

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Additional Burden for Previously Approved Information Collection					
PAGES—Participant-Level Baseline Data Collection (participants at non-Tribal grantees)	4,860	1,620	1	.5	810
Burden for Newly Requested Information Collection					
HPOG 2.0 National Evaluation					
Screening Interview to identify respondents for the HPOG 2.0 National Evaluation first-round telephone interviews	38	13	1	.5	7
HPOG 2.0 National Evaluation first-round telephone interviews with management and staff	190	63	1	1.25	79
HPOG 2.0 National Evaluation in-person implementation interviews	60	20	1	1.5	30
HPOG 2.0 National Evaluation welcome packet and participant contact update forms	45,000	15,000	4	.1	6000
HPOG 2.0 Tribal Evaluation					
HPOG 2.0 Tribal Evaluation grantee and partner administrative staff interviews	105	35	1	1	35
HPOG 2.0 Tribal Evaluation program implementation staff interviews	150	50	1	1.5	75
HPOG 2.0 Tribal Evaluation employer interviews	90	30	1	.75	23
HPOG 2.0 Tribal Evaluation program participant focus groups	405	135	1	1.5	203
HPOG 2.0 Tribal Evaluation program participant completer interviews	300	100	1	1	100
HPOG 2.0 Tribal Evaluation program participant non-completer interviews	150	50	1	1	50

Estimated Total Annual Burden Hours: 7,412.

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, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@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, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:

Desk Officer for the Administration for Children and Families.

Mary Jones,
ACF/OPRE Certifying Officer.
 [FR Doc. 2016-25787 Filed 10-25-16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Guidelines Stating Principles for Working With Federally Recognized Indian Tribes

AGENCY: Administration for Native Americans, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS), Administration for Children and Families (ACF), is issuing guidelines stating principles for working with federally recognized Indian tribes.

DATES: Effective October 20, 2016.

FOR FURTHER INFORMATION CONTACT: Camille Loya, Director of Policy, Administration for Native Americans (ANA) at (202) 401-5964, or Camille.Loya@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: ACF states the following principles for working with federally recognized Indian tribes:

Purpose: The mission of ACF is to foster health and well-being by providing federal leadership, partnership, and resources for the compassionate and effective delivery of human services. This mission has special application with respect to the government-to-government relationship with federally recognized Indian tribes, including Alaska Natives. ACF issues these Principles for Working with Federally Recognized Tribes to establish a policy standard governing ACF's relationships with federally recognized Indian tribes. The Principles are designed to build upon and complement ACF's Tribal Consultation Policy and to articulate ACF's commitment to promote and sustain strong government-to-government relationships, foster Indian self-determination, support tribal sovereignty, and demonstrate transparency in ACF's actions as public servants.

Bases and Authority: ACF's Principles are based upon the unique relationship between the federal government and Indian tribes affirmed by President Obama in the Memorandum for the Heads of Executive Departments and Agencies issued November 5, 2009. The Memorandum states:

The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions.

The HHS Consultation Policy affirms the nature of the relationship between the federal government and Indian tribes and the importance of clear policies:

The U.S. Department of Health and Human Services (HHS) and Indian Tribes share the goal to establish clear policies to further the government-to-government relationship between the Federal Government and Indian Tribes.

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Since the formation of the Union, the United States (U.S.) has recognized Indian Tribes as sovereign nations. A unique government-to-government relationship exists between Indian Tribes and the Federal Government. This relationship is grounded in the U.S. Constitution, numerous treaties, statutes, Federal case law, regulations and executive orders that establish and define a trust relationship with Indian Tribes. This relationship is derived from the political and legal relationship that Indian Tribes have with the Federal Government and is not based upon race.

The Principles are derived from the general federal trust responsibility between the United States and tribes. Since the formation of the Union, the United States has recognized the inherent sovereignty of tribal nations. As a result, a unique government-to-government relationship exists between American Indian and Alaska Native (AI/AN) tribes and the federal government. The government-to-government relationship is political and independent of race or ethnicity. This relationship is grounded in the U.S. Constitution, numerous treaties, statutes, federal case law, regulations, and executive orders, as well as political, legal, moral, and ethical principles.

ACF, as an Operating Division within HHS, hereby establishes this set of principles for working with federally recognized tribes, as defined in 25 U.S.C. 5304, in accord with ACF's vision of "children, youth, families, individuals, and communities who are resilient, safe, healthy, and economically secure." These principles are intended to foster AI/AN health and

well-being by providing federal leadership, partnership, and resources for compassionate and effective human services delivery.

ACF establishes these principles in accordance with ACF values of dedication, excellence, professionalism, integrity, and stewardship. Once implemented, these principles will help ACF advance its values by establishing clear policies that further the government-to-government relationship between ACF and Indian tribes.

