remove potential ambiguities and address several issues not included in the original draft guidance. In response to comments submitted to the public docket, at stakeholder meetings, and in calls from the public, FDA has provided additional clarifying examples to assist in complying with part 1140.

II. Significance of Guidance

FDA is issuing this guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: August 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20506 Filed 8–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day 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), 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: CAPT Michael Montello, Pharm. D., MBA, Cancer Therapy Evaluation Program, Operations and Informatics Branch, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240) 276–6080 or Email your request, including your address to: *mike.montello@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment 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.

Proposed Collection: NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI), 0925–0625, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Central Institutional Review Board (CIRB) provides a centralized approach to human subject protection and provides a cost efficient approach avoiding duplication of effort at each institution. The CIRB provides the services of a fully constituted IRB and provides a comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including: Initial reviews, continuing reviews, review of amendments, and adverse events. The Initiative consists of three central IRBs: Adult CIRB—late phase emphasis, Adult CIRB—early phase emphasis, and Pediatric CIRB. CIRB membership includes oncology physicians, surgeons, nurses, patient advocates, ethicists, statisticians, pharmacists, attorneys and other health professionals. The benefits of the CIRB Initiative reaches research participants, investigators and research staff, Institutional Review Boards (IRB), and Institutions. Benefits include: Study participants having dedicated review of NCI-sponsored trials for participant protections, access to more trials more quickly and access to trials for rare diseases, accrual to trials begin more rapidly, ease of opening trials, elimination of need to submit study materials to local IRBs, and elimination of the need for a full board review. The benefits to the National Clinical Trials Network and Experimental Therapy-Clinical Trials Network include a cost efficient approach that avoids duplication of efforts at each institution. A variety of information collection tools are needed to support NCI's CIRB activities which include: Worksheets, forms and a survey that is provided to all customers contacting the CIRB helpdesk.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,199.

ESTIMATES OF ANNUAL BURDEN HOURS

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
CIRB Customer Satisfaction Survey	Participants/ Board Members.	1500	1	10/60	250
Request for 30 Day Web site Access Form	Participants	25	1	10/60	4
Authorization Agreement and Division of Responsibilities between the NCI CIRB and Signatory Institution.	Participants	340	1	30/60	170
NCI CIRB Signatory Enrollment Form	Participants	40	1	4	160
IRB Staff at Signatory Institution's IRB	Participants	25	1	10/60	4
Investigator at Signatory Institution	Participants	65	1	10/60	11
Research Staff at Signatory Institution	Participants	65	1	10/60	11
Investigator at Affiliate Institution with an IRB	Participants	25	1	10/60	4
Research Staff at Affiliate Institution with an IRB	Participants	25	1	10/60	4
Investigator at Affiliate Institution without an IRB	Participants	25	1	10/60	4
Research Staff at Affiliate Institution without an IRB	Participants	25	1	10/60	4
Institutional Contact for Signatory Institution	Participants	65	1	10/60	11
IRB at Signatory Institution	Participants	25	1	10/60	4
Component Institution at Signatory Institution	Participants	65	1	10/60	11
IRB at Affiliate Institution	Participants	25	1	10/60	4
Affiliate Institution without an IRB	Participants	25	1	10/60	4
Facilitated Review Acceptance Form	Participants	300	1	10/60	50
Study Review Responsibility Transfer Form	Participants	80	1	10/60	13
Annual Signatory Institution Worksheet About Local Context.	Participants	120	1	20/60	40
Annual Principal Investigator Worksheet About Local Context.	Participants	120	1	20/60	40
Study-Specific Worksheet About Local Context	Participants	220	1	20/60	73
Study Closure or Transfer of Study Review Responsibility Form.	Participants	120	1	10/60	20
Potential Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form.	Participants	120	1	15/60	30
Add or Remove Signatory and/or Component Institution Personnel.	Participants	120	1	10/60	20
Add or Remove Affiliate Institution Personnel	Participants	120	1	10/60	20
Add or Remove Component Institution	Participants	120	1	10/60	20
Add or Remove Affiliate Institution	Participants	120	1	10/60	20
One Time Study Roll Over Worksheet	Participants	120	1	10/60	20
Change of Signatory Institution PI Form	Participants	120	1	10/60	20
CIRB Board Member Biographical Sketch Form	Board Members	25	1	15/60	6.25
CIRB Board Member Contact Information Form	Board Members	25	1	10/60	4
CIRB Board Member W–9	Board Members	25	1	15/60	6
CIRB Board Member Non-Disclosure Agreement (NDA)	Board Members	25	1	10/60	4
CIRB Direct Deposit Form	Board Members	25	1	15/60	6
NCI Adult/Pediatric CIRB Application for Treatment Studies.	Participants	25	1	2	50
NCI Adult/Pediatric CIRB Application for Ancillary Studies.	Participants	10	1	2	20
NCI Adult/Pediatric CIRB Application for Continuing Review.	Participants	80	1	1	80
Summary of CIRB Application Revisions	Participants	20	1	30/60	10
Locally-Developed Material Submission Form	Participants	15	1	15/60	4
Application Request to Review Translated Documents	Participants	15	1	15/60	4
Adult Initial Review of Cooperative Group Protocol	Board Members	15	1	4	60
Pediatric Initial Review of Cooperative Group Protocol	Board Members	15	1	4	60
Adult Continuing Review of Cooperative Group Protocol	Board Members	130	1	1	130
Pediatric Continuing Review of Cooperative Group Protocol.	Board Members	70	1	1	70
Adult Amendment of Cooperative Group Protocol	Board Members	10	1	2	20
Pediatric Amendment of Cooperative Group Protocol	Board Members	10	1	2	20
Adult Cooperative Group Response to CIRB Review	Participants	15	1	1	15
Pediatric Cooperative Group Response to CIRB Review.	Participants	10	1	1	10
Adult Pharmacist's Review of a Cooperative Group Study.	Board Members	10	1	2	20
Pediatric Pharmacist's Review of a Cooperative Group Study.	Board Members	20	1	2	40
CIRB Statistical Reviewer Form	Board Members	30	1	30/60	15
Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN).	Board Members	40	1	10/60	7
Adult Expedited Amendment Review	Board Members	350	1	30/60	175

ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Form name	Type of respondents	Number of respondents	Frequency of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Ped Expedited Amendment Review	Board Members ..	150	1	30/60	75
Adult Expedited Continuing Review	Board Members ..	120	1	30/60	60
Ped Expedited Continuing Review	Board Members ..	70	1	30/60	35
Adult Expedited Study Closure	Board Members ..	20	1	20/60	7
Ped Expedited Study Closure	Board Members ..	20	1	20/60	7
Adult Expedited Study Chair Response to Required Mod.	Board Members ..	350	1	15/60	88
Ped Expedited Study Chair Response to Required Mod	Board Members ..	150	1	15/60	38
Reviewer Worksheet of Translated Documents	Board Members ..	15	1	15/60	4
Reviewer Advertisement Checklist	Board Members ..	10	1	20/60	3

Dated: August 15, 2013.

Vivian Horovitch-Kelley,

Program Analyst, National Institutes of Health.

[FR Doc. 2013–20415 Filed 8–21–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biophysics, Biochemistry and Chemistry.

Date: September 18–19, 2013.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John L Bowers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4170, MSC 7806, Bethesda, MD 20892, (301) 435–1725, *bowersj@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Immune Regulation by Cannabinoids.

Date: September 23–24, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–495–1506, *jakesse@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 16, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–20422 Filed 8–21–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Assessment of the Town Hall Meetings on Underage Drinking Prevention—(OMB No. 0930–0288)—Revision

The Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Prevention (SAMHSA/CSAP) is requesting a revision from the Office of Management and Budget (OMB) of the information collection regarding the Assessment of the Town Hall Meetings (THMs) on Underage Drinking Prevention. The current data collection has approval under OMB No. 0930–0288, which expires on November 30, 2013. The assessment will continue to collect data through two existing data collection instruments: The Organizer Survey and the Participant Form.

Clarifications

Two questions were dropped from the Organizer Survey, thus bringing the total number of questions to 30. Additionally, 10 questions have been updated to provide clarification on the intent of the questions. The following table provides a summary of the proposed question clarifications and the questions that were deleted from the Organizer Survey.

Current question/item	Clarification	Rationale for clarification
q5—Did you collaborate with other organizations to coordinate the THM event? *[No change to response options]*	q5—Did any other community-based organization (e.g., business, school) collaborate with your organization/coalition in hosting this event?	Clarifies the point of question, which is community involvement beyond the host organization.