[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; Interactive Informed Consent for Pediatric Clinical Trials

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 National Institute Heart, Lung, and Blood Institute (NHBLI), 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. The 60 day FRN was published 05/9/2013 (Vol. 78, No. 90, page 27243). No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Victoria Pemberton, Clinical Trials Specialist, NHLBI, 6701 Rockledge Drive, Room 8102, MSC 7940, Bethesda, MD 20892 or call non-toll-free number (301) 435-0510 or E-mail your request, including your address to: pembertonv@nhlbi.nih.gov Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Interactive Informed Consent for Pediatric Clinical Trials, 0925-New, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will compare parents' and children's understanding of information about a hypothetical clinical trial presented using either a standard paper consent document or an interactive computer-based consent program. Parents' and children's understanding, regardless of whether they received the

standard consent or the interactive computer-based program, will be assessed by face-to-face interview. In addition, parents' and children's perceptions of, and satisfaction with, the information presented will be evaluated by completion of a short questionnaire. The primary hypothesis to be tested is that interactive computer-based research consent information is better understood and accepted by parents and children compared with the standard paper consent document. Given that many individuals have difficulty reading and interpreting standard written consent documents, this technology holds promise as a means to optimize the consent and assent process particularly among individuals with low literacy and numeracy skills.

OMB approval is requested for 18 months. There are no costs to respondents other than their time. The total estimated annualized burden hours are 190.

Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Response	Average Burden per Response (in hour)	Total Annual Burden Hours
Parents	148	1	43/60	106
Children	136	1	37/60	84

Dated: September 23, 2013.

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National Institutes of Health.	National Institutes of Health.

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