section(s) of the draft guidance document that address each recommendation.

(1) *SACHRP Recommendation:* OHRP and the Food and Drug Administration should issue expanded guidance (a) clarifying that final approval of stipulations from convened meeting review (*i.e.,* ''contingent approval'') is not a form of expedited review; and (b) permitting IRBs to describe in their written policies and procedures ''stipulation mechanisms'' for verifying changes required for approval of proposed research under which (i) the IRB Chairperson, or designated member-reviewer, may exercise reasonable judgment in verifying that the stipulations of the convened IRB have been satisfied; and (ii) a qualified IRB administrator may verify that the investigator has implemented specific language (*e.g.,* in the protocol, informed consent document, or advertisements) dictated by the convened IRB (and requiring no subjective judgment on the part of the administrator).

OHRP's Response: OHRP agrees with this recommendation. Sections B and D of the draft guidance document in particular reflect OHRP's implementation of SACHRP's recommendation.

(2) *SACHRP Recommendation:* OHRP should modify its guidance on continuing review so that, when the study has been reviewed by the IRB (at a convened meeting or through an expedited process, as appropriate) and the IRB finds that there are no substantive concerns in terms of the risk-benefit relationship, informed consent, or other key protections, suspension of all research activity is not required when the expiration date passes, provided that IRB review is completed within 30 days past the expiration date.

OHRP's Response: OHRP agrees in general with the intent of this recommendation. OHRP has addressed this recommendation through its discussion of conditional approval by the IRB at the time of continuing review in section G of the draft guidance document.

II. Electronic Access

The draft guidance document is available on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.*

III. Request for Comments

OHRP requests comments on its draft guidance document. OHRP will consider all comments before issuing a final guidance document.

Dated: November 3, 2009.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. E9–26830 Filed 11–5–09; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Institutional Review Board Continuing Review of Research

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

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 IRB Continuing Review of Research,'' and is seeking comment on the draft guidance. The draft guidance document, when finalized, will represent OHRP's current thinking on this topic and will supersede OHRP's January 15, 2007 guidance document entitled ''Guidance on Continuing Review,'' available at *http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm.* 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, Department of Health and Human Services (HHS) funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by January 5, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled, ''Guidance on IRB Continuing Review of Research,'' 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–2009–0016, 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 Web page, click on the ''Submit a Comment'' action and follow the instructions.
- *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, including any personal information, will be posted without change to *http://www.regulations.gov.*

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

A. Overview

OHRP is announcing the availability of a draft guidance document entitled, ''Guidance on IRB Continuing Review of Research.'' The draft guidance document, when finalized, will represent OHRP's current thinking on this topic and will supersede OHRP's January 15, 2007 guidance document entitled ''Guidance on Continuing Review,'' available at *http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm.* The draft document is intended primarily for IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subject research conducted or supported by HHS.

To enhance human subject protections and reduce regulatory burden, OHRP and the Food and Drug Administration have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. The draft guidance document was developed as a part of these efforts.

The guidance document would apply to non-exempt human subjects research conducted or supported by HHS. It provides guidance on the HHS regulations for the protection of human research subjects at 45 CFR part 46 related to IRB continuing review of research. In particular, the guidance addresses the following major topics:

(1) Key IRB Considerations when Evaluating Research Undergoing Continuing Review;

(2) Process for Conducting Continuing Review;

(3) Additional Considerations for Continuing Review of Multicenter Research Projects;

(4) When Expedited Review Procedures may be Used by an IRB for Continuing Review;

(5) Determining the Frequency of Continuing Review;

(6) Determining the Effective Date of Initial IRB Approval and the Dates for Continuing Review;

(7) Lapses in IRB Approval;

(8) Communicating the IRB's Continuing Review Determination to Investigators and the Institution;

(9) Suspension or Termination of IRB Approval of Research or Disapproval of Research at the Time of Continuing Review;

(10) Identifying the Point When Continuing Review is No Longer Necessary; and

(11) Continuing Review is Not Required for Exempt Human Subjects Research Projects.

B. Response to the Secretary's Advisory Committee on Human Research Protections' (SACHRP's) Recommendations Regarding OHRP's Current Guidance on Continuing Review

In a March 14, 2007 letter, SACHRP transmitted to the Secretary of Health and Human Services 14 recommendations regarding continuing review, 13 of which called for changes in OHRP's current guidance on continuing review. These recommendations were the primary impetus for OHRP to draft an updated guidance document on IRB continuing review. The following discussion describes OHRP's response to these SACHRP recommendations and identifies the section(s) of the draft guidance document that address specific recommendations.

(1) *SACHRP Recommendation:* OHRP should clarify its guidance on the required duration of continuing review. Continuing review may end when all research interventions and interactions with subjects are over and data collection for research purposes is complete, as described in the approved study plan/protocol, at the research site for which the IRB has oversight. The IRB must have reviewed and approved the investigator's plan for data analysis and the safeguards in place for confidentiality protections. The investigator still retains the responsibility to notify former subjects and the IRB if subsequent analyses and/or new information raise concerns about rights, safety, and welfare of human subjects.

OHRP's Response: Given (a) OHRP's current interpretation of what it means to *obtain* identifiable private information; (b) category (8)(c) on the list of categories of research that may be reviewed by the IRB through an expedited review procedure; and (c) the importance of continuing to require the prompt reporting of unanticipated problems involving risks to subjects or others to the IRB, appropriate institutional officials, and OHRP that may occur during the data analysis phase of a research study, OHRP believes that continuing review should continue at least annually as long as the analysis of data that includes individually identifiable private information, as described in the IRB-approved protocol, is ongoing. However, as discussed in section E.2 of the draft guidance (under the sub-heading ''*Expedited review category (8)(c) and data analysis*'') this continuing review can be expedited and done in a way that results in little, if any, burden. The draft guidance also explains that for a multicenter research project, only the institution engaged in the ongoing data analysis activities (*e.g.,* the institution operating the coordinating center or statistical center for the research project) needs to ensure that continuing review of the research by an IRB designated under the institution's FWA occurs at least annually. Finally, the draft guidance in section K clarifies that when data analysis activities for a research study progress to the point when they no longer involve analysis of identifiable private information, further continuing review of the research is no longer required.

(2) *SACHRP Recommendation:* OHRP should revise its interpretation and develop new guidance to (a) define simplified criteria and the expectations for the content of continuing review based upon current risk level; and (b) to permit IRBs to develop, within their written procedures, policies and procedures for the selective application of section 46.111 to continuing review.

OHRP's Response: OHRP has retained its interpretation that the criteria for IRB approval of research at the time of continuing review are the criteria under HHS regulations at 45 CFR 46.111, and when applicable, the criteria under subparts B, C, and D of 45 CFR part 46. However, the draft guidance explains in section B.1 that at the time of continuing review, the IRB should start with the presumption that the research, as previously approved, does satisfy these criteria and should focus on whether there is any new information provided by the investigator that would alter the prior determinations of the IRB. The guidance then recommends in sections B.2–B.5 that, when conducting continuing review and evaluating whether research continues to satisfy the criteria for IRB approval of research, IRBs should pay particular attention to the following four aspects of the research: (1) Risk assessment and monitoring; (2) adequacy of the process for obtaining informed consent; (3) investigator and institutional issues; and (4) research progress.

(3) *SACHRP Recommendation:* OHRP should modify its interpretation of expedited review category (8)(b) so that expedited review is permitted if no additional risks have been identified at any research sites and no interventions or other study activities have occurred at the IRB's research site since the preceding review. Guidance should be revised to reflect this interpretation.

OHRP's Response: Implementation of this recommendation would require revision of the expedited review list. Therefore, this recommendation cannot be addressed through revision of OHRP's guidance on IRB continuing review.

(4) *SACHRP Recommendation:* OHRP should revise its current guidance to give more examples of when continuing review is not necessary and when expedited review category (9) may be used.

