Q6

Chief Medical Officer Directorate
Chief Scientist Office

T: [redacted]
E: [redacted]@gov.scot

The Scottish Government

[redacted]
College of Medical, Veterinary and Life Sciences
University of Glasgow
University Avenue
Glasgow G12 8QQ

22nd January 2016

Our ref: PME

Dear [redacted]

PRECISION MEDICINE ECOSYSTEM AGREEMENT

On behalf of Scottish Ministers, I am pleased to offer **the University of Glasgow** the grant specified in this Agreement at Annex A for the Programme described in the Delivering a Globally Competitive Precision Medicine Ecosystem for Scotland proposal (appended). The grant is offered subject to the terms and conditions set out in Annex B to this Agreement which are incorporated herein for the sake of brevity and subject to the Scottish Parliament making the necessary funds available to the Scottish Government. It is important that you continue to consult this document for the duration of the grant. Any potential changes in the substance of the programme **must** be discussed with the appropriate CSO Senior Research Manager.

Please read the following information carefully and use the above reference number in all future correspondence with the office.

Areas Requiring Attention

The following areas require particular attention.

Start date of the programme
CSO reserves the right to withdraw its award of grant if the Programme does not commence within 6 months of the date of this Agreement. If there is any risk that the project will not begin within this timescale you must contact the appropriate CSO Senior Research Manager to explain the reason for the delay. Only in exceptional circumstances will an extension to this timetable be approved.

Governance
CSO will arrange independent peer review to be undertaken for the research components of the grant, and any funding set out in this offer with respect to these components are subject to a satisfactory peer review.

Clinical Trial Authorisation/EudraCT Number
A Clinical Trial Authorisation (CTA) is required for any trial falling within the scope of the Medicines for Human Use (Clinical Trial) Regulations 2004. Confirmation of trial authorisation must be provided to CSO along with the Clinical Trial EudraCT Number before a trial commences.

Intellectual Property Rights
Particular attention is drawn to CSO's Standard Conditions of Grant relating to Intellectual Property and Commercial Exploitation.

Publications and Communications arising from the Programme
All publications and communications arising from the Programme are subject to CSO Standard Conditions of Grant and must acknowledge the support of the CSO. The grantholder and/or Chief Investigator and/or co-Investigators must inform the CSO of any intended publication or significant public presentation of any work containing results, information or technical knowledge connected with the Programme. 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. In addition 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.

Publicity
CSO may wish to publicise the work of the Initiative and may place a summary about the Initiative on its website.

Statements and Audit
Particular attention is drawn to CSO's Conditions of Grant relating to the requirements in relation to Statements and Audit (Finance Appendix A).

Actions for the applicants to address
The following issues are identified below that the applicants should address in a workplan submitted after 3 months and update as appropriate in subsequent progress reports:

- a detailed narrative of **PME** as a unified programme;
- a report on the development of the **Service Broker Model, Platform Services and Governance and Federated Analysis** deliverables of the core informatics component of the PME;
- a plan for sustaining the Precision Medicine Ecosystem beyond the period of funding provided by the CSO/Scottish Government;
- an progress report on the two exemplar projects; **PRECISION- Panc and Future MS**

CSO will review the financial expenditure in relation to the development of this programme after 3 months and reserves the right to modify subsequent financial profiling in light of this review.

Action Required

As the administrating organisation you are asked to take the following action and to liaise with the Sponsor(s) and Principal and Co-Applicants for this Programme as appropriate.

- Sign and date both copies of this Agreement and return the original to CSO within **28 days of the date of the Agreement;**

- A Start Certificate (Annex C) must be completed by your Finance Office and returned to CSO as soon as possible.

- When CSO has received the signed Agreement and Start Certificate and the other documentation required including (where appropriate), confirmation of ethical approval(s), trial authorisation and the EudraCT number, it will issue a payment schedule to your Finance Office.

A Checklist is attached at Annex D for your information. If you would like clarification of any of the above points please contact me.

Yours sincerely

[redacted]

CC [redacted] (University of Glasgow)
[redacted] (University of Edinburgh)
[redacted]

AGREEMENT

Between

The Scottish Ministers acting through the Chief Scientist Office of the Scottish Government Health and Social Care Directorates (referred to hereafter as "CSO")

and

University of Glasgow, known hereafter as "the Grantholder"

together referred to as "the Parties"

WHEREAS the Purpose of the Grant is to support the Grantholder in hosting, supporting and carrying out the research activities as specified in the application for funding (titled 'The Scottish Genomes Partnership' and appended).

On behalf of University of Glasgow, I accept the offer of grant specified in this Agreement with Scottish Ministers acting through the Chief Scientist Office 22nd January 2016 and the terms and conditions contained herein.

SIGNED on behalf of the Parties:

For the **Scottish Ministers**

By..... ..... In the presence of

Name [redacted] Name [redacted]

Position held on behalf of CSO: Head of CSO

Date 25/1/2016

For the **Grantholder**:

By..... ..... in the presence of .....

Name Name [redacted]

Professor [redacted] .....

Position held on behalf of the Grantholder

[redacted] of College of Medical, Veterinary and Life Sciences.....

Date 25/1/16

It is agreed that:-

1 The Agreement

1.1 CSO will provide a grant to support these activities.

1.2 This Agreement shall extend from January 2016 to March 2017 or until varied or terminated in accordance with section 17 of the Standard Conditions.

1.3 This Agreement and any agreed variation thereto or other document named therein constitutes the entire agreement between the Parties relating to the subject matter of the Agreement and supersedes all prior negotiations, representations or understandings which relate to the Programme.

2 Authorisation

2.1 The following person is authorised to act as the Scottish Ministers' representative on all matters relating to this Agreement: The Scottish Ministers may authorise any other person or persons to act as their representative in substitution for or in addition to the said person.

[redacted]

3 Correspondence

3.1 All correspondence to the Scottish Ministers/CSO shall quote the Agreement reference and be sent to the following address:

Chief Scientist Office
Chief Medical Officer Directorate
Scottish Government
Room GR
St Andrew's House
Edinburgh
EH1 3DG

3.2 All correspondence to the Grantholder shall be appropriately referenced and sent to the following address:

[redacted] College of Medical, Veterinary and Life Sciences
University of Glasgow
Wolfson Medical Building
University Avenue
Glasgow
G12 8QQ

4 Grantholder's Representative

The following person is authorised to act as the Grantholder's representative on all matters relating to this Agreement: the Grantholder may authorise any other person or persons to act as their representative in substitution for or in addition to the said person.

[redacted] College of Medical, Veterinary and Life Sciences.-

ANNEX A

Chief Scientist Office

Specification of the Precision Medicine Ecosystem for Scotland Grant

1. **Grant reference**

   PME

2. **Project Title**

The Precision Medicine Ecosystem

3. **Purpose of Research**

As outlined in application appended and the supporting documents also appended.

4. **Lead Organisation**

University of Glasgow

5. **Investigators**

Principle Investigators: [redacted] and [redacted]

Co-Investigators: [redacted], [redacted]

6. **Monitoring and Progress/Final Reports**

A detailed workplan must be provided at 3 months from the start date of the Programme and should:

- describe the progress made towards the meeting the stated aims and objectives of the Precision Medicine Ecosystem. Please structure your report to specifically address the aims and objectives as stated in the proposal and also the supplementary work plan for development of solutions for data federation;
- address the actions for the applicants to address identified in page two of the award letter;
- provide details of all the collaborative research activities, publications, presentations and grant applications and awards arising from the PME initiative.
- problems/difficulties in meeting the aims and any other matters which may affect the outcome of the Programme;
- proposed changes in the objectives/plan that should be discussed with CSO in advance of action;
- staff recruitment;
- finance report including the expenditure to date.

Site visits may be organised during the course of the Programme.

A Final Report must be provided at the end of the project. The content and format of the final report should be agreed well in advance with the CSO Senior Research Manager.

7. Funding

£4million funding has been allocated to the Programme by the Scottish Government/CSO to cover the costs identified in the application (appended) and copied from the application below.

	1Q 2016	2Q 2016	3Q 2016	4Q 2016	1Q 2017	Total to end Q1 2017
Service Broker Model						
Staff: Network Co-ordinator						179
Staff PM/Contracts Mgr						179
Staff: BD/Sales						122
Staff: QA Mgr						89
Consulting: Design & scope of SBM opportunities						117
Systems: Implement Service Provider Mgmt System						100
Systems: Operate Service Provider Mgmt System						20
Legals: Secure agreements on use						10
Services: Develop engagement model with Service Providers						60
Systems: Implement Data Asset Catalogue						50
Systems: Operate Data Asset Catalogue						10
Commercial: Develop GxP compliance pack						50
Website enhancements/online marketing						34
TOTAL	287	241	237	237	261	1264
Platform Services						
Systems: Implement Clinical Trial Management System						150.0
Systems: Implement Multiuser LIMS System						150.0
Systems: Implement PaaS for Annotation						160.0
Systems: Implement Genomic Repository						80.0
Systems: Implement Metadata Services						80.0
Systems: Operate Clinical Trial Management System						20.00
Systems: Operate Multiuser LIMS System						20.00
Systems: Operate PaaS for Annotation						150.0
Systems: Operate Genomic Repository						20.00
Systems: Operate Metadata Services						20.0
TOTAL	234	283	153	129	54	850
Federated Analysis						
Systems: Implement federated analysis capability						400
Systems: Operate federated analysis capability						150
Systems: Define engagement model for federation						100
TOTAL	0	150	200	150	150	650
SUMMARY CORE INFORMATICS PROGRAMME	521	674	589	517	465	2764

PRECISION-Panc						
Kick Start Project						100
Build and Maintain Clinical Data Repository						81
Genetic Sequencing						174
Develop and Implement Patient Registration and Matching tools						97
Critical Systems Support						105
Business Development Engagement with Industry (jointly with FMS)						84
Set up/obtain/maintain ISO certification of sequencing lab - Jointly with FMS						75
TOTAL	122	139	263	76	93	716
Future MS						
Ethics and Regulatory Approval						5
Part-funded Clinical Fellow at Glasgow MS Clinic						55
Collate and store DNA						6
Extraction and Sequencing						295
Additional Data Capacity						16
Bioinformatics Analysis						60
Business Development Engagement with Industry (jointly with PP)						43
Set up/obtain/maintain ISO certification of sequencing lab - Jointly with PP						20
TOTAL	356	1	0	33	134	520
SUMMARY EXEMPLAR PROGRAMME	478	140	292	99	227	1236
SUMMARY TOTAL BUDGET	1000	812	880	616	692	4000

The funding from the Scottish Government/CSO for the Programme that is the subject of this Agreement is set out below:

Financial Year	**2015-16**	**2016-17**
Amount	**£1,000,000**	**£3,000,000**

ANNEX B

CHIEF SCIENTIST OFFICE STANDARD CONDITIONS OF GRANT

1. Definitions of Terms
2. General
3. Staff
4. Equipment
5. Finance
6. Limitation of Liability
7. Data Protection
8. Ethics
9. Health and Safety
10. Research and Financial Misconduct
11. Monitoring and Evaluation
12. Publication and Acknowledgement of Support
13. Public Engagement in Science
14. Intellectual Property and Commercial Exploitation
15. Preserving and Sharing Research Data
16. Continuing Subsistence of Conditions
17. Variation of Conditions or Specification

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 **University of Glasgow**, dated **22nd January 2016**

1. Definitions of Terms

In these conditions:

a. **application** means the application submitted to CSO titled 'The Scottish Genomes Partnership' completed by the applicants in respect of the research Programme, 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.

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 grant;

d. **CSO** means the Chief Scientist Office of the Scottish Government Health and Social Care Directorates, acting on behalf of the Scottish Ministers;

e. **grant** or **research grant** means the grant offered to the grantholder by CSO as specified in the Agreement, 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 the Chief Investigator is based;

g. **Programme** or **research Programme** means the research programme to be undertaken by the applicant(s) the objectives of which are set out in the specification attached to the Agreement and in accordance with these conditions;

h. **agreement** 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;

i. **specification** means the summary of the details of the grant award issued with the offer letter. This includes: reference number, title, purpose, 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 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. 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 programme 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 programme 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 programme and of any events occurring during the programme 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 programme 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 programme within these limits. Failure to do so may result in termination of the programme and the demand for partial or full repayment of funds.

2.10 If the programme 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 programme 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 management committee is established to oversee the programme. 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, research 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. The grantholder shall be responsible for meeting the costs of sickness and maternity absence.

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 24 months beyond the end of the grant period.

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, 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 programme, 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 health research in Scotland, 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 for the sake of brevity.

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. Ethics

8.1 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.

8.2 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.

9. Health and Safety

The grantholder is responsible for ensuring that a safe working environment is provided for all individuals associated with the research. 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.

10. Research and Financial Misconduct

10.1 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.

10.2 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 programme's suspension or termination. Reimbursement of inappropriate claims will be sought.

11. Monitoring and Evaluation

11.1 An officer of CSO, or a group appointed on its behalf, must, when reasonable notice has been given, have access to the programme 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.

11.2 The Chief Investigator is responsible for providing such progress reports as may be required by CSO (see letter of award). Such reports must conform to guidelines which are issued 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.

11.3 The Chief Investigator (or an individual nominated by) is obliged to upload recruitment data on a monthly basis to the UKCRN Portfolio database (and agreed successor to the database) through the mechanisms provided for the purpose.

11.4 The Chief Investigator is required to submit accurate and updated information on the outputs from the project through the e-VAL system, which is now accessed through the ResearchFish website - https://www.researchfish.com/.

11.5 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 by CSO.

11.6 Funding of further grant applications from the Chief Investigator will not be considered until the actions described in 11.1 to 11. 5 have been completed to the satisfaction of CSO.

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

12. Publication and Acknowledgement of Support

12.1 CSO attaches great importance to the publication and dissemination of the results of research undertaken with its 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.

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

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

12.4 The grantholder and/or Chief Investigator and/or co-Investigators must inform the CSO of any intended publication or significant public presentation 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 and any press releases should be sent to CSO at least 5 working days in advance of intended date of release.

12.5 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.

12.6 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.

12.7 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.

13. 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.

14. Intellectual Property and Commercial Exploitation

14.1 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.

14.2 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.

14.3 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.

14.4 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.

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

14.6 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.

14.7 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 grant.

15. Preserving and Sharing Research Data

15.1 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.

15.2 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.

15.3 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.

16. Continuing Subsistence of Conditions

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

17. 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 programme;
- 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.

Appendix A

FINANCE

1. General

1.1 The Grant Agreement (that includes acceptance of the grant conditions) with the Scottish Ministers acting through the Chief Scientist Office (CSO) of the Scottish Government must be signed by the grantholder and returned to CSO Programmes are expected to start (unless there are exceptional circumstances) within 6 months of the date of the grant offer letter.

1.2 When a Programme 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.

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

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 is required 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 programme will be withheld until both the final statement of expenditure **(Form 8)** and a satisfactory final report are received. Where final expenditure on the programme is less than the grant paid, CSO will recover the excess amount of grant paid. It must be noted that CSO will not provide additional funding in cases where the final expenditure is more than the grant award.

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 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.

Annex C

Chief Scientist Office Form 7

Start certificate for research grant	CSO reference number: SGP

Please complete this form in Verdana 10 point font size

1. Project title:

The Scottish Genomes Partnership

2. Chief investigator:

3. Grantholder:

4. Grantholder reference:

5. Sponsor(s):

6. Bank details (for payments):

Full address	
Sort code	Account number

To be completed by a responsible officer of the Grantholder:

I am writing to confirm, that in accordance with the starting procedures for profiled payments, this project commenced on *(the start date should always be the first of a month)*:

Signature
Name *(block capitals)*
Telephone number
Position held
Date

Finance contact	Name:
	Telephone number:

For CSO use **Computer record updated on**
Signature

Annex D

CHECK LIST

1	Signed Letter of Award	To be sent to CSO within 28 days of the date of the Award Letter.	
2	Quarterly profile	To be sent to CSO before start date	
3	Form 7 (Start Certificate)	To be sent to CSO when programme commences.	
4	Confirmation of ethical approval (if appropriate)	To be sent to CSO before start date.	
5	Confirmation of trial authorisation and EudraCT Number (if appropriate)	To be sent to CSO before start date.	
6	When documents from 1 to 5 above have been received, CSO will issue a Payment Schedule to your Finance Office, copied to the Chief Investigator.		
7	Progress Reports along with a Finance Statement will be required to be submitted to the CSO Research Manager as set out in the letter of award.		
8	A Final Report is due on the last day of the programme along with a Financial Statement (Form 8)		

NB - PLEASE ADVISE CSO OF ANY CHANGES IN SPECIFICATION OR CIRCUMSTANCES AFFECTING THE PROGRAMME AND USE THE CSO REFERENCE IN ALL CORRESPONDENCE.