



**SBScibus**

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**SBScibus AEC – Terms of Reference and Standard Procedures:  
January, 2014**

**SBScibus ANIMAL ETHICS COMMITTEE**  
(SBScibus AEC)

**TERMS OF REFERENCE**

1. The SBScibus AEC will approve guidelines for the care of animals that are bred, held and used for scientific purposes on behalf of Bovine Research Australasia.
2. The SBScibus AEC will review the specific requirements for monitoring the acquisition, transportation, production, housing, care, use and fate of animals. Care and housing of cattle used for research purposes should follow the SBScibus AEC guidelines for the care and welfare of animals. The research investigators are required to keep a record on the acquisition and transport and general health of all animals.
3. The SBScibus AEC will develop specific guidelines for the research operation and monitor the activities of Bovine Research Australasia to ensure that standards of the *Australian code of practice for the care and use of animals for scientific purposes* are maintained.
4. The appointment of SBScibus AEC members will be based on the procedures developed by SBScibus AEC (e.g. qualifications, research background and experience with animal welfare) according to the guidelines of the *Australian code of practice for the care and use of animals for scientific purposes*. These developed procedures also will have guidelines for the re-appointment of the members, or if the members intend to retire from the SBScibus AEC. Details of changes to AEC membership will be provided to the Director-General of NSW.
5. All appointed members of the SBScibus AEC are required to declare any conflict of interest in relation to the application considered for approval.
6. The SBScibus AEC will establish and document procedures to enable to cover resolution of any conflict of interest that may arise, that is, any situation where a member of SBScibus AEC has an interest that may be seen to influence the objectivity of a decision.

**7.** The SB*Scibus* AEC will examine the submitted application; and may approve the application after considering the comments of the members, may approve the application subject to minor or major modifications, or may reject the proposed application relevant to the use of animals for scientific purposes. Where necessary conditions on housing, care and use of animals will be implied.

**8.** The investigator of each research protocol are required to provide necessary information that using animals are essential and justified. The SB*Scibus* AEC will approve only those studies which conform to the requirements of the *Australian code of practice for the care and use of animals for scientific purposes*. Where possible the use of animals for research will be replaced partially or completely with alternative laboratory procedures providing the outcome of the research proposal is not compromised. The research investigators should also take into consideration factors including ethics, the impact on the animals and the anticipated scientific or educational value.

**9.** The SB*Scibus* AEC reserves the right to formally withdraw approval from any project or authorise the treatment or humane killing of any animal where standards/conditions of the approved research protocol or requirements of the *Australian code of practice for the care and use of animals for scientific purposes* are not met. In situations where the SB*Scibus* AEC's inspections detect activities that are non-compliant with the *Australian code of practice for the care and use of animals for scientific purposes*, the SB*Scibus* AEC will ask that such activities to be ceased immediately and remedial action is initiated.

**10.** In cases of emergency the research investigators are required to consult with the principal investigator before any treatment or euthanasia of any animal. All conducted procedures during the emergency situation, including treatment or euthanasia, must be reported immediately to the principal investigator. The confirmation of the actions and procedures that are taken with reasons are also required to be reported to the SB*Scibus* AEC.

**11.** The investigators are required to establish reasonable guidelines and procedures complying with the *Australian code of practice for the care and use of animals for scientific purposes*. The SB*Scibus* AEC will examine and provide comments on all institutional procedures and policies that may affect the welfare of animals used for scientific purposes.

**12.** The SB*Scibus* AEC will record and maintain all submitted proposals, projects and all communication to and from the SB*Scibus* AEC. The outcome of AEC's discussion will also be recorded and maintained. The SB*Scibus* AEC will maintain a register of all research projects which are approved by it. The investigator of each research approved by the SB*Scibus* AEC is required to ensure that records are maintained on the care and disposal of all animals used for any SB*Scibus* AEC approved research protocol. The records should be available for review by the SB*Scibus* AEC at any time.

**13.** The SB*Scibus* AEC will submit a written report annually on its activities to the Managing- Director of Bovine Research Australasia. The annual report will include

- (i) number of meetings and submitted protocols;
- (ii) numbers and types of projects assessed and approved or rejected;
- (iii) the location and facilities for the care and use of animals by the SBScibus;
- (iv) all educational activities that may have been conducted for the staff involved in the care and use of animals;
- (v) administrative or other issues being experienced; and
- (vi) any matters that may affect the SBScibus's ability to maintain compliance with the *Australian code of practice for the care and use of animals for scientific purposes* and if necessary the provision of suitable recommendations.

**14.** The SBScibus AEC will be responsible to ensure that its activities are in compliance with the *Australian code of practice for the care and use of animals for scientific purposes*

## STANDARD OPERATING PROCEDURES

### 1. Meeting Procedures

- a) Meetings will be convened as business requires but not less than four times a year.
- b) A quorum will require the presence of at least four (4) members, with at least 1 member from each of the categories A, B, C and D as outlined as outlined in the '*Australian code of practice for the care and use of animals for scientific purposes*' (2.2.2).
- c) If the AEC has more than four members, categories C + D will represent not less than one third of the members.
- d) Before appointment all members of the SBScibus AEC should acknowledge in writing their acceptance of the terms of reference of the AEC.
- e) The Chairman of the meeting will appoint a Secretary to handle administrative responsibilities.
- f) The business of the committee will be to review all matters as specified in the Terms of Reference of the '*Australian code of practice for the care and use of animals for scientific purposes*' (2.2.1).
- g) Applications for approval of animal research for review will be forwarded to each committee member at least two weeks prior to the meeting.
- h) Decisions will be by majority vote, but the committee should strive to reach consensus.

### 2. Approval for animal research

- a) Before animal research begins, the investigator must submit an AEC Protocol form (attachment B) to the SBScibus AEC for consideration and approval. The investigator may also submit any additional data he/she feels is relevant at this point. This documentation constitutes an "Application for Approval of Animal Research", referred to in these procedures as an "application".
- b) SBScibus AEC must advise the investigator, in writing, of its decision.
- c) Animal research may not commence until investigator obtains written approval from SBScibus AEC.
- d) During consideration of an application to SBScibus AEC, all submitted documents are circulated to all members. An investigator submitting an initial application may be invited to attend the meeting to discuss the application and answer questions or supply further information as required. Investigators shall not be present during final discussion and shall not participate in voting on the application.

e) Where a member of *SBScibus* AEC is listed as an investigator on an application before the Committee, he/she may be invited to appear before the Committee to discuss the application. The member shall not be present during final discussion and shall not participate in voting on the application.

f) Application for research must be approved or rejected only at meetings (excluding interim approval – refer Section 3).

g) To allow further consideration a member may request the final decision on an application be delayed for a period of up to two weeks. During this two week period the *SBScibus* AEC may issue an interim decision on the application. In a period not exceeding two weeks from the initial consideration of the application, the member requesting the delay will communicate his/her decision to the Chairman. The delaying member may:

- i) request an extraordinary meeting of the *SBScibus* AEC to further debate the matter.
- ii) record his/her dissent from the interim decision while allowing it to remain.
- iii) agree with the interim decision.

The response shall be recorded, and the interim decision ratified at the next meeting.

h) If a majority vote is not conclusive, the Chairman shall have the casting vote, including abstention. A dissenting member may request that his/her view be formally recorded in the minutes.

i) A decision of the *SBScibus* AEC may be that a research application is:

- i) approved (with or without specified conditions)
- ii) not approved (pending receipt of additional information)
- iii) rejected

*SBScibus* AEC may also suspend or withdraw approval of an application previously given.

### **3. Procedure for interim approval**

#### **3.1. Variation to previously approved application**

All major modifications to an existing application may only be approved at the AEC meeting if all of the following criteria are met:

- i) a formal request in writing has been made to the AEC by the investigator
- ii) it would be impracticable to wait until the next *SBScibus* AEC meeting
- iii) the AEC members are satisfied that all aspects of the application conform with the legislation and the *SBScibus* AEC policies

All minor modifications to an existing application may be approved out of session by an Executive of the *SBScibus* AEC which will include an external member from category C or D. Such approval cannot be made by the Chair of the *SBScibus* alone and will be reviewed at the next meeting of the AEC.

At the next meeting, the SB*Scibus* AEC considers the modified applications and the interim decision, and may ratify, modify or revoke the interim approval.

### **3.2. New application**

All new applications will be circulated to the SB*Scibus* AEC members. The new applications may be approved at the AEC meeting following the consideration of comments of the AEC members. The SB*Scibus* AEC may make a decision on an interim basis according to the criteria set down in section 3 (a).

At the next meeting, the SB*Scibus* AEC will consider the application and the interim decision, and may ratify, modify or revoke the interim approval.

### **4. Procedures for recording of decisions**

- a) All deliberations by, and decisions of, the SB*Scibus* ACEC are minuted by the Secretary.
- b) Minutes will be circulated by the Secretary to all members as soon as possible following the meeting (within 10 working days). The contents of these minutes are confidential and should only be discussed with members of SB*Scibus* AEC.
- c) Copies of the minutes are kept by the Secretary on file.

