Scope of Work
Review of Medical Surveillance of Coal Mine Dust Lung Disease Component of the Coal Mine Workers’ Health Scheme

I. Background
Coal Mine Dust Lung Disease\(^1\) (CMDLD) – the broad term for diseases caused by coal mine dust exposure, comprises a group of occupational lung diseases that result from the cumulative inhalation of respirable coal mine dust. Coal miners are at risk of developing these diseases, which include the classic fibrotic lung diseases of coal workers’ pneumoconiosis, mixed dust pneumoconiosis and silicosis, as well as chronic bronchitis, emphysema and diffuse dust related fibrosis. Spirometry can identify earlier declines in lung function than can chest x-rays (CXR) and is used to diagnose chronic bronchitis and emphysema.

All Queensland coal mine workers are required under the *Coal Mining Safety and Health Act 1999 (Qld)* and *Part 6 of Division 2 of the Coal Mining Safety and Health Regulation 2001* to undergo a Coal Mine Workers’ Health Scheme (“scheme”) medical assessment prior to the start of their employment at a coal mine and then at least once every five years during their employment. This medical assessment scheme commenced in 1983. The parts of the medical assessment relevant to the early detection of coal mine dust lung diseases includes a medical history, physical examination, spirometry to assess lung function, and a posterior-anterior CXR. A CXR is only required when the employer has advised that the coal mine worker is ‘at risk from dust exposure.

Medical assessment under the scheme is the responsibility of Nominated Medical Advisers (NMAs) who are required to complete a “Report on Health Assessment” (“report”) at the completion of the assessment. The actual medical assessment may be performed by the NMA or an Examining Medical Officer (EMO), however only the NMA may complete and sign off on the report. The report is provided to the coal mine worker and the employer. The completed full health assessment form is also forwarded to Mines Safety & Health of the Department of Natural Resources & Mines of the Queensland government.

A medical assessment conducted under the scheme covers a wide range of health matters, such as the musculoskeletal system, visual acuity, colour vision and audiometry, but this review only relates to those aspects of the medical assessment related to the early detection of respiratory disease caused by coal mine dust exposure and other components of the medical assessment are not part of this review.

As of December 2015, five confirmed and two possible cases of pneumoconiosis in coal miners had been identified in Queensland in 2015 after no new cases had been reported in many years. None of these cases had been detected within the existing coal mine workers’ health scheme and therefore it is imperative that the design and operation of the respiratory component of the medical assessments performed under the Coal Mine Workers’ Health Scheme be reviewed.
II. Objectives of the Review:
A. Determine whether the respiratory component of the medical assessment performed under the Queensland Coal Mine Workers’ Health Scheme is adequately designed and implemented to most effectively detect the early stages of coal mine dust lung diseases in Queensland coal mine workers, estimating the extent and providing feedback and, if not,
B. Recommend necessary changes to correct deficiencies identified under Objective A, recommend measures to follow up cases that may have been missed as a result of these deficiencies and identify what additional capacity is needed in Queensland to improve this scheme.

III. Scope of the review:
A. The adequacy of the scope, processes, quality and reporting of the respiratory component of the existing medical assessment program, including information provided by the employer on risk of dust exposure, medical history, physical examination, chest radiography and spirometry, in detecting the early stages of coal mine dust lung disease.
B. The expertise and resources required, firstly to undertake high quality medical assessments (respiratory component) under the scheme, secondly to have effective referral pathways for suspected of a CMDLD, thirdly to use the gathered data to effectively implement a high quality medical surveillance program for the early detection of coal mine dust lung disease in Queensland coal miners and fourthly to make the information available to relevant stakeholders for necessary action.
C. The expertise and resources currently available in Queensland to perform medical assessments, perform and interpret high quality CXR and perform and interpret high quality spirometry. This will include a review of expertise and training of the current list of Nominated Medical Advisers, the use of EMOs and the specialist respiratory physicians available for referral and subsequent patient care.
D. Where deficiencies are found, make recommendations to improve the current program for the medical assessment of coal mine dust lung disease to achieve a state of the art program for the reliable detection of early disease.
E. Recommendations to build capacity in Queensland to ensure that a list is available of sufficient numbers of suitably qualified practitioners to be NMAs, respiratory physicians, trained personnel to carry out and interpret chest x-rays (CXR) and spirometry, where the current level of expertise and/or resources are found to be inadequate.
F. Depending upon findings from A, B and C, make recommendations for an interim strategy to handle undetected cases and ensure that the current cohort of mine workers is effectively screened for coal mine dust lung disease until longer term recommendations can be implemented.
G. Develop a methodology for the review of past x-rays and spirometry to estimate the extent of coal mine dust lung disease that may have been undetected by the medical assessment scheme.
H. Develop a research plan to measure the current prevalence of CMDLD in Queensland coal mine workers.
IV. The initial phases of the review will involve the following steps:

A. Review of the confirmed or suspected cases, including a review of their medical assessment data collected under the coal mine workers’ health scheme and any additional medical testing that may have been performed (where available) to determine reasons why they were undetected under the current medical assessment scheme.

B. Review of the content and design of the respiratory component of the current seven-page “Health Assessment Form”, including information about the worker’s medical history, symptoms, job history, information provided by the employer about risk of dust exposure and access to any previous medical assessments undertaken on the worker under the medical assessment scheme. This will include a review of completeness of a sample of recent forms, exploration of possible reasons for incompleteness as well as a review of alternative forms of recording the findings, such as online completion and inclusion of digital CXR and spirometry data.

C. Review of the current criteria used to evaluate risk of dust exposure for the purposes of selecting those requiring CXR screening including when their job or job site changes.

D. Review of the list of NMAs, required expertise and training undertaken, as well as the role of EMOs.

E. Review of the x-ray testing and procedures:
   1. Information provided to the clinic performing the x-rays.
   2. Quality of the imaging performed at x-ray facilities.
   3. Procedures used to select clinic sites to take CXRs.
   4. Qualifications and training of radiologists, physicians or other medical practitioners who interpret chest radiographs for the presence of pneumoconiosis according to the International Labour Organization (ILO) International Classification of Radiographs (2011 revised edition, which includes digital images) and use of the ILO recommended reporting form.
   5. The interpretation and reporting of the CXR to NMAs/Department of Natural Resources and Mines

F. Review of the spirometry testing and procedures:
   1. Including information provided to the clinic performing the spirometry,
   2. The facilities where the spirometry is undertaken
   3. The training and certification of the technicians who perform and interpret the spirometry
   4. The quality control measures
   5. The interpretation and reporting of the spirometry to NMAs/Department of Natural Resources and Mines.

G. Review of data collection, storage system and security used by the Department of Natural Resources and Mines, including accessibility by the NMA of findings from previous medical assessments under the scheme performed on the worker.

H. Review of classification of the outcome of medical assessments and overall reporting of the results of medical assessments, at to the Department of Natural Resources and Mines.

I. Review of medical surveillance programs for coal mine workers in other states of Australia and in other countries where coal mining is common, including training and quality control measures.
J. Investigate other sources of routine health data collected in Queensland which can assist in estimating the burden of coal mine dust lung disease among Queensland coal miners.

V. Methodology to review a sample of existing chest radiographs
The aim is to review a sample of x-rays performed under the scheme, examine their quality and then compare the readings with both the original report made by the radiologist (or other x-ray reader) and what was reported by the NMA on the Report Form.

A. Human research ethics committee (Institutional Review Board) application has been submitted to the University of Illinois for this review of existing x-ray and other relevant data and waiver of informed consent has been sought. Monash University Human Research Ethics Committee approval will also be sought.

B. Collect existing chest x-rays and reports for a sample of up to 500 miners. Sample to include half from Carborough Downs Mine, Vale and the other half from a sampling of other Qld coal mines of varying sizes. We propose to limit review to coal miners with at least 10 years of total underground mining experience.

C. Chest x-ray reviewers drawn from the Royal Australian and New Zealand College of Radiologists and the USA, e.g. NIOSH B-readers, will be required to read the x-rays using the ILO protocol.

D. Methods to review existing x-rays:
1. Assess quality of the x-rays by applying the ILO criteria of quality one through three, or unreadable.
2. All CXRs will be reviewed by at least two review readers. An additional three review readers will be available if agreement is not achieved by the first two readings. The images will be categorized according to ILO criteria using the following procedure developed for the US Coal Workers’ Health Surveillance Program. (Note: NIOSH data shows agreement between 2 readers as defined in the protocol 92% of the time, the third reader allows a determination for an additional 6% of x-rays, and the remaining 2% require the full panel of 5 readers.)
3. Compare the reports by the review readers with the original reports on the x-rays to determine if there is a categorical agreement, as described below:
4. Original x-ray reports to be reviewed by two qualified radiologists or thoracic physicians (blinded to the review reports described above) and categorized as follows:

<table>
<thead>
<tr>
<th>X-Ray Categories</th>
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<tr>
<td>1. Normal</td>
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<tr>
<td>2. Abnormal consistent with simple pneumoconiosis</td>
</tr>
<tr>
<td>3. Abnormal consistent with complicated pneumoconiosis</td>
</tr>
<tr>
<td>4. Other abnormality not pneumoconiosis</td>
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The Coal Miners’ Health Scheme radiology report will be considered to agree in general with the ILO final reading, as follows:

**Agreement where:**
- Normal - ILO categories 0/-, 0/0, or 0/1
- Simple pneumoconiosis - ILO categories 1/0 through 3/+  
- Complicated pneumoconiosis - ILO category A, B or C.  
- Other abnormality - not pneumoconiosis.

E. Where important discrepancies are identified, notify the coal mine worker via appropriate practitioner(s) about results of the re-evaluation of their x-ray results according to procedures within the Coal Mine Workers’ Health Scheme.

F. Report the overall findings, focusing on agreement between the original x-ray reports and reports from the review readers. Where there is disagreement, common features, such as one particular mine, a particular job category etc, will be investigated.

