

determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 25, 2006.

**A. Federal Reserve Bank of New York** (Anne McEwen, Financial Specialist) 33 Liberty Street, New York, New York 10045-0001:

1. *NRW.Bank Duesseldorf, and WestLB Beteiligungsholding GmbH Duesseldorf*, both of Duesseldorf, Germany; to engage through its subsidiaries NY Credit Real Estate GP LLC, New York, NY; New York Credit Real Estate Fund, L.P., New York, NY; New York Credit Advisors LLC, New York, NY; and BOA Lending L.L.P., Las Vegas, NV, in extending credit and servicing loans and acting as a financial or investment advisor, through a joint venture, pursuant to section 225.28(b)(1) and 225.28(b)(6) of Regulation Y.

Board of Governors of the Federal Reserve System, July 3, 2006.

**Jennifer J. Johnson**,  
Secretary of the Board.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Protection of Human Subjects: Interpretation of Assurance Requirements

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services (HHS) is providing public notice to clarify a requirement contained in the Federalwide Assurance (FWA) form for international (non-U.S.) institutions, approved by the Office for

Human Research Protections (OHRP) under the HHS protection of human subjects regulations. HHS clarifies that the requirements of HHS regulations must be satisfied for all HHS-conducted or -supported research covered by an FWA, regardless of whether the research is conducted domestically or internationally. To date, HHS has not deemed any other procedural standards equivalent to the protection of human subjects.

#### FOR FURTHER INFORMATION CONTACT:

Irene Stith-Coleman, Office for Human Research Protections, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, (240) 453-6900, facsimile (301) 402-2071; e-mail: [Irene.Stith-Coleman@hhs.gov](mailto:Irene.Stith-Coleman@hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Department of Health and Human Services (HHS), through the Office for Human Research Protections (OHRP), regulates research involving human subjects conducted or supported by HHS. The Federal Policy for the Protection of Human Subjects (the Common Rule), adopted by 14 other departments and agencies, is codified for HHS at 45 CFR part 46, subpart A.

The HHS protection of human subjects regulations apply to all research involving human subjects conducted, supported or otherwise subject to regulation by HHS. 45 CFR 46.101(a). Each institution engaged in HHS-conducted or -supported human subjects research must provide written assurance, satisfactory to the Secretary of HHS, that it will comply with the HHS protection of human subjects regulations. [45 CFR 46.103(a)]

The FWA is the only form of assurance currently accepted by OHRP. The FWA was designed to be used by HHS as well as the other departments and agencies that have adopted the Common Rule. The FWA consists of two documents, the FWA form and the FWA Terms of Assurance, which are incorporated by reference into the FWA form. There are separate FWA forms and Terms of Assurance for U.S. domestic institutions and for international (non-U.S.) institutions. The "Applicability" section of the FWA form for international (non-U.S.) institutions includes several national and international procedural standards to which the institution can indicate its adherence, including the HHS regulations for the protection of human subjects, 45 CFR part 46. The FWA Terms of Assurance for international (non-U.S.) institutions state as follows:

If a U.S. Federal department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided by the U.S. Federal Policy for the Protection of Human Subjects, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided above [the requirements of the U.S. Federal Policy], consistent with the requirements of section 101(h) of the U.S. Federal Policy for the Protection of Human Subjects.

##### II. Clarification of HHS' Position

Some regulated institutions may have been confused by the fact that several national and international procedural standards are listed on the FWA form for international (non-U.S.) institutions, and interpreted this to mean that non-U.S. institutions have a choice of whether or not the requirements of 45 CFR part 46 must be met for HHS-conducted or -supported research conducted at their institutions. Such an interpretation would be erroneous. For HHS-conducted or -supported research, all institutions holding an OHRP-approved FWA and engaged in such research must comply with the requirements of 45 CFR part 46. That compliance is required regardless of whether the institution marked one or more other procedural standards on the FWA form for international (non-U.S.) institutions as a standard to which the institution committed itself to comply.

For example, if a non-U.S. institution selects a procedural standard on its FWA that does not explicitly require continuing review by an institutional review board (IRB) at least annually, the institution still must ensure that an IRB designated under the FWA conducts continuing review of non-exempt human subjects research supported by HHS at intervals appropriate to the degree of risk, but no less than once per year, as required by HHS regulations at 45 CFR 46.109(e). Likewise, if a non-U.S. institution selects a procedural standard on its FWA that does not explicitly require that an IRB retain IRB records for at least three years after the completion of research which is conducted, the institution still must ensure that such IRB records are retained for at least three years after completion of any non-exempt human subjects research supported by HHS, as required by HHS regulations at 45 CFR 46.115(b).

