

**TRIPARTITE CLINICAL TRIAL AGREEMENT FOR PHARMACEUTICAL AND  
BIOPHARMACEUTICAL INDUSTRY SPONSORED RESEARCH IN SCOTTISH  
HEALTH BOARDS, MANAGED BY CONTRACT RESEARCH ORGANISATIONS  
(CROs)**

**[Name – Clinical Trial]**

This agreement dated .....

is between

**[.... insert name....]** Health Board, constituted pursuant to the National Health Service  
(Scotland) Act 1978 (as amended) and having its headquarters at **[....insert address....]**  
(Hereinafter known as the “Board”)

**AND**

**[.... insert name....]**, of **[....insert address....]**  
(Hereinafter known as the “Sponsor”)

**AND**

**[....insert name....]**, of **[....insert address....]**  
(Hereinafter known as the “CRO”)

**NOW**

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

**WHEREAS** the Sponsor is developing new treatments and therapies in the field of **[....insert disease....]**

**WHEREAS** the Sponsor has entered into an agreement with the CRO, which is a contract research organisation

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

**WHEREAS** the Board has a particular interest and expertise in [....insert area of expertise....]

**WHEREAS** the Sponsor and the CRO wish to contract with the Board to undertake a sponsored clinical trial entitled:

“ ..... insert title and EUDRACT number or Unique Identifier number..... ”

It is agreed that the Sponsor, CRO and Board shall participate in the aforementioned clinical trial in accordance with this Agreement.

## **1. DEFINITIONS**

### **1.1 The following words and phrases have the following meanings:**

“Affiliate” means any business entity which controls, is controlled by, or is under the common control with the Sponsor or CRO. 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, schedules and any appendices attached to it.

“Auditor” means a person being a representative of the Sponsor or CRO 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, [the Sponsor’s Standard Operating Procedures, copies of which have been made available to the CRO and Board], ICH GCP and the applicable regulatory requirements.

“Board” means the [...insert name...] Board that is a signatory to this Agreement.

“Clinical Trial” means the investigation to be conducted at the Trial Site in accordance with the Protocol numbered [... insert identification number...].

“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 the Clinical Trial.

“Confidential Information” means any and all information, data and material of any nature belonging to the Board or to the Sponsor and/or its Affiliates or to the CRO which any 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 Board or his or her treatment or medical history, or other information, the release of which is likely to prejudice the commercial interests of the Board, the Sponsor or the CRO respectively, or which is a trade secret, including Know How.

“CRO” means the contract research organisation that is a signatory to this Agreement.

“Exploratory Clinical Trial” means a Clinical Trial designed to generate, rather than test, hypotheses, as set out in the ICH Harmonised Tripartite Guideline E9: Statistical Principles for Clinical Trials 1998.

“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 the Clinical Trial and that may be located at the 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 the person who will take primary responsibility for the conduct of the Clinical Trial at the Trial Site on behalf of the Board or any other person as may be agreed from time to time between the Parties as a 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 January 2005.

“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 Sponsor, CRO, or the Board and except where otherwise provided “Parties” shall mean all of them.

“Protocol” means the description of the Clinical Trial (a copy of which is at Appendix 1 and signed by the Investigator) and all amendments thereto as the Parties may from time to time agree in accordance with clauses 4.8, 10.2 and 14.2 and which have also been signed by the Investigator. Such amendments will be signed by the Parties and form a part of this Agreement.

“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.

“R&D Office” means the Board department responsible for the administration of this Clinical Trial on behalf of the Board.

“Site File” means the file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP (edition CPMP/ICH/135/95).

“Sponsor” means the pharmaceutical company that is a signatory to this Agreement.

“Timelines” means the dates set out in Appendix 2 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 by the Sponsor or CRO to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

“Trial Site(s)” means any premises occupied by the Board in connection with this Agreement.

“Trial Site Team Members” means the persons who will undertake the conduct of the Clinical Trial at the Trial Site on behalf of the Board 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 statutory 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. INVESTIGATOR AND TRIAL SITE TEAM MEMBERS

- 2.1 The Board represents that it is entitled to procure and the Board will procure the services of [...insert name of Investigator...] to act as Investigator and shall ensure the performance of the obligations of the Investigator set out in Appendix 7 and elsewhere in this Agreement. Where the Board is not the Investigator's principal employer, it will notify the principal employer in a timely way of his proposed involvement in the Clinical Trial. Any financial or other arrangements relating to his involvement in the Clinical Trial will be agreed directly between the Board and the principal employer.
- 2.2 The Board represents that the Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial and will ensure that the Investigator is made aware of and acknowledges the obligations applicable to the Investigator set out in Appendix 7 and elsewhere in this Agreement.
- 2.3 The Board shall notify the Sponsor and CRO if the Investigator ceases to be employed by or associated with the Board or is otherwise unavailable to continue as Investigator, and shall use all reasonable endeavours to find a replacement acceptable to all the Parties, subject to the Board's overriding obligations in relation to Clinical Trial Subjects and individual patient care. If no mutually acceptable replacement can be found the Sponsor may terminate this Agreement pursuant to clause 12.3 below.
- 2.4 The Board shall procure and shall ensure that the Investigator procures the performance of the obligations of the Trial Site Team Members as set out in this Agreement.

