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RESEARCH AND DEVELOPMENT

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Chapter 4
RESEARCH AND DEVELOPMENT

4.01. Introduction

The Department of Veterans Affairs (VA) is mandated to conduct an ongoing program of research and development to advance the knowledge, methods, techniques, and resources available for use in developing and/or implementing rehabilitation programs for Veterans.

4.02. Reference and Resources

Laws: 28 United States Code (U.S.C.) 762
 28 U.S.C. 764
 38 U.S.C. 3119

Regulations: 38 Code of Federal Regulations (CFR) 1.517
 38 CFR 1.576
 38 CFR 21.390
 45 CFR 46

Websites: www.ed.gov/about/offices/list/osers/index.html
 www.ed.gov/about/offices/list/osers/nidrr/index.html
 www.icdr.us
 www.rsa.ed.gov
 www.hhs.gov

4.03. Research and Development Overview

VA undertakes research and development projects and/or provides support to other agencies for research and development to improve the quality and delivery of rehabilitation services. Research and development efforts may encompass a wide variety of approaches to rehabilitation, including the study of social, psychological, educational, vocational and industrial factors that affect rehabilitation. Projects are designed to increase resources, thus improving the potential for obtaining and maintaining suitable employment and achieving independent living goals for Veterans with disabilities.

a. Special Consideration for Human Subjects

Special safeguards and considerations must be utilized when working with human subjects. If the research is being conducted as part of an advanced degree program, the Institutional Review Board (IRB) where the researcher is enrolled must approve the proposal. IRB approval must be obtained prior to

submitting the proposal to the Director of Vocational Rehabilitation and Employment (VR&E) Service. If the research is not being conducted as part of a formal education program, it will be subject to the provisions of applicable federal regulations regarding protection of human subjects as indicated in 45 CFR 46.

1. Institutional Review Board (IRB)

An IRB, also known as an independent ethics committee or ethical review board, is a committee formally designated to approve, monitor, and review research involving humans. The IRB is established and monitored by the educational institution associated with the research project. Each IRB has at least five members with varying backgrounds to promote complete and adequate reviews of research activities commonly conducted by the educational institution. The aim of an IRB is to protect the rights and welfare of human research subjects. An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical and regulatory. 45 CFR 46 governs IRBs.

2. Assessment of Risks

The IRB's assessment of risks and anticipated benefits involves a series of steps. The IRB must take the following actions:

- Identify the risks associated with the research
- Determine that the risks will be minimized to the extent possible
- Identify the probable benefits to be derived from the research
- Determine that the risks are reasonable and beneficial to the subjects, if any, and the importance of the knowledge to be gained
- Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts, and the anticipated benefits
- Determine intervals of periodic review
- Determine that adequate provisions are in place for monitoring the data collected

3. Types of Risk

The risks to which research subjects may be exposed are classified as physical, psychological, social and economic harm.

(a) Physical Harm

Medical research often involves exposure to minor pain, discomfort and/or injury from invasive medical procedures, or harm from possible side effects of drugs. Some of the adverse effects that result from medical procedures and/or drugs can be permanent, but most are transient.

(b) Psychological Harm

Participation in research may result in undesired changes in thought processes and emotions (e.g., episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt and loss of self-esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but the researcher should be aware that some research has the potential for causing serious psychological harm.

(c) Social and Economic Harm

Some social and behavioral research may yield information about individuals that could "label" or "stigmatize" the subjects (e.g., as actual or potential delinquents or as persons with severe mental illness). Confidentiality safeguards must be strong in these instances. The fact that a person has participated in HIV-related drug trials or has been hospitalized for treatment of a mental illness could adversely affect present or future employment, eligibility for insurance and standing in the community if the information is made public.

b. Collection of Information

Most research projects require a collection of information. The Paperwork Reduction Act of 1995 expanded the responsibilities of federal agencies when developing a proposed collection of information. These responsibilities include a 60-day public comment period before submission for clearance by the Office of Management and Budget (OMB). OMB review and approval is required whenever VA wishes to obtain or solicit information from ten or more persons. Collection of information includes the use of questionnaires, surveys, interview guides and other methods of collecting information.

c. Interagency Coordination

Per 38 CFR 3119, VA should cooperate with a number of entities regarding rehabilitation studies, research and special projects of mutual programmatic concern. The following is a list of the most prominent of those entities:

1. The Office of Special Education and Rehabilitative Services (OSERS)

OSERS is part of the Department of Education. The mission of OSERS is to provide leadership to achieve full integration and participation in society of people with disabilities by ensuring equal opportunity and access to education, employment, and community living.

For more information on OSERS visit:
www.ed.gov/about/offices/list/osers/index.html.

2. The Rehabilitation Services Administration (RSA)

RSA is a component of OSERS. The mission of RSA is to provide leadership and resources to assist agencies in providing vocational rehabilitation, independent living, and other services to individuals with disabilities to maximize their employability, independence, integration into the community and competitive labor market.

RSA oversees grant programs that assist individuals with disabilities obtain and maintain suitable employment and live more independently through the provision of supports such as counseling, medical and psychological services, job training and other individualized services.

