

Monday June 29, 1998

Part V

Department of Education

National Institute on Disability and Rehabilitation Research; Final Funding Priorities and Inviting Applications for New Rehabilitation Research Training Centers for Fiscal Years 1998–1999; Notice

DEPARTMENT OF EDUCATION

National Institute on Disability and Rehabilitation Research

AGENCY: Department of Education. **ACTION:** Notice of final funding priorities for fiscal years 1998–1999 for Rehabilitation Research and Training Centers.

SUMMARY: The Secretary announces final funding priorities for two Rehabilitation Research and Training Centers (RRTCs) under the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal years 1998–1999. The Secretary takes this action to focus research attention on areas of national need. These priorities are intended to improve rehabilitation services and outcomes for individuals with disabilities.

EFFECTIVE DATE: These priorities take effect on July 29, 1998.

FOR FURTHER INFORMATION CONTACT: Donna Nangle. Telephone: (202) 205–5880. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–9136. Internet:

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Individuals with disabilities may obtain this document in an alternate format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

SUPPLEMENTARY INFORMATION: This notice contains final priorities under the Disability and Rehabilitation Research Projects and Centers Program for two RRTCs related to: (1) aging and mental retardation; and (2) disability statistics.

These final priorities support the National Education Goal that calls for every adult American to possess the skills necessary to compete in a global economy.

The authority for the Secretary to establish research priorities by reserving funds to support particular research activities is contained in sections 202(g) and 204 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 761a(g) and 762).

Note: This notice of final priorities does *not* solicit applications. A notice inviting applications is published in this issue of the **Federal Register**.

Analysis of Comments and Changes

On May 4, 1998, the Secretary published a notice of proposed priorities in the **Federal Register** (63 FR 24718–24721). The Department of Education received three letters commenting on the notice of proposed priorities by the deadline date.

Technical and other minor changes and suggested changes the Secretary is not legally authorized to make under statutory authority—are not addressed.

Aging With Mental Retardation

Comment: The RRTC should be required to carry out research and develop models of service that support aging in place and showcase best practices that provide for an institutional admission diversion. In conjunction with this requirement, the RRTC should be required to develop informational materials that would help people with mental retardation reach a better understanding of what happens (and may happen) to them as they age. These materials and information should illustrate and guide the steps they can take to maintain a healthy lifestyle as older adults.

Discussion: Under the second and third required activities of the priority, an applicant could propose to carry out research and develop models of service that support aging in place and showcase best practices that provide for an institutional admission diversion. The peer review process will evaluate the merits of this proposal. However, NIDRR has no basis for requiring all applicants to carry out this research.

In regard to the commenter's suggestion that RRTC should be required to develop informational materials, the second general RRTC requirement states that the RRTC must develop and disseminate informational materials based on knowledge gained from the Center's research activities, and disseminate the materials to persons with disabilities, their representatives, service providers, and other interested parties. Therefore, if an applicant proposes to carry out the research suggested by the commenter, no further requirements are necessary in order for the RRTC to develop this informational material.

Changes: None.

Comment: The requirement to "identify, develop, and evaluate accommodations that help maintain employment" is not among the most significant issues facing persons aging with mental retardation and should be eliminated or made optional.

Discussion: NIDRR acknowledges that for the oldest segment of the population of persons aging with mental retardation, maintaining employment is not as significant an issue as others included in the priority. However, there are a substantial number of persons aging with mental retardation who are employed and face barriers to maintaining employment as they age. Applicants have the discretion to

emphasize or deemphasize specific activities included in the priority depending upon the importance the applicant attaches to the activity. An applicant could deemphasize this activity, and the peer review process will evaluate the merits of the proposal. NIDRR declines to eliminate the activity because the knowledge gained from this research could prove to be beneficial to those persons aging with mental retardation who are employed.

Changes: None.

Comment: The required activity on health should be revised to include: development of a model of medical education applicable to managed care; research on coincident conditions in older age; development of practice guidelines and standards for both women's and men's health; identification of care practices to address very old persons; and an examination of dementia care models that further community living.

Discussion: Under the first activity of the priority, an applicant could propose to carry out all of the projects included in the comment. The peer review process will evaluate the merits of the proposal. However, NIDRR has no basis for requiring all applicants to carry out this research.

