with consultants and expert reviewers must be approved by the Administrator prior to contract execution, except as prescribed in VA Acquisition Regulation subpart 37.2. The contracting officer will prepare a notification of intent in the form of a letter or memorandum and submit it through channels to the medical center's Chief, Supply Service. The Chief, Supply Service will review the memorandum and submit it through the medical center Director to the Director, Office of Procurement and Supply in Central Office. The Director, Office of Procurement and Supply will review the letter of intent for consistency of application of agency policy and will route the request through the appropriate channels to obtain action by the Administrator. The notification of intent shall contain the basic information detailed under paragraph 5.03c.

b. The sponsoring official will submit to the contracting officer a final evaluation of the contractor's performance which will be made part of the contract file.

c. Consultations may be provided by contracts., Although these contracts are normally negotiated, enough lead time should be afforded to the contracting officer to initiate a competitive solicitation. Requests for authority to procure contractual consultant services must be submitted through the proper channels to the appropriate R&D service director in VA Central Office. At least 6 weeks must be allowed for reply. The request includes the following information in the order indicated:

(1) **Problem or Project**

(a) Brief statement of the problem or project for which consultation is sought.

(b) Length of time this problem or condition has existed.

(c) Effect on research and development should present situation continue.

(d) Specific examples of losses or excessive costs caused by the condition.

(e) If proposed project or present condition affects a much larger project, brief description of the complete project and action to be taken when this segment is completed.

(f) Alternate approaches to proposed consultation and reasons for rejecting each.

(g) Previous attempts to solve the problem or perform the work and their results, with an explanation of the outcome.

(h) Results or end products sought.

(I) Efforts made to determine if siinflar studies or other sources of information already exist, and whether this proposed effort duplicates other efforts known to have taken place or which are ongoing.

(2) **Equipment and Skills**

(a) Statement as to effect of lack of equipment on the situation and attempts made to correct the deficiency.

(b) Type of skills required to solve the problem or accomplish the project.

(3) **Personnel**

(a) Description of any shortage of qualified personnel bearing on the problem and attempts to correct it.

(b) Number of inservice personnel by descriptive title available to work with the contractor.

(c) If a certain expert or consultant is requested, specific reasons why this individual or an equally competent person cannot be termporarily employed.

(d) If request is for a specific expert or consultant, indicate the reasons.

(4) **Firms.** If a specific firm is recommended, indicate the reasons.

(5) **Cost of Contract and Funds**

(a) Estimated cost of contract.

(b) Identification of funds to be used to pay for contract.

(c) Anticipated time consultant will be needed.

(6) **Attachments**

(a) Copies of staff studies and papers bearing on the situation.

(b) Copy of proposed contract work statement.

(7) **Automated Data Processing.** If the request includes a requirement for services related to ADP, a copy of any reports or
requests submitted to GSA pursuant to FIRMR 201-31.006.

(8) **Evaluation.** The methodology by which contractor performance will be monitored including how departures from the original contract specifications will be documented and approved. The methodology by which the final product will be evaluated and by whom.

(9) Advance Procurement Planning. Does the requirement fall within the activity's advance procurement plan, and if not, why?

5.04 OTHER SUPPORT

a. Financing of VA research and development in any way not specified in this chapter requires the prior approval of the Chief Medical Director.

b. Requests for such approval must be made in writing and forwarded through administrative channels, including the Director of the appropriate R&D service and the ACMD/R&D.

5.05 RESEARCH GENERAL POST FUND

a. **Research General Post Funds Procedures**. As set forth in MP-4, part V and DM&S Supplement to MP-4, part VII, chapter 4 the following procedures will be adhered to:

(1) All gifts Or donations for research, payable to the order of the VA, shall be received in the General Post Fund. These require prior approval of the facilitv's Research and Development (committee and the facility Director if made to specific facility. Donations to the General Post Fund for research are to be assigned to the facilltv Director for research support within the facility, not to designated investigators. These include gifts and donations of equipment or supplies as well as funding by nonprofit foundations, private donors, and companies. The funding may be administered bv the VA health care facility using the General Post Fund (see MP-4, pt. V, ch. 2).

(2) The R&D Committe must concur in writing for General Post Fund research distributions at the facility.

(3) General Post Fund research monies may not be transferred between medical centers.

b. **Policies and Procedures**. As set forth in MP-4, part V and DM&S Supplement to MP-4, part VII, chapter 4, the following policies and procedures are applicable to research General Post Funds:

(1) A Director may authorize expenditures from the balances of the facility's earmarked General Post Funds for the purposc(s) for which tile funds have been designated.

(2) All withdrawals from the General Post Funds must be approved by the Director or designee and recorded as obligations prior to release of purchase documents or expenditures of cash. The approval may be indicated oil the purchase document, VA Form 90-2237, Request, Turn-in, and Receipt for Property or Services, or by memorandum.

