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European Joint Programme on Rare Diseases

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Del 4.6
Set of template agreements for EJP RD website

Organisation name of lead beneficiary for this deliverable:
Partner 25 – FTELE

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Executive Summary

This deliverable contains information on the activities conducted in task 4.3 – Managing legal and IPR issues.
It reports the results of the following actions:

- preparation of an annotated template for a Material and Data Transfer Agreement;
- preparation of an annotated template for an Inter Institutional Agreement for the management of jointly owned results generated by two or more beneficiaries within the action.

Contents

3.1 Preparation of an annotated template for a Material and Data Transfer Agreement

On the basis of the Data Transfer Agreement attached to the EJP RD Framework Consortium Agreement, a Material and Data Transfer Agreement was prepared with annotations and guidance to implement the provisions of the General Data Protection Regulation, Regulation (EU) 2016/679 (GDPR) regarding personal data associated with biological material and sensitive (i.e., genetic and health) data. As the implementation of GDPR clauses in contracts strictly depends also on the applicable national laws, on institutional policies and on peculiarities of the specific samples and related data to be shared, a one-fits-all template would not be possible. Therefore, when specific aspects relating to the obligations of the parties to the agreement needed to be regulated, an annotated trace detailing the major issues was provided to ensure that the researchers would involve their competent offices for the drafting of tailored clauses.

The template is attached as Annex A to this D4.6

3.2 Preparation of an Inter Institutional Agreement (IIA)

The template is based on the Standard IIA Template by South Texas Technology Management as adapted initially by FTELE. Such template has been used by FTELE successfully with international institution for the management of co-owned intellectual property. The interinstitutional agreement allows the negotiation and definition of the allocation and terms of exercising their interest in the co-owned Intellectual Property Rights (IPRs), in particular with respect to:

(i) protection measures

(ii) identifying the lead party responsible for commercially exploiting jointly owned IPRs

(iii) terms of commercialisation, any share of royalties, ongoing costs incurred in respect of obtaining and maintaining patent and other forms of IPRs.

The template is attached as Annex B to this D4.6

MATERIAL AND DATA TRANSFER AGREEMENT

The Document can serve the purpose of a Material AND/OR Data transfer agreement. If human biological samples are transferred, the recent Regulation EU 2016/679 - General Data Protection Regulation (GDPR) implies that the specimen itself may contain personal and sensitive data (i.e., biological data, health data, genomic data) to which the GDPR applies. ***THE GDPR-RELATED CLAUSES SHALL BE DEFINED BY THE PARTIES ACCORDING TO THEIR POLICIES AND THE APPLICABLE NATIONAL IMPLEMENTATIONS OF THE GDPR. THE CLAUSES HEREBY PROVIDED ARE INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS AND RAISE AWARENESS BETWEEN THE PARTIES– PLEASE CONTACT YOUR COMPETENT OFFICE TO DEFINE SUCH CLAUSES****. Section highlighted in grey are for user guidance only – to be defined and removed from the final document that the parties negotiate*.

This agreement is entered into by and between:

XXX *[name, legal address, legal representative authorized to sign this type of contract]*

Hereafter referred to as the **"Provider"**

And:

YYY *[name, legal address, legal representative authorized to sign this type of contract]*,

Hereafter referred to as the **"Recipient"**
IN CASE RECIPIENT IS LOCATED OUTSIDE THE EUROPEAN UNION (EU) AND PERSONAL AND/OR SENSITIVE DATA ARE TRANSFERRED, THE GDPR IMPOSES CERTAIN STANDARD CONTRACTUAL CLAUSES – SEE ANNEX B

The Provider and the Recipient shall hereafter be referred to individually as a "**Party**" and together as "the **Parties**".

PREAMBLE

Whereas Provider has scientific and technological expertise in the field of *…To be completed….*

Whereas Recipient is active in the field of *…To be completed….*

Whereas the Parties, having considerable experience in the field concerned, have signed a Framework Consortium Agreement (The "**Consortium Agreement**") relating to the Action entitled "**Promoting Implementation of Recommendations on Policy, Information and Material and Data for Rare Diseases"**, in short **RD ACTION**, hereinafter referred to as "**Project**".

Whereas Recipient will access to the Material and Data defined below for research purposes as described in the Consortium Agreement and Provider agrees to transfer the Material and Data described below to Recipient, subject to the strict respect by the Parties of the conditions stated in the present agreement (hereinafter referred to as the "**Agreement**").

Material and Data (Short description)	_____
Personal Material and Data (If applicable)	☐ Yes ☐ No THIS SECTION SHALL IDENTIFY IF HUMAN SAMPLES AND PERSONAL DATA and/or SENSITIVE DATA (AS PER GDPR definition) ARE TRANSFERRED. UNDER GDPR, BIOLOGICAL SAMPLES AND PERSONAL DATA SHALL BE FULLY ANONYMIZED WHENEVER POSSIBLE (i.e., no connection can be made BY ANYONE between the code assigned to the sample and the Data Subject). IF THE RESEARCH REQUIRES IT, SAMPLE CAN BE PSEUDONYMIZED (i.e., CODED) and PROTECTIVE CLAUSES IN ACCORDANCE WITH GDPR SHALL BE INCLUDED: THE FACT RECIPIENT DOES NOT HAVE THE KEY TO RE-IDENTIFY THE PATIENT FROM THE CODE DOES NOT RENDER THE SAMPLES/DATA FULLY ANONYMIZED, AS e.g., PROVIDER STILL CAN RETRACE THE PATIENT.
Intended Use of Material and Data	General description of the study to be performed by Recipient: Specific purpose of the use of Material and Data by Recipient:
Foreseen period of Use of Material and Data	SHALL BE IN ACCORDANCE WITH THE TERM OF THE AGREEMENT. UNDER CERTAIN NATIONAL IMPLEMENTATION OF GDPR, A DEFINED TERM SHALL BE STATED
Transfer and Mode of Transfer	
Recipient Scientist	

DEFINITIONS

(i) Commercial Purpose:
shall mean he sale, lease, license, or other transfer of the Material and Data and/or Modifications (as defined below) to a for-profit organization. Commercial Purposes shall also include publication and uses of the Material and Data and Personal Data or Modifications by any organization, including the Recipient, to perform contract research or to conduct research activities that result in any sale, lease, license, or transfer of the Material and Data or Modifications to a for-profit organization.

(ii) Effective Date:
shall mean the date on which of the last required signature was obtained.

(iii) Progeny:
shall mean any descendant from the Reagent such as virus from virus, cell from cell, or organism from organism.

