



CORRESPONDENCE LETTER-Former Worker Medical Screening Program Annual Review

NUMBER	VERSION	APPROVED BY	PAGE
HRP-588	10/16/20	E. White/C. Hautala-Bateman	1 of 4

See HRP-001 for definitions of applicable key terms and acronyms.

Central Department of Energy Institutional Review Board (FWA 00015568)

June 2, 2021

Title of Study:	Building Trades National Medical Screening Program
Investigator:	Knut Ringen
Type of Review:	Annual Update
Submission ID:	DOE000639
Funding Source:	DOE/Office of Health and Safety (AU-10)
Documents Reviewed:	<ul style="list-style-type: none"> • BTMed 2021 BE consent • BTMed 2021 Consent for exam • BTMed 2021 Consent for interview • BTMed 2021 Consent to participate • BTMed 2021 Continuing Review Application • BTMed 2021 Covid consent • BTMed 2021 ELCD consent • BTMed 2021 Rescreen consent • BTMed 2021 Training Certificates
Review Date:	6/1/2021

Thank you for your submission of the annual update of this Former Worker Medical Screening Program. This submission was reviewed by the Central Department of Energy Institutional Review Board (CDOEIRB) for accuracy and ethical soundness. This review of this is not considered a human subjects research review because under the Federal Regulations (10 CFR 745) this former worker screening program does not meet the definition of research. **If there is an interest in doing analysis or research with the screening data collected, a new application must be submitted to the CDOEIRB for review.**

Before the anniversary date or within 30 days of study closure, whichever is earlier, you must submit a continuing review application/progress report. To submit a continuing review navigate to the active study and click "Create Modification/CR" in the IRB Electronic System.



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Please note that all Former Worker Program leads must immediately report to the IRB:

- Changes in the approved activity or to previously approved materials
- Any new information that might increase the risks or decrease the benefits to participants, or affect a participant's willingness to continue participation in the program
- **All unanticipated problems, adverse events, non-compliance issues, and complaints (see DOE Order 443.1C, Protection of Human Research Subjects).**

All records must be retained for a minimum of three years after the completion of the program.

An annual update should be provided at least two weeks before the anniversary date of 6/12/2022.

Sincerely,

James Morris, Chair
Central DOE Institutional Review Board
CDOEIRB@orau.org
865-574-4359

cc: CDOEIRB Files
L. Harmond, Manager, FWP
C. Hautala-Bateman, Manager, NNSA HSPP
E. White, Manager, DOE HSPP
S. Weatherwax, DOE IO

Attachment:

Reminder: What are my obligations as a Former Worker Program Principal Investigator after IRB approval?

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