Collection of Qualitative Research and Assessment.

OMB No.: 0990–0421.

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting an extension for their generic clearance for purposes of conducting qualitative research. ASPE conducts qualitative research to gain a better understanding of emerging health and human services policy issues, develop future intramural and extramural research projects, and to ensure HHS leadership, agencies and offices have recent data and information to inform program and policy decision-making. ASPE is requesting approval for at least four types of qualitative research which include, but are not limited to: (a) Interviews, (b) focus groups, (c) questionnaires, and (d) other qualitative methods.

ASPE's mission is to advise the Secretary of the Department of Health and Human Services on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives, coordinates the Department's evaluation, research and demonstration activities, and manages cross-Department planning activities such as strategic planning, legislative planning, and review of regulations. Integral to this role, ASPE will use this mechanism to conduct qualitative research, evaluation, or assessment, conduct analyses, and understand needs, barriers, or facilitators for HHS-related programs.

ASPE is requesting comment on the burden for qualitative research aimed at understanding emerging health and human services policy issues. The goal of developing these activities is to identify emerging issues and research gaps to ensure the successful implementation of HHS programs. The participants may include health and human services experts; national, state, and local health or human services representatives; public health, human services, or healthcare providers; and representatives of other health or human services organizations. The increase in burden from 747 in 2014 to 1,500 respondents in 2017 reflects an increase in the number of research projects conducted over the estimate in 2014.

Need and Proposed Use of the Information: The information collected for qualitative policy research and assessment will be used by ASPE to develop future intramural and extramural research projects and to shape emerging health and human services policy issues for HHS leadership, agencies, and offices. The end purpose is to obtain broad and diverse perspectives on public health, human service, and health care issues to understand emerging issues, promising practices by innovative programs or organizations funded by HHS, or examining health or human service policy issues that have as yet gone unanswered or need further examination. Additionally, ASPE will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current programs, policies, and services.

Likely Respondents: Respondents have typically been stakeholders from the health and human services fields such as state health officers, human service professionals, groups that represent health or human services interests or populations, individual experts in the fields of health, human services, science, data, or other relevant professions, and other individuals and groups relevant to the work conducted by ASPE and HHS.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Health or Human Services Stakeholder	2,000	1	1	2,000
Total	2,000	1	1	2,000

Terry S. Clark,

Asst. Information Collection Clearance Officer.

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BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

Notice is hereby given that on June 22, 2017, the Department of Health and Human Services (HHS) took final action in the following case:

Frank Sauer, Ph.D., University of California, Riverside: Based on evidence and findings of an investigation conducted by the University of California, Riverside (UCR), the Office of Research Integrity's (ORI's) review of UCR's Research Misconduct Investigation Report, the Report of Investigation by the National Science Foundation (NSF) Office of Inspector General, additional evidence obtained by ORI during its oversight review of UCR's investigation, and independent analyses conducted as part of ORI's oversight review, ORI found that Dr. Frank Sauer, former Associate Professor of Biochemistry, UCR, committed research misconduct in research supported by the following National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH) grants:

- R01 GM073776
- R01 GM066204

Images that were falsified and/or fabricated were presented in the following publications and grant applications.

- Gou, D., Rubalcava, M., Sauer, S., Mora-Bermúdez, F., Erdjument-Bromage, H., Tempst, P., Kremmer, E., & Sauer, F. ''SETDB1 is involved in postembryonic DNA methylation and gene silencing in Drosophila.'' *PLoS One* 5(5):e10581, 2010 (hereafter referred to as ''*PLoS One* 2010'').
- Sanchez-Elsner, T., Gou, D., Kremmer, E., & Sauer, F. ''Noncoding RNAs of trithorax response elements recruit Drosophila Ash1 to Ultrabithorax.'' *Science* 311(5764):1118–1123, 2006 (hereafter referred to as ''*Science* 2006'').
- Maile, T., Kwoczynski, S., Katzenberger, R.J., Wassarman, D.A., & Sauer, F. ''TAF1 activates transcription by phosphorylation of serine 33 in histone H2B.'' *Science* 304(5673):1010–

1014, 2004 (hereafter referred to as ''*Science* 2004'').

• National Institute on Drug Abuse (NIDA), NIH, grant application R21 DA025703–01.

• National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant application R21 DK082631–01.

• NIDDK, NIH, grant application R01 DK082675–01.

• NIGMS, NIH, grant application R01 GM073776–06A1.

• NIGMS, NIH, grant application R01 GM085229–01.

• NIGMS, NIH, grant application R01 GM085303–01.

• NIGMS, NIH, grant application R01 GM085303–01A1.

ORI found by a preponderance of the evidence that the Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating images in seven (7) submitted NIH grant application and three (3) published papers by manipulating, reusing, and falsely labeling images. Specifically, the Respondent falsified and/or fabricated images representing controls or experimental results for *in vitro* interactions between RNA and proteins, co-immunoprecipitation (''co-IP'') assays, histone methytransferase (''HMT'') or kinase assays and related stained SDS–PAGE gels, and reverse transcription-polymerase chain reactions (''RT–PCR'') in the following grant applications and publications.

1. The image in Figure S4, *Science* 2006, representing the *in vitro* interactions between RNA and specific proteins, was used in similar assays to represent results with other sets of protein-RNA interactions in Figure 9, R21 DA025703–01, Figure 9, R21 DK082631–01, and Figure 9, R01 DK082675–01, and again in R01 GM085229–01, Figure 11C.

2. The image in Figure 1A, R01 GM085303–01, representing a co-IP assay from the *Drosophila* cell line S2, was manipulated and used in Figure 1B of the same grant application to represent a different co-IP assay from *Drosophila* embryonic extracts.

3. The image in Figure 8A, R01 GM085303–01A1, representing an SDS–PAGE gel for an *in vitro* HMT assay, was used previously in Figure 1d in a manuscript submitted to *Nature* in 2005 to represent an SDS–PAGE gel from an unrelated experiment for an ubiquitination assay.

4. The image in Figure 1E, R01 GM085303–01 and Figure 1D, R01 GM085303–01A1, representing stained SDS–PAGE for an HMT assay, was used in Figure 1b, *Nature* 419(6909):857–862, 2002, to represent an HMT assay with different experimental conditions, and also was used in Figure 1B, *Science* 2004, to represent stained PAGE for an *in vitro* kinase assay.

5. The image in Figure 1C, R01 GM085303–01 and Figure 1B, R01 GM085303–01A1, representing an HMT assay, was manipulated and used to represent an HMT assay with different experimental conditions in Figure 1E, R01 GM085303–01 and Figure 1D, R01 GM085303–01A1, and also was used to represent another unrelated HMT assay in Figure 2 (right panel) in R01 GM085303–01.

6. The image in Figure 2 (right panel) in R01 GM085303–01 representing an HMT assay was used in Figure 1B, *PLoS One* 2010 to represent an HMT assay with different experimental conditions.

7. The image in Figure 6B, R21 DA025703–01, Figure 11B, R01 GM085229–01, Figure 6B, R01 DK082675–01, and Figure 6B, R21 DK082631–01, all representing RT–PCR experiments for transcribed ncRNAs, was used in Figure 13, R21 DK082631–01 and Figure 13, R21 DA025703–01 to represent RT–PCR experiments for transcription for different ncRNAs.

8. The image in Figure 10C (right half) in R01 GM073776–06A1, representing transcription of endodermal genes from embroid bodies, was manipulated and used in Figure 10C (left half) in the same grant application to represent the transcription of mesodermal and ectodermal genes.

Science 311(5764):1118–1123, 2006 was retracted in: *Science* 344(6187):981, 2014. *Science* 304(5673):1010–1014, 2004 was retracted in: *Science* 344(6187):981, 2014. *Nature* 419(6909):857–862, 2002 was retracted in *Nature* 521(7550):110, 2015.

ORI issued a charge letter enumerating the above findings of research misconduct and proposing HHS administrative actions. Dr. Sauer subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. The parties filed cross-motions for summary judgment. On May 22, 2017, the ALJ recommended to the Assistant Secretary for Health that summary judgment be granted in favor of ORI. On June 22, 2017, the ALJ's recommended decision became the final agency decision. Thus, the research misconduct findings set forth above became effective, and the following administrative actions have been implemented, beginning on June 22, 2017:

(1) Dr. Sauer is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant, through July 27, 2020, the end date of his government-wide debarment, which was imposed by NSF; and

(2) ORI will send a notice to *PLoS* requesting retraction or correction of *PLoS One* 5(5):e10581, 2010 (PMID: 20498723) in accordance with 42 CFR 93.411(b).

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Kathryn M. Partin,

Director, Office of Research Integrity.

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BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS Approval of Entities That Certify Medical Review Officers

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The current version of the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2010, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs. As required under Section 13.1(b) of the Mandatory Guidelines, this notice publishes a list of HHS approved MRO certification entities.

FOR FURTHER INFORMATION CONTACT: Sean J. Belouin, Pharm.D., CAPT, United States Public Health Service, Senior Pharmacology and Regulatory Policy Advisor, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 16N06D, Rockville, Maryland 20857; Telephone: (240) 276–2716; Email: *sean.belouin@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: Subpart M-Medical Review Officer (MRO), Section 13.1(b) of the Mandatory Guidelines, ''Who may serve as an MRO?'' states as follows: ''Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug testing results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual