

panelists and speakers (including a moderator) per each of the 4 sessions and will be open to the public.

III. Purpose

The purpose of this 2-day workshop is to provide an interdisciplinary forum to discuss the best practices of dose finding and dose selection for small molecule kinase inhibitors developed for oncology indications. The goal is to foster robust scientific discussion to promote a movement away from the conventional 3+3 dose escalation trial design and move toward adaptive designs that can potentially incorporate key clinical, pharmacologic, and pharmacometric data and, when appropriate, nonclinical information to guide dose selection. Ideally, this workshop will propel a movement toward integrating dose finding into the entire life cycle of product development as opposed to confining it to the Phase 1, first-in-human trial based on short-term safety measures.

IV. Goals and Scope

1. To identify key best practices in the nonclinical evaluation of a compound, including, but not limited to, selectivity, pharmacology, secondary pharmacology, and toxicology.
2. To assess whether nonclinical information can be incorporated into the statistical assumptions of an adaptive dose-finding trial.
3. To discuss the best practices of integrating human pharmacokinetic and pharmacometric data, including drug interaction, when appropriate, into dose-finding studies.
4. To assess how drug exposure can be integrated into the statistical assumptions of an adaptive dose-finding trial and to assess whether evolving exposure data can be adapted into an ongoing trial.
5. To discuss barriers in moving away from 3+3 designs toward adaptive designs and to encourage creative dose-finding trial designs that can replace the conventional 3+3 dose-finding study, where appropriate.
6. To shift from conducting a large single-arm drug trial with the maximum tolerated dose based on a 28-day window to identify tolerable, biologically effective doses for confirmatory trials through prudent search of doses based on safety, efficacy, and patient tolerability.
7. To discuss potential regulatory implications of dose-finding studies, including, but not limited to, product labeling of dose ranges, dose titration, and postmarketing studies.

Dated: May 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Administration for Children and Families

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) and the Administration for Children and Families (ACF) announce plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA and ACF seek comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 13, 2015.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10C-03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Data Request.

OMB No.: 0906-xxxx—New.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), administered by HRSA in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States and tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities.

Need and Proposed Use of the Information: In order to continuously monitor and provide oversight and quality improvement guidance and technical assistance to Home Visiting Program grantees, HHS is seeking to collect two categories of information: Service Utilization Data and Corrective Action Benchmark Data.

Service Utilization Data is made up of four data categories:

(1) *Program Capacity:* HHS is seeking to collect information related to the overall home visiting service capacity in number of families that grantees are able to provide to the communities they work in, the actual capacity being utilized at certain points in time, as well as updates of home visiting enrollment in number of families.

(2) *Place-Based Services:* HHS is seeking to collect information about the geographic areas where home visiting services are being provided. Specifically, data on zip code and locally defined communities are being requested from Home Visiting Program grantees in order to allow grantees an opportunity to provide data about geographic areas that are most salient to their respective programs. Currently, HHS has the authority to collect information related to service area zip code on an annual basis (OMB-0915-0357, expiration 7/31/2017). HHS plans to allow the grantee to describe the service community at the neighborhood, town, or city level where services are provided based on their judgment of local salience, rather than solely at the county level, which is how geographic services are currently reported.

(3) *Family Engagement:* Currently HHS has the authority to collect information related to family engagement (attrition) on an annual basis (OMB-0915-0357, expiration 7/31/2017). However, HHS has learned through grants monitoring and technical assistance efforts that family engagement is an ongoing and complex issue for home visiting service providers. In order to monitor grantee performance and target technical assistance efforts most effectively, HHS

is seeking to collect information on family engagement on a more frequent basis. HHS proposes that in addition to annual reporting, Home Visiting Program grantees will report quarterly on the existing family engagement metrics they are required to submit. These metrics are currently defined as the number of participants currently receiving services who have completed the program, who stopped services before completion, and other participants.

(4) *Staff Recruitment and Retention:* HHS is seeking to collect information related to the number of home visitors and other support staff who are currently employed directly or through sub-contracted grant funds. Staff recruitment and retention is a key component to the successful delivery of home visiting services and to maximizing the number of cases each local implementing agency can reach. Home Visiting Program grantees will report quarterly the actual number of staff and current vacancies in three categories: Home visitors, program administration, and support staff.

Corrective Action Benchmark Data is made up of one category of data: *Corrective Action Constructs*. Home Visiting Program grantees who have not shown improvement in four of six Benchmark areas after 3 years of grant funding are statutorily required to complete corrective action plans, subject to approval by the Secretary, in order to show how they plan to achieve improvement in deficient areas. Currently HHS collects information related to selected Benchmark areas from all Home Visiting Program grantees on an annual basis (OMB–0915–0357, expiration 7/31/2017). In order to monitor grantee improvement toward meeting these Benchmarks, HHS is seeking to collect information from grantees on implementation of their corrective action plans on a more frequent basis. HHS proposes that grantees with corrective action plans report on a quarterly basis for the Benchmark measures for which they were deemed as not showing improvement. It is estimated that approximately 15 grantees per year will require this more frequent reporting.

This information will be used to monitor and provide continued oversight for grantee performance and to target technical assistance resources to grantees.

Likely Respondents: Home Visiting Program grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Service Utilization Data:					
Service Utilization Data—Formula Grants	56	4	224	24	5,376
Service Utilization Data—Competitive Grants	44	4	176	24	4,224
Service Utilization Data—Tribal Grants	25	4	100	24	2,400
Corrective Action Benchmark Data:					
Corrective Action Constructs—MIECHV Grants	10	4	40	40	1,600
Corrective Action Constructs—Tribal Grants	5	4	20	40	800
Total	140	560	14,400

HHS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: May 1, 2015.

Jackie Painter,

Director, Division of the Executive Secretariat.

Linda K. Smith,

Deputy Assistant Secretary and Inter-Departmental Liaison for Early Childhood Development, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Blockson Chemical Company in Joliet, Illinois, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health

(NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice of a decision to evaluate a petition to designate a class of employees from the Blockson Chemical Company in Joliet, Illinois, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to DCAS@CDC.GOV.