Department for Environment, Food and Rural Affairs

Joint Code of Practice for Research (JCoPR)

Issued by and published on behalf of:

- Biotechnology and Biological Sciences Research Council
- Department for Environment, Food and Rural Affairs
- Food Standards Agency
- Natural Environment Research Council
- Northern Ireland Department of Agriculture and Rural Development
- Scottish Government
- Welsh Government
- Animal and Plant Health Agency
- Food and Environment Research Agency
- Forestry Commission
- Marine Management Organisation
- Natural England
- Veterinary Medicines Directorate

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Background

This Code was initially developed by a working group of representatives from the:

- Biotechnology and Biological Sciences Research Council (BBSRC)
- Department for Environment, Food and Rural Affairs (Defra)
- Food Standards Agency (FSA), and
- Natural Environment Research Council (NERC).

It was subsequently endorsed by the:

- Northern Ireland Department of Agriculture and Rural Development
- Scottish Government, and
- Welsh Government (The UK Devolved Administrations).

The Code has also been endorsed by:

- Animal and Plant Health Agency (APHA)
- Food and Environment Research Agency (Fera)
- Forestry Commission (FC)
- Marine Management Organisation (MMO)
- Natural England (NE), and
- Veterinary Medicines Directorate (VMD).

The Code was launched in May 2003, and took effect from 1 June 2004. Defra and the FSA initiated a joint audit programme in 2006 to determine whether research projects, funded after 1 June 2004, were being carried out in accordance with the Code. The United Kingdom Accreditation Service (UKAS), was commissioned to audit a sample of Defra / FSA projects against the provisions of the Code.

The generic findings from the two year UKAS audit programme were disseminated amongst QA managers and other interested parties, at a joint Defra / FSA workshop, held in Reading in March 2009. The Code has subsequently been revised by Defra and the FSA in light of both the audit findings and the workshop outputs, with input from BBSRC, NERC and the UK Devolved Administrations.

The Code applies to all research funded by Defra, the FSA, NE, VMD, APHA, MMO, Fera, FC, the UK Devolved Administrations, and to research funded by BBSRC and NERC in their own Institutes. It is intended to apply to all types of research, but the overriding

principle is fitness of purpose and therefore the individual provisions should be read with that in mind.

Principles behind the Code

Contractors funded by the above Funding Bodies are expected to be committed to:

- the quality of the research process (QP), and
- the quality of the science (QS).

QS addresses the aims of the project, its approaches, and the extraction of new knowledge and understanding from the scientific work commissioned. QP by comparison, underlies the research giving confidence the processes and procedures used to gather and interpret the results of the research are appropriate, rigorous, repeatable and auditable. Without QP, confidence in the research findings is much reduced.

The Funding Bodies wish to ensure their contractors are using “best scientific practice” from the start of all research projects. Compliance with the Code should be driven from the top of funded organisations.

The Funding Bodies have developed this Code of Practice to lay out a framework for the proper conduct of research. It sets out the key aspects of QP and the importance of making judgements on the appropriate precautions needed in every research activity. The overriding principle is “fitness for purpose”. QP is also consistent with the requirement that all research should be conducted diligently by researchers who are both competent and adequately trained.

Compliance with the Code

For the FSA, Defra, NE, VMD, APHA, MMO, Fera, FC and the UK Devolved Administrations, contractors will be expected to indicate acceptance of the Code when submitting proposals to the Funding Body through completion of the relevant research application.

Contractors are encouraged to discuss with the Funding Body any clauses in the Code they consider inappropriate or non-applicable in the context of any proposed research project(s). The Code, and records of the discussions if held, will become part of the Terms and Conditions under which the research is funded. Additionally, the Funding Body may conduct (or request from the Contractor as appropriate) a formal risk assessment on the project(s) to identify where additional controls may be needed.

Contractors are responsible for ensuring projects are compliant with the JCoPR’s provisions. Contractors are also responsible for ensuring all subcontractors are aware of, and work in accordance with, the JCoPR’s provisions in respect of any project work they carry out on behalf of the funding bodies.

For BBSRC- and NERC-funded work, acceptance of the Code should be provided annually by the Institute Director.

Monitoring of compliance with the Code

Monitoring of compliance with the Code is necessary to ensure:

- Policies and managed processes exist to ensure compliance with the Code.
- The policies and processes (as required) are being applied consistently in practice across the research organisation.

The Funding Bodies expect research organisations, where possible, will assure the quality of their research processes by means of a formal system that is audited by an impartial and competent third party against an appropriate internationally recognised standard that is fit for purpose.

The Funding Bodies reserve the right to obtain evidence that a funded project is carried out to the required standard (if deemed necessary), such as by conducting an independent audit of a contractor's research system. This premise underpinned the two year UKAS audit programme, undertaken on behalf of Defra and the FSA, initiated in 2006.

Specific requirements of the Code

1. Responsibilities

The contractor organisation is responsible for the overall quality of research conducted within it, including compliance with in-house research and management policies.

Managers, group leaders, and supervisors have a responsibility to maintain and promote a climate of good scientific practice within the research teams, including a commitment to the ongoing development of relevant scientific and technical skills.

The Principal Investigator or Project Leader is responsible for all work conducted in the project, which includes that of all subcontractors. All staff and students should have clearly defined and documented responsibilities in relation to the project and be aware of these responsibilities.

2. Competence

All project personnel must be competent to perform the technical, scientific, and support tasks required of them. Personnel undergoing training must be supervised at a level such that the quality of the results is not compromised by the inexperience of the researcher.

