

form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. 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 August 19, 2013.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

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

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the OMB control number 4040-0004 and

document identifier HHS-EGOV-16500-30D for reference.

**Information Collection Request Title:** SF-424 Discretionary.

**OMB No.:** 4040-0004.

**Abstract:** The SF-424 Application for Federal Assistance is a common form used by all Federal grant-making agencies for applicants to apply for Federal financial assistance. Need and Proposed Use of the Information: The SF-424 Application for Federal Assistance is used by the public to apply for Federal financial assistance in the form of grants. These forms are submitted to the Federal grant-making agencies for evaluation and review.

**Likely Respondents:** Organizations and institutions seeking grants.

**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 ICR are summarized in the table below.

HHS estimates that the SF-424 Application for Federal Assistance will take 1 hour to complete. We expect that 14,747 respondents will use this form.

Once OMB approves the use of this common form, federal agencies may request OMB approval to use this common form without having to publish notices and request public comments for 60 and 30 days. Each agency must account for the burden associated with their use of the common form.

#### TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
SF-424 Application for Federal Assistance .....	14,747	1	1	14,747
Total .....	14,747	.....	.....	14,747

**Keith A. Tucker,**

*Information Collection Clearance Officer.*

[FR Doc. 2013-17221 Filed 7-17-13; 8:45 am]

**BILLING CODE 4151-AE-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Scientific Information Request on Vitamin D and Calcium

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for scientific information submissions.

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public on Vitamin D and Calcium. Scientific information is being solicited to inform the *Vitamin D and Calcium: A Systematic Review of Health Outcomes* project, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent

scientific information on vitamin D and calcium will improve the quality of this systematic review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

AHRQ is republishing this document due to errors found on our first publication of July 3, 2013 (<http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/pdf/2013-5730.pdf>). Please disregard the July 3 publication.

**DATES:** *Submission Deadline by August 2, 2013.*

**ADDRESSES:** *Online submissions:* <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/>. Please select the study for which you are submitting information from the list to upload your documents.

*Email submissions:* [SIPS@epc-src.org](mailto:SIPS@epc-src.org).

*Print submissions:*

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information

Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

#### FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: 503-220-8262 ext. 58652 or Email: [SIPS@epc-src.org](mailto:SIPS@epc-src.org).

**SUPPLEMENTARY INFORMATION:** The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for *Vitamin D and Calcium: A Systematic Review of Health Outcomes*.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies

that report on *vitamin D and calcium*, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1529>.

This notice is to notify the public that the EHC program would find the following information on Vitamin D and Calcium helpful:

- A list of completed studies your company has sponsored for this indication. In the list, *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies your company has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- A description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; pharmacoeconomic, pharmacokinetic or pharmacodynamic studies; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to

be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

### Key Question 1

What is the effect of vitamin D intake or combined vitamin D plus calcium intake (but not calcium intake alone) on clinical outcomes, including cardiovascular diseases, cancer, immune function, pregnancy or birth outcomes, mortality, fracture, renal outcomes, and soft tissue calcification (the current report excludes two outcomes included in the original 2009 report: growth and weight management).

### Population(s)

- The primary population of interest is generally healthy people with no known disorders, with the following exceptions. Studies that include broad populations might include some individuals with diseases or who are at risk for diseases.
- Studies of individuals with previous cancer, previous fractures, or precancerous conditions will be included.
- With the exception of studies of older adults, studies in which more than 20 percent of the participants have been diagnosed with a disease will be excluded.
- For clinical outcomes of cardiovascular disease (CVD), only studies of adults will be included ( $\geq 18$  years of age)

### Interventions

- For observational studies (exposures):
  - Serum concentration of 25-hydroxyvitamin D [25(OH)D] or 1,25-dihydroxyvitamin D [1,25(OH)<sub>2</sub>D] and method used
  - Dietary intake of calcium from food and supplements
  - Calcium balance
- For interventional studies:
  - Vitamin D supplements with known doses
  - Calcium supplements if co-administered with vitamin D
  - Food-based interventions in which the doses of vitamin D and calcium were quantified and in which the doses differ between comparison groups

### Comparators

- For observational studies:
  - Lower serum concentrations of vitamin D
- For interventional studies:
  - Placebo, non-fortified/supplemented food

### Outcomes

- CVD clinical outcomes

- Cardiac events or symptoms
- Cerebrovascular events
- Peripheral vascular events or symptoms
- Cardiovascular death
- Study-specific combinations of cardiovascular events
- Total cancer
- Prostate cancer
- Colorectal cancer
- Breast cancer
- Pancreatic cancer
- Cancer-specific mortality
- Immune function clinical outcomes
- Infectious disease
- Autoimmune diseases
- Infectious disease-specific mortality
- Pregnancy-related outcomes
- Preterm birth or low birth weight
- Infant mortality
- Mortality, all cause
- Bone health, clinical outcomes
- Rickets
- Fracture
- Falls or muscle strength
- Adverse effects of intervention(s)
- All-cause mortality
- Cancer incidence and cancer-specific mortality
- Renal outcomes
- Soft tissue calcification
- (Other) adverse events from vitamin D or vitamin D plus calcium supplements

### Timing

- Timing of interventions or exposures will not be pre-specified, with the exception that cross-sectional and retrospective case-control studies will not be included (nested case controls within prospective cohort studies will be included).
- For studies with multiple follow-up periods, the longest follow-up times will be preferentially considered.

