Guidance document - Requirements for variations to licences or projects

The University Biosafety Committee (UBC) recognises that as research progresses projects may evolve requiring licences to be varied. In order to minimise the number of variations, the original application should include a broad range of facilities, tools and equipment, although the research process and outcomes need to be specific.

For example, add additional facilities to allow for contingency and additional equipment in the event that changes are required even if there is no immediate use. Give consideration to specifying a broad range of mouse strains, allowing for flexibility as the research progresses and avoid the need to obtain a variation.

Changes to *Dealing Not involving Intentional Release* (DNIR) licences

Variation (Unlikely to give rise to additional risks)	**New DNIR application required (May give risk to additional risks)**
OGTR Specified:	
Addition of related gene or related parent organism	Addition of a GMO unrelated to original dealing
Changes to transport of GMOs (including import)	Addition of unrelated genes/change to parent organism
Minor changes to management protocols (e.g. changes of decontamination method)	
Change facility (at same type and level or greater)	
Extension of licence period	
New project supervisor	
UBC Specified:	
New participants to be covered by the licence	

Variations for PC3 facilities

Variation (Unlikely to give rise to additional risks)	**New DNIR application required (May give risk to additional risks)**
OGTR Specified:	
	Introduction of devices that could produce an aerosol or breach contamination layer (these include Centrifuge, aerosolisation device, animal holding, class II cabinet)

Notifiable Low Risk Dealings (NLRD) and *Exempt Dealings* (ED)

Not required to be reviewed by OGTR although they are required to be submitted to the UBC.

Variation (Unlikely to give rise to additional risks)	New NLRD or ED application required (May give risk to additional risks)
Changes to staff and students working on the project. This includes additional of new staff, removal of staff, and changes to class of participants e.g. students and responsibility(s) on the project. Variation would need to justify according to relevant staff experience and risk	Changes to animals (mice/rates/chicken) strains on the project. This includes addition of GMO mouse strains and must include relevant source, and assessment of risk related to new GMO being added on to the project
Minor changes in procedure that do not increase risk or introduce new hazards related to GMO release or exposure or change the original project classification or scope – addition or removal of facilities, addition or deletion of host/vector systems, parent organism or trait.	Changes to bacterial strains on the project. Variations could cover organisms of the same or lesser BSL category and need to be justified according to procedures and risk
	Changes to gene(s) being studies and/or manipulated on the project.

High Risk Biologicals – proposed new application

Application to be submitted to UBC for approval.

Variation (Unlikely to give rise to additional risks)	New application required (May give risk to additional risks)
Research: - Variation to Section 2 (Project Leader Information) and Section 5 (Facilities Used) of the application form. If an incident has occurred.	Any change to any other section of the application form (other than section 2). Changes to legislation or applicable supporting documents such as Codes of Practice or Australian Standards. Every 3 years
Teaching:- As above	Any change to any other section of the application form (other than section 2). Changes to legislation or applicable supporting documents such as Codes of Practice or Australian Standards. Every 5 years