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Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2023–18398 Filed 8–25–23; 8:45 am]

BILLING CODE 6820–14–P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Notice of Approval of Information Collection Requirements

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of approval of information collection requirements.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Office of Government Ethics (OGE) is announcing Office of Management and Budget (OMB) approval of new information collection requirements contained in a final rule published in the **Federal Register** on May 25, 2023, “Legal Expense Fund Regulation.”

FOR FURTHER INFORMATION CONTACT: McEvan Baum at the U.S. Office of Government Ethics; telephone: 202–482–9287; TTY: 800–877–8339; Email: usoge@oge.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor a collection of information, and the public is not obligated to respond to a collection of information, unless the collection of information displays a currently valid OMB control number.

On May 25, 2023, OGE published a final rule establishing a framework to govern an executive branch employee’s acceptance of payments for legal expenses through a Legal Expense Fund (LEF) for matters arising in connection with the employee’s official position, the employee’s prior position on a campaign of a candidate for President or Vice President, or the employee’s prior position on a Presidential Transition Team. The requirements for establishing and maintaining a LEF are found in 5 CFR part 2635, subpart J (LEF regulation).

The LEF regulation requires that employees who wish to establish a legal expense fund do so through a trust with a single, named employee beneficiary and a trustee. It also requires an employee beneficiary to file quarterly reports that include information (1) regarding members of the public who make financial donations to help pay for

the employee beneficiary’s legal expenses (donors) and (2) members of the public who receive payments from a legal expense fund (payees). The employee beneficiary must also file a termination report upon the termination of the trust and/or executive branch employment. The trust documents, quarterly reports, and termination reports will be posted directly on OGE’s website in accordance with 5 CFR 2635.1007(g). Together, this information collection (IC) is titled “OGE Legal Expense Fund Information Collection.”

OGE submitted a request for approval of this information collection on May 25, 2023, and OMB approved it on July 21, 2023. It was assigned OMB Control Number 3209–0012. Therefore, in accordance with the PRA, OGE hereby announces OMB approval of the information collection requirements as contained in the final rule, which will be effective November 21, 2023.

Approved: August 23, 2023.

Shelley K. Finlayson,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2023–18526 Filed 8–25–23; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Diagnosis and Management of Obsessive Compulsive Disorders in Children

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

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Diagnosis and Management of Obsessive Compulsive Disorders in Children*, which is currently being conducted by the AHRQ’s Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before September 27, 2023.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for

Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Diagnosis and Management of Obsessive Compulsive Disorders in Children*. AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC 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 *Diagnosis and Management of Obsessive Compulsive Disorders in Children*. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/obsessive-compulsive-disorder/protocol>.

This is to notify the public that the EPC Program would find the following information on *Diagnosis and Management of Obsessive Compulsive Disorders in Children* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *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, if relevant: 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 that your organization has sponsored for this topic. In the list, please provide the*

ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

▪ Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study

types not included in the review; or information on topics not included in the review cannot be used by the EPC 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 EPC Program website and available for public comment for a period of 45 days.

If you would like to be notified when the draft is posted, please sign up for the email list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: How accurate are assessment tools compared to reference standard methods to identify OCD in symptomatic children and adolescents?

KQ 1a: How does diagnostic accuracy of assessment tools vary by patient, family, social, or other characteristics, or by respondent type?

KQ 2: What are the comparative effects and harms of treatment interventions, used alone or in combination, for OCD in children and adolescents?

KQ 2a: How do the effectiveness and harms vary with patient, family, social, or other characteristics?

Study Eligibility Criteria

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
Population	<p>Children and adolescents (<21 years):</p> <ul style="list-style-type: none"> in whom there is clinical consideration of OCD. diagnosed with OCD and/or other conditions which may be either be comorbid with OCD or may present with similar symptoms. <p><i>Include:</i></p> <ul style="list-style-type: none"> Studies evaluating only children and adolescents with OCD (to estimate test sensitivity alone). <p><i>Exclude:</i></p> <ul style="list-style-type: none"> Studies that include both adults and children that do not explicitly report a pediatric or adolescent subgroup in the abstract. Studies that perform population-based screening (among individuals without a clinical concern for OCD). 	<p>Children and adolescents (<21 years) with diagnosed OCD, including those with:</p> <ul style="list-style-type: none"> possible PANS/PANDAS (with OCD). other comorbid conditions (e.g., autism). <p><i>Exclude:</i></p> <ul style="list-style-type: none"> Children and adolescents diagnosed with other OCD-spectrum conditions (e.g., body dysmorphic disorder, body focused repetitive behaviors) without an OCD diagnosis. Subclinical OCD or obsessive or compulsive symptoms without an OCD diagnosis. Studies that include both adults and children that do not explicitly report a subgroup by age in the abstract.
Interventions	<p>Index Test(s):</p> <ul style="list-style-type: none"> Tools to diagnose OCD in symptomatic patients. For example, <ul style="list-style-type: none"> Obsessive Compulsive Inventory-Child Version (OCI-CV-R). Toronto Obsessive-Compulsive Scale (TOCS). Short Obsessive-Compulsive Screener (SOCS). Diagnostic prediction models. Must report use of specific cut-point(s) to classify an individual as having OCD or a prediction algorithm or model to predict the probability of OCD. Alternative administration (e.g., child versus parent versus teacher report, in-person versus telehealth). <p><i>Exclude:</i></p> <ul style="list-style-type: none"> Specific individual symptoms, behaviors, or characteristics. Genetic studies. Biomarker studies. 	<p>Psychological interventions for OCD, alone or in combination with pharmacological and/or other interventions, including:</p> <ul style="list-style-type: none"> Cognitive behavioral therapy (CBT). <ul style="list-style-type: none"> Exposure and response prevention (ERP). Psychoeducation. Coping skills. Cognitive therapy. Acceptance and commitment therapy (ACT). Targeted family interventions. Other psychological interventions. Delivery method. <ul style="list-style-type: none"> Therapist led, e.g., scheduled, in-person, or via telephone, video conference. Self-guided, e.g., asynchronous, therapist serves as supportive coach. <p>Pharmacological interventions, alone or in combination with psychological interventions:</p> <ul style="list-style-type: none"> Selective serotonin reuptake inhibitors (SSRIs). Tricyclic antidepressants (TCA), including clomipramine. Serotonin and norepinephrine reuptake inhibitors (SNRIs). Medication augmentation strategies: <ul style="list-style-type: none"> SSRI augmentation with clomipramine, and other medications, including neuroleptics, nonsteroidal anti-inflammatory drugs (NSAIDs). Glutamate modulating agents (e.g., D-cycloserine, riluzole). Other pharmacologic interventions, alone or in combination with psychological and/or other interventions, including dose escalation, longer treatment duration. <p>Neuromodulation interventions:</p> <ul style="list-style-type: none"> Transcranial magnetic stimulation (TMS), Transcranial direct current stimulation (tDCS), Transcranial alternating current stimulation (tACS), Deep brain stimulation (DBS). <p>Complementary/integrative therapies:</p> <ul style="list-style-type: none"> Naturopathic interventions. Mind-body practices (e.g., mindfulness, meditation, yoga). Sensory integration (e.g., deep pressure).

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
Comparators	<p>Reference standard(s):</p> <ul style="list-style-type: none"> • Clinical interview. • Validated diagnostic assessment instruments (others may be included). <ul style="list-style-type: none"> ○ Anxiety Disorders Interview Schedule for DSM–5 child version. ○ (ADIS–C). ○ Kiddie Schedule for Affective Disorders and Schizophrenia, Present and Lifetime version (K–SADS–PL) for DSM–5. ○ Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI–KID). ○ Children’s Yale-Brown Obsessive-Compulsive Scale (CY–BOCS). ○ Children’s Yale-Brown Obsessive-Compulsive Scale Second Edition (CY–BOCS–II). • Different index tests (if also compared with reference standard). • Different reference standards (i.e., comparison of reference standards). • Different respondents (e.g., clinician, self, parent, educator). • Different methods to give test (e.g., in person vs. via telehealth). • Different populations (see effect modifiers below). 	<p><i>Exclude:</i></p> <ul style="list-style-type: none"> • Specific treatments for PANS/PANDAS (e.g., antibiotics, immunomodulation, intravenous immunoglobulin). • No treatment (e.g., waitlist control). • Pill placebo or sham control. • Another active intervention or co-intervention (e.g., relaxation therapy). • Alternative delivery methods.
Outcomes (prioritized outcomes have an asterisk and are in bold font).	<p>OCD diagnosis:</p> <ul style="list-style-type: none"> • Sensitivity/Specificity.* • Positive and negative likelihood ratios. • Accuracy. • Area under the Receiver Operator Characteristic Curve (AUC ROC). • Predicted probability of OCD (model calibration/discrimination). • Time to initiation of treatment (cohort studies). <p><i>Exclude:</i></p> <ul style="list-style-type: none"> • Studies not reporting predictive validity that report other psychometric properties of scales: for example, reliability or validity (content, construct, convergent, discriminant, divergent, face). 	<p>OCD symptom severity:</p> <ul style="list-style-type: none"> • Children’s Yale-Brown Obsessive Compulsive Scale Total (CY–BOCS).* • Clinical Global Impression–Severity (CGI–S).* <p>Treatment response and remission:</p> <ul style="list-style-type: none"> • Clinical remission (posttreatment CY–BOCS total score ≤12 as defined by Farhat et. al.23, or as reported).* • Clinical Global Impression–Improvement (CGI–I).*
Potential Effect Modifiers/Subgroups of interest.	<ul style="list-style-type: none"> • Patient, family, social, and other characteristics, including: <ul style="list-style-type: none"> ○ Race/Ethnicity (racial and ethnic discrimination is the effect modifier of interest but many/most studies will not contain that so we will use race/ethnicity as a marker for likelihood of experience with discrimination and would explicitly discuss this in the review). ○ Identity and Culture (e.g., spiritual and religious beliefs and practices, native language, gender identity, sexual orientation, physical/mental disability status) ○ Age. ○ Age at symptom onset. ○ Social determinants of health, including education level, socioeconomic status, immigration status, refugee status, and geography (e.g., urban vs. rural). 	<p>Functional impairment in school, social, and home/family domains:</p> <ul style="list-style-type: none"> • The Child Obsessive Compulsive Impact Scale—Revised (COIS–R).* ○ Raters: child (COIS–C), parent (COIS–P). <p>Family accommodation:</p> <ul style="list-style-type: none"> • Family Accommodation Scale (FAS).* <p>Family functioning:</p> <ul style="list-style-type: none"> • OCD Family Functioning Scale. • Family Environment Scale (FES). • Parental Attitudes and Behaviors Scale (PABS). <p>Patient/parent reported experience measures (PREMs):</p> <ul style="list-style-type: none"> • Patient reported outcome measure (PROMs): • Top Problems assessment (TPA). • Quality of Life (QoL) General and Health Related (HRQoL) (validated scales only):* • Quality of Life Enjoyment and Satisfaction Questionnaire–Short Form (QLESQ). <p>Acceptability of treatment: *</p> <ul style="list-style-type: none"> • Parental satisfaction with services. • Withdrawals/discontinuation. <p>Sleep-related problems.</p> <p>Suicidal thoughts and behavior:</p> <ul style="list-style-type: none"> • Columbia Suicide Severity Rating Scale Recent Self-Report Screener (C–SSRS). <p>Anxiety and depression.</p> <p>Adverse events related to treatment.*</p> <p><i>Exclude:</i></p> <ul style="list-style-type: none"> • Neuroimaging (e.g., functional MRI). • Patient, family, social, and other characteristics, including: <ul style="list-style-type: none"> ○ Race/Ethnicity (racial and ethnic discrimination is the effect modifier of interest but many/most studies will not contain that so we will use race/ethnicity as a marker for likelihood of experience with discrimination and would explicitly discuss this in the review). ○ Identity and Culture (e.g., spiritual and religious beliefs and practices, native language, gender identity, sexual orientation, physical/mental disability status). ○ Age. ○ Age at symptom onset. ○ Social determinants of health, including education level, socioeconomic status, immigration status, refugee status, and geography (e.g., urban vs. rural).

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
Design	<ul style="list-style-type: none"> ○ Diagnosis of PANS/PANDAS. ○ OCD in first degree relatives. ○ Level of family accommodation. ○ Co-occurring disorders (e.g., major depressive disorder, anxiety disorders, attention-deficit hyperactivity disorder, conduct disorders, autism spectrum disorder, and Tourette syndrome, other tic disorders). ○ Diagnosis during COVID-19 pandemic (as defined by study authors). ○ Primary versus specialist care. <ul style="list-style-type: none"> ● Respondent type. <p><i>Exclude:</i></p> <ul style="list-style-type: none"> ● Neuroimaging, e.g., functional MRI. 	<ul style="list-style-type: none"> ○ Diagnosis of PANS/PANDAS. ○ OCD in first degree relatives. ○ Level of family accommodation. ○ Co-occurring disorders (e.g., major depressive disorder, anxiety disorders, attention-deficit hyperactivity disorder, conduct disorders, autism spectrum disorder, and Tourette syndrome, other tic disorders). ○ Diagnosis during COVID-19 pandemic (as defined by study authors). ○ Duration of symptoms prior to treatment. ○ Symptom severity. ○ In-session exposure and response prevention. ○ Medication dose. ○ Care settings and care intensities. <ul style="list-style-type: none"> ■ Traditional outpatient. ■ Intensive outpatient. <ul style="list-style-type: none"> ● Day programs (e.g., partial hospitalization). ● Residential. ■ Inpatient. ■ Other care settings, including school-based settings. ■ Telehealth (vs. in-person). ■ Primary versus specialist care. <p>Comparative trials:</p> <ul style="list-style-type: none"> ● Randomized controlled trials. ● Nonrandomized comparative studies. <ul style="list-style-type: none"> ○ prospective or retrospective with appropriate adjustment for confounding. <p>Single arm studies, N ≥ 50:</p> <ul style="list-style-type: none"> ● with multivariable analyses of potential effect modifiers/subgroups of interest. <p>Systematic reviews (for reference lists only).</p> <p><i>Exclude:</i></p> <ul style="list-style-type: none"> ● Cross-sectional studies (no longitudinal follow-up). ● Qualitative studies. ● Case reports and case series. ● Unpublished studies, including conference abstracts (but include studies with reported results in the <i>ClinicalTrials.gov</i> database).
Timing	Any.	Any.
Setting	Any, including administration of test(s) in-person or via telehealth.	Any.

* Prioritized outcome.

Dated: August 21, 2023.

Marquita Cullom,
Associate Director.

[FR Doc. 2023-18415 Filed 8-25-23; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC). This is a hybrid meeting, accessible both in

person and virtually. It is open to the public, limited only by the in-person space available. The public is also welcome to view the meeting by joining the audio conference (information below). Time will be available for public comment, and the public is also welcome to submit written comments in advance of the meeting (see the public participation section below).

DATES: The meeting will be held on November 8, 2023, from 8:30 a.m. to 5:30 p.m., EST, and November 9, 2023, from 8:30 a.m. to 12 p.m., EST.

ADDRESSES: Centers for Disease Control and Prevention, 2400 Century Parkway NE, Room 1020/1023, Atlanta, Georgia 30345. The conference room will have seating for approximately 60 people.

Meeting Information: All people attending the CLIAC meeting in person are required to register online for the meeting at least five business days in advance for U.S. citizens and at least 20 business days in advance for international registrants. Register at: [https://www.cdc.gov/cliac/upcoming-](https://www.cdc.gov/cliac/upcoming-meeting.html)

[meeting.html](https://www.cdc.gov/cliac/upcoming-meeting.html). Register by scrolling down and clicking the “Register for this Meeting” button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than November 1, 2023, for U.S. registrants and October 11, 2023, for international registrants. The confirmed meeting times, agenda items, and meeting materials, including instructions for accessing the live meeting broadcast, will be available on the CLIAC website at <https://www.cdc.gov/cliac/upcoming-meeting.html>.

FOR FURTHER INFORMATION CONTACT: Heather Stang, MS, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Office of Laboratory Science and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4027. Telephone: (404) 498-2769; Email: HStang@cdc.gov.

SUPPLEMENTARY INFORMATION: