Good Research Practice Policy

Role-specific summaries

Staff and Students:

All staff and students must ensure that:

- their research output is recorded to the standard detailed in the section ***"Recording of samples, procedures, primary data and analysis"***.
- they fully comply with the RVC Health and Safety, Environmental, and Research Integrity and Ethics policies and procedures
- they assist and support their project leaders in performing their duties, as summarised below.

Project leaders:

Project leaders are expected to maintain and promote a culture of good scientific practice in their laboratories. This includes:

- ensuring that an appropriate project plan is created and updated (detailed under ***"Project planning"***)
- ensuring that all researchers involved in any project receive and document appropriate training (detailed under ***"Competence"***)
- ensuring that the publication policy and procedures are followed
- specifying how the research in any individual project is recorded, typically following consultation with project GRP supervisors, staff and students (detailed under ***"Recording of samples, procedures, primary data and analysis"***)
- monitoring the quality of all research records through regular documented reviews, including independent oversight where possible (detailed under ***"Recording of samples, procedures, primary data and analysis"*** and ***"Monitoring of compliance"***).

GRP Supervisors:

GRP supervisors are designated individuals who maintain specified shared records, typically in addition to producing research data, as above. They are not routinely expected to monitor or audit GRP compliance. Their roles may include:

- maintaining records of shared laboratory reagents or experimental samples, and/or of training, maintenance or calibration of specified equipment, detailed under **"Recording of samples, procedures, primary data and analysis"**
- providing training in:
  - specific aspects of this and associated policies
  - the procedures of particular laboratories or facilities and/or
  - the use of particular pieces of equipment (all detailed under ***"Competence"***).

The level of detail recorded by GRP supervisors should be fit for purpose rather than exhaustive and should be agreed between project leaders and GRP supervisors. Any disagreement as to the scope of work required will be resolved via the line management chain.

Vice Principal for Research (VPR):

The VPR accepts overall responsibility for ensuring that this and associated policies and procedures are fit for purpose. This particularly includes responsibility for:

- leading a culture of research integrity and good research practice within the institution
- setting standards for the quality of research conducted and disseminated to the wider scientific community
- using appropriate mechanisms to monitor compliance with these policies and procedures.

Typically, many of these duties will be delegated as appropriate but the VPR retains overall responsibility on behalf of the senior management of the College.

Competence

Associated document: Staff training and development – policy and procedures

All researchers at the Royal Veterinary College (RVC) must be able to demonstrate competence in their roles. This applies to all individuals involved in carrying out, supporting or disseminating research. Demonstrating competence requires that documentary evidence be retained. Such evidence might be associated with the laboratory or individual projects. Appropriate documentary evidence might demonstrate prior training or experience. Alternatively, it might record training or continuing professional development undertaken in the course of the project. There must also be a documented commitment to the contents of this and associated policies and procedures. If an individual is generating research data while being trained in a technique, they should be supervised by someone with a documented ability to ensure the quality of the data. Training on specific RVC equipment or facilities is additionally described below.

Project planning

A documented project plan should be prepared for any research project carried out at the RVC. This will usually be 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. It should also make clear any specific details relating to ownership of reagents or data.

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

The project plan 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.

The project plan should be reviewed as necessary.

Health and safety

Associated documents: Health and safety policy statement
Health and safety organisation and arrangements
Environmental policy

All research must comply fully with all RVC Health and Safety policies and procedures. This includes compliance with all environmental protection legislation and policies.

Recording of samples, procedures, primary data and analysis

Associated policies: Research data management policy

All staff and students who generate reagents, samples or primary data or who analyse or process data are responsible for recording their methods and results. The recording must be clear, accurate and traceable. Records must meet the standard that the experiment could be recreated based on the records even many years later. These records serve to ensure that results will be reported accurately, provide a resource for future experiments and provide evidence relating to the quality and accuracy of the work.

Project leaders are responsible for ensuring that this standard of record keeping is maintained. They accept responsibility for reviewing all research records at appropriate intervals of at least every 2 months, and for documenting all such reviews. They are also responsible for ensuring that all records are archived appropriately when staff or students end their association with the project or the project ends.

