CHAPTER 4. RESEARCH AND DEVELOPMENT INFORMATION SYSTEM

4.01 GENERAL

All regular R&D (Research and Development) reporting is incorporated in the RDIS (Research and Development Information System). This system requires both an RDIS Report from the health care facilities and periodic reporting on R&D projects. RCS (Reports Control Symbol) 10-0159 has been assigned to these reports.

The RDIS database provides the Office of the Assistant Chief Medical Director for Research and Development with information needed for managing the Research and Development program and for responding to inquiries regarding this program from other VA Central Office staff, Congress, Executive Branch offices, VA investigators, the scientific community and the general public.

4.02 RDIS REPORTS

An RDIS report, part I and part 11, is required from each health care facility that has received R&D funding or in which R&D projects are conducted. Instructions are issued on an annual basis.

a. When to Submit a Report. The reporting schedule for the RDIS Report, part I and part 11, is as follows:

(1) RDIS **Report, Part 1.** This component pertains to data which do not require end-of-fiscal-year information. The following sections are reported annually by March 15:

(a) Committee and Subcommittee Membership

(b) Research and Development Space

The following sections are reported whenever an Investigator's status changes:

(a) Investigator Data (page 18)

(b) Transfer or Resignation of R&D Investigator (page 19)

(2) RDIS Report, part II. This component pertains to data which require end-of-fiscal-year information. Part 11 data must be mailed annually to be received by November 15. These data include:

(a) VA and Extra-VA Project Funding Data

(b) Project Summary Data

b. **Where to Submit Report.** All RDIS Report forms, VA Form 10-5368, are to be sent to the BECC (Biomedical Engineering and Computing Center) (151A), VA Medical Center, 161 11 Plummer Street, Sepulveda, CA 91343, with the exception of page 19, "Transfer or Resignation of R&D Investigator." VA Form 10-5368 is to be sent in duplicate to the Assistant Chief Medical Director for Research and Development (15Bl), VA Central Office, 810 Vermont Ave, N.W., Washington, DC 20420. Upon VA Central office receipt, one copy of page 19 is forwarded to the BECC and the other is given to the appropriate VA Central Office staff member in Rehabilitation Research and Development, Health Services Research and Development, or Medical Research Service.

VA medical centers assigned to the Western Regional Research and Development Office or the Eastern Regional Research and Development Office are to submit RDIS Report data through their respective office.

c. **Distribution** of **the** RDIS **Report** and **Instructions**

(1) VA Form 10-53681. RDIS **Report, Part 1:** Instructions for the RDIS Report, Part I, are distributed by the BECC in January. This distribution will include a blank copy of each form and forms preprinted with data previously reported.

(2) VA **Form** 10-5368, RDIS **Report, Part 11:** Instructions for RDIS Report, Part 11, will be distributed by the BECC in September. This distribution will include a blank copy of each form and forms preprinted with previously reported information.

4.03 PROJECT REPORTS

VA Form 10-1436 is required for research involving VA facilities, resources, employees or patients. A Project Data Sheet must be submitted to the BECC (151A) within 15 working days after the investigator begins work on the project or after first funding is obligated (whichever occurs first) and annually thereafter.

a. **Requirement for Project Reporting**

(1) **General.** A VA Form 10-1436, Research and Development Information System PDS (Project Data Sheet), is required for every VA research and development project. This includes VA pro'ects funded entirely by extra VA funds, projects which are under contract, and projects for which no centrally directed funds are provided. The principal investigator must prepare a report at the initiation of each project, annually thereafter until the project is complete, and at its completion or termination. Page 18 of the RDIS Report, VA Form 10-5368, must also be submitted to the BECC if the principal investigator submitting a Project Data Sheet has not previously been reported in the RDIS data base.

(2) VA **Cooperative Studies.** A Project Data Sheet is to be submitted only by the chairperson of the study and is to be submitted through the appropriate Cooperative Studies Coordinating Center.

(3) **Projects with Co-Principal Investigators.** A Project Data Sheet is to be submitted by only one of the co-principal investigators. The collaborators should decide which co-principal investigator will submit reports for the project. Inclusion of identifying information for the other co-principal investigators) in Item 9 of the Pro'ect Data Sheet will ensure adequate recognition of the fact that there is more than one principal investigator involved in the project.

(4) **Projects Under Contract.** A Project Data Sheet for a Rehab R&D (Rehabilitation Research and Development) Project supported by a VA contract will be prepared by the contracting officer's technical representative but reported under the name and Social Security number of the VA official designated as co-investigator. Page 18 should be submitted to the BECC if this person is not already in the RDIS data base.

(5) **HSR&D Field Programs.** A Project Data Sheet is required for any project receiving support from an HSR&D Field Programs office. This includes LIP (Locally-Initiated Projects) and SDR (Service Directed Research Pro'ects). If the project is conducted at several facilities, only the principal investigator of the project shall submit a Project Data Sheet.

b. **Project Data Sheet Form.** VA Form 10-1436 is used for reporting project data. This form is designed to accommodate the use of preprinted investigator name labels which are provided for each investigator in the RDIS data base.

c. **Where to Submit Reports.** Completed forms should be sent to: BECC (Biomedica I Engineering Computing Center) (151A), VA Medical Center, 16111 Plummer St., Sepulveda, CA 91343. Only the original is required for all reports. Project Data Sheets completed at VA medical centers assigned to the Western Regional Research and Development Office or Eastern Regional Research and Development Office should be submitted through their respective regional office.

The BECC encourages submission of reports through electronic mail or diskette. Specific instructions on these procedures are available from the BECC.

d. **Types of Reports and When to Submit**

(1) **Initial Report.** An initial report is to be submitted within fifteen (15) working days after the investigator begins work on the project or after the first funding is obligated, whichever occurs first. Generally only one type of report is marked on the Project Data Sheet form. The only exception is a short-term project in which the work has been completed before the initial project is submitted; e.g., a one-time use of a drug. In that case, the investigator should specifically state that it is a completed short-term project in the abstract and mark both the "initial" and "final/completed" boxes.

(2) **Progress Report.** A progress report is **to** be submitted annually in the anniversary month of the initiation of the project.

(3) **Final/Completed.** A final/completed report is to be submitted within 15 working days after a project is completed.

(4) **Final/Terminated.** A final/terminated report is to be submitted within 15 working days after a project has been
terminated for any reason before completion. If work on a terminated project is resumed, a new initial report with a new project number appropriate to the investigator's project number sequence must be submitted.

e. **Transfer of Investigator.** When an investigator transfers from one VA medical center to another and continues work on an on-going project, the investigator is to close the project at the original facility by submitting a final/terminated report and is to open the project at the new facility by submitting an initial report. The final/terminated report should state that the investigator has transferred to another facility. The first sentence of this initial report must state that the investigator has changed locations and must identify the previous facility and project.

f. **Transfer of** a **Project.** When a project is taken over by another investigator, the original investigator is to close the project by submitting a final/terminated report and the new investigator is to open the project by submitting an initial report. The first sentence of this initial report must indicate that the investigator has taken over the project and must identify the previous investigator and project number.

g. **Narrative Content.** The narrative content of each Project Data Sheet submitted must be limited to 500 words. Reports with abstracts exceeding the 500 word limit may be truncated upon entry into the computer. The narrative of each report (initial, progress, final/completed, or final/terminated) must include a complete description of the project, since each progress or final report replaces all previous reports submitted to the RDIS for the project. The following information should be included in each abstract:

1. Objective of the project;
2. Research/development plan;
3. Methodology (techniques and major instrumentation employed); and
4. Findings, results, or conclusions reached to date.

The narrative for each basic science project must also include a statement describing the project's possible clinical significance. The final/terminated report for a project must include only scientific reasons for termination.

Each project must contain at least three keywords to allow appropriate indexing. Keywords should be selected in accordance with the National Library of Medicine Permuted MESH (Medical Subject Headings). PDS's without appropriate keywords will be returned.

h. **Responsibility**

(1) **Investigator.** The principal investigator or one co-principal investigator is responsible for preparing Project Data Sheets according to instructions contained in this manual. The investigator must give careful attention to the professional quality and completeness of scientific information reported in the abstract.

(2) **Research and Development Committee.** The Research and Development Committee is responsible for reviewing and approving each completed Project Data Sheet prior to submission of the report to the BECC. The review should focus on the professional quality, completeness, and accuracy of the report's narrative.

(3) **Research and Development Office.** The Research and Development Office is responsible for monitoring the preparation and timely submission of all Project Data Sheets from each facility. This includes 1) reviewing identification information on each completed Pro'ect Data Sheet (e.g., Social Security number, pro'ect number, medical center number, etc.) and assuring that this information is accurate; 2) assuring that the narrative abstract is accurate and complete; 3) assuring that names or Social Security numbers of investigational sub'ects do not appear anywhere on the Project Data Sheet; 4) assuring that the reports are properly collated prior to submission to the BECC; and, 5) at least three MESH keywords are listed.

i. **Incomplete Project Data Sheets.** Those without keywords will be returned.

4.04 OBTAINING PROJECT REPORTS

Requests for project information on a particular R&D subject area should be submitted either in writing to the ACMD for Research and Development (15B), VA Central Office, or by completing the appropriate form on the Research and Development Electronic Mail System. Information available is in accordance with the routine use statement as published in the Federal Register (ud. 50, no. 136, July 16, 1985, p. 28567).

4.05 TRANSFER OR TERMINATION OF RESEARCH PROGRAM

a. The ACOS/R&D or C/R&D initiates a notice to VA Central Office within 15 days after a principal investigator:

(1) Resigns or is separated from the VA.

(2) Transfers to another VA facility, or changes employment status to less than 5/8 time.

(3) Leaves the VA R&D program for any other reason.

b. Two copies of RDIS Report, part 1, page 19 will be submitted to ACMD for Research and Development (15Bl), VA Central Office. This notice is transmitted through administrative channels to appropriate R&D service in VA Central Office.