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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1330

RIN 0985-AA12

National Institute on Disability, Independent Living, and Rehabilitation Research

AGENCY: National Institute on Disability, Independent Living, and Rehabilitation Research; Administration for Community Living; HHS.

ACTION: Final rule.

SUMMARY: This rule implements the Workforce Innovation and Opportunity Act of 2014 and reflects the transfer of the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Department of Education to the Department of Health and Human Services (HHS). The previous regulations were issued by the Department of Education. The rulemaking consolidates the NIDILRR regulations into a single part, aligns the regulations with the current statute and HHS policies, and provides guidance to NIDILRR grantees.

DATES: These final regulations are effective July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Greg Pugh, Administration for Community Living, telephone (202) 795-7422 (Voice). This is not a toll-free number. This document will be made available in alternative formats upon request.

SUPPLEMENTARY INFORMATION:

I. Discussion of Final Rule

The Workforce Innovation and Opportunity Act of 2014 (“WIOA,” Public Law 113-128), signed into law on July 22, 2014, included significant changes to Title II of the Rehabilitation Act of 1973. The first of these is the insertion of a new name, the National

Institute on Disability, Independent Living, and Rehabilitation Research (“NIDILRR,” which was previously the National Institute on Disability and Rehabilitation Research). WIOA also relocates NIDILRR from the Department of Education to the Administration for Community Living (“ACL”) of the Department of Health and Human Services. As part of the transfer, the Administrator of ACL (Administrator) drafted a Notice of Proposed Rulemaking that was published on December 21, 2015, to implement the Workforce Innovation and Opportunity Act of 2014 and reflect the transfer of the National Institute on Disability, Independent Living, and Rehabilitation Research from the Department of Education to the Department of Health and Human Services.

ACL received 13 unduplicated comments during the public comment period from individuals, state agencies, and organizations representing disability, rehabilitation, and aging constituencies. ACL has read and considered each of the comments received. We respond here to the most-commonly-received comments and those that we believe require further discussion. Several comments raised issues that are specific to the commenter. Responding to such comments is beyond the scope of the final regulation. Nevertheless, we encourage commenters with individualized questions to contact NIDILRR directly at 202-401-4634-Option 5.

Many of the comments expressed broad general support for the rule and the broader transfer of NIDILRR to the Administration for Community Living. Commenters expressed their support of the consolidation of existing NIDILRR regulations and alignment with HHS policies, a major goal of this rulemaking. Others expressed their approval of the elimination of unnecessary language from the regulatory text, while at the same time maintaining existing Department of Education language where it makes programmatic sense to do so. Finally, multiple commenters wrote in support of the inclusion of the stages of research, as well as the

new stages of development.

While no commenters expressed general opposition to the promulgation of the rule, several expressed their concerns about specific provisions of the proposed rule. We made changes to the regulatory text based on the comments as discussed below and we fixed a few non-substantive technical errors in the regulatory text. In addition, it has come to our attention that a selection criterion used at the Department of Education related to the quality of a proposed project's design was inadvertently omitted from this rule. This criterion is extremely valuable to the evaluation of applications for certain NIDILRR projects, and we have therefore included it verbatim at § 1330.24(p) as one of the criteria the Director may consider in evaluating an application. Other than the changes discussed below, we adopt our discussion of the rule in the Notice of Proposed Rulemaking published December 21, 2015 (80 FR 79283).

A. Funding out of rank order in field-initiated competitions

Comment: Six commenters (five organizations and one individual) raised concerns about a proposed change to § 1330.25. The proposed regulation gives the NIDILRR director authority to fund out of rank order in field-initiated competitions when there is an opportunity to fund a project of significant interest to the agency. Concerns ranged from the change giving too much authority to political appointees to the potential undermining of the scientific integrity of the research process. Suggestions ranged from dropping this proposed change in the regulation to increasing the scoring threshold for use of the provision or to creating a requirement for a formal explanation by the NIDILRR director justifying the proposed change.

Response: NIDILRR appreciates the concerns expressed by these commenters especially the focus on impartial peer review and its role in maintaining the scientific integrity of NIDILRR's research portfolio. Our goal in suggesting this change was to provide an opportunity for the

Director to select applications that address critical agency goals in circumstances where these applications have high scores but would not be funded in a strictly rank order framework.

NIDILRR has long had the ability to fund out of rank order, and though it was rarely used, we added the 80 percent threshold in an effort to ensure the quality of NIDILRR-funded research. NIDILRR has expanded our field-initiated research opportunities in recent years, and we think that clarifying the requirements for funding out of rank order will ensure this quality, while also allowing for funding of compelling research opportunities. In such cases where an application may have otherwise gone unfunded in a strict rank-order process, we believe that the Director should have the ability to fund highly promising studies, while setting a minimum threshold for quality assurance and providing for public notification.

After careful consideration of the concerns raised by the commenters, as well as a review of past applications, NIDILRR proposes to increase the threshold before funding out of rank order can be considered to a score of 85 points or above. We believe, based upon decades of staff experience with the grant review process, that this number strikes a reasonable balance between providing the Director the flexibility to fund applications which are uniquely promising and ensuring that all NIDILRR-funded research projects are of the quality and rigor for which NIDILRR is known. In addition, the regulation has been amended to require a public notification by the Director of any decision to fund out of rank order. Should it become advisable to raise this threshold further, we may revisit this threshold in the future. We take these steps to clarify our commitment to conducting rigorous peer review.