OHRP's Response: OHRP agrees with this recommendation. Section E.3 of the draft guidance includes two examples of research studies that would be eligible for continuing review under an expedited review procedure under category (9); one involving research that includes chest x-ray procedures, and another involving research that includes procedures for collection of blood at a frequency which exceeds the frequency described in expedited review category (2). OHRP invites the public to provide suggestions of other examples.

Section K of the draft guidance provides guidance on when continuing review of a research study would no longer be necessary.

(5) *SACHRP Recommendation:* OHRP should revise its guidance to clarify an expectation that the investigator is responsible for the review and interpretation of ''recent and relevant'' literature for IRB evaluation. Guidance should clarify that it is not an IRB responsibility to perform a review of the scientific literature.

OHRP's Response: OHRP agrees with this recommendation. The draft guidance in section C.4 includes an explicit statement that OHRP does not expect the IRB to perform an independent review of the relevant scientific literature related to a particular research project undergoing continuing review and that this

responsibility rests with the investigators and any monitoring entity for the research.

(6) *SACHRP Recommendation:* OHRP should revise its guidance to emphasize that once a research protocol is determined to be exempt, and all subsequent research activities continue to meet exemption criteria, there is no regulatory requirement for ongoing review.

OHRP's Response: OHRP agrees with this recommendation. The draft guidance in section L advises that once the determination has been made that a research project is exempt, no continuing review of the project by the IRB is required under the HHS regulations at 45 CFR part 46.

(7) *SACHRP Recommendation:* OHRP should prepare simplified, unified, and practical guidance for continuing review that focuses on the substance of review.

OHRP's Response: OHRP agrees with this recommendation. The draft guidance document in its entirety represents an attempt to consolidate in one guidance document all OHRP guidance regarding continuing review. In preparing the draft guidance on continuing review, content was taken from the following documents: (a) The January 15, 2007 Guidance on Continuing Review; (b) the January 15, 2007 Guidance on Written IRB Procedures; (c) the January 15, 2007 Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events; (d) OHRP's Frequently Asked Questions on Investigator Responsibilities; and (e) the August 11, 2003 Guidance on Expedited Review. Section B of the draft guidance focuses on the substance of continuing review through its discussion of key IRB considerations when reviewing research undergoing continuing review. Section C of the draft guidance focuses on the process for conducting IRB review and provides guidelines for facilitating and simplifying this process.

(8) *SACHRP Recommendation:* OHRP should revise its guidance to reflect that the final IRB approval of a study ''sets the clock'' for continuing review. For multi-site reviews, this may differ by site.

OHRP's Response: OHRP agrees with this recommendation with respect to setting the date for the first continuing review of a research study that was initially reviewed and approved by the IRB at a convened meeting. The draft guidance in section G clarifies that instead of the first continuing review being required within one year of the convened meeting at which the initial approval was granted, it must occur within one year of the date on which any changes or clarifications requested by the IRB at its convened meeting have been reviewed and accepted as satisfactory by the IRB chairperson (or other individual(s) designated by the IRB at the time of the convened IRB meeting). OHRP notes that adoption of this recommendation represents a change to OHRP's long-standing policy position on this issue.

(9) *SACHRP Recommendation:* OHRP should revise its ''30-day rule'' to remove unnecessary restrictions on IRBs in scheduling continuing reviews. If a defined time window is deemed necessary, 60 days would be more appropriate.

OHRP's Response: OHRP has retained its current position on this issue (*see* section G.3 of the draft guidance).

(10) *SACHRP Recommendation:* OHRP should modify its guidance on continuing review so that, when the study has been reviewed by the IRB (at a convened meeting or through an expedited process, as appropriate) and the IRB finds that there are no substantive concerns in terms of the risk-benefit relationship, informed consent, or other key protections, suspension of all research activity is not required when the expiration date passes, provided that IRB review is completed within 30 days past the expiration date.

