

CHIEF SCIENTIST OFFICE RESPONSE MODE GRANTS

STANDARD CONDITIONS OF GRANT

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These are the terms and conditions referred to in the letter of award by the Scottish Ministers acting through the Chief Scientist Office of the Scottish Executive to [Name of Grantholder], dated []

1. Definitions of Terms

In these conditions:

a. **application** means a CSO application form for a response mode grant completed by the applicant(s) in respect of the research project, and into which these conditions are incorporated;

b. **Chief Investigator** means the person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study whether or not that person is an investigator at any particular site. For the purposes of a CSO response mode grant, the Chief Investigator must be a permanent salaried member of staff in a Scottish Institution;

c. **conditions** means these standard conditions of research grant, being the basis upon which the Scottish Ministers, acting through CSO, will offer to support any research project by means of a response mode grant;

d. **core funded Unit** means a group of individuals funded by CSO over the medium to long term to develop research and research capacity in an area of strategic importance;

e. **CSO** means the Chief Scientist Office of the Scottish Executive, acting on behalf of the Scottish Ministers;

f. **grant** or **research grant** means the grant offered to the grantholder by CSO as specified in the research grant letter, as varied from time to time in accordance with the provisions of these conditions;

g. **grantholder** means the institution to whom the grant will be payable and at which the Chief Investigator is based;

h. **project** or **research project** means the research project to be undertaken by the applicant(s) the objectives of which are set out in the specification attached to the research grant letter and in accordance with these conditions;

i. **research grant letter** means the letter from CSO awarding the grant to the grantholder, setting out the objectives of the research project, and to which these conditions are annexed;

j. **specification** means the summary of the details of the grant award issued with the offer letter. This includes: reference number, title, aims, sponsor, grantholder, Chief Investigator, co-Investigators and financial details;

k. **sponsor** means an individual, organisation, or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in the Scottish Executive Research Governance Framework for Health and Community Care in Scotland that are relevant to the study.

2. General

Research Governance

2.1 The research supported by the grant must be conducted in accordance with the Scottish Executive's guidance "Research Governance Framework for Health and Community Care in Scotland" and if relevant, in accordance with the Executive's guidance "Governance Arrangements for NHS Research Ethics Committees in Scotland" or such guidelines as may be issued from time to time by the Executive.

Sponsorship

2.2 CSO does not assume sponsorship responsibility for research funded through its research grant scheme. The sponsor must be satisfied before the project begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and that arrangements are in place allocating responsibilities for the management, monitoring and reporting of the research.

Responsibilities of the Grantholder

2.3 The project shall be carried out by, or under, the general direction of the organisation named in the specification as the grantholder who will be responsible for operating the management and monitoring systems for the project and for ensuring that these terms and conditions are complied with.

2.4 The grantholder must provide the basic facilities required to support the work of the project.

2.5 The grantholder must ensure that the research supported by the grant complies with all relevant legislation and Government regulations whether in force or not as at the date of this award. This requirement includes approval or licence from any regulatory body that may be required before the research can commence.

2.6 The grantholder must ensure that the Chief Investigator, co-Investigators and other staff understand and discharge their responsibilities and observe the terms and conditions of the grant.

2.7 It is the responsibility of the grantholder to ensure that the project has documented NHS organisation approval before any work that involves the NHS commences.

2.8 The grantholder must notify CSO of the start and completion dates of the project and of any events occurring during the project which could prejudice the completion date. No change in the research protocol may be made without prior agreement in writing of CSO and, where appropriate, the Research Ethics Committee.

2.9 The grantholder is responsible for ensuring that the project is completed within the time allocated and within the financial limits of the grant and must advise CSO immediately in writing of any occurrences which may prejudice the completion of the project within these limits. Failure to do so may result in termination of the project and the demand for partial or full repayment of funds.

2.10 If the project fails to progress, the sponsor, grantholder and CSO will work together and with the Chief Investigator/co-Investigators to develop a solution. CSO will not accept financial responsibility for delays in the project due to staff changes or failure by the sponsor and grantholder to put in place appropriate management and monitoring arrangements.

2.11 It is suggested that a project management committee is established to oversee the project. The composition of the committee will be a matter for the Chief Investigator to decide, but the issues for consideration will include research conduct and governance,

project and financial management and dissemination (including where appropriate archiving of data).

3. Staff

3.1 It is the responsibility of the grantholder to enter into contracts of employment with all persons whose salaries are reimbursed from the grant. Such contracts should provide for the rate of pay and conditions of service normally applicable to the appropriate grades of the persons employed by that institution.

3.2 The grantholder is responsible for ensuring that all clinicians working on a CSO grant are aware that they are individually responsible for making appropriate cover with a professional defence organisation for any activities not covered by NHS indemnity arrangements or by any additional provision made by the grantholder. CSO will not meet the needs of such cover.

3.3 The grantholder is responsible for ensuring that any honorary contracts required by clinical or other staff working under a CSO grant have been obtained prior to the start of the award.

3.4 The Chief Investigator must have a contract which extends 6 months beyond the end of the grant period.

Chief Investigator Status for Core Funded Staff in CSO Units

3.5 It is permissible for a core funded member of staff from a CSO Unit to apply to CSO for a grant as long as the following conditions are met:

- any core funded member of staff from a CSO Unit who nominates him or herself as Chief Investigator must have a contract which extends 6 months beyond the end of the grant period;
- any application from a core funded member of staff must involve demonstrable and substantial collaboration from outwith the Unit;
- any application from a core funded member of staff must relate to one of the programmes of work which have been approved through the Unit review process.

4. Equipment

4.1 Any equipment paid for by CSO, however acquired, shall be, and remain, the property of CSO and be in the care of and maintained in good condition by the grantholder. This will include appropriate insurance or maintenance by the grantholder.

4.2 During the period when such equipment is in the care of the grantholder, the Scottish Ministers or their agents shall not be liable for any claims arising out of the presence or use of such equipment. In the event that equipment is lost, damaged or stolen it is the responsibility of the grantholder to notify the CSO and provide a replacement or reimbursement. Equipment should not be lent, re-allocated or disposed of without CSO approval.

4.3 If such equipment is transferred (with CSO's permission) to an institution other than the grantholder named in the specification, the receiving institution shall be required to accept responsibility for the care and maintenance of such equipment and also to indemnify the Scottish Ministers or his agents against any claims arising from the removal, installation and use of such equipment.

4.4 At the conclusion of the project, or following withdrawal of financial support, CSO may:

- withdraw any such equipment from the grantholder; or
- on being satisfied in writing by the grantholder that such equipment shall continue to be used for the benefit of NHSScotland, agree that it shall be retained in the care of, and maintained by the grantholder; or offer such equipment for sale to the grantholder at an agreed current valuation; or dispose of such equipment in ways that are acceptable to CSO.

5. Finance

The grantholder shall exercise financial control of the grant according to the conditions set out in Appendix A which are incorporated herein brevitatis causa.

6. Limitation of Liability

CSO accepts no responsibility, financial or otherwise, for expenditure (or liabilities arising out of such expenditure) or liabilities arising out of the work funded by the grant. CSO will not indemnify the sponsor, grantholder, the Chief Investigator, co-Investigators or any other person working on the grant (including employees, students, visiting fellows and subcontractors) against any claims for compensation or against any other claims (whether under statute or regulation or at common law) for which the grantholder may be liable as an employer or otherwise or for which any such person may be liable.

7. Data Protection

It is the responsibility of the grantholder to ensure that the requirements of the Data Protection Act and other legal provisions and guidance on handling information are fully observed. In particular, the Chief Investigator and co-Investigators shall ensure at all times that any personal data collected in the course of the project shall be securely held and handled and that the anonymity of persons to whom the data refers shall be preserved including in any report or publication.

8. Use of Animals

8.1 Wherever possible, investigators must adopt procedures and techniques which avoid the use of animals. Where this is not possible, the research must be designed to meet full compliance with all Home Office Regulations and any legal requirements regarding the use of animals including:

- ensuring that the least sentient species with the appropriate physiology is used;
- ensuring that the number of animals used is the minimum sufficient to provide the statistical power to answer the question posed;
- ensuring that the severity of procedures performed on animals is kept to a minimum. Experiments should be kept as short as possible. Appropriate anaesthesia, analgesia and humane end points should be used to avoid any pain and suffering.

