Central Department of Energy Institutional Review Board (FWA 00015568)

May 16, 2024

Title of Study:	Building Trades National Medical Screening Program
Investigator:	Knut Ringen
Type of Review:	Continuing Review
Submission ID:	DOE001023
Funding Source:	DOE/Office of Health and Safety (AU-10)
Documents Reviewed:	• BTMed HRP-595- Annual FWP Review App(0.01) • Consent - Consent Beryllium testing(0.01) • Consent - ELCD(0.01) • Stage 1 consent - Participation(0.01) • Stage 2 - Consent to be interviewed(0.01) • Stage 3 - Consent to Medical Exam(0.01)
Action:	Not Human Research
Review Date:	5/16/2024

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 research with the data collected as part of this former worker medical screen program, a new application must be submitted to the IRB for review.

Before the expiration 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.

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.

If continuing review is not granted before the expiration date of 6/1/2025, approval of this study expires on that date and all activity that involves participants must cease.

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

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

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Reminder: What are my obligations as a PI after IRB approval?

1) Do not start Human Subjects activities until you have the IRB review letter.
2) Do not start Human Subjects activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing activities that involves their resources.
3) Ensure that there are adequate resources to carry out the program activities safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified team members, equipment, and space.
4) Ensure that activities staff are qualified (e.g., including, but not limited to, appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. Note that all members of the team who have access to personally identifiable information or who are responsible for participant interaction or intervention must complete training on the protection of human participant activities. DOE offers this training to researchers at DOE laboratories/sites and to DOE-funded researchers from institutions outside the DOE complex.
5) Update the IRB office with any changes to the list of study personnel.
6) Personally conduct or supervise the program.
   a) Conduct the program in accordance with the relevant current protocol as reviewed by the IRB.
   b) When required by the IRB, ensure that consent or permission is obtained in accordance with the relevant current protocol as reviewed by the IRB.
   c) Do not modify the program without prior IRB review unless necessary to eliminate apparent immediate hazards to participants.
   d) Protect the rights, safety, and welfare of participants involved in the program.
7) Submit to the IRB:
   a) Proposed modifications.
   b) A continuing review application as requested in the approval letter.
   c) A continuing review application when the program is closed.

8) Report any of the new information items in a Reportable New Information (RNI) in the IRB Electronic System to the IRB within 48 hours **or as required by DOE O 443.1C**. In the case of loss of personally identifiable information, for example, reporting to the IRB and other authorities is required immediately.

9) Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

10) Ensure that you comply with the requirements of sponsoring organizations/agencies, which may be in addition to those that are required by the Federal Regulations and DOE. **You must comply with the more stringent requirements**. Consult with the IRB if you need clarification.