risk populations; (6) Advocate the needs for priority setting and budget allocation for hepatitis prevention.

Funded sites will use HEPTLC data for the following purposes:
(1) Understand targeted populations (demographics, risk behaviors, vaccination histories, etc.) and assess the extent to which the targeted populations have been reached;
(2) Document how well the project is progressing in meeting goals/objectives set forth by CDC (e.g. who delivered what to whom, how many, where, when, and how well), as well as performance indicators related to testing, counseling and linkage to care;
(3) Highlight opportunities for local program collaboration and service integration (PCSI) to prevent hepatitis:
(4)Fulfill data collection and reporting requirements outlined in the cooperative agreements.

The total estimated annualized hourly burden anticipated for all data collections and training would be approximately 6,080 hours. Respondents will be testing sites at multiple settings, including health departments, community based organizations (CBOs), community health centers (CHCs), person who inject drugs (PWID) treatment centers, and other settings, e.g. human immunodeficiency virus (HIV) or sexually transmitted disease (STD) clinics, Federally Qualified Health Centers (FQHCs). They will routinely collect, enter, and report information about the test site, client demographics and behaviors, testing results and linkage to care follow up information within the web-based HEPTLC system.

CDC anticipates that routine information collection will begin immediately after OMB approval. CDC intends for grantees to bear minimum burdens with minimal standardized data variables, while fulfilling mandatory reporting requirements. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
HBV—CBOs/Health Jurisdictions ..... HCV—multiple sites (IDU, CHCs, Others, ECHO).	HEPTLC Data Variables & Values (test-level monthly reporting).	40	12	12	5,760
HBV—CBOs/Health Jurisdictions ..... HCV—multiple sites (IDU, CHCs, Others, ECHO).	HEPTLC Template (program-level reporting/quarterly).	40	4	1.5	240
Training	HEPTLC System	40	1	2	80
Total	.....	.....	.....	.....	6,080

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–14209 Filed 6–11–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Affordable Care Act Tribal Maternal, Infant and Early Childhood Home Visiting Program Annual Report.

OMB No.: 0970–NEW.

Description: Section 511(h)(2)(A) of Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, Affordable Care Act or ACA), authorizes the Secretary of HHS to award grants to Indian Tribes (or a consortium of Indian Tribes), Tribal Organizations, or Urban Indian Organizations to conduct an early childhood home visiting program.

The legislation sets aside 3 percent of the total ACA Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program appropriation (authorized in Section 511(j)) for grants to Tribal entities and requires that the Tribal grants, to the greatest extent practicable, be consistent with the requirements of the Maternal, Infant, and Early Childhood Home Visiting Program grants to States and territories (authorized in Section 511(c)), and include (1) Conducting a needs assessment similar to the assessment required for all States under the legislation and (2) establishing quantifiable, measurable 3- and 5-year benchmarks consistent with the legislation.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, has awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal MIECHV). The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs assessments, plan for and implement (in accordance with an Implementation Plan submitted at the end of Year 1) high-quality, culturally-relevant, evidence-based and promising home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

Section 511(e)(8)(A) of the Social Security Act, as added by Section 2951 of the Affordable Care Act, requires that grantees under the MIECHV program for States and Jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. As described above, Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to Tribes, Tribal Organizations, and Urban Indian Organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for States and Jurisdictions. In the Tribal Maternal, Infant, and Early Childhood Home Visiting Program Guidance for Submitting a Needs Assessment and Plan for Responding to Identified Needs (Phase 2 Implementation Plan) (OMB Control No. 0970–0389, Expiration Date 6/30/14), Tribal MIECHV grantees were notified that in Years 2–5 of their grant

they must comply with the requirement for submission of an Annual Report to the Secretary regarding the program and activities carried out under the program. This report shall be submitted to HHS by Tribal MIECHV grantees 90 days following the end of Years 2–5 of the grant.

This report shall address the following:

Update on Home Visiting Program Goals and Objectives.

Update on the Implementation of Home Visiting Program in Targeted Community(ies).

Progress toward Meeting Legislatively Mandated Benchmark Requirements.

Update on Rigorous Evaluation Activities.

Home Visiting Program Continuous Quality Improvement (CQI) Efforts.

Administration of Home Visiting Program.

Technical Assistance Needs.

Respondents: Affordable Care Act Tribal Maternal, Infant, and Early Childhood Home Visiting Program Year 2–5 Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Affordable Care Act Tribal Maternal, Infant, and Early Childhood Home Visiting Program Guidance for Submitting an Annual Report to the Secretary	25	1	50	1,250

Estimated Total Annual Burden Hours: 1,250.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *oira_submission@omb.eop.gov*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–14185 Filed 6–11–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0560]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable.

DATES: Submit either electronic or written comments on the collection of information by August 13, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the