(iv) Unmodified Derivatives:
shall mean substances and genetic material created by the Recipient which constitute an unmodified functional subunit or product expressed by the Reagent. Some examples include: subclones of unmodified cell lines, recombinant constructs, subcultures, mutations, proteins expressed by DNA/RNA supplied by Provider, sub-sets of the original Reagent such as novel plasmids or vectors, monoclonal antibodies secreted by a hybridoma cell line,

and/or purified or fractioned sub-sets of the original Reagent; DNA, RNA, proteins, cells, tissues and organs either directly derived from Reagent, or reproduced by any means, specifically including cloning, PCR, cell or organ culture.

(v) Material and Data:
Shall mean the material and data described in the Premises table above and Progeny, Unmodified Derivatives and Confidential Information

(vi) Modification(s):
shall mean substances created by Recipients as a result of the Research which contains and/or incorporates the Material.

(vii) Personal Data:
shall mean Material and Data that is defined and protected as personal material and data under the provisions of the General Data Protection Regulation (EU) 2016/679 ("GDPR") and national applicable legislation(s), and that shall be subject to terms and conditions specified in article 4 of this Agreement. This term shall cover any personal data, including health and genetic data, related to the Material and Data, including the Material itself. For sake of clarity, Regulation (EU) 2016/679 define "personal data" as any information relating to an identified or identifiable natural person ("Data Subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

(viii) Research:
shall mean the experimental, non-commercial, scientific research described in the Premises table above to be performed by Recipients.

TERMS AND CONDITIONS OF THIS AGREEMENT

1. PURPOSE

The purpose of this Agreement is to define the terms and conditions of the transfer of Material and Data between the Recipient and the Provider for the performance of the Research, as well as the rights and obligations of the Parties with regard to their use of Material and Data.

2. SUPPLY OF MATERIAL AND DATA

The Provider shall send the Material and Data to the attention of the Recipient, at the Recipient's expenses, in the above specified Format and Mode of Transfer.

3. USE OF MATERIAL AND DATA

3.1. Material and Data, Personal Data and their Modifications shall be used solely for purpose of the Research, in accordance with the Consortium Plan, to the exclusion of any other use of the Material and Data thereof such as a use for Commercial Purpose

3.2. Recipients shall use the Materials only in compliance with all applicable laws, governmental regulations and guidelines, including any regulations or guidelines pertaining to research with animals or recombinant DNA that may be applicable to the Materials, in the country where the Research is carried out; The Research shall be carried out under the direct supervision and responsibility of Recipient Scientist.

3.3. The Materials shall remain in the premises of Recipient, only in the Recipient Scientist's laboratory and under the direction of the Recipient Scientist.

3.4. Recipients shall not transfer or otherwise make available, without Provider's written consent, any Materials to any third party other than Recipient Scientist and the Institution's employees who are working under the supervision of Recipient Scientist and who: (i) need to have access to Materials for the purpose of performing the Research; (ii) are apprised of the proprietary nature of the Materials and are bound to use the Materials only in the manner permitted under this Agreement

3.5. Recipients shall refer any request received by any third parties for the Materials to Provider. To the extent the Material is available, Provider will evaluate and decide, at its own discretion and without any obligation to consent, whether to make the Materials available to third parties indicated by Recipients, on condition that a proper Material Transfer Agreement is signed by each of these third parties with Provider.

3.6. Recipients shall use Materials only in vitro or in a laboratory for animal experiments.

3.7. Recipients shall not use the Materials in human subjects, in clinical trials involving human subjects, or for diagnostic purposes involving human subjects without the prior written consent of Provider.

3.8. Recipients shall acknowledge Provider in any publication and any other disclosure as the source of the Materials in accordance with scientific custom.

3.9. Recipient may not transfer or otherwise make available Modification to third parties without Provider's written consent.

3.10. The Recipient agrees to apply the same degree of security in order to protect the Material and Data as it applies to its own material and data, and in any case no less than a reasonable degree of security.

3.11. The Recipient undertakes that its use of the Material and Data shall not be subject to the terms of any research agreement according to which a third party would obtain rights to the results arising from the Research.

3.12. The Recipient acknowledges that the Material and Data are or may be covered by intellectual property rights.

3.13. Except as provided in this Agreement, no express or implied license or other right are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the Material and Data made by the Provider.

3.14. The Recipient acknowledges that nothing herein shall create or be construed to create any license to the Recipient or any obligation to enter into any other agreement.

3.15. The Parties shall respect all terms and conditions under the present article 3 at their own costs and expenses.

4. PERSONAL DATA

The following rules apply to any transfer and use of Personal Material and Data covered by this Agreement:

4.1 The Provider and the Recipient represent and warrant that they each have previously obtained all authorizations or opinions and made all proceedings or declarations that are necessary in regards of the Transfer and the Intended Use of the Material and Data and Personal Data.

4.2 The Provider represents and warrants the Recipient that:

a. The Data Subjects (Hereinafter "Data Subjects") who initially provided Personal Data have been duly informed and gave the written consent, to the full extent defined by the applicable law and regulations and covering the use of their Personal Material and Data for the Research.

b. Personal Data have been collected by fair means, in respect of applicable law and regulations.

c. Prior to the transfer of the Material and Data and Personal Data to Recipient, Provider will ensure that the Material and Data and Personal Data are coded, so that under no circumstances will Recipient be supplied with the identity of the Data Subjects, or any information that in Provider's opinion could identify the Data Subjects.

d. ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR***. *Depending on the agreement between Provider and Recipient there are two options that shall be validated by the competent offices (including DPO) of both parties (see art 4.3.a) – briefly, Recipient shall be appointed as a DATA PROCESSOR or as a DATA CONTROLLER (autonomous data controller or co-controller), and an additional DATA PROCESSOR AGREEMENT shall be stipulated*
Under GDPR, Provider has certain obligations pertaining to communication with the patients (e.g., ensuring that the Material and Data can be transferred to third parties like Recipient, that the purpose of use stated by the Recipient are in line with those agreed upon by patients in the informed consent).

[***OPTION 1: RECIPIENT AS DATA PROCESSOR, see art 4.3.a - THIS CLAUSE 4.2.d IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS – PLEASE CONTACT YOUR COMPETENT OFFICE****]* Being the Material coded, Provider will be responsible for and manage all the interactions with the Data Subjects, included and not limited to the following. In particular, by means commonly put in place by Provider and compliant with applicable law, Provider shall be responsible for: (i) informing and making Data Subjects aware that Material and Data and related Personal Data have been communicated and transferred for the Research to Recipient; (ii) collecting the consent of Data Subjects for the abovementioned purposes under point (i), ensuring that it was freely given; (iii) promptly notifying the requests made by Data Subjects to the Recipient pursuant to Art. 15 to 22 of the Regulation (EU) 2016/679; Recipient will offer the cooperation necessary for Provider in order to fulfil

its obligations towards the Data Subjects as related to Recipient's processing of Personal Data.