## 3. CLINICAL TRIAL GOVERNANCE

- 3.1 The [Sponsor] [CRO] (delete as appropriate) shall inform the Board and the Investigator of the name and telephone number of the Trial Monitor and the name of the person who will be available as a point of contact. The [Sponsor] [CRO] (delete as applicable) shall also provide the Investigator with an emergency telephone number to enable adverse event reporting at any time.
- 3.2 The Parties shall comply with all laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of the UK country in which the Trial Site is located including, but not limited to, the Human Rights Act 1998, the Data Protection Act 1998, 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' (1996 version), the Scottish Executive Health Department Research Governance Framework for Health and Community Care (version 2, February 2006). In addition, where the Clinical Trial is conducted under an IND, the Board will comply with any other relevant requirements notified by the Sponsor or CRO to the Board.

- 3.3 The Sponsor shall comply with all guidelines from time to time in force and published by The Association of the British Pharmaceutical Industry in relation to clinical trials and in particular those entitled “Clinical Trial Compensation Guidelines” (1991) a copy of which is set out in Appendix 3.
- 3.4 Neither the Sponsor nor the CRO shall commit (and each of them warrants that in entering into the Agreement it has not committed) any of the following acts:
- 3.4.1 provide or offer to provide to any person in the employment of or in the service of the Board any gift or consideration not contemplated by the financial arrangements set out at clause 10 below in relation to the negotiation or performance of this Agreement or the Clinical Trial.
- 3.4.2 make payment or agree to make payment of any commission to any person in the service of or in the employment of the Board in relation to this Agreement or the Clinical Trial.
- 3.5 If the Sponsor or the CRO or any of their employees, Agents or sub-contractors, or any person acting on their behalf, commits any of the acts referred to in clause 3.4 above or commits any offence under the Prevention of Corruption Acts 1889 to 1916, in relation to this Agreement or the Clinical Trial, the Board shall be entitled, 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 the Clinical Trial Subjects. If the Sponsor or CRO or any of their employees, Agents or sub-contractors, or any person acting on their behalf, commits any offence under the Prevention of Corruption Acts 1889 to 1916, in relation to any other agreement with the Board or an authority that is a health service body within the meaning given by Section 4(2) of the National Health Service and Community Care Act 1990, the Board shall be entitled, acting reasonably, in addition to any other remedy available, to terminate this Agreement with immediate effect, provided that before so doing, the Board shall have considered all of the circumstances of the case in consultation with the Sponsor or CRO and shall, in particular, have considered the potential effects of termination on the health of the Clinical Trial Subjects.
- 3.6 Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any other document incorporated therein, including the Sponsor’s Standard Operating Procedures, 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 The Investigator shall be responsible for obtaining and maintaining all favourable opinions from the relevant research ethics committee for the conduct of the Clinical Trial and the Investigator shall keep the [Sponsor] [CRO] (delete as appropriate) and the R&D Office fully apprised of the progress of ethics committee submissions and shall upon request provide the Sponsor, the CRO and the R&D Office with all correspondence relating to such submissions. The Investigator shall not consent to any change in the Protocol requested by the relevant ethics committee without the prior written consent of the Sponsor.

- 4.2 The CRO shall perform such of the Sponsor's trial-related duties and functions in respect of the Clinical Trial under ICH GCP, as contained in Appendix 5.
- 4.3 Unless it is an Exploratory Clinical Trial, the Sponsor shall submit the Clinical Trial for listing in a free, publicly accessible clinical trial registry within 21 days of initiation of patient enrolment.
- 4.4 Neither the CRO, nor the Board, nor the Investigator shall register either the Clinical Trial, or the results, on any publicly accessible clinical trial registry.
- 4.5 Unless it is an Exploratory Clinical Trial, the Sponsor shall ensure that the results of the Clinical Trial will be published on a free, publicly accessible clinical trial results database within one year after the Investigational Medicinal Product is first approved and made commercially available in any country, or for a post-approval Clinical Trial, within one year of Clinical Trial completion. 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.
- 4.6 The Parties shall conduct the Clinical Trial in accordance with:
  - 4.6.1 the Protocol, a copy of which is attached at Appendix 1 to this Agreement;
  - 4.6.2 the current marketing authorisation for the Investigational Medicinal Product or, as the case may be, Clinical Trial Authorisation granted by the relevant Licensing Authority; and
  - 4.6.3 the terms and conditions of the favourable opinion of the relevant [...insert name...] Research Ethics Committee(s)
- 4.7 Until the Sponsor has obtained all required documentation from the Regulatory Authority and a favourable opinion from the Research Ethics Committee, it shall not supply, nor authorise the CRO to supply, the Investigational Medicinal Product to the Board. The Board shall ensure that neither administration of the Investigational Medicinal Product to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Clinical Trial Subject until it is satisfied that all relevant regulatory approvals and a favourable opinion from the research ethics committee have been obtained.
- 4.8 In the event of any substantial amendments (relating to any of the matters referred to in the definition of "substantial amendment to the Clinical Trial Authorisation" in regulation 11 of the Medicines for Human Use (Clinical Trial) Regulations 2004) being made to the Protocol, the amendments shall be signed by the Investigator and shall be implemented by the Trial Site Team Members as required by the Sponsor or CRO. The Sponsor or CRO shall initiate simultaneously the change control procedures set out in clause 14 below.
- 4.9 The [Sponsor] [CRO] (delete as appropriate) shall make available to the Investigator copies of the documentation referred to in clause 4.6.1 and evidence of the grant of authorisations listed in clause 4.6.2 above and the Investigator shall include such documents together with the favourable opinion of the research ethics committee in the Site File.

