The Royal Veterinary College

'Good Research Practice'

Introduction

Preface

Funding bodies need to be assured of the quality and validity of research they fund and ensure their contractors are using 'best scientific practice' from the start of all research projects.As a consequence, a 'Joint Code of Practice for Research' was developed by a working group of representatives from the Biotechnology and Biological Sciences Research Council (BBSRC), the Department for the Environment, Food and Rural Affairs (DEFRA), the Food Standards Agency (FSA) and the Natural Environment Research Council (NERC)which took effect from 1 June 2004. A revised version of this code was issued in March 2012
This document defines the implementation of the principles of the 'Joint Code of Practice' which should be applied to all types of research conducted within the RVC.

The overriding principle is fitness of purpose , the implementation of which promotes the development of quality test data, high standards of data management ensuring they are freely and openly available, improvements in the quality of research processes and further improves public confidence in results.

Scope

The principles of the code should be applied to all types of research conducted by the RVC.

The principles of 'Good Research Practice,' outlined in this document, incorporate requirements defined in the 'Joint Code of Practice' and are presented as a working policy for implementation within the Royal Veterinary College.

The Principles of Good Research Practice

1. Organisation and Personnel

1.1 Management Responsibilities

It is the responsibility of each Head of Department to ensure adherence to the principles of Good Research Practice (GRP) in the department for which they are responsible. Heads of Departments are responsible to the Vice Principal of Research who is ultimately responsible for implementation of GRP within the RVC.

At a minimum this should;

a) Ensure that a sufficient number of qualified personnel, appropriate facilities, equipment and materials are available for the timely and proper conduct of the project.

b) Ensure the maintenance of a record of the qualifications and training for each professional and technical individual involved.

c) Ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions.

d) Ensure that appropriate, valid and approved Management Policies and Standard Operation Procedures (SOPs) are established and followed.

e) Ensure that appropriate procedures are in place to address quality control, internal project reviews and auditing.

f) Ensure that archive facilities and procedures are in place.

g) Ensure that an approved publication policy with authorisation procedures is in place.

h) Ensure that an appropriate level of risk assessment has been conducted for each project.

i) Ensure that a project plan is in place with correct approvals for each project.

j) Establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained appropriately.

k) Ensure adherence to Royal Veterinary College Health and Safety policies.

1.2 Project Supervisor Responsibilities

The Project Supervisor should be the single point of project control and is responsible for all work conducted in the project including that of any sub-contractors.

At a minimum this includes:

a) Approving the project plan and ensuring that significant modifications to the purpose of the plan have funding body approval.

b) Ensure all other relevant approvals are obtained.

c) Ensure that project plans, any amendments and Standard Operating Procedures are available to project personnel.

d) During development, general instructions must be documented.

e) Ensure the validity of project work by performing regular reviews of the records of each scientist.

f) Sign and date the final project report to indicate acceptance of responsibility for the validity of the data.

g) Ensure that following completion (including termination) of the project, the project plan, report and raw data are archived.

1.3 Project Personnel Responsibilities

All personnel associated with the project must be competent to perform the technical, scientific and support tasks required of them.

At a minimum this includes:

a) All project personnel must have an awareness of the content of this policy and be knowledgeable in those parts of the principles and RVC Policy Documents which are applicable to their involvement in the project.

b) All project personnel are responsible for maintaining their own training records.

c) Project personnel should have access to the project plan and appropriate Standard Operating Procedures. It is their responsibility to comply with instruction provided in these documents.

d) All project personnel are responsible for recording raw data promptly and accurately and in compliance with these principles of GRP. All personnel are responsible for the quality of raw data generated by them.

e) Project personnel should be aware of health and safety regulation that are applicable within the RVC. They should exercise health precautions to minimise risk to themselves and to ensure integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the project.

2. Project Planning

a) A risk assessment should be conducted to demonstrate awareness of the key factors that will influence the success of the project and the ability to meet its objectives.

b) The project is usually outlined as part of a research proposal. The research proposal is a document outlining the scientific context, the overall objectives and the scope of the research. The proposal should identify principal research scientists involved, outline the main stages and indicate a general timeframe.

c) The project plan should describe in detail the proposed conduct of the project. It should be written in such a way as to be as specific as necessary but at the same time to allow the project to evolve and develop. Later parts of the project plan are often written in an open and speculative way since they are dependent on initial experiments. This is to be expected in basic research.

d) The project plan must be available prior to initiation of the project. It must contain all the necessary information for compliance with these principles of Good Practice in Research, including research design, statistical methods for analysis of data and approved sampling methods. Significant milestones should be identified. A unique identification number should be given to each project. All items concerning this project should carry this identification.

e) The project plan must be agreed in collaboration with the funding body, taking account of the requirements of ethical Committees or project licences, if relevant.

f) The project plan should have documented approval from at least the funding body, the Project Supervisor and Head of Department.

g) During development of the project, the following general guidelines apply:

i) Minor deviations (unplanned changes) from the project plan may be recorded in the research notebook or on a data sheet for retention with other project data.

ii) Major significant modifications to the scientific aims and objectives of the project should be documented as 'amendments' (planned changes) which must be justified by the Project Supervisor and approved by the funding body (if applicable), prior to implementation and maintained with the project plan.

3. Quality Control

Planned procedures should be in place to assure the quality of research undertaken by scientists. This should involve at least the following:

a) Internal project reviews and auditing procedures.

b) An approved publication policy including authorisation procedures.

c) Incorporation of internal checks into systems.

d) Regular review of processes and procedures against a policy of continual improvement.

4. Quality Assurance

Quality is assured by monitoring performance for compliance with the principles of Good Research Practice, Management Policies and Standard Operating Procedures.

A Quality Assurance programme should be in place and include at least the following:

a) Personnel responsible for conducting audits who are not involved in the conduct of the project being assured.

b) Regular audits of facilities and systems.

c) Regular audits of project related procedures.

d) Retention of audit records.

e) Prompt reporting of any audit results in writing to relevant technical personnel, management and the Project Supervisor.

5. Facilities and Equipment

a) The working environment must be appropriate for safe operation of equipment, maintenance of sample quality and integrity, and good working practices.

b) Records must be maintained of any special facilities used.

c) Equipment used in the project should be used, maintained and calibrated according to Standard Operating Procedures. Records of these activities should be maintained.

d) Calibrations and validations should, where appropriate, be traceable to national standards of measurement.

6. Materials and Reagents

a) Chemicals, reagents and solutions should be labelled to indicate identity, with concentration, expiry date and specific storage instructions.

b) Information concerning source, preparation date and stability should be available.

c) All samples should be labelled (clearly, accurately, uniquely and durably) and retained for a period agreed by the funding body.

d) Storage and handling of the samples should be specified in the project plan. If storage conditions are critical, they must be monitored and recorded.

e) Samples must be readily tracked through the stages of analysis or use and have designated disposal routes and dates.

7. Documentation of Procedures and Methods

All procedures and methods used in a research project, including analytical and statistical methods, must be documented. This may be in the form of details in the project plan, in Standard Operating Procedures or in the personal records of the researcher.

Research methods must be validated and modifications must be traceable through each stage of development of the method.

7.1 Standard Operating Procedures (SOPs) and Management Policies

a) Standard Operating Procedures and policies, approved by management must be available in all research laboratories, intended to ensure the quality and integrity of the data generated by research within the department.

b) Standard Operating Procedures and policies should be written and issued as controlled documents. Any revisions must be approved.

c) Current Standard Operating Procedures and policies, should be immediately available in each research unit or area, relevant to the activities being performed therein.

7.2 Raw Data/Original Project Records

Raw data means all original records and documentation, or verified copies thereof, which are the result of the original observations and activities in a project. Raw data may also include, for example, photographs, computer readable media and print outs from automated instruments.

a) All data generated during the conduct of the project should be recorded directly, promptly, accurately and legibly by the individual entering data. These entries should be signed or initialled and dated.

b) Raw data should be written in indelible ink.

c) Any changes to the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.

d) Data generated as a direct computer input should be identified at the time of input by the individual responsible for direct data entries. The security and integrity of electronic data must be considered. Any change to electronic raw data should be documented, justified and the individual responsible identified by dated signature.

e) All original raw data for retention should including the project plan, amendments and deviations to the plan and Standard Operating Procedures. These data should be retained in a form that ensures their integrity and security and prevents unauthorised modification, for a period agreed by the funding body.