[OPTION 2: RECIPIENT AS DATA CONTROLLER, see art 4.3.a THIS CLAUSE 4.2.d IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS – PLEASE CONTACT YOUR COMPETENT OFFICE] Recipient is required to provide patients with its privacy notice, but as the Material and Data are coded (pseudonymised), Recipient can do so only through the action of Provider. Please note that providing patients with an additional privacy notice may require to prepare and-submit a new informed consent to the Ethics Committee and re-consent patient.] Being the Material coded, Provider will be responsible for and manage all the interactions with the Data Subjects, included and not limited to the following. In particular, by means commonly put in place by Provider and compliant with applicable law, Provider shall be responsible for: (i) informing and making Data Subjects aware that Material and Data and related Personal Data have been communicated and transferred for the Research to Recipient; (ii) providing data protection information of Recipient to Data Subjects; (iii) collecting the consent of Data Subjects for the above mentioned purposes under point (i), ensuring that it was freely given; (iv) Provider will promptly notify the requests made by Data Subjects to the Recipient pursuant to Art. 15 to 22 of Regulation (EU) 2016/679; Recipient will offer the cooperation necessary for Provider in order to fulfil its obligations towards the Data Subjects as related to Recipient's processing of Personal Data.

e. When required by law or regulation, the Personal Material and Data will be encrypted before Transfer.

4.3 The Recipient represents and warrants the Provider that:

a. ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR. THIS CLAUSE 4.3.a IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATIONS AND NOT AS THE FINAL CLAUSE – PLEASE CONTACT YOUR COMPETENT OFFICE*** *Depending on the agreement between Provider and Recipient there are two options that shall be validated by the competent offices (including DPO) of both parties.*
The Material and Data and related Personal and Data, once received by the Recipient, shall be processed by Recipient in accordance with the provisions of Regulation (EU) 2016/679 as [OPTION 1: Data Processor, as per Data Processor Appointment agreement in Annex A (*Agreement defined by Provider according to applicable law and regulations*)] [OPTION2: Data Controller, *the parties shall define if they are autonomous data controller or co-controller*].

b. Notwithstanding the terms and conditions set out under section 3.2, Personal Data shall be stored with relevant degree of security in order to protect them in regards of their specific nature, and adequate maintenance procedures for the proper conservation of Personal Data shall exist, pursuant to applicable laws and regulations, in order to prevent any misuse, involuntary change, loss or modification of the Personal Data.

c. Personal Data shall only be used for the Research, which shall be legitimate and lawful.

d. Personal Data shall only be used to the strict extent that is necessary and during a reasonable period of time as regard to the Research and in any case only for the term of this agreement.

e. Personal Data shall not be used for Commercial Purpose;

f. Personal Material and Data shall not be transferred to a third party including any affiliate of the Recipient, without prior written authorization from the Provider and in accordance with the authorization/declaration necessary for the transfer.
g. Recipient undertakes not to perform any activities aimed at the identification of the Patients.
h. Any communication or publication of the results of the Research shall not allow, directly or indirectly, identification of the Patients.

4.4 At any time, following at least X business day advance written notice to Recipient, Provider shall be granted access by the Recipient to the place where Personal Data are stored (including premises, compounds, websites, servers, files, authorizations, etc.), for the only purpose and to the only extent of verifying if the terms and conditions stated in section 4.3 are respected.

4.5 At the end of the Period of Use of the said Personal Data as specified above, or upon termination of this Agreement, Recipient shall terminate any use and destroy or return such Personal Material and Data to Provider with no delay.

4.6 Parties shall respect all terms and conditions under article 4 at their own costs and expenses.

5. OWNERSHIP OF MATERIAL AND DATA AND RESULTS

5.1 Material and Data shall be treated as ownership of the Provider between the Parties, subject to applicable laws and regulations.

5.2 The Recipient shall not file, or have filed in the name of third parties in any country, any patent application, or intellectual property rights (including but not limited to copyrights, trademarks, …) claiming the Material and Data and the Personal Data.

5.3 Provider retains ownership and/or control of the Material and Data and related Personal Data, even where contained or incorporated in any Modifications, and shall decide, at its sole discretion, to prepare, file, prosecute and maintain in its name patent and/or patent applications covering the Material.

5.4 Subject to third parties rights on third parties materials contained and/or incorporated in the Modifications, if any Modification and/or any result of the Research stems from the collaborative efforts of both Provider and Institution, joint ownership shall be determined in good faith by Provider and Institution pursuant to the respective inventive contribution and in such a case the Parties shall negotiate an Inter-Institutional Agreement. Each party shall have the right to use any co-owned Modification and result of the Research for its internal research activity and non-commercial purposes.

6. CONFIDENTIALITY

6.1 Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity, or otherwise the name of the Provider or any of their marks.

6.2 The Recipient undertakes to respect and maintain strictly confidential all the Material and Data and Personal Data identified by the Provider as confidential or which is confidential by its nature.

7. WARRANTIES

7.1 The Recipient accepts the Material and Data "as is". Provider makes no representation and extends no warranties of any kind, either expressed or implied. No warranties expressed or implied are offered by the Provider as to the fitness for a particular purpose of the Material and Data. Provider and their directors, officers, employees, or agents assume no liability and make no representation in connection with the Material and Data use by Recipient. Recipient will defend, indemnify and hold harmless Provider, their directors, officers, employees, and agents from any damages, claims, or other liabilities which may be alleged to result or arise from its use or its storage of the Material and Data, even where included in Modifications, except to the extent caused by the gross negligence or willful misconduct of Provider.

7.2 ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR. THIS CLAUSE IS INTENDED ONLY AS A TRACE TO DETAIL SUCH OBLIGATIONS AND NOT AS THE FINAL CLAUSE – PLEASE CONTACT YOUR COMPETENT OFFICE*** Provider represents and warrants that the Material and Data and Personal Data have been collected and processed in compliance with applicable law, rules, regulations, and other requirements set by the applicable governmental authority, including without limitation those applicable to patient informed consent. Provider confirms that the Data Subjects involved have been informed according to the provisions of the Regulation (EU) 2016/679 about potential transfer to third parties of the Material/Data and related Personal Data for research purposes.