RSA's responsibilities include the following:

- Administering grant programs authorized by Congress
- Evaluating, monitoring and reporting on the implementation of federal policy, programs and the effectiveness of vocational rehabilitation, supported employment, independent living and other related programs for persons with disabilities
- Coordinating with federal agencies, state agencies, and the private sector for the review of program planning, implementation and monitoring issues

For more information on RSA visit: www.rsa.ed.gov.

3. National Institute on Disability and Rehabilitation Research (NIDRR), previously known as Institute of Handicapped Research

NIDRR is a component of OSERS. NIDRR provides leadership and support for a comprehensive program of research related to the rehabilitation of individuals with disabilities. The mission of NIDRR is to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community. Additionally, NIDRR aims to expand society's capacity to provide full opportunities and accommodations for persons with disabilities. NIDRR conducts comprehensive and coordinated programs of research and related activities to maximize the full inclusion, social integration, employment and independent living of individuals of all ages with disabilities. NIDRR's focus includes research in areas such as employment, health, technology, independent living and community integration, and other associated disability research areas.

For additional information on NIDRR, see: 28 U.S.C. 762 and www.ed.gov/about/offices/list/osers/nidrr/index.html.

4. The Interagency Committee on Disability Research (ICDR)

The Interagency Committee on Disability Research (ICDR) facilitates the effective exchange of information on disability and rehabilitation research activities among its member agencies. VA is a member agency of the ICDR. ICDR coordinates activities that span the areas of assistive technology and universal design, medical rehabilitation, data and statistics, employment, and community participation. The ICDR is charged with the following:

- Collect input from stakeholders to inform planning
- Identify emerging research areas
- Assess gaps and duplications in existing research
- Make recommendations to strengthen the federal research agenda

For more information on the ICDR visit: www.icdr.us.

d. Funding

To carry out the provisions of 38 U.S.C. 3119 and 38 CFR 21.390, VA may provide grants to or contract with public agencies, non-profit agencies and institutions of higher learning per 28 U.S.C. 764.

4.04. Research Conducted by VR&E Divisions

VA encourages research by VR&E staff members. This research should address problems affecting service delivery, initiation and continuation in rehabilitation programs and other areas directly affecting the quality of the provision of VR&E services to Veterans.

a. Developing Research Proposals

The proposal should provide the following information:

1. A title that accurately and concisely identifies the research, variables to be studied and key concepts of the study.
2. An objective that defines the purpose, scope and content of the research.
3. A literature review of peer-reviewed studies that pertains to the topic and puts the proposal into perspective, defines the field, describes the effective/ineffective past research and helps the reader interpret the significance of results to be obtained from the study.
4. A detailed description of the methodology of how the study will be conducted to allow replication. The methodology will provide details about the research design, including: population, sampling procedures, variables, hypothesis(es) to be tested, statistical methods used to analyze the data, data collection methods, safeguards of ethics and confidentiality, instrumentation, timeframe for the research and personnel who will conduct the research.
5. Cost estimates to complete the research and a reasonable expectation of benefit from successful achievement of objectives.
6. A utilization plan that outlines the procedures to be used or steps to be taken to disseminate the results of outcomes and how the results may be used.

b. Submitting Research Proposals

The process for submitting research proposals is as follows:

1. The VR&E staff member develops a research proposal that addresses problems affecting service delivery, initiation and continuation in rehabilitation programs and other areas directly affecting the quality of the provision of VR&E services to Veterans, then submits the proposal to the VR&E Officer.

2. The VR&E Officer reviews, evaluates and recommends approval of the proposal then submits the proposal to the Regional Office (RO) Director.
3. The RO Director reviews, evaluates and recommends approval of the proposal, then submits the proposal to the VR&E Service Director.
4. The VR&E Service Director provides final approval of the proposal and ensures any additional concurrences have been obtained.

NOTE: Approval at each phase is required for the proposal to proceed from one level of review to the next.

4.05. Research Conducted by Educational Institutions in Conjunction with VA

a. Authority to Conduct Research

Educational institutions cooperating with VA in the administration of research and development activities relative to counseling, vocational rehabilitation and training of Veterans and their dependents is authorized under 38 CFR 21.390.

b. Disclosure of Information to Educational Institutions

Requests for use of VR&E records from educational institutions and agencies cooperating with VA are subject to the provisions found in 38 CFR 1.517 as indicated below:

1. An educational institution or a responsible individual sends a request to the RO Director.
2. The RO Director reviews the request and recommends review by the Under Secretary for Benefits (USB).
3. Approval of the USB is required in order to release information from VR&E records.

Once the USB approves use of VR&E records, the RO Director is authorized to release information for the study, providing any data or information obtained are not published without prior approval of the USB and the published material does not identify any individual Veteran.

NOTE: Research conducted in collaboration with educational institutions is subject to the provisions of informed consent and confidentiality safeguards per 38 CFR 1.576.

c. Proposal Format

Requests for disclosure of information submitted to the USB by the RO Director should include the same information as other research proposals, as identified in M28R.I.A.4.04(a).