B. Publication of funding opportunities and application instructions

Comment: In light of the new regulation's elimination of specific funding application instructions, two commenters suggested that NIDILRR update its website to provide clear

information to applicants on funding opportunities and on the process of submitting applications.

Response: NIDILRR shares these commenters' commitment to ensuring that potential grantees have adequate access to information on NIDILRR's research priorities and application processes.

To this end, we are publishing funding forecast documents with links to necessary application information on the ACL website, and will endeavor at all times to maximize the transparency and wide dissemination of funding opportunities and application instructions.

C. Stages of development

Comment: One commenter, while supporting the stages of development in § 1330.5, expressed concern that the rule doesn't make clear that the technology transfer plan requirement does not sufficiently convey the complexity of supply and demand and the behaviors of consumers and other stakeholders in their decisions to adopt and use technology.

Response: The stages of development provide an organizational framework to guide prospective applicants in preparing their technical proposals. The stages are not prescriptive. For this reason, we believe that identifying the relevant stage(s) of development will allow the peer review process to better determine the extent to which proposed activities to facilitate and measure product adoption are necessary and appropriate and to determine the extent to which applicants understand contextual factors that might impact product adoption.

D. Disability advisory panels and reviewer training

Comment: One organization made a number of suggestions related to NIDILRR's peer review process as described in § 1330.22. This commenter recommended that NIDILRR form advisory panels with members with diverse disabilities, including physical, sensory, intellectual, and mental disabilities, to be assigned to each peer review panel to ensure that disability perspectives are considered in the funding decision.

In addition, the commenter suggested reviewer training related to consistent weighting of scores, minimizing personal biases of reviewers, and reviewing and scoring application attachments. The commenter also suggested that NIDILRR provide training to the disability advisory panels to ensure that personal likes and dislikes of the reviewers not enter into the scoring.

Response: NIDILRR strongly supports a diversity of perspectives on peer review panels and makes every effort to include reviewers who have disabilities as well as subject-matter expertise relevant to the research or development topic. We are constantly seeking to recruit new, qualified individuals with disabilities for these purposes. We require our peer reviewers to attend an orientation session and, if they are new to our system, participate in training sessions to ensure that they understand the technical requirements of the process. NIDILRR staff monitors each panel to ensure that the review is carried out in a professional manner and further to ensure that each application is treated fairly.

To support the importance of research and development focused on the needs of individuals with disabilities, NIDILRR has already added a requirement that applicants must obtain input from individuals with disabilities and other stakeholders in shaping proposed research or development activities. NIDILRR is also finalizing approval of its Disability, Independent Living, and Rehabilitation Research Advisory Council (DILRRAC) which adheres to a statutory requirement that more than 50 % of its membership be comprised of individuals with disabilities. We believe that this committee will provide valuable guidance regarding ways that we can improve the relevance of NIDILRR's research to individuals with disabilities. We are confident that all of these steps will address the commenters concerns without adding significant administrative burden and expense to the peer review process.

E. Collaboration

Comment: Two commenters suggested additions to the peer review criterion on collaboration in § 1330.24(k). Both suggested more specific requirements for collaboration with local and national consumer organizations, and one also included a recommendation for requiring meaningful collaboration with other relevant agencies, organizations, or institutions. In addition, one of the commenters suggested weighting the collaboration criterion more heavily.

Response: NIDILRR strongly agrees that it is important to seek appropriate collaboration where relevant to the specific research or development project being proposed. To this end, we have long had a collaboration review element which is required for many funding priorities. We believe that this requirement is adequate, and that to require it of all research or development projects would be misguided, as collaboration may not be relevant for the research topic or stage of research or development being proposed.

Specific weighting of review criteria is not prescribed by regulation so as to allow weighting as appropriate to the purpose and goals of each funding priority. More specific regulatory language on weighting would significantly limit NIDILRR's ability to match individual criteria with the topic of the priority at hand.

F. Notification of review scores and comments

Comment: Two commenters suggested the insertion into regulation a requirement that applicants will receive reviewer scores and comments within 30 days of NIDILRR decisions.

Response: This is already a part of NIDILRR's grants management policy, and we make every effort to ensure that notification of scores and comments is provided within a 30 day timeframe. We believe that to specifically require this in regulation would be counter to the stated objectives of consolidating and simplifying the regulatory language, to which many commenters responded

very favorably.

G. Posting of applicant scores

Comment: One commenter suggested that NIDILRR post a list of applicants and aggregate scores on its website at the conclusion of a competition.

Response: NIDILRR's goal is to fund rigorous and relevant research, as determined by an independent panel of individuals with subject-specific expertise and with knowledge of and sensitivity to the needs of individuals with disabilities. We ask these reviewers to provide detailed and thoughtful comments on the proposals they review, and we send this feedback to applicants in an effort to help build capacity in disability and rehabilitation research. We do not believe that listing unsuccessful applicants and their scores would further this goal, and believe that doing so would be contrary to HHS grants policy with regard to applicant privacy.

H. Meaning of “product”

Comment: One organization raised several questions about the meaning of the term “product” in our discussion of stages of development, specifically requesting that NIDILRR define the term and what it includes. A related comment recommended that NIDILRR provide clarification to the concept of “proof of product” to ensure that it includes functional requirements such as accessibility and usability or market viability requirements such as price or performance. This commenter also suggested that NIDILRR elaborate on its expectations of the attributes associated with the stages of development. Finally, there was one comment asking that there be consistent use of the term product in the document.