7.3 ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR. THIS CLAUSE IS INTENDED ONLY AS A TRACE TO DETAIL SUCH OBLIGATIONS AND NOT AS THE FINAL CLAUSE – PLEASE CONTACT YOUR COMPETENT OFFICE*** Provider shall indemnify, defend and hold harmless Recipient (and its employees, agents and consultants) from and against all claims, damages and liabilities that may be asserted by third parties (including Data Subjects) directly and/or indirectly related to Provider's violation of any such laws, rules, regulations and requirements regarding collection and processing of the Material and Data and related Personal Data.

7.4 Provider makes no representation that the use of the Material and Data and Personal Data will not infringe any intellectual property right of any third party.

8. TERMS OF CONTRACT

8.1 This Agreement enters into force at the Effective Date and shall earlier be terminated: (a) thirty-six (36) months from the Effective Date, or (b) upon completion of the Project, unless otherwise agreed by the Parties. *PLEASE NOTE Option (b) may not be feasible under certain national implementation of GDPR*

8.2 At the expiration of this Agreement, the Recipient shall discontinue its use of the Material and Data and shall, according to the Provider's instructions, return or destroy any remaining Material and Data.

9. NON-TRANSFERABILITY

This Agreement has been concluded *intuitu personae* and none of the Parties may assign all or part of the Agreement to a third party without the prior written agreement of the other Parties.

10. MISCELLANEOUS

10.1 Each Party will be excused for failure to fulfill its obligations and may not be held responsible or liable for damages with regard to the other Parties, if the non-performance is due to a force majeure event within the meaning of the applicable law, or such as the disruption of its services as a result in particular of strike, resignation or any other event beyond its control. The Party which finds it impossible to perform its contractual obligations due to a force majeure event shall immediately notify the other Parties in writing.

10.2 The Agreement shall in no event be interpreted as creating a partnership relationship or a company, even a *de facto* company, between the Parties which are independent contracting parties.

10.3 ***THIS CLAUSE SHALL BE DEFINED BY THE PARTIES ACCORDING THE THEIR POLICIES AND THE NATIONAL IMPLEMENTATION OF THE GDPR. THIS CLAUSE IS INTENDED AS A TRACE TO DETAIL SUCH OBLIGATION – PLEASE CONTACT YOUR COMPETENT OFFICE*** *In case of transfer of pseudonymized biological samples and/or personal and sensitive data, the GDPR recommends that the agreement is subject to the law and jurisdiction of Provider (assuming that Provider is a member of the EU). In any case, the Recipient shall comply with GDPR (and its national implementation of GDPR) even when receiving samples from outside the EU (Standard contractual clauses).* This Agreement shall be governed by the laws of Belgium. The Belgian relevant courts shall have sole jurisdiction for any litigation related to interpretation or execution of the Agreement, which parties cannot solve in an amicable way within a period of two (2) months following notification from a Party.

In witness whereof, the Recipient and Provider have executed this Agreement as of the date below written.

Signed in original counterparts drafted in the English language, with one (1) for the Provider and the other for the Recipient.

Provider	**Recipient**
Signature_____	Signature_____
(Authorized signatory of the Provider)	(Authorized signatory of the Recipient)
Name:	Name:
Title:	Title:
Date:	Date:

READ, UNDERSTOOD AND AGREED TO BY THE SCIENTIT(S):

Signature_____

Name:

Title:

Date:

Annex A Data Processor Appointment

TO BE DEFINED BY PROVIDER

Annex B Standard Contractual Clauses

IN CASE RECIPIENT IS OUTSIDE THE EU, THE GDPR REQUIRES THAT CERTAIN STANDARD CONTRACTUAL CLAUSES SHALL BE IMPLEMENTED IN THE AGREEMENT. PLEASE CONTACT YOUR COMPETENT OFFICE ON THIS MATTER.
MORE DETAILS CAN BE FIND HERE:
https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en

INTER-INSTITUTIONAL AGREEMENT FOR JOINT INVENTION MANAGEMENT

This Inter-Institutional Agreement for Joint Invention Management (the "IIA") is between the Parties identified below.

No binding agreement between the Parties will exist until this IIA has been signed by all Parties. Unsigned drafts of this IIA shall not be considered offers.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties hereby agree as follows:

The Terms and Conditions for Inter-Institutional Agreement for Joint Invention Management attached hereto as Exhibit A are incorporated herein by reference in their entirety (the "Terms and Conditions"). In the event of a conflict between provisions of this IIA and the Terms and Conditions, the provisions in this IIA shall govern. Capitalized terms used in this IIA without definition shall have the meanings given to them in the Terms and Conditions.

The section numbers used in the left-hand column in the table below correspond to the section numbers in the Terms and Conditions.

1. Definitions				
	Parties	[Party 1] [Party 2] [Party 3]		
	Effective date	_____, 202_		
	Patent rights to Joint Invention:			
		Application no/ Date of filing	*Title*	*Inventor(s) (include employer for each)*
	Collaboration agreement	The results of the following collaboration agreement will be governed by this IIA: [Identify agreement, or enter "None"]		
	Managing party	[Specify which party will oversee prosecution and licensing]		
	Management fee	[Specify %, or state "None." If there is a cap, specify at sec. 5.3(c).]		
2.2. Third-party interests				
	[Identify specific encumbrances, or enter "None"]			
3.4. Allocable percentage of patent expenses				
	[Party 1]	___%		
	[Party 2]	___%		
	[Party 3]	___%		
3.5(a) Past patent expenses				
	[Identify € amount and Parties incurring expenses.]			
3.5(c) Patent expense cap				

	[Identify € amount per period of time or per patent]	
5.3(a) Allocable percentage of net consideration		
	[Party 1]	___%
	[Party 2]	___%
	[Party 3]	___%
5.3(b) Licensing expense cap		
	-	
5.3(c) Management Fee cap		
11.10. Address for notice		
	For [Party 1]:	Attn: _____ Addr: _____ _____ Fax: _____ Phone: _____ E-mail: _____
	For [Party 2]:	Attn: _____ Addr: _____ _____ Fax: _____ Phone: _____ E-mail: _____
	For [Party 3]:	Attn: _____ Addr: _____ _____ Fax: _____ Phone: _____ E-mail: _____

No Other Promises and Agreements; Representation by Counsel.
Each party expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to it in executing this IIA except those explicitly set forth herein and in the Terms and Conditions, and that such party is not relying upon any statement or representation of the other party or its representatives. Each party is relying on its own judgment and has been represented by legal counsel. Said legal counsel has read and explained to such party the entire contents of this IIA and the Terms and Conditions incorporated by reference herein. Each party hereby warrants and represents that it understands and agrees to all terms and conditions set forth in this IIA and said Terms and Conditions.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Inter-Institutional Agreement for Joint Invention Management.

