management. These activities aim to produce tangible outputs such as research findings on WTC-related conditions, healthcare protocols, peer-reviewed publications, quality assessment reports, and member and provider education products. Finally, the model anticipates short-, intermediate-, and long-term measurement of outcomes and serves as a communication tool for program planning and evaluation.

In 2016, NIOSH contracted with the RAND Corporation to conduct an independent evaluation of the WTCHP RTC model including the research investments to date and the effectiveness with which the Program translates its research to different stakeholder groups. RAND was selected given the project team's expertise with similar assessments and NIOSH's requirement for an objective analysis. This work will ultimately provide guidance for the WTCHP on strategic directions, as well as produce new knowledge about the translation of research into improved outcomes for individuals and populations exposed to disasters such as, but not limited to, the 9/11 attacks. In the formative stage of our assessment, we propose to hold a series of focus groups with different stakeholder groups to explore their perspectives on translational research in the context of the WTCHP. The focus groups will each consist of a well-defined stakeholder group, and will last approximately two hours. Focus group discussions will be held in-person or by telephone or webinar format. Depending on the timing of OMB approval, RAND anticipates conducting focus groups shortly after, most likely in the winter/early spring of 2019. If this occurs, results will be analyzed in the spring of 2019. If the timing of OMB approval coincides with one of the twice-yearly NIOSH-sponsored research meetings in NYC, RAND plans to hold in-person focus groups with the stakeholder groups in attendance (NIOSH and principal investigators, typically); the remainder of the focus groups will be held by webinar to minimize burden on the participants.

These focus groups are necessary to gather background information on the relationship between different stakeholders and the WTCHP that will complement data gathered during more detailed interviews with stakeholders in the interviews that will take place 6–12 months later. Specific topics to be addressed in the focus groups will include: Conceptualizations of research and ''translational research;'' relevance of WTCHP research topics, potential gaps, and stakeholder priorities, including responsiveness to regulatory issues; uses and usefulness of WTCHP research; barriers to conduct and use of WTCHP research; and understanding of and perspectives on the relevance and usefulness of the Research-to-Care model.

OMB approval is requested for one year. The total estimated burden in hours is 220. Participation is voluntary and there are no costs to the respondent 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) |
|---|---|---|---|---|
| Principal Investigators of WTCHP-Funded Research. | Focus Group Discussion Guide and Brief Demographic Survey. | 30 | 1 | 2 |
| Leadership from WTC Clinical Centers of Excellence and Other Stakeholders. | Focus Group Discussion Guide and Brief Demographic Survey. | 20 | 1 | 2 |
| WTC Health Registry staff | Focus Group Discussion Guide and Brief Demographic Survey. | 10 | 1 | 2 |
| Clinicians Caring for WTCHP Members | Focus Group Discussion Guide and Brief Demographic Survey. | 20 | 1 | 2 |
| WTCHP Responders and Survivors (State/local govt). | Focus Group Discussion Guide and Brief Demographic Survey. | 15 | 1 | 2 |
| WTCHP Responders and Survivors (private citizens). | Focus Group Discussion Guide and Brief Demographic Survey. | 15 | 1 | 2 |

**Jeffrey M. Zirger,**

*Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

[FR Doc. 2018–26633 Filed 12–7–18; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–4395]**

### Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee (Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on February 12, 2019, from 8 a.m. to 6:30 p.m.

**ADDRESSES:** Hilton Washington, DC North/Gaithersburg; Salons A, B, C, and D; 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900; additional information available online at: *https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html.* Answers to

commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–4395. The docket will close on February 11, 2019. Submit either electronic or written comments on this public meeting by February 11, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 11, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 11, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before January 27, 2019, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–4395 for ''The Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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.'' FDA 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information 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 the 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, September18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993–0002, *Evella.Washington@fda.hhs.gov,* 301–796–6683, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On February 12, 2019, the Committee will discuss and make recommendations regarding the safety and effectiveness of surgical mesh placed transvaginally in the anterior vaginal compartment to treat pelvic organ prolapse. FDA is convening this meeting to seek expert opinion on the evaluation of the risks and benefits of these devices. The Committee will be asked to provide scientific and clinical input on assessing the effectiveness, safety, and benefit/risk of mesh placed transvaginally in the anterior vaginal compartment, as well as identifying the appropriate patient population and physician training needed for these devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the

appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 5, 2019. Oral presentations from the public will be scheduled on February 12, 2019, between approximately 8:15 a.m. and 9:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 28, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 29, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *artair.mallett@fda.hhs.gov* or 301–796–9638, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 3, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–26626 Filed 12–7–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council.

*Date:* January 16, 2019.

*Open:* 8:30 a.m. to 12:00 p.m.

*Agenda:* To present the Director's Report and other scientific presentations.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

*Closed:* 1:00 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council, Diabetes, Endocrinology and Metabolic Diseases.

*Date:* January 16, 2019.

*Closed:* 1:00 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

*Open:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review the Division's scientific and planning activities.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council, Kidney, Urologic and Hematologic Diseases.

*Date:* January 16, 2019.

*Open:* 1:00 p.m. to 2:15 p.m.

*Agenda:* To review the Division's scientific and planning activities.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room F1/F2, 45 Center Drive, Bethesda, MD 20892.

*Closed:* 2:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room F1/F2, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

*Name of Committee:* National Diabetes and Digestive and Kidney Diseases Advisory Council, Digestive Diseases and Nutrition.

*Date:* January 16, 2019.

*Open:* 1:00 p.m. to 2:30 p.m.

*Agenda:* To review the Division's scientific and planning activities.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room D, 45 Center Drive, Bethesda, MD 20892.

*Closed:* 2:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Conference Center (Building 45), Conference Room D, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a