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New Zealand Food Safety Authority
Post Office Box 2835
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**ACVM
OPERATIONAL PROCEDURES STANDARD
1: THE USE OF VETERINARY
AND HUMAN MEDICINES BY
NON-VETERINARIANS FOR RESEARCH,
TESTING AND TEACHING PURPOSES**

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Endorsement:

Date:

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ACVM OPERATIONAL PROCEDURES STANDARD 1: THE USE OF VETERINARY AND HUMAN MEDICINES BY NON-VETERINARIANS FOR RESEARCH, TESTING AND TEACHING PURPOSES

1 INTRODUCTION

The purpose of this document is to define the required content of an Operational Procedure (OP) that is used whenever veterinary and human medicines are to be administered by non-veterinarians on animals in situations where the Code of Practice that includes (or references) this OP is in operation.

An OP is a set of veterinarian-endorsed instructions relating to the administration of medicines by authorised non-veterinary personnel to animals under the care of the organisation. The OP is necessary to ensure such administration is based on criteria that describe best practice and ensure risks to animal welfare are negligible.

The veterinarian providing endorsement of the OP is responsible for supervising the administration of prescription animal remedy (PAR) and human medicines by the personnel authorised to do so in the OP. In the case of PAR II and controlled medicine equivalents, the OP must be robust enough to provide a level of control over the administration of the medicines equivalent to that achieved if the veterinarian were present in the room.

The OP should NOT authorise the use of veterinary or human medicines to control or prevent persistent disease or other ongoing problems in animals requiring veterinary consultation and not described in the associated trial protocol or procedure.

The OP must not be used to authorise the use of PAR III medicines by non-veterinary personnel.

This document incorporates guidelines, which are intended to provide more detailed information and guidance to applicants to assist them in complying with these requirements.

The requirements are shown in this document in **bold font**, while the guidelines are in regular font.

1.1 Scope

All persons must follow this standard when composing an OP in compliance with the Code of Practice in which it is included.

The standard provides an indication of the detail expected in the OP.

1.2 Definitions and abbreviations

Adverse event (AE)

Any observation that is unfavourable and unintentional that occurs in an animal following treatment with a medicine.

Expected treatment outcome (ETO)

The therapeutic response predicted and intended to occur in an animal following treatment with a medicine.

Protocol or procedure register (PR)

A detailed record of all medicine used according to the standing order in individual trial protocols or procedures that must be updated at the end of each use period throughout the life of the protocol or procedure.

Review date

The date nominated at genesis by which the content of the standing order must be assessed and veterinarian-endorsed as adequate for renewal.

Undesirable treatment outcome (UTO)

A therapeutic response at variance with the predicted and intended therapeutic response in an animal following treatment with a medicine.

Use period

A discrete duration of medicine use defined as commencing with the removal of medicine from secure storage and ending upon its return.

1.3 References

- Agricultural Compounds and Veterinary Medicines Act 1997
- Agricultural Compounds and Veterinary Medicines Regulations 2001
- ACVM standards (refer www.nzfsa.govt.nz/acvm)

SECTION A: TECHNICAL CONTENT

2 IDENTIFICATION AND LIFE OF THE OPERATIONAL PROCEDURE

2.1 Each OP must be uniquely identified and linked to the trial protocol or procedure to which it is associated.

- For most organisations the identifying number can be the trial protocol or procedure number.
- Any other information considered appropriate by the organisation to ensure OPs remain uniquely linked to the relevant trial protocol or procedure should be included.

2.2 The OP must have a commencement and end or review date. All OPs will be valid for a maximum period of twelve months from the date of commencement or last review.

- If relevant, an end date should be included.
- Where the end date is not known or will fall outside twelve months of the commencement date, a review date should be stated after which time the OP will be considered invalid if not reviewed and re-endorsed by the supervising veterinarian.

3 REASON FOR THE OPERATIONAL PROCEDURE

A concise outline of the reason for the OP must be provided. This must include a summary of the aim(s) of the trial and the reason for the involvement of the drugs included in the OP.

- Enough information should be supplied to enable the user of the OP to understand how the medicines impact on the trial.
- Excessive detail is not required or expected.

4 PERSONNEL

4.1 The veterinarian who has endorsed the OP and is responsible for overseeing the trial or procedure must be named and must sign the document. The Animal Ethics Committee-approved protocol holder must be named if appropriate.

4.2 All staff members authorised to use the OP must be named, their responsibilities defined, and the skill or qualification levels required by them must be specified.

- Skills or qualifications required must be at least the minimum necessary to enable competent use of medicines on animals, as directed by the veterinarian.

- Where institution specific qualifications are nominated as appropriate levels of training, these should be veterinarian-endorsed as appropriate and available for audit.

4.3 Where there is a chain of command, this must be clearly stated.

This would apply in the situation where technicians are working under a Primary Investigator, for example.

5 ANIMALS

The animals to which the OP applies must be clearly identified.

Minimum information required:

- Species/Breed
- Gender
- Age
- Weight (actual or estimated)
- Method of identification
- Location
- Number.

Any other information considered pertinent to the OP should also be stated. This would include any reasons for non-inclusion.

6 MEDICINES AND EQUIPMENT

6.1 All medicines to which the OP applies must be named and described. Only medicines named may be used.

The name (trade name or generic), strength (if appropriate, e.g. Acepromazine 10%), formula type (e.g. tablet), product type (e.g. anaesthetic) and classification (e.g. PAR or human) of each medicine should be stated.

6.2 Precise details of medicine administration must be stated and must include preparation required (where applicable), dose, administration technique and site(s) of administration (where applicable).

- Preparation includes anything necessary to prepare the medicine for administration.
- Obvious instructions, such as removal from packaging, do not need to be stated.
- Dose should be stated as mg/kg and, where appropriate, ml, gm or tablets/kg.
- Information regarding administration technique and sites of administration should be detailed enough to ensure correct administration will occur. Techniques should preferentially be referenced to institutional standard operating procedures. Where these are included, they should be veterinarian-approved as appropriate and available for audit.

6.3 All equipment and/or techniques necessary to achieve medicine administration and the method of their disposal must be stated if such equipment or techniques are not specified elsewhere.

- Such equipment may include restraint devices considered appropriate, e.g. head bails, twitches, crushes, nets etc. and equipment used to administer the medicines.
- Where any such equipment or technique may be specifically contraindicated, this should also be stated (e.g. the type of anaesthetic machine to be used).

6.4 A precise description of the expected treatment outcome (ETO) of medicine administration must be provided.

- The depth of information required will depend on the medicine and its use, the relevance of the information to the user and the skill level of the user.
- This information is of most importance for drugs with a rapidly achieved end-point, such as anaesthetics, and should be sufficient to enable the target response of medicine administration to be recognised in the treated animal.
- Where skilled technicians are employed, such information can be justifiably brief and may be limited to a named rather than described end-point.

7 ADVERSE EVENTS AND UNDESIRABLE OUTCOMES

7.1 Anticipated adverse events (AEs) must be stated and categorised into those requiring veterinary intervention and those not requiring veterinary intervention.

- Expected AEs include incidents such as non-painful small swellings at the site of injection.
- Unexpected AEs would include incidents such as large, painful swellings and skin sloughing at the site of injection.

7.2 Undesirable treatment outcomes (UTOs) associated with the use of the medicine must be anticipated (where considered possible) and appropriate intervention methods stated.

- A commonly encountered example of a UTO is a greater depth of anaesthetic plane than would be expected with the dose given.
- Responses to commonly recognised UTOs should preferentially be referenced to institutional standard operating procedures. Where these are included, they should be veterinarian-approved as appropriate and available for audit.

SECTION B: ADMINISTRATIVE CONTENT

8 STORAGE OF MEDICINES

All medicines used under an OP must be kept in a securely locked room, safe, box or cupboard with one nominated person responsible for access and security.

9 RECORD KEEPING

9.1 A detailed protocol or procedure register (PR) must be kept for all medicines used according to the OP. All records must be kept for a minimum of four years. A suggested register page format is appended.

9.1.1 A separate page must be kept for each medicine used and each page must be identified with the name of the medicine and the identification number of the trial protocol or procedure and OP.

9.1.2 The PR must be completed after each use period.

The use period will depend on the frequency of medicine usage. For trial protocols that require ongoing use of medicines on a daily basis, an entry summarising the day's medicine usage should be made in the PR on completion of the day's work before returning the medicines to storage. Where medicines are used infrequently or on a periodic basis, an entry should be made after each use.

9.1.3 Minimum data to be included in the PR are:

- **Date of medicine usage;**
- **Initials or identification code of authorised administrator;**
- **Reason for use;**
- **Reconciliation of drug on-hand and drug used.**

The reason for use information should be a justification for the use of the drug and would expect to read similar to the following statement: "Anaesthetic for 50 hamsters according to Trial Protocol X".

9.2 Records of all drug purchases and disposals must be kept by the organisation and periodically reconciled with the PR.

This should be conducted at least every six months.

9.3 All OPs are subject to an external audit by the ACVM Group at any time. An independent party should conduct internal audits annually.

Any amendments made to the OP must be documented and endorsed by an authorised veterinarian and kept with the original OP.

