will be collected during a single site visit to each selected organization to conduct on-site observations and in-depth interviews (IDI) with each organization's key informants, such as Principal Investigators, Program Managers, Program Staff, and Program Partners. IDIs will last 1–2 hours each. Case study findings will help CDC to identify areas in which CDC can build upon existing and emerging efforts to provide support services and educational resources to YBCS, highlight barriers and facilitating factors to implementing interventions targeting YBCS, determine the added value of providing the DP11–1111 cooperative agreement (e.g., funding, technical assistance) to various entities, identify lessons learned that can be applied to future implementation of YBCS interventions, and better understand the sustainability of YBCS interventions following/in the absence of CDC funding.

Case study selection is based on a purposeful selection of CDC-funded and non-CDC funded organizations that support YBCS populations through educational or service programs. Potential organizations for this project may be funded through state, local, or Tribal government, or the private sector. Information will be collected approximately two years after initiation of CDC's cooperative agreement. OMB approval is requested for one year.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 168.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Private Sector Organizations	Worksheet for Identifying Site Visit Interviews	7	1	1
	Worksheet for Scheduling Site Visit Interviews	7	1	2
	IDI Guide for Program Directors/Principal Investigators.	7	1	2
	IDI Guide for Program Managers	7	1	1
	IDI Guide for Program Staff Members	35	1	1
	IDI Guide for Program Partners	21	1	1
State, Local, and Tribal Government Organizations.	Worksheet for Identifying Site Visit Interviews.	5	1	1
	Worksheet for Scheduling Site Visit Interviews	5	1	2
	IDI Guide for Program Directors/Principal Investigators.	5	1	2
	IDI Guide for Program Managers	5	1	1
	IDI Guide for Program Staff Members	25	1	1
	IDI Guide for Program Partners	15	1	1

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–03176 Filed 2–12–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 20, 2014, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, *Avena.Russell@fda.hhs.gov,* 301–796–3805, 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 the Agency's Web site at *http://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.

Agenda: On March 20, 2014, the committee will discuss, make recommendations, and vote on information regarding the humanitarian device exemption (HDE) application for the XVIVO Perfusion System (XPS™) sponsored by XVIVO Perfusion, Inc. The proposed Indication for Use for the XVIVO Perfusion System, as stated in the HDE, is as follows:

The XPS™ is intended to be used with STEEN Solution for flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the function of the lungs can be reassessed for transplantation.

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 Web site 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 Web site after the meeting. Background material is available at *http://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 March 13, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 March 5, 2014. 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 March 6, 2014.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: February 7, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–03139 Filed 2–12–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

National Institutes of Health

Proposed Collection; Comment Request; NIH Neurobiobank Tissue Access Request

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments received within 60 days of the date of this publication will receive fullest consideration.

Proposed Collection: National Institute of Health Neurobiobank Tissue Access Request–0925–New. National Institute of Mental Health (NIMH), National Institute of Health (NIH).

Need and Use of Information Collection: The NIH Neurobiobank Tissue Access Request form is necessary for ''Recipient'' Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access tissue or biospecimens from the National Neurobiobank for research purposes. The primary use of this information is to document, track, monitor, and evaluate the appropriate use of the Neurobiobank tissue and biospecimen resources, as well as to notify interested recipients of updates, corrections or other changes to the system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 63.

ESTIMATES ANNUAL BURDEN HOURS

Form	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Neurobiobank Tissue Access Request	50	1	15/60	13
Pre-Mortem Consent and Medical History	50	1	1	50
Total				63