MODEL AGREEMENT FOR COLLABORATIVE COMMERCIAL CLINICAL RESEARCH CONDUCTED BY COMPANIES IN THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES, UNIVERSITIES AND NHS ORGANISATIONS

[Name of Clinical Research Collaboration]

This Agreement dated [insert date]

is between

[insert name of NHS Organisation] of [insert address]
(Hereinafter known as the "NHS Organisation")

AND

[….insert name of the company….], of [….insert address….]

(Hereinafter known as the "Company")

AND

[....Insert name of the University....], of [..... Insert address....]

(Hereinafter known as the "University")

NOW

WHEREAS the Company is a company involved in the research, development, manufacture and sale of medicines for use in humans

WHEREAS the Company is developing new treatments and therapies in the field of [….insert field….]

WHEREAS the NHS Organisation is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare

WHEREAS the NHS Organisation has a particular interest and expertise in [….insert area of expertise….]

WHEREAS the University is a corporate body and an exempt charity engaged in teaching and research

WHEREAS the Company, University and NHS Organisation wish to engage in the Clinical Research Collaboration entitled:
" […… insert title of research collaboration ……] "

It is agreed that the NHS Organisation, University and Company wish to participate in the aforementioned Clinical Research Collaboration in accordance with this Agreement.

1. DEFINITIONS

1.1 The following words and phrases have the following meanings:

"Academic Partners" means the University and NHS Organisation.

"Affiliate" means any business entity which controls, is controlled by, or is under the common control with the Company. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

"Agent" shall include, but shall not be limited to, any person providing services to a Party under a contract for services or otherwise.

"Agreement" means this agreement comprising its clauses and schedules and appendices attached to it.

"Auditor" means a person who is authorised to carry out a systematic review and independent examination of Clinical Trial-related activities and documents to determine whether the evaluated Clinical Trial-related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, ICH GCP and the applicable regulatory requirements.

"Background" means Intellectual Property Rights and Know How that is provided by one Party to any other Party or Parties for use in the Clinical Research Collaboration (whether before or after the date of this Agreement), including, without limitation, [list any specific patents to be used in the Clinical Research Collaboration] and excepting any Result.

"Clinical Research Collaboration" means the programme of research to be undertaken by the Parties in accordance with the Collaboration Plan, as amended from time to time in accordance with Clause 14.

"Clinical Trial" means an investigation (including clinical trials and other well-designed studies) involving human subjects to be conducted at the Trial Site in connection with the Clinical Research Collaboration.

"Clinical Trial Authorisation" means a clinical trial authorised in accordance with Part 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

"Clinical Trial Subject" means a person recruited to participate in a Clinical Trial.

"Collaboration Plan" means the description, annexed to this Agreement as Appendix 1, of the work to be undertaken by the Parties in the Clinical Research Collaboration.

"Confidential Information" means any and all information, data and material of any nature belonging to or licensed to Parties or Company's Affiliates which another Party may receive or obtain in connection with this Agreement which is Personal Data or Sensitive Personal Data (as both terms are defined in the Data Protection Act 1998) which relates to any patient of the NHS Organisation or his or her treatment or medical history, or other information, the release of which is likely to prejudice the interests of the Parties, or which is a trade secret, including without limitation, Know How and Background.

"Data" means all work, reports, writings, ideas, designs, methods, computer software, results of experimentation and testing, laboratory records, clinical data, manufacturing data, and data recorded in any form that are created, developed, written, conceived or made by a Party (whether solely or jointly with others) in the course of the Clinical Research Collaboration or the performance of their obligations under this Agreement, including, without limitation, all case report forms, source documents and clinical and other information generated as a result of the Clinical Trial.

"Effective Date" means [the Agreement date] [the date on which the last Party signs this Agreement] [.....insert date when it is intended that this Agreement comes/came into effect.....].

"Field" means [….insert field as per 2nd recital….].

"Good Data Management Practices" means the practices and procedures set out in Appendix 7.

"Guidelines" means any anti-bribery and prevention of corruption principles and guidelines of the Company as detailed in Appendix 8.

"ICH GCP" means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive.

"IND" means the Investigational New Drug application process by which the United States Food and Drug Administration exempts pharmaceutical companies from the Federal statute that prohibits an unapproved drug from being shipped in interstate commerce.

"Inspector" means a person, acting on behalf of a Regulatory Authority, who conducts an official review of documents, facilities, records and any other resources that are deemed by the Regulatory Authority to be related to a Clinical Trial and that may be located at a Trial Site.

"Intellectual Property Rights" means patents, trade marks, trade names, service marks, domain names copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.

"Investigational Medicinal Product" means the study drug or control material as defined in the Protocol.

"Investigator" means [...insert name...], the person(s) who will take primary responsibility for the conduct of the Clinical Research Collaboration and any associated Clinical Trial at a Trial Site on behalf of the [NHS Organisation] [University] [Company] or any other person(s) as may be agreed from time to time between the Parties as replacement.

"Joint Position" means the 'Joint Position on the Disclosure of Clinical Trial Information Via Clinical Trial Registries and Databases' agreed by the innovative pharmaceutical industry and published by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in November 2008.

"Know How" means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to Regulatory Authorities, whether or not protected by Intellectual Property Rights or any applications for such rights.

"Licensing Authority" means the licensing authority within the meaning of section 6 of the Medicines Act 1968 (c.67).

"Party" means the Company, the University or the NHS Organisation and "Parties" shall mean all of them.

"Protocol" means the description of a Clinical Trial signed by the Investigator that has received a favourable opinion from the relevant research ethics committee and amendments agreed by the Steering Committee in writing which have been signed by the Investigator.

"Regulatory Authority" includes, but is not limited to, the Medicines and Healthcare products Regulatory Agency, the U.S. Food and Drug Administration, the European Medicines Agency and the General Medical Council.

"Results" means all Data including, without limitation, any reports generated thereto under this Agreement, Know How, patentable inventions and other Intellectual Property Rights generated, identified or first reduced to practice or writing in the course of the Clinical Research Collaboration.

"Sponsor" means the Party or Parties, named in the Collaboration Plan, sponsoring any Clinical Trial under the Medicines for Human Use (Clinical Trial) Regulations 2004 or the relevant Research Governance Framework.

"Staff" means all scientific and technical staff who are employees, students, officers, contractors, independent consultants, visiting researchers or otherwise of a Party and who participate in the Clinical Research Collaboration, including [....insert name of Investigator and any other relevant staff.....].

"Steering Committee" means the individuals nominated by each of the Parties in accordance with Clause 2 to supervise the conduct of the Clinical Research Collaboration.

"Study Samples" means biological and/or physical samples and materials that may be collected by any of the Parties in the course of the Study from Clinical Trial Subjects including blood samples and any DNA derived from such blood samples.

"Territory" means [worldwide] [*…insert geographical area…*].

"Timelines" means the dates set out in the Collaboration Plan hereto as may be amended by agreement between the Parties and Timeline shall mean any one of such dates.

"Trial Monitor" means one or more persons appointed to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

"Trial Site(s)" means any premises approved by the Parties in which a Clinical Trial will be conducted.

"Trial Site Staff" means the persons who will conduct the Clinical Research Collaboration at the Trial Site on behalf of the Parties under the supervision of the Investigator.

1.2 Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

1.3 The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.

1.4 Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.

2. MANAGEMENT ARRANGEMENTS

2.1 There will be a Steering Committee made up of […insert number…] representatives from the Company and […insert number…] representatives from each of the Academic Partners. The Investigator will be a representative of one of the Academic Partners on the Steering Committee. The Steering Committee's terms of reference are to supervise the conduct of the Clinical Research Collaboration and, where necessary, to establish a data safety and monitoring committee to advise the Steering Committee. The Steering Committee has no authority to amend the terms of this Agreement.

2.2 Any member of the Steering Committee may participate in meetings of the Steering Committee in person, by tele-conference, video-conference or any other technology that enables everyone participating in the meeting to communicate interactively and simultaneously with each other. The quorum for a meeting of the Steering Committee will be one representative of each of the Parties, or his alternate, present in person or by tele-conference, video-conference or other technology mentioned above.

2.3 […insert name…](if present at a meeting) or, in his absence, any other individual the members of the Steering Committee may from time to time agree, will chair meetings of the Steering Committee.

2.4 The Parties will ensure that the Steering Committee meets at least every [3] months at venues to be agreed, and in default of agreement at [insert location], or at any other time at the request of any of the Parties. Meetings of the Steering Committee will be convened with at least twenty-one (21) days written notice in advance. That notice must include an agenda. Minutes of the meetings of the Steering Committee will be prepared by the chair of the meeting and sent to each of the Parties within 14 days after each meeting.

2.5 The Steering Committee shall have access to all Data subject to any applicable restrictions relating to patient confidentiality or the integrity of the Clinical Trial. A copy of each report will be circulated to each member of the Steering Committee with the written notice for the relevant meeting.

2.6 Each member of the Steering Committee or his alternate shall have one vote in the Steering Committee. Decisions will be taken by [a simple majority except where a decision necessitates change to the Collaboration Plan in which case any decision must be unanimous. The chairman will [not] have a casting vote.][a unanimous vote][a simple majority where the member(s) representing the [Company] [NHS Organisation] University][Academic Partners] voted with the majority]. If the Steering Committee is unable to reach a decision in two consecutive meetings the Steering Committee shall refer the relevant matter to an appropriate senior representative of each Party who will negotiate with each other in good faith to take a decision that shall be adopted by the Steering Committee.

2.7 Although the Parties will use reasonable endeavours to carry out the Clinical Research Collaboration in accordance with Appendix 1, they acknowledge and agree that the research may not lead to any particular result, nor is a successful outcome to the Clinical Research Collaboration guaranteed.

2.8 Each of the Parties warrants to the other that it has full power and authority under its constitution, and has taken all necessary actions and obtained all authorisations, licences, consents and approvals, to allow it to enter into this Agreement.

3. CLINICAL TRIAL GOVERNANCE

3.1 The Sponsor of any Clinical Trial shall inform the other Parties and the Investigator of the name and telephone number of a Trial Monitor and the name of the person who will be available as a point of contact. The Sponsor shall also provide the Investigator with an emergency telephone number to enable adverse event reporting at any time.

3.2 All Parties shall comply with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of the country in which a Trial Site is located including but not limited to, the Human Rights Act 1998, the Data Protection Act 1998, the Human Tissue Act 2004, the Medicines Act 1968, the Medicines for Human Use (Clinical Trial) Regulations 2004, and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, the ICH GCP**,** the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects', the relevant NHS Research Governance Framework, MRC Guidelines entitled “Human Tissue and Biological Samples for use in Research”. In addition, where the Clinical Trial is conducted as part of an IND, the Academic Partners will comply with any other relevant requirements notified in writing by the Company to them.

3.3 A Company acting as Sponsor of any Clinical Trial shall comply with all compensation guidelines from time to time in force and published by The Association of the British Pharmaceutical Industry (“ABPI”).

3.4 Each Party shall ensure that its Staff complete accurate records of all research, development and other work carried out in connection with the Clinical Research Collaboration and of all Results and observations, signed by the people who obtained each Result and shall comply with Good Data Management Practices as set out in Appendix 7.

3.5 The Parties agree to comply at all times with any applicable laws and regulations relating to anti-bribery and corruption including the Bribery Act 2010 and any other applicable laws and regulations of the country in which a Trial Site is located.

3.6 Each Academic Partner agrees to perform its obligations under this Agreement in accordance with any Guidelines (Appendix 8) for prevention of corruption notified by the Company and agreed by each Academic Partner.

3.7 If a Party or any of its Staff, Agents or sub-contractors, or any person acting on its behalf, commits any offence under the Bribery Act 2010, in relation to this Agreement or any Clinical Trial, or any other agreement between the Company and NHS Organisation or University, the Company shall be entitled if the Party was a NHS Organisation or University and the NHS Organisation or University shall be entitled if the Party was the Company, acting reasonably, in addition to any other remedy available, to terminate this Agreement with immediate effect, taking into consideration the potential effects of termination on the health of Clinical Trial Subjects.

3.8 Should there be any inconsistency between a Protocol and the other terms of this Agreement, or any other document incorporated therein, including any standard operating procedures of a Party, the terms of the Protocol shall prevail to the extent of such inconsistency except insofar as the inconsistency relates to Clauses 5, 6, 8, and/or 9 of this Agreement.

4. OBLIGATIONS OF THE PARTIES AND THE INVESTIGATOR

4.1 Each of the Parties will use reasonable endeavours to carry out the tasks allotted to it in the Collaboration Plan set out in Appendix 1 and in the Timelines (Appendix 2), and will provide the Background, Staff, materials, facilities and equipment that are designated as its responsibility in Appendix 1. The Clinical Research Collaboration will be carried on under the direction and supervision of the Investigator specified in Clause 1.1 and 4.2. For each Clinical Trial the Parties will allocate responsibilities as set out in Appendix 3.

4.2 The [Company][NHS Organisation][University] represent that they are entitled to procure the services of […insert name(s) of Investigator…] to act as Investigator and shall ensure the performance of the obligations of the Investigator set out in Appendix 1 and Appendix 4 and elsewhere in this Agreement.

4.3 The [Company] [NHS Organisation] [University] represent that the Investigator(s) holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Research Collaboration and will ensure that the Investigator is made aware of and acknowledges the obligations applicable to the Investigator set out in Appendix 4 and elsewhere in this Agreement.

4.4 The Party identified in Appendix 3 as applicable Sponsor shall [procure that the Investigator shall] obtain and maintain all Clinical Trial Authorisations (if required) and favourable opinions from the relevant research ethics committee for the conduct of any Clinical Trial.

4.5 The Investigator shall keep the other Parties fully apprised of the progress of the Licensing Authority and ethics committee submissions and shall upon request provide the [Sponsor] [Steering Committee] with all correspondence relating to such submissions.

4.6 The Party identified in Appendix 3 shall be responsible for preparing the Protocol in accordance with the Collaboration Plan and shall obtain the approval for the Protocol from each of the Parties before submission to any ethics committee. That Party shall not consent to any change in the Protocol requested by a relevant ethics committee without the prior written consent of each of the Parties.

4.7 The Sponsor of a Clinical Trial shall submit required information for listing in a free, publicly accessible clinical trial registry within 21 days of initiation of patient enrolment, in accordance with the principles set out in the Joint Position.

4.8 Except as expressly provided by this Agreement, the Academic Partners shall not register either the Clinical Trial, or the Results, on any publicly accessible clinical trial registry.

4.9 The Sponsor of any Clinical Trial shall ensure that, in consultation with the other Parties, the results of any Clinical Trial will be published on a free, publicly accessible clinical trial results database in accordance with the principles of the Joint Position. In respect of a Clinical Trial that is under review by peer-reviewed journals that prohibit disclosure of results pre-publication, the results will be posted at the time of publication. The Investigator shall give consent to the disclosure of the Investigator's name. The Academic Partners agree that the Company is permitted to post Clinical Trial Results on the Company's publicly available Clinical Data Registry System (if any exist).

4.10 The Parties shall conduct the Clinical Research Collaboration including any Clinical Trial in accordance with:

4.10.1 The Collaboration Plan;

4.10.2 any Protocols;

4.10.3 the current marketing authorisation for the Investigational Medicinal Product or, as the case may be, the Clinical Trial Authorisation granted by the relevant Licensing Authority; and

4.10.4 the terms and conditions of the favourable opinion of any research ethics committee.

4.11 Until all required documentation from the Regulatory Authority and a favourable opinion from the relevant research ethics committee have been obtained, the Company shall not be entitled to supply the Investigational Medicinal Product to the other Parties for use in a Clinical Trial. The Investigator shall ensure that neither administration of the Investigational Medicinal Product to any Clinical Trial Subject nor any other clinical intervention mandated by a Protocol takes place in relation to any Clinical Trial Subject until the Academic Partners are satisfied that all relevant regulatory approvals and a favourable opinion from the research ethics committee have been obtained.

4.12 The Investigator(s) shall make any necessary disclosures of financial interests and arrangements as specified by the Company in connection with regulatory requirements and for the purposes of these obligations the Company shall advise the Investigator in writing of the completion date of each Clinical Trial and the Clinical Research Collaboration.

4.13 No Party shall permit any Investigational Medicinal Product supplied under this Agreement to be used for any purpose other than the conduct of a Clinical Trial and upon termination or expiration of this Agreement all unused Investigational Medicinal Product shall, at the [Company's] [supplier's] option, either be returned to the Company or disposed of in accordance with the Protocol or the [Company's] [supplier's] written instructions.

4.14 The following provisions relate to access, research misconduct and Regulatory Authorities:

4.14.1 The NHS Organisation and University shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice. Such monitoring or auditing may take such form as the Parties reasonably agree appropriate including the right to inspect any facility or systems to be or being used for the conduct of the Clinical Trial and to examine any procedures or records relating to the Clinical Trial, in accordance with the provisions of Clause 6.2 of this Agreement.

4.14.2 In the event that any Party reasonably believes there has been any research misconduct in relation to the Clinical Research Collaboration, the Investigator(s) shall provide all reasonable assistance to any investigation undertaken by or on behalf of the Parties and all Parties shall provide all reasonable assistance to any investigation. The results of any investigation shall, subject to any obligations of confidentiality, be communicated to all Parties.

