

CHIEF SCIENTIST OFFICE

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 Government to [Name of Grantholder], dated []

1. Definitions of Terms

In these conditions:

a. **application** means a CSO application form for a Clinical Academic Training Fellowship completed by the applicant(s) in respect of the Fellowship, 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 this Fellowship, the Chief Investigator of the research carried out during the fellowship is the Fellow;

c. **conditions** means these standard conditions of research grant, being the basis upon which the Scottish Ministers, acting through CSO, will offer to support an individual by means of a Clinical Research Fellowship;

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

e. **grant** means the award offered to the grantholder on behalf of the Fellow by CSO as specified in the fellowship award letter, as varied from time to time in accordance with the provisions of these conditions;

f. **grantholder** means the institution to whom the grant will be payable and at which fellow is based;

g. **fellowship** means the research and training to be undertaken by the fellow, the objectives of which are set out in the specification to the fellowship award letter and in accordance with these conditions;

h. **fellowship award letter** means the letter from CSO awarding the Fellowship to the grantholder, setting out the objectives of the research Fellowship, and to which these conditions are annexed;

i. **fellow** means the individual, named in the specification, who is to be supported by the fellowship. This individual will be the Chief Investigator for the research carried out under the fellowship and his/her supervisors will be Co-Investigators;

j. **specification** means the summary of the details of the Fellowship issued with the award letter. This includes - reference number, title, sponsor(s), grantholder, Chief Investigator, co-Investigators and financial details;

k. **sponsor** means the individual or organisation or group of individuals/organisations that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance (or arranging to finance) a study. For any research that takes place in the context of the NHS or community care services in Scotland, there must be a sponsor. Normally, the sponsor will be one of the organisations taking the lead for particular aspects of the arrangements for the study. It may be the chief investigator's employing organisation, or the lead organisation providing health or community care, or the main funder. For any research study covered by the research governance framework, it is for the sponsor to be satisfied that clear agreements are reached, documented and carried out, providing for proper initiation, management and monitoring and financing. Others will rely on reasonable assurances that the sponsor has taken steps to do this.

2. General

Research Governance

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

Sponsorship

2.2 CSO does not assume sponsorship responsibility for research funded through its Fellowship schemes. 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 Fellowship 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 Fellowship 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 Fellowship.

2.5 The grantholder must ensure that the research carried out during the Fellowship 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 Fellowship.

2.7 It is the responsibility of the grantholder to ensure that the Fellowship 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 Fellowship and of any events occurring during the Fellowship 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 Fellowship 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 Fellowship within these limits. Failure to do so may result in termination of the Fellowship and the demand for partial or full repayment of funds.

2.10 If the Fellowship fails to progress, the sponsor, grantholder and CSO will work together and with the Chief Investigator/co-Investigators to develop a solution. CSO will fully engage with AD and MDC in this process. CSO will not accept financial responsibility for delays in the Fellowship 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 Fellowship. 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 If, during the course of the Fellowship, a Fellow decides to take up a post at an institution other than the grantholder named in the specification, CSO should be notified in advance. If, upon review, CSO agrees that

the Fellowship can continue, this agreement will be terminated and a new agreement entered into with the new grantholder for the remainder of the award.

3.3. If, during the course of the Fellowship, a Fellow applies for a substantive University post, CSO should be notified. If a Fellow is successful in obtaining such a post CSO will review the continuation of the Fellowship, however it is unlikely that the salary component of the award would continue to be paid.

3.4. In the event of progression to CCT for Fellows in the later stages of specialist training additional salary costs as a result will not be met by CSO.

3.5. The grantholder is responsible for ensuring that all clinicians supported by a CSO Fellowship 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.

3.6. The grantholder is responsible for ensuring that any honorary contracts required by clinical/other staff supported by a CSO Fellowship have been obtained prior to the start of the grant.

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. At the end of the award period such equipment should be returned to CSO.

