

Our comments are born from our experience as an institutional biosafety committee and with respect to gene technology regulation from a medical research perspective.

1. In the context of **writing and assessing NRLDs**, FINDING the relevant practical guidance on the OGTR website as well as the OGTRs interface with other relevant regulatory schemes such as the Australian Standard is difficult and overly complicated to access and navigate.

- This impacts on how well researchers understand of the aims of the OGTR and how to best mitigate risk.
- Improving the content and orientation of the information on the website would researchers in finding and understanding the content.

Once you have found the relevant information, we acknowledge that the guidance offered by the OGTR to complete NRLDs is good (eg. flow charts for classifying GMOs), and when we have contacted the OGTR directly for specific help we have found the staff to be responsive, knowledgeable and helpful. In addition, the guidance for administrative procedures related to running an IBC are fine.

2. **CRISPR and related technologies** now make genetic modification a universal tool in the research laboratory and is already being used in animal and human tissue/organisms. Because of its ease of use and versatility, experiments that would previously not been feasible can now being carried out routinely in the lab. e.g. making modifications that are inheritable or making modifications into genes of unknown function that may have an unpredictable effects (including effects that are oncogenic, pathogenic or confer an advantage).

- Clear and continuously updated regulation that conveys the pertinent information to the researchers is needed. This will ensure research in Australia can take advantage of these technologies, while still protecting Australians health, food, environment and agriculture interests.