

CLINICAL INVESTIGATION AGREEMENT FOR MEDICAL TECHNOLOGY INDUSTRY
SPONSORED RESEARCH IN SCOTTISH HEALTH BOARDS

[Name – Clinical Investigation]

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”)

NOW

WHEREAS the Sponsor is a medical technology company involved in the research, development, manufacture and sale of medical devices for use in humans

WHEREAS the Sponsor is developing new devices, treatments and interventions in the field of [...insert field...]

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 wishes to contract with the Board to undertake a sponsored clinical investigation entitled:

“ insert title and Sponsor’s Unique Identifier number..... ”

It is agreed that the Board and Sponsor shall participate in the aforementioned clinical investigation 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. 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 who is authorised to carry out a systematic review and independent examination of Clinical Investigation related activities and documents to determine whether the evaluated Clinical Investigation related activities were conducted, and the data were recorded, analysed and accurately reported according to the Clinical Investigation Plan, the Sponsor’s Standard Operating Procedures, EN ISO 14155 or ICH GCP and the applicable regulatory requirements.

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

“CE Marked” means bearing the CE Mark to indicate compliance of the medical device with the essential requirements of Council Directive 93/42/EEC concerning medical devices or Council Directive 90/385/EEC concerning active implantable medical devices. A CE marked medical device may be placed on the market and put into service in the EU for its intended purpose.

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

“Clinical Investigation Completion Date” means the date that the final Clinical Investigation Subject was examined or received an intervention for the purposes of collection of data for the primary outcome.

“Clinical Investigation Plan” means the document (a copy of which is at Appendix 1 and signed by the Investigator) that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the Clinical Investigation and all amendments thereto as the Parties may from time to time agree in accordance with clauses 4.9, 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.

“Clinical Investigation Subject” means a person recruited to participate in the Clinical Investigation.

“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 which either 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

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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 or the Sponsor respectively, or which is a trade secret, including Know How.

“CRF” means Case Report Form.

“EN ISO 14155” means EN ISO 14155: Parts 1 and 2: the harmonised International and European standard entitled “Clinical investigation of medical devices for human subjects” which provides voluntary guidance on good clinical practice for medical device clinical investigations.

“ICH GCP” means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95).

“IDE” means the Investigational Device Exemption application process by which the United States Food and Drug Administration exempts medical device companies from the Federal statute that prohibits an unapproved device 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 Investigation and that may be located at the Investigation Site.

“Instructions for Use” means the information provided by the manufacturer to inform the device user of the product’s proper use and of any precautions to be taken.

“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.

“Investigation Monitor” means a person appointed by the Sponsor responsible for ensuring the Investigator’s compliance with the Clinical Investigation Plan and for reporting to the Sponsor on the progress of the Clinical Investigation.

“Investigation Site(s)” means any premises approved by the Board in which the Clinical Investigation will be conducted.

“Investigation Site Team Members” means the persons who will undertake the conduct of the Clinical Investigation at the Investigation Site on behalf of the Board under the supervision of the Investigator.

“Investigational Medical Device” means the CE marked or non-CE marked study device(s) or control material(s) identified in the Clinical Investigation Plan.

“Investigator” means the person who will take primary responsibility for the conduct of the Clinical Investigation at the Investigation Site on behalf of the Board or any other person as may be agreed from time to time between the Parties as a replacement.

“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, software, 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.

“Non-CE Marked” means not bearing a CE Mark for the intended purpose of the medical device for the purposes of the Clinical Investigation.

“Non-regulated Clinical Investigation” means a Clinical Investigation where the Investigational Medical Device is being used for the purpose for which it was CE marked and therefore the Clinical Investigation is not subject to regulatory approval under the Medical Device Regulations 2002. This includes postmarketing clinical studies.

“Party” means the Sponsor, or the Board and “Parties” shall mean both of them.

“Regulated Clinical Investigation” means a Clinical Investigation where an Investigational Medical Device that is not CE Marked, or a CE Marked medical device being used for a new intended purpose, is being investigated following regulatory approval under the requirements of the Medical Devices Regulations 2002.

“Regulatory Authority” includes, but is not limited to, the Medicines and Healthcare products Regulatory Agency, Notified Bodies, as defined in the Medical Devices Regulations 2002, the U.S. Food and Drug Administration, Japan Ministry of Health, Labour and Welfare, and the General Medical Council.

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

“Site File” means the file maintained by the Investigator containing the documentation specified in EN ISO 14155 or ICH GCP.

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

“Substantial Amendment” means an amendment to the terms of the Clinical Investigation Plan that requires approval by the Research Ethics Committee or is likely to significantly affect the obligations of the Parties in respect of the safety, conduct or management or costs of the Clinical Investigation.

“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.

- 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. INVESTIGATOR AND INVESTIGATION 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 6 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 Investigation. Any financial or other arrangements relating to his involvement in the Clinical Investigation 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 Investigation and will ensure that the Investigator is made aware of and acknowledges the obligations applicable to the Investigator set out in Appendix 6 and elsewhere in this Agreement.
- 2.3 The Board shall notify the Sponsor 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 both the Sponsor and the Board, subject to the Board's overriding obligations in relation to Clinical Investigation 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 Investigation Site Team Members as set out in this Agreement

3. CLINICAL INVESTIGATION GOVERNANCE

- 3.1 The Sponsor shall inform the Board and the Investigator of the name and telephone number of the Investigation Monitor and the name of the person who will be available as a point of contact.
- 3.2 The 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 UK country in which the Investigation Site is located including but not limited to, the Human Rights Act 1998, the Data Protection Act 1998, the Medical Devices Regulations 2002 and with all relevant guidance relating to medical devices and clinical investigations from time to time in force including, but not limited to, EN ISO 14155 or 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 Investigation is conducted as part of an IDE, the Board will comply with any other relevant requirements notified by the Sponsor to the Board.
- 3.3 The Sponsor shall comply with all guidelines from time to time in force and published by The Association of British Healthcare Industries in relation to clinical investigations and in particular those entitled "Clinical Investigation Compensation

- 3.4 The Sponsor shall not commit (and 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 Investigation;
 - 3.4.2 make payment or agree to make payment of any commission to any person in the employment of or in the service of the Board in relation to this Agreement or the Clinical investigation.
- 3.5 If the Sponsor or any of his 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 Investigation, 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 Investigation Subjects. If the Sponsor or any of his 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 and shall, in particular, have considered the potential effects of termination on the health of the Clinical Investigation Subjects.
- 3.6 Should there be any inconsistency between the Clinical Investigation Plan and the other terms of this Agreement, or any other document incorporated therein, including the Sponsor's Standard Operating Procedures, the terms of the Clinical Investigation Plan 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 where required for the conduct of the Clinical Investigation and the Investigator shall keep the Sponsor and the R&D Office fully apprised of the progress of any ethics committee submissions and shall upon request provide the Sponsor and the R&D Office with all correspondence relating to such submissions. The Investigator shall not consent to any change in the Clinical Investigation Plan requested by a relevant ethics committee without the prior written consent of the Sponsor.
- 4.2 Subject to clause 4.3, to satisfy public interest in the open registration of

information concerning Clinical Investigations involving NHS patients and facilities, the Sponsor shall submit the Clinical Investigation for listing in a free, publicly accessible clinical trial registry within twenty one (21) days of initiation of patient enrolment.

4.3 Deferred registration

If, having considered all the circumstances, the Sponsor is of the view that the public interest benefits of registering the Clinical Investigation on the timescale specified in clause 4.2 are outweighed by the harm that registration at that time might do to the commercial value of the Investigational Medical Device or the commercial interests of the Sponsor, registration of the Clinical Investigation may be deferred as follows:

4.3.1 Regulated Clinical Investigation

The Sponsor may defer registration until thirty (30) days after the date that the Investigational Medical Device is CE Marked for the intended purpose being investigated. In the event that the Sponsor decides not to CE Mark the Investigational Medical Device for the intended purpose being investigated, the Sponsor may defer registration for up to twenty four (24) months after the Completion Date. The Clinical Investigation shall also be registered within twenty one (21) days of a decision to close the Clinical Investigation on safety grounds. In any event, the Sponsor shall register the Clinical Investigation within thirty six (36) months of the date scheduled for resolution of all CRF queries set out in Appendix 2.