### **5. Procedures for notifying investigators of decisions of SB*Scibus* AEC**

- a) **Where the application is approved** (with or without specified conditions) by SB*Scibus* AEC, the investigator shall be informed in writing of the decision as soon as practical after the meeting at which the decision is made. Where specified conditions apply, the investigator is required to lodge an acceptance of these conditions. Approval does not commence until the specified conditions, if any, are met.
- b) **Where interim approval of an application has been given**, the investigator shall be informed in writing of the interim approval, together with the date of the meeting at which the matter will be considered by the Committee. The notification shall advise the investigator that interim approval does not represent automatic ratification by the Committee.
- c) **Where the application is not approved pending receipt of additional information**, the investigator shall be informed in writing of the requirements and advise of the date of the next meeting at which the matter will be considered. The investigator may be invited to discuss the matter with the Chairman.
- d) **Where the application is rejected**, the investigator shall be informed in writing of the reasons. The investigator may be invited to discuss the matter with the Chairman and may be invited to submit a revised application, which addresses the concerns of the SB*Scibus* AEC.
- e) **Where approval is suspended**, the investigator must be advised of the decision to suspend approval in writing or, in urgent circumstances, immediate notification may be made orally, and confirmed in writing. The written notification

shall give reasons for suspending approval and invite the investigator to respond, either orally or written. Once a response is received from the investigator, SBScibus AEC will then consider the matter and may make a decision according to section 2.

f) **Where approval is withdrawn**, SBScibus AEC shall notify the investigator of the decision and the reasons for that decision.

## **6. Procedures for serious breaches of the legislation.**

If SBScibus AEC is made aware that a serious breach of the legislation has occurred, the Committee shall notify the investigator, and the institution in which that research is being undertaken, of that breach. Such breaches may constitute reason for the suspension or withdrawal of an approval.

## **7. Animal Care Emergency Procedures**

SBScibus AEC shall nominate the investigator of each trial to respond to any emergency that may arise during that trial.

## **8. Grievance Procedures**

**Bovine Research Australasia** understands that concerns and complaints may arise from staff within the organisation and also from people outside the organisation. It is also understood that disputes may arise between researchers and members of the Animal Ethics Committee.

The following guidelines are offered for resolution of disputes and complaints:

### **8.1. Complaints from independent people not associated with the research and from staff within the organisation**

- a. Complaints from independent people not associated with the research and from staff within the organisation should initially be presented in writing to the principle investigator directing the project from when concern has arisen. The investigator will then arrange a meeting with the complainant and every effort made to resolve the point of contention.
- b. Failing satisfactory resolution, complaints will be directed to the next AEC meeting for discussion. The complainant will be invited to sit on that meeting for the period of time where the issue of contention is discussed. Every effort shall be made to resolve the issue of contention.
- c. Failing satisfactory resolution by the AEC, complaints will be directed to an external arbiter for hearing and mediation (NSW Agriculture Animal Welfare Unit).

### **8.2. Disputes between investigators and the AEC**

- a. Every effort should be made for disputes between investigators and the AEC to be resolved within the committee. Investigators should prepare scientific evidence to support their argument. Similarly, if the AEC or a member of the AEC wishes to continue the dispute, appropriate supportive evidence should also be sought and presented to the committee and the investigator.

b. Failing satisfactory resolution, complaints will be directed to an external arbiter for hearing and mediation. The Animal Welfare Unit, NSW Agriculture has been nominated by this organisation to fulfil this role. All supporting evidence will also be presented to the mediator.

**1. Serious disagreement between AEC members will be dealt with as in section 2 above.**

**2. Disagreements between the AEC and the institutions management.**

a. If disagreements between the AEC and the institutions management arise, the organisations Chief Executive Officer will be invited to attend the next AEC meeting to present his case. Every effort should be made to resolve disputes within the committee.

b. Failing satisfactory resolution, complaints will be directed to an external arbiter for hearing and mediation. The Animal Welfare Unit, NSW Agriculture has been nominated by this organisation to fulfil this role. All supporting evidence will also be presented to the mediator between the parties.

**Note:**

1. The research organisation reserves the right to call extraordinary AEC meetings to allow rapid resolution of any dispute or conflict that may arise.

2. All complaints will be treated with confidentiality and will remain within the AEC unless further mediation is required.

3. Any member of the AEC receiving a welfare complaint is obliged to raise the matter with the AEC as soon as possible

On commencing employment, all research staff within Bovine Research Australasia are to be made aware that grievance procedures exist. This is the responsibility of the chief executive officer.