

NATIONAL COAL WORKERS' AUTOPSY STUDY PROGRAM (NCWAS)
Regulation 42 CFR 37.204

Request for Office of Management and Budget (OMB) Review and Approval
for a Federally Sponsored Data Collection
(0920-0021) **RENEWAL**

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Table of Contents

A. Justification	3
A1. Circumstances Making the Collection of Information Necessary.....	3
A2. Purpose and Use of Information Collection.....	4
A3. Use of Improved Information Technology and Burden Reduction.....	5
A4. Efforts to Identify Duplication and Use of Similar Information.....	5
A5. Impact on Small Businesses or Other Small Entities.....	5
A6. Consequences of Collecting the Information Less Frequently.....	5
A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	5
A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	5
A9. Explanation of Any Payment or Gift to Respondents.....	5
A10. Assurance of Confidentiality Provided to Respondents.....	5
A11. Justification for Sensitive Questions.....	6
A12. Estimates of Annualized Burden Hours and Costs.....	6
A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	7
A14. Annualized Cost to the Government.....	7
A15. Explanation for Program Changes or Adjustments.....	7
A16. Plans for Tabulation and Publication and Project Time Schedule.....	7
A17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	8
A18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	8
B. Collection of Information Employing Statistical Methods	8
B1. Respondent Universe and Sampling Methods.....	8

Attachments

Attachment A - The Federal Coal Mine and Safety Act 1977

Attachment B - CFR 42, Chapter 1. Subchapter C, Part 37

Attachment C - Consent Form (CDC/NIOSH 2.6)

Attachment D - Sample Invoice

Attachment E - NCWAS Checklist

Attachment F - 60 Day Federal Register Notice

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

This is a renewal package with no changes to the collection instrument. There is a change in annualized cost to the government. We have eliminated the second opinion of the pathologist resulting in a decrease of cost to the government (Section A14, #B).

The Federal Coal Mine Health and Safety Act of 1977, PL91-173, (amended the Federal Coal Mine and Safety Act of 1969) provides in Title II, Section 203(d), (**Attachment A**) that, “If the death of any active miner occurs in any coal mine, or if the death of any active or inactive miner occurs in any other place, the Secretary of Health and Human Services is authorized to provide for any autopsy to be performed on such miner, with the consent of his surviving widow or, if he has no such widow, then with the consent of his surviving next of kin. The results of such autopsy shall be submitted to the Secretary of Health and Human Services and, with the consent of such survivor, to the miner’s physician or other interested person. Such autopsy shall be paid for by the Secretary of Health and Human Services.” The regulations concerning the authority for the program were published in Title 42 CFR, Chapter 1, Subchapter C, Part 37, (**Attachment B**). Through delegation of authority, the National Institute for Occupational Safety and Health (NIOSH) is authorized to make the necessary arrangements for providing this service to the next-of-kin of the deceased miner through the National Coal Workers’ Autopsy Study (NCWAS) which is a component of the Coal Workers’ Health Surveillance Program (CWHSP). The Consent, Release and History form (CDC/NIOSH 2.6) (**Attachment C**) is used to obtain written authorization from the next-of-kin to perform an autopsy on the deceased miner. The NCWAS post-mortem examinations are used for research purposes (both epidemiological and clinical). A minimum of essential information regarding the deceased miner, his occupational history, and his smoking history is collected. The latter is included because of the strong association between chronic lung diseases and smoking. Medical evidence obtained from the autopsy may also be used by the next-of-kin in support of Black Lung Benefits claims.

Renewal is requested for both the regulatory requirements as well as the reporting instrument contained in the following regulatory citations:

42 CFR Part 37.204 specifies the procedure for payment to pathologists for autopsies performed.

42 CFR 37.204(a) Invoice - Reporting.

The invoice submitted by the pathologist should contain a statement that the pathologist is not receiving any other compensation for the autopsy. A sample invoice is attached (**Attachment D**).

42 CFR 37.204(b) Consent, Release and History Form - Reporting.

CDC/NIOSH 2.6, is completed by the next-of-kin with the assistance of the attending physician, coroner, mortician, or other appropriate responsible person. It authorizes the performance of the autopsy and collects basic information on the miner's smoking history and occupational history related to mining.

42 CFR 37.204(c) Report of Autopsy - Reporting.

The pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. Autopsy reports are variable depending on the pathologist conducting the autopsy. A checklist of the requirements for the NCWAS program is included (**Attachment E**) and a copy is given to the pathologist. Information pertaining to the items on this checklist is maintained in the NCWAS database. All information and specimens (slides and blocks of tissue) are maintained by NIOSH in the Morgantown, West Virginia location.

A2. Purpose and Use of Information Collection

The purpose of this collection is to provide information that will be used by the staff of NIOSH for research purposes in defining the diagnostic criteria for coal workers' pneumoconiosis (black lung) and will be correlated with pathologic changes and x-ray findings. The Consent, Release and History Form is completed on a one-time basis by each individual respondent (next-of-kin of the miner) for use as claim for payment for autopsies performed on miners. The form will be completed with the assistance of the attending physician, coroner, mortician, or other appropriate responsible person. Medical evidence obtained from the autopsy may also be used in support of Black Lung Benefits claims by the survivor.

The NCWAS is part of a Federally mandated program, and as such, will have budgetary support throughout the approval period. Although the study is a research program, IRB/HSRB approval does not apply. 45 CFR 46 defines a human subject as "... a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

If the collection of information/authorization to perform an autopsy was not conducted, no autopsy could be performed, and there would be no administration of the mandated NCWAS.

A3. Use of Improved Information Technology and Burden Reduction

To maintain the burden at a minimum, only essential information is requested. The data collection form is completed by the next-of-kin of deceased coal miners and electronic data collection technology is very limited or nonexistent. The required autopsy specimens (slides and blocks) can not be provided electronically. There are no known legal or technical obstacles to reducing burden.

A4. Efforts to Identify Duplication and Use of Similar Information

The NCWAS is a unique program and is not a duplication of any existing programs. No other government agency is collecting information needed to administer this program.

A5. Impact on Small Businesses or Other Small Entities

Portions of the data collection must be submitted by pathologists. Many pathologists/physicians are incorporated as small businesses. The questions and required documentation have been held to the absolute minimum required for the intended use of the data. In addition, the data collection design allows for minimum burden.

A6. Consequences of Collecting the Information Less Frequently

Completion of this form is performed only once. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection of information is consistent with and fully complies with the guidelines in 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The 60-day notice was published in the Federal Register (May 17, 2006, Vol. 71, No. 95, pages 28702-28703) (**Attachment F**). To date, no comments have been received from the public.

B. The NIOSH project officer routinely discusses the use of the data collection instrument with major organizations of pathologists, pulmonary specialists, and occupational safety and health organizations. No changes have been recommended in the form since it was approved in 1996.

A9. Explanation of any Payment or Gifts to Respondents

Respondents (next-of-kin) are not being paid, remunerated or given any type of incentive to respond. The pathologist providing the autopsy is paid \$200 per case as outlined in 42 CFR 37.204.

A10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this collection and has determined that the Privacy Act is not applicable because information being collected pertains to deceased individuals. While names of the coal worker's next-of-kin are collected on the "Consent, Release and History Form," no other personal information on that individual

is collected. Name, Social Security Number, employment and smoking history of the deceased miner are entered on the form as required under Title 42, Chapter 1, Subchapter C, Part 37, Figure 1. Within the NIOSH NCWAS, cases are not filed by Social Security Number, but rather by a number assigned as they are received and accepted for payment.

All records are stored at the NIOSH facility in Morgantown, West Virginia (1095 Willowdale Rd.). Forms and specimens are transmitted to NIOSH from the respective pathologists via regular U.S. Postal Service (usually overnight delivery). No privacy act safeguards are applicable. Data is protected in accordance with standard security safeguards: records are maintained in locked cabinets within locked rooms, and access is limited to staff directly involved in the study. Computerized files are password protected. No identifiable information is released from the NCWAS database without prior written permission of the next-of-kin.

A11. Justification for Sensitive Questions

In collecting data through the NCWAS, the Social Security Number of the deceased is obtained strictly for correlative and verification purposes and as a tool to avoid duplicate payment for autopsies. By checking Social Security Numbers, we are able to determine whether or not we have received an autopsy and made payment for it previously. This guards against error in reimbursement which could result in the same autopsy being paid for more than one time. As a correlative and verification instrument, the Social Security Number enables the NCWAS to match the autopsy report received to the x-ray, if available, and, if necessary, to medical records maintained by various hospitals and/or physicians. This is particularly important in the establishment of parameters to be used in the diagnosis of coal workers’ pneumoconiosis. The number is also used to match autopsy reports to death certificates maintained by the individual state governments, for the purpose of correlating causes of death.

Race and ethnicity are not collected as they are not applicable to the outcomes of the NCWAS.

A12. Estimates of Annualized Burden Hours and Costs

- A. It is estimated that only 5 minutes is required for the pathologist to put a statement on the invoice affirming that no other compensation is received for the autopsy. In as much as an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request of an abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the autopsy report. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete form CDC/NIOSH 2.6.

12A Estimated Annualized Burden Hours

Type of Respondent	Number of	Number of	Average Burden	Total Burden
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	Respondents	Responses/ Respondent	per Response (in hrs.)	Hours
Pathologist (Invoice)	50	1	5/60	4.2
Pathologist (Final diagnosis)	50	1	5/60	4.2
Next-of-Kin (CDC.NIOSH 2.6)	50	1	15/60	12.5
Total	50			21

- B. Based on an average of \$60.00 per hour for the pathologist at 8.4 burden hours, and \$12.00 per hour for the next-of-kin respondent at 12.5 burden hours, the annualized cost for all possible respondents is \$654.00. The rate of pay for pathologists was determined by comparing what a government pathologist is paid (GS-14, \$43 per hour) and raising the cost to reflect private industry wages. This amount is considered to be accurate. The rate of \$12 as an hourly wage for the Next-of-Kin is considered to be an accurate wage.

12B Estimated Annualized Burden Costs

Type of Respondent	Number of Respondents	Frequency of Response	Total Burden (in hrs.)	Hourly Wage Rate	Respondent Cost
Pathologist	50	1	8.4	\$60.00	\$504.00
Next-of Kin	50	1	12.5	\$12.00	\$150.00
Total					\$654.00

A13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no other cost burdens to respondents or recordkeepers.

A14. Annualized Cost to the Government

- A. 50 autopsy cases per annum @ \$200/case = \$10,000.00 per annum
(U.S. Govt. Cost - Reimbursement to Pathologists)
- B. 2.5 hours per case @ \$16/hour (\$40) x 50 cases = \$ 2,000 per annum
(U.S. Govt. Administrative Cost - for government support staff GS-5/5)

C. 200 printed forms @ .04 (U.S. Govt. Cost)	= \$ 8.00 per annum
D. 50 cases per annum @ \$3.00/case (U.S. Govt. Cost - Nosology Coding Services)	= \$150.00 per annum
Total:	\$ 12,158.00 per annum

A15. Explanation for Program changes or Adjustments

Burden hours for this data collection remain the same as in previous approvals.

A16. Plans for Tabulation and Publication and Project Time Schedule

The purpose of this collection is to provide information that will be used by the staff of NIOSH for research purposes in defining the diagnostic criteria for coal workers' pneumoconiosis (black lung) and will be correlated with pathologic changes and x-ray findings. Medical evidence obtained from the autopsy may also be used in support of Black Lung Benefits claims by the survivor. Regular project reports including figures of participation are reviewed quarterly. Epidemiologic data will be presented at scientific meetings as various trends are discovered.

This is an ongoing mandated project with no expected termination date or project time schedule.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

An exemption from displaying the OMB expiration date is requested. The data collection for the NCWAS is a constant and consistent collection. In order to make the most efficient use of stockpiled forms, we request approval not to print the expiration date on all forms associated with the NCWAS.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exemption requested.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Data collection procedures are outlined below. This collection of information does not employ statistical methods. The following procedures are used to collect information:

In the event of death of an active or inactive miner, the next-of-kin is informed by the attending physician, mortician, or any other responsible person of the autopsy provision. If

necessary, these individuals will also assist the next-of-kin with the completion of the form. If the next-of-kin authorizes the autopsy, the pathologist who performs the autopsy must submit a claim for payment to NIOSH stating that no other compensation has been received from any other source and include the original autopsy report with those items on the NCWAS checklist (**Attachment E**) being required.

1. Respondent Universe and Sampling Methods

The respondent universe includes all of the pathologists who perform the autopsies and submit the claim to NIOSH, and includes the items on the NCWAS checklist.

2. Procedures for the Collection of Information

In the event of death of an active or inactive miner, the next-of-kin is informed by the attending physician, mortician, or any other responsible person of the autopsy provision. If the next-of-kin authorizes the autopsy, the pathologist who performs the autopsy must submit a claim for payment to NIOSH stating that no other compensation has been received from any other source and include the original autopsy report with those items on the NCWAS checklist being required. All records are stored at the NIOSH facility in Morgantown, West Virginia. Forms and specimens are transmitted to NIOSH from the respective pathologists via regular U.S. Postal Service.

3. Methods to Maximize Response Rates and Deal with Nonresponse Rates

This section does not apply to this data collection because 42CFR 37.204 is a federally mandated law requiring collection of this data.

4. Tests of Procedures or Methods to be Undertaken

The NIOSH project officer routinely discusses the use of the data collection instrument with major organizations of pathologists, pulmonary specialists, and occupational safety and health organizations. No changes have been recommended in the form since it was approved in 1996.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

This project has been ongoing since NIOSH was given the statutory authority under 42 CFR 37.204 (1977). The project officers are available for consultation. Their contact information is on the following page.

The purpose of this collection is to provide information that will be used by the staff of NIOSH for research purposes in defining the diagnostic criteria for coal workers' pneumoconiosis (black lung). Additionally, medical evidence obtained from the autopsy may be used in support

of Black Lung Benefits claims by the survivor. Regular project reports including figures of participation are reviewed quarterly.

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LIST OF ATTACHMENTS

- A. Federal Coal Mine Health and Safety Act of 1977, Title II, Sec. 203(d)
- B. Code of Federal Regulations 42, Chapter 1, Subchapter C, Part 37
- C. Consent, Release and History Form (CDC/NIOSH 2.6)
- D. Sample Invoice
- E. National Coal Worker's Autopsy Study Checklist (NCWAS)
- F. Federal Register Notice Announcing 60-Day Comment Period