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 Fellowship, 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 Fellowship according to the conditions set out in Appendix A which are incorporated herein brevity 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 Fellowship. 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 Fellowship 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 research carried out under the Fellowship 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 the Fellow. 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 Fellowship being suspended or terminated. 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 Fellowship to discuss its progress with the Chief Investigator/co-Investigators and to inspect equipment or other materials provided from the award.

12.2. The Fellow is responsible for providing progress reports to CSO - see Form 3(CAF). Such reports must conform to guidelines which are issued from time to time by CSO. Any change of objective must be agreed

with CSO and approved by AD and MDC.. Progress reports are required at 6, 18 and 30 months from the start of the Fellowship. If, after due assessment, the Fellowship 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 Fellow is responsible for ensuring that a final report will be available at the end of the Fellowship. This should conform to the guidelines given with Form 4(CAF) and be submitted to CSO within the correct timescale.

12.4. The final payment due on any Fellowship will be withheld until the final statement of expenditure and the final report are received and the latter deemed satisfactory by CSO. The final statement of expenditure should be completed by the Finance Office of the grantholder and should be sent to CSO at the same time as the final report or within the specified timescale. If it is not received, CSO retains the right not to pay the final payment. In the case of Fellowships the Co-Investigators share the responsibility with the Fellow for ensuring the final report is submitted in good time.

12.5. Funding of further grant applications will not be considered until a satisfactory report is received.

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

12.7. The Chief Investigator (or an individual nominated for this purpose by the CI) is required to upload recruitment data on a monthly basis to the UKCRN Portfolio Database (or future replacement) through the mechanisms provided for this purpose.

12.8. The Chief Investigator is required to submit accurate information on the outputs from the project through the e-VAL system, which is now accessed through the ResearchFish website - <https://www.researchfish.com/>. More information can be found in the Dissemination section of the CSO website.

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 Fellowship and of the scientific objectives of the associated research and periodically to submit publishable details to the UKCRN Portfolio Database and 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 Fellowship. 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 and any press releases should be sent to CSO at least 5 working days in advance of intended date of release.

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 at least 5 working days 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 - Europe PubMed Central (<http://europepmc.org>) and be made freely available within 6 months. All papers derived from the Fellowship must acknowledge CSO funding and cite the CSO grant reference number.

13.8 In order to facilitate compliance with condition 13.7 a separate application may be made for open access publication charges (up to a limit of £2000) on form 6a. This support is limited to papers presenting the methods and/or findings of the study, and which are accepted for publication within 12 months of acceptance of the final report. Other dissemination costs (such as feedback of findings to research participants or healthcare practitioners, or other decision makers) may be applied for using form 6b. This form may also be used for costs associated with data-sharing, such as preparation of datasets for archiving or compilation of metadata. These costs do not count towards the £2000 limit for open access publication charges.

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, and after consultation with AD and MDC, 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 Fellowship 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. CSO will consider applications for the costs associated with archiving and data sharing, which should be made on form 6b (see para 13.7).

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 Fellowship. 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, including approval by AD And MDC. In particular:

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

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 When a new Fellowship is recommended for funding an offer of grant is made to the grantholder. The Acceptance of Grant Conditions (Form 5(CAF)) must be completed by the sponsor, Chief Investigator, co-Investigators and the grantholder and returned to CSO. Fellowships are expected to start (unless there are exceptional circumstances) within 6 months of the offer being made.

1.2 When a Fellowship commences the Start Certificate (Form 7(CAF)) must be completed by the grantholder's Finance Office and returned to CSO. Note that 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 Fellowship until a signed Start Certificate is received from the grantholder.

1.3 Payments are made by profile on completion of a proposed payment schedule proforma that is sent to the Finance Officer of the grantholder. Payments are normally made quarterly in arrears

1.4 No transfer of funds between awarded categories of expenditure may take place without the prior agreement of CSO. CSO reserves the right to recover any sum so transferred if prior agreement has not been sought, or to recover any sum for expenditure out with the agreed specification.

