| Trans No. | Acquiring | Acquired | Entities |
|---|---|---|---|
| **TRANSACTIONS GRANTED EARLY TERMINATION—11/14/2008** | | | |
| 20081781 ..... | Aon Corporation ..... | Benfield Group Limited ..... | Benfield Group Limited |
| 20090090 ..... | Spectrum Equity Investors IV, L.P ..... | RiskMetrics Group, Inc. ..... | RiskMetrics Group, Inc. |

**FOR FURTHER INFORMATION CONTACT:** Sandra M. Peay, Contact Representative, or Renee Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580 (202) 326–3100.

By Direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. E8–28164 Filed 11–28–08; 8:45 am]

**BILLING CODE 6750–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–New]**

### Agency Information Collection Request. 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

Proposed Project: Evaluation of the National Bone Health Campaign Pilot Site Project—OMB No. 0990–NEW—Office on Women's Health (OWH)

*Abstract:* The Office on Women's Health (OWH) is requesting clearance for forms to evaluate the implementation and effectiveness of the revised BodyWorks program; an obesity prevention program targeting parents and girls that highlights behaviors known to improve bone health. Using a technical assistance model, the revised BodyWorks program will be implemented by local coalitions in three pilot sites. Clearance is also requested for forms to assess the success of this technical assistance model.

ESTIMATED ANNUALIZED BURDEN TABLE

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| Parent/Caregiver participant in the Revised BodyWorks program. | Parent/Caregiver Pre test Questionnaire. | 171 | 1 | 30/60 | 85.5 |
| | Parent/Caregiver Post test Questionnaire. | 153 | 1 | 30/60 | 76.5 |
| | Parent/Caregiver Session Evaluation Forms (10 forms). | 153 | 10 | 3/60 | 76.5 |
| Parent/Caregiver Revised BodyWorks program comparison group participant. | Parent/Caregiver Pre test Questionnaire. | 63 | 1 | 30/60 | 31.5 |
| | Parent/Caregiver Post test Questionnaire. | 50 | 1 | 30/60 | 25 |
| Adolescent participant in the Revised BodyWorks program. | Adolescent Pretest Questionnaire ... | 228 | 1 | 30/60 | 114 |
| | Adolescent Post test Questionnaire | 204 | 1 | 30/60 | 102 |
| | Adolescent Session Evaluation Forms (10 forms). | 204 | 10 | 3/60 | 102 |
| Adolescent Revised BodyWorks program comparison group participant. | Adolescent Pre test Questionnaire | 63 | 1 | 30/60 | 31.5 |
| | Adolescent Post test Questionnaire | 50 | 1 | 30/60 | 25 |
| Trainers of the Revised BodyWorks program. | Facilitator Feedback Forms (10 forms). | 22 | 10 | 5/60 | 18.3 |
| Coalition leaders, members, and site coordinators. | Coalition Pre test Survey ..... | 86 | 1 | 20/60 | 28.7 |
| | Coalition Post test Survey ..... | 72 | 1 | 30/60 | 36 |
| Total Hours ..... | ..... | ..... | ..... | ..... | 752.5 |

**John Teeter,**
*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*
[FR Doc. E8–28389 Filed 11–28–08; 8:45 am]
**BILLING CODE 4150–33–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Draft Guidance on Important Considerations for When Participation of Human Subjects in Research Is Discontinued

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

**ACTION:** Notice.

**SUMMARY:** The Office for Human Research Protections (OHRP), Office of Public Health and Science, is announcing the availability of a draft guidance document entitled, ''Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued,'' and is seeking comment on the draft guidance. The draft guidance document, when finalized, would provide OHRP's first formal guidance on this topic. The draft document, which is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/,* 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). OHRP will consider comments received before issuing the final guidance document.

**DATES:** Submit written comments by January 30, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled, ''Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued,'' 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 draft guidance document.

You may submit comments by any of the following methods:

- *E-mail: discontinueparticipation@hhs.gov.* Include ''Guidance on Discontinuation of Subject Participation'' in the subject line.
- *Fax:* 301–402–2071.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:* Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received within the public comment period, including any personal information, will be made available to the public upon request.

**FOR FURTHER INFORMATION CONTACT:** Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240–453–6900; e-mail *Michael.Carome@hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The OHRP, Office of Public Health and Science, is announcing the availability of a draft guidance document entitled, ''Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued.'' The draft guidance document, when finalized, would provide OHRP's first formal guidance on this topic. The draft 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 proposed guidance document would apply to non-exempt human subjects research conducted or supported by HHS. It would provide guidance on important considerations for when participation of human subjects in research is discontinued, either because a subject voluntarily chooses to discontinue participation during the course of the research, or because an investigator terminates a subject's participation in the research without regard to the subject's consent. In particular, the proposed guidance addresses the following topics:

(1) What does the word *participation,* as used in HHS regulations at 45 CFR part 46, subpart A, mean?

(2) What does *discontinuation of a subject's participation* in research mean?

(3) The distinction between a *complete* versus a *partial* discontinuation of a subject's participation in research.

(4) Clarification that investigators may continue to analyze already collected individually identifiable private information about a subject even when the subject's participation has been completely discontinued.

(5) Considerations regarding the discontinuation of a subject's participation in emergency research for which the requirements for obtaining informed consent were waived by the IRB.

(6) Clarification that research can continue to involve human subjects even when the participation of all subjects has been completed or discontinued.

(7) Recommendations for documenting the discontinuation of subjects' participation in research.

OHRP notes that the Food and Drug Administration (FDA) is publishing elsewhere in this issue a notice announcing the availability of a final guidance document entitled ''Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.'' OHRP believes the interpretations provided in the proposed draft guidance are harmonious with those provided in FDA's final guidance document. In particular, FDA's guidance document explains that under applicable FDA law and regulations, data collected on study subjects enrolled in an FDA-regulated clinical trial up to the time of subject withdrawal must remain in the trial database in order for the study to be scientifically valid. Likewise, OHRP's proposed draft guidance clarifies that when a subject informs an investigator of his/her decision to discontinue participation in research, or an investigator decides to terminate a subject's participation regardless of the subject's consent, the investigator may continue to analyze already collected individually identifiable private information about that subject. In addition, OHRP believes that its proposed draft guidance document is consistent with the HIPAA Privacy Rule (45 CFR part 160 and Subparts A and E of 56 CFR part 164), where applicable. The Privacy Rule gives an individual the right to revoke Authorization in writing, except to the extent a covered entity has taken action in reliance on the Authorization. In the context of research, this reliance exception permits the continued use and disclosure of protected health information already obtained pursuant to the Authorization prior to its revocation, to the extent necessary to protect the integrity of the research study.

#### II. Electronic Access

Persons with access to the Internet may obtain the draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.*