(3) Expenditures from the General Post Fund for research activities are limited to funds specifically earmarked bv the donor for such purpose(s).

(4) Prior Central Office approval is required for General Post Fund facility construction projects exceeding S I $15,000 in estimated costs, including the cost of equipment and facility labor and materials, or purchase of equipment designated as Central Office controlled. These requests will be prepared in accordance with DM&S Supplement MP-4, part VII.

(5) Directors may authorize travel from earmarked General Post Fund monies which support an approved research project, provided the travel is essential to the conduct of the project, and the donation is not exclusively for travel or travel related expenses of VA staff members. Such travel will be authorized and performed in accordance with existing VA directives and Federal Travel Regulations. Foreign travel is subject to the procedures outlined in DM&S M-8, part V, chapter 6.

(6) Employees will not be journalized to the General Post Fund and direct expenditures will not be made from the fund for personal services and benefits.

(7) In those instances, where personnel services are required to accomplish the purposes specified by the donor, the appropriation from which the employee is paiid will be reimbursed from the (General Post Fund for the actual personal services and benefits expense incurred.

(8) When funds are donated for a specific purpose are expended to the extent that further execution of the purpose specified is impractical, residual balances will be transferred to the applicable general purpose account. However, wherethe residual balance is $100 or more, reasobable effort will be made to obtain the approval of the donor before the residual balance is transferred to thegeneral purpose account.

(9) Doctors, or their designees, will express in writing their appreciation of any gift or donation accepted **,iiid** will acknowledge with thanks offers that cannot be accepted, indicating reasons for nonacceptittice. Acknowledgment of gifts up to $500 may be accomplished by staff personnel authorized to sign for the Director. Gifts over $500 must be acknowledged with a letter detailing the use of the funds consistent with the purpose of the donation. These letters should include such information as the estimated expenditures for travel, administrative costs, etc. (if any) related to accomplishing the research for for the purpose of the donation. In the written acknowledgment of any gift or donation or proposed gift or donation, the Director or his/her designee will inform the donor or the proposed donor of the policies and procedures according to which the gift or donation will be received in the Research General Post Fund and be administered at the VA facility. VA medical center Directors must inform outside sponsors of research, including drug companies, that:

(a) The studies will be performed by VA investigators as part of their official VA duties,

(b) Federal Law prohibits all VA employees from receiving compensation from outside the Agency for services performed in connection with their official VA duties and prohibits anyone from providing such compensation; and

(c) All payments made in connection with the studies should be made to the General Post Fund or an outside institution, approved a VA medical center research and development committee, and not to individual VA investigators.

This information must be provided before donations to the (General Post Fund are accepted and before studies are initiated in VA medical facilities. One way of acquainting donors with these policies and procedures is to enclose a copy of the most recent Research General Post Fund policy.

(10) Officals and employees of the VA will not solicit contributions from the public nor will they authorize the use of their the names, the name of the Administrator, or the name of the VA by any individual or orgailization in any campaign or drive for money or articles for the purpose ofmaking a donation to the VA. This restriction does not preclude discussion with the individual offering a gift or donation to the General Post Fund for research relative to the gift or donation offered. However, the discussion should also serve to acquaint the potential donor with the policies and regulations pertaining to the Research General Post Fund. Such discussion shaill not be initiated by VA officials and employees.

c. **Research General Post Fund Guidelines**. The following guidelines will be followed by Research Offices for use of research General Post Funds after the facility Director has accepted the donation, gift, etc.:

(1) The Principal Investigator will initiate a request to use research General Post Funds for R&D Committee approved research projects to the ACOS/R&D (if appointed).

(2) The request will be presented to the facility's R&D Committee and the request will be recorded in the R&D Committee minutes.

(3) The R&D Committee Chairman will initial approved requests and the ACOS/R&D or Chief of Staff will be the signature authority (if so designated by the facility Director); such approving authority can be delegated only to the Chief of Staff or the ACOS/R&D.

(4) The approved request will be forwarded to the appropriate medical center service.

Department of Medicine and Surgery
Veterans Administration
Washington, DC 20420

January 6, 1988

Part I, "General," VA Department of Medicine and Surgery Manual M-3, "Research and Development in Medicine," is changed as indicated below:

NOTE: The purpose of this change in Chapter 5, "Research and Development Support," is to incorporate policy regarding extra-VA research funding previously published in Circular 10-86-85.

Pages 5-7 and 5-8: Remove these pages and substitute pages 5-7 and 5-8 attached.

RESCISSION: DM&S Circular 10-86-85.

John A Gronvall, M.D.

JOHN A. GRONVALL, M.D.
Chief Medical Director

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