

### § 1330.3

(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

### 45 CFR Ch. XIII (10–1–23 Edition)

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.