All research records are the property of the RVC. They must be kept secure. They also must remain confidential until made publically available by an agreed method.

There is a range of tools available at the RVC to be used in recording research data. The appropriate method(s) for a given project should be determined and documented by the project leader. The main types of record are:

1) Laboratory notebooks

The RVC provides standardised research notebooks. For most projects longer than 3 months in duration, these are expected to be used as the primary record of research. Any other records will be referenced from the primary record. The following principles should be followed in using the notebooks or similar record systems:

1. All records should be written into the notebooks at the time that the work is carried out. All entries should clearly indicate when and (if not by the person named on the notebook cover) by whom the record was made. If the original record is made on a different document, it is recommended that that original be attached to the notebook rather than transcribed.
2. All entries should be permanent and so should be entered in indelible ink. Deletions or changes should be avoided where possible and made such that the original text can still be read (for example with a single line through the text). It should be clear when and by whom any changes or deletions were made.
3. As a primary record, the research notebooks should contain unambiguous references to all associated information, whether physical or electronic. This will include:
    - unique identification of any standardised procedures or protocols (including the version number)
    - unique references to any catalogued samples or reagents
    - specific references to all training or agreements relating to the project, such as email correspondence.

    In the case of referenced physical or electronic data, the method used to acquire it should be clear from the notebook.
4. Any data, such as printouts or films, fixed into the notebook should be fixed permanently. Sellotape is not recommended, as it tends to detach with age. It is suggested that any such attachment is labelled with the date and identification of the person or project with which it is associated.
5. Reviews of the notebook should be recorded by a statement signed by both the researcher and reviewer
6. It is recommended that the major features of the notebook are used to their best potential. This includes:
    - A title page on which details of the project and researcher(s) should be recorded.
    - A signature page that can be used to identify any signatures within the notebook. This is intended to save the need to print names with every signature.
    - Index pages whose use is discretionary but could, for example, indicate the locations of published data or significant protocols.

- The pages are numbered and none should be removed. The numbered pages each have space for the date, which should always be used, and for signatures, for use when the data are reviewed.

7. If an alternative form of notebook is used, for example for short projects, the above elements should be incorporated so far as is reasonable.

2) Supplementary physical data files

Other stores of physical data could take a variety of forms. This could include additional notebooks, ring binders or stores of loose-leaf documents. They could also vary in scope. Many will cover the work of individuals or research groups. Some, however, might be used by whole departments or even the entire College. In all cases, they should be assessed as fit for purpose by the project leader or Head of Department as appropriate. Any physical data file should maintain the principles that the information is clear, accurate and traceable. To meet this need, documents should be uniquely identified. Sequential labels are recommended as these clearly identify any gaps in the record.

3) Electronic data

The College provides both personal storage space and research data storage space on College servers. Substantial flexibility is offered to the project leaders and researchers as to how data are organised. Responsibility for the organisation of data on College servers rests with the project supervisor. This includes ensuring its long-term stability and security and determining the allocated permissions to read or modify any data. College Information Technology support staff can advise and support project leaders in these matters, in accordance with applicable policies.

Electronic data should be stored according to the same principles as physical data. This means it must be uniquely identified and referenced. The identification and referencing must connect the data to all information on how and when they were collected. It is recommended that the necessary information is contained within file names rather than in the name of a containing folder. The use of tags or databases should be evaluated to ensure that they are fit for purpose in the long term.

Care should be taken to distinguish original from processed electronic data and to document the processing that was carried out. Where appropriate, version tracking should be used to indicate the stages in data processing or analysis.

All researchers generating electronic data should be aware what metadata are collected and saved within or alongside data files. Appropriate care should be taken to ensure the accuracy of, and preserve, all metadata.

Recording of samples, materials and reagents

Research projects typically make use of a wide range of samples and reagents. All chemicals and reagents should be clearly labelled with all important information required to unambiguously identify it. Reagents from commercial suppliers should be checked to ensure that the labelling present is sufficient. Typically, the date of delivery should also be recorded. Solutions or other materials prepared in house should also be sufficiently labelled. Minimally, this should include the identity of the contents, date of preparation and name or initials of the person preparing it. Additional information should be included as required, including concentration, pH, storage conditions, batch numbers or expiry date. The required level of detail will be determined by the researcher under the guidance of the project leader.

