

Form is designed to collect data from health care providers who have requested certification to participate in the Medicare Part A program. As part of the Medicare certification process, health care facilities must receive a civil rights clearance from the Office for Civil Rights (OCR). OCR uses the information to determine compliance with civil rights statutes and regulations. The civil rights information is requested only when a health care provider applies for Medicare Part A certification; it is *not* necessary on a regular yearly basis. Entities that are affected by the Civil Rights Information Request Form are: health care providers applying for Medicare certification, and individuals who, as a result of civil rights clearances, should be granted equal access to quality health care, regardless of race, color, national origin, disability, age and sex.

Need and Proposed Use of the Information: To ensure adherence to the statutory requirements, compliance

reviews are requested when health care providers, such as hospitals, nursing homes and home health agencies, apply to participate in the Medicare Part A program. When a provider seeks Medicare certification, OCR conducts a compliance review to determine whether the provider will be able to comply with Title VI, Section 504, and the Age Discrimination Act. Such reviews are an effective means of working with health care providers because potential civil rights concerns can be identified prior to receipt of Federal financial assistance. The technical assistance available to recipients on the OCR Web site helps providers take steps to comply with their obligations to refrain from prohibited discrimination.

Likely Respondents: Healthcare providers.
Burden Statement: In conducting a complaint investigation or compliance review of a health care or social service provider, OCR determines whether a compliance review was performed by

OCR. In many instances, the procedure decreases the burden on the recipient since the compliance review and corrective actions, as necessary, may reduce or eliminate the need for a formal investigation involving interviews, examination of records, collection and submission of data associated with issues already addressed through a recent compliance review certification process. To further reduce provider burden in completing the compliance review process, OCR has developed several Corporate Agreements with health care corporations. These Agreements are designed to expedite the civil rights compliance review process by implementing a practice whereby all of a corporation's national policies and procedures are reviewed and approved at OCR's headquarters' level. Subsequent to such approval, only local facility-specific information is reviewed by OCR for civil rights compliance during the review process.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
The Civil Rights Information Request Form	2900	1	8	23,200

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,
Deputy, Information Collection Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI)

has taken final action in the following case:

Dong-Pyou Han, Ph.D., Iowa State University of Science and Technology: Based on the report of an inquiry conducted by the Iowa State University of Science and Technology (ISU), a detailed admission by the Respondent, and additional analysis conducted by ORI, ORI and ISU found that Dr. Dong-Pyou Han, former Research Assistant Professor, Department of Biomedical Services, ISU, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants P01 AI074286, R33 AI076083, and U19 AI091031.

ORI and ISU found that the Respondent falsified results in research to develop a vaccine against human immunodeficiency virus-1 (HIV-1) by intentionally spiking samples of rabbit sera with antibodies to provide the desired results. The falsification made it appear that rabbits immunized with the gp41-54 moiety of the HIV gp41 glycoprotein induced antibodies capable of neutralizing a broad range of HIV-1 strains, when the original sera were

weakly or non-reactive in neutralization assays. Falsified neutralization assay results were widely reported in laboratory meetings, seven (7) national and international symposia between 2010 and 2012, and in grant applications and progress reports P01 AI074286-03, -04, -05, and -06; R33 AI076083-04; U19 AI091031-01 and -03; and R01 AI090921-01. Specifically:

a. Respondent falsified research materials when he provided collaborators with sera for neutralization assays from (i) rabbits immunized with peptides from HIV gp41-54Q (and related antigens HR1-54Q, gp41-54Q-OG, gp41-54Q-GHC, gp41-54Q-Cys and Cys-gp41-54Q) to assay HIV neutralizing activity, when Respondent had spiked the samples with human IgG known to contain broadly neutralizing antibodies to HIV-1; and (ii) rabbits immunized with HIV gp41-54Q to assay HIV neutralizing activity, when Respondent had spiked the samples with sera from rabbits immunized with HIV-1 gp120 that neutralized HIV.

b. Respondent falsified data files for neutralization assays, and provided

false data to his laboratory colleagues, to make it appear that rabbits immunized with gp41–54Q and recombinant Lactobacillus expressing gp41–64 (LAB gp41–64) produced broadly reactive neutralizing antibodies, by changing the numbers to show that samples with little or no neutralizing activity had high activity.

Dr. Han has entered into a Voluntary Exclusion Agreement and has voluntarily agreed for a period of three (3) years, beginning on November 25, 2013:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to HHS’ Implementation (2 CFR Part 376 *et seq*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180 (collectively the “Debarment Regulations”); and

(2) to exclude himself voluntarily from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

David E. Wright,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day 14–0138]

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 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email 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

Pulmonary Function Testing Course Approval Program, 29 CFR 1910.1043 (OMB No. 0920–0138, Expiration 8/31/2014)—Revision—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH has the responsibility under the Occupational Safety and Health Administration’s Cotton Dust Standard, 29 CFR 1920.1043, for approving courses to train technicians to perform pulmonary function testing in the cotton industry. Successful completion of a NIOSH-approved course is mandatory under the standard.

To carry out its responsibility, NIOSH maintains a Pulmonary Function Testing Course Approval Program. The program consists of an application submitted by potential sponsors (universities, hospitals, and private consulting firms) who seek NIOSH

approval to conduct courses, and if approved, notification to NIOSH of any course or faculty changes during the approval period, which is limited to five years. The application form and added materials, including an agenda, curriculum vitae, and course materials are reviewed by NIOSH to determine if the applicant has developed a program which adheres to the criteria required in the standard. Following approval, any subsequent changes to the course are submitted by course sponsors via letter or email and reviewed by NIOSH staff to assure that the changes in faculty or course content continue to meet course requirements. Course sponsors also voluntarily submit an annual report to inform NIOSH of their class activity level and any faculty changes. Sponsors who elect to have their approval renewed for an additional 5 year period submit a renewal application and supporting documentation for review by NIOSH staff to ensure the course curriculum meets all current standard requirements.

Approved courses that elect to offer NIOSH-Approved Spirometry Refresher Courses must submit a separate application and supporting documents for review by NIOSH staff. Institutions and organizations throughout the country voluntarily submit applications and materials to become course sponsors and carry out training. Submissions are required for NIOSH to evaluate a course and determine whether it meets the criteria in the standard and whether technicians will be adequately trained as mandated under the standard. NIOSH will disseminate a one-time customer satisfaction survey to course directors and sponsor representatives to evaluate our service to courses, the effectiveness of the program changes implemented since 2005, and the usefulness of potential Program enhancements.

The annualized figures slightly overestimate the actual burden, due to rounding of the number of respondents for even allocation over the three-year clearance period. The estimated annual burden to respondents is 201 hours. There will be no cost to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Potential Sponsors	Initial Application	3	1	3.5	11
	Annual Report	35	1	30/60	18
	Report for Course Changes	12	1	45/60	9
	Renewal Application	13	1	6	78