Changes: None.

Comment: The RRTC should be required to identify aging models that are successful with the general population and demonstrate their applicability with persons aging with mental retardation.

Discussion: Under the first and third activities, an applicant could propose to identify aging models that are successful with the general population and demonstrate their applicability with persons aging with mental retardation. The peer review process will evaluate the merits of the proposal. However, NIDRR has no basis for requiring all applicants to carry out this research.

Changes: None.

Comment: More and more States are developing consumer-directed models of supporting adults with mental retardation. However, not enough empirical data exist about the effectiveness of these service models. The topic of self-direction or consumer direction should be incorporated into the third required activity.

Discussion: NIDRR agrees that integrating research on consumer choice or self-direction in the activities of the RRTC is important and needed.

Changes: The priority has been revised to require the RRTC to address issues of self-direction in all of the required activities except the fourth activity.

Rehabilitation Research and Training

The authority for RRTCs is contained in section 204(b)(2) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 760-762). Under this program, the Secretary makes awards to public and private organizations, including institutions of higher education and Indian tribes or tribal organizations, for coordinated research and training activities. These entities must be of sufficient size, scope, and quality to effectively carry out the activities of the Center in an efficient manner consistent with appropriate State and Federal laws. They must demonstrate the ability to carry out the training activities either directly or through another entity that can provide that training.

The Secretary may make awards for up to 60 months through grants or cooperative agreements. The purpose of the awards is for planning and conducting research, training, demonstrations, and related activities leading to the development of methods, procedures, and devices that will benefit individuals with disabilities, especially those with the most severe disabilities.

Description of Rehabilitation Research and Training Centers

RRTCs are operated in collaboration with institutions of higher education or providers of rehabilitation services or other appropriate services. RRTCs serve as centers of national excellence and national or regional resources for providers and individuals with disabilities and the parents, family members, guardians, advocates or authorized representatives of the individuals.

RRTCs conduct coordinated, integrated, and advanced programs of research in rehabilitation targeted toward the production of new knowledge to improve rehabilitation methodology and service delivery systems, to alleviate or stabilize disabling conditions, and to promote maximum social and economic independence of individuals with disabilities.

RRTCs provide training, including graduate, pre-service, and in-service training, to assist individuals to more effectively provide rehabilitation services. They also provide training including graduate, pre-service, and inservice training, for rehabilitation research personnel.

RRTCs serve as informational and technical assistance resources to providers, individuals with disabilities, and the parents, family members,

guardians, advocates, or authorized representatives of these individuals through conferences, workshops, public education programs, in-service training programs and similar activities.

RRTCs disseminate materials in alternate formats to ensure that they are accessible to individuals with a range of disabling conditions.

NIDRR encourages all Centers to involve individuals with disabilities and individuals from minority backgrounds as recipients of research training, as well as clinical training.

The Department is particularly interested in ensuring that the expenditure of public funds is justified by the execution of intended activities and the advancement of knowledge and, thus, has built this accountability into the selection criteria. Not later than three years after the establishment of any RRTC, NIDRR will conduct one or more reviews of the activities and achievements of the Center. In accordance with the provisions of 34 CFR 75.253(a), continued funding depends at all times on satisfactory performance and accomplishment.

General RRTC Requirements

The following requirements apply to the RRTCs pursuant to these absolute priorities, unless noted otherwise. An applicant's proposal to fulfill these requirements will be assessed using applicable selection criteria in the peer review process.

The RRTC must provide: (1) Applied research experience; (2) training on research methodology; and (3) training to persons with disabilities and their families, service providers, and other appropriate parties in accessible formats on knowledge gained from the Center's research activities.

The RRTC must develop and disseminate informational materials based on knowledge gained from the Center's research activities, and disseminate the materials to persons with disabilities, their representatives, service providers, and other interested parties.

The RRTC must involve individuals with disabilities and, if appropriate, their representatives, in planning and implementing its research, training, and dissemination activities, and in evaluating the Center.

The RRTC must conduct a state-ofthe-science conference and publish a comprehensive report on the final outcomes of the conference. The report must be published in the fourth year of the grant.