4.14.3 The NHS Organisation or University shall promptly inform the other Parties of any intended or actual inspection, written enquiry and/or visit to the Trial Site by any Regulatory Authority in connection with any Clinical Trial and communicate to the other Parties copies of any correspondence from any Regulatory Authority relating to the Clinical Trial. When the Company is the Sponsor, the NHS Organisation or University will use reasonable endeavours to procure that the Company may have a representative present during any such visit.

4.14.4 The Academic Partners will permit the Company to examine the conduct of the Clinical Trial and the Trial Site upon reasonable advance notice during regular business hours to determine that the Clinical Trial is being conducted in accordance with the Protocol, ICH GCP and the applicable regulatory requirements.

4.15 Upon completion of a Clinical Trial (whether prematurely or otherwise), the Sponsor of the Clinical Trial shall produce a report of the Clinical Trial and the employer of the Investigator shall procure that the Investigator co-operate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions. Each such report will be provided by the Sponsor to the Steering Committee within […insert number…] days of completion of the Clinical Trial as defined in the Protocol (whether prematurely or otherwise) in such format as the Steering Committee reasonably requests.

4.16 After Results become available to a Sponsor of a Clinical Trial or the Investigator [the Steering Committee] [a Party] may request the Sponsor to provide certain Results and Sponsor will provide such Results, suitably anonymised, to the [Steering Committee] [Party] in such a format as is reasonably requested within [14] days.

4.17 Any relevant Party shall ensure that any Study Samples required to be tested by it during the course of any Clinical Trial are tested by it in accordance with the Protocol, in compliance with relevant standards and at a laboratory approved by the Parties.

4.18 All Study Samples shall remain under the custodianship of the collecting Party, unless otherwise provided in the Protocol, and provided that the Study Samples shall be made accessible in accordance with the Protocol and the Human Tissue Act 2004.

4.19 Subject to the NHS Organisation's and the Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care, neither the NHS Organisation nor the Investigator nor Trial Site Staff shall during the term of this Agreement conduct any other studies or clinical trials which are likely to hinder performance of the Clinical Research Collaboration.

5. LIABILITIES AND INDEMNITY

5.1

5.1.1 If the Company is a Sponsor, and in the event of any claim or proceeding in respect of personal injury being made or brought against a Party that is not the Sponsor of a Clinical Trial by a Clinical Trial Subject participating in the Clinical Trial, the Sponsor shall indemnify the Party and its Staff in accordance with the terms of the indemnity set out in Appendix 5.

5.1.2 If the NHS Organisation is a Sponsor, and in the event of any claim or proceeding in respect of personal injury being made or brought against a Party that is not the Sponsor of a Clinical Trial by a Clinical Trial Subject participating in the Clinical Trial, the Sponsor shall indemnify that Party and its Staff against any claims, proceedings and related costs, expenses, losses and damages arising from the Sponsor's negligent performance of the management, design or conduct of the Clinical Trial or of the Sponsor's obligations set out in Appendix 3, save to the extent that they were caused, or contributed to, by the negligence, wrongful acts, omissions, or breach of statutory duty of the indemnified Party or its Staff.

5.1.3 If the University is a Sponsor, and in the event of any claim or proceeding in respect of personal injury being made or brought against a Party that is not the Sponsor of a Clinical Trial by a Clinical Trial Subject participating in the Clinical Trial, the Sponsor shall indemnify that Party and its Staff against any claims, proceedings and related costs, expenses, losses and damages arising from the Sponsor's negligent performance of the management, design or conduct of the Clinical Trial or of the Sponsor's obligations set out in Appendix 3, save to the extent that they were caused, or contributed to, by the negligence, wrongful acts, omissions, or breach of statutory duty of the indemnified Party or its Staff.

5.2 If the NHS Organisation is Sponsor of a Clinical Trial, any support provided under the Clinical Research Collaboration to the NHS Organisation in connection with the Clinical Trial does not relieve the NHS Organisation of any obligation to compensate a Clinical Trial Subject in the event of any claim or proceeding in respect of personal injury caused by the negligence of the NHS Organisation in the management, conduct or design of the Clinical Trial. The other Parties will not be obliged to make any arrangements for no-fault compensation of such Clinical Trial Subject under this Agreement. The NHS Organisation acknowledges and agrees that it has a duty of care to the Clinical Trial Subjects it treats and will remain liable for clinical negligence.

5.3 The Parties have agreed that they have clearly defined and documented their roles and responsibilities under any Clinical Trial in the "Division of Responsibilities" document as set out in Appendix 3 and therefore the Parties' respective liabilities under any Clinical Trial shall be in accordance with their designated responsibilities contained therein.

5.4 The Party responsible for the manufacture of the Investigational Medicinal Product shall indemnify and hold harmless the other Parties against any claim or proceeding brought by a Clinical Trial Subject in respect of personal injury arising from that Party's failure to ensure manufacture of the Investigational Medicinal Product in accordance with Good Manufacturing Practice, save to the extent that such failure was caused, or contributed to, by the negligence, wrongful acts, omissions, or breach of statutory duty of the indemnified Party or its Staff.

5.5 Nothing in this Clause 5 shall operate so as to restrict or exclude the liability of any Party under Clause 5.1 or 5.2 or in relation to death or personal injury caused by the negligence of that Party or its Staff or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

5.6 Nothing in this Clause 5 shall operate as a waiver by the University of the right to claim that its Staff should receive cover under the relevant Indemnity Scheme (in England the Clinical Negligence Scheme for Trusts; in Scotland the Clinical Negligence and Other Risks Indemnity Scheme; in Wales the Welsh Risk Pool and in Northern Ireland, the Clinical Negligence Fund) where its Staff are carrying out clinical duties in any Clinical Trial.

5.7 Each Party's agreement to indemnify and hold the other harmless is conditional on the indemnified Party:

5.7.1 providing written notice to the indemnifying Party of any claim, demand, cause of action or suit arising out of the indemnified activities within thirty (30) days after the indemnifying Party has knowledge of such claim, demand or action;

5.7.2 permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim, demand, causes of action or suit;

5.7.3 assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defence of any such claim, demand, causes of action or suit; and

5.7.4 not compromising or settling such claim, demand, causes of action or suit without the indemnifying Party's prior written approval. In turn, the indemnifying Party will not make any settlement which adversely affects in a material manner the reputation of an indemnified Party without such indemnified Party's prior approval, which approval shall not be unreasonably withheld or delayed.

5.8 In no circumstances shall any Party be liable to another Party in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of any other Party.

5.9 Subject to Clause 5.1, 5.3 and 5.5, a Party's liabilities to the other Parties arising out of or in connection with any breach of this Agreement or any act or omission in connection with the performance of the Clinical Research Collaboration shall in no event exceed [….insert amount…]. In the case of equipment loaned to the Academic Partners for the purposes of the Clinical Research Collaboration, the Academic Partners' liabilities arising from their negligence shall exclude fair wear and tear and shall not exceed the value of the equipment. The cap mentioned in this Clause will not apply in the event of wilful misconduct or fraud.

5.10 The Sponsor of any Clinical Trial carried out in connection with the Clinical Research Collaboration will take out appropriate insurance cover or will provide an indemnity satisfactory to the other Parties in respect of its potential liability. The Sponsor shall produce to the other Parties, on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect, or other evidence concerning the indemnity. The terms of any insurance or the amount of cover shall not relieve the Sponsor of any liabilities under this Agreement.

6. CONFIDENTIALITY, DATA PROTECTION AND FREEDOM OF INFORMATION

6.1 Medical Confidentiality, Data Protection and Freedom of Information

The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects involved in any Clinical Trial. Personal data (as defined in the Data Protection Act 1998) shall not be disclosed to the Company or University by the NHS Organisation save where this is required to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by a Clinical Trial Subject in connection with any Clinical Trial. The Company and University shall not disclose the identity of Clinical Trial Subjects to third parties without prior written consent of the Clinical Trial Subject, except in accordance with the provisions of the Data Protection Act 1998 and the principles set out in the NHS Confidentiality Code of Practice (November 2003), unless in relation to a claim or proceeding brought by the Clinical Trial Subject in connection with any Clinical Trial carried out in connection with the Clinical Research Collaboration.

6.2 Each Party shall comply with the Data Protection Act 1998 ("the 1998 Act") and any other applicable data protection legislation. In particular where any Party is acting as the data processor of another Party ("data controller"), the Party processing data on behalf of the data controller agrees to comply with the obligations placed on the data controller by the seventh data protection principle ("the Seventh Principle") set out in the 1998 Act, namely:

6.2.1 to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the data controller by the Seventh Principle;

6.2.2 only to process Personal Data for and on behalf of the data controller, in accordance with the instructions of the data controller and for the purpose of any Clinical Trial carried out in connection with the Clinical Research Collaboration and to ensure the data controller's compliance with the 1998 Act;

6.2.3 to allow the data controller to audit the processing Party's compliance with the requirements of this clause on reasonable notice and/or to provide the data controller with evidence of its compliance with the obligations set out in this Clause 6.2.

6.2.4 the processing Party shall obtain prior agreement of the data controller to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

6.2.5 all Parties agree to use all reasonable efforts to assist each other to comply with the 1998 Act. For the avoidance of doubt, this includes providing the other with reasonable assistance in complying with subject access requests served under Section 7 of the 1998 Act and consulting with the others prior to the disclosure of any Personal Data created in connection with the conduct or performance of any Clinical Trial carried out in connection with the Clinical Research Collaboration in relation to such requests.

6.3 **Freedom of Information**

The Company acknowledges that the Academic Partners are subject to the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002 ("FOIA") and the Codes of Practice issued under the FOIA as may be amended, updated or replaced from time to time.

6.3.1 If either Academic Partner receives a request under the FOIA to disclose any information that belongs to the other Academic Partner or the Company or its Affiliates, it will notify the other Party in accordance with Clause 16 as soon as is reasonably practicable, in any event, not later than five (5) working days after receiving the request and will consult with the other Party in accordance with all applicable guidance.

6.3.2 The Parties acknowledge and agree that:

(a) subject to Clause 6.3.2(b), the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA is a decision solely for the requested Academic Partner;

(b) where the Academic Partner is managing a request as referred to in Clause 6.3.1, the other Party shall co-operate with that Academic Partner and shall use its reasonable endeavours to respond within ten (10) working days of that Academic Partner's request for assistance in determining whether or not an exemption to the FOIA applies.

6.3.3 Where the Academic Partner determines that it will disclose the Confidential Information, notwithstanding any objections from the other Party, it will notify that other Party in writing, giving at least two (2) working days notice of its intended disclosure.

6.4 **Confidential Information**

6.4.1 Each Party shall ensure that only those of its Staff (and in the case of the Company those of its Affiliates) directly concerned with the carrying out of this Agreement have access to the Confidential Information of the other Parties. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance with the FOIA, in accordance with Clauses 6.3, 6.3.1 and 6.3.2 above). The Party required to make the disclosure shall inform the other within a reasonable time prior to being required to make the disclosure (and, where appropriate in accordance with Clause 6.3.1), of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party, other than in accordance with this Agreement, without the prior written consent of the other Party.

6.4.2 The obligations of confidentiality set out in this Clause 6.4 shall not apply to Confidential Information which is (i) published or becomes generally available to the public other than as a result of a breach of the undertakings hereunder by the receiving Party, (ii) in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality, (iii) independently developed by the receiving Party and is not subject to a duty of confidentiality, (iv) obtained by the receiving Party from a third party not subject to a duty of confidentiality.

6.4.3 In the event of a Party visiting the establishment of another Party, the visiting Party undertakes that any further Confidential Information which may come to the visiting Party's knowledge as a result of any such visit shall be treated as Confidential Information in accordance with this sub-Clause 6.4.

6.4.4 This Clause 6 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, this Clause 6 shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

7. PUBLICITY

7.1 The Company will not use the names or logos of either Academic Partner, nor of any member of their staffs, in any publicity, advertising or news release without the prior written approval of an authorised representative of the respective Academic Partner, as appropriate, such approval not to be unreasonably withheld. Each Academic Partner will not, and will ensure that its Staff and Agents do not, and the Investigator will not, use the name of the Company, its Affiliates or their respective Staff, nor the name of any Clinical Trial, nor the name of any of the Company's Investigational Medicinal Products, in any publicity, advertising or news release without the prior written approval of the Company, such approval not to be unreasonably withheld.

7.2 No Party will issue any information or statement to the press or public relating to the Clinical Research Collaboration, including but not limited to advertisements for the enrolment of Clinical Trial Subjects, without, where appropriate, its review and the delivery of a favourable opinion by the research ethics committee and the prior written permission of the other Parties.

8. PUBLICATION

8.1 The Company recognises that the Academic Partners have a responsibility under the relevant Research Governance Framework and/or its charitable objectives and/or its obligations to research funders to ensure that results of scientific and/or clinical interest arising from any clinical research are appropriately published and disseminated.

8.2 The Company agrees that Staff of the Academic Partners and the Investigator shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and Results of the Clinical Research Collaboration, subject to this Clause 8.

8.3 The Parties agree that the Steering Committee shall approve a publication policy in connection with the Clinical Research Collaboration which shall be consistent with the Joint Position.

8.4 Upon completion of a Clinical Trial or when the Data from a Clinical Trial are adequate (in each of the Parties' reasonable judgements), any Party and/or the Investigator may prepare the Results of the Clinical Trial for publication in accordance with the Collaboration Plan. If the Results are prepared by the Academic Partners or Investigator, such Results will be submitted to the Company for review and comment prior to publication. In order to ensure that the Company will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Company for review at least sixty (60) days (or the time limit specified in the Protocol if longer), or thirty (30) days in the case of conference abstracts, prior to submission for publication, public dissemination, or review by a publication committee.

8.5 Each Academic Partner and the Investigator agree that all reasonable comments made by the Company in relation to a proposed publication by either the Academic Partner and/or the Investigator will be incorporated by them into the publication.

8.6 The Academic Partners acknowledge that the Company or its Affiliates may present at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise of their own choosing, methods and Results of the Clinical Research Collaboration, subject to this Clause 8.

8.7 During the period for review of a proposed publication by the Academic Partners or Investigator referred to in clause 8.4 above, the Company shall be entitled to make a reasoned request to the Academic Partners or Investigator as the case may be that publication be delayed for a period of up to six (6) months from the date of first submission to the Company in order to enable the Company to take steps to protect its proprietary information and/or Intellectual Property Rights and Know How and neither the Academic Partners nor Investigator as the case may be shall unreasonably withhold its consent to such a request. Neither the Academic Partners nor the Investigator as the case may be shall unreasonably withhold or delay its consent to a request from the Company for an exceptional additional delay if, in the reasonable opinion of the Company, the Company's proprietary information and/or Intellectual Property Rights and Know How might otherwise be compromised or lost.

9. INTELLECTUAL PROPERTY RIGHTS

[Parties may select from Versions 1, 2, 3, 4 or 5 below, for the clauses to follow Clause 9.4]

9.1 Nothing in this clause 9 shall be construed so as to prevent or hinder the NHS Organisation from using Know How gained during the performance of the Clinical Research Collaboration in the furtherance of its normal clinical activities, to the extent such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right of the Company.

9.2 This Agreement does not affect the ownership of any Background or in any other technology, design, work, invention, software, data, technique, Know How, or materials that are not results arising from the Clinical Research Collaboration. The Intellectual Property Rights in them will remain the property of the Party that contributes them to the Clinical Research Collaboration (or its licensors). No licence to use any Intellectual Property Rights is granted or implied by this Agreement except the rights expressly granted in this Agreement.

9.3 Each Party grants the others a royalty-free, non-exclusive licence to use its Background, Results and any Intellectual Property Rights subsisting therein, for the purpose of carrying out the Clinical Research Collaboration, but for no other purpose. No Party may grant any sub-licence to use another's Background except that the Company may allow its Affiliates, and any person working for or on behalf of the Company or any Affiliate, to use the Academic Partners' Background for the purpose of carrying out the Clinical Research Collaboration, but for no other purpose.

9.4 All Parties involved in the Clinical Research Collaboration will notify the other Parties promptly after identifying any Result that it believes is patentable, and will supply the other Parties with copies of that Result.

[Insert here the remainder of clause 9 (9.5 onwards), selected from Versions 1 to 5 that follow:]

[Delete after selecting version to be used

Version 1 - The Academic Partners own IP in the Results and grant the Company a non-exclusive licence to use the Results in a specified Field.]

9.5 The Academic Partners will own the Results and Intellectual Property Rights subsisting in the Results, and may take such steps as they may decide from time to time, and at their own expense, to register and maintain any protection for those Intellectual Property Rights, including filing and prosecuting patent applications for any of the Results. Where any other party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know How, they may have in the Results in order to be able to give effect to the provisions of this Clause 9. The Company will ensure that its Staff involved in the creation of the Results give the Academic Partners such assistance as they may reasonably request in connection with the registration and protection of the Intellectual Property Rights subsisting in the Results, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of that Intellectual Property Right.

9.6 The Academic Partners grant to the Company a non-exclusive, indefinite, [fully paid-up, royalty free][royalty bearing on fair and reasonable terms][royalty bearing with Appendix [9]] licence (with the right to sub-license to any Affiliate and to any person working for, or on behalf of, the Company or any Affiliate, but only for the purpose of carrying out that work, and otherwise without the right to sub-license) to use the Results and Intellectual Property Rights subsisting in any of the Results for any purpose within the Field in the Territory.

9.7 As between the Academic Partners, the Results and any Intellectual Property Rights subsisting therein shall be owned by the Academic Partner that created or generated them or jointly owned if jointly created or generated. Academic Partners jointly owning Results and Intellectual Property Rights subsisting therein shall agree, by separate agreement, which Academic Party shall take the lead on protecting and exploiting the same.

9.8 Each Academic Partner grants the other Academic Partner a non exclusive royalty free licence to use its Results and any Intellectual Property Rights subsisting therein for non-commercial research, clinical patient care and teaching purposes. Further usage rights will be subject to a separate agreement between the relevant Academic Partners.

[Delete after selecting version to be used

Version 2 - The Academic Partners own IP in the Results and grant the Company a non-exclusive licence to use the Results in a specified Field. The Company also has the right to negotiate an exclusive licence or assignment.]

9.5 The Academic Partners will own Results and the Intellectual Property Rights subsisting in the Results and, provided they comply with Clause 9.7.4, may take such steps as they may decide from time to time, and at their own expense, to register and maintain any protection for those Intellectual Property Rights, including filing and prosecuting patent applications for any of the Results. Where any other party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know How, they may have in the Results in order to be able to give effect to the provisions of this Clause 9. The Company will ensure that its Staff involved in the creation of the Results give the Academic Partners such assistance as they may reasonably request in connection with the registration and protection of the Intellectual Property in the Results, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of that Intellectual Property Right.

9.6 The Academic Partners will grant to the Company a non-exclusive, indefinite, [fully paid-up, royalty free][royalty bearing on fair and reasonable terms][royalty bearing with Appendix [9]] licence (with the right to sub-license to any Affiliate and to any person working for, or on behalf of, the Company or any Affiliate, but only for the purpose of carrying out that work, and otherwise without the right to sub-license) to use the Results and Intellectual Property Rights subsisting in any of the Results for any purpose within the Field in the Territory.

9.7 Negotiation of an exclusive license or assignment

9.7.1 The Academic Partners and the Company will, if the Company gives the Academic Partners written notice (an Option Notice) at any time during the period of the Clinical Research Collaboration plus a further [6][12] months, negotiate the terms on which the Academic Partners will grant the Company an exclusive licence (with the right to sub-license) to use certain of the Results and Intellectual Property Rights subsisting in the Results (the Licence) or assignment of certain of the Results and Intellectual Property Rights subsisting in the Results (the Assignment). [The Licence or Assignment may be granted by an Academic Partner's subsidiary company, [XYZ] Limited.]

9.7.2 Following the Academic Partners' receipt of an Option Notice, the Parties will negotiate in good faith, for a period of up to [90 days][6 months] after the date of receipt of the Option Notice (the Negotiation Period) an agreement for the grant of the Licence or Assignment as the case may be. If the Parties are unable to agree the terms of the Licence or Assignment as the case may be within the Negotiation Period, the Company's rights under Clauses 9.7.1, 9.7.3 and 9.7.4 (but not the licence in Clause 9.6) will lapse.

9.7.3 The Academic Partners will not, during the Negotiation Period, negotiate with any third party with a view to granting a licence to use the Results or assigning the Intellectual Property Rights subsisting in the Results nor, during the [3][6][12] months following the end of the Negotiation Period, will the Academic Partners grant a licence of any Result or assign the Intellectual Property Rights subsisting in any Result to any third party on any terms more favourable than those offered to the Company pursuant to this Clause 9.7.

9.7.4 Until the earlier of the end of the Negotiation Period and the granting of the Licence, the Academic Partners will consult with the Company about making patent applications in respect of the Results. If, during the Negotiation Period, the Company wishes the Academic Partners to apply for any patent in relation to any of the Results, the Company will reimburse to the Academic Partners the reasonable costs and expenses incurred by the Academic Partners since the date of this Agreement in relation to the filing and prosecution of that patent application, including (without limitation) patent agents' fees, as a result of any request to apply for, or to maintain, any patent at the Company's request. If the Academic Partners later license or assign to a third party any of the Results for which the Company has paid any such costs and expenses, the Academic Partners will reimburse those costs and expenses to the Company.

9.8 Despite the provisions of Clause 9.7 or the grant of any licence under Clause 9.7, the Academic Partners and their Staff will have the irrevocable, royalty-free right to use the Results for the purposes of academic teaching and academic research and clinical patient care, including (after the Company's rights under Clause 9.7 have lapsed, but not in any other case) non-commercial research sponsored by any third party. The rights in this clause are subject to the rules on Academic Publication in Clause 8.

9.9 As between the Academic Partners, the Results and any Intellectual Property Rights subsisting therein shall be owned by the Academic Partner that created or generated them or jointly owned if jointly created or generated. Academic Partners jointly owning Results and Intellectual Property Rights subsisting therein shall agree, by separate agreement, which Academic Party shall take the lead on protecting and exploiting the same.

9.10 Each Academic Partner grants the other Academic Partner a non exclusive royalty free licence to use its Results and any Intellectual Property Rights subsisting therein for non-commercial research, clinical patient care and teaching purposes. Further usage rights will be subject to a separate agreement between the relevant Academic Partners.

[Delete after selecting version to be used

Version 3 - The Company owns the IP directly related to the IMP alone and the Academic Partners own the remaining IP in the Results. Company grants licence for academic non-commercial research and Academic Partners grant the Company a non-exclusive licence to use the Results in a specified Field. The Company also has the right to negotiate an exclusive licence or assignment.]

9.5 The Company will own the Results and Intellectual Property Rights subsisting in the Results directly related to the Investigational Medicinal Product and/or the use of the pharmaceutical compounds [for the treatment of …insert…] alone and may take such steps as it may decide from time to time, and at its own expense, to register and maintain any protection for such Intellectual Property Rights, including filing and prosecuting patent applications for such Results. Where any third party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know-How, they may have in such Results in order to be able to give effect to the provisions of Clause 9. The Academic Partners will ensure that their Staff involved in the creation of such Results give the Company such assistance as the Company may reasonably request in connection with the registration and protection of the Intellectual Property Rights subsisting in such Results, including filing and prosecuting patent applications for such Results, and taking any action in respect of any alleged or actual infringement of those Intellectual Property Rights.

9.6 The Company grants the Academic Partners a royalty-free, non-exclusive licence to use the Results referred to in Clause 9.5 for the purpose of carrying out the Clinical Research Collaboration, but for no other purpose. The Academic Partners may not grant any sub-licence to use such Results.

9.7 Subject to Clause 9.5, the Academic Partners will own the Results and the Intellectual Property Rights subsisting in the Results and, provided they comply with Clause 9.9.4, may take such steps as they may decide from time to time, and at their own expense, to register and maintain any protection for those Intellectual Property Rights, including filing and prosecuting patent applications for such Results. Where any third party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know How, they may have in the Results in order to be able to give effect to the provisions of Clause 9. The Company will ensure that its Staff involved in the creation of the Results give the Academic Partners such assistance as the Academic Partners may reasonably request in connection with the registration and protection of the Intellectual Property Rights subsisting in the Results, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of those Intellectual Property Rights.

9.8 The Academic Partners grant to the Company a non-exclusive, indefinite, fully paid-up, royalty-free licence (with the right to sub-license to any Affiliate and to any person working for or on behalf of the Company or an Affiliate, but only for the purpose of carrying out that work, and otherwise without the right to sub-license) to use the Results and Intellectual Property Rights subsisting in the Results for any purpose within the Field in the Territory.

9.9 Negotiation of an exclusive license or assignment

9.9.1 The Academic Partners and the Company will, if the Company gives the Academic Partners written notice (an Option Notice) at any time during the term of this Agreement referred to in Clause 11 plus a further [6] [12] months, negotiate the terms on which the Academic Partners will exclusively licence or assign to the Company the Results and Intellectual Property Rights subsisting in certain of the Results referred to in Clause 9.7 .

9.9.2 Following the Academic Partner's receipt of an Option Notice, the Parties will negotiate in good faith, for a period of up to [90 days][6 months] after the date of receipt of the Option Notice (the Negotiation Period) the terms of the exclusive licence or assignment as the case may be. If the Parties are unable to agree the terms of the exclusive licence or assignment as the case may be within the Negotiation Period, the Company's rights under Clauses 9.9.1, 9.9.3 and 9.9.4 (but not the licence in Clause 9.8) will lapse.

9.9.3 The Academic Partners will not, during the Negotiation Period, negotiate with any third party with a view to granting a licence to use the Results or assigning the Intellectual Property Rights subsisting in the Results nor, during the [3][6][12] months following the end of the Negotiation Period, will the Academic Partners grant a licence of any Result or assign the Intellectual Property Rights subsisting in any Result to any third party on any terms more favourable than those offered to the Company pursuant to this Clause 9.9.

9.9.4 Until the earlier of the end of the Negotiation Period and the date of the Assignment, the Academic Partners will consult with the Company about making patent applications in respect of the Results. If, during the Negotiation Period, the Company wishes the Academic Partners to apply for any patent in relation to any of the Results, the Company will reimburse to the Academic Partners the reasonable costs and expenses incurred by the Academic Partners since the date of this Agreement in relation to the filing and prosecution of that patent application, including (without limitation) patent agents' fees, as a result of any request to apply for, or to maintain, any patent at the Company's request. If the Academic Partners later license or assign to a third party any of the Results for which the Company has paid any such costs and expenses, the Academic Partners will reimburse those costs and expenses to the Company.

9.10 Despite the provisions of Clause 9.8 or any exclusive licence or assignment under Clause 9.9, the Academic Partners and their Staff will have the irrevocable, royalty-free right to use the Results for the purposes of academic teaching and academic research and clinical patient care, including (after the Company's rights under Clause 9.9 have lapsed, but not in any other case) non-commercial research sponsored by any third party. The rights in this clause are subject to the rules on Academic Publication in Clause 8.

9.11 Subject to Clause 9.5, and as between the Academic Partners, the Results and any Intellectual Property Rights subsisting therein shall be owned by the Academic Partner that created or generated them or jointly owned if jointly created or generated. Academic Partners jointly owning Results and Intellectual Property Rights subsisting therein shall agree, by separate agreement, which Academic Party shall take the lead on protecting and exploiting the same.

9.12 Each Academic Partner grants the other Academic Partner a non exclusive royalty free licence to use its Results and any Intellectual Property Rights subsisting therein for non-commercial research, clinical patient care and teaching purposes. Further usage rights will be subject to a separate agreement between the relevant Academic Partners.

[Delete after selecting version to be used

Version 4 - The Company owns the IP directly related to the IMP alone and in combination, and the Academic Partners own the remaining IP in the Results. The Company grants licence for academic non-commercial research and the Academic Partners grant the Company a non-exclusive licence to use the Results in a specified Field. The Company also has the right to negotiate an exclusive licence or assignment.]

9.5 The Company will own the Results and Intellectual Property Rights subsisting in the Results directly related to the Investigational Medicinal Product and/or the use of the pharmaceutical compounds [for the treatment of …insert…] alone or in combination with other compounds including biomarkers relating to the use of the Investigational Medicinal Product and may take such steps as it may decide from time to time, and at its own expense, to register and maintain any protection for such Intellectual Property Rights, including filing and prosecuting patent applications for such Results. Where any third party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know-How, they may have in such Results in order to be able to give effect to the provisions of Clause 9. The Academic Partners will ensure that their Staff involved in the creation of such Results give the Company such assistance as the Company may reasonably request in connection with the registration and protection of the Intellectual Property Rights subsisting in such Results, including filing and prosecuting patent applications for such Results, and taking any action in respect of any alleged or actual infringement of those Intellectual Property Rights.

9.6 The Company grants the Academic Partners a royalty-free, non-exclusive licence to use the Results referred to in Clause 9.5 for the purpose of carrying out the Clinical Research Collaboration, but for no other purpose. The Academic Partners may not grant any sub-licence to use such Results.

9.7 Subject to Clause 9.5, the Academic Partners will own the Results and the Intellectual Property Rights subsisting in the Results and, provided they comply with Clause 9.9.4, may take such steps as they may decide from time to time, and at their own expense, to register and maintain any protection for those Intellectual Property Rights, including filing and prosecuting patent applications for such Results. Where any third party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know How, they may have in the Results in order to be able to give effect to the provisions of Clause 9. The Company will ensure that its Staff involved in the creation of the Results give the Academic Partners such assistance as the Academic Partners may reasonably request in connection with the registration and protection of the Intellectual Property Rights subsisting in the Results, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of those Intellectual Property Rights.

9.8 The Academic Partners grant to the Company a non-exclusive, indefinite, fully paid-up, royalty-free licence (with the right to sub-license to any Affiliate and to any person working for or on behalf of the Company and or Affiliate, but only for the purpose of carrying out that work, and otherwise without the right to sub-license) to use the Results and the Intellectual Property Rights subsisting in the Results for any purpose within the Field in the Territory.

9.9 Negotiation of an exclusive license or assignment

9.9.1 The Academic Partners and the Company will, if the Company gives the Academic Partners written notice (an Option Notice) at any time during the term of this Agreement referred to in Clause 11 plus a further [6] [12] months, negotiate the terms on which the Academic Partners will exclusively licence or assign to the Company the Intellectual Property Rights in certain of the Results referred to in Clause 9.7.

9.9.2 Following the Academic Partner's receipt of an Option Notice, the Parties will negotiate in good faith, for a period of up to [90 days][6 months] after the date of receipt of the Option Notice (the Negotiation Period) the terms of the exclusive licence or assignment as the case may be. If the Parties are unable to agree the terms of the exclusive licence or assignment as the case may be within the Negotiation Period, the Company's rights under Clauses 9.9.1, 9.9.3 and 9.9.4 (but not the licence in Clause 9.6) will lapse.

9.9.3 The Academic Partners will not, during the Negotiation Period, negotiate with any third party with a view to granting a licence to use the Results or assigning the Intellectual Property Rights subsisting in the Results nor, during the [3][6][12] months following the end of the Negotiation Period, will the Academic Partners grant a licence of any Result or assign the Intellectual Property Rights subsisting in any Result to any third party on any terms more favourable than those offered to the Company pursuant to this Clause 9.9.

9.9.4 Until the earlier of the end of the Negotiation Period and the date of the Assignment, the Academic Partners will consult with the Company about making patent applications in respect of the Results. If, during the Negotiation Period, the Company wishes the Academic Partners to apply for any patent in relation to any of the Results, the Company will reimburse to the Academic Partners the reasonable costs and expenses incurred by the Academic Partners since the date of this Agreement in relation to the filing and prosecution of that patent application, including (without limitation) patent agents' fees, as a result of any request to apply for, or to maintain, any patent at the Company's request. If the Academic Partners later licenses or assigns to a third party any of the Results for which the Company has paid any such costs and expenses, the Academic Partners will reimburse those costs and expenses to the Company.

9.10 Despite the provisions of Clause 9.9 or any exclusive licence or assignment under Clause 9.9, the Academic Partners and their Staff will have the irrevocable, royalty-free right to use the Results for the purposes of academic teaching and academic research and clinical patient care, including (after the Company's rights under Clause 9.9 have lapsed, but not in any other case) non-commercial research sponsored by any third party. The rights in this clause are subject to the rules on Academic Publication in Clause 8.

9.11 Subject to Clause 9.5, and as between the Academic Partners, the Results and any Intellectual Property Rights subsisting therein shall be owned by the Academic Partner that created or generated them or jointly owned if jointly created or generated. Academic Partners jointly owning Results and Intellectual Property Rights subsisting therein shall agree, by separate agreement, which Academic Party shall take the lead on protecting and exploiting the same.

9.12 Each Academic Partner grants the other Academic Partner a non exclusive royalty free licence to use the Results and any Intellectual Property Rights subsisting therein for non-commercial research, clinical patient care and teaching purposes. Further usage rights will be subject to a separate agreement between the relevant Academic Partners.

[Delete after selecting version to be used

Version 5 - The Company owns IP in the Results and grants the Academic Partners the right to use the Results for academic teaching, academic research and clinical patient care.]

9.5 The Company will own the Results and Intellectual Property Rights subsisting in the Results and may take such steps as it may decide from time to time, and at its own expense, to register and maintain any protection for those Intellectual Property Rights, including filing and prosecuting patent applications for any of the Results. Where any third party such as a student or contractor is involved in the Clinical Research Collaboration, the Party engaging the other party (as the case may be) will ensure that the other party assigns any Intellectual Property Rights, and to the extent possible Know How, they may have in the Results in order to be able to give effect to the provisions of Clause 9. The Academic Partners will ensure that their Staff involved in the creation of the Results give the Company such assistance as the Company may reasonably request in connection with the registration and protection of the Intellectual Property Rights subsisting in the Results, including filing and prosecuting patent applications for any Result, and taking any action in respect of any alleged or actual infringement of those Intellectual Property Rights.

9.6 To the extent that any Intellectual Property Rights, and to the extent possible Know How, subsisting in the Results is capable of prospective assignment, the Academic Partners now assign those Intellectual Property Rights, and to the extent possible Know How, to the Company; and to the extent any Intellectual Property Rights or Know How subsisting in the Results cannot prospectively be assigned, the Academic Partners will assign those Intellectual Property Rights, and to the extent possible Know How, to the Company as and when they are created, at the request of the Company.

9.7 The Company grants the Academic Partners a royalty-free, non-exclusive licence to use the Results for the purpose of carrying out the Clinical Research Collaboration, but for no other purpose. The Academic Partners may not grant any sub-licence to use the Results.

9.8 Despite the assignment or agreement to assign under Clause 9.6, the Academic Partners and their Staff will have the irrevocable, royalty-free right to use the Results for the purposes of academic teaching and academic research and clinical patient care, including non-commercial research sponsored by any third party. The rights in this clause are subject to the rules on Academic Publication in Clause 8.

10. FINANCIAL ARRANGEMENTS

10.1 Arrangements relating to the financing of the Clinical Research Collaboration are set out in Appendix 6.

10.2 All payments will be made according to the schedule contained in Appendix 6 after presentation of a VAT invoice to the Company by the [NHS Organisation] [University].

10.3 Any relevant payment shall be made within [thirty (30)] [forty five (45)] [sixty (60)] days of the date of receipt of the invoice mentioned in Clause 10.2 above.

10.4 Any delay in the payment of invoices by the Company will entitle the Academic Partners to exercise their respective statutory rights to claim interest and compensation for debt recovery costs under legislation regarding late payment of commercial debts.

10.5 The Company shall have no responsibility to provide any further financial reimbursement to the Academic Partners or Investigator over and above that set out in this Agreement.

11. TERM

11.1 The Clinical Research Collaboration [will begin on] [began on] the Effective Date and will continue until […insert date…] or until any later date agreed in writing between the Parties, or until this Agreement is terminated in accordance with Clauses 11 and 12. If this Agreement is entered into after the Effective Date, it will apply retrospectively to work carried out in relation to the Clinical Research Collaboration on or after the Effective Date.

11.2 This Agreement will remain in effect until completion of the Clinical Research Collaboration, completion of the obligations of the Parties under this Agreement or earlier termination in accordance with this Agreement.

12. TERMINATION, WITHDRAWAL AND NEW PARTIES

12.1 If they unanimously agree to do so, the other Parties may treat any Party as having withdrawn from the Clinical Research Collaboration with immediate effect by giving notice to that Party if:

12.1.1 that Party is in breach of any provision of this Agreement (including an obligation to make payment) and (if it is capable of remedy) the breach has not been remedied within [30] [60] [90] days after receipt of written notice specifying the breach and requiring its remedy; or

12.1.2 that Party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of its assets, or if it makes any arrangement with its creditors and in either case that Party will be deemed to have withdrawn from the Clinical Research Collaboration.

12.2 The Investigator will notify the other Parties promptly if at any time the Investigator is unable or unwilling to continue to be involved in the Clinical Research Collaboration. Within [30] [60] days after the date of that notice, the [insert name of Party controlling the Investigator] will nominate a successor. The other Parties will not unreasonably refuse to accept the nominated successor, but if the successor is not acceptable to the other Parties on reasonable grounds, the other Parties may treat that Party as having withdrawn from the Clinical Research Collaboration by giving not less than [3] months' notice.

12.3 Prior to commencement of any Clinical Trial, any Party may withdraw from such Clinical Trial or from the Clinical Research Collaboration by giving to each of the other Parties not less than 3 months' written notice if it is unable or unwilling to continue to be involved in the Clinical Research Collaboration. Once the first patient has been screened for inclusion in any Clinical Trial, then no party may terminate that Clinical Trial other than in accordance with Clauses 12.1 or 12.2 of this Agreement.

12.4 A Sponsor of a Clinical Trial may terminate the Clinical Trial on written notice to the other Parties with immediate effect if, following referral to and discussion with the Steering Committee, it is reasonably of the opinion that the Clinical Trial should cease in the interests of the health of Clinical Trial Subjects involved in the Clinical Trial.

12.5 A Party may terminate this Agreement on written notice to the other Parties with immediate effect if, following referral to and discussion with the Steering Committee, it is reasonably of the opinion that the Clinical Research Collaboration should cease in the interests of the health of Clinical Trial Subjects involved in the Clinical Research Collaboration.

12.6 In the event of early termination of this Agreement by the Company, pursuant to Clause 12.4 and subject to an obligation on the Academic Partners to mitigate any loss, the Company shall pay all costs incurred and falling due for payment up to the date of termination, and also all expenditure falling due for payment after the date of termination which arises from commitments reasonably and necessarily incurred by the relevant Academic Partner for the performance of the Clinical Trial prior to the date of termination, and agreed with the Company.

12.7 In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Company to the Academic Partners in advance for work not completed, such monies shall be applied to termination related costs and the relevant Academic Partner shall issue a credit note and repay the remainder of the monies within 45 days of receipt of written notice from the Company.

12.8 If a Party withdraws or is treated as having withdrawn from the Clinical Research Collaboration in accordance with Clause 12.1, the other Parties will use reasonable endeavours to reallocate the obligations of that Party under this Agreement amongst themselves or to a third party acceptable to the remaining Parties, provided that that third party agrees to be bound by the terms of this Agreement.

12.9 A Party that withdraws or that is treated as having withdrawn from the Clinical Research Collaboration in accordance with Clause 12.1 may not recover from any of the other Parties any of its costs incurred in connection with the Clinical Research Collaboration to the extent that those costs were incurred after the date of its withdrawal.

12.10 Rights granted under Clause 9.3 by a Party that withdraws or that is treated as having withdrawn from the Clinical Research Collaboration in accordance with Clause 12.1 to any of the other Parties in respect of the withdrawing Party's Background will continue for the duration of the Clinical Research Collaboration and will be extended to any new party to this Agreement.

12.11 Rights granted under Clause [9.5-9.10] by a Party that withdraws or that is treated as having withdrawn from the Clinical Research Collaboration in accordance with Clause 12.1 to any of the other Parties in respect of the withdrawing Party's Results will continue and will be extended to any new Party to this Agreement.

12.12 All rights to use any other Party's Intellectual Property granted under this Agreement to a Party that withdraws or that is treated as having withdrawn from the Clinical Research Collaboration in accordance with Clause 12.1 will cease immediately.

12.13 At close-out of the Trial Site following termination or expiration of this Agreement the NHS Organisation shall immediately deliver, and shall make sure that the Investigator delivers, to the Company all Confidential Information and any other unused materials provided to the Academic Partners and/or the Investigator pursuant to this Agreement.

12.14 Subject to Clause 12.12, termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

13. RELATIONSHIP BETWEEN THE PARTIES

13.1 No Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, and neither Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Any Party who so sub-contracts shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

13.2 Nothing shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.

14. AGREEMENT AND MODIFICATION

14.1 Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.

14.2 This Agreement including its Appendices contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Clinical Research Collaboration, which is the subject of this Agreement.

15. FORCE MAJEURE

No Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance ("a Delay") and where they cease to do so. In the event of a Delay lasting for four (4) weeks or more the non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the other Party.

16. NOTICES

Any notices under this Agreement shall be in writing, signed by the relevant Party to this Agreement and delivered personally, by courier or by recorded delivery post.

Notices to the Company shall be addressed to:

[….insert address….]

Notices to the University shall be addressed to:

[….insert address….]

Notices to the NHS Organisation shall be addressed to:

[….insert address….]

17. RIGHTS OF THIRD PARTIES (Not applicable in Scotland)

A person who is not a Party has no right under the Contracts (Rights of Third Parties) Act 1999 ("Third Party Rights Act") to enforce the benefit of any provisions of this agreement

18. WAIVER

No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.

19. DISPUTE RESOLUTION

19.1 In the event of any dispute or difference between the Parties arising in connection with this Agreement, the authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within 7 days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to the senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further 14 days.

19.2 If the Parties are unable to resolve a dispute using the procedure outlined in Clause 19.1, the Parties will attempt to resolve the dispute by the appropriate method of:

19.2.1 In England or Wales, Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or

19.2.2 In Scotland, Parties will refer the dispute to an independent third party. If the Parties are unable to agree on the identity of the third party, the Parties will ask the President of the Law Society of Scotland to appoint a suitable individual to consider the matter. The person so appointed will act as an expert and not as an arbiter; or

19.2.3 In Northern Ireland, Parties will refer the dispute to a mediator agreed by the Parties. Where the Parties are unable to agree on the identity of a mediator, the Parties will ask the President of the Law Society of Northern Ireland to appoint a suitable mediator.