Party 1

By _____
Name _____
Title _____
Date _____

Party 2

By _____
Name _____
Title _____
Date _____

Party 3

By _____
Name _____
Title _____
Date _____

Exhibit A
TERMS AND CONDITIONS FOR INTER-INSTITUTIONAL AGREEMENT FOR JOINT INVENTION MANAGEMENT

These Terms and Conditions ("Terms and Conditions") are attached to and incorporated into an Inter-Institutional Agreement for Joint Invention Management ("IIA"). All Section number references in these Terms and Conditions shall be references to provisions in these Terms and Conditions unless explicitly stated otherwise.

Background

A. As co-owners of the Joint Invention, the Parties are entering into the IIA for the management of the Joint Invention, for their mutual benefit and for the public benefit.

B. The Agreement does not provide for any right or obligation with respect to any future research project or any future research collaboration between the Parties, unless a specific joint research collaboration agreement is identified in Section 1 of the IIA.

1. Definitions.

"Agreement" means collectively (i) the Terms and Conditions, and (ii) the IIA.

"Allocable Percentage of Net Consideration" means the respective percentage allocated to each Party of Net Consideration, as set forth in Section 5.3(a) of the IIA.

"Allocable Percentage of Patent Expenses" means the respective responsibility allocated to each Party for Patent Expenses, as set forth in Section 3.4 of the IIA.

"Collaboration Agreement" means a joint research collaboration agreement, if any, the results of which the Parties wish to have governed by the Agreement, as set forth in Section 1 of the IIA.

"Confidential Information" means any non-public information which is maintained by a Party as confidential, including as examples, biological materials, computer source codes, diagrams, electronic files, trade secrets, patent applications, technical information, research data, draft publications, License Agreements, terms, and so forth, but excluding however any information which the recipient Party can establish by competent written proof (a) was in the public domain through no act or omission of the recipient Party or its employees, agents, successors or assigns in breach of this Agreement; or (b) was lawfully disclosed to the recipient Party by third parties having a right to disclose it; or (c) was already known by the recipient Party at the time of disclosure by the disclosing Party; or (d) was independently developed by the recipient Party without any reliance on the Confidential Information from the recipient Party; or (e) is required by law or regulation to be disclosed publicly.

"Effective Date" means such date as set forth in Section 1 of the IIA.

"Inventors" mean individuals who are joint inventors of the Patent Rights, and who made inventive contributions to the Patent Rights

"Joint Invention" means the Joint Invention set forth in Section 1 of the IIA.

"License Agreement" means individually or collectively any and all license agreements, options for license agreements (an "Option Agreement"), or any other agreements involving the granting of rights to a third party in the Joint Invention, or any portion thereof.

"License Consideration" means collectively all of the money or other items of value (excluding research grants) payable by a Licensee (or its sublicensees, successors and assigns) under a License or Option Agreement for rights to use the Joint Invention, which payments are payable to the Parties pursuant to the License or Option Agreement. Examples of such License Consideration include up-front license fees (whether cash, equity, or other consideration), annual maintenance fees, patent expense reimbursements, milestone fees, minimum royalties, earned royalties, and so forth.

"Licensee" means any third party who has been granted rights pursuant to an Option Agreement or License Agreement in the Joint Invention or any portion thereof.

"Licensing Expenses" means all reasonable out-of-pocket costs and expenses incurred by the Managing Party for negotiating and entering into License and Option Agreements for the Joint Invention, including for example outside attorneys' fees and expenses. In addition, other related expenses, such as travel relating to negotiation of a License Agreement, may be treated as Licensing Expenses if mutually agreed upon in writing by the Parties. For avoidance of doubt, the salaries and costs of each Party's technology transfer office or legal affairs office are not included as outside costs for purposes of calculating the Licensing Expenses.

"Management Fee" means a portion of the License Consideration, excluding Patent Expense reimbursements, retained by and payable to the Managing Party as consideration for the Managing Party performing the management duties set forth in Sections 3, 4 and 5, as set forth in Section 1 of the IIA.

"Managing Party" means the Party so designated in Section 1 of the IIA, who has the management responsibilities with respect to the Joint Invention as set forth in Sections 3, 4 and 5. There may be changes in the designated Managing Party pursuant to Section 10.6.

"Net Consideration" means all of the License Consideration, minus the Patent Expenses, Licensing Expenses and Management Fee.

"Other Parties" means Parties other than the Managing Party, each of whom is a non-Managing Party.

"Parties" means the entities identified as the Parties in Section 1 of the IIA; and "Party" means any one of the Parties.

"Patent Expenses" means all reasonable outside expenses incurred in connection with obtaining patent protection for the Joint Invention, both past and future, including for example, (i) attorneys' fees payable to the patent attorney who prepares, files and prosecutes patent applications for the Joint Invention, (ii) fees payable to the United States Patent and Trademark Office and to other governmental foreign patent offices, (iii) translation fees, and (iv) costs for prior art searches. For avoidance of doubt, the salaries and costs of each Party's technology transfer office or legal affairs office are not included as outside costs for purposes of calculating the Patent Expenses.

"Patent Rights" means all patents and patent applications set forth in Section 1 of the IIA or that result from the joint efforts of two or more Parties under the Collaboration Agreement, if any, and any corresponding foreign patent application, issued patent, continuations, continuations-in-part (but only to the extent that the claims in the continuations-in-part have Inventors from two or more Parties and are entitled to a priority date from a patent application otherwise included in this definition), divisionals, substitutions, re-examinations, re-issues, and so forth.

2. Representations, Warranties and Covenants.

2.1 Assignment by Inventors. Each Party represents and warrants that, wherever required under the applicable law, its Inventors have already assigned to it or its governing system or board all of their rights in the Joint Invention, and that such Party will use diligent efforts to cause its Inventors to sign any additional papers as may be necessary to evidence such assignment.

2.2 Ownership and No-Conflict. Each Party represents and warrants to the knowledge of its technology transfer office or other licensing office or department, it has not granted any rights to any entity or person to acquire any rights in the Joint Invention. If there is any conflict between the Agreement and any applicable law, regulation or governmental act, then the provisions of such applicable law, regulation or governmental act shall prevail.

2.3 Grant of Authority. Each Party represents and warrants that it has authority to delegate the duties concerning the Joint Invention as set forth in Section 3, 4 and 5 to the Managing Party. The Managing Party represents and warrants to each Other Party that it has the power and authority to act on behalf of all Other Parties as the Managing Party with respect to its designated duties respecting the Joint Invention.