8.2 The grantholder is responsible for ensuring that the provisions of the Animals (Scientific Procedures) Act 1986 and any amendments are observed and that all necessary licences have been received before any work requiring approval takes place.

9. Ethics

9.1 The grantholder is responsible for ensuring that ethical issues relating to the research project are identified and brought to the attention of the approval or regulatory body.

9.2 Ethical approval to undertake the research must be granted before any work requiring approval begins. Confirmation of ethical approval must be submitted to CSO before a grant is paid.

10. Health and Safety

The grantholder is responsible for ensuring that a safe working environment is provided for all individuals associated with a research project. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health and Safety Executive. Appropriate care must be taken where researchers are working off-site. The grantholder must satisfy itself that all reasonable health and safety factors are addressed and to monitor and audit the actual arrangements made.

11. Research and Financial Misconduct

11.1 The grantholder must have in place adequate systems for ensuring the quality and financial management of research that is carried out by its staff so that scientific misconduct (e.g. plagiarism, falsification of data, improper selection of data) or financial misconduct can be prevented. The grantholder should have effective mechanisms in place for identifying scientific and financial misconduct and clearly publicised and agreed procedures for investigating allegations of such misconduct.

11.2 It is the responsibility of the Chief Investigator, co-Investigators, the head of department and the grantholder to notify CSO immediately if there is any indication that research or financial misconduct has occurred. Failure to do so may lead to the project's suspension or termination. Reimbursement of inappropriate claims will be sought.

12. Monitoring and Evaluation

12.1 An officer of CSO, or a group appointed on its behalf by the Chief Scientist, must, when reasonable notice has been given, have access to the project to discuss its progress with the Chief Investigator, co-Investigators and the staff involved, and to inspect equipment or other materials provided from the grant.

12.2 The Chief Investigator is responsible for providing such progress reports as may be required by CSO (see **Form 3**). Such reports must conform to guidelines which are issued from time to time by CSO. Any change of objective must be agreed with CSO. The timing and frequency of such reports, which shall depend on the nature of the project, shall be notified to the Chief Investigator by CSO. If, after due assessment, the research is not considered to be making satisfactory progress, CSO reserves the right to discontinue the provision of financial support under the terms of the grant.

12.3 The Chief Investigator is responsible for ensuring that a final scientific report will be available to CSO by the end of the funding period. This should conform to the guidelines given with **Form 4**.

12.4 Funding of further grant applications from the Chief Investigator will not be considered until a satisfactory report is received.

12.5 Copies of all publications originating from the CSO sponsored research, published either before or after the final report, must be provided to CSO.

13. Publication and Acknowledgement of Support

13.1 CSO attaches great importance to the publication and dissemination of the results of research undertaken with its grant support. Grantholders must acknowledge CSO's support in publications and communications (including media appearances and releases, as well as journals and conferences). CSO financial support should always be acknowledged even when the contribution to individual papers may be small.

13.2 The grantholder is responsible for ensuring that articles, programmes or papers give an accurate account of the research.

13.3 CSO reserves the right to publish details of financial support given for the project and of the scientific objectives of the project and periodically to submit publishable details to the National Research Register and the National Cancer Research Institute and to other partner organisations as appropriate.

13.4 In addition to the presentation of progress and final reports, the grantholder and/or Chief Investigator and/or co-Investigators must inform the CSO of any intended publication of any work containing results, information or technical knowledge connected with the project. The grantholder and/or Chief Investigator and/or co-Investigators shall forward a copy of the work to CSO so that, prior to submission for publication, CSO may comment on any matters of policy raised in the work. In particular any results that might be considered "sensitive" and exploitable by the media must be indicated to CSO in good time.

13.5 Where new or previously unreported results are to be made public at any meeting where representatives of the specialist or general news media may be present, the data and any text to be used should be sent to CSO in advance of the presentation, together with full information about the meeting.

13.6 Where publication of the research results is to be made by poster display or oral presentation to a medical or scientific meeting, abstracts should be sent to CSO in advance of submission to the organisers of the meeting, and additional results and any text used should be submitted as soon as possible, prior to the meeting. When publication is to be achieved by presentation in written text, and delay will occur before the research becomes public, the text should be sent to CSO before submission to the journal, naming the journal. CSO may at its discretion, for the purposes of NHSScotland or elsewhere in the United Kingdom and for the purposes of social work activities in Scotland or elsewhere in the United Kingdom, inform, as appropriate, any Minister of the Crown, any Health Board or similar statutory body, and any Local Authority in the UK, of any results of the project.

13.7 A copy of the final, peer-reviewed version of all papers arising from the funded research and accepted for publication must be deposited in a publicly accessible repository (UK PubMed Central) and be made freely available within 6 months. Papers must cite the CSO grant reference number.

14. Public Engagement in Science

The grantholder and/or Chief Investigator and/or co-Investigators are expected to participate in activities which seek to raise awareness of science amongst lay audiences. Research active NHS organisations are expected to develop and deliver their own communication strategies and in some cases, if relevant, local Investigators might be able to involve themselves with those communication initiatives. Universities also have a role in developing opportunities for science dialogue with lay audiences. Key audiences for CSO grantholders to consider in their communication activities are:

- opinion formers, influencers and policy makers;
- scientific community;
- health professionals;
- consumers/patients;
- the public.

15. Intellectual Property and Commercial Exploitation

15.1 Unless stated otherwise, and subject to the conditions set out below, the ownership of intellectual property, and responsibility for its exploitation, rests with the grantholder. CSO may, at its discretion, retain ownership of intellectual property. This right, if exercised, will be set out in an additional condition.

15.2 The grantholder is responsible for ensuring that CSO is informed in writing of any discovery, development, application or technical knowledge ("innovation") arising in the course of the project which could have commercial value.

15.3 The grantholder is responsible for ensuring that the CSO is notified of any proposed discussion or negotiation with any person, company or firm with a view to commercial use or exploitation of such results.

15.4 It is the responsibility of the grantholder and all engaged in the research, to make every effort to ensure that any potential innovation generated or created in the course of the research is appropriately exploited. If at the end of a period of 5 years from the final payment of the grant CSO takes the view that the grantholder has not taken adequate steps to exploit the intellectual property in relation to that potential innovation, and CSO takes the view that the potential innovation has such potential for exploitation, ownership of all intellectual property generated through the grant shall revert to CSO immediately. In arriving at such a view CSO will first consult the grantholder and shall subsequently notify any such view in writing.

15.5 The grantholder must ensure that all those associated with the research are aware of, and accept, the arrangements and conditions for exploitation.

15.6 Collaborative arrangements are expected to be put on a formal basis through an agreement covering the contributions and rights of the organisations and individuals concerning exploitation.

15.7 Such agreements must be in place before the research begins. The terms of collaboration agreements must not conflict with CSO's terms and conditions of response mode research grants.

16. Preserving and Sharing Research Data

16.1 CSO, in common with other public research funders, strongly encourages the sharing of data from research it supports. Where the data may be of interest to researchers other than the original investigators, consent from research participants should be worded in terms that enable the data to be used for secondary analysis, and datasets should be preserved in a way that encourages other analysts to use them. The

best method for ensuring this is to deposit the data with full supporting documentation in a public archive, such as the UK Data Archive.

16.2 CSO recognises that the original investigator has a right to a limited period of exclusive use of the data, that secondary analyses may be most fruitfully conducted in collaboration with the original investigator, and that publications making secondary use of the data should acknowledge the intellectual property of the original investigator.

16.3 Whether or not the data is likely to be used for secondary analysis, the Chief Investigator must ensure that the raw data or results are stored for a minimum period of 5 years after completion of the project. At any time during this period the data or results may be requested by CSO. If a longer period of storage is required this will be indicated in the notice of funding.

17. Continuing Subsistence of Conditions

The grant conditions described above shall subsist notwithstanding the termination of the project or the grant period, unless otherwise agreed.

18. Variation of Conditions or Specification

No alteration, deletion or addition may be made to any of these conditions, or any part of the specification without the prior agreement in writing of CSO. In particular:

- Any change of substance in the objectives of the project;
- Any change of Chief Investigator/co-Investigators;
- Any change of the maximum expenditure figure for each element of the grant given in the Specification;
- Any change in the duration of the grant

must be so approved. If CSO does not approve a change proposed by the sponsor and/or grantholder, CSO may, after consultation with the sponsor and/or grantholder, cancel or renegotiate the arrangements for support of the project or seek recompense.