Priorities:

Under 34 CFR 75.105(c)(3), the Secretary proposes to give an absolute preference to applications that meet the following priorities. The Secretary proposes to fund under this competition only applications that meet one of these absolute priorities.

Priority 1: Aging With Mental Retardation

Background

There are an estimated 550,000 adults 40 years and older with mental retardation (McNeil, J., "Special Report on Mental Retardation and Mental Illness," Bureau of the Census, Survey of Income and Program Participation, 1997). This population has aging-related health and social care needs specific to their condition (McCarthy, J. and Mullan, E., "The Elderly with a Learning Disability (Mental Retardation): An Overview,' International Psychogeriatrics, 8 (3),

pgs. 489-501, 1996).

Current research has begun to identify secondary conditions that are causally related to aging with mental retardation. For instance, there is evidence that persons aging with mental retardation and a lifelong history of certain medications (e.g., psychotropic, antiseizure) have a higher risk of developing secondary conditions such as osteoporosis or tardive dyskinesia (Adlin, M., "Health Care Issues," Older Adults with Developmental Disabilities: Optimizing Choice and Change, Baltimore, Paul H. Brookes Pub. Co., pgs. 49–60, 1993). Persons with Downs Syndrome have a higher prevalence of Alzheimer's disease at an earlier age than the general population (Janicki, M., "Practice Guidelines for the Clinical Assessment and Care Management of Alzheimer's Disease and Other Dementias Among Adults with Intellectual Disability," Journal of Intellectual Disability Research, 40, pgs. 374-382, 1996). In addition, persons aging with mental retardation experience aging-related conditions like hypertension, osteoarthritis, heart disease, obesity, and high cholesterol levels. Treating such conditions in persons aging with mental retardation is complicated by difficulty in communicating about nutrition, exercise, and prescribed treatment protocols (Edgerton, R. "Some People Know How to Be Old," *Life Course* Perspectives on Adulthood and Old Age, American Association on Mental Retardation Monograph Series, pgs. 53-66, 1994) and by poor health maintenance practices (Edgerton, R. et al., "Health Care for Aging People with

Mental Retardation," *Mental Retardation*, 32 (2), pgs. 146–150, April, 1994).

The health status and needs of older women with mental retardation have received little research attention and merit special consideration. We have limited information on the availability of screening for breast or cervical cancers, onset and reactions to menopause, and treatment for osteoporosis in menopausal and postmenopausal women, or the general health status of women with mental retardation as they age (Murphy, L., Aging with Developmental Disabilities: Women's Health Issues, Texas Arc, 1997).

Approximately 80 percent of adults with mental retardation live at home, often with their families of origin, and many are known to the service system (Seltzer, M., "Aging Parents with Co-Resident Adult Children: The Impact of Lifelong Caregiving," Life Course Perspectives on Adulthood and Old Age, American Association on Mental Retardation, pgs. 3-18, 1994). A major issue facing older family caregivers is planning for the future of their children aging with mental retardation. A shortage of alternative living arrangements and the aging of family members contribute to this concern (Heller, T., "Support Systems, Wellbeing, and Placement Decision-making Among Older Parents and Their Adult Children with Developmental Disabilities," Older Adults with Developmental Disabilities: Optimizing Choice and Change, pgs. 107-122, 1993). For many families, planning for the future financial needs of their members with mental retardation is a particular concern.

There has been little research examining family caregiving throughout the life of the person aging with mental retardation, particularly analysis of sibling roles in the caregiving process. Cross-sectional studies have suggested that older family caregivers perceive less personal burden than do younger caregivers (Hayden, M., "Support, Problem-Solving/Coping Ability, and Personal Burden of Younger and Older Caregivers of Adults with Mental Retardation," Mental Retardation, 35, pgs. 364-372, 1997). With increasing age, there appears to be greater acceptance of the family member and greater reciprocity in caregiving as the child with mental retardation takes on caregiving roles with aging parents (Heller, T., "Adults with Mental Retardation as Supports to their Parents: Effects on Parental Caregiving Appraisal," Mental Retardation, 35, pgs. 338-346, 1997).

For adults living in residential settings, family involvement has been low. However, such involvement has many benefits for the adult including increasing social interaction, oversight of residential conditions, provision of recreational opportunities, assistance with financial planning activities (Feinstein, C., "A Survey of Family Satisfaction with Regional Treatment Centers and Community Services to Persons with Mental Retardation in Minnesota," Philadelphia: Conroy and Feinstein Associates, 1988). Older adults with mental retardation have lower rates of family involvement than vounger adults (Hill, B., Living in the Community: A Comparative Study of Foster Homes and Small Group Homes for People with Mental Retardation, Minneapolis: University of Minnesota, Center for Residential and Community Services, 1989)

Approximately 40 percent of working age persons with mental retardation work outside the home (McNeil, J., "Current Population Reports: Americans With Disabilities," U.S. Census Bureau, P70-61, 1997). Research indicates that as persons with mental retardation grow older, they experience new work-related problems because of functional decline and changing job requirements. Furthermore, many individuals with mental retardation and their employers are unaware of the resources and services available to help them solve these problems (Parent, W., "Social Integration in the Workplace; An Analysis of the Interaction Activities of Workers with Mental Retardation and their Co-workers," Education and Training in Mental Retardation, 27, pgs. 28-37, 1992).

Many individuals aging with mental retardation have limited access to assistive technology that might help them cope with aging-related functional limitations such as decreased mobility. Assistive technology has generally been underutilized by persons with mental retardation of all ages because few devices successfully incorporate accommodations that assist persons with cognitive impairments in their use (Wehmeyer, M., "The Use of Assistive Technology by People with Mental Retardation and Barriers to This Outcome: A Pilot Study," Technology and Disability, 4, pgs. 195-204, 1995). Also, staff and families often are insufficiently aware of assistive technology solutions or of options for its funding.

Information on health care utilization rates and educational and employment status of persons with mental retardation is not readily available. Although a number of Federal agencies,

some States, and private research institutions collect mental retardation data, too often these data are unanalyzed. Secondary analysis of existing data on mental retardation would help identify research questions and gaps in service for persons with mental retardation and their families.

Priority 1

The Secretary will establish an RRTC on Aging with Mental Retardation to assist individuals aging with mental retardation and their families to prevent secondary conditions, maintain general overall health, plan for the future, and maximize independence. The RRTC shall:

(1) Identify, develop, and evaluate programs that promote health, including early recognition and treatment of secondary conditions, with special emphasis on the needs of women aging with mental retardation;

(2) Investigate determinants of the role played by the family of origin in providing care for persons aging with mental retardation, with special emphasis on adults in residential settings and the role of siblings in the caregiving process;

(3) Identify, develop, and evaluate techniques that assist individuals with mental retardation and their families to plan for future needs, including future financial needs;

(4) Analyze and disseminate information from national data sets and public health surveillance data on adults with mental retardation to identify health care utilization.

educational, and employment patterns;

(5) Identify, develop, and evaluate accommodations that help maintain employment;

(6) Identify best practices in the use of assistive technology or universal design to compensate for physical and psychological consequences of aging with mental retardation.

In carrying out these purposes, the RRTC must:

- Coordinate with other relevant research and demonstration activities sponsored by the National Center on Medical Rehabilitation Research at the National Institutes of Health, the National Institute on Mental Health, the National Institute on Aging, the Rehabilitation Services Administration, the Department of Veteran Affairs, the Social Security Administration, the Health Care Financing Administration, and the Rehabilitation Research Training Centers on Managed Care and Personal Assistance Services; and
- Address issues of consumer choice or self-direction in all of the activities except the fourth activity.

Priority 2: Disability Statistics Background

A number of Federal, State, and private agencies collect information on persons with disabilities. While some of this information is analyzed, significant amounts of unanalyzed data are generated. The National Health Interview Survey, the Survey of Income and Program Participation, the California Work and Health Survey, other surveys, population data, information on program participation, data on institutions, and market research profiles provide many indicators about the lives of persons with disabilities. Policy makers, program directors, and others need information on the incidence, prevalence and distribution of disabilities, as well as the integration of persons with disabilities into society. Likewise, reliable information on use of services such as long-term care, transportation, vocational rehabilitation and personal care assistance is extremely valuable to individuals with disabilities and their organizations, planners, researchers and policy makers.