ACF establishes this statement of principles to further the shared goal of thriving, resilient, safe, healthy, and economically secure children, families, and communities. Shared ACF and tribal goals also include, but are not limited to, strengthening health care by eliminating health and human service disparities Indians experience; ensuring access to critical health and human services; and advancing or enhancing health, safety, and well-being of AI/AN people. Finally, ACF and Indian tribes share the goal of establishing clear policies to further the government-to-government relationship between the federal government and Indian tribes.

ACF establishes this statement of principles in order to complement existing ACF Tribal Consultation Policies. On November 5, 2009, President Obama signed an Executive Memorandum reaffirming the government-to-government relationship between Indian tribes and the federal government, directing each executive department and agency to submit a plan on consultation with tribal governments before developing regulatory policies that substantially affect this population. The importance of consultation with Indian tribes was affirmed through Presidential Memoranda in 1994, 2004, and 2009, and Executive Order 13175 in 2000. The purpose of the ACF Tribal Consultation Policy is to build meaningful relationships with federally recognized tribes by engaging in open, continuous, and meaningful consultation that leads to information exchange, mutual understanding, and informed decision-making.

The principles build upon communication and decision-making protocols articulated in the ACF Tribal Consultation Policy by setting forth specific leadership and partnership principles intended to guide effective day-to-day human services delivery to AI/AN peoples.

Section I. Overarching Principles for Working With Federally Recognized Indian Tribes

- ACF strives to honor the unique legal relationship between the federal

government and Indian tribes as defined at 25 U.S.C. 5304, and supports tribes' authority to exercise their inherent tribal powers.

- ACF recognizes tribal sovereignty and the principle that tribal nations have authority over tribal citizens.

- ACF recognizes tribal members as American citizens, as well as citizens of their respective tribes, who are entitled to all the benefits of other citizens of the states where they reside.

- ACF is committed to furthering the government-to-government relationship with each tribe, which forms the heart of all federal Indian policy. ACF respects and supports tribes' authority to exercise their inherent sovereign powers, including the authority to manage their own affairs, to exist as nations, and exercise authority over their citizens and territory.

- ACF strives to act in accordance with the general trust responsibility between the United States and tribes. Trust responsibility is derived from treaties with tribes, statutes, and opinions of the U.S. Supreme Court and provides a fundamental basis for the relationship between the federal government and federally recognized Indian tribes.

- While not legally binding, in accord with the December 2010 Presidential Proclamation under which the United States fully endorsed the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), ACF promotes and pursues the objectives of UNDRIP, including, but not limited to, recognition that indigenous peoples are entitled to all human rights recognized in international law.

- ACF is committed to tribal self-determination, tribal autonomy, tribal nation-building, and the long-term goal of maximizing tribal control over governmental institutions in tribal communities recognizing that tribal problems are best addressed in federal-tribal partnership informed by tribal traditions, values, and custom.

- ACF works to evaluate and improve AI/AN children and families' health and well-being by collecting and analyzing AI/AN data, including, but not limited to, child welfare data, workforce and employment data, child development and school readiness data, data on at-risk and vulnerable youth, and evaluative social and economic data, with the goal of sharing information and knowledge gained to collaboratively address established tribal priorities.

- ACF supports state and tribal governments, courts, and human services systems to strengthen AI/AN families, protect AI/AN children, and ensure that AI/AN children and youth

have and maintain familial and cultural connections with their tribes and Indian, as defined at 25 U.S.C. 5304, extended families.

- In all its actions, ACF respects, supports, and promotes Indian tribes' authority to exercise inherent sovereign powers, including authority over both tribal citizens and property.

Section II. Consultation and Communication With Tribes

- ACF recognizes that the government-to-government relationship with Indian tribes merits regular, meaningful, and informed consultation with AI/AN tribal officials in the development of new or amended funding; amended funding formulas; and programmatic policies, regulations, and legislative actions initiated by ACF that affect or may affect tribes.

- ACF recognizes that—in addition to, but not in lieu of, formal consultation—there can be great benefit in timely, detailed, and informal communications with tribal officials and other community leaders.

- ACF acts to facilitate on-going, routine, informal communication with tribal programs in its day-to-day work.

- ACF seeks to integrate tribal consultation and communication responsibilities into the operational duties of all staff positions including managers, federal project officers, and program specialists.

- ACF recognizes that meaningful communication and, to the extent practicable, consultation on a government-to-government basis is sound ACF management policy and good governance.

- ACF supports the Intradepartmental Council on Native American Affairs, the HHS Secretary's Tribal Advisory Committee, the ACF Tribal Advisory Committee, and other task forces, advisory groups, and work teams that provide input from elected tribal representatives to ACF leaders and components, and to otherwise ensure human services coordination around issues affecting AI/AN populations.

- ACF supports Regional Office strategic partnerships and/or regionally structured coordinated communications with tribes and tribal programs to promote and facilitate strong tribal-state relationships and policy and to foster improved outcomes for Indian children, youth, and families through training on tribal consultation, providing introductions, sharing information, and ensuring timely follow-up on issues and concerns.

Section III. Culture and Mutual Respect

- ACF recognizes that each tribe's history and contemporary culture are unique, and that solutions that work for one tribe may not be suitable for others.

- ACF respects traditional tribal cultural practices and values and is committed to ensuring cultural competence and effective cross-cultural communication in day-to-day work.

- ACF seeks to foster an internal ACF culture at every level that encourages all staff to identify and be responsive to the needs of tribes and Indian people as part of routine deliberative and other work demonstrating respect for the Indian tribes we serve and with whom we partner.

Section IV. Nation-Building and Effective Delivery of Human Services to Indian Communities

- ACF believes that continuity of funding at sufficient levels for essential tribal social service functions is critical to the long-term growth of tribal nations and the economic, health, and social well-being of Indian peoples.

- In accord with Executive Order 13175, ACF seeks to maximize tribes' flexibility to administer grant programs within the prescribed statutory and regulatory parameters and thus design solutions responsive and appropriate to their communities while ensuring accountability.

- ACF believes that pilot and demonstration projects that are available to state or local governments should be available to tribal governments to the extent authorized by law, and endeavors, where appropriate and practicable, to locate pilot and demonstration projects in tribal communities.

- ACF is committed to partnering with tribes to build a continuum of research, as described ACF's Common Framework for Research, from descriptive studies to impact studies that build understanding of human service needs in tribal communities, high quality and culturally responsive services, and efficacy and effectiveness of services in improving relevant outcomes in tribal communities.

- ACF aims, through flexible provision of technical support, to help tribal grantees develop and operationalize their own performance measures and indicators, allowing for performance measurement over time and in a manner most meaningful to local tribal communities.

- ACF supports using data to collaborate in identifying and testing changes that support data-driven improvements in ACF-funded programs and projects.

- ACF is committed to implementing all statutes authorizing ACF programs and to working in partnership with tribes to strengthen tribal systems and institutions critical to fulfilling the purposes of these statutes.

V. Coordination and Outreach

- ACF, when working with external agencies on issues involving tribes, advocates respect for tribal self-determination, tribal autonomy, tribal nation-building, and the government-to-government relationship.

- The Administration for Children and Families, through its regional offices, is committed to supporting tribes, states, and local jurisdictions to improve communication and meaningful consultation, and to build relationships among tribes, states, local, and private entities that promote resilient, safe, healthy, and economically secure Indian children, youth, families, and communities.

- ACF works to facilitate communication and build relationships among the federal agencies engaged with tribal governments and to promote the sharing of federal resources and expertise, including, but not limited to, identifying cross-training opportunities.

- Because of the relationship between the work of external institutions and the health and well-being of Indian children, youth, and families, ACF is committed to fostering coordinated efforts with educational, public safety, justice, housing, environmental protection, and public health services.

VI. Administrative Data Management

- In collaboration with Indian tribes, ACF aims to build knowledge of effective models, strategies, and approaches for addressing the needs and lifting the strengths and capacities of Indian children, youth, and families through a focus on collaborative research and evaluation.

- In collaboration with Indian tribes, ACF develops and implements a research agenda that identifies and addresses data gaps, builds tribal research and evaluation capacities, and disseminates research findings on issues determined, in partnership with tribes, to be significant.

VII. Sustainability

- ACF will ensure the ACF Guiding Principles are institutionalized through management and staff training so that progress in areas important to tribes and tribal communities continues consistent with ACF values of dedication, excellence, professionalism, integrity, stewardship, and respect.

- These ACF Guiding Principles are intended solely to improve the internal awareness and management of the ACF. They may only be implemented to the extent permitted by statute and regulations and are not intended to and do not create any right or benefit, substantive or procedural, enforceable at law or equity by any party in any matter, civil or criminal, against the United States, its departments, agencies, officers, employees, or agents, or any other person.

Dated: October 20, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

Dated: October 20, 2016.

Lillian Sparks Robinson,

Commissioner, Administration for Native Americans.

[FR Doc. 2016-25794 Filed 10-25-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2817]

Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in developing drugs for the treatment of low sexual interest, desire, and/or arousal in women. Specifically, this guidance addresses FDA’s current thinking regarding the overall clinical development program, with a focus on phase 3 trial designs, to support an indication for the treatment of these conditions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 27, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-2817 for Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment; Draft Guidance for Industry; Availability. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Mercier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5390, Silver Spring, MD 20993-0002, 301-796-0957.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs