TERMS AND CONDITIONS

BETWEEN

The parties as set out on the Referral Form to which these Terms and Conditions are attached, each a "**Party"** and together the "**Parties**".

WHEREAS:

(A) The Purchaser is experienced in the field of healthcare science and requires certain testing services to be provided in respect of the project described at Schedule 1.

(B) NHSBT has expertise in various analytical and laboratory testing services.

(C) The Purchaser has agreed to purchase and NHSBT has agreed to provide testing services on these Terms and Conditions.

(D) These Terms and Conditions together with the Referral Form contains the whole agreement between the Parties relating to the provision of the Services and it supersedes all prior agreements, arrangements and understandings between the Parties. The legal status of this document will vary with the corporate nature of the Purchaser:

(E) If the Purchaser is a health service body identified under Section 9 of the National Health Service Act 2006 as subsequently amended then these Terms and Conditions and the Referral Form will constitute an NHS Contract.

(F) If the Purchaser is an NHS Trust at the Effective Date but during the life of these Terms and Conditions the NHS Trust receives its Terms of Authorisation from Monitor then these Terms and Conditions will cease to be an NHS Contract upon receipt of such Authorisation. In this situation any claim or remedy arising from that part of these Terms and Conditions when it was an NHS Contract will be treated as if it arose during the time the NHS Contract was in effect, even though it may only come to light after Authorisation.

1 DEFINITIONS AND INTERPRETATION

1.1 In these Terms and Conditions unless the context otherwise requires, the following terms shall have the following meanings:

"**Terms and Conditions**" means these terms and conditions

	including the attached Schedules and the Referral Form;
"**Bribery Act**"	means the Bribery Act 2010 and any subordinate legislation made under that Act from time to time together with any guidance or codes of practice issued by the relevant government department concerning the legislation;
"**GMP Regulations**"	means Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use regulations;
"Confidential Information"	means information, data and material of a confidential nature which either Party may receive or obtain in connection with the operation of these Terms and Conditions and: (a) which comprises Personal Data or Sensitive Personal Data (as both terms are defined in the Data Protection Act 1998) or which relates to any patient or his or her treatment or medical history; or (b) which is of a confidential nature (whether or not it is marked as 'confidential') or which ought reasonably considered to be confidential, concerning the business or finances of the party disclosing the information; and

(c) the release of which is likely to prejudice the commercial interests of NHSBT or Purchaser; or

(d) which is a trade secret;

"**Data Controller**"	means a Data Controller as defined in the Data Protection Act 1998;
"**Data Processor**"	means a Data Processor as defined in the Data Protection Act 1998;
"Dispute"	means a dispute, conflict or other disagreement between the parties;
"**Department of Health"**	means the Department of Health in England of the government of the United Kingdom and Northern Ireland or other relevant body, or such other body superseding or replacing it from time to time;
"**Effective Date**"	means the date specified on the front of any relevant Referral Form;
"Expert"	means the person designated to determine the Dispute appointed under Schedule 3;
"Expert Determination Notice"	means a notice in writing showing an intention to refer the Dispute for expert determination;
"**Facility**"	means NHSBT's premises at which the Services are performed;
"**FOIA**"	means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time

	together with any guidance and/or codes of practice issued by the Information Commissioner in relation to such legislation;
"**Force Majeure Event**"	means any event beyond the reasonable control of the party seeking to rely on such event pursuant to Clause 20 including (but without limitation) any one or more of the following: industrial action taken whether by its employees or those of any other person firm or organisation; a failure by its agents or sub-contractors to meet any obligation in relation to these Terms and Conditions which does not result from a Force Majeure Event; war, civil war, armed conflict or terrorism; or nuclear, chemical or biological contamination of NHSBT's premises from any of the events referred to; pressure waves caused by devices travelling at supersonic speeds; strikes or lock outs beyond the reasonable control of the affected party; or riot, flood, pandemic or earthquake;
"**Information Disclosure Requirements**"	means the requirements to disclose information under: (a) the FOIA; (b) the Environmental Information Regulations 2004; and (c) any applicable code of practice;
"**Information System**"	means a system for generating, sending, receiving, storing or otherwise processing

	electronic communications;
"**Intellectual Property**"	means all and any patents, trade marks, service marks, domain names, registered designs, utility models, applications for and any right to make application for any of such rights , inventions, Know-How (as defined below), unregistered trademarks and service marks, trade and business names, including rights in any get-up or trade dress, and all copyright in any item delivered to the Purchaser or used by NHSBT in doing anything pursuant to these Terms and Conditions as well as all confidential information, experience, drawings, other technical information and information concerning anything done by NHSBT pursuant to or for the purposes of these Terms and Conditions and the right to apply for any of the foregoing anywhere in the world;;
"**Know How**"	means all information not publicly known which is used or required to be used in or in connection with the Services existing in any form (including, but not limited to technical and clinical knowhow and that comprised in or derived from engineering, chemical and other specifications, formulae, experience, drawings, manuals, component lists, instructions, designs and diagrams, brochures, catalogues and other descriptions);
"Law"	means (i) any applicable statute or proclamation or any delegated or subordinate

legislation or regulation;

(ii) any applicable European Union directive, regulation, decision or law;

(iii) any enforceable community right within the meaning of section 2(1) European Communities Act 1972;

(iv) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; and

(v) any applicable code of practice;

in each case as applicable in England and Wales;

"Monitor" means the body corporate known as Monitor as provided by section 61 of the 2012 Act";

"**Material**" means any materials, samples, substances, products or other similar items;

"**Milestone**" means a particular objective agreed and identified as such in the Specification;

"**Milestone Date**" in respect of any Milestone the date set out in or calculated in accordance with the Specification for the achievement of that Milestone or such other timetable as may be set out in Schedule 1;

"NHS Body" means a health service body as defined in section 275 of the 2006 Act as amended by section 138(2)(c) of the 2012 Act;

"NHS Contract"	means a contract as defined in Section 9 of the 2006 Act;
"NHS Foundation Trust"	means a public benefit corporation under Section 30 of the 2006 Act;
"NHS Trust"	means a body established under the Section 25 of the 2006 Act;
"Other Body"	means any Purchaser who is not an NHS Foundation Trust or an NHS Body;
"**NHSBT Employees**"	means all persons employed or engaged by NHSBT from time to time in connection with the Services;
"**NHSBT Improvements**"	means improvements, modifications or adaptations to the NHSBT IPR developed by NHSBT whilst performing the Services which are not exclusively capable of use in or in relation to the Material provided by the Purchaser to NHSBT for testing;
"**NHSBT IPR**"	means any and all Intellectual Property belonging to NHSBT which exists at the Effective Date (including any subsequent patent/trademark applications made after the Effective Date in respect of any inventions which exist at the Effective Date and any patents/trademarks issued in respect of such patent applications) which are or will be disclosed to the Purchaser or used by NHSBT in carrying out or performing the Services; means the right to exploit any Intellectual Property or any right which is similar or analogous to any Intellectual Property;

"Party in Dispute"	means NHSBT and the Purchaser as the case may be in Dispute with the other;
"Personal Data"	means data as defined by the Data Protection Act 1998 which relates to a living individual who can be identified from such data, and/or from such data and other information which is in the possession of or is likely to come into the possession of the Purchaser and includes any expression of opinion about an individual and any indication of the intentions of the Purchaser in respect of an individual;
"**Price**"	means the fees payable by the Purchaser to NHSBT in respect of the provision of the Services;
"Prohibited Act"	the following constitute Prohibited Acts: (a) to directly or indirectly offer, promise or give any person working for or engaged by NHSBT a financial or other advantage to: (i) induce that person to perform improperly a relevant function or activity; or (ii) reward that person for improper performance of a relevant function or activity; (b) to directly or indirectly request, agree to receive or accept any financial or other advantage as an inducement or a reward for

improper performance of a relevant function or activity in connection with these Terms and Conditions;

(c) commit any offence:

(i) under the Bribery Act;

(ii) under legislation creating offences concerning fraudulent acts;

(iii) at common law concerning fraudulent acts relating to these Terms and Conditions or any other contract with NHSBT; or

(iv) defrauding, attempting to defraud or conspiring to defraud NHSBT.

"**Purchaser IPR**" means any and all Intellectual Property and Know-How belonging to the Purchaser which exists at the Effective Date (including any subsequent patent applications made after the Effective Date in respect of any inventions which exist at the Effective Date and any patents issued in respect of such patent applications) which are or will be disclosed to NHBST in relation to the Services; and any Intellectual Property or Know-How developed by the Purchaser and disclosed to NHSBT by the Purchaser after the Effective Date in relation to the Services;

"**Purchaser Personnel**"	all employees, agents, consultants and contractors, including any sub-contractors and all personnel of such contractors or sub-contractors;
"Referral Form"	means the referral form by which the Purchaser requests the Services from NHSBT to which these Terms and Conditions are annexed;
"**Request for Information**"	shall have the meaning set out in FOIA or any apparent request for information under the FOIA, the Environmental Information Regulations 2004 or any applicable code of practice;
"**Schedule**"	means all or any of the schedules annexed to and forming part of these Terms and Conditions;
"**Services**"	means the testing services to be provided by NHSBT and detailed in Schedule 1;
"**Specification**"	means the specification as agreed by the Parties and detailed at Schedule 1;
"**Start Date**"	means the date upon which the Parties agree that the Services are to commence, as specified in Schedule 1 or if no such date is specified the Effective Date;
"Terms of Authorisation or Authorisation"	means the Authorisation issued by Monitor under Section 35 of the 2006 Act;
"Variation Procedure"	means the variation procedure set out in Clause 18.

1.2 In these Terms and Conditions unless the contrary intention appears the following rules of interpretation shall apply:

1.2.1 words importing the masculine gender includes the feminine and the neuter, and the singular includes the plural and vice versa as the context admits or requires; and

1.2.2 the expression “person” means any individual, firm, body corporate, unincorporated association, or partnership, government, state or agency of a state or joint venture; and

1.2.3 the index and headings of the Clauses and Schedules are for convenience only have no legal effect; and

1.2.4 references to any statute or statutory provision in these Terms and Conditions shall be deemed to refer to any modification or extension or re-enactment or consolidation and all statutory instruments, thereof for the time being in force whether by statute or by directive or regulation (which is, in the case of a directive or regulation, continued to have direct application within the United Kingdom and has been adopted by the Council for the European Communities); and

1.2.5 any reference in these Terms and Conditions to a Clause, paragraph or Schedule is a reference to a Clause, paragraph or Schedule of these Terms and Conditions and references in any Schedule to paragraphs relate to the paragraphs in that Schedule; and

1.2.6 any reference to a “day” will mean a period of 24 hours running from midnight to midnight; and

1.2.7 all covenants, agreements, undertakings, indemnities, representations and warranties by more than one person are entered into, given or made by such persons jointly and severally; and

1.2.8 any references to “writing” or “written” includes references to any communication effected by post, facsimile or any comparable means but not including e-mail; and

1.2.9 any obligations on a Party not to do or omit to do anything include an obligation not to allow that thing to be done or omitted by a third party and

1.2.10 any phrase in these Terms and Conditions introduced by the term “include”, “including” “in particular” or any similar expression will be construed as illustrating and will not limit the sense of the words proceeding that term; and

1.2.11 the word “indemnify” in these Terms and Conditions will mean to indemnify, keep indemnified and hold harmless the indemnified party from and against all costs (including the costs of enforcement), expenses, liabilities (including any tax liability), injuries, direct, indirect or consequential loss (all three of which terms include, without limitation, pure economic loss, loss of profits, loss of business, depletion of goodwill and like loss), damages, claims, demands, proceedings or legal costs (on a full indemnity basis) and judgements which the indemnified party incurs or suffers and “indemnity”, “indemnities” and “indemnifies” have a corresponding meaning; and

1.2.12 all references to these Terms and Conditions include (subject to all relevant approvals) a reference to these Terms and Conditions as amended, supplemented, substituted, novated or assigned from time to time.

2 AGREEMENT AND DURATION

2.1 NHSBT shall perform and the Purchaser shall pay for the Services in accordance with the terms set out in these Terms and Conditions.

2.2 These Terms and Conditions will commence on the Effective Date and shall continue until:

2.2.1 completion of the Services in accordance with the Milestone Dates set out in Schedule 1; and

2.2.2 payment by the Purchaser for all Services provided by NHSBT, unless terminated earlier in accordance with Clause 11, Clause **Error! Reference source not found.** or Clause 20.6.

3 SERVICES

3.1 NHSBT shall commence provision of the Services on the agreed Start Date. NHSBT will provide the Services using all reasonable skill and care and shall use all reasonable endeavours to achieve each Milestone on or before the relevant Milestone Date in accordance with the provisions of Schedule 1 or as may be otherwise agreed as set out in Schedule 1 or under Clause **Error! Reference source not found.**. For the avoidance of doubt, time is not of the essence in these Terms and Conditions and any failure by NHSBT to meet a Milestone Date shall not be deemed to be a breach of these Terms and Conditions.

3.2 Under the terms of these Terms and Conditions the Purchaser shall be required to complete the relevant Referral Form accurately in order that NHSBT can correctly identify the Services being requested by the Purchaser. The Purchaser shall be required to complete all the information required in the relevant Referral Form.

3.3 NHSBT does not guarantee to the Purchaser the achievement of a successful outcome for the Services. For the avoidance of doubt, it shall not be considered a breach of these Terms and Conditions by NHSBT if an objective or outcome of the Services is not achieved:

3.3.1 due to any delay caused or contributed to by the Purchaser, including without limitation any defects in the Materials;

3.3.2 due to any failure by the Purchaser to meet its obligations under these Terms and Conditions;

3.3.3 due to an error in the Specification; or

3.3.4 so long as NHSBT reports any difficulty, discrepancy or other issue to the Purchaser upon becoming aware of such difficulty, discrepancy or other issue or as soon as reasonably practicable thereafter.

3.4 On completion of the Services, NHSBT will send a copy of the final report in such format as may be set out in Schedule 1.

3.5 If detailed in the Specification, NHSBT will use all reasonable endeavours to comply with the GMP Regulations in the provision of the Services to the extent so detailed in the Specification.

3.6 NHSBT will ensure all those employed or engaged in the provision of the Services are suitably qualified and trained. NHSBT shall provide such facilities as are necessary to carry out the Services.

3.7 If an incident occurs within the Facility which could potentially jeopardize the ability of NHSBT to comply with Clause 3.6, NHSBT will inform the Purchaser in writing of the incident as soon as is reasonably practicable to do so and use its reasonable endeavours to continue provision of the Services. For the avoidance of doubt if NHSBT is unable to continue providing the Services as a result of such

incident, this will constitute a Force Majeure Event and the provisions of Clause 17 shall apply.

4 CHARGES AND TERMS OF PAYMENT

4.1 The Purchaser shall pay NHSBT the Price in accordance with this Clause 4 and Schedule 2.

4.2 Unless otherwise expressly set out in Schedule 2, NHSBT shall invoice the Purchaser the Price immediately following and in respect of each calendar month in which the Services were provided.

4.3 Unless otherwise expressly set out in Schedule 2, the Purchaser shall pay for expenses incurred by NHSBT in connection with its performance of the Services. Such expenses shall be limited to travel and living expenses that NHSBT incurs in the performance of the Services. NHSBT shall submit details of the expenses to the Purchaser and if so requested by the Purchaser, NHSBT shall provide copies of supporting documentation for the invoiced expenses. NHSBT shall include such travel and living expenses, and any other costs and expenses that the Purchaser has agreed to pay to NHSBT and are set out in Schedule 2, in its invoice issued pursuant to Clause 4.2 or Schedule 2.

4.4 The Purchaser shall pay NHSBT within thirty (30) days of the date of each invoice. All sums properly due and payable under these Terms and Conditions will be paid by the Purchaser in full, free of any retention, set-off, counterclaim, deduction or withholding.

4.5 All amounts referred to in these Terms and Conditions are expressed net of value added tax which may be chargeable, which will be payable by the Purchaser in addition to the sum in question at the rate for the time being prescribed by law on delivery by NHSBT to the Purchaser of a valid VAT invoice.

4.6 If the Purchaser fails to pay any invoice submitted by NHSBT under these Terms and Conditions within thirty (30) days of the date of any invoice, NHSBT shall be entitled (without prejudice to any other right or remedy it may have) to:-

4.6.1 charge interest on any amount outstanding at the rate of 3% above the annual base lending rate of the Bank of England from time to time in respect of any sums properly due and payable but unpaid from the due date until the date of actual payment, calculated on a daily basis. NHSBT

further reserves the right to claim interest under the Late Payment of Commercial Debts (Interest) Act 1998; and

4.6.2 suspend provision of the Services until all outstanding sums are paid in full, and any additional costs incurred by such suspension shall be paid by the Purchaser or terminate these Terms and Conditions pursuant to Clause 11.3

4.7 All payments will be made to NHSBT either by cheque or BACS.

4.7.1 Payments by cheque shall be made payable to such location and such bank account as from time to time notified by NHSBT to the Purchaser and sent to:

NHS Blood and Transplant
Finance Department
Bridal Path
Leeds
LS15 7TW

4.7.2 Payment by BACS shall be to A/C No. 12498804 - sort code 08-33-00

5 PURCHASER'S OBLIGATIONS

5.1 The Purchaser shall fulfil all its obligations in these Terms and Conditions and as may be set out in the Specification strictly in accordance with these Terms and Conditions including without limitation providing Materials to NHSBT in the manner, at the dates and to the quality so specified.

5.2 The Purchaser shall promptly provide NHSBT with access to such of the Purchaser's Materials, information, documents, facilities or Purchaser Personnel as NHSBT reasonably requires or requests to perform the Services. The Purchaser acknowledges that NHSBT's ability to perform the Services as contemplated in the Specification will depend upon the proper fulfilment by the Purchaser of the Purchaser's obligations contained in these Terms and Conditions and NHSBT shall not be liable in respect of any delay or other default which is attributable to the Purchaser.

6 AUDITS AND VISITS

6.1 The Purchaser will have the right to audit and inspect the Facility during normal business hours by giving NHSBT at least fourteen (14) days prior written notice on the condition that the Purchaser:

6.1.1 does not unnecessarily or unreasonably interfere with or cause any delay to the Services or any other services or projects;

6.1.2 is liable for all acts and omissions of all Purchaser Personnel whilst they are on NHSBT's premises;

6.1.3 has insurance in place to cover the risks created by the Purchaser in the carrying out of the audit; and

6.1.4 shall ensure that all Purchaser Personnel whilst they are on NHSBT's premises will comply with NHSBT's policies and procedures.

7 MATERIALS

7.1 NHSBT confirms and agrees that Material supplied by the Purchaser and any written information provided by the Purchaser to NHSBT pursuant to these Terms and Conditions is and will remain the property of the Purchaser. Subject to Clause 7.2, NHSBT will return such Material and information to the Purchaser or destroy such Material and Information upon receipt of reasonable written notice.

7.2 The Purchaser confirms and agrees that NHSBT may retain sufficient quantities of the Materials supplied by the Purchaser, and copies of associated written information for quality testing, archive samples and for regulatory compliance requirements.

8 WARRANTIES AND REPRESENTATIONS

8.1 NHSBT warrants, represents and undertakes to the Purchaser that:

8.1.1 it will comply with all laws relating to the provision of the Services;

8.1.2 it owns or has all necessary right, title or interest to deal with NHSBT IPR; and

8.1.3 it shall use all reasonable skill and care in the performance of its obligations under these Terms and Conditions including (but not limited to) its provision of the Services.

8.2 If either Party is of the opinion that NHSBT has breached the warranty set out at Clause 8.1.3 or otherwise has failed to provide the Services as set out in these Terms and Conditions ('**NHSBT Breach**'), the following provisions shall apply:

8.2.1 if NHSBT identifies that it has committed an NHSBT Breach, then it shall notify the Purchaser in writing. Unless within seven (7) days of receipt of such notification, the Purchaser waives such NHSBT Breach (where capable of being waived) in writing, NHSBT shall at its own expense and sole option either re-perform the relevant Services within a reasonable time or provide a refund to the Purchaser of the Price paid in respect of the relevant part of the Services;

8.2.2 if the Purchaser, acting reasonably, is of the opinion that NHSBT has committed an NHSBT Breach, it shall notify NHSBT in writing forthwith of becoming aware of such NHSBT Breach. If:-

(a) NHSBT agrees with the Purchaser that there has been an NHSBT Breach NHSBT shall, unless the Purchaser waives such breach (where capable of being waived) in writing, at its own expense and sole option either re-perform the relevant Services within a reasonable time or provide a refund to the Purchaser of the Price paid in respect of the relevant part of the Services;

(b) if NHSBT does not agree with the Purchaser that there has been a NHSBT Breach, then the Dispute shall be resolved in accordance with Clause 0, provided always that should the outcome of the dispute resolution procedure be that NHSBT has committed an NHSBT Breach, the only remedy available to the Purchaser shall be that NHSBT shall either re-perform the relevant Services within a reasonable time or provide a refund to the Purchaser of the Price paid in respect of the relevant part of the Services;

8.3 If the Purchaser does not notify NHSBT of any NHS Breach within thirty (30) days of the Purchaser becoming aware of an NHSBT Breach or in respect of a breach of Clause 8.1.3 within thirty (30) days of receipt by the Purchaser of the relevant

test results or such other report as may be appropriate, then NHSBT shall have no liability whatsoever in respect of such NHSBT Breach.

8.4 Except as otherwise set out in these Terms and Conditions all conditions, warranties, terms and undertakings, express or implied, whether by statute, common law, trade practice, custom, course of dealing or otherwise (including without limitation as to quality, performance or fitness or suitability for purpose) in respect of the provision of the Services and the results of the Services are hereby excluded to the fullest extent permissible by law.

8.5 The Purchaser warrants, represents and undertakes to NHSBT that:

8.5.1 it has obtained all necessary approvals, consents, licences and permissions relating to these Terms and Conditions;

8.5.2 it will comply with all laws relating to these Terms and Conditions;

8.5.3 it owns and has all necessary right, title or interest to deal with the Purchaser IPR;

8.5.4 it has all necessary corporate standing and authorisation to enter into and be bound by the terms of these Terms and Conditions. At all times in connection with these Terms and Conditions, the Purchaser will be an independent contractor and nothing in these Terms and Conditions will create a relationship of agency or partnership or a joint venture as between the Purchaser and NHSBT and accordingly the Purchaser will not be authorised to bind NHSBT.

8.5.5 prior to providing the Materials or any related information to NHSBT it will undertake a full risk and safety assessment (compliant with all appropriate regulatory and health and safety legislation) of all Materials and related information and where appropriate it will obtain all necessary clearances, licences and consents in relation to the use of these Materials by NHSBT in accordance with these Terms and Conditions, including such consents as may be required pursuant to the Data Protection Act 1998. The Purchaser will provide NHSBT with copies of these assessments, clearances, licences and consents as is reasonably requested by NHSBT;

8.5.6 it has provided, or will at the appropriate time provide to NHSBT in writing all relevant health and safety information required for the correct storage,

handling and use of any Materials provided to NHSBT by the Purchaser, including all information regarding known or potential hazards which may arise from such handling, storage and use of the Materials;

8.5.7 it will at all times ensure that any Materials supplied to NHSBT pursuant to these Terms and Conditions, will not cause any loss of or damage to the property of NHSBT nor to NHSBT Employees, agents, contractors or sub-contractors, save to the extent that such loss or damage is caused by the negligent act of NHSBT or to a failure by NHSBT to comply with any written information provided to NHSBT by the Purchaser pursuant to Clause 8.5.5; and

8.5.8 if any Purchaser Personnel have cause to visit the Facility, the Purchaser will use all reasonable endeavours to ensure that such Purchaser Personnel comply with any policies and procedures that may from time to time operate at the Facility.

9 LIABILITY

9.1 Nothing in these Terms and Conditions shall in any way exclude or limit either Party's liability for death or personal injury (including any alleged injury caused by clinical or medical negligence) caused by that Party's negligence or for fraud.

9.2 Subject to Clauses 9.1 and 9.3, the entire liability of NHSBT (including any liability for the acts or omissions of any NHSBT Employee) for direct loss in contract, tort, negligence, breach of statutory duty or otherwise arising out of or in connection with these Terms and Conditions or the Purchaser's use of the results of the Services shall not exceed the invoice value of any item or Service provided delivered to the Purchaser which has given rise to the liability in question..

9.3 Subject to the provisions of Clause 9.1, in no circumstances shall NHSBT be liable to the Purchaser whether in contract, tort, negligence, breach of statutory duty or otherwise in respect of loss of profits, revenue, goodwill, business opportunity or loss of or cost of restoration of data or any other indirect, consequential, financial or economic loss or damage, costs or expenses whatsoever or howsoever arising out of or in connection with these Terms and Conditions or the Purchaser's use of the results of the Services.

9.4 The Purchaser will indemnify and keep indemnified NHSBT in respect of all losses, costs, claims, demands, liabilities, expenses, judgements, awards, orders proceedings and findings of whatsoever nature caused by any acts or omissions of the Purchaser of its obligations under these Terms and Conditions.

10 INTELLECTUAL PROPERTY

10.1 The Purchaser IPR is and shall remain the exclusive property of the Purchaser. The Purchaser hereby grants to NHSBT a non-exclusive, royalty free licence to use, exploit and otherwise deal with the Purchaser IPR as NHSBT may reasonably require in order to carry out the Services.

10.2 NHSBT IPR is and shall remain the exclusive property of NHSBT.

10.3 NHSBT hereby assigns to the Purchaser with full title guarantee by way of present and future assignment all right, title and interest in any and all Intellectual Property in the results of the Services undertaken by NHSBT. To the extent that it is not possible to assign any such intellectual property rights now, NHSBT shall assign on creation all such right, title and interest to the Purchaser and shall hold any such rights, title and interest on trust for the Purchaser until assigned. The costs of any such assignment shall be borne by the Purchaser.

10.4 The Purchaser will not without NHSBT's prior consent publish or disclose any information relating to the Services supplied by NHSBT to the Purchaser if to do so would result in disclosure of any Intellectual Property Rights belonging to or used by NHSBT.

10.5 Title to and property in all NHSBT Improvements developed by NHSBT in performance of these Terms and Conditions shall vest in NHSBT.

10.6 To the extent necessary to allow NHSBT to use NHSBT Improvements, the Purchaser hereby grants to NHSBT a royalty free, irrevocable licence to use all necessary Purchaser IPR.

11 TERMINATION

11.1 These Terms and Conditions may be terminated by either Party by written notice with immediate effect if:

11.1.1 the other Party fails to observe or perform any of its material obligations contained in these Terms and Conditions and, if such failure shall be remediable, it does not remedy that failure within thirty (30) days of being requested to do so by the other Party; or

11.1.2 the other Party, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction..

11.2 In addition, when the Purchaser is an NHS Foundation Trust, NHSBT may at any time give notice to the Purchaser to terminate these Terms and Conditions with immediate effect or as such longer notice as NHSBT considers to be necessary when:

11.3 the Purchaser's Terms of Authorisation issued by the Regulator are amended such that the Purchaser is no longer able to purchase (whether temporarily or permanently) any or all of the Services;

11.4 the Purchaser applies to the Regulator for an order pursuant to Section 57A of the 2006 Act;

11.5 the Purchaser applies to the Regulator for its dissolution and transfer of its property and liabilities to another body corporate pursuant to Section 56 of the 2006 Act; or

11.6 the Purchaser applies to the Regulator for its dissolution and the establishment of two or more new NHS foundation trusts pursuant to Section 56B

11.7 NHSBT may terminate these Terms and Conditions if the Purchaser fails to pay any reasonable sum properly due and payable hereunder within thirty (30) days of the due date and fails to rectify such payment within a subsequent fifteen (15) days of receipt of a final reminder from NHSBT for payment of such outstanding amount (but failure by NHSBT to notify the Purchaser in accordance with this Clause shall not be considered a waiver of NHSBT's right to receive payment).