- 4.10 The Investigator shall make any necessary disclosures of financial interests and arrangements as specified by the Sponsor and for the purposes of these obligations the Sponsor shall advise the Investigator in writing of the completion date of the Clinical Trial.
- 4.11 Neither the Board nor the Investigator shall permit the Investigational Medicinal Product to be used for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement all unused Investigational Medicinal Product shall, at the Sponsor's option, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor's written instructions.
- 4.12 The Board shall use its best endeavours to ensure that the Investigator recruits [... insert number ...] Clinical Trial Subjects to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the Timelines.
- 4.13 In the event that the Clinical Trial is part of a multi-centre clinical trial (which for the purposes of this Agreement shall mean that at least one other institution is taking part), the Sponsor or CRO may amend the number of patients to be recruited pursuant to clause 4.12 above as follows:
- 4.13.1 if in the reasonable opinion of the Sponsor or CRO recruitment of Clinical Trial Subjects is proceeding at a rate below that required to enable the relevant Timeline to be met the Sponsor or CRO may by notice to the Board require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Clinical Trial Subjects who have been enrolled in the Clinical Trial at the date of such notice; or
- 4.13.2 if recruitment of Clinical Trial Subjects is proceeding at a rate above that required to meet the relevant Timeline, the Sponsor or CRO may with the agreement of the Board increase the number of Clinical Trial Subjects to be recruited
- 4.14 The following provisions relate to access, research misconduct and Regulatory Authorities.
- 4.14.1 The Board 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 may take such form as the Sponsor or CRO reasonably thinks appropriate including the right to inspect any facility 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. The CRO will alert the R&D Office of the Board promptly to significant issues (in the opinion of the Sponsor or CRO) relating to the conduct of the Clinical Trial.
- 4.14.2 In the event that the Sponsor or CRO reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Board and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the

Sponsor or the CRO, the results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, communicate to the Board. In the event that the Board reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor and CRO shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Board, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor and CRO.

- 4.14.3 The Board shall promptly inform the Sponsor and CRO of any intended or actual inspection, written enquiry and/or visit to the Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward to the Sponsor and CRO copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Board will use all reasonable endeavours to procure that the Sponsor and CRO may have a representative present during any such visit.
- 4.14.4 The Board will permit the Sponsor and CRO 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 The Board shall ensure that any clinical biological samples required to be tested by the Board during the course of the Clinical Trial are tested in accordance with the Protocol and at a laboratory approved by the [Sponsor][CRO][delete as appropriate].
- 4.16 Upon completion of the Clinical Trial (whether prematurely or otherwise) the Investigator shall cooperate with the Sponsor and CRO in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.
- 4.17 Subject to the Board's and the Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care, neither the Board nor the Investigator nor Trial Site team Members shall during the term of this Agreement conduct any other trial which might hinder the Board's or Investigator's ability to recruit and study the required cohort of Clinical Trial Subjects.

## **5. LIABILITIES AND INDEMNITY**

- 5.1 In the event of any claim or proceeding in respect of personal injury made or brought against the Board by a Clinical Trial Subject, the Sponsor shall indemnify the Board, its servants, Agents and employees in accordance with the terms of the indemnity set out at Appendix 4 hereto.
- 5.2 Nothing in this clause 5 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence of that Party or its servants, Agents or employees or to restrict or exclude any other liability of any Party which cannot be so restricted or excluded in law. The CRO expressly disclaims any liability in connection with the Investigational Medicinal Product

caused by or allegedly caused by the use or misuse of the Investigational Medicinal Product other than liability for death, personal injury or loss of or damage to property which liability is the result of negligence on the part of the CRO.

- 5.3 In no circumstances shall any Party be liable to another Party in contract, delict (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.
- 5.4 Subject to clauses 5.2 and 5.5, the Board's liability to the Sponsor and CRO arising out of or in connection with any breach of this Agreement or any act or omission of the Board in connection with the performance of the Clinical Trial shall in no event exceed in total the amount of fees payable by the Sponsor or CRO to the Board under this Agreement. In the case of equipment loaned to the Board for the purposes of the Clinical Trial, the Board's liability arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment.
- 5.5 In respect of any wilful and/or deliberate breach by the Board, or any breach of clauses 6, 8 and/or 9, the Board's liability to the Sponsor and CRO arising out of or in connection with the breach shall not exceed in total twice the value of the contract.
- 5.6 The Sponsor will take out appropriate insurance cover or will provide an indemnity satisfactory to the Board in respect of its potential liability under clause 5.1 above and such cover shall be for a minimum of £[...insert amount...] in respect of any one occurrence or series of occurrences arising from one event. The Sponsor shall produce to the Board, 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 the Clinical Trial. Personal data (as defined in the Data Protection Act 1998) shall not be disclosed to the Sponsor or CRO by the Board 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 the Clinical Trial Subject in connection with the Clinical Trial. Neither the Sponsor nor CRO shall 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 Scotland Code of Practice on Protecting Patient Confidentiality (August 2003), unless in relation to a claim or proceeding

brought by the Clinical Trial Subject in connection with the Clinical Trial.

- 6.2 All Parties 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 other 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 the Clinical Trial 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.
- 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 the others 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 other prior to the disclosure of any Personal Data created in connection with the conduct or performance of the Clinical Trial in relation to such requests.

**6.2.6 Freedom of Information**

The Sponsor and CRO acknowledge that the Board is subject to 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.

- 6.2.7 If the Board receives a request under the FOIA to disclose any information that belongs to the Sponsor or its Affiliates, it will notify the Sponsor and CRO 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 Sponsor and CRO in accordance with all applicable guidance.
- 6.2.8 The Sponsor and CRO acknowledge and agree that:
- (a) subject to clause 6.2.8(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 Board;
  - (b) where the Board is managing a request as referred to in clause 6.2.7, the Sponsor and CRO shall co-operate with the Board and shall use their reasonable endeavours to respond within ten (10) working days of the Board's request for assistance in determining whether or not an exemption to the FOIA applies.
- 6.2.9 Where the Board determines that it will disclose the Confidential Information, notwithstanding any objections from the Sponsor or CRO, it will notify the Sponsor and CRO in writing, giving at least two (2) working days notice of its intended disclosure.

### **6.3 Confidential Information**

- 6.3.1 Each Party shall ensure that only those of their officers, Agents and employees (and in the case of the Sponsor or CRO, those of its Affiliates) directly concerned with the carrying out of this Agreement have access to the Confidential Information of the other Parties. All Parties undertake to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Parties, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance by the Board with the FOIA, in accordance with clauses 6.2.6, 6.2.7 and 6.2.8 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 6.2.7), 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 Parties, other than in accordance with this Agreement, without the prior written consent of the other Parties.
- 6.3.2 The obligations of confidentiality set out in this clause 6.3 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.

6.3.3 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 6.3.

6.3.4 This clause 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 shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

## **7. PUBLICITY**

7.1 Neither the Sponsor nor the CRO will use the name of the Board, nor of any member of the Board's staff, in any publicity, advertising or news release without the prior written approval of an authorised representative of the Board, such approval not to be unreasonably withheld. The Board will not, and will ensure that the Investigator and Trial Site Team Members do not, use the name of the Sponsor or CRO or any of their employees, nor the name of the Clinical Trial, nor the name of the Investigational Medicinal Product, in any publicity, advertising or news release without the prior written approval of the Sponsor or CRO as appropriate, such approval not to be unreasonably withheld.

7.2 Neither the Board nor the Investigator will issue any information or statement to the press or public, 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 Sponsor or CRO as appropriate.

## **8. PUBLICATION**

8.1 The Sponsor recognises that the Board and Investigator have a responsibility under the Research Governance Framework for Health and Community Care to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated. The Sponsor agrees that employees of the Board 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 Trial subject to this clause 8 and any publication policy described in the Protocol, provided any such policy is consistent with the Joint Position. If the Clinical Trial is multi-centred (as defined in clause 4.13 above) any publication based on the results obtained at the Trial Site (or a group of sites) shall not be made before the first multi-centre publication. If a publication concerns the analyses of sub-sets of data from a multi-centred Clinical Trial the publication shall make reference to the relevant multi-centre publication(s).