Response: NIDILRR carefully considered these comments which helped us think about the extent to which we wanted to make the definition of “product” to be enumerative or non-enumerative and to allow for changes in conceptualization over time. Our conclusion is that

flexibility is needed and beneficial. To this end, we are defining products as potentially encompassing but not necessarily limited to models, methods, tools, applications, and devices. Applicants can associate proposed products to these types or clarify and defend why proposed products lie outside of these types. Finally, we agree that it would contribute to clarity to use the term, “product” consistently in the document, and we have made this change accordingly.

I. Removal of “scientific” from peer review panels

Comment: A commenter suggested that NIDILRR remove the term “scientific” from the description of its peer review panels.

Response: NIDILRR’s authorizing statute specifically requires the NIDILRR Director to provide for scientific review of all applications over which the Director has authority. 29 U.S.C. 762 (f)(1). Given the statutory requirement, NIDILRR feels that it must adhere to this standard which confirms Congressional intent to ensure that NIDILRR carry out its peer review so that scientific expertise supports rigorous review that help ensures that NIDILRR funds the research that is likely to generate findings that will help improve the lives of individuals with disabilities. However, NIDILRR also notes that this section of the statute references inclusion of expertise regarding needs of individuals with disabilities and their families. To this end, we make every effort to have peer review panels that balance scientific expertise with knowledge relevant to individuals with disabilities and their families.

J. Role of the Director

Comment: One organization asked for clarification of the role of the Director in conducting evaluation of applications for NIDILRR funding, specifically inquiring whether the Director has sole discretion over the review.

Response: As stated in §1330.21, the NIDILRR Director is required to refer each application to a

peer review panel that reviews the application using the applicable peer review criteria as defined in § 1330.23. The ranking of the applications by the peer review panels determines which applicants are awarded funds, subject to special considerations in § 1330.25.

K. Role of the Director, consistency

Comment: One commenter pointed out that, in § 1330.24(d), the reference to Secretary should refer to the NIDILRR Director for consistency with the rest of the section.

Response: We concur, and have corrected the regulatory text accordingly.

L. Applications address the needs of individuals with diverse backgrounds

Comment: One commenter suggested that the language in § 1330.11 be changed so that the Director must require that applicants demonstrate how they will address the needs of individuals with disabilities from minority backgrounds.

Response: NIDILRR appreciates the concern behind this comment, and this language is often inserted into NIDILRR priorities. However, we feel that it is too prescriptive to require that the Director must do this in every instance, and that making this an absolute requirement will restrict the ability of the Director to establish criteria that support topics of research initiatives that may not benefit from such a requirement.

M. Composition of Panels

Comment: One commenter suggested that the language in § 1330.22 be changed so that the Director shall take into account factors including does the peer review panels include knowledgeable individuals with disabilities or disability advocates such as parents or family members and does the panel include individuals from diverse populations.

Response: NIDILRR appreciates the concern behind this comment. However, we feel that it is too prescriptive to require that the Director shall do this in every instance and that making this an

absolute requirement will restrict the ability of the Director to establish peer review panels that best match the topics of proposed research proposals.

II. Impact Analysis

A. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Department has determined that this rule is consistent with the priorities and principles set forth in Executive Order 12866. Executive Order 12866 encourages agencies, as appropriate, to provide the public with meaningful participation in the regulatory process. The rulemaking implements the Workforce Innovation and Opportunity Act of 2014. In developing the final rule, we considered input we received from the public including stakeholders. This final rule is not being treated as a “significant regulatory action” under section 3(f)(1) of Executive Order 12866. Accordingly, the final rule has not been reviewed by the Office of Management and Budget.

B. Regulatory Flexibility Analysis

The Secretary certifies under 5 U.S.C. 605(b), the Regulatory Flexibility Act (Public Law 96-354), that this regulation will not have a significant economic impact on a substantial number of small entities. The primary impact of this regulation is on entities applying for NIDILRR funding opportunities, specifically researchers, States, public or private agencies and organizations, institutions of higher education, and Indian tribes and tribal organizations. The regulation does not have a significant economic impact on these entities. This rule is in fact significantly shorter than, but with identical compliance requirements to, the regulations it

replaces.

C. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before an information collection request is submitted to the Office of Management and Budget (OMB) for review and approval. We are not introducing any new information collections in this rule however, nor revising reporting requirements.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that a covered agency prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in expenditures by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million, adjusted for inflation, or more in any one year.

If a covered agency must prepare a budgetary impact statement, section 205 further requires that it select the most cost-effective and least burdensome alternatives that achieves the objectives of the rule and is consistent with the statutory requirements. In addition, section 203 requires a plan for informing and advising any small government that may be significantly or uniquely impacted by a rule.

ACL has determined that this rule does not result in the expenditure by State, local, and Tribal governments in the aggregate, or by the private sector of more than \$100 million in any one year.

E. Congressional Review

This rule is not a major rule as defined in 5 U.S.C. Section 804(2).

F. Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires

Federal agencies to determine whether a policy or regulation may affect family well-being. If the agency's conclusion is affirmative, then the agency must prepare an impact assessment addressing seven criteria specified in the law. These regulations do not have an impact on family well-being as defined in the legislation.

