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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-0990-New-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will

accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before December 7, 2015.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.Collection.Clearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS-OS-0990-New-30D for reference.

Information Collection Request Title: Information Collection Request Title: Evaluation of the Office on Women's Health Coalition for a Healthier Community Initiative.

Abstract: This collection is to provide data for the national evaluation of the U.S. Department of Health and Human Services (HHS), Office on Women's Health (OWH) Coalition for a Healthier Community (CHC) Initiative. The initiative supports 10 communities with grants to support coalitions in implementing gender-based public health systems approaches, evidence-based health interventions, and outreach and education activities to reduce barriers to and enhance

facilitators of improvements in women and girls' health. Each of the grantees has implemented an IRB-approved local evaluation; however, OWH is seeking to collect core data across grantees to examine the extent to which the Government's investment has resulted in achieving OWH-related *Healthy People 2020* priorities and yields lessons learned upon which to plan future initiatives related to its mission.

Likely Respondents: The proposed collection includes plans for interviews with key staff (project directors, project coordinators, local evaluators), coalition members (including chairs and co-chairs), and community leaders connected to the coalitions. These respondents will also complete online surveys about their perceptions of the changes in their community as a result of coalition activities. Program participants and other community members exposed to the coalitions' activities through social media will also complete online surveys. Project directors and local evaluators also annually provide information to OWH on their coalition's functioning, the status of the cost-effectiveness analysis for their coalition's interventions, and the coalition's plans for sustainability. The following table summarizes the "Total Estimated Annualized Burden—Hours" by form and type of respondent.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
1—Key Persons Discussion Guide for Telephone Interviews	90	2	1	180
2—Key Persons, Coalition Members, and Community Leaders Online Survey	200	1	20/60	67
3—Coalition Participants and Other Community Members Online Survey	510	1	20/60	170
4—Grantee Annual Report on Coalition Functioning, Cost-Effectiveness, and Sustainability Planning	10	2	2	40
Total	457

Terry Clark,
Asst Information Collection Clearance
Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA-2015-D-3638]

Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled "Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs." The draft guidance is intended for institutions and IRBs that are responsible for the review and oversight of human subject research conducted or supported by the U.S. Department of Health and Human Services (HHS) or regulated by FDA. The purpose of the