- 8.2 Upon completion of the Clinical Trial, and any prior publication of multi-centre data, or when the Clinical Trial data are adequate (in Sponsor's reasonable judgement), the Board and/or the Investigator may prepare the data derived from the Clinical Trial for publication. Such data will be submitted to the Sponsor for review and comment prior to publication. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days (or the time limit specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.
- 8.3 The Board agrees, and shall ensure that the Investigator agrees, that all reasonable comments made by the Sponsor in relation to a proposed publication by the Board and/or the Investigator will be incorporated by the Board and/or the Investigator into the publication.
- 8.4 The Board acknowledges that the Sponsor or CRO 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 Trial and in particular, but without limiting the foregoing, post a summary of study results in on-line clinical trials register(s) before or after publication by any other method. In the event the Sponsor or CRO coordinates a multi-centre publication, the participation of the Investigator or other representatives of the Board as a named author shall be determined in accordance with the Sponsor's or CRO's policy and generally accepted standards for authorship. If the Investigator or other representatives of the Board is a named author of the multi-centre publication, such person shall have access to the Clinical Trial data from all Clinical Trial sites as necessary to participate fully in the development of the multi-centre publication.
- 8.5 During the period for review of a proposed publication referred to in clause 8.2 above, the Sponsor shall be entitled to make a reasoned request to the Board that publication be delayed for a period of up to six (6) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information and/or Intellectual Property Rights and Know How and the Board shall not unreasonably withhold its consent to such a request. The Board shall not unreasonably withhold or delay its consent to a request from the Sponsor for an exceptional additional delay if, in the reasonable opinion of the Sponsor, the Sponsor's proprietary information and/or Intellectual Property Rights and Know How might otherwise be compromised or lost.

## **9. INTELLECTUAL PROPERTY**

- 9.1 All Intellectual Property Rights and Know How owned by or licensed to the Sponsor prior to and after the date of this Agreement other than any Intellectual Property Rights and Know How arising from the Clinical Trial are and shall remain the property of the Sponsor.
- 9.2 All Intellectual Property Rights and Know How owned by or licensed to the CRO prior to and after the date of this Agreement other than any Intellectual Property Rights and Know How arising from the Clinical Trial are and shall remain the property of the CRO.

- 9.3 All Intellectual Property Rights and Know How owned by or licensed to the Board prior to and after the date of this Agreement other than any Intellectual Property Rights and Know How arising from the Clinical Trial are and shall remain the property of the Board.
- 9.4 All Intellectual Property Rights and Know How arising from and relating to the Clinical Trial, the Investigational Medicinal Product (including but not limited to its formulation and use alone or in combination with other drugs) or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Board, shall vest in the Sponsor in accordance with clauses 9.5 and 9.6 below.
- 9.5 In accordance with clause 9.4 above, the Board hereby assigns, and shall procure that the Investigator assigns, its rights in relation to all Intellectual Property Rights and in all Know How, falling within clause 9.4 above, to the Sponsor and at the request and expense of the Sponsor, the Board shall execute, and shall procure that the Investigator executes, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know How in the Sponsor or its nominee.
- 9.6 The Board and the Investigator shall promptly disclose to the Sponsor and CRO any Know How generated pursuant to this Agreement and falling within clause 9.4 above and, subject to clause 9.7, undertake not to use or disclose such Know How other than for the purposes of this Agreement.
- 9.7 Nothing in this clause 9 shall be construed so as to prevent or hinder the Board from using the Sponsor's Know How gained during the performance of the Clinical Trial in the furtherance of its normal business 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 Sponsor.

## **10. FINANCIAL ARRANGEMENTS**

- 10.1 Arrangements relating to the financing of this Clinical Trial by the Sponsor are set out in Appendix 6 hereto.
- 10.2 In the event that amendments to the Protocol require changes to the trial financing arrangements, an amended financial schedule will be signed by the Parties pursuant to clause 14.2 below and attached as a supplement at Appendix 6 of this Agreement.
- 10.3 All payments will be made according to the schedule contained in Appendix 6 on presentation of a VAT invoice from the Board to the Party making payment.
- 10.4 The Party making payment shall promptly respond to any reasonable request for invoicing data received from the Board within 45 days of the close-out of the Trial Site. The Board will send its final invoice, (or, as the case may be, issue a credit note and make repayment of any monies previously paid for work not completed), to the party making payment as soon as possible and, in any event, within 45 days of receipt of the said data where such a request has been made, or

within 45 days of study close-out in all other circumstances unless there is a written agreement between the Board and the Party making payment to extend these periods.

10.5 The Party making payment shall do so within forty-five (45) days of the date of receipt of the invoice mentioned in clause 10.3 above.

10.6 Any delay in the payment of the payee invoices by a Party will incur an interest charge on any amounts overdue of 2 per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.

## **11. TERM**

This Agreement will remain in effect until completion of the Clinical Trial, close-out of the Trial Site and completion of the obligations of the Parties under this Agreement or earlier termination in accordance with this Agreement.

## **12. EARLY TERMINATION**

12.1 The [Sponsor][CRO][delete as appropriate] or the Board (the Terminating Party) may terminate this Agreement with immediate effect at any time if any other Party or the Investigator (the Defaulting Party) is:

12.1.1 in breach of any of the Defaulting Party's obligations hereunder (including a failure without just cause to meet a Timeline) and fails to remedy such breach where it is capable of remedy within 28 days of a written notice from the Terminating Party specifying the breach and requiring its remedy;

12.1.2 declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business or, in the case of the Board, if the Scottish Ministers make an order under the National Health Service (Residual Liabilities) Act 1996 in respect of the Board transferring its property rights and liabilities to one of the bodies referred to in Section 2(2) of that Act.

12.2 A Party may terminate this Agreement on notice to the other Parties with immediate effect if 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.

12.3 The Sponsor or CRO may terminate this Agreement on notice to the Board if the Investigator is no longer able (for whatever reason) to act as Investigator and no replacement mutually acceptable to the Parties can be found.

12.4 The Sponsor may terminate this Agreement immediately upon notice in writing to the Board for reasons not falling within clauses 12.1.1, 12.2 or 12.3 above. In all such circumstances the Sponsor shall confer with the Investigator and use its best endeavours to minimise any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial.

- 12.5 In the event of early termination of this Agreement by the Sponsor or CRO, pursuant to clauses 12.2, 12.3 or by the Sponsor pursuant to clause 12.4 and subject to an obligation on the Board and the Investigator to mitigate any loss, the Party making payment 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 Board for the performance of the Clinical Trial prior to the date of termination, and agreed with the Party making payment.
- 12.6 In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Sponsor or CRO to the Board in advance for work not completed, such monies shall be applied to termination related costs and the Board shall issue a credit note and repay the remainder of the monies within 45 days of receipt of a written notice from the Sponsor or CRO.
- 12.7 At close-out of the Trial Site following termination or expiration of this Agreement the Board shall immediately deliver, and shall make sure that the Investigator delivers, to the Sponsor and CRO all Confidential Information and any other unused materials provided to the Board pursuant to this Agreement.
- 12.8 Termination of this Agreement will be without prejudice to the accrued rights and liabilities of any Party under this Agreement.

### **13. RELATIONSHIP BETWEEN THE PARTIES**

- 13.1 The CRO may assign or otherwise transfer this Agreement in whole including all prior rights and responsibilities but not in part or otherwise to the Sponsor or another party subject to the consent of the Sponsor. The CRO shall promptly inform the Board of any such transfer and provide the Board with a copy of the assignment or other transfer agreement duly executed by the CRO and the Sponsor or other party and a copy of the Sponsor's written consent thereto.
- 13.2 Except as provided in clause 13.1, no Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed, and no Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Parties, 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.
- 13.3 The Sponsor shall use all reasonable endeavours to procure the punctual, true and faithful performance and observance by the CRO of its obligations under Appendix 5. In the event of any material breach of the obligations of the CRO under Appendix 5, and on receipt of notice from the Board to do so, the Sponsor shall from the date of such notice assume all rights and obligations of the CRO under Appendix 5 and at its own expense perform or, subject to the agreement of the Board (such agreement not to be unreasonably withheld or

delayed) take whatever steps may be necessary to procure the performance of the obligations of the CRO under Appendix 5 by another party.

13.4 In the event that the CRO passes a resolution or the court makes an order that the CRO be wound up otherwise than for the purpose of bona fide reconstruction or amalgamation, or a receiver, manager or administrator on behalf of a creditor is appointed in respect of the CRO's business or any part thereof or the CRO is unable to pay his debts within the meaning of Section 123 of the Insolvency Act 1986, then on receipt of notice from the Board to do so, the Sponsor shall from the date of such notice assume all the rights and obligations of the CRO under Appendix 5 and at its own expense perform or, subject to the agreement of the Board (such agreement not to be unreasonably withheld or delayed) take whatever steps may be necessary to procure the performance of the obligations of the CRO under Appendix 5 by another party.

13.5 Nothing in this Agreement shall be construed as creating a partnership, contract of employment or relationship of principal and agent between any of 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 Any amendment to the Protocol pursuant to clause 4.8 ("Protocol Amendment") shall be managed by means of the change control procedure set out in this clause 14.2

14.2.1 For the purposes of this Agreement a "change request" is a request to change the obligations of the Parties arising from a Protocol Amendment.

14.2.2 Where the Sponsor or CRO originates a change request, the Board shall provide the Sponsor or CRO, within thirty five (35) days of receiving the change request, details of the impact which the proposed Protocol Amendment will have upon the costs of carrying out the Clinical Trial and the other terms of this Agreement.

14.2.3 A change request shall become a "change order" when the requirements of the change control procedure have been satisfied and any necessary change to this Agreement is signed by the authorised representatives of all Parties.

14.2.4 An amended financial schedule shall be signed and appended to this Agreement according to clause 10.2 above.

14.2 This Agreement including its Appendices contains the entire understanding between the Parties and supersedes all other negotiations, representations and undertakings whether written or oral of prior date between the Parties relating to

the Clinical Trial which is the subject of this Agreement. Nothing in this Agreement will, however, operate to limit or exclude any liability for fraud.