G. Executive Order 13132

Executive Order 13132 on "federalism" was signed August 4, 1999. The purposes of the Order are: "...to guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies, and to further the policies of the Unfunded Mandates Reform Act..."

The Department certifies that this rule does not have a substantial direct effect on States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government.

ACL is not aware of any specific State laws that would be preempted by the adoption of the regulation.

List of Subjects in 45 CFR Part 1330

Grant programs, Research, Scholarships and fellowships.

Dated: April 20, 2016.

Kathy Greenlee,

Administrator,

Administration for Community Living.

Approved: May 2, 2016.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

For the reasons stated in the preamble, the U.S. Department of Health and Human Services amends 45 CFR subchapter C by adding part 1330 to read as follows:

PART 1330 – NATIONAL INSTITUTE FOR DISABILITY, INDEPENDENT LIVING, AND REHABILITATION RESEARCH

Subpart A – Disability, Independent Living, and Rehabilitation Research Projects and Centers
Program

Sec.

1330.1 General.

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Subpart D – Disability, Independent Living, and Rehabilitation Research Fellowships

1330.30 Fellows program.

Subpart E – Special Projects and Demonstrations for Spinal Cord Injuries

1330.40 Spinal cord injuries program.

Authority: 29 U.S.C. 709, 3343.

Subpart A - Disability, Independent Living, and Rehabilitation Research Projects and

Centers Program

§ 1330.1 General.

(a) The Disability, Independent Living, and Rehabilitation Research Projects and Centers

Program provides grants to establish and support:

(1) The following Disability, Independent Living, and Rehabilitation Research and

Related Projects:

(i) Disability, Independent Living, and Rehabilitation Research Projects;

(ii) Field-Initiated Projects;

(iii) Advanced Rehabilitation Research Training Projects; and

(2) The following Disability, Independent Living, and Rehabilitation Research Centers:

(i) Rehabilitation Research and Training Centers;

(ii) Rehabilitation Engineering Research Centers.

(b) The purpose of the Disability, Independent Living, and Rehabilitation Research Projects and

Centers Program is to plan and conduct research, development, demonstration projects, training,

dissemination, and related activities, including international activities, to:

(1) Develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, education, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities; and

(2) Improve the effectiveness of services authorized under the Rehabilitation Act of 1973, 29 U.S.C. 701 et seq.

§ 1330.2 Eligibility for assistance and other regulations and guidance.

(a) Unless otherwise stated in this part or in a determination by the NIDILRR Director, the following entities are eligible for an award under this program:

- (1) States.
- (2) Public or private agencies, including for-profit agencies.
- (3) Public or private organizations, including for-profit organizations.
- (4) Institutions of higher education.
- (5) Indian tribes and tribal organizations.

(b) Other sources of regulation which may apply to awards under this part include but are not limited to:

- (1) 45 CFR part 16 – Procedures of the Departmental Grant Appeals Board.
- (2) 45 CFR part 46 – Protection of Human Subjects.
- (3) 45 CFR part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.
- (4) 2 CFR parts 376 and 382 – Nonprocurement Debarment and Suspension and Requirements for Drug-Free Workplace (Financial Assistance).
- (5) 45 CFR part 80 – Nondiscrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services – Effectuation of title VI of the Civil Rights Act of 1964.
- (6) 45 CFR part 81 – Practice and Procedure for Hearings under part 80 of this title.
- (7) 45 CFR part 84 – Nondiscrimination on the Basis of Handicap in Programs or Activities Receiving Federal Financial Assistance.
- (8) 45 CFR part 86 – Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance.

(9) 45 CFR part 87 – Equal Treatment of Faith-Based Organizations.

(10) 45 CFR part 91 – Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS.

(11) 45 CFR part 93 – New Restrictions on Lobbying.

§ 1330.3 Definitions.

As used in this part:

(a) *Secretary* means the Secretary of the Department of Health and Human Services.

(b) *Administrator* means the Administrator of the Administration for Community Living.

(c) *Director* means the Director of the National Institute on Disability, Independent Living, and Rehabilitation Research.

(d) *Research* is classified on a continuum from basic to applied:

(1) *Basic research* is research in which the investigator is concerned primarily with gaining new knowledge or understanding of a subject without reference to any immediate application or utility.

(2) *Applied research* is research in which the investigator is primarily interested in developing new knowledge, information, or understanding which can be applied to a predetermined rehabilitation problem or need.

(e) *Development activities* use knowledge and understanding gained from research to create materials, devices, systems, or methods beneficial to the target population, including design and development of prototypes and processes.

(f) *Products* encompass models, methods, tools, applications, and devices, but are not necessarily limited to these types.

§ 1330.4 Stages of research.

For any Disability, Independent Living, and Rehabilitation Research Projects and Centers Program competition, the Department may require in the application materials for the competition that the applicant identify the stage(s) of research in which it will focus the work of its proposed project or center. The four stages of research are:

(a) Exploration and discovery mean the stage of research that generates hypotheses or theories through new and refined analyses of data, producing observational findings and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes of individuals with disabilities, as well as identifying or describing existing practices, programs, or policies that are associated with important aspects of the lives of individuals with disabilities. Results achieved under this stage of research may inform the development of interventions or lead to evaluations of interventions or policies. The results of the exploration and discovery stage of research may also be used to inform decisions or priorities;

(b) Intervention development means the stage of research that focuses on generating and testing interventions that have the potential to improve outcomes for individuals with disabilities. Intervention development involves determining the active components of possible interventions, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the feasibility of conducting a well-designed intervention study. Results from this stage of research may be used to inform the design of a study to test the efficacy of an intervention;

(c) Intervention efficacy means the stage of research during which a project evaluates and tests whether an intervention is feasible, practical, and has the potential to yield positive outcomes for individuals with disabilities. Efficacy research may assess the strength of the relationships between an intervention and outcomes, and may identify factors or individual characteristics that affect the relationship between the intervention and outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support “scaling-up” an intervention to other sites and contexts. This stage of research may include assessing the training needed for wide-scale implementation of the intervention, and approaches to evaluation of the intervention in real-world applications; and

(d) Scale-up evaluation means the stage of research during which a project analyzes whether an intervention is effective in producing improved outcomes for individuals with disabilities when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based intervention in different settings. The project examines the challenges to successful replication of the intervention, and the circumstances and activities that contribute to successful adoption of the intervention in real-world settings. This stage of research may also include well-designed studies of an intervention that has been widely adopted in practice, but lacks a sufficient evidence base to demonstrate its effectiveness.

§ 1330.5 Stages of development.

For any Disability, Independent Living, and Rehabilitation Research Projects and Centers Program competition, the Department may require in the notice inviting applications for the

competition that the applicant identify the stage(s) of development in which it will focus the work of its proposed project or center. The three stages of development are:

(a) *Proof of concept* means the stage of development where key technical challenges are resolved. Stage activities may include recruiting study participants, verifying product requirements; implementing and testing (typically in controlled contexts) key concepts, components, or systems, and resolving technical challenges. A technology transfer plan is typically developed and transfer partner(s) identified; and plan implementation may have started. Stage results establish that a product concept is feasible.

(b) *Proof of product* means the stage of development where a fully-integrated and working prototype, meeting critical technical requirements is created. Stage activities may include recruiting study participants, implementing and iteratively refining the prototype, testing the prototype in natural or less-controlled contexts, and verifying that all technical requirements are met. A technology transfer plan is typically ongoing in collaboration with the transfer partner(s). Stage results establish that a product embodiment is realizable.

(c) *Proof of adoption* means the stage of development where a product is substantially adopted by its target population and used for its intended purpose. Stage activities typically include completing product refinements; and continued implementation of the technology transfer plan in collaboration with the transfer partner(s). Other activities include measuring users' awareness of the product, opinion of the product, decisions to adopt, use, and retain products; and identifying barriers and facilitators impacting product adoption. Stage results establish that a product is beneficial.

Subpart B – Requirements for Awardees

§ 1330.10 General requirements for awardees.

(a) In carrying out a research activity under this program, an awardee must:

(1) Identify one or more hypotheses or research questions;

(2) Based on the hypotheses or research question identified, perform an intensive systematic study in accordance with its approved application directed toward:

(i) New or full scientific knowledge; or

(ii) Understanding of the subject or problem being studied.

(b) In carrying out a development activity under this program, an awardee must create, using knowledge and understanding gained from research, models, methods, tools, systems, materials, devices, applications, or standards that are adopted by and beneficial to the target population. Development activities span one or more stages of development.

(c) In carrying out a training activity under this program, an awardee shall conduct a planned and systematic sequence of supervised instruction that is designed to impart predetermined skills and knowledge.

(d) In carrying out a demonstration activity under this program, an awardee shall apply results derived from previous research, testing, or practice to determine the effectiveness of a new strategy or approach.

(e) In carrying out a utilization activity under this program, a grantee must relate research findings to practical applications in planning, policy making, program administration, and delivery of services to individuals with disabilities.

(f) In carrying out a dissemination activity under this program, a grantee must systematically distribute information or knowledge through a variety of ways to potential users or beneficiaries.

(g) In carrying out a technical assistance activity under this program, a grantee must provide expertise or information for use in problem-solving.

§ 1330.11 Individuals with disabilities from minority backgrounds.

(a) If the director so indicates in the application materials or elsewhere, an applicant for assistance under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds.

(b) The approaches an applicant may take to meet this requirement may include one or more of the following:

(1) Proposing project objectives addressing the needs of individuals with disabilities from minority backgrounds.

(2) Demonstrating that the project will address a problem that is of particular significance to individuals with disabilities from minority backgrounds.

(3) Demonstrating that individuals from minority backgrounds will be included in study samples in sufficient numbers to generate information pertinent to individuals with disabilities from minority backgrounds.

(4) Drawing study samples and program participant rosters from populations or areas that include individuals from minority backgrounds.

(5) Providing outreach to individuals with disabilities from minority backgrounds to ensure that they are aware of rehabilitation services, clinical care, or training offered by the project.

(6) Disseminating materials to or otherwise increasing the access to disability information among minority populations.

Subpart C – Selection of Awardees

§ 1330.20 Peer review purpose.

The purpose of peer review is to insure that:

- (a) Those activities supported by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) are of the highest scientific, administrative, and technical quality; and
- (b) Activity results may be widely applied to appropriate target populations and rehabilitation problems.

§ 1330.21 Peer review process.

- (a) The Director refers each application for an award governed by these regulations in this part to a peer review panel established by the Director.
- (b) Peer review panels review applications on the basis of the applicable selection criteria in § 1330.23.

§ 1330.22 Composition of peer review panel.

- (a) The Director selects as members of a peer review panel scientists and other experts in disability, independent living, rehabilitation or related fields who are qualified, on the basis of training, knowledge, or experience, to give expert advice on the merit of the applications under review.
- (b) The scientific peer review process shall be conducted by individuals who are not Department of Health and Human Services employees.
- (c) In selecting members to serve on a peer review panel, the Director may take into account the following factors:
 - (1) The level of formal scientific or technical education completed by potential panel members.

- (2) The extent to which potential panel members have engaged in scientific, technical, or administrative activities appropriate to the category of applications that the panel will consider; the roles of potential panel members in those activities; and the quality of those activities.
- (3) The recognition received by potential panel members as reflected by awards and other honors from scientific and professional agencies and organizations outside the Department.
- (4) Whether the panel includes knowledgeable individuals with disabilities, or parents, family members, guardians, advocates, or authorized representatives of individuals with disabilities.
- (5) Whether the panel includes individuals from diverse populations.

§ 1330.23 Evaluation process.

- (a) The Director selects one or more of the selection criteria to evaluate an application:
 - (1) The Director establishes selection criteria based on statutory provisions that apply to the Program which may include, but are not limited to:
 - (i) Specific statutory selection criteria;
 - (ii) Allowable activities;
 - (iii) Application content requirements; or
 - (iv) Other pre-award and post-award conditions; or
 - (2) The Director may use a combination of selection criteria established under paragraph (a)(1) of this section and selection criteria from § 1330.24 to evaluate a competition.
 - (3) For Field-Initiated Projects, the Director does not consider § 1330.24(b)

(Responsiveness to the Absolute or Competitive Priority) in evaluating an application.

(b) In considering selection criteria in § 1330.24, the Director selects one or more of the factors listed in the criteria, but always considers the factor in § 1330.24(n) regarding members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(c) The maximum possible score for an application is 100 points.

(d) In the application package or a notice published in the FEDERAL REGISTER, the Director informs applicants of:

(1) The selection criteria chosen and the maximum possible score for each of the selection criteria; and

(2) The factors selected for considering the selection criteria and if points are assigned to each factor, the maximum possible score for each factor under each criterion. If no points are assigned to each factor, the Director evaluates each factor equally.

(e) For all instances in which the Director chooses to allow field-initiated research and development, the selection criteria in § 1330.25 will apply, including the requirement that the applicant must achieve a score of 85 percent or more of maximum possible points.

§ 1330.24 Selection criteria.

In addition to criteria established under § 1330.23(a)(1), the Director may select one or more of the following criteria in evaluating an application:

(a) *Importance of the problem.* In determining the importance of the problem, the Director considers one or more of the following factors:

- (1) The extent to which the applicant clearly describes the need and target population.
- (2) The extent to which the proposed activities further the purposes of the Rehabilitation Act.
- (3) The extent to which the proposed activities address a significant need of individuals with disabilities.
- (4) The extent to which the proposed activities address a significant need of rehabilitation service providers.
- (5) The extent to which the proposed activities address a significant need of those who provide services to individuals with disabilities.
- (6) The extent to which the applicant proposes to provide training in a rehabilitation discipline or area of study in which there is a shortage of qualified researchers, or to a trainee population in which there is a need for more qualified researchers.
- (7) The extent to which the proposed project will have beneficial impact on the target population.

(b) *Responsiveness to an absolute or competitive priority.* In determining the application's responsiveness to the application package or the absolute or competitive priority published in the FEDERAL REGISTER, the Director considers one or more of the following factors:

- (1) The extent to which the applicant addresses all requirements of the absolute or competitive priority.
- (2) The extent to which the applicant's proposed activities are likely to achieve the

purposes of the absolute or competitive priority.

(c) *Design of research activities.* In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the research activities constitute a coherent, sustained approach to research in the field, including a substantial addition to the state-of-the-art.

(2) The extent to which the methodology of each proposed research activity is meritorious, including consideration of the extent to which:

(i) The proposed design includes a comprehensive and informed review of the current literature, demonstrating knowledge of the state-of-the-art;

(ii) Each research hypothesis or research question, as appropriate, is theoretically sound and based on current knowledge;

(iii) Each sample is drawn from an appropriate, specified population and is of sufficient size to address the proposed hypotheses or research questions, as appropriate, and to support the proposed data analysis methods;

(iv) The source or sources of the data and the data collection methods are appropriate to address the proposed hypotheses or research questions and to support the proposed data analysis methods;

(v) The data analysis methods are appropriate;

(vi) Implementation of the proposed research design is feasible, given the current state of the science and the time and resources available;

(vii) Input of individuals with disabilities and other key stakeholders is

used to shape the proposed research activities; and

(viii) The applicant identifies and justifies the stage of research being proposed and the research methods associated with the stage.

(3) The extent to which anticipated research results are likely to satisfy the original hypotheses or answer the original research questions, as appropriate, and could be used for planning additional research, including generation of new hypotheses or research questions, where applicable.

(4) The extent to which the stage of research is identified and justified in the description of the research project(s) being proposed.

