

UNSW Sydney Feedback to the Review of the National Gene Technology Scheme

In the opinion of Researchers at UNSW Sydney, the Scheme has been working well. However, there is a number of important issues we wish to bring to the attention of the Forum under its terms of reference.

1. Current developments and techniques

UNSW's submission of feedback to the OGTR Technical Review of Gene Technology in December 2016 covered the salient points on the issues of new techniques.

2. Existing and potential mechanisms to facilitate an agile and effective Scheme

There is an opportunity to improve the efficiency and effectiveness of the Scheme.

- **The need to harmonise OGTR inspections between licensed dealings (DNIR/DIR) and certified facility (PC3) monitoring inspections.**

These inspections are currently conducted by two distinct units of the OGTR, each inspecting at different times and presenting and following up on different findings. For example, UNSW underwent four separate inspections of a single DNIR and the respective facility within the last three years, with considerable impact on research and management efforts. Instead, we suggest the units tasked with the inspections could be combined to allow for a single inspection to cover both licensed dealings and monitoring inspections which are closely related. This harmonisation would greatly assist in improving efficiency and avoiding disruption to research. It would also remove the potential for conflicting findings during competing inspections.
- **The need to reduce the 90 working days for OGTR to make decisions on an application/submission.**
 - a) *DNIR applications:* There is currently a 90 working day requirement for OGTR to make a decision on applications and on submissions to vary license conditions, many of which involve relatively minor changes. This period is disruptive to timely research and impedes the ability of Australian researchers to compete internationally. Delay often prevents a researcher from progressing their research, can be costly, and is a substantive disadvantage in a highly competitive global environment.
 - b) *Facility certification/variation applications:* Institutional IBCs already inspect PC facilities, in particular if they are at the level of PC2 and above. As the OGTR is relying on the inspection reports of Institutions and their IBCs, it would be appropriate that these committees are also be permitted to give provisional approval for PC1 and PC2 facilities, subject to ratification by the OGTR. This would avoid potentially costly delays to research currently experienced by universities and research institutes due to the 90 day application period.

3. Appropriate Legislative Arrangements

- **Amend the oversight regulations to better support and review medical research.**

Currently the Gene Technology Technical Advisory Committee (GTTAC) reviews the risk assessment of pathogens in DNIR/DIR license applications against the Regulations which are reviewed every five years. Institutional IBCs review Exempt and NLRD applications, also against the Regulations. However, our knowledge of risk profiles for pathogens used in medical research advances faster than the five-year cycle, typically outdating the risk management for pathogens in medical research as specified in the Regulations.

Ideally, experts would regularly review and update management practices for pathogens used in medical research so that practices can be adapted as knowledge of the pathogens advances. However, the time frame required to update the Regulations makes it difficult to update appropriate risk management practices for pathogens used in medical research to reflect these advances. Therefore, new oversight regulations for pathogens and their risk management, specifically for medical research, are required. UNSW supports an agile framework that better supports the field through which new regulatory practices can be implemented as the new knowledge emerges. To do this, current oversight over the regulations would benefit from the inclusion of experts, as mentioned above, to include active medical researchers. These experts could contribute either by expanding the membership and terms of reference of the GTTAC, or by establishing a national IBC analogous to the National Health & Medical Research Council national committees on human and animal research. Either model should draw on researchers with expertise in a range of epidemiological, clinical and basic science research. Risk profiles of pathogens used in medical research could then be updated considerably more quickly than in the current model, and thus facilitate effective and globally competitive medical research in Australia.

- **Modification to the Exempt Organism list**

Schedule 2 - Part 2 Host/vector systems for Exempt dealings should be amended to include all Risk Group 1 organisms where they meet other conditions as set out for Item 4 – Part 2 – Schedule 2 in terms of implication in disease, characterization, toxin coding and viral sequence. For instance, *Bacillus megaterium* is a non-pathogenic soil bacterium that has been used industrially for more than 50 years to produce a variety of enzymes, some of which are used in the food industry (Vary et al. 2007; Bunk et al. 2010; Eppinger et al. 2011). It is classified as a Risk Group 1 organism by the NIH, ATCC and DSMZ, and a kit is commercially available for recombinant protein expression in *B. megaterium* from [MoBioTec](#). It is analogous to *B. subtilis*, which is currently considered an exempt host, yet under the current system it would be classified as NLRD 2.1(c). Other candidates for inclusion in the Exempt host list are members of the Archeobacteria which have no substantiated record of pathogenicity (Cavicchioli et al. 2003; Gill et al. 2011; Aminov et al. 2013).

A more frequent review of the exempt organism list, preferably by an expert committee as proposed in the previous dot point, would improve the competitiveness of Australian researchers.

4. Sustainable Funding Arrangements

We regard the current funding arrangements as appropriate. We suggest that any changes would need to be made in consultation with universities and research institutes to ensure that Australian research remains internationally competitive.