MATERIAL AND DATA TRANSFER AGREEMENT

between

The Public Law Institution for Healthcare and Scientific Research "ISTITUTO ORTOPEDICO RIZZOLI" (hereinafter referred to as "IOR" or as "Provider"), with registered office in Bologna, Via di Barbiano n.1/10 (CAP. 40136), Tax ID and VAT n. 00302030374, in the person of Legal Representative or its delegate, Dr. xxxx (da inserire dopo delega)

and

the xxx ("xxx" or "Recipient") xxx xxx (*address*), xxx (*city*) xxx in the person of xxxx, born dd/mm/yyyy at xxx

hereafter referred to as the "Parties"

Whereas

RECIPIENT wishes to conduct RESEARCH with ORIGINAL MATERIAL and DATA. PROVIDER is willing to provide ORIGINAL MATERIAL and DATA to RECIPIENT under the terms and conditions as follows hereafter.

The biological material and preanalytical data as described in Annex 1 will be delivered by PROVIDER to RECIPIENT under the terms of this Agreement.

Now, therefore, the parties hereto agree as follows:

Art. 1 - Definitions

PROVIDER: Organization providing the ORIGINAL MATERIAL.

PROVIDER SCIENTISTS: Name: Dr. xxx. Contacts - mail: xxx - phone: xxx

RECIPIENT: Organization receiving the ORIGINAL MATERIAL.

RECIPIENT SCIENTIST: Name: Dr. xxx. Contacts - mail: xxx - phone: xxx

ORIGINAL MATERIAL: Biological material that is to be delivered by PROVIDER to RECIPIENT as described in Annex A.

PROGENY: unmodified descendant material from the original material, such as virus from virus, cell from cell, or organism from organism.

DATA Preanalytical data provided by PROVIDER to RECIPIENT related to ORIGINAL MATERIAL as described in Annex a.

UNMODIFIED DERIVATIVES: substances created by the Recipient which constitute an unmodified functional subunit or product deriving from the Original Material, e.g. sub-clones of unmodified cell lines, purified or fractionated subsets of the Original Material, proteins expressed by DNA/RNA.

MODIFICATIONS: substances created by the Recipient which contain/incorporate the Original Material, e.g. homologous recombination products, cassette exchange products, germ line transmission

products, crosses, new varieties, cell fusions, etc.

RESEARCH, RESEARCH PROJECT, RESEARCH PURPOSE: Research project and experiments with the MATERIAL to be performed by RECIPIENT, as specified in Annex b. Any use will be only for the described research purpose.

RESULTS: Any output of the RESEARCH, which are not PROGENY or UNMODIFIED DERIVATIVES, such as invention, data, software, algorithms, knowledge, know-how or information that is generated in the RESEARCH, whatever its form or nature, whether it can be protected, as well as any rights attached to it, including INTELLECTUAL PROPERTY RIGHTS.

INTELLECTUAL PROPERTY RIGHTS: all intellectual property rights throughout the world, whether existing under statute, at common law or equity, registered or unregistered, now or hereafter in force or recognized including trade secrets and know-how.

COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

NONPROFIT ORGANIZATION(S): Any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

Art. 2 - Purpose

2.1 For the performance of this Agreement, the Provider undertakes to send the MATERIAL as per Annex A to the RECIPIENT, who intends to use it for scientific research purposes for the Project as per Annex B and in accordance with the provisions herein.

2.2 The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

2.3 The RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). lf either 2 (a) or 2 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated.

2.4 The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:

(a) is to be used solely for the RESEARCH PURPOSE;

(b) may not itself be commercialized and is to be used solely by RECIPIENT. The RESEARCH to be

conducted by RECIPIENT is restricted to the RESEARCH PROJECT described in Annex B;
(c) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER; it will only be used in laboratory animals or in vitro experiments;
(d) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision. The RECIPIENT will ensure that RECIPIENT's scientist does not transfer the MATERIAL or MODIFICATIONS to anyone who does not work under his or her direct supervision and responsibility.
(e) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER;
(f) MATERIAL will be stored in a secure location and the remaining MATERIAL shall be returned to Provider upon termination.
2.3 The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision.
Further restrictions on distribution include:
(a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.
(b) Under a separate agreement that is at least as protective of the PROVIDER's rights as this Agreement, the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.
(c) The RECIPIENT will use the Materials solely for its internal non-commercial biomedical research purposes in connection with the Project and must not use them for any products or for the generation of other products or processes for profit-making or commercial purposes.

