

(2) May an investigator retain and analyze already collected data about a subject who withdraws from the research or whose participation is terminated by the investigator?

(3) Can investigators honor subjects' requests to have their data destroyed or excluded from any analysis?

(4) Should the withdrawal of a subject from a research study be documented?

(5) What is the relationship of this guidance to FDA's guidance on this issue and to the HIPAA Privacy Rule?

(6) When seeking the informed consent of subjects, what should investigators tell subjects about data retention in the event the subjects withdraw?

Of particular importance, the guidance document clarifies that when a subject chooses to withdraw from (*i.e.*, discontinue his or her participation in) an ongoing research study, or when an investigator terminates a subject's participation in such a research study without regard to the subject's consent, the investigator may retain and analyze already collected data relating to that subject, even if that data includes identifiable private information about the subject.

The guidance document announced in this notice finalizes the draft guidance entitled, "Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued," that was made available for public comment through a notice in the **Federal Register** on December 1, 2008 (73 FR 72804). OHRP received comments on the draft guidance document from 30 individuals and organizations, and those comments were considered as the guidance was finalized.

In addition to the change in the title, the final guidance document differs from the draft guidance document that was made available for public comment in the following three key ways:

(1) All content regarding biospecimens that was included in the draft guidance document has been removed from the final guidance document. This change makes the final guidance document more harmonious with the Food and Drug Administration's (FDA's) corresponding guidance entitled, "Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials," which also focuses on data retention when subjects withdraw from research and is silent on issues related to biospecimens. Furthermore, research involving the banking and use of biospecimens for research purposes is a complex, evolving area of research.

OHRP believes that guidance on the use of biospecimens obtained from subjects who subsequently withdraw from research should be addressed in the future by a more comprehensive guidance document that addresses more broadly research involving biospecimens. In the meantime, individuals with questions regarding how to handle biospecimens obtained from subjects who subsequently withdraw from a research study should contact OHRP by telephone at 240-453-6900 or 866-447-4777 or by e-mail at ohrp@hhs.gov.

(2) The final guidance document includes more examples of social and behavioral research activities in order to emphasize that the guidance applies to such research, in addition to its applicability to biomedical research.

(3) The final guidance includes a recommendation that investigators plan for the possibility that subjects will withdraw from research and that they include a discussion of what withdrawal will mean and how it will be handled in their research protocols and informed consent documents. Furthermore, the final guidance addresses the question of what investigators, when seeking the informed consent of subjects, should tell the subjects about data retention in the event the subjects withdraw.

For HHS-conducted or supported research that is regulated by FDA, FDA's guidance on this issue also should be consulted. FDA's guidance entitled, "Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials" can be found at <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0576-gdl.pdf>.

II. Electronic Access

Persons with access to the Internet may obtain the guidance document on OHRP's Web site at <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html> or <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.pdf>.

III. Comments

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

Dated: September 15, 2010.

Jerry Menikoff,
Director, Office for Human Research
Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Proposed Collection; Comment Request; Customer and Other Partners Satisfaction Surveys

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the National Institutes of Health Clinical Center (CC) 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: Customer and Other Partners Satisfaction Surveys. *Type of Information Collection Request:* Extension request. *Need and Use of Information Collection:* The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the satisfaction of various Clinical Center customers and other partners with Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; and (4) to evaluate the satisfaction of various Clinical Center customers and other partners with implemented service modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization. *Frequency of Response:* The participants will respond yearly. *Affected public:* Individuals and households; businesses and other for profit, small businesses and organizations. *Types of respondents:* These surveys are designed to assess the satisfaction of the Clinical Center's major internal and external customers with the services provided. These customers include, but are not limited to, the following groups of individuals:

Clinical Center patients, family members of Clinical Center patients, visitors to the Clinical Center, NIH intramural collaborators, private

physicians or organizations who refer patients to the Clinical Center, volunteers, vendors and collaborating commercial enterprises, small

businesses, regulators, and other organizations. The annual reporting burden is as follows:

FY 2010

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
NIH Intramural Collaborators	2000	1	.17	340
Vendors and Collaborating Commercial Enterprises	2500	1	.33	833
Professionals and Organizations Referring Patients	2000	1	.33	833
Regulators	30	1	.33	10
Volunteers	275	1	.5	138
Total	14,805	5,824

FY 2011

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	3000	1	.5	1500
Visitors to the Clinical Center	1500	1	.17	255
NIH Intramural Collaborators	1500	1	.25	375
Vendors and Collaborating Commercial Enterprises	1000	1	.25	250
Professionals and Organizations Referring Patients	3000	1	.33	1000
Regulators	30	1	.33	10
Volunteers	275	1	.33	92
Total	15,305	5,982

FY 2012

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
NIH Intramural Collaborators	1000	1	.17	170
Vendors and Collaborating Commercial Enterprises	2500	1	.25	625
Professionals and Organizations Referring Patients	3000	1	.33	1000
Regulators	25	1	.25	6
Volunteers	300	1	.25	75
Total	14,825	5,546

Estimated costs to the respondents consists of their time; time is estimated using a rate of \$10.00 per hour for patients and the public; \$30.00 for vendors, regulators, organizations and \$55.00 for health care professionals. The estimated annual costs to respondents for each year for which the generic clearance is requested is \$127,885 for 2010, \$126,895 for 2011, and \$120,730 for 2012. Estimated Capital Costs are \$7,000. Estimated Operating and Maintenance costs are \$75,000.

Requests for Comments: 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 functions of the Clinical Center and the agency, including whether the information shall 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 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: Dr. David K. Henderson, Deputy Director for Clinical Care, National Institutes of Health Clinical Center, Building 10, Room 6-1480, 10 Center Drive, Bethesda, Maryland 20892, or call non-toll free: 301-496-3515, or e-mail your request or comments, including your address to: dkh@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: September 6, 2010.

David K. Henderson,
Deputy Director for Clinical Care, CC National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC): Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the BCCEDCAC, HHS, has been renewed for a 2-year period through September 12, 2012.

For information, contact Ms. Jameka Blackmon, Designated Federal Officer, BCCEDCAC, CDC, 1600 Clifton Road, NE., M/S K57, Atlanta, Georgia, 30333, telephone (770) 488-4740; fax (770) 488-3230.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 14, 2010.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-23588 Filed 9-20-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0456]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Critical Path Programs, in cosponsorship with the Clinical Trials Transformation Initiative (CTTI), is announcing a 3-day training course for health care

professionals responsible for, or involved in, the conduct and/or design of clinical trials (clinical investigators). This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials.

DATES: The training course will be held on November 8 and 9, 2010, from 8 a.m. to 5 p.m. and on November 10, 2010, from 8 a.m. to 3 p.m.

ADDRESSES: The training course will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: Nancy Masiello, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4166, Silver Spring, MD 20993-0002, 301-796-8498, Nancy.Masiello@fda.hhs.gov.

Registration: Register by November 1, 2010, at the registration/information Web site at <https://www.trials.transformation.org/fda-clinical-investigator-training-course/>. Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site. The registration fee is \$350 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets. If you need special accommodations due to a disability, please contact Nancy Masiello at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials.

The training course is designed to provide clinical investigators with an overview of the following topics:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
 - Fundamental issues in the design and conduct of clinical trials;
 - Statistical and analytic considerations in the interpretation of trial data;
 - Appropriate safety evaluation during studies;
 - The ethical considerations and regulatory requirements for clinical trials; and
 - Application and compliance issues.
- In addition, the course should:
- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
 - Promote communication between clinical investigators and FDA;
 - Enhance investigators' understanding of FDA's role in experimental medicine; and
 - Improve the quality of data while enhancing subject protection in the performance of clinical trials.

On November 8, 2010, the course will address the role of FDA in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an "investigator's brochure," i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presentations will also discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. On November 9, 2010, the course will include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 10, 2010, the course will include discussions of safety assessment in clinical trials, including hepatic and cardiovascular safety, approaches to special populations (e.g., pregnant women and pediatrics), and breakout sessions to discuss how to put together an application, including related compliance issues.

Dated: September 16, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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