(d) *Design of development activities.* In determining the extent to which the project design is likely to be effective in accomplishing project objectives, the Director considers one or more of the following factors:

(1) The extent to which the proposed project identifies a significant need and a well-defined target population for the new or improved product;

(2) The extent to which the proposed project methodology is meritorious, including consideration of the extent to which:

(i) The proposed project shows awareness of the state-of-the-art for current, related products;

(ii) The proposed project employs appropriate concepts, components, or systems to develop the new or improved product;

(iii) The proposed project employs appropriate samples in tests, trials, and other development activities;

(iv) The proposed project conducts development activities in appropriate

environment(s);

(v) Input from individuals with disabilities and other key stakeholders is obtained to establish and guide proposed development activities; and

(vi) The applicant identifies and justifies the stage(s) of development for the proposed project; and activities associated with each stage.

(3) The new product will be developed and tested in an appropriate environment.

(e) *Design of demonstration activities.* In determining the extent to which the design of demonstration activities is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the proposed demonstration activities build on previous research, testing, or practices.

(2) The extent to which the proposed demonstration activities include the use of proper methodological tools and theoretically sound procedures to determine the effectiveness of the strategy or approach.

(3) The extent to which the proposed demonstration activities include innovative and effective strategies or approaches.

(4) The extent to which the proposed demonstration activities are likely to contribute to current knowledge and practice and be a substantial addition to the state-of-the-art.

(5) The extent to which the proposed demonstration activities can be applied and replicated in other settings.

(f) *Design of training activities.* In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or

more of the following factors:

- (1) The extent to which the proposed training materials are likely to be effective, including consideration of their quality, clarity, and variety.
- (2) The extent to which the proposed training methods are of sufficient quality, intensity, and duration.
- (3) The extent to which the proposed training content:
 - (i) Covers all of the relevant aspects of the subject matter; and
 - (ii) If relevant, is based on new knowledge derived from research activities of the proposed project.
- (4) The extent to which the proposed training materials, methods, and content are appropriate to the trainees, including consideration of the skill level of the trainees and the subject matter of the materials.
- (5) The extent to which the proposed training materials and methods are accessible to individuals with disabilities.
- (6) The extent to which the applicant's proposed recruitment program is likely to be effective in recruiting highly qualified trainees, including those who are individuals with disabilities.
- (7) The extent to which the applicant is able to carry out the training activities, either directly or through another entity.
- (8) The extent to which the proposed didactic and classroom training programs emphasize scientific methodology and are likely to develop highly qualified researchers.
- (9) The extent to which the quality and extent of the academic mentorship,

guidance, and supervision to be provided to each individual trainee are of a high level and are likely to develop highly qualified researchers.

(10) The extent to which the type, extent, and quality of the proposed research experience, including the opportunity to participate in advanced-level research, are likely to develop highly qualified researchers.

(11) The extent to which the opportunities for collegial and collaborative activities, exposure to outstanding scientists in the field, and opportunities to participate in the preparation of scholarly or scientific publications and presentations are extensive and appropriate.

(g) *Design of dissemination activities.* In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the content of the information to be disseminated:

- (i) Covers all of the relevant aspects of the subject matter; and
- (ii) If appropriate, is based on new knowledge derived from research activities of the project.

(2) The extent to which the materials to be disseminated are likely to be effective and usable, including consideration of their quality, clarity, variety, and format.

(3) The extent to which the methods for dissemination are of sufficient quality, intensity, and duration.

(4) The extent to which the materials and information to be disseminated and the methods for dissemination are appropriate to the target population, including consideration of the familiarity of the target population with the subject matter,

format of the information, and subject matter.

(5) The extent to which the information to be disseminated will be accessible to individuals with disabilities.

(h) *Design of utilization activities.* In determining the extent to which the design of utilization activities is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the potential new users of the information or technology have a practical use for the information and are likely to adopt the practices or use the information or technology, including new devices.

(2) The extent to which the utilization strategies are likely to be effective.

(3) The extent to which the information or technology is likely to be of use in other settings.

(i) *Design of technical assistance activities.* In determining the extent to which the design of technical assistance activities is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the methods for providing technical assistance are of sufficient quality, intensity, and duration.

(2) The extent to which the information to be provided through technical assistance covers all of the relevant aspects of the subject matter.

(3) The extent to which the technical assistance is appropriate to the target population, including consideration of the knowledge level of the target population, needs of the target population, and format for providing information.

(4) The extent to which the technical assistance is accessible to individuals with

disabilities.

(j) *Plan of operation.* In determining the quality of the plan of operation, the Director considers one or more of the following factors:

(1) The adequacy of the plan of operation to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, and timelines for accomplishing project tasks.

(2) The adequacy of the plan of operation to provide for using resources, equipment, and personnel to achieve each objective.

(k) *Collaboration.* In determining the quality of collaboration, the Director considers one or more of the following factors:

(1) The extent to which the applicant's proposed collaboration with one or more agencies, organizations, or institutions is likely to be effective in achieving the relevant proposed activities of the project.

(2) The extent to which agencies, organizations, or institutions demonstrate a commitment to collaborate with the applicant.

(3) The extent to which agencies, organizations, or institutions that commit to collaborate with the applicant have the capacity to carry out collaborative activities.

(l) *Adequacy and reasonableness of the budget.* In determining the adequacy and the reasonableness of the proposed budget, the Director considers one or more of the following factors:

(1) The extent to which the costs are reasonable in relation to the proposed project activities.

(2) The extent to which the budget for the project, including any subcontracts, is adequately justified to support the proposed project activities.

(3) The extent to which the applicant is of sufficient size, scope, and quality to effectively carry out the activities in an efficient manner.

