DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–OPHS–2011–0014]

Guidance on Exculpatory Language in Informed Consent, Draft

AGENCY: Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health and the Food and Drug Administration (FDA), are announcing the availability of a draft guidance entitled, ''Guidance on Exculpatory Language in Informed Consent.'' The draft guidance, when finalized, will represent OHRP's and FDA's current thinking on this topic and will supersede OHRP's November 15, 1996 guidance document entitled '''Exculpatory Language' in Informed Consent'' and question number 52 in FDA's January 1998 guidance entitled, ''Institutional Review Boards Frequently Asked Questions—Information Sheet Guidance for Institutional Review Boards and Clinical Investigators.'' The draft guidance is intended primarily for institutional review boards (IRBs), investigators, sponsors, and funding agencies that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS or regulated by FDA.

DATES: Submit written comments by November 7, 2011.

ADDRESSES: Submit written requests for copies of the draft Guidance on Exculpatory Language in Informed Consent document to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway,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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.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 identified by docket ID number HHS–OPHS–2011–0014, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Enter the above docket ID number in the ''Enter Keyword or ID field and click on ''Search.'' On the next page, click the ''Submit a Comment'' action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:* Irene Stith-Coleman, PhD., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

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* or Sara Goldkind, M.D., Office of Good Clinical Practice, 10903 New Hampshire Ave., WO32–5110, Silver Spring, MD 20993, 301–796–8342; e-mail *Sara.Goldkind@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a draft guidance entitled, ''Guidance on Exculpatory Language in Informed Consent.'' The draft guidance is intended primarily for institutional review boards (IRBs), investigators, sponsors, and funding agencies that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS or regulated by FDA. This guidance, which is available on the OHRP Web site at *http://www.hhs.gov/ohrp/newsroom/rfc/index.html* and the FDA Web site at *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm,* is intended to assist IRBs in making the required regulatory determinations when reviewing research under 21 CFR 50.20 and 45 CFR 46.116 by providing recommendations regarding what language is considered to be exculpatory under HHS and FDA regulations, and thus inappropriate to include in informed consent. The draft guidance should also help clinical investigators and sponsors better understand the regulatory requirements as to what language is permissible to include in informed consent. The draft guidance, when finalized, will represent OHRP's and FDA's current thinking on this topic and will supersede OHRP's November 15, 1996 guidance document entitled, '' 'Exculpatory Language' in Informed Consent'' and question number 52 in FDA's January 1998 guidance entitled, ''Institutional Review Boards Frequently Asked Questions—Information Sheet Guidance for Institutional Review Boards and Clinical Investigators.''

To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the agencies' regulatory requirements and guidance for human subject research. This draft guidance document was developed as part of these efforts. OHRP and FDA believe that it will be most helpful to the regulated community to issue a joint guidance document which will clearly demonstrate the agencies' harmonious approach to the topic of what language could be considered exculpatory and thus prohibited in informed consent versus what language could be acceptable in informed consent.

OHRP and FDA are issuing this as draft guidance because the agencies have revised and clarified what constitutes exculpatory language in informed consent and therefore prohibited under 21 CFR 50.20 and 45 CFR 46.116 in response to numerous questions and comments from the IRB and research communities. The draft guidance includes a detailed discussion about what OHRP and FDA consider to be exculpatory language, examples of informed consent language that OHRP and FDA would consider to be acceptable, and examples of informed consent language that OHRP and FDA would consider to be exculpatory.

This draft guidance is part of the Information Sheet Guidance Initiative, announced in the Federal Register of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as ''Information Sheets,'' these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are updated, consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue guidances that address current issues, and develop new guidance documents as needed.

The draft guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The draft guidance, when finalized, will represent OHRP's and FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind OHRP or FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov, http://www.hhs.gov/ohrp/newsroom/rfc/index.html,* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.*

III. Request for Comments

OHRP and FDA are making their joint draft guidance document available for public comment. The guidance document will be finalized and issued after the public comments have been considered.

Dated: September 1, 2011.

Jerry Menikoff,

Director, Office for Human Research Protections.

David Dorsey,

Acting Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration.

[FR Doc. 2011–22883 Filed 9–6–11; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Postponement of Release of Draft NTP Monograph on Potential Developmental Effects of Cancer Chemotherapy During Pregnancy and Panel Meeting To Peer Review Draft Monograph

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Notice of postponement of draft NTP monograph and peer review panel meeting.

SUMMARY: The NTP is postponing the release of the Draft NTP Monograph on Potential Developmental Effects of Cancer Chemotherapy during Pregnancy and the peer review panel meeting. Release of the draft monograph was scheduled for September 9, 2011, and the meeting for October 19–20, 2011; both were announced on August 17, 2011 (76 FR 51034). Information about rescheduling the release of the draft monograph and the peer review will be announced in the **Federal Register** and posted on the NTP Web site at *http://ntp.niehs.nih.gov/go/36639.*

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, NTP Designated Federal Officer, (919) 541–9834, *whiteld@niehs.nih.gov.*

Dated: August 29, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011–22823 Filed 9–6–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–11–0765]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Fellowship Management System, OMB No. 0920–0765 exp. 03/31/2014—Revision—Scientific Education and Professional Development Program Office (SEPDPO), Office of Surveillance, Epidemiology and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

SEPDPO requests an additional three years to continue CDC's use of the online Fellowship Management System (FMS) for its electronic application and directory processes that allow individuals to apply to fellowships online and tracks applicant and alumni information; and a revision that will allow public health agencies and organizations to submit fellowship assignment proposals electronically, using FMS.

The mission of SEPDPO is to provide leadership in public health training and education, and manage innovative, evidence-based programs to prepare the health workforce to meet public health challenges of the 21st century. Professionals in public health, epidemiology, medicine, economics, information science, veterinary medicine, nursing, public policy, and other related professions seek opportunities, through CDC fellowships, to broaden their knowledge, skills, and experience to improve the science and practice of public health. CDC fellows are assigned to state, tribal, local and territorial public health agencies; federal government agencies, including CDC, and HHS operational divisions, such as Indian Health Service; and to nongovernmental organizations, including academic institutions, tribal organizations, and private public health organizations.

FMS provides an efficient and effective way for processing fellowship application data, selecting qualified candidates, maintaining a current alumni database, documenting the impact of the fellowships on alumni careers, and generating reports. This proposed revision will provide a secure site within this existing electronic system for designated employees of public health agencies and organizations to submit fellowship assignment proposals electronically.

Designated employees of public health agencies or organizations will answer a standardized set of core questions within FMS about the proposed assignments, including the type of public health agency or organization submitting the proposal; proposed fellow activities, including training and opportunities for service and collaboration; and how the fellow will be supported, including the type and extent of mentorship and supervision the fellow will receive.

This revision enhances FMS to include a function that will result in a standardized process for submitting and reviewing host assignment proposals across fellowships. The electronic assignment proposal process that FMS provides optimizes the matching of qualified fellowship candidates with host sites and will result in an optimal fit between fellows and their assignments — ultimately leading to