**VI. Review of existing spirometry results.**
The aim is to review a sample of the spirometry data, examine their quality, and compare the findings with those reported by the NMA on the Report Form.

A. Monash University Human Research Ethics Committee approval will be sought.

B. Collect 300 existing spirographs and reports performed under the scheme for a sample of coal mine workers drawn from a sample of coal mines of varying sizes and from a variety of NMAs, including if possible some serial spirometry data.

C. Review of the spirometry data will require two reviewers experienced in interpreting lung function data.

D. Methods to review the existing spirometry data:
The aim will be to evaluate the quality of past spirometry testing to determine quality, interpretability, and severity and pattern of impairment according to TSANZ criteria.

1. The quality of each test will be assessed as follows:
   - Interpretable – meets criteria for quality
   - Usable – meets criteria for usability of FEV₁
   - Uninterpretable – does not meet criteria

2. The two reviewers will independently examine the spirometry data to determine the pattern and severity of impairment, using a classification similar to the following:

3. The Coal Miners’ Health Scheme spirometry reports will then be blindly assessed, using the criteria as noted in the shaded box below:
Pattern of Impairment

- **Obstructive**: FEV1/FVC < LLN; FVC > LLN; and FEV1 < LLN, or
- **Restrictive**: FEV1/FVC > LLN; and FVC < LLN or
- **Mixed**: FEV1/FVC < LLN; and FVC < LLN

Severity of Impairment

- **FEV1 ≥ LLN** (Normal)
- 70% reference ≤ FEV1 < LLN (Mild)
- 60% reference ≤ FEV1 < 70% reference (Moderate)
- 50% reference ≤ FEV1 < 60% reference (Moderately Severe)
- 35% reference ≤ FEV1 < 50% reference (Severe)
- FEV1 < 35% reference (Very Severe)

E. Where a major discrepancy is found, notify the coal mine worker via appropriate practitioner(s) about results of the re-evaluation of their spirometry according to procedures within the Coal Mine Workers’ Health Scheme.

F. Report the overall findings, focusing on agreement between the existing reports and new reviewer reports. Where there is disagreement, any common features, e.g. one particular mine, a particular job category etc, will be investigated.

VII. Timelines

A. Preparation of protocols: January/February 2016
B. Meeting of the study team and the Reference Group in mid January 2016.
C. Site visit and meetings with reference group and stakeholders February 2016
D. It is planned that interim findings on several aspects of the scope of work will be available and reported by the end of the first quarter of 2016.
E. Further findings from those aspects of the review requiring review of medical records, including ethics committee approval, will be available by the end of June 2016.

VIII. Expertise

A. Monash University

1. Prof Malcolm Sim BMedSc, MBBS, MSc(Lond), GDipOccHgy, PhD, FAFOEM, FAFPHM, FFOM is Director of the Monash Centre for Occupational and Environmental Health (MonCOEH) and an occupational physician and epidemiologist with extensive experience in medical monitoring programs and undertaking long term studies of workers in a wide range of industries investigating, cancer, respiratory disease and other health outcomes.

2. A/Prof Deborah Glass MA, MSc, PhD, COH FAIOH is a qualified occupational hygienist at MonCOEH with many years of experience in exposure
assessment for epidemiological studies of workers, such as the national Firefighter Cohort Study. A/Prof Glass is a member of the Threshold Limit Value (TLV) Committee of the American Conference of Governmental Industrial Hygienists.

3. Dr Ryan Hoy MBBS, MPH, FRACP is an occupational respiratory physician with appointments at Monash University and the Alfred Hospital in Melbourne.

4. Prof Bruce Thompson FANZSRS PhD is Head Physiology Service, Dept of Allergy, Immunology & Respiratory Medicine, Alfred Hospital which performs lung function tests on more than 7000 patients per year. Prof Thompson has a particular interest in training and quality control of spirometry.

5. Dr Mina Roberts, MBChB, GDOEH, MPH is an occupational medicine trainee and research assistant.

6. Other staff will be co-opted, as required

B. University of Illinois

1. Prof Robert Cohen MD, FCCP is a Clinical professor at The School of Public Health, University of Illinois at Chicago, and Professor of Medicine, Director of Occupational Lung Disease at Northwestern University Feinberg School of Medicine. He is a pulmonary physician and Certified X-ray B reader with extensive clinical and research experience in coal mine dust lung disease. He also has an appointment in the Respiratory Health Division at NIOSH and is a consultant and contractor for the U.S. Department of Labor, Mine Safety and Health Administration.

2. A/Prof Leonard Go MD is an occupational pulmonary physician. Dr. Go is a consultant with the U.S. Department of Labor reviewing the quality and procedures used by the Black Lung Benefits program.

3. Kirsten Almberg, MS, Research assistant.

4. Other staff will be co-opted, as required

C. Reference Group: To assist the review team, a reference group comprising members from trade unions, mining companies and other stakeholders has been established.

IX. References

