redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Good Clinical Practice (OGCP), Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993; or Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OGCP at 301–796–8340 or OHRP at 240–453–6900 or 866–447–4777. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5167, Silver Spring, MD 20993, 301–796–4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a guidance document entitled ''Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional Review Boards.'' OHRP and FDA are providing recommendations on the type and amount of information to include in minutes.

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 guidance document was developed as a part of these efforts. In addition, on December 13, 2016, the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law. Title III, section 3023 of the Cures Act requires the Secretary of HHS to harmonize differences between the HHS human subject regulations and FDA's human subject regulations. This guidance document is consistent with the goals of section 3023 of the Cures Act.

In the **Federal Register** of November 5, 2015 (80 FR 68545), OHRP and FDA announced the availability of the draft guidance of the same title dated November 2015. OHRP and FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. Changes include modifying certain recommendations for inclusion of information in minutes when such information may be addressed in other IRB records. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2015.

II. Significance of Guidance

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of OHRP and FDA on minutes of IRB meetings. It does not establish any rights for any person and is not binding on OHRP, FDA, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115 have been approved under OMB control numbers 0910–0755 and 0910–0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115 have been approved under OMB control number 0990–0260.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/alphabetical-list/index.html,* or *https://www.regulations.gov.*

Dated: August 30, 2017.

Don Wright,

Acting Assistant Secretary for Health.

Dated: Sept. 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20405 Filed 9–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance to Conduct Formative Research (NIAID)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Allergy and Infectious Diseases (NIAID) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dione Washington, Health Science Policy Analyst, Strategic Planning and Evaluation Branch, 5601 Fishers Lane, Room 5F32, Rockville, Maryland, 20892 or Email your request, including your address to:

washingtondi@niaid.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Generic Clearance to Conduct Formative Research (NIAID), 0925–NEW, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this Generic is for information collections to improve research approaches and final product development to identify emergent infectious disease threats and comorbidities related to the needs of diverse audiences. The information to be collected as part of this generic clearance will allow the agency to make appropriate adjustments in content and methods used in developmental and testing stages in order to improve research approaches and final product development.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 31,950.

ESTIMATED ANNUALIZED BURDEN HOURS

Research method	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden in hours
Focus Group Screeners	2,000	1	15/60	500
Interview Screeners/Surveys	2,000	1	15/60	500
Focus Groups	4,000	1	2	8,000
Pretesting	1,000	1	1	1,000
Dyad/Triad Interviews	4,000	1	90/60	6,000
In-depth Interviews (IDI)	6,000	1	90/60	9,000
Surveys	7,000	1	30/60	3,500
Patient questionnaires	4,500	1	30/60	2,250
Market research	300	1	4	1,200
Total	30,800	30,800	.....	31,950

Dated: August 31, 2017.

Brandie Taylor,

Project Clearance Liaison, NIAID, NIH.

[FR Doc. 2017–20367 Filed 9–22–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4336–DR; Docket ID FEMA–2017–0001]

Puerto Rico; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Puerto Rico (FEMA–4336–DR), dated September 10, 2017, and related determinations.

DATES: This amendment was issued September 16, 2017.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Puerto is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of September 10, 2017.

The municipalities of Aguas Buenas, Barranquitas, Bayamón, Camuy, Cataño, Ciales, Comerio, Hatillo, Jayuya, Las Piedras, Quebradillas, Salinas, San Juan, Vega Baja, and Yauco for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2017–20444 Filed 9–22–17; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4332–DR; Docket ID FEMA–2017–0001]

Texas; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the