

the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 571.1 and 571.6 have been approved under 0910–0546.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: September 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Society of Clinical Research Associates-Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Educational Conference Co-Sponsored With the Society of Clinical Research Associates (SoCRA).” The public workshop regarding FDA’s clinical trial requirements is designed to aid the clinical research professional’s understanding of the mission, responsibilities, and authority of FDA, and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs).

Individual FDA representatives will discuss the informed consent process including the informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRBs, and of research sponsors.

Date and Time: The public workshop will be held on November 6 and 7, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the JW Marriott Atlanta Buckhead Hotel, 3300 Lenox Rd. NE., Atlanta, GA 30326, 404–262–3344.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of \$185.00 plus applicable taxes (available until October 15, 2013, or until the SoCRA room block is filled).

Contact Person: JoAnn Pittman, Food and Drug Administration, 60 Eighth Street NE., Atlanta, GA 30309, voicemail: 404–253–1272, FAX: 404–253–1202, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: SoCRAMail@aol.com, Web site: www.socra.org.

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows:

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| SoCRA member | \$575.00. |
| SoCRA nonmember (includes membership). | \$650.00. |
| Federal Government SoCRA member. | \$450.00. |
| Federal Government SoCRA non-member. | \$525.00. |
| FDA Employee | (Free) Fee Waived. |

If you need special accommodations due to a disability, please contact SoCRA, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or email: SoCRAMail@aol.com at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category

1 Credit(s)TM. Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education for physicians:* SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for nurses:* SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205–3–A–09.

Registration instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to “SoCRA”. Mail to: Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914.

To register via the Internet, go to: http://www.socra.org/html/FDA_Conference.htm. (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document is published in the **Federal Register**).

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the public workshop, contact SoCRA, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, or email: SoCRAMail@aol.com.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA’s Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working with FDA’s Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working

Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with FDA—Why, When, and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the safety and effectiveness of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government Agencies to small businesses.

Dated: September 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden

estimate below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Uniform Project Description and Application Guide—SF 424 Non-Construction.

OMB No. 0915-xxxx—New.

Abstract: The Health Resources and Services Administration is requesting clearance for the Uniform Project Description (UPD) and Application Guide to be used in conjunction with the SF–424 Non-Construction application kit by program offices to solicit application information for grants and cooperative agreements.

Need and Proposed Use of the Information: The HRSA SF–424 Application Guide provides detailed standard instructions to help applicants prepare and submit applications electronically to HRSA through Grants.gov. The Guide is used in conjunction with the HRSA UPD that provides a menu of narratives from which the program office can select for inclusion within a program-specific grant or cooperative agreement funding opportunity announcement (FOA). UPD text options selected for use in a given FOA define the required project description portion to the applicant. The ability to pick and choose standard language that is appropriate for any given FOA reduces the burden associated with application preparation by eliminating irrelevant portions of the application for a given announcement. In addition, it provides consistency in the application review process.

Much of the information required in applications for project grants and

cooperative agreements is required by HHS Uniform Administrative Requirements for Grants and Cooperative Agreements at the following citations: 45 CFR part 74, 45 CFR part 92, applicable program regulations in 42 CFR chapters I and IV, and applicable administrative regulations in 45 CFR subtitle A.

HRSA program offices, grants management officials, and expert non-federal and federal panel reviewers use the collected information provided through grant applications to select and award discretionary grants. Program offices use the information to ensure that the authorizing legislation and applicable program regulations will be implemented through any funded project, and that applicant entities are eligible to receive HRSA funds. Expert non-federal and federal objective review panelists score the information provided in applications as they evaluate applications in the context of the FOA's published criteria to ensure that the best proposed projects are recommended for funding. Grants management officials use the information to ensure appropriate federal stewardship of federal grant funds and that proposed budgeted project costs are allowable, allocable, and reasonable.

Likely Respondents: Eligible organizations may include state, local, and Indian Tribal governments; institutions of higher education; other non-profit organizations (including faith-based, community-based, and Tribal organizations); and hospitals. In limited cases, foreign organizations may apply.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.