The 1994-95 National Health Interview Survey on Disability (NHIS-D) conducted by the National Center for Health Statistics was developed, in part, to meet the demands for data from numerous agencies (Verbrugee, L. M., "The Disability Supplement to the 1994–95 National Health Interview Survey," for the National Center for Health Statistics). The 1994–95 NHIS-D offers an excellent opportunity to analyze many variables related to persons with disabilities. Researchers can use the NHIS-D to determine access to health care and personal services, use of assistive technologies, and community participation, among other key descriptors.

The major Federal agencies that routinely collect information on disability publish only a small fraction of statistical information derived from that data. Most agency data collections are driven by statutory requirements and agencies report statistics about receipt of program services and subsets of eligible individuals. These constraints limit the usefulness of the data that are collected. Easier access to a full range of data on disability for policy makers and others may be assured, in part, by providing a central resource for disability statistics and information and an organized and comprehensive system for the collection, analysis, and synthesis of the data. A disability statistics center can use existing data to conduct metaanalyses focused on problems such as employment, use of health care and social services, household situations, family composition, and educational levels.

Researchers, policy makers and others have begun to work within the framework of the "New Paradigm of Disability," a contextual model of disability that recognizes the role of the built environment and of social and cultural factors in the disablementenablement process. Most national surveys fail to measure the role of environmental factors in the operational definitions of disability used, tending to focus solely on health problems as the locus of disability. (Kirchner, C., "Looking Under the Streetlamp: Inappropriate Use of Measures Just Because They Are There" Journal of Disability Policy Studies, 7:77-90. 1996). The Americans with Disabilities Act (ADA) emphasizes barrier removal, accessibility, and reasonable accommodations. Barriers may be physical or may involve programmatic exclusions and other social obstacles. Despite increasing recognition that data systems must be enhanced to meet newly developing information needs, such as those suggested by the New Paradigm of Disability and the ADA, there is a lack of environmental measures that have been tested for accuracy and reliability. This has been an impediment to the development of survey and census measures of disability at the national and State levels.

New survey measures must be developed to accurately and reliably depict disability in the context of individual health and environmental factors. The resulting questions must take into account the interaction between the individual and the environment and examine the effects of that interaction on the ability to carry out daily activities and normative social roles. This includes examination of the immediate living arrangements of the person's household and the larger community environment. Architectural accessibility features, assistive technologies, transportation, and other accommodations and supports must be addressed.

With increased global interest in disability, researchers must be aware of new developments in the World Health Organization sponsored International Committee on Impairments, Disabilities, and Handicaps, and consider international data sets for purposes of comparison with U.S. data and, as appropriate, to generate hypotheses to be tested against U.S. data.

Given these needs and opportunities in the promotion and use of disability statistics, a Center that can identify major sources and perform secondary analyses of existing data, including meta-analyses on important topics, will be a cornerstone of a future disability data initiative. The Center can also contribute to the future of disability research through the development, testing, and dissemination of data collection items that address the New Paradigm of Disability.

Priority 2

The Secretary will establish an RRTC to improve collection and analysis of disability statistics to guide development of disability policies. The RRTC shall:

- (1) Conduct secondary analyses of critical and relevant data sets, including estimates of the incidence, prevalence, and distribution of various disabilities, and disseminate analytical reports;
- (2) Develop new measures, designed for inclusion in general population surveys, addressing the effect of physical, policy, and social environments on persons with disabilities; and disseminate these to survey designers, researchers, and statistical agencies;
- (3) Conduct meta-analyses on key variables such as, but not limited to, employment, income and health status, using a range of relevant existing data sets on disability; and analyze the policy implications based upon the results of these analyses;
- (4) Identify major gaps in demographic and program data on the disabled population and develop strategies for addressing those gaps; and
- (5) Serve as a resource to researchers, consumers and consumer groups, planners, and policy makers for statistical information on disability and develop and implement a marketing plan to support dissemination of that information.

