

speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2011.

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FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The SSA–NIH Collaboration To Improve the Disability Determination Process: Validation of IRT–CAT Tools

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Clinical Center, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The SSA–NIH Collaboration to Improve the Disability Determination Process: Validation of IRT–CAT tools. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The Epidemiology and Biostatistics section in RMD will be collecting information through a contractor (Boston University—Health and Disability Research Institute (BU–HDR)) and subcontractor for validation of the Computer Adaptive Tests which are being developed to assist in the SSA disability determination process. The utilization of CAT technology could potentially allow the SSA to collect

more relevant and precise data about human functioning in a faster, more efficient fashion. To validate the CAT assessments that have been developed, the contractor will administer both the BU–HDR CAT and established legacy instruments in a small sample of adults who report their current employment status as “permanently disabled”. Individuals will complete the CAT tools for the functional domains of Physical Demands and Interpersonal Interactions along with established legacy instruments. For the domain of physical function, individuals will complete the BU–HDR CAT; the PROMIS Item Bank v 1.0—Physical Functioning © PROMIS Health Organization and PROMIS Cooperative Group; and The Short Form (36) Health Survey™ (SF–36). For the domain of interpersonal interactions, individuals will complete the BU–HDR CAT, the SF–36 and the BASIS–24© (Behavior and Symptom Identification Scale). Data collected will be used to validate the BU–HDR CAT tools. Without this information, completion of the BU–HDR CAT tools will not be possible. *Frequency of Response:* Once. *Affected Public:* Individuals who have opted in to participate in web surveys through a survey research firm. *Type of Respondents:* Adults who indicate “permanently disabled” as a working status. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report. The annual reporting burden is as follows:

A.12–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Patients	1,000	1	0.5	500.00
Totals	500.00

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use

of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Meghan Gleason, Rehabilitation Medicine Department, Clinical Research Center, NIH, Building 10, Room 1–2420, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 443–9085 or E-mail your request, including your address to: meghan.gleason@nih.gov.

DATES: Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 29, 2011.

Elizabeth K Rasch,

Chief, Epidemiology and Biostatistics Section, Rehabilitation Medicine Department, Clinical Research Center, National Institutes of Health.

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