11.8 At any time after six months following the Effective Date, either Party may terminate these Terms and Conditions by providing the other party with not less than six (6) months prior written notice.

12 CONSEQUENCES OF TERMINATION

12.1 Any termination or expiry of these Terms and Conditions shall not relieve either Party of any obligation under these Terms and Conditions which is expressed or which by implication is intended to continue after termination or expiry including Clause 4 (Charges and Terms of Payment), Clause 8 (Warranties and Representations), Clause 9 (Liability), Clause 10 (Intellectual Property), Clause 13 (Confidentiality), Clause 14 (Freedom of Information), Clause 0 (Dispute Resolution Procedure) and Clause **Error! Reference source not found.** (Law and Jurisdiction)..

12.2 For the avoidance of doubt in the event of termination of these Terms and Conditions howsoever arising, all rights and licences granted by either party to the other shall automatically cease and both Parties shall cease all and any use of the other's Intellectual Property and any Confidential Information.

12.3 After termination or expiry all data, documents and records (whether stored electronically or otherwise) relating in whole or in part to the Services (including any Services which remain to be completed as at the date of termination or expiry) and all other items provided on loan or otherwise to the Purchaser by NHSBT will be delivered by the Purchaser to NHSBT provided that the Purchaser will be entitled to keep copies thereof to the extent that the information contained therein does not relate solely to the Services or to the extent that the Purchaser is required by Law to maintain copies thereof or to the extent that the Purchaser was possessed of such data, documents and records prior to the date of these Terms and Conditions. In addition, the Purchaser will co-operate fully with NHSBT during the handover leading to the termination of these Terms and

Conditions. This co-operation will extend to full access to all documents, reports, summaries and any other information required to achieve an effective transition without disruption to routine operational requirements.

12.4 Termination of these Terms and Conditions for any reason shall not prejudice the rights or remedies which may have accrued to either party and both parties shall use all reasonable endeavours to mitigate their losses upon such termination.

13 CONFIDENTIALITY

13.1 Both Parties recognise the commercial importance of the other's Confidential Information. The party receiving Confidential Information ("**Receiving Party**") will treat it as secret and confidential and will not use it for its own benefit or for the benefit of any other party or for any purpose other than those required or permitted by these Terms and Conditions. The Receiving Party will not disclose any part of the Confidential Information to any third party without the express prior written consent of the Party making the Confidential Information available ("**Disclosing Party**"), other than to such of the Receiving Party's employees or consultants who reasonably require such disclosure and who are bound by similar confidentiality provisions.

13.2 The provisions contained in Clause 13.1 shall not apply:

13.2.1 to any information, which is in or enters the public domain other than as a result of a breach of these Terms and Conditions or where the Receiving Party receives the information from a third party which is not under any obligation of confidence to the Disclosing Party;

13.2.2 where the information has been developed by the Receiving Party independently of the disclosure; and/or

13.2.3 the disclosure of which is required to ensure the compliance of NHSBT

13.2.4 to any information, which is required to be disclosed by the courts, process of law or to enable NHSBT to comply with its transparency obligations, FOIA requests or any other statutory obligation on NHSBT, Government policy as may apply from time to time to public sector bodies.

13.3 Each Party shall apply to the Confidential Information of the other Party no less security measures and degree of care as it applies to its own confidential information, but in no event less than a reasonable degree of care.

13.4 During the course of these Terms and Conditions if either Party possess any data, regardless of ownership, that is relevant to the other and this data becomes lost or misplaced, the Party who lost or misplaced the data must inform the other of the loss within 1 (one) day of the loss becoming apparent

13.5 Upon termination of these Terms and Conditions or upon the Disclosing Party's written request, the Receiving Party will return all the Confidential Information supplied to the Receiving Party by the Disclosing Party within twenty eight (28) days of such request. Each party may retain one copy of the Confidential Information but only if it requires to hold such information to ensure legal compliance with its obligations under these Terms and Conditions including regulatory compliance.

14 FREEDOM OF INFORMATION

14.1 The Purchaser acknowledges that NHSBT, as public body, is subject to the requirements of the FOIA, the Codes of Practice and the Environmental Information Regulations 2004 ("**Environmental Regulations**"). The Purchaser must assist and co-operate with NHSBT to enable NHSBT to comply with its disclosure obligations under the FOIA, the Codes of Practice and the Environmental Regulations. The Purchaser agrees:

14.1.1 that these Terms and Conditions and other recorded information held by the Purchaser on NHSBT's behalf for the purposes these Terms and Conditions, are subject to the obligations and commitments of NHSBT under FOIA, Codes of Practice and the Environmental Regulations;

14.1.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for NHSBT;

14.1.3 that where the Purchaser receives a request for information under FOIA, Codes of Practice and/or the Environmental Regulations and the Purchaser itself is subject to FOIA, it will liaise with NHSBT as to the contents of any response

before a response to a request is issued and will promptly (and in any event within two (2) Operational Days) provide a copy of the request and any response to NHSBT;

14.1.4 that where the Purchaser receives a request for information under the FOIA, Codes of Practice and/or the Environmental Regulations and the Purchaser is not itself subject to FOIA, Codes of Practice and/or the Environmental Regulations, it will not respond to that request (unless directed to do so by NHSBT) and will promptly (and in any event within two (2) Operational Days) transfer the request to NHSBT;

14.1.5 that NHSBT, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of the FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Purchaser and these Terms and Conditions without either consulting with the Purchaser, or following consultation with the Purchaser and having taken its views into account;

14.1.6 to assist NHSBT in responding to a request for information, by processing information or environmental information (as the same are defined in the FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of the FOIA, and to provide copies of all information requested by NHSBT within five (5) Operational Days of that request and without charge.

14.2 The Parties acknowledge that, except for any information that is exempt from disclosure in accordance with the provisions of the FOIA, the content of these Terms and Conditions is not Confidential Information of the Purchaser.

14.3 Notwithstanding any other term of these Terms and Conditions, the Purchaser consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and the Environmental Regulations.

14.4 In preparing a copy of these Terms and Conditions for publication in accordance with Clause 14.3 NHSBT may consult with the Purchaser to inform decision making regarding any redactions but the final decision in relation to any redaction of information will be at the absolute discretion of NHSBT.

14.5 The Purchaser must assist and cooperate with NHSBT to enable NHSBT to publish these Terms and Conditions.

14.6 In the event that the Purchaser fails to comply with this Clause 14, NHSBT reserves the right to terminate these Terms and Conditions by notice in writing within immediate effect.

15 DATA PROTECTION ACT

15.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties.

15.2 NHSBT, in undertaking its core activities, collects, holds and processes Personal Data and Sensitive Personal Data information (as such terms are defined in the Data Protection Legislation), which is personal and identifiable to living individuals. NHSBT is designated a Data Controller for that purpose under the provisions of the Data Protection Legislation and a notification to this effect has been lodged with the office of the Information Commissioner.

15.3 There may be some occasions where NHSBT Processes Personal Data and Sensitive Personal Data on behalf of the Purchaser. In such cases where Personal Data or Sensitive Personal Data related to a patient or a donor is provided by the Purchaser to NHSBT, then unless otherwise stated by the Purchaser in relation to that information NHSBT will be entitled to assume that the patient concerned has given consent to the disclosure of their Personal Data and Sensitive Personal Data by NHSBT to a third party for the Services and all other relevant medical purposes in accordance with Data Protection Legislation and medical ethical requirements and that the Personal Data and Sensitive Personal Data may be Processed for that purpose. Purchaser will ensure that all patients and donors have given their express written consent to the Processing of Personal Data and Sensitive Personal Data for such purposes.

15.4 There may be some occasions where the Purchaser Processes Personal Data on behalf of NHSBT. In such cases the Purchaser will comply with the Data Protection Legislation. In particular the Purchaser must:

15.4.1 put in place and maintain appropriate technical and organisational security measures against any unauthorised or unlawful Processing of that Personal Data, and against the accidental loss or destruction of or damage to such

personal data having regard to this Clause 15, the state of technical development and level of harm that may be suffered by a data subject whose Personal Data is affected by unauthorised or unlawful Processing or by its loss, damage or destruction; and

15.4.2 only to process Personal Data for and on behalf of the NHSBT, in accordance with the instructions of the NHSBT and for the purpose of performing its obligations under these Terms and Conditions; and

15.4.3 take reasonable steps to ensure the reliability of Staff who will have access to Personal Data, to ensure that those Staff are aware of and trained in the policies and procedures set out in this Clause 15 and that such policies and procedures are vigorously enforced; and

15.4.4 not cause or allow Personal Data to be transferred outside the European Economic Area without the prior consent of NHSBT; and

15.4.5 comply with all NHS and NHSBT Processing, information governance policies and reporting requirements in force from time to time; and

15.4.6 allow NHSBT to audit the Purchaser's compliance with the requirements of this Clause 15 on reasonable notice and/or to provide the NHSBT with evidence of its compliance with the obligations set out in this Clause 15.

15.5 Both Parties shall ensure that Personal Data is safeguarded at all times in accordance with the Law and this obligation will include (if transferred electronically) only transferring Personal Data (i) if essential, having regard to the purpose for which the transfer is conducted; and (ii) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to NHSBT and the Purchaser under and Law and Guidance (including data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

15.6 The Purchaser agrees to Indemnify and keep indemnified NHSBT against all claims and proceedings and all liability, loss, costs, claims and expenses incurred in connection therewith by NHSBT as a result of any claim made or brought by any individual or other legal person in respect of any loss, damage or distress caused to that individual or other legal person as a result of the Purchaser's unauthorised processing, unlawful Processing, destruction of and/or damage to any Personal Data processed by the

Purchaser, its employees or agents in connection with the Contract. The limitations of liability set out in Clause 9 shall not apply to this indemnity.

15.7 The Purchaser will provide NHSBT with reasonable assistance in complying with any subject access request served on the NHSBT under Data Protection Legislation and the Purchaser shall consult NHSBT prior to the disclosure by the Purchaser of any Personal Data or Sensitive Personal Data in relation to such requests.

16 ASSIGNMENT

16.1 Neither Party may assign or otherwise transfer all or any part of its duties or obligations under these Terms and Conditions to any other third party without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except in the case of a statutory reorganisation of all or part of NHSBT.

17 FORCE MAJEURE

17.1 Neither Party shall be liable for any delay or failure to perform all or any of its obligations under these Terms and Conditions (other than an obligation to make payment to NHSBT for the Products or Services) nor be liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent that such failure or delay results from a Force Majeure Event. Notwithstanding the foregoing, each party will use reasonable endeavours to continue to perform its obligations hereunder during any Force Majeure Event.

17.2 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under these Terms and Conditions, and to resume the performance of its obligations affected by the Force Majeure Event as soon as reasonably practicable.

17.3 If either Party is prevented or delayed in the performance of its obligations under these Terms and Conditions by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.

17.4 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue

and for such time after they cease as is necessary for that Party, using reasonable endeavours, to recommence its affected operations in order for it to perform its obligations.

17.5 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.

17.6 If any Force Majeure Event causes the Purchaser or NHSBT to be unable to comply with its obligations hereunder to a material extent for thirty (30) days or more, either Party may by serving notice on the other terminate this Contract with immediate effect and neither Party shall have any liability to the other.

17.7 Any rights and liabilities of either Party that accrued prior to termination in accordance with Clause 17.6 shall continue in full force and effect unless otherwise specified in these Terms and Conditions.

18 NOTICES

18.1 Any notice required to be given by either Party under these Terms and Conditions shall be in writing quoting the date of these Terms and Conditions and shall be delivered by hand or sent by prepaid first class recorded delivery. The address for service for each Party is the address set out in these Terms and Conditions or such other address as either Party may previously have notified to the other Party in writing.

18.2 A notice shall be treated as having been received:

18.2.1 if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours on the next Operational Day; or

18.2.2 if sent by first class recorded delivery mail on a normal Operational Day, at 9.00 am on the second Operational Day subsequent to the day of posting, or, if the notice was not posted on an Operational Day, at 9.00 am on the third Operational Day subsequent to the day of posting.

18.3 All written and oral communications referred to in these Terms and Conditions shall be in English.

19 DISPUTE RESOLUTION

19.1 In the case of a Dispute, the Parties shall use reasonable efforts to communicate and cooperate with each other with a view to resolving the dispute and to follow the procedure set out in Clause 19.2 before commencing court proceedings.

19.2 If any dispute arises out of these Terms and Conditions either Party may serve a notice on the other Party to commence formal resolution of the dispute. Those responsible for the Products and Services for each of NHSBT and the Purchaser shall have five (5) Operational Days to resolve the dispute. If they are unable to do so the matter will be escalated to the Authorised Representatives of the Parties who shall have five (5) Operational Days to resolve the dispute. If the authorised representatives are unable to do resolve the dispute within five (5) Operational Days, the dispute shall be escalated to the most senior officer of each Party (or such person as they may delegate) for resolution who will have ten (10) Operational Days to resolve the dispute.

19.3 If the procedure set out in Clause 19.2 of these Terms and Conditions fails to resolve such dispute, the Parties will attempt to settle it by mediation either: (a) with the Centre for Effective Dispute Resolution ("CEDR"); or (b) if agreed in writing by the Parties, with any other alternative mediation organisation, using the respective model procedures of CEDR or such other mediation organisation.

19.4 To initiate mediation a Party shall:

19.4.1 give notice in writing ("Mediation Notice") to the other Party requesting mediation of the dispute; and

19.4.2 send a copy of the Mediation Notice to CEDR or an equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator if the Parties are not able to agree such appointment by negotiation.

19.5 Neither Party may issue a Mediation Notice until the process set out in Clause 19.2 has been exhausted.

19.6 The mediation shall commence within twenty eight (28) days of the Mediation Notice being served. Neither Party will terminate such mediation until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. Neither Party will commence legal proceedings against the other until thirty (30) days after such mediation of the dispute in question has failed to resolve the dispute. Each Party will cooperate

with any person appointed as mediator providing them with such information and other assistance as they shall require and will pay their costs, as they shall determine or in the absence of such determination such costs will be shared equally.

19.7 Nothing in these Terms and Conditions shall prevent:

19.7.1 either Party taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with negligence of the other Party; or

19.7.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients and other service users or the security of Confidential Information, pending resolution of the relevant dispute in accordance with the CEDR or other mediation organisation procedure.

19.8 This Clause 19 shall survive the expiry of earlier termination of these Terms and Conditions for any reason.

20 PREVENTION OF BRIBERY

20.1 The Purchaser:

20.1.1 shall not, and shall procure that any Purchaser Personnel shall not, in connection with these Terms and Conditions commit a Prohibited Act;

20.1.2 warrants, represents and undertakes that it is not aware of any financial or other advantage being given to any person working for or engaged by NHSBT, or that an agreement has been reached to that effect, in connection with the execution of these Terms and Conditions, excluding any arrangement for which full details have been disclosed in writing to NHSBT before execution of these Terms and Conditions.

20.2 The Purchaser shall:

20.2.1 if requested, provide NHSBT with any reasonable assistance, at NHSBT's reasonable cost, to enable NHSBT to perform any activity required by any relevant government or agency in any relevant jurisdiction for the purpose of compliance with the Bribery Act;

20.2.2 within ten (10) days of the Start Date, and annually thereafter, certify to NHSBT in writing (such certification to be signed by an officer of the

Purchaser) compliance with this Clause 0 by the Purchaser and all persons associated with it or other persons who are purchasing goods or services in connection with these Terms and Conditions. The Purchaser shall provide such supporting evidence of compliance as NHSBT may reasonably request.

20.3 The Purchaser shall have an anti-bribery policy (which shall be disclosed to NHSBT on NHSBT's request) to prevent any Purchaser Personnel from committing a Prohibited Act and shall enforce it where appropriate.

20.4 If any breach of Clause 20.1 is suspected or known, the Purchaser must notify NHSBT immediately.

20.5 If the Purchaser notifies NHSBT that it suspects or knows that there may be or has been a breach of Clause 20.1, the Purchaser must respond promptly to NHSBT's enquiries, co-operate with any investigation, and allow NHSBT to audit books, records and any other relevant documentation.

20.6 NHSBT may terminate these Terms and Conditions by written notice with immediate effect if the Purchaser or Purchaser Personnel (in all cases whether or not acting with the Purchaser's knowledge) breaches Clause 20.1.

20.7 Any notice of termination under Clause 20.6 must specify:

20.7.1 the nature of the Prohibited Act;

20.7.2 the identity of the party whom NHSBT believes has committed the Prohibited Act; and

20.7.3 the date on which these Terms and Conditions will terminate.

20.8 Despite Clause 0 (Dispute Resolution), any dispute relating to:

20.8.1 the interpretation of Clause 0; or

20.8.2 the amount or value of any gift, consideration or commission, shall be determined by NHSBT and its decision shall be final and conclusive.

20.9 Any termination under Clause 20.6 will be without prejudice to any right or remedy which has already accrued or subsequently accrues to NHSBT.

21 CONTRACTS (RIGHTS OF THIRD PARTIES)

21.1 A person who is not a Party to these Terms and Conditions shall have no rights pursuant to the Contracts (Rights of Third Parties) Act 1999 to enforce or enjoy the benefit of any term of these Terms and Conditions except that a successor may directly enforce any indemnity or other rights provided to a Party in connection with these Terms and Conditions. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of these Terms and Conditions.

22 WAIVER

22.1 Any failure, relaxation or delay by either Party to exercise an option or right conferred by these Terms and Conditions shall not of itself constitute a waiver of such option or right and will not affect the ability of that Party subsequently to exercise that right.

22.2 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of these Terms and Conditions or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

22.3 A waiver of any default will not constitute a waiver of any other default.

22.4 No waiver of any of the terms, conditions or provisions of these Terms and Conditions will be effective unless it is expressed to be a waiver in writing and communicated in accordance with Clause 18.

23 ENTIRE AGREEMENT

23.1 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of these Terms and Conditions and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in these Terms and Conditions or unless such representation, undertaking or warranty was made fraudulently.

23.2 These Terms and Conditions, any variation in writing signed by the Authorised Officers of each Party and any document referred to (explicitly or by implication) in these Terms

and Conditions or any variation to these Terms and Conditions, contain the entire understanding between the Parties relating to the Services to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in these Terms and Conditions. Nothing in these Terms and Conditions seeks to exclude either Party's liability for Fraud.

24 STATUTORY INVALIDITY

24.1 Any provision in these Terms and Conditions which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of these Terms and Conditions and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

25 REMEDIES CUMULATIVE

25.1 Except as otherwise expressly provided by these Terms and Conditions, all remedies available to the Purchaser or NHSBT for breach of these Terms and Conditions are cumulative and may be exercised concurrently or separately. The exercise of any one remedy will not be deemed an election of such remedy to the exclusion of other remedies.