**15. FORCE MAJEURE**

No Party shall be liable to any other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, 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 Parties in writing when such circumstances cause a delay or failure in performance ("a Delay") and when they cease to do so. In the event of a Delay lasting for four (4) weeks or more the non-affected Parties shall have the right to terminate this Agreement immediately by notice in writing to the other Parties.

**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 Sponsor shall be addressed to:

[....insert address....]

Notices to the CRO shall be addressed to:

[....insert address....]

Notices to the Board shall be addressed to:

[....insert address....]

**17. This clause (Rights of Third Parties) intentionally deleted for use in Scotland**

**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 a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within seven (7) days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) days.

19.2 In the event of failure to resolve the dispute through the steps set out in clause 19.1 the same may be referred to an independent third party for resolution. In the event that the Parties cannot mutually agree on the identity of an independent third party, the Parties will ask the President for the time being of the Law Society of Scotland to appoint a suitable individual to consider the matter in dispute. The person so appointed will act as an expert and not as an arbiter. The Parties shall each bear their own costs and expenses in relation to settlement of any disputes in terms of this clause 19 and shall share equally the costs of the independent third party.

19.3 If the Parties are unable to resolve a dispute arising out of or in connection with this Agreement in accordance with clauses 19.1 and 19.2, any Party shall be entitled to submit to the exclusive jurisdiction of the Scottish Courts.

19.4 Nothing in this Agreement shall prevent any Party from seeking an interim interdict in respect of a breach of this Agreement. For the avoidance of doubt nothing in this clause shall amount to an agreement that any of the Parties is entitled to an interim interdict.

## **20. SURVIVAL OF CLAUSES**

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

1.1	Definitions
3.2- 3.6 (inclusive)	Clinical Trial Governance
4.4, 4.5 and 4.14	Obligations of the Parties
5	Liabilities and Indemnity
6	Medical Confidentiality, Data Protection and Freedom of Information
7	Publicity
8	Publication
9	Intellectual Property
12.5-12.8 (inclusive)	Early Termination
13 to 16, 18 to 21 (inclusive)	Miscellaneous provisions

Subject to clause 6.3.4, clause 6.3 (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 interpreted and governed by the laws of Scotland.

Signed on behalf of the:

**SPONSOR:** .....

.....

Date:

.....

(Print name and position of authorised signatory)

Signed on behalf of the:

**CRO:** .....

.....

Date:

.....

(Print name and position of authorised signatory )

Signed on behalf of the:

**BOARD** .....

.....

Date:

.....

(Print name and position of authorised signatory)

Authorised signatory (Chief Executive, Director of R&D, or Finance Director)

**APPENDIX 1**

**THE CLINICAL TRIAL PROTOCOL**

## APPENDIX 2

### TIMELINES FOR PARTIES

Milestone	Sponsor responsibility	CRO responsibility	Board responsibility	Date
Provision of materials for Ethics Committee submission	[X]	X		
Ethics Committee submission	[X]		X	
Trial Site initiation visit		X	X	
First patient recruited			X	
Last patient recruited			X	
Clinical Report Form queries submitted		X		
Clinical Report Form queries completed			X	

## APPENDIX 3

### CLINICAL TRIAL COMPENSATION GUIDELINES

#### Preamble

The Association of the British Pharmaceutical Industry favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by a participation in clinical trials. The Association therefore recommends that a member company sponsoring a clinical trial should provide without legal commitment a written assurance to the investigator - and through him to the relevant research ethics committee - that the following Guidelines will be adhered to in the event of injury caused to a patient attributable to participation in the trial question.

#### 1. Basic principles

- 1.1 Notwithstanding the absence of legal commitment, the company should pay compensation to patient-volunteers suffering bodily injury (including death) in accordance with these Guidelines.
- 1.2 Compensation should be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.
- 1.3 Compensation should be paid to a child injured in utero through the participation of the subject's mother in a clinical trial as if the child were patient-volunteer with the full benefits of these Guidelines.
- 1.4 Compensation should only be paid for the more serious injury of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.
- 1.5 Where there is an adverse reaction to a medicinal product under trial and injury is caused by a procedure adopted to deal with that adverse reaction, compensation should be paid for such injury as if it were caused directly by the medicinal product under trial.
- 1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these Guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.
- 1.7 For the avoidance of doubt, compensation should be paid regardless of whether the patient is able to prove that the company has been negligent in relation to research or development of the medicinal product under trial or that the project is defective and therefore, as the producer, the company is subject to strict liability in respect of injuries caused by it.

#### 2. Type of Clinical Research Covered

- 2.1 These Guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended but for which a product licence does not exist or does not authorise supply for administration under the conditions of the trial.
  - 2.2 These Guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate Guidelines for compensation already exist.<sup>1</sup>
  - 2.3 These guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply for administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial.
  - 2.4 These guidelines do not apply to clinical trials, which have not been initiated or directly sponsored by the company providing the product for research. When trials of products are initiated independently by doctors under the appropriate Medicines Act 1968 exemptions, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).
3. Limitations
- 3.1 No compensation should be paid for the failure of the medicinal product to have its intended effect or to provide any other benefit to the patient.
  - 3.2 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.
  - 3.3 No compensation should be paid to patients receiving placebo in consideration of its failure to provide a therapeutic benefit.
  - 3.4 No compensation should be paid (or should be abated as the case may be) to the extent that the injury has arisen:
    - 3.4.1 through a significant departure from the agreed protocol;
    - 3.4.2 through the wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction; or
    - 3.4.3 through contributory negligence by the patient.
4. Assessment of compensation

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<sup>1</sup> Guidelines for medical experiments in non-patient human volunteers, ABPI March 1988, as amended May 1990.

- 4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English Court in cases where legal liability is admitted.
- 4.2 Compensation may be abated, when certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):
  - 4.2.1 the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given; or
  - 4.2.2 the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given the particular patient's circumstances. As an extreme example, there may be a patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of an adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high-risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

- 4.3 In any case where the company concedes that a payment should be made to a patient but there exists the difference of opinion between company and patient as to the appropriate level of compensation, it is recommended that the company agrees to seek at its own costs (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his opinion should be given substantial weight by the company in reaching its decision on the appropriate payment to be made.
5. Miscellaneous
- 5.1 Claims pursuant to the Guidelines should be made by the patient to the company, preferably via the investigator, seeking out details of the nature and background of the claim and, subject to the patient providing on request an authority for the company to review any medical records relevant to the claim, the company should consider the claim expeditiously.
  - 5.2 The undertaking given by a company extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor and in this regard attention is drawn to the advice provided to doctors in MAL 302 concerning the desirability of doctors notifying their protection society of the use of unlicensed products.

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2 MAL30 A guide to the provisions affecting doctors and dentists, DHSS, revised June 1985.

- 5.3 The fact that company has agreed to abide by these Guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nonetheless, patients will normally be asked to accept that any payment made under the Guidelines will be in full settlement of their claims.
- 5.4 A company sponsoring a trial should encourage the investigator to make clear to participating patients that the trial is being conducted subject to the ABPI guidelines relating to compensation for injury arising in the course of clinical trials and have available copies of the Guidelines should they be requested.

## APPENDIX 4

### FORM OF INDEMNITY

1. The Sponsor indemnifies and holds harmless the Board and its employees 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 Board or any of its employees 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 the Board, its employees 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 Sponsor 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 the Board, its employees or Agents;
  - 2.2 to the extent that such personal injury (including death) is caused by the failure of the Board, its employees, or Agents 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 Board shall have notified the Sponsor in writing of it and shall, upon the Sponsor's request, and at the Sponsor's cost, have permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing;
  - 2.4 if the Board, its employees, or Agents 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 Sponsor such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any statement properly made by the Board, its employees or Agents in connection with the operation of the Board's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such a statement is required by law.
3. The Sponsor shall keep the Board and its legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with the Board on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Board (such approval not to be unreasonably withheld).

4. Without prejudice to the provisions of paragraph 2.3 above, the Board will use its reasonable endeavours to inform the Sponsor 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 Sponsor reasonably informed of developments in relation to any such claim or proceeding even where the Board decides not to make a claim under this indemnity. Likewise, the Sponsor shall use its reasonable endeavours to inform the Board of any circumstances and shall keep the Board reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
5. The Board and the Sponsor will each give to the other 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 Sponsor 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.
7. For the purpose of this indemnity, the expression “Agents” shall be deemed to include without limitation any nurse or other health professional providing services to the Board under a contract for services or otherwise and any person carrying out work for the Board under such a contract connected with such of the Board’s facilities and equipment as are made available for the Clinical Trial.

**APPENDIX 5**

**SPONSOR'S TRIAL-RELATED DUTIES AND FUNCTIONS UNDER ICH GCP TO BE  
PERFORMED BY CRO**

## **APPENDIX 6**

### **FINANCIAL ARRANGEMENTS**

When the Board is not the Investigator's principal employer, this should include, after the schedule of payments, the statement that:

It shall be the responsibility of the Board to make the appropriate agreed pass-through payments to the Investigator's principal employer, as indicated above.

## APPENDIX 7

### CONDITIONS APPLICABLE TO THE INVESTIGATOR

- (a) he is free to participate in the Clinical Trial 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 Board 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 Team Members. 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 Board to perform the Clinical Trial efficiently and in accordance with its obligations under the Agreement.
- (e) he is employed by, or has a contract for services (commonly known as an honorary contract) with, the Board, which is a member of the Clinical Negligence Scheme for Trusts (CNST), or the Welsh Risk Pooling Scheme for Trusts (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.