Australian Government
National Health and Medical Research Council

NHMRC

Targeted Call for Research into Biotoxin-related Illnesses in Australia (Biotoxin TCR)

Consultation Response Form

The purpose of this survey is to seek input from experts, research end-users and policy makers in the field of biotoxin-related illnesses. The information you provide will inform the design of this TCR, by helping NHMRC better understand the research gaps the TCR seeks to address. NHMRC will not share your responses with other respondents to this survey. Please provide your responses in the fields below.

Name	Mr. Caleb Rudd
Institution[1]	Toxic Mould Support Australia (http://toxicmould.org/)
Position	Facebook administrator, Website editor.
Affiliations (related to biotoxin/biotoxin-related illnesses research, impacted community, etc.)	
Please describe any real or perceived conflicts of interests you may have to this TCR:	I'm employed by Dr. Sandeep Gupta for research and design of educational materials including the online course, Mold Illness Made Simple. Employed by US non-profit International Society for Environmentally Acquired Illness (ISEAI) for research, design of educational materials and technical support.

[1] Leave blank if the responses are your personal views and not that of your institution, organisation or agency.

The responses below will inform development of NHMRC's TCR into Biotoxin-related Illnesses in Australia.

We suggest not exceeding **250 words** (1/2 page) per answer.

What are the gaps in evidence for biotoxin-related illnesses and CIRS-like symptoms caused by indoor mould that most urgently need to be addressed in Australia?	Gaps include the unknown prevalence of CIRS/biotoxin-related illness in the Australian population; validation of previously identified biomarkers, and new biomarkers, for diagnosis of CIRS; and a lack of clinical studies identifying efficacious treatments for CIRS. Types of studies needed: A) Large scale cohort/cross-sectional epidemiological studies to screen portions of the population for CIRS-like symptoms and other multi-system, multi-symptom illnesses, such as ME/CFS, Fibromyalgia, MCS, MCAS, and EHS, along with past or current exposure to WDB. Should include symptom cluster[1], WDB-exposure questionnaires[2] plus (ideally) online VCS test[3]. B) Cohort or clinical studies that seeks to validate previously published biomarker testing for CIRS[4 5 6], plus mycotoxin levels in blood[7 8] and urine[9], presence of microbial infection or colonisation, including fungal, in those with CIRS symptoms/diagnosis and those without (healthy controls). Include WDB assessment (see D). C) Clinical studies, preferably RCTs, that seek to replicate, and expand upon, previously published studies on treatment protocols for CIRS patients, that included removal from WDB and the use of medications including cholestyramine[10] and VIP[11 12 13]. (Subset of participants from B.) D) Concurrent studies establishing criteria for classification of WDBs. Criteria could include visual assessment and moisture mapping by an IEP, microbial growth sampling (viable and non-viable air sampling, qPCR and NGS testing of settled dust of fungi and bacteria, direct swab), gases and mVOC/VOC measurements. [14 15 16 17 18] Once WDB criteria is established, further studies should be undertaken to determine the prevalence of WDB across the housing stock of Australia including private, commercial and public buildings, including public housing, across multiple demographics and geographics.
How would addressing these gaps benefit the diagnosis, treatment and/or management of patients?	Once prevalence, diagnostic and treatment studies have been completed as per question 1, there should be a validated method to screen patients presenting to GPs or specialists with multi-system, multi-symptom syndromes for CIRS, possibly using symptom-cluster analysis and VCS. If positive, or equivocal, screening via a panel of blood, urine, MRI, nasal (or other culture) biomarker testing (identified by Q1, B) should be able to diagnose patients with a high degree of sensitivity and specificity.

	Once diagnosed a validated treatment protocol (identified by Q1, C) can be prescribed. This may include commercial and compounded medications and non-prescription nutritional supplements. The protocol may also include referral to (or advice to obtain the services of) an IEP for building inspection. Biomarkers used in the diagnosis may be needed to be repeated over the course of treatment to track progress.
What research, if any, is already underway or planned to address these gaps and how could a TCR best complement these activities?	I'm not aware of research already underway in this area. However, PANDIS (https://pandis.org/) headed by Prof. Gilles Guillemin, is planning research into this area via their Biotoxin-CIRS mould working group. Another working group with Dr. Sandeep Gupta, Ms. Nicole Bijlsma, Prof. Marc Cohen, Dr. Georgina Hale, Mr. Sean Di Lizio, and myself are in the process of forming.
What are the challenges in addressing the need for research into these conditions?	Challenges include the acceptance of CIRS and related syndromes of innate immune activation due to exposure to WDB -- mold illness, mycotoxicosis, mixed mold mycotoxicosis (MMT), indoor mold sensitivity, sick-building syndrome (SBS), damp building-related illnesses (DBRI), biotoxin-related illnesses, toxic mold syndrome, toxicant-induced loss of tolerance (TILT), and dampness and mold hypersensitivity syndrome (DMHS) -- by medical professionals, public health officials and the community at large. Certain arms of the medical profession including allergists and immunologists, view mould as contributing to allergy, and respiratory conditions only, and may not accept the CIRS model even if high quality studies as outlined in 1 are published. A separate challenge is to integrate the built environment side, and inspection and remediation of WDBs, in conjunction with the medical side. Also, the inspection and remediation of Australian private and public housing WDBs is a huge area with regards to resources and cost. Another challenge is having access to CIRS biomarker tests, such as C4a, TGF-b1, MMP-9, VEGF and MSH, urinary mycotoxin analysis, plasma mycotoxin antibody analysis, in Australia via NATA/RCPA accredited laboratories. This is needed for the research studies as outlined in 1, and then for use in the greater community, ideally with Medicare item numbers. CIRS biomarkers including HLA DR/DQ, Leptin, ADH, VIP, NeuroQuant MRI analysis, are available to much of the Australian community but only VIP and HLA are currently covered by Medicare, while the MRI imaging scan part of NeuroQuant is covered but only if certain conditions are met. Affordability for testing and treatment is a huge need flagged by the Toxic Mould Support Australia community.
What research areas are likely to: **a. reduce the impact of biotoxin-related illnesses on affected individuals and communities**	If studies are undertaken as per Q1 an estimate of the prevalence and incidence of CIRS/biotoxin-illness will be known. This along with validated screening and diagnostic testing will enable education of health professionals and public on the burden that CIRS and WDBs present to the Australian population plus a diagnostic and treatment course for those suffering from CIRS.

b. assist health services to manage these health issues, and/or enable policy makers to make informed decisions?	If WDB criteria are created (Q1, D) public buildings can be assessed and remediated using established IICRC S520 Mold Remediation standards[19]. Records of such assessments per a standard would enable policy makers to make better informed decisions.

ACRONYMS

ADH – Antidiuretic Hormone
CIRS – Chronic Inflammatory Response Syndrome
EHS – Electromagnetic Hypersensitivity Syndrome
HLA – Human Leukocyte Antigen
VEGF – Vascular Endothelial Growth Factor
VIP – Vasoactive Intestine (Poly)peptide
MCAS – Mast Cell Activation Syndrome
MCS – Multiple Chemical Sensitivity
ME/CFS – Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
MMP-9 – Matrix Metalloproteinase 9
MRI – Magnetic Resonance Imaging
MSH – alpha-Melanocyte Stimulating Hormone
TGF-b1 – Transforming Growth Factor beta-1
mVOC – microbial Volatile Organic Compound
VOC - Volatile Organic Compound
WDB – Water-damaged Building

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