For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled (see definition of enrollment in *Section I–E–7*) at the clinical trial site until the following documentation has been submitted to NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

The fifth paragraph of Section III–C–1 will be amended to add ''if required'' at the end of the statement regarding IBC approval in order to recognize that some trials will not need IBC review. In addition, a new final paragraph outlining the exemption will be added. The new proposed language is as follows:

For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled (see definition of enrollment in Section I–E–7) at the clinical trial site until the following documentation has been submitted to the NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site), if required; (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

Institutional Biosafety Committee review and approval will not be required for gene transfer protocols that meet *all* of the following criteria:

(1) A previous clinical trial using this investigational gene transfer agent (vector and transgene) enrolled more than one subject and was reviewed by an Institutional IBC and is now complete.

(2) The investigational gene transfer agent uses a plasmid or viral vector derived from a virus listed in Appendix B–V–2 that is: (a) Not designed to integrate, and (b) attenuated compared to the wild-type virus or is not known to have ever caused disease in humans.

(3) The previous clinical trial:

a. Was conducted in the same country as the proposed trial;

b. Enrolled a comparable population in terms of age (i.e. adult and/or pediatric); and

c. Tested a dose equal to or less than the dose proposed for the new trial, using the same administration route and, if concomitant interventions (e.g. radiation and/or chemotherapy) are proposed, they have been used in a prior trial with the same agent.

Appendix M–I–C–1 currently states:

Appendix M–I–C–1: Initiation of the Clinical Investigation

No later than 20 working days after enrollment (see definition of enrollment in Section I–E–7) of the first research participant in a human gene transfer experiment, the Principal Investigator(s) shall submit the following documentation to NIH OBA: (1) A copy of the informed consent document approved by the Institutional Review Board (IRB); (2) a copy of the protocol approved by the Institutional Biosafety Committee (IBC) and IRB; (3) a copy of the final IBC approval from the clinical trial site; (4) a copy of the final IRB approval; (5) a brief written report that includes the following information: (a) How the investigator(s) responded to each of the RAC's recommendations on the protocol (if applicable); and (b) any modifications to the protocol as required by FDA; (6) applicable NIH grant number(s); (7) the FDA Investigational New Drug Application (IND) number; and (8) the date of the initiation of the trial. The purpose of requesting the FDA IND number is for facilitating interagency collaboration in the Federal oversight of human gene transfer research.

Appendix M I–C–1 would be amended to again recognize that IBC approval may not be needed for every trial. The proposed Appendix M–I–C–1 is as follows:

Appendix M–I–C–1: Initiation of the Clinical Investigation

No later than 20 working days after enrollment (see definition of enrollment in Section I–E–7) of the first research participant in a human gene transfer experiment, the Principal Investigator(s) shall submit the following documentation to the NIH OBA: (1) A copy of the informed consent document approved by the Institutional Review Board (IRB); (2) a copy of the protocol approved by the Institutional Biosafety Committee (IBC) and/or IRB; (3) a copy of the final IBC approval from the clinical trial site, if required; (4) a copy of the final IRB approval; (5) a brief written report that includes the following information: (a) How the investigator(s) responded to each of the RAC's recommendations on the protocol (if applicable), and (b) any modifications to the protocol as required by FDA; (6) applicable NIH grant number(s); (7) the FDA Investigational New Drug Application (IND) number; and (8) the date of the initiation of the trial. The purpose of requesting the FDA IND number is for facilitating interagency collaboration in the federal oversight of human gene transfer research.

Appendix M–I–C–2 will likewise be revised to recognize that not all clinical trials will require IBC review. Appendix M–I–C–2 now states:

Appendix M–I–C–2: Additional Clinical Trial Sites

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) at a clinical trial site until the following documentation has been submitted to NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site); (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

The proposed Appendix M–I–C–2 is:

Appendix M–I–C–2: Additional Clinical Trial Sites

No research participant shall be enrolled (see definition of enrollment in Section I–E–7) at a clinical trial site until the following documentation has been submitted to the NIH OBA: (1) Institutional Biosafety Committee approval (from the clinical trial site), if required; (2) Institutional Review Board approval; (3) Institutional Review Board-approved informed consent document; (4) curriculum vitae of the Principal Investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

A new section will be added to Appendix B.

Appendix B–V–2. Viruses Used in Vectors for Human Gene Transfer That Present Low Biosafety Risk and Are Eligible for Exemption From IBC Review Under Section III–C–1

—Adenovirus, serotypes 2 and 5
—AAV, all serotypes
—Herpes Simplex virus 1
—Pox Viruses, with the exception of vaccinia

Dated: May 6, 2013.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: 2013 National Survey on Drug Use and Health (NSDUH) Dress Rehearsal (OMB No. 0930–0334)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used

by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

In order to continue producing current data, SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ) must update the NSDUH periodically to reflect changing substance abuse and mental health issues. CBHSQ is in the process of redesigning the NSDUH for the 2015 survey year. The goals of the overall redesign are to: (1) Revise the questionnaire to address changing policy and research data needs, and (2) modify the survey methodology to improve the quality of estimates and the efficiency of data collection and processing. To achieve these goals, a Questionnaire Field Test (QFT) was conducted in late 2012 to test revisions to the questionnaire, study materials, and procedures. A Dress Rehearsal (DR) is planned for September and October 2013 to further refine and test changes implemented in the QFT as well as test all additional changes that have been identified for the 2015 redesign. These additional changes include an assessment of a new lightweight laptop used to administer the questionnaire, the addition of a Spanish language interview that was not included in the QFT to control costs, and additional select changes to the NSDUH questionnaire. The vast majority of differences in questionnaire content between the QFT and the proposed DR are minor. Changes include: (a) The addition of two sexual orientation questions to be asked of adults; (b) routine updates to routing and logic; (c) minimal changes to question wording throughout the instrument to clarify intent; and (d) the deletion of a question in the Back-end Demographics module about the number of employees who work at the respondent's business.

The DR will consist of 2,000 English and Spanish-speaking respondents in the continental United States. The sample size of the survey will be large enough to detect differences in key estimates between data collected using the annual NSDUH compared to the redesigned procedures. The total annual burden estimate is shown below:

ESTIMATED BURDEN FOR 2013 NSDUH DRESS REHEARSAL

Instrument	Number of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage rate	Annualized costs
Household Screening	3,673	1	0.083	305	$14.54	$4,435
Interview	2,000	1	1.000	2,000	14.54	29,080
Screening Verification	100	1	0.067	6.7	14.54	97
Interview Verification	300	1	0.067	20	14.54	291
Total	3,673				2,332	33,903

Written comments and recommendations concerning the proposed information collection should be sent by June 12, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Regulations To Implement SAMHSA's Charitable Choice Statutory Provisions—42 CFR Parts 54 and 54a (OMB No. 0930–0242)—Extension

Section 1955 of the Public Health Service Act (42 U.S.C. 300x–65), as amended by the Children's Health Act of 2000 (Pub. L. 106–310) and Sections 581–584 of the Public Health Service Act (42 U.S.C. 290kk et seq., as added by the Consolidated Appropriations Act (Pub. L. 106–554)), set forth various provisions which aim to ensure that religious organizations are able to compete on an equal footing for federal funds to provide substance abuse services. These provisions allow religious organizations to offer substance abuse services to individuals without impairing the religious character of the organizations or the religious freedom of the individuals who receive the services. The provisions apply to the Substance Abuse Prevention and Treatment Block Grant (SABG), to the Projects for Assistance in Transition from Homelessness (PATH) formula grant program, and to certain Substance Abuse and Mental Health Services Administration (SAMHSA) discretionary grant programs (programs that pay for substance abuse treatment and prevention services, not for certain infrastructure and technical assistance activities). Every effort has been made to assure that the reporting, recordkeeping and disclosure requirements of the proposed regulations allow maximum flexibility in implementation and impose minimum burden.

No changes are being made to the regulations or the burden hours.

Information on how states comply with the requirements of 42 CFR part 54 was approved by the Office of Management and Budget (OMB) as part of the Substance Abuse Prevention and Treatment Block Grant FY 2012–2013 annual application and reporting requirements approved under OMB control number 0930–0168.