OHRP's Response: OHRP has addressed this recommendation through its discussion of conditional approval by the IRB in section C.9 of the draft guidance on continuing review and its new draft *Guidance on IRB Approval of Research with Conditions* that is also being made available for public review and comment, as noted in another notice of availability published in this same issue of the **Federal Register.**

(11) *SACHRP Recommendation:* Regarding the issue of continued participation of already enrolled subjects in research during temporary lapses in IRB approval, wording in current OHRP guidance that refers to ''individual requests'' should be revised to clarify that approval of a general request for all research subjects to continue in the research during the review process is acceptable.

OHRP's Response: OHRP agrees with this recommendation. The draft guidance in section H advises that the determination regarding whether it is in the best interests of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made for all enrolled subjects as a group or for each individual subject.

(12) *SACHRP Recommendation:* OHRP guidance on continuing review should be revised to state that a ''protocol summary'' may or may not be a separate document; and that combination of information sources, such as consent forms and the continuing review application, may appropriately constitute a ''summary'' for the IRB members.

OHRP's Response: OHRP agrees with this recommendation. The draft guidance in section C.4 clarifies that a project summary could be included as part of a continuing review progress report, provided as a separate document, or addressed by referencing other documents made available to the IRB, including the informed consent document.

(13) *SACHRP Recommendation:* OHRP should clarify its guidance to state that qualified IRB staff may act as a consultant to the IRB and accomplish the review of the full study protocol.

OHRP's Response: OHRP agrees with this recommendation in part. OHRP believes that IRB staff who are not IRB members can carry out review activities of the IRB file to facilitate the review conducted by IRB members at the time of continuing review. However, determinations that the IRB must make under the regulations at 45 CFR 46.111 and, when applicable, subparts B, C, and D, must be made by the IRB members, and individuals who are not IRB members may not approve research on behalf of the IRB. The draft guidance in section C.7 discusses the involvement of IRB staff in preliminary review of IRB records as part of the continuing review process.

C. Summary of Additional Key Changes and New Content

(1) The draft guidance does not include a reference to ''substantive and meaningful continuing review'' that is found in OHRP's current guidance on continuing review. Instead, the new draft guidance has been expanded to include a section on key IRB considerations when evaluating research undergoing continuing review (*see* section B) and to provide more details regarding regulatory requirements and recommendations for the process for conducting continuing review (*see* section C).

(2) The draft guidance recommends that IRBs act and vote on research studies individually. It further clarifies that if an IRB adopts a procedure under which the IRB votes on groups of studies undergoing continuing review, such a procedure must provide IRB members with the ability to vote ''yes'' on some studies, ''no'' on others, and abstain on others.

(3) The draft guidance provides new guidance on the involvement of IRB staff, regardless of whether they are IRB members, in preliminary reviews of continuing review documents and IRB files in order to facilitate the continuing review of research by the IRB (*see* section C.7).

(4) The draft guidance describes how continuing review of research at convened meetings can be accomplished in an efficient and timely manner (*see* section C.8).

(5) The draft guidance discusses the concept of conditional IRB approval in the context of continuing review (*see* section C.9).

(6) The draft guidance discusses issues unique to continuing IRB review of multicenter research studies (*see* section D).

(7) The draft guidance clarifies the point in time when continuing review is no longer necessary (*see* section K).

II. Electronic Access

The draft guidance document is available on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.*

III. Request for Comments

OHRP requests comments on its draft guidance document. OHRP will consider all comments before issuing a final guidance document.

Dated: November 3, 2009.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. E9–26828 Filed 11–5–09; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5280–N–43]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Rita, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Coast Guard:* Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2100 Second St., SW., Stop 7901, Washington, DC 20593–0001; (202) 475–5609; *Energy:* Mr. Mark Price, Department of Energy, Office of Engineering & Construction Management, MA–50, 1000 Independence Ave, SW., Washington, DC 20585: (202) 586–5422; *GSA:* Mr. Gordon Creed, Acting Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th & F Streets, NW., Washington, DC 20405; (202) 501–0084; *Navy:* Mrs. Mary Arndt, Acting Director, Department of the Navy, Real Estate Services, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9305; (These are not toll-free numbers).