Research samples often require more comprehensive labelling. The level of detail and method of recording will be determined by the project leader. This determination should consider all experimental and statutory requirements. Often unique identifiers should be used to unambiguously identify the sample.

In cases where the storage or handling of samples or reagents has specific requirements, these should be clearly recorded. If there is a need to monitor compliance with these requirements, such as monitoring freezer temperatures, then the methods and records must be recorded according to the principles in this policy.

In addition to labelling of the sample or reagent itself, logs or databases of some classes of material may be required. Typical classes of sample or reagent could include hazardous chemicals or clinical samples. This may take the form of a physical data file or electronic record. The project leader is responsible for defining when this is necessary and for which materials. They should also define who is responsible for contributing to the log or database and who is responsible for keeping it up to date. The purpose of the log should be documented and the principle of "fitness for purpose" applied.

Regardless of any central records, individual researchers are responsible for recording all important details regarding their experimental reagents and samples. This will include whether and how the calibration of equipment used in reagent preparation was verified. It will also include any information that will later need reporting as part of publication. This may include manufacturer or supplier details. Any information that might be required for future troubleshooting, such as batch numbers of sera or antibodies, should also be recorded.

Recording relating to facilities and equipment

A wide range of equipment is used as part of research projects, ranging from pipettes to complex imaging systems. The management of these pieces of equipment will depend on its owner, user base and how it is used.

All equipment meeting criteria set by the VPR must be recorded in an inventory. This inventory must be maintained by the Research Office and in a format approved by the VPR. Equipment must be labelled with a unique identifier corresponding to that inventory.

A designated person or group of people, often the GRP supervisors, should be assigned responsibility for ensuring that training on, maintenance of and calibration of each piece of equipment is carried out and recorded.

That designated person is responsible for maintaining equipment records for each piece of equipment assigned to them. That record should uniquely identify the equipment, normally by reference to the inventory, and list the make, model and serial number. Requirements for training, calibration, servicing and maintenance of all equipment should be agreed by that designated person in consultation with project leaders using the equipment. These requirements and procedures should be clearly documented within the equipment record. The goal should be that such documentation is as simple as is practicable. For most equipment, a brief statement of who can carry out the training, which protocols, manuals, standard operating procedures and/or risk assessments are relevant and whether any routine calibration or maintenance is required will suffice. Either physically or by reference, any manuals, training documents or standard operating procedures (see below) should be recorded. Each should minimally be labelled with a version number and the date and all versions should be retained.

It is recommended that a standardised format is used for equipment records and so their creation and updating is as simple as possible.

Training

The form of training required, and methods for recording it, should be appropriate to the equipment or procedure. For simple equipment, training might be permitted by any experienced user. The method and details of training would be recorded by the trainee in their research records. For the most complex or demanding equipment: only specified trainers might be permitted to offer training; the training might be done according to standardised, version tracked documents and the training be recorded and countersigned in records held by the GRP supervisor and/or the trainee. The agreed requirements should be recorded in the equipment record and typically posted close to the equipment. In all cases, documentary evidence must be retained in an accessible form associated with the project records, equipment records or both.

Calibration

Equipment used to generate quantitative data should be calibrated or validated according to an agreed protocol. Again, the requirements should be specified based on the nature of the equipment. For simple equipment, users might be required to confirm the calibration themselves (in a manner included in the training) before using equipment. For more critical or complex equipment, validation might be required by qualified individuals, who might be external contractors, according to a specified schedule. In all cases, the calibration or validation must be clearly recorded.

Maintenance and repairs

Specific items of equipment will be subject to regular servicing. If equipment is under warranty or service contract then this should be recorded in the equipment inventory. Requirements for routine servicing or maintenance should be recorded in the equipment record.

All faults and repairs should also be recorded in the equipment record.

