JOINT CODE OF PRACTICE FOR RESEARCH

Issued by the Biotechnology and Biological Sciences Research Council, the Department for Environment, Food and Rural Affairs, the Food Standards Agency and the Natural Environment Research Council.

This Code was developed by a working group of representatives from the Biotechnology and Biological Sciences Research Council (BBSRC), the Department for Environment, Food and Rural Affairs (Defra), the Food Standards Agency (FSA) and the Natural Environment Research Council (NERC). It has subsequently been endorsed by The Northern Ireland Department of Agriculture and Rural Development, The Scottish Executive Environment and Rural Affairs Department and the Welsh Assembly Government Agriculture and Rural Affairs Department (The UK Devolved Administrations). The Code applies to all research funded by DEFRA, the FSA and 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 interpreted with that in mind.

PRINCIPLES BEHIND THE CODE OF PRACTICE

Contractors funded by the above Funding Bodies are expected to be committed to the quality of the research process (QP) in addition to quality of science (QS). QS addresses the aims of the project, its approaches and the extraction of new knowledge and understanding from the scientific work. QP underlies the research giving confidence that 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. Thus the Funding Bodies wish to ensure that their contractors are using “best scientific practice” from the very start of all research projects.

The Funding Bodies have developed this Code of Practice which lays 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 competent researchers.

Most contractors will already have in place many of the measures set out in the Code and its adoption should not require great effort. As such, this document can be viewed as a helpful checklist for contractors to review and improve their existing research systems.

COMPLIANCE WITH THE CODE OF PRACTICE

For the FSA, DEFRA and the UK Devolved Administrations a Contractor will be expected to indicate acceptance of the Code when submitting proposals to the Funding Body through completion of the appropriate research application form. Contractors are encouraged to discuss with the Funding Body any clauses in the Code that they consider inappropriate or unnecessary in the context of the proposed research project. 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 to identify where additional controls may be needed.

For BBSRC- and NERC-funded work, acceptance of the Code would be provided on an annual basis by the Institute Director.

MONITORING OF COMPLIANCE WITH THE CODE OF PRACTICE

Monitoring of compliance with the Code is necessary to ensure:

- Policies and managed processes exist to support compliance with the Code
- That these are being applied in practice.

In the short term, the Funding Bodies can require contractors to conduct planned internal audits although the Funding Bodies reserve the right to obtain evidence that a funded project is carried out to the required standard. The Funding Bodies may also conduct an audit of a Contractor's research system if deemed necessary.

In the longer term it is expected that most research organisations 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.

SPECIFIC REQUIREMENTS IN THE CODE OF PRACTICE

1. Responsibilities

The 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 ensure a climate of good scientific practice in the research teams, including a commitment to the development of scientific and technical skills.

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

2. Competence

All personnel associated with the project 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.

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 written project plan showing that these factors (including research design, statistical methods and others) have been 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. Significant amendments to the plan or milestones must be recorded and approved by the Funding Body if applicable.

4. Quality Control

The organisation should have planned processes in place to assure the quality of the research undertaken by its scientists. Projects should be subjected to formal 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.

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

5. Health and Safety

All research must 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 retained for a period to be agreed by the Funding Body. The storage and handling of the samples and materials should be as 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 if necessary, and be in good working condition. If critical, there should be contingency plans in case of power failure or other disruption.

8. Documentation of procedures and methods

All the procedures and methods used in a research project must be documented, at least in the personal records of the researcher. This includes analytical and statistical procedures and the generation of a clear audit trial linking secondary processed information to primary data.

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

9. Research/work records

All records must be of sufficient quality 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 each scientist.

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 by the Funding Body.

DECLARATION TO ACCOMPANY RESEARCH PROPOSALS.

I confirm that I am aware of the requirements of the Joint Code of Practice and, in the proposed project, I will use my best efforts to ensure that the procedures used conform to those requirements under the following headings:

- Responsibilities
- Competence
- Project planning
- Quality Control
- Health and safety
- Handling of samples and materials
- Facilities and equipment
- Documentation of procedures and methods
- Research/work records

I understand that the funding body has the right to inspect our procedures and practices against the requirements of the Code of Practice, and that I may be asked to provide documentary evidence of our working practices or provide access and assistance to auditors appointed by the Funding Body.

(There is some flexibility in the application of the Code of Practice to specific research projects. Contractors are encouraged to discuss with the Funding Body any aspects that cause them concern, in order to reach agreement on the interpretation of each requirement.)

ANNEX - Examples of documentary evidence

Quality Issue	Evidence
1. Responsibilities	Organisation structure showing line management responsibilities. List of personnel associated with the project, including sub-contractors.
2. Personnel competence	CV's of personnel associated with the project. Specific training records.
3. Project planning	Risk assessment (if required) Up-to-date approved project plan with milestones. Statistical validation of experimental plan and procedures for analysis of data. Approved procedures for sampling materials. Ethical approval documentation and project licences.
4. Quality Control	Internal project reviews and auditing procedures relevant to the research undertaken by the organisation. Approved publication policy with authorisation procedures.
5. Health and safety	Laboratory Health and Safety Plan. Documentation on specific measures (e.g. for pathogenic organisms or radioactive substances).

6. Handling of samples and materials	Procedures for receiving samples, labelling and tracking them. Procedures for handling samples and materials. Storage logbooks.
7. Facilities and equipment	Maintenance and calibration records of equipment used in the project. Maintenance records of special facilities.
8. Documentation of procedures and methods	Validated Standard Operating Procedures. Document control procedures.
9. Research/work records	Counter-signed laboratory notebooks or indexed computer data-files. Archiving procedures.