2. Statements and Audit

Annual Statement

2.1 CSO will issue an annual statement which the grantholder will be required to return confirming expenditure to date for each award 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 awards until this statement is returned.

Expenditure Statements

2.2 The final payment due on any Fellowship will be withheld until both the Final Statement of Expenditure (Form 8(CAF)) and a satisfactory final report are received. Where final expenditure on the Fellowship is less than the sum paid, CSO will recover the excess amount. In cases where the final expenditure is more than the Fellowship award, CSO may approve at its discretion, an increase in the final payment to cover the additional costs. Where a final report is unduly delayed, or judged as unsatisfactory, the final payment will be withheld. In the case of Fellowships the Co-Investigators share the responsibility with the Fellow for ensuring the final report is submitted in good time.

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. If this is not received, CSO retains the right not to pay.

2.4 Expenditure statements should detail expenditure under the same headings as in the specification and the expenditure profile.

2.5 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

2.6 CSO is required to undertake an annual audit of expenditure on awards, randomly selected for this purpose. Each April, CSO will contact the grantholder for the selected awards grant(s) who will be required to provide documentation confirming the expenditure incurred to date on the Fellowship including salaries, consumables, travel and subsistence, equipment and other expenditure. For salaries, this may be a signed statement of staff costs from the Finance Department 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 Fellowship.

Higher Education Institutions: Annual Assurance Exercise

2.7 Higher Education Institutions (HEIs) in receipt of CSO Fellowship grants will be required to provide an annual assurance from the Institution's Head of Internal Audit or equivalent person(s), on the effectiveness of the systems for controlling CSO awards. An assurance will be sought by CSO each October from the appropriate HEIs for the previous financial year ended 31 March.

3. Staff Costs

3.1 CSO shall reimburse the grantholder in respect of the Fellow's salary based on the sums notified in the Finance section of the application, or up to any amended maximum which has been agreed, and shall in addition pay:

- the employer's share of National Insurance and superannuation contributions.
- any increased costs which arise from nationally agreed revisions of salary scales or from normal increments arising from nationally agreed salary scales and of which the grantholder has notified CSO at the time they arise.

4. Consumables and Travel

4.1A budget not to exceed £10,000 per annum will be available for consumables, to be paid as detailed in the payment proforma.

Consumables

4.2 Consumables are those items which are required to carry out the research and the items that may be paid under this heading are detailed in the award Specification

Travel

4.3 The cost of travel and subsistence relating to the Fellowship, the cost of general/study visits to other establishments, travel to conferences etc. are NOT included - applications for assistance with these costs should be made separately on each occasion on which they arise and on Form 6. At least 6 weeks' notice is required before the journey is due to commence. Claims for reimbursement of such costs will NOT be accepted if prior written approval has not been obtained. The grantholders should ensure that such costs are not claimed inappropriately.

4.4 CSO will consider applications for travel costs for no more than one conference per year, and applications for attending conferences out with the UK will only be considered in the final year of the Fellowship. There is no guarantee that applications will be successful.

5. Compliance with the Medicines for Human Use (Clinical Trial) Regulations 2004

5.1 For trials falling within the scope of the Medicines for Human Use (Clinical Trial) Regulations which transposed the EU Clinical Trials Directive 2001/20/EC into UK law from 1 May 2004, the following costs may be met:

- Authorisation fees, charges and support;
- Trial specific pharmacy costs in respect of drug dispensing and labelling and stock reconciliation and destruction at the end of a trial;

5.2. Justification for these costs should be fully explained in the application

6. NHS Support Costs

NHS Support Costs incurred during Research carried out under CSO funded Fellowships are reimbursed through NRS Service Support funding, which is allocated separately to NHS organisations.

Please advise CSO of any changes in specification or circumstances affecting the Fellowship and use the CSO reference in all correspondence.