26 DISBURSEMENT OF PUBLIC FUNDS

26.1 NHSBT has a duty to account for the disbursement of public funds. The Purchaser will keep comprehensive and accurate records in respect of the Price and all amounts due to it under these Terms and Conditions. The Purchaser will allow inspection of such records at all reasonable times by NHSBT’s duly authorised representatives for the sole purpose of verifying the Purchaser’s fulfilment of its obligations under these Terms and Conditions and amounts due to NHSBT therefore. The Purchaser will make available such facilities and give such assistance, including the provision of copies or extracts of such records as NHSBT may reasonably request in connection with the performance of such audit and will afford NHSBT’s authorised representatives all reasonable access to all other information, reports, documents, records and data, whether in human or machine readable form, solely relevant to the performance of its obligations.

26.2 Representatives of NHSBT who are authorised to perform such inspection will enter into a confidentiality undertaking in the form contained in Schedule 4 with the Purchaser prior to such inspection.

26.3 All confidential information of NHSBT made available to the Purchaser under this Clause 30 will be treated by the Purchaser in accordance with Clause 13.

26.4 In pursuance of its legitimate requirements, NHSBT may, where necessary, request from the Purchaser, information for clinical audit or medical research purposes. In such cases, the Purchaser will disclose such information, provided that NHSBT data protection and information security policies and procedures are applied. Only a health care professional or a person owing an equivalent duty of care will undertake the processing of such information. So that these arrangements can work effectively NHSBT and the Purchaser agree that they will provide any necessary authorisations to their respective auditors (Internal and External) to disclose information necessary for the audit. The Audit report will be shared with the organisations to which it provides services.

27 SEVERABILITY

27.1 If any provision of these Terms and Conditions is held invalid, illegal or unenforceable for any reason, such provision will be severed and the remainder of the provisions hereof will continue in full force and effect as if this Contract had been executed with the invalid provision eliminated.

28 PROVISIONS SURVIVING TERMINATION

28.1 Any rights, duties or obligations of any of the Parties which are expressed to survive, or which otherwise by necessary implication survive the expiry or termination for any reason of this Contract, together with all indemnities, will continue after expiry or termination, subject to any limitations of time expressed in this Contract.

29 LAW AND JURISDICTION

29.1 These Terms and Conditions, and any dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.

29.2 Subject to Clause 19, the Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Contract or its subject matter.

SCHEDULE 1
SPECIFICATION

International Blood Group Reference Laboratory (IBGRL) Molecular Diagnostics

IBGRL Molecular Diagnostics is part of NHS Blood and Transplant and provides specialist diagnostic services for NHS hospitals, and other health service and commercial customers.

The Molecular Diagnostics department is an accredited laboratory and all work is carried out within the framework of a documented quality system. The department participates in external quality assurance exercises for blood group genotyping. Information about patients and donors is held in compliance with the Data Protection and Freedom of Information Acts

http://www.nhsbt.nhs.uk/download/information_charter.pdf

The department undertakes:

1) Blood group specific genetic investigations to identify women with antigen-positive fetuses who are at risk of haemolytic disease of the fetus and newborn (HDFN).

2) A fetal sex typing service for pregnancies affected by X-linked genetic conditions or when early treatment of the fetus differs according to fetal gender.

3) Blood group genotyping to predict the most clinically important blood groups of patients who have been multi-transfused or where serological phenotyping is not possible.

Samples must be accompanied by the appropriate **signed** and completed request form (FRM4674, FRM4738, FRM4739) as outlined in the department user guide, INF1135, available on the website: http://ibgrl.blood.co.uk/. Acceptance of this sample for testing by the laboratory constitutes an agreement between the Purchaser and NHS Blood and Transplant as outlined in these terms and conditions.

Part 1: Services available at IBGRL

1. Molecular Diagnostics – Offers the following services within the scope of this contract

1.1. **Fetal Genotyping** from cell free fetal DNA in maternal plasma. This is carried out on maternal blood samples for antigen-negative women whose pregnancies are at risk of HDFN using real-time PCR analysis of blood group genes.

1.1.1. Samples for **RhD, C, c, E typing** are accepted from 16 weeks gestation. In some circumstances we will test samples before the recommended gestation, please contact IBGRL to discuss.

1.1.2. Samples for **Kell (K1) typing** are accepted from 20 weeks gestation. In some circumstances we will test samples before the recommended gestation, please contact IBGRL to discuss. In such cases, where a negative blood group is predicted, another sample should be sent after 20 weeks gestation. All referrals for fetal Kell status which achieve a K-negative prediction should be repeated after 28 weeks gestation. A K-negative result reported prior to 28 weeks gestation should be considered to be a preliminary result.

1.2. **Determination of fetal sex** from 7 weeks' gestation on cell free fetal DNA in maternal plasma using real-time PCR analysis of *DYS14* gene. This is carried out on a maternal blood sample and is provided for clinical purposes only.

1.3. **Blood group genotyping from tissues:** The blood group phenotype of a fetus can be determined by analysis of DNA derived from fetal cells in amniotic fluid or chorionic villus (CV). The laboratory uses allelic discrimination analysis of blood group genes or HEA Beadchip to perform the investigation.

1.3.1. **Standard blood group genotyping:** RhD, C, c, E, e, K/k, $Fy^{a/b}$, $Jk^{a/b}$, M/N, S/s, U-, U^{var}

1.3.2. **Extended blood group genotyping:** RhD, C, c, E, e, V, VS, K/k, $Kp^{a/b}$,$Js^{a/b}$, $Fy^{a/b}$, Fy^{X}, $Jk^{a/b}$, M/N, S/s, U-, U^{var} , $Lu^{a/b}$, $Di^{a/b}$, $Co^{a/b}$, $Do^{a/b}$, $LW^{a/b}$, Sc

1.3.3. **ABO blood group** may be requested – please note that any clinical decisions relating to transfusion and transplantation must not be made on the basis of the ABO group predicted from these results.

1.4. **Blood group genotyping from blood sample**: Normally performed for multi-transfused patients or DAT positive patients, where the presence of transfused red cells or presence of autoantibodies can prevent determination of blood group phenotype by serological techniques, however, analysis of genotype can be performed to predict blood group phenotype. The laboratory uses allelic discrimination analysis of blood group genes or HEA Beadchip to perform the investigation.

1.4.1. **Standard blood group genotype** RhD, C, c, E, e, K/k, $Fy^{a/b}$, $Jk^{a/b}$, M/N, S/s, U-, U^{var}

1.4.2. **Extended blood group genotyping:** which includes standard genotype plus V, VS, Fy^X, $Kp^{a/b}$, $Js^{a/b}$, $Lu^{a/b}$, $Di^{a/b}$, $Co^{a/b}$, $Do^{a/b}$, $LW^{a/b}$, Sc

1.4.3. **ABO blood group** may be requested – please note that any clinical decisions relating to transfusion and transplantation must not be made on the basis of the ABO group predicted from these results.

1.4.4. ***RHD* zygosity:** determination of homozygosity or hemizygosity of *RHD* gene for partners of RhD negative women, using real-time PCR gene dosage estimation.

2. Service availability

2.1. The IBGRL Molecular Diagnostics laboratory is open Monday to Friday 09:00-17:00 and is closed on weekends and bank Holidays. Answer phone and email services are in place to take requests outside normal working hours. We will endeavour to respond to the request on the next business day.

3. IBGRL reporting and test turnaround times

3.1. For test turnaround times please see paragraph 4.5 of the Technical Agreement in part 2 of this schedule.

3.2. All written reports of investigations referred to IBGRL will be sent to the Purchaser (originator) by Royal Mail post. A single report will be posted to the address of the Purchaser or other nominated address as specified on the referral form. The responsibility for acting on the results of such investigations rests with the Purchaser (originator)

3.3. Urgent reports can be sent by email on request and the Purchaser must provide secure email details. In addition it is also the responsibility of the Purchaser to ensure details provided for the return of this information are accurate. IBGRL is not responsible for failure of this information to be transmitted if the information is not accurate or relevant at time of being actioned.

3.4. The Purchaser will be notified by email if a significant delay in reporting is anticipated.

Part 2 Technical agreement for IBGRL

The IBGRL User Guides can be found on the website http://ibgrl.blood.co.uk/

Service user responsibilities

The Purchaser is responsible for ensuring that samples referred to IBGRL for testing meet the following specifications:

1. **Consent.** It is the responsibility of the Purchaser to ensure that the patient has been informed of the tests being requested and has provided valid consent to the tests.

2. **Provision of the correct samples / request form.** The Purchaser is responsible for providing suitable samples (including minimum sample volume) as specified on the IBGRL request forms and in the user guide INF1135. All request forms are available for printing http://ibgrl.blood.co.uk/. The current version of the request form must be used.

   2.1. **Provision of correct request form:**

   2.1.1. Fetal blood group genotyping from maternal blood FRM4674

   2.1.2. Fetal blood group genotyping from amniotic fluid or chorionic villus FRM4738

   2.1.3. Fetal sex typing from maternal blood FRM4739

   2.1.4. Blood Group genotyping (standard and extended) and *RHD* zygosity testing FRM4738

   2.2. **Provision of correct sample and volume**

   See the User Guide for referring samples to IBGRL Molecular Diagnostics (INF1135) available at http://ibgrl.blood.co.uk/

   2.2.1. Samples sent for fetal genotyping from maternal plasma must not be opened following blood collection or used for any testing prior being sent to IBGRL

   2.2.2. Samples sent for fetal genotyping from maternal plasma should be stored at room temperature at all times, prior to reaching the IBGRL laboratory

   2.2.3. Fetal blood group genotyping from maternal plasma (blood group genotyping and fetal sexing) – 16mL maternal EDTA blood per test requested (plus 3ml EDTA blood from partner, when requesting fetal RhD status, however this is not essential) or frozen maternal plasma aliquots prepared from 16mL EDTA blood according to INF1291, shipped on dry ice.

   2.2.4. Genotyping from amniotic fluid – 5mL sample.

2.2.5. Genotyping from chorionic villus DNA – DNA must be at a minimum concentration of 10ng / µL and a minimum volume of 60 µL

2.2.6. Blood Group genotyping (standard and extended) minimum 0.5mL EDTA blood or 1mL clotted blood sample.

3. Sample Quality

3.1. The Purchaser is responsible for providing a sample of suitable quality for testing as the quality of test results will be compromised if samples are not of an adequate standard.

3.2. Samples in the following sub-standard conditions will not be accepted. The report will state why the sample was not and will incur a charge, see 3.3 of this schedule:

3.2.1. Samples taken at gestational ages less than stated in Part 1, section 1.1 of this schedule

3.2.2. Haemolysed samples (for fetal genotyping from maternal plasma)

3.2.3. Leaking, broken or samples contaminated by leaking samples

3.2.4. Inadequate blood volume (see section 2.2 above for volumes)

3.2.5. Sample sent in incorrect type of tube (see section 2.2 above)

3.2.6. Inadequate labelling of sample tube / or referral form

3.2.7. Maternal blood samples must not be older than 3 days from date of venepuncture for fetal RhD/C/c and E genotyping on arrival at NHSBT

3.2.8. Maternal blood samples must not be older than 2 days from date of venepuncture for fetal Kell genotyping on arrival at NHSBT

3.2.9. Amniotic fluid samples must not be older than 7 days

3.2.10. Samples sent too early in gestation unless it has been pre-agreed with IBGRL (see sections 1.2.1 & 1.2.2)

3.2.11. Samples suspected of being used for any testing prior to being sent to NHSBT

3.2.12. Samples with addressograph labels– see 3.7 of this section

3.2.13. Hand written alterations on either the sample or request form – see 3.7.1 of this section

3.2.14. Samples of amniotic fluid or CVS DNA which have been in transit more than seven days.

3.2.15. Maternal plasma aliquots which are not frozen upon receipt

3.3. **Sample labelling and request form completion:** Information regarding sample labelling requirements and request forms is also detailed within the IBGRL User Guides found at http://ibgrl.blood.co.uk/. In the event the Purchaser fails to adhere to the labelling and sample requirements, NHSBT reserves the right to charge the Purchaser a fee as detailed within the Price List. These charges apply for samples where:

3.3.1. A sample has been rejected on receipt

3.3.2. A concession for testing has been requested by the Purchaser following initial rejection on receipt.

3.3.3. A sample has been tested on a concession, requested by the purchaser, but subsequently rejected by IBGRL during the testing process

3.4. When the Purchaser requires Services they will provide a request form to NHSBT for each sample to be analysed. See **'provision of correct request forms'** under part 2, point 2.1 of this schedule. Samples must be accompanied by the appropriate **signed** and completed request form (FRM4674, FRM4738, FRM4739, FRM1597) as outlined in the department user guide, INF1135. Each request form has a guide for completion of the form (INF1341, INF1342, INF1343, INF417) available at http://ibgrl.blood.co.uk/. Request forms are the basis of the correct identification of the patient. The points of identification provided on the request form must match the information provided on the sample. IBGRL will not accept referrals with an inadequate request form or sample labelling.

Minimum patient identification: (Surname and first name are one identifier)

- Surname,
- Forename or forenames in full,
- Date of birth,

- Hospital number, or other unique identifier (the same number must be on both the tube and the form)
- Date of venepuncture
- Estimated delivery date (by scan) or gestational age (for the appropriate test requests)
- Samples **MUST** be labelled, dated and signed by the person taking the sample.

3.5. The form must also identify the Purchaser / Requester including contact details, the reason for the test and relevant diagnosis. The form must be signed by the Purchaser or person with authority to request the test. The reverse of the request form and / or user guide explains sample labelling requirements, sample volumes and request form completion. This information can be found at http://ibgrl.blood.co.uk/.

3.6. Samples MUST be labelled, dated and signed by the person taking them.

3.7. Labels pre-printed prior to phlebotomy e.g. Addressograph labels are not acceptable on samples. They are, however, acceptable on request forms providing they do not obscure other vital details.

3.7.1. Hand written alterations on either the sample or request form may make the sample unacceptable for testing.

3.7.1.1. Any minor alterations must be initialled by the person taking the sample to be acceptable for testing.

3.7.2. The request form must be completed with clinical information as requested and the expected date of delivery where applicable.

3.8. **Packaging of samples**

3.8.1. It is the responsibility of the Purchaser to ensure that all samples are packaged in accordance with the current European Agreement concerning Carriage of Dangerous Goods by Road Regulations (packaging instructions 650) to prevent breakage or spillage in transit. The outside of the box or package containing the samples must be clearly addressed to the appropriate department.

3.9. **Transport of samples**

3.9.1. The Purchaser is responsible for arranging transport of samples to IBGRL and will pay for the cost of transport.

3.9.2. The outer container must be addressed to:

Molecular Diagnostics

International Blood Group Reference Laboratory

NHS Blood and Transplant

500 North Bristol Park

Northway

Filton

BS34 7QH

UK

3.9.3. The outer container should state

3.9.3.1. The date sent

3.9.3.2. The senders address

3.9.4. The container must be stored and transported at **room temperature**

3.9.5. Samples must reach the laboratory in Filton in time to be processed during laboratory working hours (Monday to Friday 09:00 to 17:00) within set time limits after venepuncture. Sample reception is open at all times but samples must arrive so that they can be processed within the time limits below:

3.9.5.1. Referrals for RhD, RhC, Rhc and RhE: must be processed within 3 days of venepuncture

3.9.5.2. Referrals for Kell: must be processed within 2 days of venepuncture

3.9.5.3. Referrals for Fetal sex: must be processed within 7 days of venepuncture

3.9.5.4. Genotyping of amniotic fluid within 7 days of sampling and CVS DNA within 7 days of sending the sample at room temperature.

3.9.5.5. Blood group genotyping: blood sample should be received within 14 days of sampling, but may be tested up to 3 months of venepuncture depending on sample condition.

3.9.6. Maternal blood samples which would not reach IBGRL in the specified time for testing should be prepared as frozen aliquots of plasma shipped on dry ice. These frozen plasma aliquots must be prepared according to our requirements (INF1291) and IBGRL must receive them still frozen. This information can be found at

http://ibgrl.blood.co.uk/

3.9.7. Samples not of an adequate standard or quality will not be tested and will incur a charge. Please refer to section 2.1 of this schedule for full information.

4. IBGRL responsibilities

4.1. **Testing in accordance with current guidelines and standards:** Samples will be tested in accordance with current published guidelines and standards as given in the IBGRL user guides and documented in the departmental quality manual.

4.2. **The implementation of appropriate Quality Systems as described in the IBGRL user guide**

4.2.1. IBGRL will maintain appropriate laboratory accreditation and will participate in relevant external quality assurance schemes

4.3. **Customer complaints and suggestions**

4.3.1. IBGRL Molecular Diagnostics is committed to continuously improving the quality and range of services provided and welcomes any comments or suggestions from users. Please contact the Laboratory Manager or Head of Department in the first instance regarding complaints and suggestions. Complaints are managed via our Quality Management system or Customer Services as appropriate. We always strive to provide a satisfactory response to any complaint. In the unlikely event that your complaint is not resolved to your satisfaction please refer to the NHSBT complaints procedure http://hospital.blood.co.uk/customer-services/complaints-compliments-and-feedback/

4.4. **IBGRL reporting and test turnaround times**

4.4.1. The turnaround time for samples is based on those stages of the process which the department can control and measure, i.e. from the date of receipt of sample at IBGRL Molecular Diagnostics to the date of authorisation of the report.

4.5. **Turnaround times** will depend on the complexity of the test required. IBGRL normally issues 85% of reports within the following times:

4.5.1. Fetal genotyping tests within 7 business days

4.5.2. Fetal sex typing within 5 business days

4.5.3. Genotyping of amniotic fluid and chorionic villus samples within 10 business days

4.5.4. Standard and extended patient genotyping within 10 business days

4.5.5. Standard patient genotyping requests can be performed within 48 hours of arrival at IBGRL, if required, for an added premium, provided that the sample is received by mid-day Monday to Friday before testing is required.

4.5.6. Urgent reports can be sent by facsimile or email

4.5.7. The Purchaser will be notified by email or telephone if a significant delay in reporting the test result is anticipated.

5. **Limitations of testing (see user guide for details):**

5.1 **Blood group genotyping:** The molecular biology of blood groups, and particularly of the Rh system, is complex and genetic differences may be found in ethnic groups. It remains a possibility that on very rare occasions genotyping results may not correspond to serological phenotype. Clinical decisions should not therefore rest solely on genotyping results. People who have received a transplant following which incomplete engraftment has taken place may exhibit chimerism in their blood cell populations and therefore in their DNA; this may give incorrect genotyping results or prevent a conclusive result being issued. Clinical history of transplantation should be recorded on the request form.

5.2 **Non-Invasive Genotyping**: Please note that we cannot confirm the presence of fetal DNA in a maternal blood sample. There is a possibility that failure to detect the fetal gene of interest may be due to undetectable levels of fetal DNA in the sample and may not indicate that the fetus is negative for that blood group or lacks the Y chromosome.

There is a theoretical possibility that in a very small number of pregnancies we may detect fetal DNA from a fetus that has subsequently been lost as a result of the 'vanishing twin' phenomenon (Landy & Keith, 1998). In addition, due to the complexity of some blood group systems, there remains the possibility that on very rare occasions, genotyping results may not correspond to phenotype by conventional serology.

6. Our requirements of the Purchaser

6.1. In order to ensure the standards of our service are maintained and to aid improvement, we try to monitor the accuracy of our testing procedures. We appreciate receiving information on the infant's blood group or sex after delivery. **If there is a discrepancy between the baby's phenotype at birth and the predicted phenotype or baby's sex please inform the IBGRL laboratory as soon as possible.**

6.2. If samples are referred for fetal genotyping before the recommended gestation, and an antigen negative or female gender result is predicted, the Purchaser should send a repeat sample after the recommended gestational age (and at 28 weeks gestation for Kell genotyping requests). This will reduce the small chance of a false negative genotyping result being undetected during the pregnancy.

7. Service Variation

7.1. Every effort is made to provide diagnostic services as detailed in relevant user information documents such as user guides, service level agreements and technical agreements. However, NHSBT may have to alter the range or specification of services on offer due to technological or scientific advances, or changes in national quality or safety requirements. All changes, which might arise from such circumstances, will be notified in writing to Purchasers or Users in advance.

SCHEDULE 2

PRICE AND PAYMENT

Price List 2018/19

Commercial in Confidence

NHS Blood and Transplant

This Price List is distributed to our customers upon request as its contents are confidential under no circumstances should the Price List be disclosed to any third party without the prior written consent of NHSBT

Molecular Diagnostics

Item Code	Item Description	Price £ 2018/19
E101	Rh D Fetal Genotype	£ 366.40
E102	Rh C Fetal Genotype	£ 366.40
E103	Rh E Fetal Genotype	£ 366.40
E104	Rh c Fetal Genotype	£ 366.40
E105	Rh Fetal Genotype x2	£ 732.80
E106	Rh Fetal Genotype x3	£ 1099.19
E107	Fetal Sex Typing	£ 366.68
E108	Kell (K1) Fetal Genotype	£ 366.40
E109	Kell (K1) Fetal Genotype & Rh Fetal Genotype	£ 732.80
E110	Kell (K1) Fetal Genotype & Rh Fetal Genotype x2	£ 1099.19
E200	IBGRL Full Genotype (Blood)	£ 186.33
E201	IBGRL Rh Genotype	£ 186.33
E202	IBGRL Genotype Extended	£ 291.33
E203	IBGRL Full Genotype (CVS)	£ 186.33
E204	IBGRL Full Genotype (Amnio)	£ 186.33
E300	ABO Genotyping	£ 186.33
E301	ABO Genotyping + Rh	£ 356.92
E302	ABO Genotyping + Full Genotype	£ 356.92
E303	ABO Genotyping + Extended Genotype	£ 461.92
E400	Paternal Zygosity Test	£ 356.92
E500	IBGRL Genotype Sickle (Haemoglobinopathy)	£ 291.33
E700	Urgent IBGRL Full Genotype (Blood)	£ 317.58
E701	Urgent ABO Genotyping	£ 317.58
E800	Sample Rejected at Receipt (Not Tested)	£ 12.00
E801	Sample Rejected in Process	£ 100.00
E802	Sample Rejected at Receipt (Not Tested + paper surcharge)	£ 14.00
E997	IBGRL - No Charge (process failure)	£ 0.00
E998	IBGRL - No Charge (complimentary)	£ 0.00
E999	IBGRL - No Charge	£ 0.00

Foot notes: Additional Charges

1) Urgent Investigation Requirment £125.00

2) Sample Concession £30.00

SCHEDULE 3

ESCALATION PROCEDURE

1 Where settlement of any dispute, difference or question of interpretation arising between the Parties has not been achieved after escalation within NHSBT and the Purchaser to the levels of their respective chief executive officers then the procedure set out in this Schedule 10 shall be followed: .

2 If the Parties in Dispute have agreed upon the identity of an expert and the expert has confirmed in writing their readiness and willingness to embark upon the expert determination, then that person will be appointed as the Expert.

3 Where the Parties in Dispute have not agreed upon an expert, or where that person has not confirmed their willingness to act, then any Party in Dispute may apply to CEDR for the appointment of an expert. The request must be in writing, accompanied by a copy of the Expert Determination Notice and the appropriate fee and must be copied simultaneously to the other Parties in Dispute. The other Parties in Dispute may make representations to CEDR regarding the expertise required in the expert. The person nominated by CEDR will be appointed as the Expert.

4 Once appointed the Expert will act as expert and not as arbitrator so that the provisions of the Arbitration Act 1996 will not apply.

5 The Party in Dispute serving the Expert Determination Notice must send to the Expert and to the other Parties in Dispute within 5 Operational Days of the appointment of the Expert a statement of its case, including a copy of the Expert Determination Notice, these Terms and Conditions, details of the circumstances giving rise to the Dispute, the reasons why it is entitled to the solution sought, and the evidence upon which it relies. The statement of case must be confined to the issues raised in the Expert Determination Notice.

6 The Parties in Dispute not serving the Expert Determination Notice must reply to the Expert and to the other Parties in Dispute within 5 Operational Days of receiving the statement of case, giving details of what is agreed and what is disputed in the statement of case and the reasons why.

7 The Expert must produce a written decision with reasons within 30 Operational Days of receipt of the statement of case referred to in paragraph 5, or any longer period as is agreed by the Parties in Dispute after the Dispute has been referred.

8 The Expert will have complete discretion as to how to conduct the expert determination, and will establish the procedure and timetable.

9 The Parties in Dispute must comply with any request or direction of the Expert in relation to the expert determination.

10 The Expert must decide the matters set out in the Expert Determination Notice, together with any other matters which the Parties in Dispute and the Expert agree are within the scope of the expert determination. The Expert must send their decision in writing simultaneously to all Parties in Dispute. Within 5 Operational Days following the date of the decision the Parties in Dispute must provide the Expert and the other Parties in Dispute with any requests to correct minor clerical errors or ambiguities in the decision. The Expert must correct any minor clerical errors or ambiguities at their discretion within a further 5 Operational Days and send any revised decision simultaneously to the Parties in Dispute.

11 The Parties in Dispute must bear their own costs and expenses incurred in the expert determination and are jointly liable for the costs of the Expert.

12 The decision of the Expert is final and binding, except in the case of fraud, collusion, bias, or material breach of instructions on the part of the Expert, in which case a Party will be permitted to apply to Court for an Order that:

13 the Expert reconsider his decision (either all of it or part of it); or

14 the Expert's decision be set aside (either all of it or part of it).

15 If a Party in Dispute does not abide by the Expert's decision the other Parties in Dispute may apply to Court to enforce it.

16 All information, whether oral, in writing or otherwise, arising out of or in connection with the expert determination will be inadmissible as evidence in any current or subsequent litigation or other proceedings whatsoever, with the exception of any information which would in any event have been admissible or disclosable in any such proceedings.

17 The Expert is not liable for anything done or omitted in the discharge or purported discharge of their functions, except in the case of fraud or bad faith, collusion, bias, or material breach of instructions on the part of the Expert.

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The Expert is appointed to determine the Dispute or Disputes between the Parties in Dispute and the Expert's decision may not be relied upon by third parties, to whom the Expert shall have no duty of care.

The Parties will treat as confidential, in accordance with the provisions of these Terms and Conditions, any information obtained in relation to the reference and the assessments and recommendations resulting from it.

SCHEDULE 4
CONFIDENTIALITY UNDERTAKING

Example of letter to be signed by the party undertaking an inspection under these Terms and Conditions, from Representative carrying out inspection or audit pursuant to the provisions of these Terms and Conditions.

Dear Sirs

In this letter "Confidential Information" means all information of a confidential or proprietary nature relating to your finances, business, patients and affairs that may be disclosed to me by you whilst I am carrying out an inspection pursuant to the Terms and Conditions between ourselves. [.....]

I confirm that I will not disclose or use any Confidential Information otherwise than for the purposes of that inspection or as required by law. I will be free to disclose the same to NHS Blood and Transplant and to [……..]

This undertaking will not extend to Confidential Information which:

1. has ceased to be secret;
2. was already in my possession of both Parties prior to disclosure; or
3. has been received from a third party who did not acquire it in confidence; or
4. Disclosure is required by any competent authority or court having jurisdiction.

Yours faithfully,

[**insert name of Representative**]

SCHEDULE 5

VARIATIONS

Terms and Conditions Variation Notice

1	**Date of issue**	
2	**Issued by:** **Individual:** **Organisation:**	
3	**Details of Variation**	
4a	**Activity Type**	
4b	**Speciality**	
5	**Activity, Quantity**	
6	**Total Value**	
7	**Implementation Timeframe**	
8	**Impact on other aspects of the Terms and Conditions**	
9	**Background Information**	
10	**Basis for Terms and Conditions Variation**	
11	**Discussion Forum**	