FIAT LUX

Walter+Eliza Hall
Institute of Medical Research

DISCOVERIES FOR HUMANITY

Submission to the 2017 Review of the National Gene Technology Scheme

The Walter and Eliza Hall Institutional Biosafety Committee is pleased to have the opportunity to be able to comment on the review of the Gene Technology Scheme.
The past reviews have provided important changes leading to the sturdy Scheme currently in place. This current review of the Scheme will allow discussion on several points raised that are outside the scope of the technical review of the Gene Technology Regulations.

Based on the 4 points from the Terms of Reference we have the following comments.

1. **Current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continual technological development**

Consideration towards a review of the definitions in both the Act and Regulations to enable capture of new technologies. There is a need for discussion whether gene technology and genetically modified organism as defined in the Act still remain relevant.

2. Existing and potential mechanisms to facilitate an agile and effective Scheme which ensures continued protection of health and safety of people and the environment.

IBC membership requires expertise in specific areas and members often need to volunteer their time to ensure the organization meets it responsibilities under the Act.
IBC members spend considerable time assessing and approving low risk dealings with higher risk dealings forwarded to the OGTR for approval.
The Walter and Eliza Hall Institute IBC proposes changes to NLRDs. Currently an NLRD cannot be extended past the 5 year approval period leading to the submission of a new application even when there is no change to the dealing. Similarily, an NLRD cannot be varied to add simple changes such as a new facility or a new vector, without requiring a new submission.
It would reduce administrative burden to an IBC if the IBC had the ability to extend or vary a dealing where there is no change to the risk.

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The WEHI IBC recommends the downgrading to an exempt dealing, GM laboratory animals currently classified under Schedule 3 Part 1 1.1(a), where it has been demonstrated there has been no history of risk to the health and safety of people and the environment.

3 The appropriate legislative agreements to meet the needs of the Scheme now and into the future, including the Gene Technology Agreement

That all areas of government continue to strive to deliver a truly national scheme that is free of any confusion from additional laws that may regulate GMOs in different states or territories.

4. Funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the Scheme.

The Walter and Eliza Hall Institute supports that current arrangements remain in place but the Department of Health will need to fully resource the OGTR to enable them to continue to carry out their activities. Any implementation of a cost recovery system would place further financial burden on stakeholders from universities and not-for-profit medical research institutes who already struggle to support costs incurred to maintain regulatory compliance.