19.3 The Parties shall each bear their own costs in relation to the settlement of any disputes and shall share equally the costs of any independent third party involved to assist in the resolution of the dispute unless the independent third party directs that costs be apportioned differently.

19.4 Any decision reached in accordance with this Clause 19 shall be final and binding upon the Parties.

20. SURVIVAL OF CLAUSES

The following Clauses shall survive the termination or expiry of this Agreement:-

1.1	Definitions
3.2, 3.3,	Clinical Trial Governance
4.9, 4.13, 4.15,	Obligations of the Parties and the Investigator
5	Liabilities and Indemnity
6	Medical Confidentiality, Data Protection and Freedom of Information
7	Publicity
8	Publication
9	Intellectual Property
12.6, 12.7, 12.11 to 12.14 (inclusive)	Termination, Withdrawal and New Parties
13 and 16 to 21 (inclusive)	miscellaneous provisions

Subject to Clause 6.4.4, Clause 6.4 (Confidential Information) shall survive the termination or expiry of this Agreement for a period of ten (10) years commencing on the date of such termination or expiry.

21. GOVERNING LAW

This Agreement shall be governed and construed in accordance with the laws of [England and Wales] [Scotland] [Northern Ireland].

Signed on behalf of the:

COMPANY: .....

..... Date: .....

.....……

(Print name and position of authorised signatory)

Signed on behalf of the:

UNIVERSITY: .....

..... Date: .....

.....

(Print name and position of authorised signatory)

Signed on behalf of the:

NHS ORGANISATION: .....

..... Date: .....

.....……

(Print name and position of authorised signatory)

APPENDIX 1

THE COLLABORATION PLAN

APPENDIX 2

TIMELINES FOR PARTIES

APPENDIX 3

DIVISION OF RESPONSIBILITIES for [Insert designation of Clinical Trial]

The Parties will undertake responsibilities as attributed in the table below. Some responsibilities are only applicable to particular types of study. Where a particular responsibility is not applicable to the Clinical Trial, "not applicable" should be entered in the column designating "Responsible Party". Any additional responsibilities to those set out in this table should be added at the end.

Responsibility	Company	University	NHS Organisation
Sponsor in accordance with the Medicines for Human Use (Clinical Trial) Regulations 2004 and the relevant Research Governance Framework			
Provide insurance or indemnity arrangements			
i) for negligent harm to Clinical Trial Subjects			
a) design of the Protocol			
b) management of the research			
c) conduct of the research			
ii) non negligent harm to Clinical Trial Subjects			
iii) manufacture of the Investigational Medicinal Product			
Provide funding for the Clinical Trial			
Secure and contract for the supply of resources other than Investigational Medicinal Product			
Write the Protocol in compliance with the relevant regulations/ guidelines			
Prepare and submit materials for Clinical Trial Authorisation and to relevant ethics committee			
Prepare and submit proposed substantial amendments of the Protocol to the Regulatory Authority(ies), relevant ethics committee and NHS Organisation			

Maintain detailed records of all adverse events as specified in the Protocol, and report adverse events in accordance with legal and regulatory requirements			
Ensure that Serious Adverse Events are reviewed by an appropriate committee for the monitoring of trial safety			
Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are identified and fully reported to the Regulatory Authority and relevant ethics committee within the required Timelines			
Ensure that Investigators are aware of any SUSARs occurring in relation to the Investigational Medicinal Product			
Analyse Data			
Initiate and coordinate review and submission of abstracts, posters and publications			
Archive all Clinical Trial records on conclusion of the Clinical Trial			
Ensure that Investigational Medicinal Product is manufactured in accordance with Good Manufacturing Practice			
Ensure Investigational Medicinal Product is manufactured, provided, packaged and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, including QP certification			
Store Investigational Medicinal Product in appropriate conditions			
Recall of Investigational Medicinal Product			
Store tissue samples on conclusion of the Clinical Trial			

APPENDIX 4

CONDITIONS APPLICABLE TO THE INVESTIGATOR

(a) he is free to participate in the Clinical Research Collaboration and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

(b) where the Party identified in Clause 4.2 and 4.3 is not the Investigator's principal employer, he has notified his principal employer of his proposed participation in the Clinical Trial and, where relevant, his supervision of Trial Site Staff. He has obtained all necessary consents from his principal employer relating to this.

(c) he is not involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration, the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency, the General Medical Council or other regulatory authorities. No data produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

(d) he has considered, and is satisfied that, facilities appropriate to the Clinical Trial are available to him at the Trial Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the Parties to perform the Clinical Trial efficiently and in accordance with their obligations under the Agreement.

(e) he is employed by, or has a contract for services (commonly known as an honorary contract) with, an NHS organisation, which is a member of the Clinical Negligence Scheme for NHS organisations (CNST), or the Welsh Risk Pooling Scheme for NHS organisations (WRPST) or the Clinical Negligence and Other Risk Indemnity Scheme (CNORIS), as appropriate.

(f) during the Clinical Trial, he will not serve as an Investigator or other significant participant in any clinical trial for another sponsor if such activity might adversely affect his ability to perform his obligations under this Agreement.

APPENDIX 5

FORM OF INDEMNITY

1. The Company indemnifies and holds harmless each Academic Partner and their Staff and Agents against all claims and proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):

    1.1 by or on behalf of Clinical Trial Subjects and (or their dependants) against the Academic Partners or any of their Staff or Agents for personal injury (including death) to Clinical Trial Subjects arising out of or relating to the administration of the Investigational Medicinal Product under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Clinical Trial Subjects would not have been exposed but for their participation in the Clinical Trial;

    1.2 by an Academic Partner, its Staff, or Agents or by or on behalf of a Clinical Trial Subject for a declaration concerning the treatment of a Clinical Trial Subject who has suffered such personal injury.

2. The above indemnity by the Company shall not apply to any such claim or proceeding:

    2.1 to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of that Academic Partner, or its Staff;

    2.2 to the extent that such personal injury (including death) is caused by the failure of that Academic Partner, or its Staff to conduct the Clinical Trial in accordance with the Protocol;

    2.3 unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Academic Partner seeking the indemnity shall have notified the Company in writing of it and shall, upon the Company's request, and at the Company's cost, have permitted the Company to have full care and control of the claim or proceeding using legal representation of its own choosing;

    2.4 if the Academic Partner seeking the indemnity or its Staff shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the written consent of the Company such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any statement properly made by that Academic Partner or its Staff in connection with the operation of that Academic Partner's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such a statement is required by law.

3. The Company shall keep the relevant Academic Partner(s) and its legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with that Academic Partner on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of that Academic Partner (such approval not to be unreasonably withheld).

4. Without prejudice to the provisions of paragraph 2.3 above, the Academic Partners will use their reasonable endeavours to inform the Company promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep the Company reasonably informed of developments in relation to any such claim or proceeding even where an Academic Partner decides not to make a claim under this indemnity. Likewise, the Company shall use its reasonable endeavours to inform the Academic Partners of any circumstances and shall keep the Academic Partners reasonably informed of developments in relation to any such claim or proceeding made or brought against the Company alone.

5. The Parties shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Clinical Trial Subjects (or their dependants) or concerning such a declaration as is referred to in paragraph 1.2 above.

6. Without prejudice to the foregoing if injury is suffered by a Clinical Trial Subject while participating in the Clinical Trial, the Company agrees to operate in good faith the guidelines published in 1991 by The Association of the British Pharmaceutical Industry and entitled “Clinical Trial Compensation Guidelines” and shall request the Investigator to make clear to the Clinical Trial Subjects that the Clinical Trial is being conducted subject to the Association Guidelines.

APPENDIX 6

FINANCIAL ARRANGEMENTS

APPENDIX 7

GOOD DATA MANAGEMENT PRACTICES

1. Research data must be generated using sound scientific techniques and processes;
2. Research data must be accurately recorded in accordance with good scientific practices by the people conducting the research;
3. Research data must be analysed appropriately, without bias and in accordance with good scientific practices;
4. Research data and the Results must be stored securely and be easily retrievable;
5. Data trails must be kept to allow people to demonstrate easily and to reconstruct key decisions made during the conduct of the research, presentations made about the research and conclusions reached in respect of the research; and
6. Each Party must have the right, on not less than 30 days written notice, to visit any other Party to verify that it is complying with the above practices and procedures.

APPENDIX 8

ANTI-BRIBERY AND PREVENTION OF CORRUPTION PRINCIPLES ("GUIDELINES")

Blank if Company does not provide Guidelines