**RETRIEVABILITY:**

The data are retrieved by an individual identifier *i.e.*, name of beneficiary.

**SAFEGUARDS:**

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

**RETENTION AND DISPOSAL:**

CMS will retain information for a total period of 10 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

**SYSTEM MANAGER AND ADDRESS:**

Director, Office of Clinical Standards and Quality, CMS, Room S2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

**NOTIFICATION PROCEDURE:**

For the purpose of access, the subject individual should write to the system manager who will require the system name, address, age, gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

**RECORD ACCESS PROCEDURE:**

For the purpose of access, use the same procedures outlines in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5).

**CONTESTING RECORDS PROCEDURES:**

The subject individual should contact the system manager named above and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

**RECORD SOURCE CATEGORIES:**

Records maintained in this system are derived from Carrier and Fiscal Intermediary Systems of Records, Common Working File System of Records, clinics, institutions, hospitals and group practices performing the procedures, and outside registries and professional interest groups.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 05–18489 Filed 9–19–05; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission of OMB Review; Comment Request

*Title:* Compassion Capital Fund Evaluation.

*OMB No.:* New Collection.

*Description:* This proposed information collection activity is for two rounds of surveys to be completed by faith-based and community organizations participating in two studies within the Compassion Capital Fund (CCF) evaluation project. The first survey will be conducted as a baseline survey and the second will be a follow-up survey conducted several months later.

The CCF evaluation is an important opportunity to examine the effectiveness of the Compassion Capital Fund in meeting its objective of improving the capacity of faith-based and community organizations. The evaluation includes three distinct studies: a random assignment impact study, an outcome study, and a retrospective study. This notice pertains to the impact and outcome studies. The impact study will involve up to 1,000 faith-based and community organizations that seek services from CCF-funded intermediary organizations. Information will be collected from these faith-based and community-based organizations to assess change and improvement in various areas of capacity. The study design includes the random assignment of faith-based and community organizations to either a treatment group that receives capacity-building services from a CCF intermediary grantee or to a control group that does not. The impact of the services provided by intermediaries, primarily through sub-awards and/or technical assistance (TA), will be determined by comparing the changes in organizational and service capacity of the recipient organizations with those of the control group.

The outcome study will examine changes and improvements in a representative sample of about 750 faith-based and community organizations served by all CCF intermediaries operating in FY2005 and FY2006, except those already part of the impact study. The survey instruments will be used to track changes in the faith-based and community organizations' organizational capacity between baseline and follow-up.

*Respondents:* The respondents for both studies will be faith-based and community organizations that seek sub-awards or TA from CCF intermediary grantees. The baseline survey will be primarily self-administered and is expected to be completed as part of the intermediary's sub-award application or TA request process. The follow-up survey also will be primarily self-administered and contain questions similar to those in the baseline survey as well as additional questions related to services received from the intermediary or other organizations. It is expected that the follow-up survey will be administered approximately 12 months after the baseline survey. As needed to increase response rates, the survey will be administered by telephone to organizations that do not initially return a completed survey.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Baseline Survey | 1,750 | 1 | .33 hours (approx. 20 minutes) | 577.5 |
| Follow-up Survey | 1,750 | 1 | .42 hours (approx. 25 minutes) | 735 |
| Estimated Total Annual Burden Hours | 3,500 | | | 1,312.5 |

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov*.

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, *E-mail address: Katherine_T._Astrich@omb.eop.gov*.

Dated: September 13, 2005.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 05–18735 Filed 9–19–05; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Industry Exchange Workshop on Food and Drug Administration Clinical Trials Statutory and Regulatory Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Cincinnati District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

*Date and Time*: The public workshop will be held on Wednesday, December 7, 2005, from 8:15 a.m. to 5 p.m. and Thursday, December 8, 2005, from 8:15 a.m. to 4 p.m.

*Location*: The public workshop will be held at The Westin Cincinnati, 21 East 5th St., Cincinnati, OH 45202–3160, 513–621–7700, FAX: 513–852–5670.

*Contact*: Marie Falcone, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–717–3703, FAX: 215–597–5798, e-mail: *mfalcone@ora.fda.gov*.

*Registration*: Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of $485 (member), $560 (nonmember), or $460 (government employee nonmember) (includes a 1-year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101, Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/FDA_Conference.htm*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–345–7749, or FAX: 215–345–7369, or e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at The Westin Cincinnati at the reduced conference rate, contact The Westin Cincinnati see *Location*) through November 7, 2005, or until the SoCRA room block is full.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The ''FDA Clinical Trials Statutory and Regulatory Requirements'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

The following topics will be discussed at the workshop:

- FDA and confidence in the conduct of clinical research;
- Medical device, drug, and biological product aspects of clinical research;
- Investigator initiated research;
- Pre-investigational new drug application (IND) meetings and FDA meeting process;
- Informed consent requirements;
- Ethics in subject enrollment;
- FDA regulation of Institutional Review Boards;
- Electronic records requirements;
- Adverse event reporting;
- How FDA conducts bioresearch inspections; and
- What happens after the FDA inspection.