As stated in the FWA Terms of Assurance for international (non-U.S.) institutions, the Secretary has the authority to determine that alternative procedural standards provide protections at least equivalent to those provided by the HHS protection of

human subjects regulations, and to allow compliance with the alternative procedures rather than with the HHS regulatory requirements. 45 CFR 46.101(h). However, to date, the Secretary has not made any determinations that other procedures provide equivalent protections to those afforded by the HHS regulations. HHS continues to consider whether, and how, to implement the regulatory authority to allow compliance with alternative procedural standards in place of compliance with 45 CFR part 46. One or more determinations that alternative procedural standards provide protections at least equivalent to those of 45 CFR part 46 may be made at some time in the future, but until such time, 45 CFR part 46 is the procedural standard which must be complied with for all HHS-conducted or -supported human subjects research conducted domestically or internationally.

The heads of other Common Rule departments and agencies may independently reach different conclusions about which, if any, procedural standard(s) to accept as providing protections at least equivalent to the Common Rule. This is among the reasons that multiple procedural standards are included on the FWA form for international (non-U.S.) institutions, which may be relied upon by all Common Rule departments and agencies.

HHS believes that this view provides the greatest protection to human subjects of research conducted or supported by HHS, and is the most ethically defensible position.

Dated: June 23, 2006.

**Bernard A. Schwetz,**

Director, Office for Human Research Protections.

[FR Doc. E6-10511 Filed 7-6-06; 8:45 am]

BILLING CODE 4150-36-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

#### Availability of Funding Opportunity Announcement

*Funding Opportunity Title/Program Name:* Performance Outcomes Measures Project.

*Announcement Type:* Initial.

*Funding Opportunity Number:* Program Announcement No. HHS-2006-AoA-PO-0612.

*Statutory Authority:* The Older Americans Act, Public Law 106-501.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.048, Title IV and Title II, Discretionary Projects.

*Dates:* The deadline date for the submission of applications is August 15, 2006.

#### I. Funding Opportunity Description

The purpose of this announcement is to solicit applications for POMP projects that will complete work on the POMP-developed performance measurement surveys and enhance their utility for the Aging Network as follows:

- Conduct validity tests for POMP surveys.
- Conduct pilot testing for statewide performance measurement methodology.
- Assist in the development of performance measurement toolkits for use by the Aging network.

A detailed description of the funding opportunity may be found at <http://www.grants.gov>.

#### II. Award Information

1. *Funding Instrument Type:* Grants.
2. *Anticipated Total Priority Area Funding per Budget Period:* These

grants are two-year projects. For the first year, AoA intends to make available, under this program announcement, grant awards for 6 to 10 projects at a federal share of approximately \$35,000-\$50,000. The maximum award will be \$50,000. Second year award amounts will be similar to first year amounts, contingent on the availability of federal funds and satisfactory progress.

#### III. Eligibility Criteria and Other Requirements

##### 1. Eligible Applicants

Eligibility for grant awards is limited to State Agencies on Aging.

##### 2. Cost Sharing or Matching

Grantees are required to provide at least 25 percent of the total program costs from non-federal cash or in-kind resources in order to be considered for the award.

##### 3. DUNS Number

All grant applicants must obtain a D-U-N-S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number is free and easy to obtain from: [http://www.dnb.com/US/duns\\_update/](http://www.dnb.com/US/duns_update/).

##### 4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal

Programs, is not applicable to these grant applications.

#### IV. Application and Submission Information

##### 1. Address To Request Application Package

Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Office of Evaluation, Washington, DC 20201, by calling 202-357-0145, or online at <http://www.grants.gov>.

Please note AoA is requiring applications for this announcement to be submitted electronically through <http://www.grants.gov>. The Grants.gov registration process can take several days. If your organization is not currently registered with [www.grants.gov](http://www.grants.gov), please begin this process immediately. For assistance with <http://www.grants.gov>, please contact Arthur Miller at AoA's Grants.gov helpdesk at 202-357-3438. At <http://www.grants.gov>, you will be able to download a copy of the application packet, complete it off-line, and then upload and submit the application via the Grants.gov Web site.

##### 2. Address for Application Submission

Applicants unable to submit their application via <http://www.grants.gov> may request permission to submit a hard copy from Stephen Daniels, Director, Office of Grants Management at [Stephen.Daniels@aoa.hhs.gov](mailto:Stephen.Daniels@aoa.hhs.gov).

With prior approval, applications may be mailed to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, Washington, DC 20201, attn: Stephen Daniels.

With prior approval, Applications may be delivered (in person, via messenger) to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, One Massachusetts Avenue, NW., Room 4604, Washington, DC 20001, attn: Stephen Daniels.

If you elect to mail or hand deliver your application, you must submit one original and two copies of the application. Instructions for electronic mailing of grant applications are available at <http://www.grants.gov>.

##### 3. Submission Dates and Times

To receive consideration, applications must be received by the deadline listed in the **Dates** section of this Notice.

#### V. Responsiveness Criteria

Each application submitted will be screened to determine whether it was received by the closing date and time.