(m) *Plan of evaluation.* In determining the quality of the plan of evaluation, the Director considers one or more of the following factors:

(1) The extent to which the plan of evaluation provides for periodic assessment of progress toward:

(i) Implementing the plan of operation; and

(ii) Achieving the project's intended outcomes and expected impacts.

(2) The extent to which the plan of evaluation will be used to improve the performance of the project through the feedback generated by its periodic assessments.

(3) The extent to which the plan of evaluation provides for periodic assessment of a project's progress that is based on identified performance measures that:

(i) Are clearly related to the intended outcomes of the project and expected impacts on the target population; and

(ii) Are objective, and quantifiable or qualitative, as appropriate.

(n) *Project staff.* In determining the quality of the project staff, the Director considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Director considers one or more of the following:

- (1) The extent to which the key personnel and other key staff have appropriate training and experience in disciplines required to conduct all proposed activities.
- (2) The extent to which the commitment of staff time is adequate to accomplish all the proposed activities of the project.
- (3) The extent to which the key personnel are knowledgeable about the methodology and literature of pertinent subject areas.
- (4) The extent to which the project staff includes outstanding scientists in the field.
- (5) The extent to which key personnel have up-to-date knowledge from research or effective practice in the subject area covered in the priority.

(o) *Adequacy and accessibility of resources.* In determining the adequacy and accessibility of the applicant's resources to implement the proposed project, the Director considers one or more of the following factors:

- (1) The extent to which the applicant is committed to provide adequate facilities, equipment, other resources, including administrative support, and laboratories, if appropriate.
- (2) The quality of an applicant's past performance in carrying out a grant.
- (3) The extent to which the applicant has appropriate access to populations and organizations representing individuals with disabilities to support advanced disability, independent living and clinical rehabilitation research.
- (4) The extent to which the facilities, equipment, and other resources are appropriately accessible to individuals with disabilities who may use the facilities, equipment, and other resources of the project.

(p) *Quality of the project design.* In determining the quality of the design of the proposed project, the Director considers one or more of the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(2) The quality of the methodology to be employed in the proposed project.

(3) The extent to which the design of the proposed project includes a thorough, high-quality review of the relevant literature, a high-quality plan for project implementation, and the use of appropriate methodological tools to ensure successful achievement of project objectives.

(4) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(5) The extent to which the proposed development efforts include adequate quality controls and, as appropriate, repeated testing of products.

(6) The extent to which the proposed project will be coordinated with similar or related efforts, and with other appropriate community, State, and Federal resources.

(7) The extent to which the design of the proposed project reflects up-to-date knowledge from research and effective practice.

(8) The extent to which the proposed project represents an exceptional approach to the priority or priorities established for the competition.

§ 1330.25 Additional considerations for field-initiated priorities.

(a) The Director reserves funds to support field-initiated applications funded under this

part when those applications have been awarded points totaling 85 percent or more of the maximum possible points under the procedures described in § 1330.23.

(b) In making a final selection from applications received when NIDILRR uses field-initiated priorities, the Director may consider whether one of the following conditions is met and, if so, use this information to fund an application out of rank order:

(1) The proposed project represents a unique opportunity to advance rehabilitation and other knowledge to improve the lives of individual with disabilities.

(2) The proposed project complements or balances research activity already planned or funded by NIDILRR through its annual priorities or addresses the research in a new and promising way.

(c) If the Director funds an application out of rank order under paragraph (b) of this section, the public will be notified through a notice on the NIDILRR web site or through other means deemed appropriate by the Director.

Subpart D – Disability, Independent Living, and Rehabilitation Research Fellowships

§ 1330.30 Fellows program.

(a) The purpose of this program is to build research capacity by providing support to highly qualified individuals, including those who are individuals with disabilities, to perform research on rehabilitation, independent living, and other experiences and outcomes of individuals with disabilities.

(b) The eligibility requirements for the Fellows program are as follows:

(1) Only individuals are eligible to be recipients of Fellowships.

(2) Any individual is eligible for assistance under this program who has training

and experience that indicate a potential for engaging in scientific research related to rehabilitation and independent living for individuals with disabilities.

(3) This program provides two categories of Fellowships: Merit Fellowships and Distinguished Fellowships.

(i) To be eligible for a Distinguished Fellowship, an individual must have seven or more years of research experience in subject areas, methods, or techniques relevant to disability and rehabilitation research and must have a doctorate, other terminal degree, or comparable academic qualifications.

(ii) The Director awards Merit Fellowships to individuals in earlier stages of their careers in research. To be eligible for a Merit Fellowship, an individual must have either advanced professional training or experience in independent study in an area which is directly pertinent to disability and rehabilitation.

(c) Fellowships will be awarded in the form of a grant to eligible individuals.

(d) In making a final selection of applicants to support under this program, the Director considers the extent to which applicants present a unique opportunity to effect a major advance in knowledge, address critical problems in innovative ways, present proposals which are consistent with the Institute's Long-Range Plan, build research capacity within the field, or complement and significantly increases the potential value of already planned research and related activities.

Subpart E – Special Projects and Demonstrations for Spinal Cord Injuries

§ 1330.40 Spinal cord injuries program.

(a) This program provides assistance to establish innovative projects for the delivery,

demonstration, and evaluation of comprehensive medical, vocational, independent living, and rehabilitation services to meet the wide range of needs of individuals with spinal cord injuries.

(b) The agencies and organizations eligible to apply under this program are described in § 1330.2.

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