### Settings

- Settings will not be pre-specified

### Key Question 2

What is the effect of vitamin D or combined vitamin D and calcium intake on surrogate or intermediate outcomes, such as hypertension, blood pressure, and bone mineral density?

### Populations

- As described for KQ 1, with the exception that for blood pressure and other CVD intermediate outcomes, only studies of adults 18 years of age or older will be included.

### Interventions

- As described for KQ 1, with the following exceptions:
  - For CVD outcomes, only randomized controlled trials (RCTs)

will be included

- For bone health outcomes, only RCTs of greater than 1 year in duration will be included

#### Comparators

- As described for KQ 1.

#### Outcomes

- As specified in the original 2009 report, unless otherwise noted:
  - CVD intermediate outcomes
  - Cancer intermediate outcomes (colorectal adenoma, aberrant crypt cells, and mammographic breast density)
  - Bone health intermediate outcomes (only bone mineral density/content)
  - Pregnancy-related intermediate outcomes
  - Pre-eclampsia
  - High blood pressure with or without proteinuria

#### Timing

- As described for KQ 1, except for intermediate bone health for which studies of less than 1 year in duration will be excluded.

#### Settings

- As described for KQ 1.

#### Key Question 3

What is the association between serum 25(OH)D concentrations and clinical outcomes?\*

#### Populations

- As described for KQ 1.

#### Interventions

- Serum concentration of 25(OH)D or 1,25 (OH)2D and the method used.

#### Comparators

- The serum concentration of 25(OH)D or 1,25 (OH)2D and the method used for the placebo or other comparison group.

#### Outcomes

- As described for KQ 1.

#### Timing

- As described for KQ 1.

#### Settings

- As described for KQ 1.

#### Key Question 4

What is the effect of vitamin D or combined vitamin D and calcium intake on serum 25(OH)D concentrations?

#### Populations

- As described for KQ 1.

#### Interventions

- Randomized controlled trials (RCTs) identified to answer all other KQs.

#### Comparators

- Placebo or lower dose supplement.

#### Outcomes

- Dose-response relationship between intake levels and indices of exposure.

#### Timing

- As described for KQs 1 and 2.

#### Settings

- As described for KQs 1 and 2.

#### Key Question 5

What is the association between serum 25(OH)D concentration and surrogate or intermediate outcomes?

#### Populations

- As described for KQ 2.

#### Interventions

- As described for KQ 2.

#### Comparators

- As described for KQ 2.

#### Outcomes

- As described for KQ 2.

#### Timing

- As described for KQ 2.

#### Settings

- As described for KQ 2.

Dated: July 11, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013-17177 Filed 7-17-13; 8:45 am]

BILLING CODE 4160-90-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Scientific Information Request on Imaging Tests for the Staging of Colorectal Cancer

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for scientific information submissions.

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions on imaging tests for the staging of colorectal cancer (e.g., Chest x-ray, computed tomography, multidetector computed tomography (MD-CT), CT colonography, magnetic resonance

imaging (MRI), transabdominal ultrasound (TUS), endoscopic ultrasound (EUS), transrectal ultrasound (TRUS), positron emission tomography (PET), positron emission tomography combined with computed tomography (PET/CT fusion), or positron emission tomography combined with magnetic resonance imaging (PET/MRI fusion)) from medical device manufacturers. Scientific information is being solicited to inform our Comparative Effectiveness Review of Imaging Tests for the Staging of Colorectal Cancer, which is currently being conducted by one of the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on these devices will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

AHRQ is republishing this document due to errors found on our first publication of June 27, 2013 (<http://www.gpo.gov/fdsys/pkg/FR-2013-06-27/pdf/2013-15288.pdf>). Please disregard the June 27 publication.

**DATES:** Submission Deadline by July 29, 2013.

**ADDRESSES:** Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/>. Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: [SIPS@epc-src.org](mailto:SIPS@epc-src.org).

Print submissions: Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

#### FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Research Librarian, Telephone: 503-220-8262 ext. 58652 or Email: [SIPS@epc-src.org](mailto:SIPS@epc-src.org).

**SUPPLEMENTARY INFORMATION:** The Agency for Healthcare Research and Quality has commissioned one of the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness