

COLLABORATION AGREEMENT FOR [NAME OF PROJECT]

1. DEFINITIONS.....	2
2. PURPOSE.....	5
3. VALIDITY AND ENTERING INTO FORCE.....	6
4. UNDERTAKING THE PROJECT.....	6
5. LIABILITIES OF THE PARTIES.....	8
6. CONFIDENTIALITY.....	10
7. MATERIAL TRANSFER OBLIGATIONS.....	11
8. OWNERSHIP OF BACKGROUND.....	12
9. OWNERSHIP OF FOREGROUND.....	13
10. OWNERSHIP OF SIDEGROUND.....	14
11. GENERAL PROVISIONS APPLYING TO ACCESS RIGHTS.....	14
12. ACCESS RIGHTS TO PARTIES FOR COMPLETING THE PROJECT.....	14
13. ACCESS RIGHTS TO THE PARTIES AND AFFILIATED ENTITIES FOR RESEARCH USE.....	15
14. ACCESS RIGHTS TO THIRD PARTIES FOR RESEARCH USE.....	16
15. ACCESS RIGHTS FOR DIRECT EXPLOITATION.....	16
16. ACCESS RIGHTS FOR NEW AND DEPARTING PARTIES.....	17
17. DISSEMINATION.....	18
18. ADDITIONAL PARTIES.....	19
19. TERMINATION.....	19
20. TERMINATION FOR BREACH.....	20
21. CONTINUING OBLIGATIONS.....	20
22. ASSIGNMENT.....	20
23. DISPUTE RESOLUTION.....	21
24. NOTICES.....	22
25. ENTIRE AGREEMENT.....	22
26. LAW.....	23
SIGNATURES.....	24
<u>Appendix 1</u>	26
<u>Appendix 2</u>	27
<u>Appendix 3</u>	28
<u>Appendix 4</u>	29
<u>Appendix 5</u>	30
<u>Appendix 6</u>	32

THIS AGREEMENT dated [] 20[16] is made
BETWEEN:

- (1) [.....], whose administrative offices are at [.....] ;
- (2) [.....], whose administrative offices are at [.....] ;
- (3) [.....], whose administrative offices are at [.....] ;

WHEREAS:

IFD has announced its intention to make a grant in respect of the project entitled “[insert name of project]”, subject to the terms of the Investment Agreement, and subject to the Parties entering into an agreement governing their collaboration, the “Collaboration Agreement”.

This Collaboration Agreement governs the Parties’ collaboration in relation to that project.

THEREFORE IT IS AGREED AS FOLLOWS:

1. DEFINITIONS

Any word(s) or expression(s) appearing in this Collaboration Agreement shall have the meaning ascribed to them herein unless such word(s) or expression(s) are defined in the Investment Agreement.

“Access Rights” means the rights to use; [Parties to consider whether it could be relevant to expand the definition.]

“Administrator” means the Party appointed in accordance with the Investment Agreement, and approved by IFD, to be responsible for the receipt from IFD of IFD’s investment under the Investment Agreement and distribution thereof amongst the Parties in accordance with the Investment Agreement. The rights and obligations of the Administrator are further described in the Investment Agreement;

“Affiliated Entity” means any legal entity that is under the direct or indirect control of a Party, under the same direct or indirect control as a Party, or is directly or indirectly controlling a Party, control taking any of the following forms: (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders of that entity; (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned; [If

only Danish Parties, this definition should be considered amended to refer to the understanding of "Affiliated Entity" under the Danish Companies Act.]

“Allocated Work” means the research work and the related activities and services allocated to a Party in accordance with the Project Plan;

“Background Knowledge” means information, including data and know-how which is held by a Party prior to, on or after the accession to the Investment Agreement, as well as copyrights or other intellectual and industrial property rights pertaining to such information, and which is necessary for carrying out the Project and which is defined in Appendix 3 to this Collaboration Agreement;

“Collaboration Agreement” means this agreement and all of its appendices, together with amendments validly agreed in writing amongst the Parties;

“Company” means each of [name]..... and [name];

“Companies” means [name]..... and [name];

“Confidential Information”: all information, including, but not limited to, information deemed to be Background Knowledge under the Collaboration Agreement, as well as all information, including, but not limited to, all results and derived intellectual property rights arising in connection with the Project, or information otherwise deemed to be Foreground Knowledge under the Collaboration Agreement. Notwithstanding the foregoing, information provided orally shall be deemed to be Confidential Information only if the Receiving Party within ten (10) days from receipt of the information receives written notice from the Providing Party describing the information in question and stating that such information shall be treated as Confidential Information;

“Direct Exploitation” means to develop for commercialization or to commercialise Foreground Knowledge itself; [Parties to consider amending the definition to suit the actual collaboration.]

“Disseminate”/“Dissemination” means disclosure by any appropriate means other than that resulting from the formalities for protection, and including the publication in any medium;

“Eligible Costs” means those costs incurred by each Party in carrying out its Allocated Work under the Project; the nature of such costs is more particularly detailed in Exhibit [3] (Budget) of the Investment Agreement;

“Fair and Reasonable Conditions” means appropriate conditions including financial terms (where appropriate) taking into account the actual or potential value of the Foreground Knowledge or Background Knowledge to which access is requested and other characteristics of the Research Use envisaged;

“Field” means the area of this Project within which the Institution is willing to give Access Rights for Direct Exploitation, cf. Clause 15. The Field is defined in Appendix 7;

“Field of Use” means the area within the Field in which each Company intends to make Direct Exploitation of the Foreground Knowledge, which is defined in Appendix 8;

“Foreground Knowledge” means the results, including data, know-how and information, whether or not they can be protected, which are generated under the Project and excluding Sideground Knowledge. Such results include rights related to copyright; design rights; patent rights; or similar forms of protection; [Parties to consider amending the definition to suit the actual collaboration.]

“IFD” means the Innovation Fund Denmark, as established by the Minister for Higher Education and Science pursuant to Act no. 306 of 29 March 2014;

“Institution” means each of [name]..... and [name];

“Institutions” means [name]..... and [name];

[“Intellectual Property Rights” - Parties to consider whether it could be relevant to include a definition of intellectual property rights.]

“Investment Agreement” means the Investment Agreement ([project name to be inserted]) Journal no. ([number to be inserted]), entered into or to be entered into between the Parties and IFD for the undertaking by the Parties of the Project;

Material Receiving Party has the meaning given to it in Clause 7;

“Materials” means chemical and/or biological materials;

“Party” means a party to this Collaboration Agreement, and “Parties” shall be interpreted accordingly. The Parties to this Collaboration Agreement are the Project Participants as specified in the Investment Agreement;

“Project” means the project and the research activities to be carried out by the Parties as defined in the Project Plan as amended from time to time;

“Project Leader” means in accordance with the Investment Agreement, the person appointed by the Steering Committee, and approved by IFD, to act as the project leader for the Project;

“Project Objectives” means the objectives which are defined in the Project Plan;

“Project Partner” has the meaning given to it in the Investment Agreement;

“Project Plan” means the project plan enclosed in the Investment Agreement as its Exhibit [1], as amended from time to time;

“Project Share” means for each Party that Party’s share of the total cost of the Project as outlined in Exhibit [3] (Budget) of the Investment Agreement and as shall be more specifically determined in accordance with the provisions of the Investment Agreement and this Collaboration Agreement;

”Providing Party” has the meaning given to it in Clause 6;

“Receiving Party” has the meaning given to it in Clause 6;

“Representative” means the person chosen by a Project Partner, who is employed by the Project Partner or by an Affiliated Entity, to represent it on the Steering Committee;

“Research Use” means the use of Foreground Knowledge or Background Knowledge necessary to use Foreground Knowledge for all purposes other than for completing the Project or for Direct Exploitation; [Parties to consider amending the definition to suit the actual collaboration.]

“Royalty-free Basis” means that there is no obligation to pay royalties, fees, milestone payments or to make any other payments in order to obtain the rights in question;

“Sideground Knowledge” means the results, including data, know-how and information, whether or not they can be protected, which are generated by a Party under the Project but outside of the Project Objectives and which are not needed for undertaking and completing the Project or the Research Use of Foreground Knowledge. Sideground Knowledge specifically excludes Foreground Knowledge;

“Steering Committee” means a committee comprised of, collectively, the Representatives and the Investment Manager(s) appointed by IFD and shall be the ultimate decision-making body for the Project as specified in the Investment Agreement;

“Sub-contractor” means a Third Party which has entered into an agreement on business conditions with a Party, in order to carry out part of the work of the Project without the direct supervision of the Party and without a relationship of subordination;

“Third Party” means any individual or legal entity which is not a Party; and

“Transferring Party” has the meaning given to it in Clause 7.

2. PURPOSE

- 2.1 The purpose of this Collaboration Agreement is to facilitate the completion of the Project by the Parties in accordance with the provisions of the Investment Agreement, by supplementing the contractual provisions of the Investment Agreement to more specifically detail the rights and obligations of the Parties

amongst each other in relation to, inter alia, financial provisions, the performance of the Project, issues relating to intellectual property rights, and access to arising Foreground Knowledge and Background Knowledge by the Parties and Third Parties, and the liability and indemnification of the Parties amongst each other.

- 2.2 This Collaboration Agreement is not intended, and nothing contained herein shall be deemed, to create any partnership, agency or joint venture amongst the Parties or any of the Parties, nor to establish any other legal entity constituted amongst any or all of the Parties.

3. VALIDITY AND ENTERING INTO FORCE

- 3.1 This Collaboration Agreement shall be entered into between the Parties at the same time as the Parties' and IFD's entering into of the Investment Agreement, and is deemed to have been validly entered into between the Parties, and to be legally binding, when signed on behalf of each Party by the appropriate authorised signatories, as of the date that the Investment Agreement comes into effect.
- 3.2 This Collaboration Agreement shall remain in force until the Project has been completed and the Parties have performed their obligations in respect thereof, unless earlier terminated in accordance with this Collaboration Agreement and the Investment Agreement.

4. UNDERTAKING THE PROJECT

- 4.1 Each Party shall carry out the tasks specifically allotted to it in the Project, both in relation to the completion of each such Party's Allocated Work, and in relation to all other undertakings and obligations pursuant to the Investment Agreement and the Collaboration Agreement. Each Party shall use [reasonable]/[best] efforts to complete each such Party's Allocated Work.
- 4.2 Without limitation to the generality of Clause 4.1, each Party shall promptly, at the request of the Project Leader and/or the Administrator or as may be otherwise specified in this Collaboration Agreement or in the Investment Agreement, provide or forward to the Project Leader and the Administrator all data, information or material which the Project Leader and the Administrator are required to collect, pursuant to the provisions of this Collaboration Agreement, (and in particular the provisions of Clause 8), or under the Investment Agreement.
- 4.3 Although each Party will use [reasonable]/[best] efforts to carry out its Allocated Work, neither Party undertakes that any research will lead to any particular result, nor does it guarantee a successful outcome to the Project. See also Clause [7.9] of the Investment Agreement.

- 4.4 Where a Party intends to sub-contract a share of its Allocated Work to a Sub-contractor, pursuant to the Project Plan, such Party shall be liable for the acts and omissions of its Sub-contractor as if those acts and omissions had been performed by such Party and, as such, shall remain responsible for and liable in respect of the implementation of such share and for the satisfaction of all obligations relative to such share arising under this Collaboration Agreement and under the Investment Agreement. Other than to the extent provided in the Project Plan, or as may be otherwise expressly permitted either under the Investment Agreement or pursuant to any provision of this Collaboration Agreement, no Party shall be entitled to sub-contract any part of its Allocated Work to a Sub-Contractor.

[Where no Party has been pre-designated as responsible for obtaining sub-contraction in respect of certain services, etc. which have to be sub-contracted to the Project as per the Project Plan/Budget, and which services, etc. are funded by IFD, the Collaboration Agreement shall contain provisions ensuring that any and all rights to such services, etc. sub-contracted to the Party who eventually is designated as responsible for such sub-contraction shall be acquired by the Party for the purpose of the Project and shall be made available to the Project and the other Parties, and shall not be applied by the Party for the purpose of its own business.]

- 4.5 [The Collaboration Agreement shall contain relevant and sufficient undertakings by the Parties with regard to the handling of any human tissue or biological samples which may be used in the Project, including in respect of the obtaining of informed consents where required.]
- 4.6 [Particularly where one or more Parties to the Project comes from outside the Scandinavian countries, the following undertakings should be considered included in the Collaboration Agreement.][Unless otherwise required or prohibited by law, the Parties warrant, to the best of their knowledge, that in relation to the performance of this Collaboration Agreement:
- (i) they do not employ engage or otherwise use any child labour
 - (ii) they do not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;
 - (iii) they provide a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Parties to their employees is safe for habitation. The Parties provide access to clean water, food, and emergency healthcare to their employees in the event of accidents or incidents in the workplace;
 - (iv) they do not discriminate against any employees on any ground (including race, religion, disability or gender).

- (v) they do not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;
- (vi) they comply with the laws on working hours and employment rights in the countries in which they operate;
- (vii) they are respectful of their employees' right to join and form independent trade unions and freedom of association.

The Parties agree that they are responsible for controlling their own supply chain and that they shall encourage compliance with ethical standards and human rights by any subsequent supply of goods and services that are used by the Parties when performing their obligations under this Collaboration Agreement.]

[The Parties shall in all cases consider whether it could be relevant to include specific warranties in this Collaboration Agreement.]

- 4.7 The Parties shall perform their obligations and exercise their rights under this Collaboration Agreement and the Investment Agreement in accordance with Danish law.
- 4.8 [Where the Project involves use of animals, this Collaboration Agreement should include undertakings by the Parties ensuring that all work involving the use of animals in research will be performed in accordance with all applicable laws, regulations and ethical guidelines, as outlined in Appendix 4.]
- 4.9 [Where the Project involves clinical trials, this Collaboration Agreement should include undertakings by the Parties ensuring that clinical trials will be performed in accordance with all applicable laws and the Parties should include in this Collaboration Agreement, or agree in separate agreement, provisions governing the clinical trials and the Parties' obligations in respect thereof][See template attached in Appendix 5.]

5. LIABILITIES OF THE PARTIES

To each other

- 5.1 In respect of information or materials, including Materials, supplied by one Party to another hereunder or pursuant to the Investment Agreement, the supplier Party shall be under no obligation or liability other than as expressly stated herein or in the Investment Agreement, and unless so stated no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials, or the absence of any infringement of any proprietary rights of Third Parties or the other Parties, by the use of such information and materials, and the recipient Party shall in any case be entirely responsible for the use to which it puts such information and materials.

[Parties to consider including provisions concerning the Parties' liability to each other outside situations of Third Party claims.]

- 5.2 Each Party shall indemnify each other Party against all loss, damage or injury incurred by each such other Party resulting from any claim, complaint, proceeding or cause of action brought by a Third Party alleging or arising from (i) negligent or wilful misconduct or (ii) infringement of Third Party intellectual property rights by itself, its employees, Sub-contractors or its agents; provided always that the foregoing obligation to indemnify shall not extend to claims for indirect or consequential loss or damage, including but not limited to loss of profit, revenue or contracts, [and provided that the total limit of liability of any Party to the other Parties collectively in respect of any one claim or series of connected claims, shall not exceed that Party's Project Share][Parties to consider whether an overall cap on the individual Party's liability could be relevant.] The indemnitee shall immediately advise the indemnitor of any such claim in writing. The indemnitor shall have the right to select defence counsel and to direct the defence or settlement of any claim which is the subject of this indemnity. The indemnitee shall reasonably co-operate with the indemnitor and its legal representatives in the investigation and defence of any such claim. The indemnitee shall refrain from making any admission of liability or any attempt to settle the claim without the indemnitor's prior written consent. The indemnitee may obtain representation by separate legal counsel, at its own expense.
- 5.3 Nothing in this Collaboration Agreement may be construed to limit (i) the right of any Party to bring an action for damages against any Third Party, including claims for indirect, special or consequential damages, based on any acts or omissions of such Third Party or (ii) the liability of a Party for personal injury or death resulting from the negligence of such Party or its employees, officers, directors, agents, or representatives (as applicable).

Towards Sub-contractors

- 5.4 Subject always to such other undertakings and warranties as are provided for in this Collaboration Agreement and the Investment Agreement, each Party shall be solely liable for any loss, damage or injury to its Sub-contractors resulting from carrying out its Allocated Work and from its use of Foreground Knowledge and/or Background Knowledge, or from entering into or defaulting under any contractual or other relationship with any such Sub-contractor(s).

Freedom to Operate

- 5.5 Without prejudice to any of the foregoing provisions of this Clause 5, each Party acknowledges that it shall be solely responsible for ensuring that it has all necessary licences under intellectual property owned by Third Parties (that are not Affiliated Entities of a Party) to enable it to complete the Project and make any Research Use of Foreground Knowledge or carry out the Direct Exploitation of Foreground Knowledge whether owned by it or to which is has been granted Access Rights hereunder.

6 CONFIDENTIALITY

- 6.1 No Confidential Information which a Party (the “Receiving Party”) receives from another Party (the “Providing Party”) under the Collaboration Agreement, including in connection with the Project, shall be disclosed by the Receiving Party to any third party except in the permitted situations as stated below (Permitted Disclosure). Any Permitted Disclosure of Confidential Information shall be conditional upon the receiving third party being sufficiently informed about the confidential nature of the information disclosed and prior to receipt entering into a confidentiality obligation that is not less extensive than the obligation under this Clause 6.
- 6.2 Confidential Information which a Party’s Affiliated Entities and/or sub-contractors receive from another Party under the Collaboration Agreement, including in connection with the Project, shall be deemed to have been received by the Party. The Receiving Party is liable to the Providing Party for any disclosure of Confidential Information by such Affiliated Entities and/or sub-contractors contrary to the provisions of this Clause 6.
- 6.3 Disclosure of Confidential Information is permitted in the following cases (“Permitted Disclosure”):
- (i): To the Receiving Party’s employees, Affiliated Entities, agents, executive managers, Board members, auditors, advisors, stakeholders, consultants, license holders, sub-license holders, students or sub-contractors to the extent, and only to the extent, that they need the Confidential Information in connection with the Party’s obligations under the Collaboration Agreement, including in connection with the Project.
 - (ii) If such an obligation is imposed on the Receiving Party under mandatory legislation or in connection with legal action or the Receiving Party is ordered to do so by a competent court of law. The Receiving Party shall immediately notify the Providing Party in writing of any such requirement with a view to agreeing on the time and content of such disclosure and with a view to giving the Providing Party an opportunity to provide information about the rights in the information in question and its confidential nature. Such disclosure shall in all cases be limited as much as possible. As regards the duty to disclose Confidential Information under the Danish Access to Public Administration Files Act, Clause **Fejl!** **Henvisningskilde ikke fundet.** below shall apply.
- 6.4 The Receiving Party shall not use the Confidential Information received from the Providing Party for any other purpose than fulfilment of the Receiving Party’s obligations or exercise of the Receiving Party’s rights under the Collaboration Agreement, including in connection with the Project.
- 6.5 The provisions of this Clause 6 shall not apply to Confidential Information which:

- (a) at the time of receipt by the Receiving Party is in the public domain,
- (b) after its receipt by the Receiving Party is made public as a result of publication or otherwise, except by the Receiving Party's breach of its confidentiality obligations under this Clause 6,
- (c) at the time of receipt was or later has come into the possession of the Receiving Party from a third party not subject to any confidentiality obligation in respect of the information at the time of disclosure, or
- (d) was in the possession of the Receiving Party prior to its Receipt under the Agreement and/or was developed independently by the Receiving Party's students, employees, agents, executive managers, auditors, advisors, stakeholders, consultants, license holders, sub-license holders or sub-contractors, who at the time did not have access to the Confidential Information, provided that the independent development can be documented.

6.6 At the request of the Providing Party, the Receiving Party shall return to the Providing Party all documents or other material containing the Providing Party's Confidential Information in the possession of the Receiving Party or within its power of control, or in the possession of persons or within the power of control of persons who have received the Confidential Information from the Receiving Party under this Clause 6. However, the Receiving Party shall not have any obligation to comply with the Providing Party's demand if the Confidential Information is necessary for the fulfilment of the Receiving Party's obligations or exercise of the Receiving Party's rights under the Agreement, including in connection with the Project.

6.7 In relation to the individual Party, the provisions of this Clause 6 shall remain in force after the expiry or premature termination (irrespective of the cause) of the Investment Agreement or termination of a Party's participation as a party to the Investment Agreement for a period of five (5) years from such expiry or termination or for a longer period as agreed by the Parties.

6.8 If a Party receives a request for access to files under the Danish Access to Public Administration Files Act or other relevant legislation regarding Confidential Information belonging to another Party, the Party shall, without undue delay, inform the relevant Party in writing. Within five (5) weekdays of receipt of such notice, the relevant Party shall provide notice in writing of whether the Party, with reference to the relevant provisions of the Danish Access to Public Administration Files Act or other relevant legislation, has arguments against the Confidential Information in question being disclosed as part of the compliance with the request for file access.

7 MATERIAL TRANSFER OBLIGATIONS

- 7.1 If any Materials are transferred from one Party (“Transferring Party”) to another Party (“Material Receiving Party”), or between their Sub-Contractors and/or Affiliated Entities, each Material Receiving Party shall be bound by the following provisions and shall be responsible for ensuring that its Sub-Contractors and/or Affiliated Entities comply with such provisions:
- 7.1.1 The Material Receiving Party has all the required authorisations under all applicable laws and regulations to perform the experimental work in vitro at the place of investigation using the Materials.
- 7.1.2 The Materials will be used in full compliance with all applicable laws and regulations.
- 7.1.3 The Materials will be used solely for performance of the Project in accordance with this Collaboration Agreement. The Materials will under no circumstances be administered to humans unless this is specifically required in the Project Plan. [The Materials or animals treated therewith will under no circumstances be used as food for humans or animals.]
- 7.1.4 The Materials will not be analysed or modified except as necessary for the purpose of the Project.
- 7.1.5 The Materials will not be transferred or made available to any individual other than those under the supervision and control of the Material Receiving Party, its Affiliated Entities or Sub-contractors. Upon completion of the Project, or the expiry or termination of this Collaboration Agreement, any unused Materials will be either returned to the Transferring Party which made them available or disposed of/destroyed in accordance with all applicable laws and regulations and the instructions of the Transferring Party.
- 7.6 All Materials are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Transferring Party represents or warrants that the use of the Materials will not infringe or violate any patent or proprietary rights of Third Parties, see also Clause 5.1.
- 7.7 The Materials are to be used, stored and handled with caution and prudence in any experimental work, since not all of the characteristics are necessarily known. The Material Receiving Party using the Materials shall bear all risk to it and/or any other Party and/or any Third Party resulting, directly or indirectly, from its use, application, storage or disposal/destruction of the Materials.

8 OWNERSHIP OF BACKGROUND

- 8.1 Each Party shall remain the exclusive owner of its Background Knowledge and participation to the Project shall not affect such ownership rights in its Background Knowledge, without prejudice to any rights and obligations under this Collaboration Agreement and the Investment Agreement.

- 8.2 The Background Knowledge shall be identified in the Collaboration Agreement, as outlined in Appendix 3.
- 8.3 Each of the Parties have informed the Project Leader of any legal restrictions of which they are aware that may affect the use of their respective Background Knowledge for Research Use or for completing the Project. The Project Leader shall inform IFD of such restrictions and include such information in Appendix 3 of this Collaboration Agreement.
- 8.4 Each Party may license, assign, or otherwise dispose or transfer ownership of its own Background Knowledge (a "Disposition"). However, when making such Disposition the Party shall ensure and warrant that the rights of the other Parties under the Investment Agreement and this Collaboration Agreement will not be affected by the Disposition.

9 OWNERSHIP OF FOREGROUND

- 9.1 Foreground Knowledge shall belong to the Parties who generated it under the Project.
- 9.2 Foreground Knowledge created jointly by the Parties shall be jointly owned by the Parties *pro rata* to their intellectual contribution to the developed Foreground Knowledge. Where several Parties have generated Foreground Knowledge and where it is not reasonably possible to distinguish their respective shares therein, such Foreground Knowledge shall be jointly owned between/amongst them (the "Co-owners") in equal shares. The Parties shall enter into an agreement setting out the details concerning the handling of Foreground Knowledge jointly owned by the Parties, including for Direct Exploitation, patenting and other protection thereof in accordance with the principles set out in this Collaboration Agreement. Such Co-Owners shall fully disclose any such joint interest to all other Parties through the Steering Committee.

[Parties to consider whether it could be relevant to include more detailed regulation of their rights and obligations with regard to jointly owned Foreground Knowledge]

- 9.3 Where a Party in accordance with the Investment Agreement and/or this Collaboration Agreement, has sub-contracted any part of such Party's Allocated Work, that Party shall ensure that any Foreground Knowledge arising thereunder will be owned in accordance with Clause 9.1
- 9.4 Each Party may license, assign, or otherwise dispose or transfer ownership of its own Foreground Knowledge [and of that Party's share of the jointly owned Foreground Knowledge] (a "Disposition"). However, when making such Disposition the Party shall ensure and warrant that the rights of the other Parties under the Investment Agreement and this Collaboration will not be affected by the Disposition.

[Parties to ensure that any agreed limitations in a Party's disposition with regard to its share of jointly owned Foreground Knowledge are reflected correctly]

- 9.5 If employees or any Third Party working on behalf of a Party are entitled to claim rights to Foreground Knowledge, the Party shall ensure that it is possible to exercise those rights in a manner compatible with its obligations under the Investment Agreement and this Collaboration Agreement.

10 OWNERSHIP OF SIDEGROUND

- 10.1 Ownership of Sideground Knowledge belongs to the Party/Parties who generated it.

11 GENERAL PROVISIONS APPLYING TO ACCESS RIGHTS

- 11.1 Parties, may, in their sole discretion, introduce into the Project any data, know-how, information, copyrights or other intellectual and industrial property rights pertaining to such information that are generated, held or acquired by it outside the Project after the date of this Collaboration Agreement, by updating the details of Appendix 3.

- 11.2 All Access Rights granted pursuant to this Collaboration Agreement are granted on a non-exclusive basis, and do not include any right to sub-license except [(i) to Sub-contractors for the purpose of performing the sub-contracted aspects of the Project, (ii) to Affiliated Entities [and Third Party collaborators] for Research Use and (iii) where the Access Rights are such as described in Clause 15.2.]

[Parties to consider the extent of sublicensing rights.]

- 11.3 Foreground Knowledge and Background Knowledge shall be used only for the purposes for which Access Rights to the same have been granted and only for so long as is necessary for those purposes.

[Parties to consider how the Access Rights are to be handled with regard to notification of request for such and whether there shall be a formal granting of Access Rights by separate agreement.]

12 ACCESS RIGHTS TO PARTIES FOR COMPLETING THE PROJECT

Foreground Knowledge

- 12.1 Subject to the provisions of this Collaboration Agreement (including Clauses 6 and 11), each Party is hereby granted Access Rights to the Foreground Knowledge of any other Party solely and to the extent necessary to carry out its own Allocated Work or for its Sub-contractor to perform such Allocated Work.

12.2 Such Access Rights are granted under Clause 12.1 on a Royalty-free Basis.

Background Knowledge

12.3 Subject to the provisions of this Collaboration Agreement (including Clauses 6 and 10), each Party is hereby granted Access Rights to the Background Knowledge of the other Parties solely and to the extent necessary to carry out its own Allocated Work or for its Sub-contractor to perform such Allocated Work. As provided for in Clause 8.3, prior to the execution of this Collaboration Agreement, the Parties shall identify any limitation to the granting of Access Rights to Background Knowledge or of any other restriction which might substantially affect the granting of Access Rights. Such restrictions shall be identified in Appendix 3.

12.4 Such Access Rights are granted under Clause 12.3 on a Royalty-free Basis.

13 ACCESS RIGHTS TO THE PARTIES AND AFFILIATED ENTITIES FOR RESEARCH USE

Foreground Knowledge

13.1 Subject to the provisions of this Collaboration Agreement (including Clauses 6 and 11), each Party and its Affiliated Entities is hereby granted Access Rights to the Foreground Knowledge of the other Parties, solely and to the extent necessary for the purposes of Research Use.

13.2 Such Access Rights to Foreground Knowledge for the purposes of Research Use are granted under Clause 13.1 on a Royalty-free Basis.

13.3 Any Research Use of the Foreground Knowledge belonging to any other Party pursuant to this Clause 13 shall acknowledge the ownership of such Party and shall identify the Project as the source thereof.

[Parties to consider whether the Collaboration Agreement shall include such right for all Parties as per this Clause 13 and e.g. not only the Institution(s).]

Background Knowledge to use Foreground Knowledge

13.4 The Parties have listed or summarised in Appendix 3 certain Background Knowledge which each such Party shall offer Access Rights to in accordance with the provisions of this Collaboration Agreement.

13.5 Subject to the provisions of this Collaboration Agreement (including Clauses 6 and 11), each Party and its Affiliated Entities is hereby granted Access Rights to the Background Knowledge of the other Parties solely and to the extent necessary for the purposes of Research Use of Foreground Knowledge.

13.6 Such Access Rights as granted under Clause 13.5 shall be granted on Royalty-free Basis.

14 ACCESS RIGHTS TO THIRD PARTIES FOR RESEARCH USE

Foreground Knowledge

- 14.1 After completion of the Project, subject to the provisions of this Collaboration Agreement (including Clauses 6 and 11), Third Parties shall have a right to claim and be entitled to receive under licence from a Party, Access Rights to the Foreground Knowledge of the Party, solely and to the extent necessary for the purposes of Research Use.
- 14.2 Upon receiving such request, the Party shall enter into negotiations with the requesting Third Party of the conditions for such Access Rights. Such Access Rights to Foreground Knowledge for the purposes of Research Use are granted under Clause 14.1 on Fair and Reasonable Conditions.

Background Knowledge to use Foreground Knowledge

- 14.3 After completion of the Project, subject to the provisions of this Collaboration Agreement (including Clauses 6 and 11), Third Parties shall be entitled to claim and receive under licence, Access Rights to the Background Knowledge of the Parties solely and to the extent necessary for the purposes of Research Use of Foreground Knowledge. In connection with the entering into of this Collaboration Agreement, a Party may identify specific elements of the Background Knowledge that shall be wholly or partially excluded from the obligations referred to in this Clause 14. Any exceptions shall be included in Appendix 3 and cannot be changed unless such change is permitted as per this Collaboration Agreement.
- 14.4 Upon receiving such request, the Party shall enter into negotiations with the requesting Third Party of the conditions for such Access Rights. Such Access Rights shall be granted on Fair and Reasonable Conditions. [Such terms can be outlined in Appendix 3]

[Parties to consider whether the Collaboration Agreement shall include such right as per this Clause 14.]

15 ACCESS RIGHTS FOR DIRECT EXPLOITATION

- 15.1 Parties may carry out Direct Exploitation of their solely owned Foreground Knowledge, [share of jointly owned Foreground Knowledge], and their Background Knowledge and Sideground Knowledge as they see fit. However, see Clause 8.4 and Clause 9.4.
- 15.2 Where Direct Exploitation by a Party or a Third Party requires Foreground Knowledge and/or Background Knowledge necessary to use Foreground Knowledge owned by another Party, the Party or Third Party shall have Access Rights to such other Party's Foreground Knowledge or Background Knowledge

necessary to use Foreground Knowledge to the extent necessary for the Party or Third Party to carry out the Direct Exploitation. The terms and conditions for such Access Right shall be negotiated between the parties involved.

- 15.3 Where the Institution desires to either wholly or partly assign its rights to its Foreground Knowledge or share of jointly owned Foreground Knowledge or give its Foreground Knowledge or share of jointly owned Foreground Knowledge in exclusive license, the Institution hereby grants to the Companies a first right of refusal to purchase such Foreground Knowledge or acquire an exclusive license to such Foreground Knowledge within each Company's Field of Use. In the event that the Foreground Knowledge completely or partially covers the Field of Use of several Companies, the Company whose Field of Use has most connections with such Foreground Knowledge shall be entitled to acquire the offered rights to the Institution's Foreground Knowledge. If the Companies disagree about the issue regarding connections, the dispute shall be determined by an independent Third Party expert appointed by the Parties. The Company/Companies that do not acquire the offered rights to the Institution's Foreground Knowledge shall be entitled to acquire a[n exclusive] licence to the Foreground Knowledge in question within its/their Field(s) of Use.
- 15.4 The right of first refusal according to Clause 15.3 shall be offered on market conditions. The time limit for acceptance of such offer is six (6) weeks, reckoned from the date of the letter containing the offer. Should the Company to which the offer was made refuse the offer or fail to reply within the time limit for acceptance, the right of first refusal shall lapse, and the Institution shall then be entitled to offer its Foreground Knowledge to one or more Third Parties. The terms of the transfer shall be negotiated with the central management of the Institution.
- 15.5 If a Company has refused the first offer made by the Institution cf. Clause 15.4 above, the Institution shall, before making an offer to a Third Party which is significantly more advantageous than the offer made to the Company, be obliged to make an offer to the Company on the same terms offered to the Third Party. The time limit for acceptance of such offer is thirty (30) days, reckoned from the date of the letter from the Institution containing the offer. If the Company also declines this offer, the Institution shall then be entitled to offer the rights in question to one or more Third Parties on the terms offered the Company as per this Clause 15.5.

[Parties to consider whether the Collaboration Agreement should contain other or more elaborate mechanisms with regard to the Companies' Access Rights in respect of the Institution's Foreground Knowledge and share of jointly owned Foreground Knowledge.]

16 ACCESS RIGHTS FOR NEW AND DEPARTING PARTIES

- 16.1 Parties joining the Project in accordance with the provisions of Clause 18, will be granted the Access Rights as provided for in Clauses 12 - 15 hereof as from the date of their accession to this Collaboration Agreement.

16.2 For Parties leaving the Project in accordance with the provisions of Clauses 19 and 20 hereof, the following provisions will apply:

- (a) With the exception of the cases where the participation of a Party is terminated by reason of default (breach), the Access Rights accrued up to the date of termination (meaning Access Rights with regard to such Foreground Knowledge, share of jointly owned Foreground Knowledge and Background Knowledge which has been conceived or created up to the date of the termination) and the obligations to grant Access Rights pursuant to the Investment Agreement and this Collaboration Agreement shall continue in full force and effect.
- (b) Defaulting Parties shall be obliged to continue to grant Access Rights pursuant to the Investment Agreement and this Collaboration Agreement, but the Access Rights granted to the Party pursuant to this Collaboration Agreement shall cease [immediately upon termination of the participation of the Party as a Party to this Collaboration Agreement, or the Investment Agreement, if earlier].

17 DISSEMINATION

17.1 A Party wishing to Disseminate information relating to its Foreground Knowledge will inform the other Parties via the Steering Committee with prior written notice of any such publication. Reference is made to Clause [9.4] of the Investment Agreement regarding the Parties' obligation to forward information to IFD before Dissemination. Any Party may object to Dissemination within thirty (30) days of notification, in which case the publishing Party will:

- (a) extend the review period and delay the proposed Dissemination for a period of sixty (60) days;
- (b) and, if included in the publication, delete such other Party's Confidential Information from the intended Dissemination.

17.2 For the avoidance of doubt, a Party may not Disseminate or communicate Foreground Knowledge owned by another Party or any Background Knowledge of such other Party, even if such Foreground Knowledge or Background Knowledge is amalgamated with such Party's Foreground Knowledge, without the other Party's prior written approval, except to its Sub-contractors for the purpose of the performance of Allocated Work on behalf of the Party.

17.3 Nothing in this Collaboration Agreement shall be construed as conferring rights to use in Dissemination, advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

17.4 See Clause [9] of the Investment Agreement with regard to the Parties' obligation to apply the IFD logo and provide statement concerning IFD's

investment in connection with Dissemination and communication of Foreground Knowledge.

- 17.5 [Each Party shall Disseminate its Foreground Knowledge within one (1) year of the end of the termination or expiry of the Project. If the Parties do not Disseminate within such time period without good reason (e.g. patent application filings still pending), the Institution(s) has the right to request Dissemination of such Foreground Knowledge in a manner consistent with the Investment Agreement, and the other Parties owning the Foreground Knowledge in question are obliged to comply with such request.]

18 ADDITIONAL PARTIES

- 18.1 Where, during the continuance of the Project, and with the prior approval of IFD, the Parties shall agree to admit additional Parties to the Project, each such additional Party shall, as a condition of admission, be required to accede to the Investment Agreement and this Collaboration Agreement. Reference is made to Clauses [3.3] and [8.1.5] of the Investment Agreement regarding the requirements in respect of the accession of new Parties.

19 TERMINATION

- 19.1 Any Party may terminate its participation in the Project in accordance with the Investment Agreement (see Clauses [15.3 and 16.1] of the Investment Agreement), [which termination shall cause the simultaneous termination of the Party's participation under this Collaboration Agreement.] [The participation of that Party's Sub-contractor(s) under this Collaboration Agreement shall be deemed to have been terminated on the same date as such termination by the Party.]
- 19.2 Where a Party receives notice of termination of its participation under the Investment Agreement (see Clause [15.4] of the Investment Agreement), the Party shall promptly provide all other Parties with notice to that effect [and this Collaboration Agreement shall be deemed to have been terminated in respect of that Party with effect at the effective date of the termination of the Party's participation under the Investment Agreement.] [The participation of that Party's Sub-contractor(s) under this Collaboration Agreement shall be deemed to have been terminated on the same date as such termination by IFD.]
- 19.3 As per Clause 19.4 and Clause 19.5 a Party's participation under this Collaboration Agreement may be terminated by the other Parties in case of force majeure affecting the Party for more than twenty (20) days. The participation of that Party's Sub-contractor(s) under this Collaboration Agreement shall be deemed to have been terminated on the same date as such termination by the other Parties.
- 19.4 No Party shall be liable for non-fulfilment of its obligations under the Collaboration Agreement if such non-fulfilment is attributable to force majeure.

Force majeure shall be taken to mean events over which the relevant Party has no control and which that Party could not have prevented, avoided or anticipated, including, but not limited to, stoppage of work, strikes, lock-outs, war, terrorism, natural disasters, states of emergency and similar.

- 19.5 The Party claiming force majeure shall notify the other Parties and the Steering Committee without undue delay. Such notice shall be provided in writing and shall contain information about the nature of the force majeure event and its estimated duration and consequences for the performance of the Project, including the participation of the Party affected by the force majeure. If the force majeure event persists for more than twenty (20) days, the other Parties shall be entitled to terminate the Collaboration Agreement without prior notice as regards the affected Party's participation in the Collaboration Agreement. In such a situation the affected Party shall otherwise be situated as if the Party had terminated the Collaboration Agreement.
- 19.6 Termination of a Party under the Project and of such Sub-contractor's participation thereunder, pursuant to the foregoing provisions of this Clause 19, shall in each case be subject to the continuation in force of Clause 21.

20 TERMINATION FOR BREACH

- 20.1 Where a Party receives notice of termination of its participation under the Investment Agreement (see Clause [16] of the Investment Agreement), the Party shall promptly provide all other Parties with notice to that effect and this Collaboration Agreement shall be deemed to have been terminated in respect of that Party with effect at the effective date of the termination of the Party's participation under the Investment Agreement. [The participation of that Party's Sub-contractor(s) under this Collaboration Agreement shall be deemed to have been terminated on the same date as such termination by IFD.]

21 CONTINUING OBLIGATIONS

- 21.1 The following Clauses shall survive termination, whether of the participation of any Party in the Project and under this Collaboration Agreement, or of the Investment Agreement and this Collaboration Agreement: Clauses 6 to 17, this Clause 21 and Clauses 24 - 26.

[Parties to consider, in respect of the actual collaboration, whether the description of surviving Clauses should be amended.]

22 ASSIGNMENT

- 22.1 With the exception of terms expressly set out in this Collaboration Agreement, no Party shall assign any rights and/or obligations under this Collaboration Agreement to any Third Party without the prior written consent of every other Party and of IFD and any such assignment shall be subject to such Third Party assignee agreeing in writing to (i) continue the performance of the Project

undertaken by the assignor; and (ii) comply with the provisions of the Investment Agreement and this Collaboration Agreement.

- 22.2 Where a Party wish to assign its rights and/or obligations, as referred to in Clause 22.1, such Party shall, within the limits of confidentiality, provide the remaining Parties and IFD with such information as may be reasonably requested in connection with such proposed assignment and that Party's Allocated Work, including, without limitation, the extent to which such Allocated Work has been completed and Eligible Costs incurred to date. That Party shall, notwithstanding such assignment, remain liable under the Investment Agreement to IFD for any additional information which IFD may reasonably request, either through the Project Leader and/or the Administrator or directly of such Party, regarding that Party's Allocated Work and/or Eligible Costs.
- 22.3 Where the assignment, in whole or in part, of a Party's rights and/or obligations under this Collaboration Agreement requires approval, see Clause 22.1, such Party shall, irrespective of such approval, remain liable to all other Parties for all additional costs incurred by such other Third Party assignee in the performance of such assignor Party's Allocated Work to the extent that such additional costs shall not be fully recoverable as Eligible Costs. This obligation shall survive the cessation of such Party's participation in the Project.
- 22.4 Where a Party shall properly assign any or all of its interest in accordance with this Collaboration Agreement that Party's participation in the Project and under this Collaboration Agreement shall, to the extent of such assignation, and with respect of Clause 22.3, be deemed to have terminated, and the provisions of Clause 21 shall apply.

23 DISPUTE RESOLUTION

- 23.1 Any dispute arising out of or in connection with this Collaboration Agreement, including any dispute regarding the existence or validity of the Collaboration Agreement, shall be sought to be settled by mediation arranged by the Danish Institute of Arbitration in accordance with the rules on mediation adopted by the Danish Institute of Arbitration and in force at the time when such proceedings are commenced.
- 23.2 Mediation proceedings shall not affect the right of a Party to commence arbitration proceedings in accordance with the provisions below.
- 23.3 If the mediation proceedings are terminated without a settlement, the dispute shall be subject to arbitration arranged by the Danish Institute of Arbitration in accordance with the rules of arbitration procedure adopted by the Danish Institute of Arbitration and in force at the time when such proceedings are commenced.
- 23.4 The language of the meditation and the arbitration (both in relation to documents and oral proceedings) is [Danish/English], however, any

documentary evidence may be submitted in [French/German/Danish, etc.] if that is the original language of the document.

23.5 The place of mediation and arbitration is Copenhagen, Denmark.

[Parties to consider referring to the dispute resolution provisions in the Investment Agreement. If the Parties decide to have separate dispute resolution provisions in this Collaboration Agreement they must in such case ensure alignment between the provisions in the two agreements in order to avoid any conflicting wording.]

24 NOTICES

24.1 Any contractual, financial/administrative notice to be given under this Collaboration Agreement shall be in writing and delivered to the relevant Party at the address and marked for the attention of a named recipient, all as more specifically detailed in Appendix 2, or as a Party shall under separate cover advise. A Party may, by notice in writing to the Project Leader, amend its contact details as included in Appendix 2, or as otherwise advised. Any such notice shall be deemed to have been served when personally delivered or delivered by courier service or, if transmitted by fax, electronic or digital transmission, at the time of such transmission, provided that such transmission is confirmed by receipt of a successful transmission report and thereafter confirmed by surface/air mail or delivered by internationally recognized courier service within three (3) working days. [Parties to consider, in respect of their actual collaboration, what is practically possible and relevant with regard to method of notification.]

[Parties to consider referring to the notice provisions in the Investment Agreement. If the Parties decide to have separate notice provisions in this Collaboration Agreement they must in such case ensure alignment between the provisions in the two agreements in order to avoid any conflicting wording.]

25 ENTIRE AGREEMENT

25.1 This Collaboration Agreement, its Appendices [(1-8)] and the Investment Agreement and its Exhibits [(1-5)] constitute the entire agreement between the Parties in respect of the Project, and supersede all previous negotiations, commitments and writings.

25.2 Although the provisions of this Collaboration Agreement have been drafted to reflect the provisions of the Investment Agreement as far as possible, in the event of any conflict between this Collaboration Agreement and the Investment Agreement, (or any Exhibit of the Investment Agreement (other than this Collaboration Agreement)), the Investment Agreement (its Exhibits) shall prevail.

25.3 Amendments or changes to this Collaboration Agreement may be made only by written instrument signed by an authorised signatory of each of the Parties, other than where any such amendment shall relate solely to the contact details of a Party, or shall otherwise be permitted under any provision hereof, in which event that Party's written notice in accordance with the provisions of this Collaboration Agreement shall suffice. Any amendments to this Collaboration Agreement require the prior written approval of IFD in order to be valid, see Clause 11.4 of the Investment Agreement.

26 LAW

26.1 This Collaboration Agreement shall be governed by Danish law, with the exception of Danish conflict of laws rules where such rules would lead to application of the law of another country.

SIGNATURES

AS WITNESS the Parties have caused this Collaboration Agreement, together with the Appendices [1 to 8] annexed hereto, to be duly signed by the undersigned authorised representatives as follows:

THE COORDINATOR (give name)

Authorised to sign on behalf of:

Signature

Name

Title

Date

Stamp (if applicable)

Authorised to sign on behalf of: **Name of Party**

Signature

Name

Title

Date

Stamp (if applicable)

Appendix 1

NAME AND ADDRESS OF A REPRESENTATIVE FOR EACH PARTY, FOR
WHOSE ATTENTION SCIENTIFIC NOTICES ARE TO BE ADDRESSED

Party 1 (organisation name)

Name

Department

Phone

Fax

Email

Party 2 (organisation name)

Name

Department

Phone

Fax

Email

Appendix 2

NAME AND ADDRESS OF EACH PARTY, FOR WHOSE ATTENTION CONTRACTUAL, FINANCIAL, ADMINISTRATIVE NOTICES ARE TO BE ADDRESSED

Party 1 (organisation name)

Name

Department

Phone

Fax

Email

Party 2 (organisation name)

Name

Department

Phone

Fax

Email

Appendix 3

BACKGROUND KNOWLEDGE TO BE THE SUBJECT OF ACCESS
(INCLUDING ANY RESTRICTIONS TO THE USE OF THIS BACKGROUND
KNOWLEDGE)

Appendix 4

ANIMAL WELFARE AND ETHICAL STANDARDS

1. The Parties, Affiliated Entities, associated Third Parties and Sub-Contractors agree to comply with all relevant statutes, legislation, regulations and guidelines for the care, welfare and ethical treatment of animals used in research in the country where the research is being performed. In conducting any research involving the use of animals, the Parties, Affiliated Entities, associated Third Parties and Sub-Contractors further agree to comply with the ["3R" Principles] - reducing the number of animals used, replacing animals with non-animal methods whenever possible and refining the research techniques used. All work must be conducted in adherence to the core principles for animals on research studies identified below. Local customs, norms, practices or laws may be additive to the core principles, but the Parties, Affiliated Entities, associated Third Parties and Sub-Contractors agree to comply, as a minimum, with these core principles:
 - 1.1 Access to species appropriate food and water,
 - 1.2 Access to species specific housing, including species appropriate temperature and humidity levels,
 - 1.3 Access to humane care and a programme of veterinary care,
 - 1.4 Ability to demonstrate species-specific behaviour,
 - 1.5 Adherence to principles of replacement, reduction and refinement in the design of *in vivo* studies,
 - 1.6 Study design reviewed by institutional ethical review panel,
 - 1.7 Commitment to minimizing pain and distress during *in vivo* studies, and
 - 1.8 Work performed by appropriately trained staff
- 2 Parties, Affiliated Entities, any associated Third Parties and Sub-Contractors may be required to provide evidence to other Parties within the Project that they can confirm adherence to the above principles and guidelines. Parties reserve the right to conduct due diligence, that could require site visits, to be assured of such compliance. If any material deficiencies are subsequently identified, the Party, Affiliated Entity or associated Third Party and Sub-Contractor concerned shall endeavour in good faith to take reasonable and practical corrective measures to remedy any such material deficiencies.

Appendix 5**PROJECTS INVOLVING HUMAN TISSUE OR OTHER BIOLOGICAL SAMPLES**

"Sample(s)" means any human tissue or biological material, including any portion of an organ, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative of such human biological material such as stem cells or cell lines; and any human biological product, including, but not limited to, hair, nail clippings, teeth, urine, faeces, breast milk, and sweat.

1. Application

Parties will have to comply with the following principles and applicable local regulations when collecting, obtaining, or using any Samples for research that is conducted, sponsored, supported or funded pursuant to the Project.

2. Samples collection

2.1 When Samples are collected by a Party or by another entity specifically for use in the Project, Parties' staff members must ensure that Samples are collected with informed consent and ethics committee/ Institutional Review Board (IRB) approval in accordance with the applicable research requirements of Good Clinical Practice (International Conference on Harmonisation) and applicable local regulation. Additionally, through informed consent, donors must be made aware if the research is being undertaken by a commercial entity and that, where applicable, the research involves the analysis of DNA and/or medical information.

2.2 When a Party obtains Samples from a source where the collection was made for reasons unrelated to the Project, the relevant Party's staff members must confirm that the entity complied with relevant requirements for informed consent, ethics committee/IRB approval and data privacy. In this event, the Parties shall need to become informed about the origin of the Samples and any other relevant information.

The Parties will not utilize Samples that are collected for reasons unrelated to the Project unless prior written approval of the ethics committee is obtained.

2.3 In general, cells lines (e.g. HeLa), derivatives (e.g. isolated proteins) and preparations of human biological materials (e.g. sub-cellular fractions) that are well established and made available for research use, do not require re-consent and/or ethics committee/IRB approval for the intended research use. Parties will need to make a case-by-case analysis in order to determine whether consent is required or not.

3. Use of Samples

3.1 Parties must use Samples only for purposes that are consistent with the consent obtained and in compliance with relevant laws and regulations.

- 3.2 Additional individual donor consent and ethics committee/IRB approval must be obtained when the research use intended is inconsistent with or beyond the scope of the original consent.
- 3.3 Additional consent should also be obtained if the original consent did not include analysis of DNA (if relevant to the research proposal) or use of any associated medical information (if relevant to the research proposal).
- 3.4 In circumstances where individual re-consent cannot practicably be obtained, approval of an ethics committee or IRB (if permissible under the relevant laws and regulation) must be sought to determine whether the research can proceed in the absence of individual consent.

Appendix 6

PROJECTS INVOLVING CLINICAL TRIALS

For Projects involving the performance of clinical trials, the Collaboration Agreement shall include provisions as appropriate which normally appear in a Third Party clinical trial agreement, including without limitation:

Which Party(s) will be the sponsor of the clinical trial;

Obligation on the sponsor(s) to ensure that the clinical trial is conducted in accordance with all applicable laws and regulations, [the Declaration of Helsinki, and ICH GCP];

Obligation on the sponsor to ensure that regulatory and ethics committee approvals and patient informed consents have been obtained before the clinical trial commences;

Which Party(s) is responsible for preparing and reviewing the protocol;

Which Party(s) will make the study drug available;

Auditing rights and access to records of “essential documents” for the Party making the study drug available;

Reporting requirements re adverse events and an annual safety report;

Which Party(s) is responsible for reporting adverse events to regulatory authorities;

Detailed allocation of responsibilities for drug supply (including recall);

Detailed allocation of responsibilities for the clinical study – e.g. site selection, preparation of investigator’s brochure, negotiation and execution of clinical trial agreements;

Obligation on the sponsor to comply with the requirements of [the European Union legislation on Good Manufacturing Practices for Investigational Medicinal Products to the extent that the Institution performs the activities described in Annex 13 of the Good Manufacture Practice, Volume 4, “Manufacture of Investigational Medicinal Products”];

Right of Party(s) making the study drug available to terminate the clinical study for safety reasons;

Obligation on sponsor to arrange clinical trial insurance for all study subjects, in accordance with all applicable laws and regulations, and to provide evidence of such insurance to Party(s) making study drug available upon request

Indemnification by the sponsor(s) in the event that a study subject injured in the clinical trial seeks to claim against the Party(s) making the study drug available;

Responsibility for registering the clinical trial and the results on publicly accessible databases.

If the sponsor of the trial is not a Party under this Collaboration Agreement, a separate agreement will be required between the sponsor and the Party making the study drug available.

[Ref]

[Date]

[Name & Address]

Dear.....,

AGREEMENT FOR CLINICAL TRIALS

This letter sets out the terms and conditions upon which it is agreed that clinical work entitled (the "Study") will be undertaken for [insert contracting entity name here](herein after "XXXXX") by you at (the "Investigational Site").

1. a) The Study shall be carried out under your strict supervision and in accordance with the protocol reference("the "Protocol"). Procedures associated with the Protocol will be delegated only to suitably qualified members of staff. Initial examination for the purposes of fulfilling the entry criteria into the study and the authorisation of release of study medication shall only be undertaken by medically qualified personnel.
- b) You shall be aware of, and comply with all applicable aspects of the current [ICH/GCP guidelines] and all legal and regulatory requirements for the [insert information about relevant country/countries].
- c) Prior to commencing the Study in respect of any patient you shall inform the patient of the nature of the Study and obtain the written consent of that patient to undergo the clinical trial.
- d) You will submit the study protocol to the appropriate ethics committee for approval prior to commencement and shall not commence the study until approval by the committee. A copy of the letter of approval will be supplied to XXXXX before study initiation.
- e) You shall not commence the study until the Protocol is approved by the regulatory authority.
2. XXXXX shall supply you with such quantities of (the "Compound") as shall be required for the purpose of the Study and you acknowledge that you have no claim to the Compound so supplied and that it shall remain the sole and exclusive property of XXXXX and be used by you solely for the purposes of this Agreement. You shall have responsibility for the accountability of the Compound as stated in the current [ICH/GCP guidelines] and ensure that the Compound is only used as per protocol.
3. XXXXX shall supply you with such information (the "Information") as shall be necessary to enable you to carry out the Study. You shall hold in strict confidence all Information so supplied and all data and results arising out of the Study. Such Information, data and results shall at all times be and remain the property of XXXXX and shall not be used for any purpose other than the performance of this Agreement and

shall not be disclosed to any third party without XXXXX's prior written consent. You shall not seek to arrange for publication of any of the Information, or of the data or results arising out of the Study, in any scientific journal or other publication, or by way of lecture, without XXXXX's prior written consent. Such consent shall not be unreasonably withheld and will be given as soon as practicable and in any event within six (6) months from the date of a written request.

4. The provisions of paragraph 3 of this Agreement shall not apply to any of the Information:
 - a) which at the time of receipt by you is in the public domain; or
 - b) which after its receipt by you is made public by a third party acting without impropriety in so doing; or
 - c) which you can establish was in your possession before receipt from XXXXX and was developed independently or acquired directly or indirectly from a source wholly independent of XXXXX.
5. You agree to communicate the results of the Study promptly to XXXXX in such format as XXXXX shall require. You and the [Investigational Site] shall immediately assign to XXXXX all [Intellectual Property rights] and interests (including copyright) in all countries in any inventions or developments arising from the Study and agree to assist XXXXX in connection with any application for [Letters Patent] or other forms of protection and do all such other things and execute all such documents and authorisations as may be necessary in connection with any such applications. XXXXX will have the sole rights to decide in which countries to apply for and obtain [Letters Patent] or other forms of protection and shall be liable for all expenses incurred in filing, prosecuting to grant and maintaining in force such [Letters Patent] or other forms of protection.
6. You and the Investigational Site shall restrict access to the Information on a need-to-know basis and shall ensure that any employees and consultants to whom Information is disclosed hold the Information upon conditions of secrecy as set out in this Agreement.
7. The provisions of Clauses 3 to 6 shall remain in full force and effect after expiry of the term of this Agreement.
8. It is hereby expressly understood that XXXXX shall not be responsible for any aspects of the employment of the Investigational Site personnel involved in the Study and neither they nor any other member of the Investigational Site staff shall at any time be or be deemed to be, or to act as, employees of XXXXX.
9. XXXXX agrees that it will keep itself insured against legal liability for bodily injury (including death) resulting from the administration of the Compound in accordance with the Protocol and to hold you, your staff and the Investigational Site harmless and indemnify the same against damages or compensation or costs arising out of any legal action resulting from such injury PROVIDED THAT XXXXX shall not be liable if such injury results from any wrongful act or negligence on the part of any person undertaking or involved in the Study AND PROVIDED FURTHER THAT no admissions or settlements are made without the prior written approval of XXXXX, XXXXX is promptly informed of any claims or prospective claims and is given full conduct and control of any defence proceedings/negotiations.

10. *[Financial Agreement: NB: This will be specific to each study but must be within the scope of the specific study budget. Avoid references to pro rata payments, salaries or advance payments unless this has been specifically authorised for the particular study/centre.]*

You agree to recruit [number] eligible patients by [target recruitment date]. However Recruitment shall cease once the overall target number of patients for the Study is reached.

In respect of investigational staff time, commitment and workload, XXXXX agrees to fund the Study up to a maximum of £ subject to patients completing the Study. Pharmacy and other additional investigations including laboratory blood tests (*shall be funded separately/are included). Payments shall be made according to progress at [specify frequency] (*following receipt of invoice/by cheque payable to:.....) [*delete as applicable].

In the event of patients withdrawing from the Study, the level of funding provided for such patients shall reflect the time and effort expended by investigational staff whilst performing Study specific procedures (see attached sheet) [list costs for assessments to be used in calculations for withdrawn patients, or protocol violators – these should be in line with those detailed in the [Master Investigator Agreement]].

If you are able to find more patients than are specified above, provided that XXXXX has agreed to the inclusion of any such patients in the Study, XXXXX agrees to pay you the sum per patient referred to above in respect of each extra patient so agreed.

11. In the event of any conflict between this Agreement and the Protocol, the terms of this Agreement shall prevail.
12. You agree to allow drug regulatory agency and XXXXX auditors to inspect your study records and associated source data, whenever requested.
13. You agree to return to XXXXX all unused quantities of the Compound and to send to XXXXX all [Case Report Forms] duly completed (where applicable) upon termination of this Agreement for any reason.
14. This Agreement shall remain in force for a period of months fromafter which period the Study shall have been completed unless otherwise mutually agreed between us.

Notwithstanding the foregoing, you agree that XXXXX reserves the right to terminate the Study at any time for medical reasons or reasons of administrative or commercial policy provided that any such termination shall be without prejudice to your right to reasonable compensation for any actual loss or direct expense caused thereby.

15. This Agreement shall be governed by the law of the country in which the study is being conducted.

If the foregoing terms and conditions are acceptable to you, kindly indicate your acceptance and agreement by signing and dating both copies of this letter in the spaces provided and return one signed copy to XXXXX.

Yours sincerely

For and on behalf of
[Name of contracting entity]

Agreed and Accepted by:

Signed:

Date:.....

Name:

Title:

Agreed and Accepted by:

Signed:

Date:.....

Name:
.....

Title:
.....

For and on behalf
of.....(Hospital/University)

THE SCHEDULE

The pro rata payment for patient assessments
(Attached)

INVESTIGATOR AGREEMENT APPROVAL
[to appear on file copy of investigator agreement only]

Reviewed by:

Signature:

Name: DATE:
CLINICAL RESEARCH MANAGER

Appendix 7

DESCRIPTION OF FIELD

Appendix 8

DESCRIPTION OF FIELD OF USE