

## **Protocol for Handling Oocytes and *In Vitro* Fertilized (IVF) Bovine Embryos for Export to Australia**

### **A. Collection and Transport of the Oocytes to the IVF Processing Laboratory**

1. Oocytes must be collected in a facility approved at least annually by an embryo production team (EPT) or embryo collection team (ECT) approved for export of *in vitro* produced embryos to Australia. Approval of the oocyte collection facility must be documented on the “Australia IVF Oocyte Collection Facility Approval Form” and these forms must be available for review by APHIS during semiannual inspections. APHIS reserves the right to inspect an oocyte collection facility at any time.
2. Any biological product of animal origin, including media constituents, used in oocyte recovery, maturation, washing and storage presented no animal disease risk. Media were sterilized prior to use by approved methods in accordance with the current IETS Manual and handled in such a manner as to ensure that sterility is maintained.
3. Oocytes must be transported to the IVF laboratory in a cleaned and disinfected incubator. The incubator must be sealed by an EPT or ECT member and the seal number must be documented on the “Australia Oocyte Collection Form.”
4. Oocytes may be transported either in an Australia-dedicated incubator, or in an incubator with non-Australia qualified oocytes. If the latter, then the vials containing oocytes intended to create *in vitro* produced embryos for Australia must be clearly labelled as Australia only, and there must be a comprehensive written Standard Operating Procedure (SOP) to ensure separation from non-Australian oocytes.
5. An EPT or ECT veterinarian must complete the “Australia Oocyte Collection Form” at the time of oocyte collection. This document must accompany the oocytes during transport to the IVF processing laboratory and include the following information:
  - Name and address of the oocyte collection facility
  - Name and address of the donor’s herd of origin (if different from the oocyte collection facility)
  - Donor’s registration name and number
  - Donor’s official identification number
  - EPT or ECT name and address
  - Date of oocyte collection
  - Number of seal applied to transport incubator
  - Attestation that the oocytes were collected in accordance with the International Embryo Transfer Society (IETS) recommendations
  - Name and signature of the EPT or ECT veterinarian

B. Laboratory Protocols for Receiving and Handling Oocytes/IVF Embryos

1. Laboratory personnel that process and handle oocytes and embryos for export to Australia may break the seal on the oocyte transport incubator.
2. Oocytes and embryos for export to Australia must be handled separately in the IVF laboratory, and must not come into contact with oocytes and embryos or equipment used to collect, process and store embryos that are not qualified for export to Australia.
3. All maturation media and other processing additives that contain animal-origin material must present no risk of transmission of animal diseases.

C. Semen Used to Fertilize the Oocytes

Semen used to fertilize the oocytes must be qualified for export to Australia, including storage only with semen of equivalent health status. Documentation to support eligibility must be provided at the time of endorsement of the health certificate.

D. Final Processing of IVF Embryos and Issuance of Health Certificates

1. Final processing, storage and dispatch of the embryos may be done either by the EPT where the embryos were produced, by the ECT that collected the oocytes, or by another Australia-approved ECT. If fresh embryos are transferred from the EPT to an ECT, the consignment must be transported under seal, and accompanied by a written statement by the EPT veterinarian that the oocytes and embryos were handled and processed in accordance with Australian import requirements. The ECT veterinarian receiving the fresh embryos must document the date of receipt of the embryos and the seal number.
2. The final “Veterinary Health Certificate for Export of *In Vitro* Produced Bovine Embryos from the United States to Australia” may be issued either by the EPT or ECT veterinarian. If final processing is done at the EPT, then the final health certificate must be issued by the EPT, regardless of whether the embryos are subsequently stored and dispatched from an ECT.
3. If the oocytes were not collected by the EPT or ECT veterinarian issuing the health certificate, then an accredited veterinarian who is a member of the approved EPT or ECT and who was present at the time of oocyte collection must complete the “Australia Oocyte Supplementary Certification” form and provide it to the EPT or ECT veterinarian prior to issuance of the health certificate.

## Australia IVF Oocyte Collection Facility Approval Form

<p><b>Oocyte Collection Facility:</b></p> <p>Name: _____</p> <p>Address: _____</p> <p>_____</p>	<p><b>Approved Embryo Production Team (EPT) / Embryo Collection Team (ECT):</b></p> <p>Name: _____</p> <p>Address: _____</p> <p>_____</p>
<p>1. The oocyte collection facility was subjected to, and passed, inspection at least once a year by the Team Veterinarian.</p> <p>Name of Team Veterinarian: _____</p> <p>Date of last inspection: _____</p>	<p><b>Y or N</b></p>
<p>2. The oocyte collection facility is not located in a zone subject to prohibition or quarantine measures due to an animal disease outbreak.</p>	
<p>3. The oocyte collection facility has a separate area for recovering oocytes (ovum pick-up or OPU room) which is isolated from other parts of the premises, is in good repair, and can be easily cleaned and disinfected. (Attach detailed schematic or Google Earth aerial view indicating oocyte recovery area on the premises.)</p>	
<p>4. The OPU room is adequately ventilated and is sufficiently warm (about 25° C or 77° F).</p>	
<p>5. There are chutes, headgates, and/or restraints in the OPU room that are easily cleaned and disinfected and allow effective and safe handling of donor cows.</p>	
<p>6. Floors and walls in the OPU room are easy to clean and disinfect, and are resistant to the corrosive effects of common disinfectants.</p>	
<p>7. There is a table in the OPU room that is easily cleaned and disinfected to hold ultrasonography equipment, a suction pump, and miscellaneous supplies.</p>	
<p>8. Lighting in the OPU room allows clear viewing of the ultrasound screen.</p>	
<p>9. The oocyte collection facility has a separate laboratory for preparing oocytes for transport to the IVF laboratory which is in good repair and the floors, walls and work surfaces can be easily cleaned and disinfected.</p>	
<p>10. Access to the laboratory is restricted to authorized personnel only.</p>	
<p>11. Materials and equipment coming into direct contact with oocytes are sterilized before use or disposable and are used exclusively for collection of oocytes for export to Australia.</p>	

\_\_\_\_\_  
**Signature of Approving EPT/ECT Veterinarian**

\_\_\_\_\_  
**Date of approval**

## Australia Oocyte Collection Form

<b>Name and address of oocyte collection facility:</b> _____ _____ _____	<b>Name and address of oocyte donor's herd of origin (if different than oocyte collection facility):</b> _____ _____ _____
<b>Oocyte donor's registration name and number:</b> _____ _____	<b>Oocyte donor's official ID number:</b> _____
<b>Name/address of approved embryo production team (EPT) of destination:</b> _____ _____ _____	<b>Date of oocyte collection:</b> _____
<b>Seal number placed on the transport incubator:</b> _____	<b>Date oocytes transported to Approved EPT:</b> _____

I, the undersigned Australian EPT/ECT Team Member, hereby certify that the oocytes were collected in accordance with the International Embryo Transfer Society (IETS) recommendations.

\_\_\_\_\_  
**Signature of EPT/ECT Team Member**

\_\_\_\_\_  
**Date**

## Supplementary Certification: Oocyte Collection for *In Vitro* Produced Bovine Embryos for Export to Australia

**NOTE:** If the approved embryo production team (EPT) or embryo collection team (ECT) veterinarian issuing the final Australia health certificate was not present during collection of the oocytes, this form must be completed by an accredited veterinarian who is a member of the EPT/ECT and under the supervision of the EPT/ECT Team Veterinarian. The owner of the oocyte donor must also complete the 2<sup>nd</sup> page of the form. The form must be provided to the EPT/ECT team veterinarian prior to issuance of the health certificate.

<b>Name/address of oocyte collection facility:</b> _____ _____ _____	<b>*Oocyte donor registration name:</b> _____ <b>*Oocyte donor registration #:</b> _____ <b>Date of oocyte collection:</b> _____ *For more than one donor, please use additional sheets
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I, the undersigned accredited veterinarian, certify that:

1. I am a member of \_\_\_\_\_ (name of EPT/ECT), approved by USDA-APHIS for export of *in vitro*-produced bovine embryos for export to Australia.
2. The oocytes used to produce the embryos were collected and handled in accordance with the recommendations of the International Embryo Transfer Society (IETS).
3. Only animals associated with oocyte collection and meeting health requirements for export of *in vitro* produced bovine embryos for export to Australia were permitted to enter the ovum pick-up (OPU) room during collection of oocytes for processing of *in vitro* produced embryos for export to Australia.
4. Each female donor was inspected by a veterinarian who is a member of the EPT/ECT on each day that the oocytes were collected for this consignment and was found to be free of clinical signs of contagious and infectious diseases.

<b>Name/Address of Accredited Veterinarian:</b> _____ _____ _____	<b>USDA accreditation number:</b> _____  <b>Date:</b> _____
<b>Signature of Accredited Veterinarian:</b> _____	

## Oocyte Donor Owner Declaration

I, \_\_\_\_\_, the owner of the oocyte donor(s) referenced above, hereby declare:

The donors resided in the United States for at least 90 days prior to oocytes collection for this consignment.

**Name/Address of the Oocyte Donor Owner:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Signature of Oocyte Donor Owner:**

\_\_\_\_\_

**Date:** \_\_\_\_\_