In carrying out the purposes of the priority, the RRTC must coordinate with relevant activities sponsored by the Centers for Disease Control and Prevention, the Office of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services, the Bureau of the Census, the Department of Labor, and the National Institutes of Health.

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Note: The official version of this document is the document published in the **Federal Register**.

Applicable Program Regulations: 34 CFR Parts 350.

Program Authority: 29 U.S.C. 760–762. (Catalog of Federal Domestic Assistance Numbers 84.133B, Rehabilitation Research and Training Centers)

Dated: June 23, 1998.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

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DEPARTMENT OF EDUCATION

[CFDA No.: 84.133B]

Office of Special Education and Rehabilitative Services; National Institute on Disability and Rehabilitation Research; Notice Inviting Applications for New Rehabilitation Research and Training Centers for Fiscal Year (FY) 1998

Note to Applicants: This notice is a complete application package. Together with the statute authorizing the programs and applicable regulations governing the programs, including the Education Department General Administrative Regulations (EDGAR), this notice contains information, application forms, and instructions needed to apply for a grant under these competitions.

This program supports the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

The estimated funding levels in this notice do not bind the Department of Education to make awards in any of these categories, or to any specific number of awards or funding levels, unless otherwise specified in statute.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, and 86; and Disability and Rehabilitation Research Projects and Centers—34 CFR Part 350, particularly Rehabilitation Research and Training Centers in Subpart C.

Program Title: Rehabilitation
Research and Training Centers (RRTCs).

CFDA Number: 84.133B.

Purpose of Program: RRTCs conduct coordinated and advanced programs or research on disability and rehabilitation that will produce new knowledge that will improve rehabilitation methods and service delivery systems, alleviate or stabilize disabling conditions, and promote maximum social and economic independence for individuals with disabilities. RRTCs provide training to service providers at the pre-service, inservice training, undergraduate, and graduate levels, to improve the quality and effectiveness of rehabilitation services. They also provide advanced research training to individuals with disabilities and those from minority backgrounds engaged in research on disability and rehabilitation. RRTCs serve as national and regional technical assistance resources and provide training for service providers, individuals with disabilities and families and representatives, and rehabilitation researchers.

Eligible Applicants: Parties eligible to apply for grants under this program are States, public or private agencies, including for-profit agencies, public or private organizations, including for-profit organizations, institutions of higher education, and Indian tribes and tribal organizations.

Program Authority: 29 U.S.C. 762.

APPLICATION NOTICE FOR FISCAL YEAR 1998, REHABILITATION RESEARCH AND TRAINING CENTERS, CFDA No. 84-133B

Funding priority	Deadline for transmittal of applications	Estimated number of awards	Maximum award amount (per year)*	Project period (months)
Aging with mental retardation	8/28/98 8/28/98	1 1	\$700,000 700,000	60 60

*Note: The Secretary will reject without consideration or evaluation any application that proposes a project funding level that exceeds the stated maximum award amount per year (See 34 CFR 75.104(b)).

RRTC Selection Criteria: The Secretary uses the following selection criteria to evaluate applications for RRTCs on aging with mental retardation and disability statistics under the Disability and Rehabilitation Research Project and Centers Program.

- (a) *Importance of the problem* (9 points total).
- (1) The Secretary considers the importance of the problem.
- (2) In determining the importance of the problem, the Secretary considers the following factors:
- (i) The extent to which the applicant clearly describes the need and target population (3 points).

- (ii) The extent to which the proposed activities address a significant need of those who provide services to individuals with disabilities (3 points).
- (iii) The extent to which the proposed project will have beneficial impact on the target population (3 points).
- (b) Responsiveness to an absolute or competitive priority (4 points total).
- (1) The Secretary considers the responsiveness of the application to the absolute or competitive priority published in the **Federal Register**.
- (2) In determining the responsiveness of the application to the absolute or competitive priority, the Secretary considers the following factors:

- (i) The extent to which the applicant addresses all requirements of the absolute or competitive priority (2 points).
- (ii) The extent to which the applicant's proposed activities are likely to achieve the purposes of the absolute or competitive priority (2 points).
- (c) Design of research activities (35 points total).
- (1) The Secretary considers the extent to which the design of research activities is likely to be effective in accomplishing the objectives of the project.
- (2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the