2.4 Competing Technologies. The Agreement does not restrict any Party from developing or acquiring interests in technologies which may compete with a Joint Invention or improve upon a Joint Invention, and from commercializing such technologies.

3. Patent Prosecution.

3.1 Authority and Coordination. The Managing Party shall have the responsibility and authority to take all reasonable actions necessary and appropriate to seek national, European, foreign, or

international patent protection for the Patent Rights (e.g.: EPC, PCT) in accordance with the terms of the Agreement and in line with the decisions taken by the Parties. The patent strategy for the Patent Rights shall be determined jointly by the Parties and the Managing Party shall keep the Other Parties informed as to all material matters relevant to the patent prosecution process and decisional matters, and the Managing Party shall give due consideration to any recommendations made by the Other Parties concerning the patent prosecution matters. Without limiting the generality of the foregoing, the Managing Party shall confer with the Other Parties regarding (i) selecting the outside patent counsel to prepare and prosecute the patent application for the Patent Rights; (ii) the scope of claims to be included in the patent application; (iii) if Patent Expenses are being shared by the Parties and are not being paid or reimbursed by a Licensee, a budget for the Patent Expenses for the Joint Invention and performance against such budget; (iv) responses to inquiries and actions from the patent agencies; and (v) an action plan with respect to any challenges against the Patent Rights if the Managing Party is responsible for defending such challenge under Section 7. If a Licensee has been delegated authority over patent prosecution, the Managing Party can fulfill its obligations under the preceding sentence by conferring with the Other Parties regarding such matters and conveying the collective input of the Parties to the Licensee in accordance with a License Agreement mechanism that allows the Managing Party such input.

3.2 Patent Ownership. The patent applications and issued patents for the Joint Invention shall be in the name of, and jointly owned by, the Parties or their written designees.

3.3 Information. The Managing Party shall instruct the patent attorney who is hired to prosecute the patent applications (i) to furnish copies to the Other Parties of all draft and final patent applications, and all correspondence with patent agencies, and all material reports and analysis by the patent attorney, with respect to the Patent Rights, and (ii) to respond openly and promptly to the Other Parties' inquiries; provided, however, that Other Parties shall direct any comments or recommendations on patent drafting, strategy, responses to National Patent Offices and the like to the Managing Party and not to the patent attorney. In addition, a Managing Party can, with the consent of the Other Parties, satisfy its obligations under clause (i) above with respect to USPTO, EPO filings, and any other national filings, whether or not the Patent Rights have been licensed, by providing to the Other Parties information to allow them to access the USPTO Private PAIR, or epoline or the relevant further national database, for such filing.

3.4 Patent Expense Allocation. Section 3.4 of the IIA sets forth the manner in which the Patent Expenses will be allocated among the Parties.

3.5 Patent Expenses Shared Among the Parties. The Patent Expenses are being shared among the Parties, and the following provisions shall apply:

(a) Section 3.5(a) of the IIA shows the Patent Expenses incurred prior to the Effective Date and the Parties incurring such expenses. Within 60 days of the Effective Date, the other Parties shall pay their Allocable Percentages of Patent Expenses with respect thereto to the Parties that incurred such expenses, except as provided for in the following Section 3.5 (c).

(b) Each Party is responsible for ensuring that payment of all Patent Expenses, except as provided for in the following Section 3.5 (c), is made in a timely manner.

(c) Notwithstanding the foregoing, expenditures for Patent Expenses, incurred prior and/or after the Effective Date (according to Sections 3.5.(a) and 3.5.(b) above), may not exceed the cap set forth in Section 3.5(c) of the IIA, if any, absent the advance written consent of the Other Parties. This Section 3.5(c) shall not apply in the event that a Licensee is paying or reimbursing the Patent Expenses.

(d) Upon at least a 60-day prior written notice from a Party (the "Withdrawing Party") to all other Parties, the Withdrawing Party may decline to make future payments of its Allocable Percentage of Patent Expenses for one or more types of anticipated Patent Expenses (e.g., expense for continuing to prosecute a particular patent application, or for maintenance of a particular patent, etc.). Upon such notice, the other Parties are entitled to take over the ownership share of the Withdrawing Party (divided into equal parts, unless otherwise agreed by such assignee Parties) free-of-charge but against reimbursement of costs of this transfer and pursue prosecution or maintenance in its own name and at its own risk and expense while the Withdrawing Party shall reasonably assist the other Parties. Upon execution of this right (e.g., non-payment of costs), the Withdrawing Party shall cease to have any rights, interest or Allocable Percentage in Net Consideration realized from the Patent Rights for which the Withdrawing Party has elected to cease paying its

Allocable Percentage of Patent Expenses. The same shall apply accordingly when a Party does not intend to file for patent protection and/or does not intend to initiate national phases in certain countries.

3.6 Cooperation of Inventors. Each Party shall use its good faith and diligent efforts to cause its Inventors under its employ to cooperate and provide assistance as is reasonably requested in connection with the preparation or prosecution of the patent applications for the Joint Invention, in connection with any proceedings applicable to a challenge to the Patent Rights or an infringement of the Patent Rights, and in connection with the provisions of Section 9 with respect to prior review of publications by Licensees.

4. Licensing.

4.1 Authority and Coordination. The Managing Party shall have the responsibility, obligation and authority to diligently pursue all reasonable efforts to identify suitable prospective Licensees for the Joint Invention, and to negotiate and enter into one or more License Agreements for the Joint Invention for the mutual benefit of the Parties. The Managing Party shall keep the Other Parties promptly and reasonably informed as to the plans and activities of the Managing Party with respect to the licensing matters, and the Managing Party shall give due consideration to the recommendations made by the Other Parties with respect to the licensing matters. Without limiting the generality of the foregoing, examples of the foregoing are that the Managing Party shall confer with the Other Parties regarding (i) term sheets for potential License Agreements; (ii) business plans of prospective Licensees for commercializing the Joint Invention; (iii) alternative licensing opportunities; and (iv) the draft License Agreement before it is signed. The Managing Party will respond in a timely manner to status inquires from the Other Parties regarding its licensing efforts. The Other Parties shall promptly communicate to the Managing Party any inquiries they receive regarding licensing the Joint Invention.

