

TO: Acting Assistant Secretary for Health  
FROM: Office for Human Research Protections  
SUBJECT: Paperwork Reduction Act Submission for OMB No. 0990-0279 - Registration of an Institutional Review Board Form -- ACTION

Attached for your approval and transmittal to the Department of Health and Human Services (HHS) Reports Clearance Officer is a Paperwork Reduction (PRA) package. The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form, currently approved through August 31, 2015. This form was modified in 2009 to be consistent with IRB registration requirements that were adopted in July 2009 by OHRP and FDA, respectively. At that time OMB recommended that the information collection request required by OHRP's and FDA's IRB Registration rules be combined because the information would be submitted using the same form. A similar mechanism was used in 2012 and is proposed for this three-year extension of the OMB form No. 0990-0279 request.

The burden estimates decreased.

DECISION

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

Jerry Menikoff, M.D., J.D.

Attachment

TO: Reports Clearance Officer, HHS

FROM: Assistant Secretary for Health

SUBJECT: Paperwork Reduction Act Submission for OMB No. 0990-0279 - Registration of an Institutional Review Board Form

This is a request for extension of the Office of Management and Budget (OMB Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990-0279, Institutional Review Board (IRB) Registration Form, currently approved through August 31, 2015. This form was modified in 2009 to be consistent with IRB registration requirements that were adopted in July 2009 by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). At that time OMB recommended that the information collection request required by OHRP's and FDA's IRB Registration rules, respectively, be combined because the information would be submitted using the same form. A similar mechanism was used in 2012 and is proposed for this three-year extension of the OMB form No. 0990-0279 request.

The burden estimate decreased. A draft 60-day *Federal Register* notice is attached at Tab B.

If you require any additional information or assistance, please feel free to contact Dr. Irene Stith-Coleman, Director, Division of Policy and Assurances, Office for Human Research Protections, Office of Public Health and Science at (240) 453-8138.

Karen B. DeSalvo, M.D., M.P.H., M.Sc.

2 Attachments

Tab A – PRA package for OMB No. 0990-0279

Tab B – Draft 60-Day *Federal Register* Notice