In addition, informed consent documents for clinical trials within all three categories are to include a specific statement relating to posting of clinical trial information at *ClinicalTrials.gov*.

Each NIH-funded clinical trial should have only one entry in *ClinicalTrials.gov* that contains its registration and results information. Awardees and investigators need not and should not create a separate record of the applicable clinical trial to comply with this policy.

The NIH will publicly post registration information and results information in *ClinicalTrials.gov*.

Definitions

Clinical Trial. For purposes of this policy, a ''clinical trial'' means ''a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.'' [3] This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, *e.g.,* behavioral interventions. This definition of ''clinical trial'' [4] is broader than the term ''applicable clinical trial'' as defined in the regulation.[5]

Responsible Party. In the policy, the awardee or the investigator is responsible for meeting the expectations of this policy. In the regulation, a ''responsible party'' means, in part, ''with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under [42 CFR part 11] for the submission of clinical trial information.'' [6]

Primary Completion Date. In the policy, this term has the same meaning as the term ''primary completion date'' in the regulation, which is ''the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.'' [7]

Registration Information. In the policy, this term has the same meaning as the term ''registration information'' in the regulation. In the regulation, registration information consists of descriptive information, recruitment information, location and contact information, and administrative data.[8]

Results Information. In the policy, this term has the same meaning as the term ''results information'' in the regulation. In the regulation, results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.[9]

Compliance

If the clinical trial is NIH-funded in whole or in part, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award. Failure to comply with the terms and conditions of the NIH award may provide a basis for enforcement actions, including termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 U.S.C. 282(j) and 42 CFR part 11 may also lead to the actions described in 42 CFR 11.66.

Effective Date

This policy is effective January 18, 2017.

Date: September 12, 2016.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2016–22379 Filed 9–16–16; 11:15 am]

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[3] Further information about this definition is available from the NIH Office of Science Policy at *http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials.*

[4] Note that the regulation also includes a definition of ''clinical trial.'' That definition is ''a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health related outcomes'' (*see* 42 CFR 11.10 (a)). For the purposes of this policy, the regulatory definition and the definition in this policy are treated as synonymous.

[5] In the regulation, applicable clinical trial is defined as an applicable device clinical trial or an applicable drug clinical trial. The regulation defines an applicable device clinical trial to mean, in part, ''a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes).'' The regulation defines an applicable drug clinical trial to mean, in part, ''a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where ''clinical investigation'' has the meaning given in 21 CFR 312.3 (or any successor regulation) and ''phase 1'' has the meaning given in 21 CFR 312.21 (or any successor regulation).''

[6] See 42 CFR 11.10 (a) and 42 CFR 11.4.

[7] See the complete definition at 42 CFR 11.10 (a).

[8] See 42 CFR 11.10 (b) and 42 CFR 11.28 for the specific data elements.

[9] See 42 CFR 11.28 for complete results information and specific data elements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; TRND2.

Date: October 13, 2016.

Time: 11:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 1087, 6701 Democracy Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892–4878, 301–451–2405, *henriquv@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 15, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22669 Filed 9–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5915–N–10]

60-Day Notice of Proposed Information Collection: Small Area Fair Market Rent Demonstration Evaluation

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 21, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone (202) 402–5534 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone (202) 402–5535. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Small Area Fair Market Rent Demonstration Evaluation.

OMB Approval Number: N/A.

Type of Request: New.

Description of the need for the information and proposed use: HUD generally publishes a single FMR for each metropolitan area and provides public housing agencies with discretion to vary local voucher payment standards between 90 and 110 percent of the Fair Market Rent (FMR) (unless HUD approves an exception). The SAFMR demonstration is testing the alternative approach of setting FMRs at the ZIP Code level. The core hypothesis is that this will significantly expand the ability of Housing Choice Vouchers (HCV) holders to access housing in neighborhoods with high-quality schools, low crime rates, and other indicators of opportunity, as well as integrated neighborhoods in furtherance of HUD's goal of affirmatively furthering fair housing.

HUD is evaluating the SAFMR demonstration and an important consideration in this evaluation is how voucher holders and landlords perceive the shift from traditional area-wide FMRs to SAFMRs. HUD will look into whether both existing and new voucher holders understood how the change to using SAFMRs affected their housing options and whether it led movers to search in new neighborhoods or affected the rate of moving of existing voucher holders. Similarly, HUD wants to know whether landlords were aware of the change in the HCV program and whether this affected their willingness to rent to voucher holders and the level at which they set rents. In order to address these perceptions, 70 tenants and 35 landlords will be interviewed in the areas served by the five PHAs that are in the SAFMR demonstration: Housing Authority of Cook County (IL); Housing Authority of the City of Long Beach (CA); Chattanooga (TN) Housing Authority; Town of Mamaroneck (NY) Housing Authority; Housing Authority of the City of Laredo (TX); and two PHAs from the Dallas metropolitan area—Dallas Housing Authority (TX), and the Plano Housing Authority (TX). To build rapport during recruitment, by acknowledging the value of their time, an incentive payment of $20 for tenants and $40 for landlords will be made.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Cost per response	Annual cost
Tenants	70	1	1	0.5	35	$20	$1,400
Landlords	35	1	1	1	35	40	1,400
Total	105				70		2,800

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions 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;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.