FINANCE

1. General

1.1 The letter of award of grant by the Scottish Ministers acting through the Chief Scientist Office (CSO) of the Scottish Executive must be signed by the grantholder and returned to CSO along with the Acceptance of Grant Conditions (**Form 5**) which must be completed by the sponsor, Chief Investigator, and co-Investigators. Projects are expected to start (unless there are exceptional circumstances) within 6 months of the date of the grant offer letter.

1.2 When a project commences, usually when the first staff are appointed on the project, the Start Certificate (**Form 7**) must be completed by the grantholder's Finance Office and returned to CSO. The start and finish dates must always be the first and last days of a month respectively. A finance contact for the grant must be identified. No money will be paid for a new project until a signed Start Certificate and, where appropriate, ethics approval is received from the grantholder. No transfer of funds between awarded categories of expenditure may take place without the prior agreement of CSO.

Full Grants

1.3 These are normally 80% of full economic costs up to a maximum of £225,000 over a maximum period of 3 years or £450,000 if a multi-centre study. Payments are made by profile on completion of a payment schedule proforma that is sent to the Finance Officer of the grantholder. Payments are made quarterly in arrears. All payments made by CSO may be recovered and/or future payments withheld if expenditure by the grantholder is not in accordance with that agreed by CSO.

Small Grants

1.4 These are normally 80% of full economic costs up to a maximum of £50,000 over one year. It is expected in general that a Small Grant will be used to fund a discrete piece of research and will not be supplemented from other sources.

1.5 Eighty percent of the value of the grant is payable at the start of the project and the remaining 20%, if required, is payable on receipt of a satisfactory final report and a final statement of expenditure (**Form 8**) at the end of the project. If the total expenditure is less than 80% of the grant limit, the balance must be returned to CSO within 4 weeks of the end of the funding period. Payments made by CSO may be recovered and/or final payments withheld if expenditure by the grantholder is not in accordance with that agreed by CSO.

2. Statements and Audit

Annual Statements

2.1 CSO will issue an annual statement which the grantholder will be required to return confirming expenditure to date for each project administered. The grantholder must certify by completing the statement and signing the enclosed certificate "that expenditure has been incurred in accordance with the grant conditions". The grantholder will also be certifying that it agrees with the details on the statement. No further payments will be made to the grantholder for any of its held projects until this statement is returned. When a Chief Investigator requires to submit a progress report, no further payments will be made on the project when the report is overdue. All payments made by CSO may be recovered and/or future payments withheld if expenditure by the grantholder is not in accordance with that agreed by CSO.

Expenditure Statements

2.2 The final payment due on any project will be withheld until both the final statement of expenditure (**Form 8**) and a satisfactory final report (as deemed by the appropriate Research Committee) are received. Where final expenditure on the project is less than the grant paid, CSO will recover the excess amount of grant paid. In cases where the final expenditure is more than the grant award, CSO may approve at its discretion, an increase in the final payment to cover the additional costs. Where a final report is judged as unsatisfactory, the final payment will be withheld.

2.3 The final statement of expenditure should be completed by the Finance Office of the grantholder and sent to CSO at the same time as the final report or within 4 weeks of the end of the funding period.

2.4 All payments made by CSO may be recovered if:

- the final report or final statement of expenditure is not received within 6 months of the end of the funding period;
- expenditure by the grantholder is not in accordance with that agreed by CSO.

Audit of Expenditure

2.5 CSO is required to undertake an annual audit of expenditure on project grants, randomly selected for this purpose. CSO will contact the grantholder for the selected project grant(s) who will be required to provide documentation confirming the directly incurred expenditure to date on the project including salaries, consumables, travel and subsistence, equipment and other expenditure. For salaries, this may be a signed statement of staff costs from the Finance Office or details of total payments made from payroll clearly laid out in summarised format. Dated invoices will be required for all consumables, travel and subsistence and equipment costs along with any invoices detailing other costs incurred on the project. All payments made by CSO may be recovered and/or future payments withheld if expenditure by the grantholder is not in accordance with that agreed by CSO.