Electronic data

Where equipment generate, process or analyse electronic data, the equipment record should describe the file formats created and the software necessary to open them. In the event that any such file format is becoming obsolete then project leaders, Heads of Department and/or VPR should be informed. Those people should, so far as reasonably practicable, develop a solution to ensure that data remain accessible. Even once equipment have been mothballed or disposed of, monitoring of access to the electronic data that it produced should continue so long as those data are retained (typically at least 10 years).

Protocols and standard operating procedures

Often a manual or other instructions can be used in training or documentation of procedures. Where they are not appropriate, a protocol or standard operating procedure might be prepared. These are instructional documents prepared in-house. They describe how specific procedures are carried out or specific equipment is used. They should be uniquely identified, ideally with a short code, to identify their function and affiliation (such as facility or department) followed by a number unique to each document. They should also be labelled with a version number, the date of issue and the person responsible for its preparation. That person accepts responsibility for the contents of the document, for taking reasonable steps to ensure that an issued document cannot be modified and for reviewing the contents of the document at reasonable intervals. All versions should be retained. It is recommended that suitable repositories be established for these documents at the facility, laboratory and/or departmental level as appropriate.

Researchers should record which protocol or standard operating procedure they used, including the version number, and any deviations from it. This could be done by reference or by retention of a copy of the protocol or standard operating procedure.

Publication of research data

Associated documents: *Publications policy (GRP policy 09)*
Policy and procedure for dealing with allegations of research misconduct

The VPR is responsible for setting standards and policies for the publication of research data. This includes requiring the sharing of reagents or data as appropriate following publication. The senior author of any publication is responsible for ensuring that these standards are followed.

Everyone contributing to the published research is responsible for ensuring that the work complies with the requirements for Good Research Practice and for Research Integrity and Ethics. This includes a responsibility to report any errors or concerns regarding the work that might be discovered subsequent to publication.

Monitoring of compliance

Associated information: *Staff appraisals*
Code of Practice for Postgraduate Research Degrees

The VPR is ultimately responsible for monitoring compliance with this and associated policies. Where failings are identified, rectification will typically be sought via the project leader and/or their line management chain.

Additionally, project leaders are responsible for ensuring that all staff and students contributing to the project comply with this and associated policies. They must also ensure that the quality of the research records and data relating to their projects is fit for purpose.

It is recommended that compliance be assessed by the following main mechanisms:

1. At least annually, project leaders must monitor, with documentation, the extent to which researchers working under their leadership are meeting the standards of Good Research Practice. They should also evaluate whether the overriding policies and project-specific procedures are fit for purpose. It is recommended that this evaluation make use of the existing annual appraisals procedure for staff. For post-graduate students it is recommended that this form part of their existing supervisory meetings. Hence, the assessment of compliance and fitness for purpose will be documented and subject to oversight from individuals outside the researcher – project leader relationship.
2. At the discretion of the VPR, audits might be arranged of particular projects, individuals or processes. The terms of reference and organisation of such audits will be at the discretion of the VPR. As required by the Joint Code of Practice for Research, where possible such audits should be formal, make use of an independent third party and evaluate against appropriate internationally recognised standards.
3. This policy shall be reviewed and updated as required at least every two years.

Associated documents

This policy is based upon the following documents, whose principles should be followed by all researchers:

Joint Code of Practice for Researchers (https://www.gov.uk/government/publications/joint-code-of-practice-for-research-jcopr)

Guidelines on good research practice (https://wellcome.ac.uk/funding/managing-grant/guidelines-good-research-practice)

This policy is also based upon, and supersedes, the following documents:

RVC Good Practice in Research Version 03
Policy Document 01 version 05 Use and Maintenance of Research Data
Policy Document 02-03 Policy for Receipt, Logging and Disposal of Chemicals
Policy document 03-03 Equipment Policy
Policy Document 04-04 Preparation, Approval and Distribution of Standard Operating Procedures
Policy Document 05-03 Responsibilities of Laboratory Supervisors
Policy Document 06-03 Responsibilities of the Project Supervisor
Policy Document 07-03 Monitoring of compliance with the principles of Good Research Practice
Policy Document 08-02 Receipt, storage and Transfer of Biological Samples and Project Materials
Policy Document 10-02 GRP Policy Document on Personnel Training Records