Contractors should be able to provide documented evidence that personnel are capable of completing the work required competently and safely. Training records should show evidence that personnel are aware of their requirements to conform to the JCoPR's provisions.

3. Project planning

An appropriate level of 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.

There should be a clear, written project plan showing that these factors (including research design, statistical methods, and others) have been considered and addressed. Project plans must be agreed in collaboration with the Funding Body, taking account of the requirements of ethical committees or the terms of project licences, if relevant.

Contractors should schedule regular reviews of their timetables and project plans to monitor progress and make any necessary amendments. Significant amendments to the plans, milestones or deliverables must be recorded and pre approved by the Funding Body.

4. Quality Control

The contractor organisation should have planned processes in place to assure the quality of the research undertaken by its scientists. Projects should be subjected to formal ‘fit-for-purpose’ reviews of an appropriate frequency.

The authorisation of outputs shall be as agreed by the Funding Body, and subject to senior approval in the organisation, where appropriate. Errors identified after publication must be notified to the Funding Body and agreed corrective action initiated at the earliest opportunity.

Processes and procedures should be regularly reviewed as part of a policy of continual improvement.

5. Health and Safety

All research must fully comply with the relevant Health and Safety regulatory requirements.

6. Handling of samples and materials

All samples and other experimental materials should be labelled clearly, accurately, uniquely, and durably, and be retained for a period to be agreed with the Funding Body. The storage and handling of the samples and materials should be clearly specified in the project plan or proposal, and must be appropriate to their nature. If the storage conditions are critical, they must be monitored and recorded.

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

7. Facilities and equipment

The working environment must be appropriate for safe operation of equipment, maintenance of sample quality and integrity, and good working practices. Where special facilities are used (e.g. fume cupboards) they must be regularly checked and maintained.

All equipment must be appropriate for the measurements to be made, calibrated at appropriate interval and be in good working condition. If critical, there should be contingency plans in case of power failure or other disruption. Contractors should ensure there are standard operating procedures for all project critical equipment.

8. Documentation of procedures and methods

All the procedures and methods used in a research project must be documented, as part of the contractor's file records for the project. This includes analytical and statistical procedures and the generation of a clear audit trail, including document and version controls, linking secondary processed information to primary research data.

There must be a procedure for the validation of research methods as 'fit for purpose' and modifications must be traceable through each stage of development of the method.

9. Research / work records

The contractor's project records must be of sufficient quality and detail to present a complete picture of the work performed, enabling it to be repeated if necessary.

The Project Leader must ensure the validity of the work by carrying out regular reviews of the records of all project staff.

The location of all project records, including critical data, must be recorded. They must be retained in a form that ensures their integrity and security, and prevents unauthorised modification, for a period to be agreed with the Funding Body.

10. Field-based research

All field-based research must comply with all relevant environmental legislation, where appropriate. Laboratories have a duty to manage any discharges and emissions to the environment, such that any pollution risks are minimised. All provisions of the JCoPR, as above, will also apply.

ANNEX - Examples of documentary evidence

QUALITY ISSUE	EVIDENCE REQUIRED
1. **Responsibilities**	• Organisation structure showing line management responsibilities (organogram) • Updated and maintained list of personnel involved with the project (including sub-contractors) • Documented agreement with sub-contractors to adhere to JCoPR & evidence of rationale for appointment. • Documented roles & responsibilities for all project staff (including subcontractors)
2. **Personnel competence**	• Consistent collation of CV's of all personnel associated with the project (including subcontractors) • Maintenance of relevant, up-to-date training records for all project staff (including evidence showing awareness of obligation to comply with the Code's provisions)
3. **Project planning**	• Risk assessment (where appropriate) • Records of regular reviews of project timetables & plans • Up-to-date approved project plan with milestones & deliverables • Statistical validation of experimental plans & procedures for analysis of data • Documented, approved procedures for sampling materials • Ethical approval documentation & project licences (as appropriate)
4. **Quality Control**	• Documented internal 'fit for purpose' review procedures • Records of consistently applied internal audits , findings & corrective actions taken • Approved publication policy with authorisation procedures
5. **Health & safety**	• Documentation to demonstrate both training & compliance (e.g. Laboratory Health & Safety Plan) • Documentation on specific measures as appropriate (e.g. for pathogenic organisms or radioactive substances)
6. **Handling of samples & materials**	• Consistent application of a standardised system for controlling, labelling & tracking samples • Documented procedures for handling samples & materials • Up-to-date storage logbooks

7. **Facilities & equipment**	• Documented maintenance & calibration records of project equipment (as appropriate) • Records of regular maintenance of special facilities, like refrigeration units (as appropriate) • Documented standard operating procedures for project critical equipment, including emergency procedures
8. **Documentation of procedures & methods**	• Robust process for document & version control in all key project documentation • Validated Standard Operating Procedures
9.**Research/work records**	• Where facilities exist, research / work records should be stored consistently in both hard copy & electronic form (counter-signed laboratory notebooks or indexed computer data files) • Consistent & documented archiving procedures
10. **Field-based research**	• Documented risk assessment for field-based research, showing proactive steps taken to counter any risks identified

This document/publication is also available on our website at:

http://www.defra.gov.uk/publications/2012/03/20/pb13725-research-code-practice/

Any enquiries regarding this document/publication should be sent to us at:

StrategicEvidence@defra.gsi.gov.uk

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