4.3.2 Non-regulated Clinical Investigation

In the case of a Non-regulated Clinical Investigation, the Sponsor may defer registration for up to twelve (12) months after the Clinical Investigation Completion Date. In any event, the Sponsor shall register the Clinical Investigation within eighteen (18) months of the date scheduled for resolution of all CRF queries set out in Appendix 2.

4.4 In addition to any publications in learned journals relating to the Clinical Investigation, as set out at clause 8 below, to satisfy public interest in the results of Clinical Investigations involving NHS patients and facilities, the Sponsor shall ensure that the analysis of the results of the Clinical Investigation are published on a free, publicly accessible clinical trial results database as follows:

4.4.1 Regulated Clinical Investigation

The Sponsor shall publish the analysis of the results within thirty (30) days of CE Marking for the intended purpose being investigated. In respect of a Clinical Investigation that is under review by peer-reviewed journals that prohibit disclosure of results pre-publication, the analysis of the results shall be posted at the time of publication.

Following analysis of data from the Clinical Investigation, in the event that the Sponsor decides not to CE Mark the Investigational Medical Device

for the intended purpose being investigated, the Sponsor shall publish the analysis of the results within twenty four (24) months of the Clinical Investigation Completion Date. In the case of Clinical Investigations closed on safety grounds, the Sponsor shall publish the analysis of the results within twelve (12) months of the date of closure. In any event, the analysis of the results of the Clinical Investigation shall be posted within thirty six (36) months of the date scheduled for resolution of all CRF queries set out in Appendix 2.

4.4.2 Non-regulated Clinical Investigation

The Sponsor shall publish the analysis of the results of the Clinical Investigation within twelve (12) months of the Clinical Investigation Completion Date. In any event, Sponsor shall publish the analysis of the results of the Clinical Investigation within eighteen (18) months of the date scheduled for resolution of all CRF queries set out in Appendix 2.

4.5 Neither the Board nor the Investigator shall register either the Clinical Investigation or the results on any publicly accessible clinical trial registry or results database.

4.6 The Parties shall conduct the Clinical Investigation in accordance with:

4.6.1 the Clinical Investigation Plan, a copy of which is attached at Appendix 1 to this Agreement;

4.6.2 the manufacturer's recommended Instructions for Use for the Investigational Medical Device

4.6.3 in the case of a Non-regulated Clinical Investigation, the intended purpose for which the Investigational Medical Device has been CE Marked as detailed in the Instructions for Use.

4.6.4 the Letter of No Objection to the Clinical Investigation issued by the Medicines and Healthcare products Regulatory Agency for a Regulated Clinical Investigation;

4.6.5 the terms and conditions of the favourable opinion of the relevant [...insert name...] Research Ethics Committee where an opinion is required under National Research Ethics Service (NRES) guidance on medical device studies, copies of which the Board shall supply to the Sponsor on request.

4.7 For Regulated Clinical Investigations, until the Sponsor has obtained all required documentation from the Regulatory Authority (where necessary) and a favourable opinion from the Research Ethics Committee, it shall not supply the Investigational Medical Devices to the Board. For Regulated Clinical Investigations, the Board shall ensure that neither administration of the Investigational Medical Device to any Clinical Investigation Subject nor any other clinical intervention mandated by the Clinical Investigation Plan takes place in relation to any such Clinical Investigation Subject until it is satisfied that all

relevant regulatory approvals and a favourable opinion from the research ethics committee have been obtained.

- 4.8 For Non-regulated Clinical Investigations, the Board shall ensure that neither administration of the Investigational Medical Device to any Clinical Investigation Subject nor any other clinical intervention mandated by the Clinical Investigation Plan takes place in relation to any such Clinical Investigation Subject until it is satisfied that where necessary, a favourable opinion from the research ethics committee has been obtained.
- 4.9 In the event of any Substantial Amendments being made to the Clinical Investigation Plan, the amendments shall be signed by the Investigator and shall be implemented by the Investigation Site Team Members as required by the Sponsor. The Sponsor shall initiate simultaneously the change control procedures set out in clause 14 below.
- 4.10 The Sponsor shall make available to the Investigator copies of the documentation referred to in clauses 4.6.1 and 4.6.2 and evidence of grant of the authorisation listed in clause 4.6.4 above and the Investigator shall include such documents together with the favourable opinion of the research ethics committee in the Site File, where this was required under NRES Guidance mentioned at clause 4.6.5.
- 4.11 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 date the Clinical Investigation has been completed.
- 4.12 Neither the Board nor the Investigator shall permit a non-CE marked Investigational Medical Device to be used for any purpose other than the conduct of the Clinical Investigation. Upon termination or expiration of this Agreement, the disposal or return of Investigational Medical Devices supplied by the Sponsor for the Clinical Investigation shall be managed in accordance with the Clinical Investigation Plan or the Sponsor's written instructions.
- 4.13 The Board shall use its best endeavours to ensure that the Investigator recruits [...insert number...] Clinical Investigation Subjects to participate in the Clinical Investigation and the Parties shall conduct the Clinical Investigation in accordance with the Timelines.
- 4.14 In the event that the Clinical Investigation is part of a multi-centre clinical investigation (which for the purposes of this Agreement shall mean that at least one other institution is taking part) the Sponsor may amend the number of Clinical Investigation Subjects to be recruited pursuant to clause 4.13 above as follows:
 - 4.14.1 if in the reasonable opinion of the Sponsor recruitment of Clinical Investigation Subjects is proceeding at a rate below that required to enable the relevant Timeline to be met the Sponsor may by notice to the Board require recruitment at the Investigation Site to cease and the terms of the Agreement shall relate thereafter to the number of Clinical Investigation Subjects who have been enrolled in the Clinical Investigation at the date of such notice; or

- 4.14.2 if recruitment of Clinical Investigation Subjects is proceeding at a rate above that required to meet the relevant Timeline the Sponsor may with the agreement of the Board increase the number of Clinical Investigation Subjects to be recruited.
- 4.15 The following provisions relate to access, research misconduct and Regulatory Authorities:
- 4.15.1 The Board shall permit the Investigation Monitor, Sponsor's appointed representatives and any Auditor or Inspector access to all relevant clinical data of Clinical Investigation Subjects for monitoring, source data verification and adverse event reporting or investigation, such access to be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Clinical Investigation, reasonable access to Investigation Site Team Members and to examine any procedures or records relating to the Clinical Investigation, in accordance with the provisions of clause 6.2 of this Agreement. The Sponsor will alert the R&D Office of the Board promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Investigation.
- 4.15.2 In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Investigation, 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, 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 Investigation, the Sponsor 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.
- 4.15.3 The Board shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and/or visit to the Investigation Site by any Regulatory Authority in connection with the Clinical Investigation and forward to the Sponsor copies of any correspondence from any such Regulatory Authority relating to the Clinical Investigation. The Board will use all reasonable endeavours to procure that the Sponsor may have a representative present during any such visit.
- 4.15.4 The Board will permit the Sponsor to examine the conduct of the Clinical Investigation and the Investigation Site upon reasonable advance notice during regular business hours to determine that the Clinical Investigation is being conducted in accordance with the Clinical Investigation Plan, EN ISO 14155 or ICH GCP and the applicable regulatory requirements.
- 4.15.5 The Board and Investigator will co-operate with the Sponsor in the

investigation and reporting of any unanticipated adverse events and incidents to the relevant Regulatory Authority.

- 4.15.6 The Sponsor shall provide, and the Board shall permit the Investigator and Investigation Site Team Members to participate in, product training as necessary, investigation-related training, EN ISO 14155 or ICH GCP training as appropriate, and investigator meetings organised by the Sponsor.
- 4.16 The Board shall ensure that any clinical biological samples required to be tested by the Board during the course of the Clinical Investigation are tested in accordance with the Clinical Investigation Plan and at a laboratory approved by the Sponsor.
- 4.17 Upon completion of the Clinical Investigation (whether prematurely or otherwise) the Investigator shall co-operate with the Sponsor in producing a report of the Clinical Investigation detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.
- 4.18 Subject to the Board's and the Investigator's overriding obligations in relation to Clinical Investigation Subjects and individual patient care, neither the Board nor the Investigator nor Investigation Site Team Members shall during the term of this Agreement conduct any other investigation or trial which might hinder the Board's or Investigator's ability to recruit and study the required cohort of Clinical Investigation 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 Investigation 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 either Party which cannot be so restricted or excluded in law.
- 5.3 In no circumstances shall either Party be liable to the other 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 or 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 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 Investigation shall in no event exceed the amount of fees payable by the Sponsor to the Board under this Agreement. In the case of equipment loaned to the Board for the purposes of the Clinical Investigation, 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 arising out of or in connection with the breach shall not exceed 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 Investigation Subjects involved in the Clinical Investigation. Personal data (as defined in the Data Protection Act 1998) shall not be disclosed to the Sponsor by the Board save where this is required to satisfy the requirements of the Clinical Investigation Plan or for the purpose of monitoring, auditing or adverse event reporting or investigation, or in relation to a claim or proceeding brought by the Clinical Investigation Subject in connection with the Clinical Investigation. The Sponsor shall not disclose the identity of Clinical Investigation Subjects to third parties without prior written consent of the Clinical Investigation 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 Investigation Subject in connection with the Clinical Investigation.

- 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 either Party is acting as the data processor of the other 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 Investigation 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 both 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 other prior to the disclosure of any Personal Data created in connection with the conduct or performance of the Clinical Investigation in relation to such requests.
- 6.2.6 **Freedom of Information**
- The Sponsor acknowledges that the Board is subject to the Freedom of Information Act (Scotland) 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 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 in accordance with all applicable guidance.
- 6.2.8 The Sponsor acknowledges and agrees 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 shall co-operate with the Board and shall use its reasonable endeavours to respond within eight (8) 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, it will notify the Sponsor in writing, giving at least four (4) working days notice of its intended disclosure.

6.3 Confidential Information

- 6.3.1 The Sponsor and the Board shall ensure that only those of its officers, Agents and employees (and in the case of the Sponsor those of its Affiliates) directly concerned with the carrying out of this Agreement have access to the Confidential Information of the other Party. 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 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 Party, other than in accordance with this Agreement, without the prior written consent of the other Party.
- 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 the other 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 ten (10) years after the termination or expiry of this Agreement.

7. PUBLICITY

- 7.1 The Sponsor will not 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 Investigation Site Team Members do not, use the name of the Sponsor or Affiliate or of any of its employees, nor the name of the Clinical Investigation, nor the name of the Investigational Medical Device, in any publicity, advertising or news release without the prior written approval of the Sponsor, 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 Investigation 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.

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 Investigation 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 Investigation, subject to this clause 8 and any publication policy described in the Clinical Investigation Plan. If the Clinical Investigation is multi-centred (as defined in clause 4.12 above), any publication based on the results obtained at the Investigation 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 Investigation the publication shall make reference to the relevant multi-centre publication(s).
- 8.2 Upon completion of the Clinical Investigation, and any prior publication of multi-centre data, or when the Clinical Investigation data are adequate (in Sponsor's reasonable judgement), the Board and/or the Investigator may prepare the data derived from the Clinical Investigation 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 Clinical Investigation Plan 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 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 Investigation 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 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 policy and generally accepted standards for authorship. If the Investigator or other representative of the Board is a named author of the multi-centre publication, such person shall have access to the Clinical Investigation data from all Clinical Investigation 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 and subject to the provisions of clause 4.4 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 Investigation Plan are and shall remain the property of the Sponsor.
- 9.2 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 Investigation Plan are and shall remain the property of the Board.
- 9.3 All Intellectual Property Rights and Know How arising from and relating to the Clinical Investigation Plan or the Investigational Medical Device (including but not limited to its design and use alone or in combination with other medical devices or medicinal products), and including the results of the Clinical Investigation, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Board, shall vest in the Sponsor in accordance with clauses 9.4 and 9.5 below.
- 9.4 In accordance with clause 9.3 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 9.3 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.
- 9.5 The Board and the Investigator shall promptly disclose to the Sponsor any Know How generated pursuant to this Agreement and falling within clause 9.3 above and undertake not to use or disclose such Know How other than for the purposes of this Agreement.
- 9.6 Nothing in this clause 9 shall be construed so as to prevent or hinder the Board from using Know How gained during the performance of the Clinical Investigation 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 Investigation by the Sponsor are set out in Appendix 5 hereto.
- 10.2 In the event that amendments to the Clinical Investigation Plan require changes to the investigation 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 5 of this Agreement.
- 10.3 All payments will be made according to the schedule contained in Appendix 5 on presentation of a VAT invoice to the Sponsor by the Board.
- 10.4 The Sponsor shall promptly respond to any reasonable request for invoicing data received from the Board within forty five (45) days of the close-out of the Investigation 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 Sponsor as soon as possible and, in any event, within forty five (45) days of receipt of the said data where such a request has been made, or within forty five (45) days of study close-out in all other circumstances unless there is a written agreement between the Board and the Sponsor to extend these periods.
- 10.5 The Sponsor shall make payment 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 the Sponsor will incur an interest charge on any amounts overdue of two (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 Investigation, close-out of the Investigation 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 Either the Sponsor or the Board (the Terminating Party) may terminate this Agreement with immediate effect at any time if the 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 twenty eight (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 Party with immediate effect if it is reasonably of the opinion that the Clinical Investigation should cease in the interests of the health of Clinical Investigation Subjects involved in the Clinical Investigation.
- 12.3 The Sponsor 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 Board and the Sponsor 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 Investigation Subjects caused by the premature termination of the Clinical Investigation.
- 12.5 In the event of early termination of this Agreement by the Sponsor, pursuant to clauses 12.2, 12.3 and 12.4 and subject to an obligation on the Board and the Investigator to mitigate any loss, the Sponsor 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 Investigation prior to the date of termination, and agreed with the Sponsor.
- 12.6 In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Sponsor 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 written notice from the Sponsor.
- 12.7 At close-out of the Investigation 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 at the Sponsor's expense, all Confidential Information and any other unused materials and/or equipment provided to the Board and/or the Investigator pursuant to this Agreement.
- 12.8 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 Neither 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 Any amendment to the Clinical Investigation Plan pursuant to clause 4.9 ("Clinical Investigation Plan 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 Clinical Investigation Plan Amendment.

14.2.2 Where the Sponsor originates a change request, the Board shall provide the Sponsor, within thirty five (35) days of receiving the change request, details of the impact which the proposed Clinical Investigation Plan Amendment will have upon the costs of carrying out the Clinical Investigation 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 both Parties.

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

14.3 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 Investigation, 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

Neither 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 Sponsor 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 either 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 , either Party shall be entitled to submit to the exclusive jurisdiction of the Scottish Courts.

19.4 Nothing in this Agreement shall prevent either 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 either 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 to 3.6 (inclusive)	Clinical Investigation Governance
4.3, 4.4, 4.5, 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
12.5 to 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 governed and construed in accordance with the laws of Scotland.

Signed on behalf of the:

SPONSOR:

.....

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 Investigation Plan

APPENDIX 2

TIMELINES FOR PARTIES

Milestone	Sponsor responsibility	Site responsibility	Target date
Provision of materials for Ethics Committee submission	X		
Ethics Committee submission	[X]	X	
Investigation Site initiation visit	X	X	
First Clinical Investigation Subject recruited		X	
Last Clinical Investigation Subject recruited		X	
All CRF queries submitted	X		
All CRF queries completed		X	

APPENDIX 3

CLINICAL INVESTIGATION COMPENSATION GUIDELINES

Preamble

The Association of British Healthcare Industries favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by a participation in clinical investigations. The Association therefore recommends that a member company sponsoring a clinical investigation 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 investigation in 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 use of a medical device under investigation or any clinical intervention or procedure provided for by the clinical investigation plan that would not have occurred but for the inclusion of the patient in the investigation.
- 1.3 Compensation should be paid to a child injured in utero though the participation of the subject's mother in a clinical investigation as if the child were a patient-volunteer with the full benefit 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 curable complaints.
- 1.5 Where there is an adverse event caused by a medical device under investigation and injury caused by a procedure adopted to deal with that adverse event, compensation should be paid for such injury as if it were caused directly by the medical device under investigation.
- 1.6 Neither the fact that the adverse event 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 investigation 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 medical device under investigation or that the product 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 clinical investigations, that is to say, patients under treatment and surveillance (usually in hospital) which the use of the medical device under investigation is intended to assist but where the device does not bear “CE” marking in relation to the aspect(s) under investigation.
- 2.2 These Guidelines do not apply to injuries arising from clinical investigations on medical devices bearing “CE” marking, denoting compliance with Directives 90/385/EEC or 93/42/EEC, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the clinical investigation plan (but not any product administered or used) to which the patient would not have been exposed had treatment been other than in the course of the investigation.
- 2.3 These Guidelines do not apply to clinical investigations which have not been initiated or directly sponsored by the company providing the product for research. Where investigations of products are initiated independently by doctors or third parties, responsibility for the health and welfare of patients rests with that doctor (or third party) alone (see also paragraph 5.2 below).

3. Limitations

- 3.1 No compensation should be paid for the failure of a medical device 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 any other “CE” marked medical device or product used on the patient for the purpose of comparison with the medical device under investigation.
- 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 it 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 clinical investigation plan;
 - 3.4.2 through the wrongful act or default of a third party, including a doctor’s failure to deal adequately with an adverse event; or
 - 3.4.3 through contributory negligence by the patient.

4. Assessment of Compensation

- 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, or in 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 events will occur and their seriousness, any warnings and precautions given; or

4.2.2 the risk and benefits of established treatments relative to those known or suspected of the medical device.

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 event. Participation in the investigation is then based on an expectation that the risk/benefit 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 incident 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 a 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 cost (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, setting out details of the nature and background of the claim and, subject to the patient providing on request and 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 investigation but not to treatment extended beyond the end of the investigation at the instigation of the investigator. The use of products not bearing CE marking beyond the investigation period is wholly the responsibility of the investigator.

5.3 The fact that a company has agreed to abide by these Guidelines in respect of an investigation 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. Nevertheless, 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 an investigation should encourage the investigator to make clear to participating patients that the investigation is being conducted subject to these Guidelines relating to compensation for injury arising in the course of clinical investigations 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 Investigation Subjects and (or their dependants) against the Board or any of its employees or agents for personal injury (including death) to Clinical Investigation Subjects arising out of or relating to the administration of the Investigational Medical Devices under investigation or any clinical intervention or procedure provided for or required by the Clinical Investigation Plan to which the Clinical Investigation Subjects would not have been exposed but for their participation in the Clinical Investigation;
 - 1.2 by the Board, its employees or Agents or by or on behalf of a Clinical Investigation Subject for a declaration concerning the treatment of a Clinical Investigation 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 Investigation in accordance with the Clinical Investigation Plan;
 - 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

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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 Investigation 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 Investigation Subject while participating in the Clinical Investigation, the Sponsor agrees to operate in good faith the guidelines published in 1995 by The Association of the British Healthcare Industries and entitled "Clinical Investigation Compensation Guidelines" and shall request the Investigator to make clear to the Clinical Investigation Subjects that the Clinical Investigation 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 Investigation.

APPENDIX 5

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 6

CONDITIONS APPLICABLE TO THE INVESTIGATOR

- (a) he is free to participate in the Clinical Investigation 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 Investigation and, where relevant, his supervision of Investigation 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 Investigation are available to him at the Investigation 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 Investigation efficiently and in accordance with its obligations under the Agreement.
- (f) 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.
- (g) during the Clinical Investigation, he will not serve as an investigator or other significant participant in any clinical investigation or trial for another sponsor if such activity might adversely affect his ability to perform his obligations under this Agreement.