

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 14, 2010.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *GLAASS Financial, LLC*; to become a bank holding company through the acquisition of 36.4 percent of the voting shares of EMSWATER Financial, LLC, both in Exeter, Nebraska. In connection with this application, Applicant also has applied to acquire EMSWATER Financial, LLC and First National Insurance Agency, Inc., both of Exeter, Nebraska pursuant to section 225.28(b)(11)(A) of Regulation Y.

Board of Governors of the Federal Reserve System, September 16, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010-23522 Filed 9-20-10; 8:45 am]

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FEDERAL RESERVE SYSTEM

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 12 p.m., Monday, September 20, 2010.

The business of the Board requires that this meeting be held with less than one week's advance notice to the public, and no earlier announcement of the meeting was practicable.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

Matters To Be Considered

1. Implications of Dodd-Frank Reform Act for Board Organization and Staffing.

FOR MORE INFORMATION PLEASE CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202-452-2955.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: September 17, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010-23669 Filed 9-17-10; 4:15 pm]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Guidance on Withdrawal of Subjects From Research: Data Retention and Other Related Issues

AGENCY: Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), within the Office of the Assistant Secretary for Health, is announcing the availability of a guidance document entitled, "Guidance on Withdrawal of Subjects From Research: Data Retention and Other Related Issues." The guidance document provides OHRP's first formal guidance on this topic. The document, which is available on the OHRP Web site at <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html> or <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.pdf>, is intended primarily for institutional review boards (IRBs), investigators, and funding agencies that may be responsible for the review or oversight of human subject research conducted or supported by the Department of Health and Human Services (HHS). 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.

DATES: Comments on OHRP guidance documents are welcome at any time.

ADDRESSES: Submit written requests for a single copy of the guidance document entitled, "Guidance on Withdrawal of Subjects From Research: Data Retention and Other Related Issues," to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-402-2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit written comments to COMMENTS ON SUBJECT WITHDRAWAL GUIDANCE, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to ohrp@hhs.gov or via facsimile at 240-402-2071.

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, PhD, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail Irene.StithColeman@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of a guidance document entitled, "Guidance on Withdrawal of Subjects From Research: Data Retention and Other Related Issues." The guidance document provides OHRP's first formal guidance on this topic. The document is intended primarily for IRBs, investigators, and funding agencies that may be responsible for the review or oversight of human subject research conducted or supported by HHS.

The guidance document applies to non-exempt human subjects research conducted or supported by HHS. The guidance addresses the following six topics:

(1) What does it mean when a subject withdraws from a research study?

(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.

[FR Doc. 2010-23517 Filed 9-20-10; 8:45 am]

BILLING CODE 4150-36-P

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: