

GENERATION SCOTLAND COLLABORATION AGREEMENT

Agreement between:

- (1) **THE UNIVERSITY OF DUNDEE** Perth Road, Dundee, Scotland, DD1 4HN ("Dundee");
- (2) **THE UNIVERSITY COURT OF THE UNIVERSITY OF EDINBURGH** incorporated under the Universities (Scotland) Acts and having its principal office at Old College, South Bridge, Edinburgh EH8 9YL ("Edinburgh");
- (3) **THE UNIVERSITY COURT OF THE UNIVERSITY OF GLASGOW**, University Avenue, Glasgow G12 8QQ ("Glasgow");
- (4) **THE COMMON SERVICES AGENCY ACTING THROUGH ITS DIVISION NHS NATIONAL SERVICES SCOTLAND INFORMATION SERVICES**, constituted pursuant to the National Health Service (Scotland) Act 1978 and having its headquarters at 1 South Gyle Crescent, Gyle Square, Edinburgh, Scotland, EH12 9EB, ("ISD" which expression shall include its statutory successors and assignees);
- (5) **THE UNIVERSITY COURT OF THE UNIVERSITY OF ABERDEEN**, University Office, King's College, Regent Walk, Aberdeen, AB24 3FX ("Aberdeen");
- (6) **GRAMPIAN HEALTH BOARD**, constituted pursuant to the National Health Service (Scotland) Act 1978 and having its headquarters at Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE ("NHS Grampian" which expression shall include its statutory successors and assignees);
- (7) **LOTHIAN HEALTH BOARD**, constituted pursuant to the National Health Service (Scotland) Act 1978 and having its headquarters at Deaconess House, 148 The Pleasance, Edinburgh, EH8 9RS ("NHS Lothian" which expression shall include its statutory successors and assignees);
- (8) **GREATER GLASGOW HEALTH BOARD**, constituted pursuant to the National Health Service (Scotland) Act 1978 (as amended) and having its principal office at Dalian House, PO Box 15329, 350 St Vincent Street, Glasgow, G3 8YZ ("NHS Greater Glasgow and Clyde" which expression shall include its statutory successors and assignees); and
- (9) **TAYSIDE HEALTH BOARD**, constituted pursuant to the National Health Service (Scotland) Act 1978 and having its headquarters at King's Cross Hospital, Clepington Road, Dundee, DD3 8EA ("NHS Tayside" which expression shall include its statutory successors and assignees)

(hereinafter together referred to as "the Parties" and each of them being a "Party"). ISD, NHS Grampian, NHS Lothian, NHS Greater Glasgow and Clyde and NHS Tayside being individually and collectively known as "NHS Parties".

WHEREAS, certain of the Parties have entered into a Funding Agreement for the Project entitled "Genetics and Healthcare Initiative" all the Parties to this Agreement now wish to enter into a Collaboration Agreement (the "Agreement") to fulfil the terms of the Funding

Agreement and cover their relationship and define their rights and obligations in relation to the management of the Project.

IT IS HEREBY AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 The words and phrases below shall have the following meanings unless the context otherwise requires:

1998 Act	means the Data Protection Act 1998;
Background Information	means Information (other than the Project Data or NHS Data) which at the Commencement Date is in, or during the continuance of the Project, and other than as a result of the Project, comes into, the ownership or control of a Party, and which such Party is free to disclose;
Background Rights	means Intellectual Property Rights arising out of, or existing in, Background Information (other than Project Rights);
Chair	means the person appointed to chair the Generation Scotland Scientific Committee as detailed in Schedule Part 2;
Commencement Date	means 1 June 2005, notwithstanding the date or dates hereof;
Confidential Information	means: <ul style="list-style-type: none">(i) all information relating to the identity, condition or medical history of any Participant or information which otherwise constitutes sensitive personal data, and NHS Data; and(ii) information, the disclosure of which would, or would be likely to, prejudice substantially the commercial interests of any Party, including trade secrets, know-how and other Intellectual Property Rights;
Data Controller	has the meaning given to it in the 1998 Act;
Derived Data	means the collective combination of Project Data and NHS Data;
Funding Agreement	means the agreement entered into by the Chief Scientist Office, NHS National Services Scotland Information Services (a division of The Common Services Agency) and the Universities of Aberdeen,

Dundee, Edinburgh and Glasgow dated 22 December 2004, attached as Schedule Part 1;

Future Directions Group	means a sub-group of the Generation Scotland Scientific Committee responsible for the identification of research opportunities, sources of funding and commercialisation opportunities as detailed in Schedule Part 2;
Future Project	means any programme of work relating to the Project utilising Derived Data, Project Data, NHS Data and or Samples, or adding to Derived Data and or Project Data, identified by the Parties and approved by the Generation Scotland Scientific Committee and for which one Party or a collaboration of more than one Party may seek or be offered external funding;
Generation Scotland	means the informal collaboration between the Scottish University Medical Schools, Biomedical Research Institutes, the NHS in Scotland, the Chief Scientist Office and the Scottish Funding Council with the aim of creating more effective treatments based on gene knowledge;
Generation Scotland Advisory Board	means the Advisory Board as detailed in Schedule Part 4 to be appointed by the Chief Scientist Office on behalf of the Scottish Executive to oversee the activities of the Generation Scotland Scientific Committee as detailed in Schedule Part 3;
Generation Scotland Scientific Committee	means the Committee responsible for managing and administering the Project, and any delegated sub-groups, as detailed in Schedule Part 3;
Genetics and Healthcare Initiative Proposal	means the successful application to the Chief Scientist Office and Scottish Executive Health Department attached hereto as Schedule Part 1;
Income	means all cash sums or other monetary consideration or non-financial proceeds in whatever form actually received in respect of the exploitation of any Project Results including without limitation licence fees, sale income, signing and option fees, milestone payments, equipment, discounts, stock and stock options;
Information	means (without limitation) drawings, specifications, photographs, models, processes, inventions, procedures, instructions, software, reports, papers, correspondence and any other technical or commercial information, data and documents of any kind, and including oral information if confirmed in writing within 30 days after the disclosure thereof;

Intellectual Property Rights	means processes and procedures, patents, design rights, (both registered and unregistered), including semiconductor topography rights, trade secrets, know-how, copyrights, trade marks, database rights and any other form of intellectual property protection either arising automatically at law, or arising further to any statutory procedure and including any application for registration of the same;
Joint Project Rights	has the meaning given to that term in Clause 7.6;
Net Revenue	means all Income less deductions for any properly incurred costs incurred directly in connection with the development and commercial exploitation of the relevant Project Rights including, but not limited to revenue sharing obligations owed to third party funders, legal and other professional adviser costs, insurance, carriage and freight and Value Added Tax or other sales tax, import duties or similar applicable governmental levies or export insurance costs, patent costs including patent filing, prosecution, maintenance and renewal fees;
NHS Data	means data in relation to a Participant in respect of which an NHS Party is the Data Controller and in respect of which data the Participant in question has given his/her informed and valid consent to its use in connection with the Project and/or a Future Project, and which is provided by that NHS Party in response to a request therefor from a Party in connection with the Project or relevant Future Project;
Participant	means a healthy volunteer or NHS patient who has consented to provide, and has provided, Samples and/or data to be used for the Project and any subsequent Future Projects;
Personal Data	has the meaning given to it in the 1998 Act;
Processed	has the meaning given to it in the 1998 Act;
Project	means the work programme outlined in the Genetics and Healthcare Initiative Proposal subsequently funded by the Chief Scientist Office, Scottish Executive Health Department, attached hereto as Schedule Part 1;
Project Data	means any data in relation to Participants that is collected pursuant to and in the course of the Project and Future Projects, but always excluding NHS Data;
Project Results	means results arising directly from the use of Derived Data, Information, Project Data and Samples, including but not limited to genetic analysis capability, informatics

tools, educational tools, novel drug targets and novel diagnostic methods, arising as a direct result of the Project or Future Projects;

Project Rights

means Intellectual Property Rights (other than Background Rights) in any Project Results; and

Samples

means human samples of body tissue or bodily secretions, or excretions of fluids, all taken from a Participant, and/or any material directly derived from or incorporating the Sample created and/or collected during the course of the Project or a Future Project.

1.2 In this Agreement, unless otherwise expressly provided or unless the context otherwise requires:-

1.2.1 References to the singular include the plural and vice versa.

1.2.2 References to words denoting any gender shall include all genders.

1.2.3 References to persons include companies, partnerships, government departments and agencies and all other forms of body corporate or unincorporate.

1.2.4 References to Clauses and to the Schedule are to Clauses of, and the Schedule to, this Agreement.

1.2.5 References to laws and statutory provisions shall include reference to any subordinate legislation made pursuant thereto and shall be construed as referring to those laws, provisions and subordinate legislation as respectively amended or re-enacted from time to time.

1.2.6 The headings of this Agreement are for ease of reference only and are not part of this Agreement for the purposes of construction.

1.2.7 Any undertaking by a Party not to do an act or thing shall be deemed to include an undertaking not to permit or suffer such act or thing to be done by another person.

1.2.8 References to the Parties include their respective successors in title, permitted assigns and legal personal representatives.

1.3 The Schedule and Recitals form part of this Agreement and shall have effect as if set out in full in the body of this Agreement and accordingly any reference to this Agreement includes the Schedule and Recitals.

2. COLLABORATION GOVERNANCE

2.1 The Parties acknowledge that the Generation Scotland Advisory Board will oversee the activities of the Generation Scotland Scientific Committee in accordance with Schedule Part 2. The Parties agree that during the term of this Agreement they will

collectively procure and ensure that the directions of the Generation Scotland Scientific Committee are adhered to.

- 2.2 The Parties agree and will collectively procure that the Generation Scotland Scientific Committee will govern the Project in accordance with Schedule Part 3.
- 2.3. The Generation Scotland Scientific Committee will be supported by a number of sub-groups which are identified in Schedule Part 2. A schematic representation of the governance and project management structure is presented in Schedule Part 2.
- 2.4 The Generation Scotland Scientific Committee will establish a Future Directions Group consisting of at least one representative of each Party. It is recommended that the Future Directions Group consists of researchers and representatives of the Party's technology transfer offices.

3. DURATION

This Agreement shall come into force as of the Commencement Date and shall thereafter continue in full force and effect unless terminated earlier in accordance with the terms of this Agreement.

4. SCOPE OF OBLIGATIONS

- 4.1 The performance of the Project shall be shared between the Parties according to the tasks allocated to them in the Funding Agreement and accepted by them, or such tasks as are mutually agreed between Parties and the Generation Scotland Scientific Committee.
- 4.2 Each Party undertakes to:
 - 4.2.1 use all reasonable endeavours to perform in a timely manner those tasks accepted by it and to promptly notify the other Parties of any delay or anticipated delay in such performance;
 - 4.2.2 carry out the Project, any Future Projects, and its obligations under this Agreement with reasonable care and skill and using appropriately qualified personnel;
 - 4.2.3 ensure the collection and subsequent use, storage, transportation and destruction of Samples and all Personal Data (including NHS Data) is carried out to the appropriate national standards and in accordance with all relevant legal requirements and with appropriate ethical approval and patient consent;
 - 4.2.4 make available to the other Parties without unreasonable delay, the rights and information defined herein and in the Funding Agreement and to promptly notify the other Parties of any delay or anticipated delay in such availability, or of any restriction in relation thereto;
 - 4.2.5 promptly prepare and present such reports relative to the performance of the tasks hereunder in order to enable the Parties to review progress.

5. USE OF DERIVED DATA AND PROJECT DATA BY THE PARTIES

- 5.1 It is the intention of the Parties to use the Samples, Derived Data and Project Data generated during the Project to identify Future Projects and to seek external funding for such Future Projects where appropriate.
- 5.2 Future Project proposals may be presented to the Generation Scotland Scientific Committee only by those investigators listed in Schedule Part 5. This list of investigators may be amended by approval of the Generation Scotland Scientific Committee.
- 5.3 Future Projects will be costed in accordance with the terms and conditions of the relevant funding body. Where possible, full economic costing is to be applied according to the relevant lead Party's and any collaborating Parties' costing policy. Where relevant costings for Future Projects will include NHS costs, for example costs associated with access to NHS Data and prescribing data and the relevant NHS Party shall be entitled to be reimbursed in respect of the same.
- 5.4 In addition to the demands of clause 6.4, each of the Parties in conjunction with the Generation Scotland Scientific Committee will agree a costing policy ("Costing Policy") for the use of Derived Data and/or Project Data, including a fee for access to the Derived Data or Project Data (other than in the circumstances referred to in Clause 6.5), such fee to be included and used as a direct cost when costing Future Projects. The Parties agree that the Costing Policy shall be informed by the policies of the funding bodies and acknowledge that the level of payment of the access fee may vary across different funding bodies. Such access fee will be paid by the relevant lead Party, subject to payment of such fee by the funding body, and dispersed among the other Parties in accordance with the Costing Policy or as otherwise agreed by the Generation Scotland Scientific Committee or following termination of this Agreement, as agreed among the Parties.
- 5.5 Unless otherwise agreed between the Parties, the fee in respect of the lead Party's access to and use of the Derived Data and/or Project Data will be paid by the lead Party into a designated and nominated Generation Scotland account where it will be held for and on behalf of the Parties collectively until the lead Party is directed to distribute or remit it to such destination as the Generation Scotland Scientific Committee shall specify or, following termination of this Agreement, until the Parties have agreed upon the division and distribution of such monies.

6. OWNERSHIP AND ACCESS TO DERIVED DATA, NHS DATA, PROJECT DATA AND SAMPLES

- 6.1 The Parties agree that the Project Data and all rights therein will be owned by all the Parties jointly and that the Samples will be controlled by the relevant custodians. Any database rights in the Derived Data will be owned by all the Parties jointly. Copyright and other Intellectual Property Rights in the constituent elements of the Derived Data shall be owned as specified in this Clause 6.1 and in Clause 6.2.
- 6.2 The NHS Data and all rights therein remains the property of the NHS Party providing the same. During the term of this Agreement, and subject to compliance by all Parties with the conditions specified in Clause 16, each NHS Party agrees to make available to another Party requesting the same, any NHS Data requested by that

other Party in respect of a Participant in respect of which it is the Data Controller, under a non-exclusive, royalty free licence for the duration of the Project or Future Projects (as the case may be) and solely for the purpose of the Project and Future Projects. Such licence only applies to NHS Data actually provided to a Party during the term of this Agreement and in respect of which the Party requesting access to such NHS Data can demonstrate to the satisfaction of the relevant NHS Party that the relevant Participant has consented to such disclosure. Nothing herein will oblige any NHS Party to provide NHS Data other than during the term of this Agreement, and other than for use by another Party in direct connection with the Project or a Future Project.

- 6.3 The Parties agree that no Derived Data, Project Data or Samples will be provided by any Party to third parties without the prior written approval of the Generation Scotland Scientific Committee and (in the case of Derived Data) the consent of the appropriate NHS Party which is the Data Controller in respect of the NHS Data comprised within the Derived Data and (in the case of Samples) the Party which is custodian of such Samples (if applicable).
- 6.4 Within six (6) months of execution of this Agreement, the Generation Scotland Scientific Committee will agree standard operating procedures to manage the Parties' use of the Derived Data and Project Data and Samples. The Generation Scotland Scientific Committee will retain full supervision and control of all access to and uses of Derived Data and Project Data and Samples by the Parties and by any third party collaborators identified for the Project or Future Projects.
- 6.5 In addition to the Costing Policy referred to at Clause 5.4 the Generation Scotland Scientific Committee will develop a policy and detailed terms of access to Derived Data and Project Data, addressing fairness and transparency of decision making, the handling of conflicts of interest and the prioritisation of use of Samples. Such policy will provide that all Parties shall be entitled to use Derived Data and Project Data, without charge, for research, training and education, and in connection with the health and medical care of NHS patients.
- 6.6 Each Party unconditionally and irrevocably undertakes to make available all items of Project Data and/or Derived Data in its possession or under its control promptly following any valid request for any such items received from another Party.
- 6.7 Any use of the Derived Data, Project Data or Samples for Future Projects must be approved by the Generation Scotland Scientific Committee and have approval by a Medical Research Ethics Committee to ensure such use is consistent with the Participants' consent, Generation Scotland's purpose and this Agreement.
- 6.8 The Parties will agree template material transfer agreements ("MTA") to govern the movement of Samples between Parties for use in the Project and for Future Projects.
- 6.9 It is the responsibility of the Party obtaining Project Data and/or Samples from a Participant to ensure adequate and appropriate consents from such Participant have been obtained including, where necessary, consent to access and use NHS Data in respect of such Participant in relation to the Project or a Future Project. In the event that the Party obtaining Project Data and/or Samples from a Participant fails to ensure that adequate and appropriate consents are obtained from such Participant, with the result that any of the other Parties suffers any loss, damage, claim or expense, the Party obtaining the Project Data and/or Samples in question shall

indemnify the other Parties who have suffered any such loss, damage, claim or expenses on demand in respect thereof.

- 6.10 Parties will be required to place both positive and negative findings (for example those failing to show some association) in the public domain, through publication in peer-reviewed literature whenever possible, in accordance with Clause 13. The Parties, through the Generation Scotland Scientific Committee, will explore strategies for disseminating negative findings (for example by establishing an accessible archive for them).

7 OWNERSHIP OF PROJECT RESULTS AND PROJECT RIGHTS

- 7.1 Background Information, Background Rights and NHS Data used in connection with the Project shall remain the property of the Party introducing the same. Nothing in this Agreement shall affect ownership of any Background Information, Background Rights and/or NHS Data.
- 7.2 Notwithstanding the terms of clause 7.1 above, each Party shall, where it is free to do so, grant to the other Parties a non-exclusive royalty free licence to use its Background Information and Background Rights to such extent as is reasonably required to enable the other Parties to carry out their respective parts of the Project.
- 7.3 If the use of Background Rights is required for a Future Project the terms for access to the Background Rights will be negotiated in good faith with the Party which owns the Background Rights.
- 7.4 Prior to the commencement of any Future Project, each of the participating Parties will complete a due diligence report on any access to and use of Background Rights required by it, as detailed in Schedule Part 6.
- 7.5 Project Results and Project Rights generated or conceived solely by a single Party shall be owned by that Party. Each Party shall inform all other Parties in writing of any Project Rights which come into existence as soon as reasonably practicable as and when such Project Rights are generated and subject to formal registration. Each Party shall complete a report on Project Rights as detailed in Schedule Part 7, for submission to meetings of the Future Directions Group.
- 7.6 Any Projects Results and Project Rights generated and/or conceived by two or more Parties (hereinafter "Joint Project Results" and "Joint Project Rights") shall be owned by such Parties jointly.
- 7.7 Identification, protection and management of Project Results and Project Rights will be the responsibility of each of the Parties owning the relevant Project Rights.
- 7.8 The costs of the preparation, filing, maintenance and protection of any patent(s) relating to the Project and any Future Projects shall be the responsibility of the Party (Parties) owning the relevant Project Rights. That Party (Parties) will provide regular updates on progress to the Future Directions Group.
- 7.9 The costs of the preparation, filing, maintenance and protection of the patent(s) relating to Joint Project Results and Joint Project Rights shall be shared equally between the joint owners.

- 7.10 Unless agreed otherwise, each Party shall undertake and continue at its expense the timely prosecution, maintenance and protection of all Project Rights which are solely owned by that Party. In the event that the owner of the said Project Rights is unable or unwilling to comply with its obligations under this Clause 7.10, the Future Directions Group shall consider how best to deal with such Project Rights and shall have the option to require an assignment of such Project Rights to another Party, subject to agreement by both Parties, to enable prosecution, maintenance and protection of such Project Rights by that other Party at its own cost. In the event that any Party wishes to exploit commercially any Project Rights assigned pursuant to this Clause 7.10 that Party shall pay to the assigning Party a royalty and/or other appropriate form of remuneration which is fair and reasonable taking into consideration the factors set out under Clause 7.11
- 7.11 In the event that any Party wishes to commercially exploit Project Rights owned by another Party or Parties it shall request a licence to do so from the owner(s) of the Project Rights. Where it is free to do so, but for the avoidance of doubt the owner of the Project Rights is under no obligation to do so, the owner of the Project Rights shall grant a licence to use such Project Rights for that purpose, subject to the agreement of appropriate terms in relation thereto, including a royalty and/or other appropriate form of remuneration which is fair and reasonable taking into consideration the respective financial and technical contributions of the Parties involved in the development of the Project Rights, the expenses incurred in securing intellectual property protection thereof, and the costs of its commercial exploitation and any use of Background Information and Background Rights.
- 7.12 Unless otherwise agreed between the Parties, each Party shall grant to each of the other Parties a non-exclusive royalty free licence to use its share in Project Results (other than Project Results arising out of Future Projects) and Project Rights (other than Project Rights arising out of Future Projects) to the extent reasonably required to enable each of the other Parties to carry out their respective parts of the Project. Each Party shall grant to each of the other Parties a non-exclusive royalty free licence to use its share in Project Results (other than Project Results arising out of Future Projects) and Project Rights (other than Project Rights arising out of Future Projects) for internal, non-commercial research, teaching and/or clinical applications, provided that the Parties (acting reasonably) will collectively consider and, if considered appropriate, agree, any amendment to any such internal, non-commercial research, teaching and/or clinical applications licence that may be required in light of a commercial licensing opportunity which arises in respect of any particular Project Rights/Project Results. The Parties agree that a licence to Project Results and Projects Rights arising from Future Projects for use in Future Projects and for internal, non-commercial research, teaching and/or clinical applications (as the case may be) shall be negotiated by the relevant Parties on a case by case basis.

8. COMMERCIAL EXPLOITATION OF PROJECT RESULTS AND PROJECT RIGHTS

- 8.1 The Parties recognise that the Project and subsequent Future Projects will generate information including Derived Data, Project Data, and Samples, and may generate Project Results including but not limited to genetic analysis capability, informatics tools, educational tools, novel drug targets and novel diagnostic methods.
- 8.2 In terms of the Participant consent form attached as Schedule Part 8, consent will be given by Participants for the use of their data (including NHS Data), Samples and materials prepared from it for genetic studies, and for the making of patent applications relating to the results of those studies, and for other uses and

commercial exploitation of such Samples and materials prepared from it, and data (including NHS Data), without any payment to the Participant or their heirs and without any individual acknowledgement of individual patient contribution.

- 8.3 Each Party shall be responsible for the commercial exploitation of Project Results and Project Rights generated or conceived solely by that Party. Regular updates on such commercial exploitation shall be provided to the Future Directions Group. In the case of Joint Project Results and Joint Project Rights the relevant Parties will agree who shall take the lead role in the commercial exploitation of Joint Project Results and Joint Project Rights and shall inform the other Parties of such decision via the Future Directions Group.
- 8.4 If any Party requires access to the Background Information and/or Background Rights of another Party to facilitate the commercial exploitation of Project Rights that other Party shall grant their consent to such use (on a non-exclusive basis), but only to the extent that any existing obligations they may have permit and subject to such terms and conditions, including financial terms, as are reasonable in the circumstances. If any Party requires to access and/or use the Background Rights of another Party to allow it to enjoy the rights permitted to it under Clause 7.12, a licence to use such Background Rights shall be sought from the owner of the relevant Background Rights on terms to be agreed. The owner of the relevant Background Rights shall be under no obligation to grant such a licence.

9. INCOME SHARING – PROJECT RIGHTS

- 9.1 Following deductions the resulting Net Revenue derived from the commercial exploitation of Project Rights shall be divided between the parties as follows: 25% to the University Parties, 25% to the NHS Parties, 25% to the Party(ies) which own the commercialised Project Rights, 25% to support the Project. The accounting and revenue transfer arrangements in respect of such Net Revenue shall be agreed and during the term of this Agreement applied by the Generation Scotland Scientific Committee.
- 9.2 Each Party carrying out commercial exploitation of their Project Rights will at all times keep true and accurate records and books of accounts containing all data necessary for the determination of Net Revenue payable under Clause 9.1.
- 9.3 Within six (6) months of execution of this Agreement, the Generation Scotland Scientific Committee will seek to agree a policy to allocate funds accrued to the Project under Clause 9.1.
- 9.4 Following completion of each Party's respective obligations in respect of the Project the share allocated in terms of Clause 9.1 to "support the Project" shall be distributed as decided by the Generation Scotland Scientific Committee.
- 9.5 Following the termination of this Agreement the Parties shall continue to share Net Revenue in accordance with the above formula, provided that the share allocated to "support the Project" in terms of Clause 9.1 shall, unless already re-allocated by the Generation Scotland Scientific Committee, be re-allocated as agreed between the Parties or, failing agreement, shared equally among them.
- 9.6 The accounting and revenue transfer arrangements in respect of Net Revenue following termination of this Agreement shall be agreed among the Parties as a pre-condition to termination pursuant to Clause 15.3.

10. WITHDRAWALS

- 10.1 Any Party may withdraw from the Project with the unanimous consent of the other Parties, such party being known as a "Withdrawing Party". The consent of the other Parties may, if given, be given subject to certain conditions to be fulfilled and/or adhered to by the Withdrawing Party.
- 10.2 In the event that a Party wishes to be a Withdrawing Party, the Generation Scotland Scientific Committee will make all reasonable attempts to agree the reallocation of the obligations of the Withdrawing Party under this Agreement including those relating to the storage of Samples where appropriate, to one or more of the remaining Parties or to a third party acceptable to the remaining Parties provided that such third party agrees to be bound by the terms of this Agreement. If no such reallocation can be successfully achieved then the Party seeking to withdraw from the Agreement shall not be entitled to withdraw unless the remaining Parties unanimously agree otherwise.
- 10.3 The Withdrawing Party shall be entitled to recover its unavoidable costs incurred in connection with the Project, up to the time of notifying the Generation Scotland Scientific Committee of its intention to withdraw, provided that such costs can be reimbursed solely from funds disbursed under the Funding Agreement. The Withdrawing Party shall use reasonable endeavours to minimize said unavoidable costs and shall comply with all conditions imposed pursuant to this Clause 10 which shall include (without limitation):-
- 10.3.1 rights granted to the other Parties in respect of the Withdrawing Party's Background Information and Background Rights shall continue notwithstanding the Withdrawing Party's exit from this Agreement, subject always to the restrictions contained in this Agreement;
- 10.3.2 to the extent that exploitation of any other Party's Project Rights is dependent on the Withdrawing Party's Background Information and Background Rights, then the Withdrawing Party shall, subject to any existing third party obligations, and to the extent such licence rights have not already been granted, forthwith grant to the other Parties a license to such Background Information or Background Rights on fair and reasonable terms to be agreed;
- 10.3.3 unless otherwise agreed by the Parties the Withdrawing Party shall grant to the other Parties a non-exclusive, royalty-free license to use the Withdrawing Party's Project Rights for the purposes of carrying out the Project, any Future Projects and the purposes detailed in Clause 7.12, and all in accordance with the provisions of Clause 7.12;
- 10.3.4 all rights granted to the Withdrawing Party in respect of the Background Information and Background Rights and Project Rights of the other Parties and in respect of any NHS Data shall cease immediately other than in respect of the Withdrawing Party's interest in any Joint Project Rights;
- 10.3.5 the Withdrawing Party shall continue to be bound by any obligations of confidentiality contained in this Agreement for a period of five (5) years following its exit from this Agreement, or until such time as the information in question ceases to be confidential in nature;

- 10.3.6 the Withdrawing Party shall be liable for the direct costs (if any) which any Party can demonstrate resulted from its acceptance and performance of the Withdrawing Party's obligations pursuant to the re-allocation process referred to in sub-clause 10.2 and hereby agrees to indemnify such Party on demand in respect of the same.
- 10.4 A Withdrawing Party shall continue to be bound by the provisions of Clause 9.1 notwithstanding their withdrawal from the Agreement.

11. CONFIDENTIALITY

- 11.1 All Confidential Information shall remain the property of the Party disclosing the Confidential Information ("Disclosing Party"). In no event shall the Party to whom Confidential Information is disclosed ("Receiving Party") be deemed to have acquired any right, title or interest in or to the Confidential Information. Subject to Clauses 8 and 13 the Receiving Party shall maintain in strict confidence the Confidential Information and shall afford it at least the same level of care and protection as that applied to its own Confidential Information.
- 11.2 The Receiving Party shall not use the Confidential Information other than to carry out the Project, any Future Projects, and its obligations under this Agreement in any manner without the prior written consent of the Disclosing Party.
- 11.3 The provisions of this Clause 11 shall survive the expiration or termination of this Agreement for five (5) years or, in respect of NHS Data and details relating to any Participant, until such Confidential Information is no longer confidential.
- 11.4 This Clause 11 shall not apply to any Confidential Information: -
- (a) which, at the time of disclosure, has already been published or is otherwise in the public domain other than through breach of the terms of this Agreement;
 - (b) which, after disclosure to the Parties, is subsequently published or comes into the public domain by means other than an action or omission on the part of any of the Parties;
 - (c) which a Party can demonstrate was known to him or subsequently independently developed by him and not acquired as a result of membership of the Generation Scotland Scientific Committee, nor using, derived from, referring to or in any way relates to the Confidential Information;
 - (d) lawfully acquired from third parties who had a right to disclose it with no obligations of confidentiality to any of the Parties; or
 - (e) is required to be disclosed by applicable law or court order or by any Party's regulatory body, which is empowered by Statute or Statutory Instrument, but only to the extent of such disclosure and the receiving Party shall notify the disclosing Party promptly of any such request.
- 11.5 No term of this Agreement, whether express or implied (including this Clause 11.5), shall preclude any of the Parties from making public under the Freedom of Information (Scotland) Act 2002 and/or any codes applicable from time to time

relating to access to public authorities' information, details of all matters relating to this Agreement unless:

- (i) such information relates to the identity, condition or medical history of an NHS patient or is otherwise sensitive personal data;
- (ii) such details constitute a trade secret;
- (iii) the disclosure of such details would or would be likely to prejudice substantially the commercial interests of any person;
- (iv) such details fall with such other exemption as may be applicable as determined by the relevant Party in terms of the said Act

PROVIDED THAT the relevant Party of whom the request is made shall take all reasonable steps to provide the other Parties with notice of such intended disclosures prior to making such information public. All Parties will co-operate and work together to facilitate the compliance by each of them with their obligations under this Clause 11.5 and the said Act.

- 11.6 All Parties warrant and undertake that all necessary steps will be taken to maintain full compliance by all Parties with the 1998 Act, the Health Records Act 1990 and the Guidance entitled "Protecting and Using Patient Information – A Manual for Caldicott Guardians" (SEHD 1999 and HDL (2003)37 on "The Use of Personal Health Information") and with the spirit of the CASPE Health Records Service Guidelines, to ensure that Participants and others have their personal data properly managed and adequately protected.
- 11.7 The Party holding any information requested under the Freedom of Information (Scotland) Act 2002 or the 1998 Act will handle information or subject access requests. In the case of all Parties holding information, all and each will provide the data to third parties and to each other only in compliance with the 1998 Act and the aforementioned guidance, HDL and guidelines.

12. LIABILITIES

- 12.1 The Parties will exercise reasonable care to ensure the accuracy of the advice, information and drawings provided in connection with the Project but the Parties accept no liability, contractual or delictual to each other or any other person in respect of any claim or claims arising from the use by the Parties or by any third party of any such advice, information or drawings.
- 12.2 The Parties make no representation or warranty that advice information and drawings provided by its servants or agents is accurate, conform to contract or are free from defects, latent or patent; nor does it warrant that the use of any information provided in connection with the Project will provide the desired objective or not result in infringement of third party Intellectual Property Rights and the Parties do not accept any responsibility whatsoever for infringement of such Intellectual Property Rights. However, each Party represents and warrants that it will not knowingly use the property of a third party (other than another Party) in performing its obligations under this Agreement in any way that will infringe such a third party's Intellectual Property Rights nor will it provide any such third party property to any of the other Parties if the use of such third party property by such other Parties would result in the infringement

of a third party's Intellectual Property Rights or in some other enforceable claim being available to the third party in question.

- 12.3 Except as otherwise stated in Clause 12.2 it is agreed that a Party utilising any Information, Derived Data or Project Data and/or Samples is fully responsible and liable for any subsequent loss, costs, claims or demands arising from that use, unless such loss, costs, claims and demands arise out of the default or negligence on the part of another Party.

13 PUBLICATIONS AND PRESS RELEASES

- 13.1 Subject to Clause 13.6, each Party hereto shall be entitled to publish in academic or other journals, articles relating to the Project or to the results arising thereunder, but that are subject to the confidentiality provisions contained herein. Any such Party (the "Submitting Party") shall, at least thirty (30) days in advance of the proposed date of submission, submit the text of any such article via the Generation Scotland Scientific Committee (or approved sub-committee thereof) for consideration by the other Parties, who will have a period of thirty (30) days therefrom in which to provide written comment. If the Generation Scotland Scientific Committee believes that the publication contains any Confidential Information of a Party or Parties it shall so notify the Submitting Party not later than 30 days after receipt of the publication and the Submitting Party shall not publish such Confidential Information. The Submitting Party will identify any Project Results or Project Rights which may be patentable. The Submitting Party shall amend the text of any proposed publication to take into account any reasonably made claim that the text as drafted will materially prejudice the commercial interests of any Party, in a way which has not been anticipated hereunder.
- 13.2 If any Party believes that the publication contains any Project Rights which may be patentable, then such a Party shall so notify the Submitting Party within thirty (30) days of receipt of the publication and the Submitting Party shall delay submission for publication for up to an additional thirty (30) days in order that a patent application can be filed.
- 13.3 The Generation Scotland Scientific Committee will agree a fast track process to clear abstracts and poster presentations for publication within six (6) months of execution of this Agreement.
- 13.4 Exceptions: Articles which are written about the Project by a Submitting Party and which refer only to information already in the public domain shall be submitted to the Generation Scotland Scientific Committee (or approved sub-committee thereof) for approval and will acknowledge the Project and third party funders in an agreed manner. There will be no other delay to submission for publication.
- 13.5 Exceptions: Articles written by Submitting Parties in which the Project is the subject of the research, but which does not generate any Project Rights which may be patentable shall be submitted to the Generation Scotland Scientific Committee (or approved sub-committee thereof) for approval and will acknowledge the Project in an agreed manner. There will be no other delay to submission for publication.
- 13.6 Under no circumstances will any Party publish or disclose any information if such publication or disclosure would, or may be likely to, result in the relevant Data Controller(s) of any Personal Data being in breach of the 1998 Act. Any Party which does so shall indemnify the relevant Data Controller(s) in respect of any loss or claim

they suffer as a result of any breach of this Clause 13.6 or otherwise arising out of the disclosure.

14. ASSIGNATION

No Party shall, without the prior written consent of the other Parties, assign or otherwise transfer or sublicense, delegate or novate, partially or totally any of its rights and obligations under this Agreement.

15. TERMINATION

15.1 In addition to the remedies contained in Clause 10 (Withdrawals), in the event that any Party shall commit any breach of or default in any terms or conditions of this Agreement, the Generation Scotland Scientific Committee may decide by unanimous vote of the non-defaulting Parties to instruct the Chair to serve written notice of such breach or default on the defaulting Party ("Defaulting Party") and, in the event that such Defaulting Party fails to remedy such default or breach within sixty (60) days after receipt of such written notice, the Generation Scotland Scientific Committee may decide, by unanimous vote of the non-defaulting Parties, at their option and in addition to any other remedies which they may have at law, to terminate the Defaulting Party's involvement in the Agreement and the Project, and continue with the Agreement. Any removal of the Defaulting Party's involvement in this Agreement shall be effective as of the date of the receipt of such notice whereupon the provisions of Clause 10.3 and 10.4 shall apply to the Defaulting Party as if the Defaulting Party was a Withdrawing Party, excepting that a Defaulting Party will have no right to recover its unavoidable costs incurred in connection with the Project.

15.2 If any Party (a) materially breaches any provisions of this Agreement; or (b) passes a resolution for its winding-up; or if (c) a court of competent jurisdiction makes an order for that Party's winding-up or dissolution, or makes an administration order in relation to that Party; or if any Party (d) appoints a receiver over, or an encumbrancer takes possession of or sells an asset of, that Party; or (e) makes an arrangement or composition with its creditors generally; or (f) makes an application to a court of competent jurisdiction for protection from its creditors generally (which Party also being then known as a "Defaulting Party"); the remaining members of the Generation Scotland Scientific Committee shall meet to either suspend or terminate that Defaulting Party's involvement in the Generation Scotland Scientific Committee, this Agreement and the Project. Any suspension or termination of the Defaulting Party's involvement in this Agreement and the Project shall be effective as of the date of the receipt of such notice whereupon the provisions of Clause 10.3 and 10.4 shall apply to the Defaulting Party as if the Defaulting Party was a Withdrawing Party, excepting that a Defaulting Party will have no right to recover its unavoidable costs incurred in connection with the Project.

15.3 In the event that it is agreed at any time by a majority of the Parties (other than Defaulting Parties) that there is no longer valid reasons for continuing with the Project the Generation Scotland Scientific Committee may decide by simple majority vote to terminate this Agreement by sending notice of termination in writing to all the Parties to that effect. In case of, and as a pre-condition to, termination of the Agreement arising under this Clause 15.3 the Parties will agree *inter alia* (1) the conditions under which the Derived Data, Project Data and Samples are to be stored or destroyed as appropriate following termination of this Agreement; (2) the basis on which future use of Derived Data, Project Data and Samples will be governed following termination of

this Agreement; and (3) the allocation of Net Revenue from the commercialisation of Project Rights following termination of this Agreement.

16. DATA PROTECTION AND PARTICIPANT INFORMATION

- 16.1 All of the Parties recognise that each of them may have obligations under the 1998 Act in relation to Personal Data which is Processed in relation to the Project or a Future Project. In particular, it is recognised and agreed by all Parties that the NHS Parties are each Data Controllers in respect of the NHS Data which they each may make available pursuant to this Agreement.
- 16.2 The Parties recognise and agree that they may be joint Data Controllers in respect of the Derived Data.
- 16.3 All Parties agree to comply with the requirements on Data Controllers under the 1998 Act to the extent they are a Data Controller (including on a joint basis) in relation to any Personal Data Processed pursuant to this Agreement.
- 16.4 All Parties agree and accept that all Personal Data which is comprised within or constitutes Project Data and/or NHS Data or can be ascertained from the Derived Data is made available by the relevant Data Controller for use only in accordance with this Agreement.
- 16.5 Each of the Parties agrees, where it is provided with any Personal Data in respect of which it is not the Data Controller, to store and/or process any such Personal Data supplied to it and/or accessed by it for the purposes of or in connection with the Project and/or a Future Project only as specifically agreed in advance with the relevant Data Controller(s).
- 16.6 No Party receiving any Personal Data and which is not the Data Controller in respect of such Personal Data may transfer any such Personal Data out of the United Kingdom unless such transfer has been previously approved in writing by the Data Controller of such Personal Data.
- 16.7 Each of the Parties warrants that it has and undertakes that it will at all times have in place technical and organisation measures consistent with good industry practice to protect against accidental or unlawful destruction of any Personal Data which is supplied to it and/or accessed by it for the purposes of or in connection with the Project and/or Future Projects or accidental loss, alteration, unauthorised or unlawful disclosure of or access to the same, and security programs and procedures consistent with good industry practice to ensure that unauthorised persons will not have access to any such Personal Data or to the data processing equipment used to process any such Personal Data, and that any persons it authorises to have access to such Personal Data will respect and maintain the confidentiality and security of such Personal Data.
- 16.8 No Party shall make any use whatsoever of any Personal Data provided to it by the relevant Data Controller other than for the purposes of performance of its obligations under the Agreement and/or the furtherance of the Project and/or any Future Projects.
- 16.9 Under no circumstances shall any NHS Data (whether on its own or as part of a collection or subset of the Derived Data), be released to any third party, or made

available to or accessible by any third party, unless such NHS Data has been anonymised to the satisfaction of the relevant NHS Party.

17. SETTLEMENT OF DISPUTES

- 17.1 In the event of any dispute or difference between the Parties to this Agreement arising in connection with this Agreement, senior representatives of the Parties shall, within twenty eight days of a written request from one Party to the others, meet in a good faith effort to resolve the dispute without recourse to proceedings.
- 17.2 If the Parties fail to resolve the dispute or difference and are unable to reach agreement at the meeting referred to in Clause 17.1, either Party may refer any dispute or difference between them to an independent arbiter appointed by mutual agreement between the Parties. All discussions connected with the dispute shall be conducted in confidence and without prejudice to the rights of the Parties in any future proceedings. In the event that the Parties fail to agree on a mutually acceptable arbiter, the matter shall be referred to an arbiter to be appointed by the President for the time being of the Law Society of Scotland, and will be conducted in accordance with the Rules of the Law Society of Scotland. The decision of such arbiter shall be binding and final on the Parties and the provisions of s.3 of the Administration of Justice (Scotland) Act 1972 are hereby excluded.

18. NOTICES

Any notice to be given under this Agreement shall be sent by fax and confirmed by mail to the following addresses:

- (1) University of Dundee: The Director, Research & Innovation Services, Perth Road, Dundee DD1 4HN. Fax +44 (0)1382 385423
- (2) University of Edinburgh: Director, Edinburgh Research and Innovation, The University of Edinburgh, 1-7 Roxburgh Street, Edinburgh EH8 9TA, Scotland, UK. Fax +44 (0)131 650 9019
- (3) University of Glasgow: Senior Contracts Manager, Research & Enterprise, University of Glasgow, 10 The Square, Glasgow, G12 8QQ. Fax No: +44 (0)141-330-5611
- (4) The Common Services Agency: Deputy Director, Information Services Division, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB. Fax 0131 275 7514
- (5) University Court of the University of Aberdeen: Deputy Director, Research & Innovation, University Office, King's College, Regent Walk, Aberdeen AB24 3FX. Fax +44 (0) 1224 272319
- (6) Grampian Health Board: Director, NHS Grampian Research & Development, Foresterhill House Annexe, Foresterhill, Aberdeen AB25 2ZB. Fax 01224 550559
- (7) Lothian Health Board: Commercial Research Manager, Research and Development Office, Room E1.12, NHS Lothian, The Queen's Medical

Research Institute, 47 Little France Crescent, Old Dalkeith Road, Edinburgh, EH16 4TJ. Fax: 0131 242 3343

- (8) Greater Glasgow Health Board: R&D Director – Commercialisation, c/o Tennent Institute, Western Infirmary, 38 Church Street, Glasgow G11 6NT. Fax 0141 211 3814
- (9) Tayside Health Board: Head of IPR and Enterprise Management, Research & Development, Level 9, Ninewells Hospital and Medical School, Dundee, DD1 9SY Fax +44 (0)1382 496207

Any notice so sent shall be deemed to have been served on the date of transmission of the fax.

19 FORCE MAJEURE

- 19.1 In this Clause "Force Majeure" means any event outside the reasonable control of any Party affecting its ability to perform any of its obligations under this Agreement including Act of God, fire, flood, lightning, war, revolution, riot or civil commotion but excluding strikes, lock-outs or other industrial action, of the affected Party's own employees.
- 19.2 No Party shall have any liability to the others for failure to fulfil its obligations under this Agreement to the extent that it is prevented from carrying them out by an event of Force Majeure provided that the Party affected by Force Majeure shall immediately inform and keep informed the other Parties of the matters constituting the Force Majeure and take all reasonable steps available to it to minimise the effects of such an event on the performance of its obligations under this Agreement.
- 19.3 If a Party affected by such an occurrence causes a delay of three months or more, and if such delay may reasonably be anticipated to continue, then the Parties shall, in consultation with the Generation Scotland Scientific Committee, discuss whether continuation of the Project is viable, or whether the Project and this Agreement should be terminated.

20. CONTINUING OBLIGATIONS

The provisions of Clauses 1, 5, 6, 7, 8, 9, 11, 12, 13, 15, 16, 17, 20, 21 and 22 shall survive termination of this Agreement.

21. GENERAL

- 21.1 Nothing in this Agreement shall create or be deemed to create a partnership or joint venture or relationship of employer and employee or principal and agent between the Parties.
- 21.2 No Party shall have the power or right to bind or obligate any other Party, nor shall it hold itself out as having such authority.
- 21.3 This Agreement sets out the entire agreement between the Parties in relation to its subject matter and overrides any prior correspondence or representations. Each Party acknowledges that it has not been induced to enter into this Agreement by

reason of any representation made by or on behalf of the other Parties. Nothing in this Agreement is intended to limit or exclude any liability for fraud or for fraudulent misrepresentation.

- 21.4 Any variation to this Agreement must be in writing and signed by an authorised representative of each Party.
- 21.5 The waiver of or delay in enforcing any breach of this Agreement by any Party shall not prevent the subsequent enforcement of that provision and shall not be deemed to be a waiver of any subsequent breach of that or any other provision. Any waiver of any breach of this Agreement shall be in writing.
- 21.6 If any provision of this Agreement is ruled to be invalid for any reason, that invalidity will not affect the rest of this Agreement which will remain valid and enforceable in all respects. The Parties shall use their reasonable efforts to agree a new or varied provision which achieves to the extent permitted by law the original business purpose of the invalid provision.

22. APPLICABLE LAW

This Agreement shall be construed according to and governed by the law of Scotland and the Parties hereby submit to the exclusive jurisdiction of the Scottish Courts **IN WITNESS WHEREOF** these presents consisting of this and the preceding 20 pages together with the Schedule in eight (8) Parts attached hereto are executed on behalf of the Parties as follows:

SIGNED FOR AND ON BEHALF OF UNIVERSITY OF DUNDEE

Full Name:

Signed:

Designation:

Date:

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SIGNED FOR AND ON BEHALF OF THE UNIVERSITY COURT OF THE UNIVERSITY OF EDINBURGH

Full Name:

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Designation: