

department, and the industry and community partners.

Industry leaders who participate on the Mayor's Task Force for Convenience Store Safety will provide support and

voluntarily contact approximately 90 stores and recommend they participate. Additionally, approximately 3 community leaders in each city will

voluntarily contact approximately 90 stores and recommend they participate. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Store manager interviews	600	1	30/60	300
Store owners/upper management approve manager interviews	35	1	3	105
Stakeholders Industry leader recommend stores	90	1	30/60	45
Community leader recommend stores	90	1	30/60	45
Total				495

Dated: August 8, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010-19835 Filed 8-13-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)

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 Cancer Institute (NCI), the 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.

Proposed Collection: Title: NIH NCI Central Institutional Review Board (CIRB). *Type of Information Collection Request:* Existing Collection in Use Without an OMB Number. *Need and Use of Information Collection:* The CIRB was created to reduce the administrative burden on local IRBs and investigators while protecting human research participants. To accomplish this, the CIRB uses several information collection tools to ensure that CIRB operations occur with high level of reviewer and board member satisfaction and is absent of conflicts of interest with the protocols under review. Tools utilized to accomplish this include the new member packets which are completed once a new member joins the CIRB to provide background information on workflow and processes of CIRB operations as well as a non-disclosure agreement. A conflict of interest form is

completed occasionally or each time the reviewer is requested to serve as a reviewer for a study. CIRB helpdesk surveys measure satisfaction of helpdesk users and is conducted occasionally or each time the person contacts the helpdesk. *Frequency of Response:* Once, except for the SAE Reviewer Worksheet. *Affected Public:* Includes the Federal Government, business or other for-profits and not-for-profit institutions. *Type of Respondents:* Respondents include any customer who contacts the CIRB Helpdesk, institutional review board members and CIRB review participants. The annual reporting burden is estimated at 2221 hours (see Table below for the estimated time burden). The average annual cost to the government over a 12 month period is approximately \$153,574 per year for a six year contract. This includes total annualized capital/start up costs of \$25,108 and operating costs of \$150,637.

TABLE A.12-1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (Min/Hr)	Annual burden hours
Participants/Board Members.	CIRB Helpdesk Survey (Attachment 1)	1500	1	10/60 (.17 hour)	255
Participants	NCI CIRB Institution Enrollment Worksheet (Attachment 2A).	30	1	3.5 hours	105
Participants	IRB Staff at Signatory Institution's IRB (Attachment 2B).	65	1	10/60 (.17 hour)	11
Participants	Investigator at Signatory Institution (Attachment 2C).	65	1	10/60 (.17 hour)	11
Participants	Research Staff at Signatory Institution (Attachment 2D).	65	1	10/60 (.17 hour)	11
Participants	Investigator at Affiliate Institution (Attachment 2E).	65	1	10/60 (.17 hour)	11
Participants	Research Staff at Affiliate Institution (Attachment 2F).	65	1	10/60 (.17 hour)	11
Participants	IRB at Signatory Institution (Attachment 2G).	65	1	10/60 (.17 hour)	11
Participants	Component Institution at Signatory Institution (Attachment 2H).	65	1	10/60 (.17 hour)	11

TABLE A.12-1—ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (Min/Hr)	Annual burden hours
Participants	IRB at Affiliate Institution (Attachment 2I).	65	1	10/60 (.17 hour)	11
Participants	Institution Affiliate Institution without an IRB (Attachment 2J).	65	1	10/60 (.17 hour)	11
Participants	Request for 30-Day Access Form (Attachment 2K).	50	1	10/60 (.17 hour)	9
Participants	Facilitated Review (FR) Acceptance Form (Attachment 2L).	1450	1	10/60 (.17 hour)	247
Participants	Study Review Responsibility Transfer Form (Attachment 2M).	120	1	10/60 (.17 hour)	20
Board Members	CIRB New Board Member Biographical Sketch Form (Attachment 3B).	16	1	30/60 (.5 hour)	8
Board Members	CIRB New Board Member Contact Information Form (Attachment 3C).	16	1	15/60 (.25 hour)	4
Board Members	CIRB New Board Member W-9 (Attachment 3D).	16	1	15/60 (.25 hour)	4
Board Members	CIRB New Board Member Non-Disclosure Agreement (NDA) (Attachment 3E).	16	1	15/60 (.25 hour)	4
Board Members	Direct Deposit Form (Attachment 4)	16	1	15/60 (.25 hour)	4
Participants	NCI Adult CIRB Application (Attachment 5A).	150	1	2 hours	300
Participants	NCI Pediatric CIRB Application (Attachment 5B).	62	1	2 hours	124
Participants	Adult/Pediatric CIRB Application—Ancillary Studies (Attachment 5C).	10	1	2 hours	20
Participants	Summary of CIRB Application Revisions (Attachment 5D).	20	1	30/60 (.5 hour)	10
Participants	Adult/Pediatric CIRB Application for Continuing Review (Attachment 5E).	230	1	1 hour	230
Board Members	Adult CIRB Reviewer Findings—Initial Review of Cooperative Group Protocol (Attachment 6A).	20	1	4 hours	80
Board Members	Pediatric CIRB Reviewer Findings—Initial Review of Cooperative Group Protocol (Attachment 6B).	12	1	4 hours	48
Board Members	Adult CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6C).	25	1	1 hour	25
Board Members	Pediatric CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6D).	70	1	1 hour	70
Board Members	Adult CIRB Reviewer Findings Amendment Cooperative Group Protocol (Attachment 6E).	130	1	1.5 hours	195
Board Members	Pediatric CIRB Reviewer Findings Amendment to Cooperative Group Protocol (Attachment 6F).	50	1	1.5 hours	75
Board Members	Adult CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6G).	150	1	.5 hour	75
Board Members	Pediatric CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6H).	110	1	.5 hour	55
Board Members	CIRB Reviewer Form (Attachment 6I) ...	20	1	2 hours	40
Board Members	CIRB Statistical Reviewer Form (Attachment 6J).	20	1	2 hours	40
Board Members	CIRB SAE Reviewer Worksheet (Attachment 6K).	10	15	30/60 (.5 hour)	75
Total					2221

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following

points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael Montello, Pharm. D., CTEP, 6130 Executive Blvd., Rockville, MD 20852. At non-toll-free number 301-435-9206 or e-mail your request, including your address to: montellom@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 9, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010-20167 Filed 8-13-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

General and Plastic Surgery 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: General and Plastic Surgery 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 November 18, 2010, from 8 a.m. to 6 p.m.

Location: Holiday Inn College Park, Grand Ballroom, 10000 Baltimore Ave., College Park, MD.

Contact Person: Margaret McCabe-Janicki, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-7029, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512519. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 18, 2010, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for MelaFind, sponsored by MELA Sciences. MelaFind is a computer-controlled multi-spectral dermoscope that uses light, wavelengths from 430 nanometers (nm) (blue) through 950 nm (near infrared), to image the skin through a thin layer of liquid (alcohol or oil), making lesion structures under the skin surface visible to the observer. A complementary metal oxide semiconductor digital camera inside the probe captures the images and then differentiates them among pigmented skin lesions for melanoma risk using predefined software statistical pattern recognition algorithms.

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 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 November 9, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 October 28, 2010. 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 November 2, 2010.

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, Conference Management Staff, 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: August 11, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-20156 Filed 8-13-10; 8:45 am]

BILLING CODE 4160-01-S

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 (5 U.S.C. App.), 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