

**THE UNIVERSITY OF MELBOURNE**  
**ANIMAL WELFARE COMMITTEE**

**GUIDELINES ON MONOCLONAL ANTIBODY PRODUCTION**

**Purpose**

This document provides guidelines for the production of monoclonal antibodies (Mabs) in animals at The University of Melbourne. It is designed to assist researchers, animal technicians and Animal Ethics Committees (AECs) to ensure that the scientific aims of a proposal to produce monoclonal antibodies are achieved with minimal discomfort for the animals involved.

**Policy**

All scientific procedures carried out on animals must comply with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (2004), which states:

- 3.3.69 *In vitro* methods should be used for the routine amplification of hybridomas for the production of monoclonal antibodies. Investigators wishing to use the *in vivo* (ascites) method must provide in their proposal to the AEC recent laboratory evidence to show that *in vitro* methods are unsuitable for the specific monoclonal antibody that is the subject of the proposal.
- 3.3.70 In the immunisation phase, investigators must ensure the minimisation of pain and distress to animals from factors including:
- (i) the type, volume, site and frequency of injection of adjuvants; and
  - (ii) the method and frequency of blood sampling.
- 3.3.71 If the ascitic tumour method is to be used, investigators must ensure the minimisation of pain and distress to animals from factors including:
- (i) the type and volume of the priming agent;
  - (ii) accumulation of ascites fluid;
  - (iii) body weight loss (which may be difficult to discern due to overall weight gain from accumulation of ascites fluid and/or the growth of solid tumours);  
and
  - (iv) the removal of ascites fluid.

The University of Melbourne Animal Welfare Committee endorses the NHMRC Guidelines on monoclonal antibody production.

## **Guidelines**

### ***General***

The ascites fluid method of Mab production is no longer acceptable, except in rare cases where in vitro methods are shown to be unsuitable.

### ***Approval***

The AEC should be satisfied that reasonable attempts have been made to ensure that the antibody is not available commercially or from another research group. Investigators wishing to request an external source to produce Mabs for them using the ascites method must obtain AEC approval.

The ascites method of antibody production will only be approved where it has been shown that in vitro methods are unsuitable for the production of the specific antibody required for the project.

### ***Animal Welfare***

When producing Mabs, the overriding consideration must be to minimise the pain and distress experienced by the animals.

### ***Training and Resources***

Investigators and animal technicians involved in Mab production must have appropriate training in all the techniques they are required to perform. Where investigators lack experience or resources to use in vitro methodologies, alternative suppliers of Mabs must be sought.

### ***Immunisation Protocol***

The AEC must evaluate immunisation protocols with respect to animal welfare outcomes and the 3Rs (replacement, reduction, refinement). The committee should be satisfied that reasonable attempts have been made to ensure that the antibody is not available commercially or from another research group. Standard operating procedures for routine production of Mabs should be established and presented to the AEC for approval.

### ***Monitoring of Animals***

Animals must be monitored daily and records of observations and interventions must be maintained.