4.2 Managing Party Authority. The Managing Party shall have the exclusive right and authority to negotiate any and all Option Agreements and License Agreements for the Joint Invention; all of which Option and License Agreements shall be for the mutual benefit of the Parties. The Managing Party shall not have the authority to execute any License Agreement in the name and on behalf of the Other Parties; each License Agreement shall be undersigned for approval by each Party having interest in exploiting the Joint Invention, whose consent will not be unreasonable withheld. The Other Parties shall not be entitled to enter into any Option or License Agreement for the Joint Invention with respect to the Other Parties' interest in the Joint Invention. Each Party's consent or decline to such Option or License Agreement shall be communicated within 10 business days starting from the date when the Party has received the final proposal for such License Agreement. In case of decline, the declining Party shall also indicate in such communication the grounded reason for decline (e.g., inadequate economic terms of the agreement; previous agreement with third parties on the specific field).

4.3 License Agreements. The form of License Agreements to be entered into by the Managing Party with respect to the Joint Invention shall contain financial terms and general legal terms which are customary for a university license agreement for the type of technology involved in the Joint Invention, including for example:

a. Customary financial terms, generally including license fees, maintenance fees, milestone fees, royalties and sublicense fees.
b. Terms as to "field of use," territory, and exclusive or non-exclusive nature.
c. In the event of an exclusive license grant, an obligation on the Licensee to pursue commercially reasonable and diligent efforts to commercialize the Joint Invention and the provision of due diligence milestones.
d. In the event of any exclusive license, an obligation on the Licensee to pay all past and future Patent Expenses.
e. The reserved right for the Parties to use the Joint Invention for academic, research and non-commercial clinical purposes of the Parties.
f. The reserved right for the Parties to publish the general scientific findings from their research related to the Joint Invention, subject to customary terms for prior review by the Licensee in accordance with Section 9.
g. No assignment of any ownership interests in the Joint Invention.
h. Standard indemnity obligations on the Licensee in favor of the Parties, and standard disclaimers by the Parties against all warranties, express or implied.

i. Restriction to using the names of the Parties only in connection with factually based materials related to the Licensed Invention and the business of the Licensee, and specifically restricting the use of the name of any Party or its governing system or board in any name, brand or trademark related to Licensed Invention or any product created therefrom.

j. Standard confidentiality terms regarding licensed Know-How, if any.

5. Calculation of Net Consideration Shares.

5.1 License Consideration Shares. The Managing Party shall have the responsibility, obligation and authority to diligently manage, administer and enforce the Licensee's performance of the License Agreement, including without limitation, communicating and requesting the License Consideration payable under the License Agreement, and performing such audit under the License Agreement as the Managing Party deems appropriate. The Managing Party shall keep and shall be fully informed by Other Parties as to all receipts of the License Consideration in accordance with Section 5.4. The Parties shall keep each other reasonably informed of any material delinquencies, deficiencies or defaults by the Licensee in performing the License Agreement.

5.2 Recovery of Patent Expenses from Licensee. To the extent that the Licensee reimburses previously incurred Patent Expenses, said reimbursements shall be paid to the Parties in proportion to the prior Patent Expenses actually paid by each Party, except in the circumstances described in Section 3.5(*d*).

5.3 Net Consideration. The Managing Party shall communicate to the Other Parties the Allocable Percentages of Net Consideration calculated after deduction of the following amounts:

(a) first, the Patent Expenses (which shall be distributed to the Parties in proportion to the prior Patent Expenses actually paid by each Party, except in the circumstances described in Section 3.5(*d*)),

(b) second, the Licensing Expenses due to the Managing Party (not to exceed the cap set forth in Section 5.3(b) of the IIA, if any, except to the extent that a Licensee is explicitly reimbursing those expenses or paying a license documentation fee or similar fee for that purpose) and

(c) third, the Management Fee, due to the Managing Party (not to exceed the cap set forth in Section 5.3(c) of the IIA, if any, except to the extent that a Licensee is explicitly reimbursing those expenses).

5.4 Reports and Payments to Other Parties. The Managing Party shall make the calculations as to the allocation of the License Consideration in accordance with the terms of the Agreement and furnish to the Other Parties a written report of such receipts and calculations (including itemized amounts for Licensing Expenses). The reports and payments shall be mailed to the Other Parties at their addresses as specified in Section 11.10.

5.5 Inventors' Distribution. With respect to the Parties' policies and agreements for sharing with its Inventors a portion of the Net Consideration, each Party shall be responsible for making its own distributions to its respective Inventors.

5.6 Allocation of Proceeds. The Parties acknowledge that in some circumstances gross licensing proceeds received by the Managing Party must be allocated for the purposes of making payments under the Agreement. Such circumstances include the licensing of the Joint Invention together with other inventions or a Party withdrawing under Section 3.5(*d*) from participating in payment of Patent Expenses for some portion of the Joint Invention. If allocation is required, the Parties shall negotiate in good faith an equitable allocation of the gross licensing proceeds. If the Parties are unable to agree upon an equitable allocation, such matter shall be resolved in accordance with Section 11.3.

6. Infringement by Third Parties.

If any Party learns of a potential infringement of the Patent Rights, they will promptly notify in writing the other Parties. The Parties acknowledge that an exclusive License Agreement will generally provide a first right to the Licensee to pursue patent infringement claims against third parties who infringe the licensed Patent Rights. In the absence of a Licensee pursuing third party infringers of the licensed Patent Rights, the Parties will determine in good faith how to proceed against such potential infringer.

7. Challenge against Patent Rights.

If any challenge is made against the Patent Rights, the Parties shall confer and endeavor to agree how best to defend against such challenge. If no agreement is reached within 30 (thirty) days from the

notice of the challenge, then the Parties may jointly or separately defend against the challenge, as they deem most appropriate and at their sole cost and expense. In the event of License Consideration, the Party defending the rights at their sole costs should be reimbursed for the total costs.

8. Confidential Information.

Each Party agrees to maintain the confidentiality of the Other Parties' Confidential Information, and to not use the Other Party's Confidential Information, other than in accordance with the terms and purposes of the Agreement. If any Confidential Information from another Party is required by law, regulation or court order to be disclosed, the disclosing Party shall be given written notice and an opportunity to challenge such disclosure.

9. Publications.

Each Party reserves the right to publish the general scientific findings from its own research related to the Joint Invention, in accordance with each Party's own policies and practices as communicated in writing time by time by the Parties. If a License Agreement or Option Agreement provision requires that the Licensee receive an advance copy of the proposed publication by any of the Parties relating to the Joint Invention to review for disclosure of Licensee's confidential information or other customary reasons, then the Parties shall comply with such provision, provided that the Parties shall not be required to furnish advanced copies more than 30 days prior to the submission and the Parties shall not be prevented from publishing.

10. Term and Termination; Change in Managing Party.

10.1 Term Duration. The term of the Agreement shall continue for the life of the last to expire of the Patent Rights for the Joint Invention and the last to expire of the License Agreements, unless terminated earlier in accordance with the provisions below.

10.2 No Termination without Cause. There shall be no right of termination except as provided for in clause 10.3 below

10.3 Breach. If a Party is in breach of its obligations under the Agreement, and the breach is not cured within 30 days after written notice of the breach is delivered to the breaching Party, then any other Party may elect to terminate the Agreement.

10.4 Joint Agreement. If all Parties agree in writing to terminate the Agreement, then the Agreement shall be so terminated.

10.5 Effect of Termination.

(a) Upon any termination, the Managing Party shall make available to the Other Parties copies of all relevant documents called for under the Agreement applicable to the Joint Invention, to the extent that copies have not been furnished previously.

(b) Upon any termination, each Party shall continue to be co-owners of the Joint Invention and the related Patent Rights and License Agreements.

(c) Upon any termination of the Agreement, such termination shall not affect any previously signed License Agreement; and the applicable provisions of the Agreement shall continue to be applied with respect to each such previously signed License Agreement, notwithstanding the termination of the Agreement.

10.6 Change in the Managing Party.

(a) The Party serving as Managing Party may resign from that position upon 60 days prior written notice to the Other Parties (or is deemed to have resigned in the circumstances set forth in Section 3.5(d)).

(b) If the Managing Party is in breach of its obligations under the Agreement and does not cure its breach in the time period set forth in Section 10.3, or if the Managing Party has not been successful in signing a License Agreement within three years of serving as Managing Party, then at the option of the Other Parties they may elect by written notice to the Parties to terminate a Party's service as Managing Party.

(c) In the event of a resignation or termination of a Party's service as Managing Party pursuant to Section 10.6(a) or (b), the Other Parties may elect a new Party to become the Managing Party and to so replace the initial Managing Party, subject to obtaining the written consent of such Party to act as the new Managing Party. Upon any such election, all Parties shall cooperate to effect a smooth and orderly transition and change in roles.

(d) In the event of a termination and/or replacement of a Managing Party in accordance with the provisions of this Section 10.6, responsibility for Patent Expenses will be determined in the manner set forth in Sections 3.5.

(e) In the event of a resignation or termination of a Party's service as Managing Party in accordance with the provisions of this Section 10.6, the old Managing Party shall be entitled to keep and/or receive any Management Fee, if any, that accrued and was payable out of License Consideration received prior to the effective date of resignation or termination. The Party serving as replacement Managing Party shall be entitled to the Management Fee, if any, which accrues and is payable after such Party becomes Managing Party. If there is a cap on Management Fees specified in the IIA (Section 5.3.(c)), then the Parties shall determine in good faith whether that cap requires equitable adjustment or allocation in the circumstances.

11. General Provisions.

11.1 Assignment. The Parties shall not assign their ownership share or grant any right in their ownership share (e.g., a security interest) in the Joint Invention or the Patent Rights to any third party without the prior written consent of the other Parties. The Agreement may not be assigned by any Party without the prior written consent of the other Parties, which consent shall not be unreasonably withheld. The Agreement binds and inures to the benefit of the Parties and their respective successors and permitted assigns.

11.2 Use of Names; Exception for Managing Party. The Parties may issue a press release concerning the Agreement or any License Agreement, only so long as it is reviewed and approved in writing by the Parties, which approval will not be withheld unreasonably. The Agreement does not confer any right on any Party to use any name, trademark or other designation of any other Party (including any contraction, abbreviation or simulation of a Party's name) in advertising, publicity, or any promotional activities. Notwithstanding the foregoing, the Managing Party may use the name of the Other Parties in connection with pursuing any Patent Rights for the Joint Invention and with respect to entering into and managing any License or Option Agreement for the Joint Invention.

11.3 Jurisdiction. The parties shall make every attempt to amicably resolve any dispute or claim relating to this Agreement. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be the exclusive competence of the Court of Rome.

11.4 Disclaimers. Except as set forth in Section 2, no Party extends any warranties of any kind, either express or implied, including but not limited to the warranties or merchantability or fitness for a particular purpose, with respect to the Joint Invention. In addition, each of the Parties expressly disclaims any warranty that the practice of the Joint Invention will not infringe any patent, copyright, trademark, or other rights of third parties. No Party will make statements, representations, or warranties, or accept liabilities or responsibilities, with respect to or potentially involving the other Party, that are inconsistent with this Section. In no event will a Party be liable to the Other Parties for any indirect, incidental, special, consequential or punitive damages arising out of the Agreement.

11.5 Entirety. The Agreement, together with the Collaboration Agreement (if any), constitutes the entire agreement between the Parties with respect to the Joint Invention. The Agreement supersedes and replaces all prior understandings, negotiations, representations, agreements and commitments related to the Joint Invention. The Agreement may be amended or altered only by a written instrument which is signed by all Parties. In case of contradictions between any provision of this Agreement and similar provisions of the Collaboration Agreement, the provisions of this Agreement shall prevail.

11.6 No Implied Rights. Nothing in the Agreement shall be construed to imply any license rights or other commitments with respect to any future research, or any intellectual property rights, or any Know-How or technology, other than for the express terms set forth in the Agreement relative to the Joint Invention. It is understood that each Party shall be entitled to use the Joint Invention for its internal research purposes (including internal research sponsored by third parties), excluding any kind of direct or indirect commercial exploitation.

11.7 No Waiver. Any delay by a Party to enforce any right under the Agreement shall not act as a waiver of that right, nor as a waiver of the Party's ability to later assert that right relative to any particular factual situation.

11.8 Construction. The headings for the paragraphs for the Agreement have been added for convenience only and shall not be used to construe or alter the meaning of the words in such paragraphs. Each Party has participated in the negotiations and drafting for the Agreement.

11.9 Enforceability. If any provision of the Agreement is found to be unenforceable for any reason, all other provisions of the Agreement shall nevertheless remain in full force and effect, so long as

the essential rights and benefits of the Agreement are realizable.

11.10 Notices. Any notice required by the Agreement shall be given in writing and given by any reasonable means, such as mail, overnight delivery service, telecopy facsimile transmission (with receipt verified), or hand delivery; but not electronic mail transmission. Notices to the Parties shall be given as specified in Section 11.10 of the IIA. A Party may change its address from time to time by delivering written notice of the change of address to the other Parties.

11.11 Compliance with Law. Each Party agrees to comply with all national, state and local laws and regulations which may be applicable to its activities pursuant to the Agreement.

11.12 Governing Law. The Agreement shall be construed and enforced in accordance with [PARTIES SHALL DEFINE THE PREFERRED LAW] laws.

[End of Terms and Conditions]