Art. 3 - Intellectual property rights

3.1 The MATERIAL is not the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights 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 made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.
3.2 If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive

or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

3.3 The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.

Art. 4 - Compliance with law, rules and regulations

4.1 The MATERIAL has been collected and processed by PROVIDER in compliance with GDPR and all applicable laws, at national and European level. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA. If any internal Ethical Authorizations are required by RECIPIENT for the RESEARCH PURPOSE, the RECIPIENT SCIENTISTS shall be required to obtain such Ethical Authorizations. RECIPIENT agrees to comply with all laws applicable to the research, the handling of biological material and data (*SPECIFY if under a judge of adequacy or under specific warranty clauses)*

4.2 RECIPIENT confirms that the RESEARCH PROJECT has been subject to review and approved by the [*Name of Ethical Committee (approval number)]* as further described in Annex b and attach such as REC Opinion.

4.3 The MATERIAL shall be used only (i) under the conditions, if any, specified by PROVIDER, including any conditions specified at the time of collection, as set forth in Annex A and (ii) as provided for by law.

4.4 PROVIDER confirms that a written consent covering the intended use has been signed by the relevant person providing the MATERIAL or by his legal representative. In case such consent is lacking and cannot be obtained, PROVIDER guarantees/requests lawful authorization from the competent Ethical Committee and the Guarantor of Privacy for the use of MATERIAL.

4.4 RECIPIENT agrees to protect MATERIAL against misuse through appropriate organizational and technical measures. Secure MATERIAL access and security shall be guaranteed at all stages of the process.

Art. 5 – Liability, rights & guarantees

5.1 Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER makes no representations and extends no warranties of any kind, either expressed or implied. there are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the MATERIAL will not infringe any patent, copyright, trademark, or other proprietary rights.

5.2 Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable at the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.
5.3 PROVIDER and RECIPIENT ensure to each other that they will protect, in their respective areas of responsibility under applicable law and the present Agreement, the fundamental rights of the person providing the MATERIAL, in particular (i) the protection of privacy, (ii) the right to autonomy and informational self-determination, (iii) the right of access, (iv) the right of portability and (v)the right of withdrawal. If any authorization or advisory opinion will be required, in the course of activities, Recipient Scientist shall commit himself/herself to obtain it and the activities in question can only be started after obtaining this authorization / opinion.

5.4 In case of full or partial withdrawal of consent, the PROVIDER must inform the RECIPIENT of this revocation without delay. A written notification shall be sent to the PROVIDER upon receipt and after completion of the request.

The RESPONSIBLE for the processing of DATA is *xxxxx* and these are its contacts *xxxxx*

5.5 The PROVIDER and RECIPIENT SCIENTISTS assume the responsibilities that the transport takes place with the authorizations and the modalities according to the current regulations.

Art. 6 - Publications and research results

6.1 The most important purpose of biological resources' use is scientific research and RECIPIENT shall publish its RESULTS related to the MATERIAL or MODIFICATIONS. In those cases where only basic data (e.g., age, sex, disease) are requested, the RECIPIENT must clearly acknowledge the source of the MATERIAL in all written publications, posters or oral presentations.

This applies to any publication on MATERIAL or MODIFICATIONS that discloses or relates in any way to RECIPIENT's use of the MATERIAL, unless otherwise agreed in writing by PROVIDER.

RECIPIENT will acknowledge the name of the biobank and/or individual(s) who have collected the MATERIAL in all publications and that any publications directed to the RESEARCH PURPOSE or from use of the MATERIAL. Where proactively involved in biobanking, the RECIPIENT will also acknowledge the name of Patient Organization.

RECIPIENT agrees to submit written publications to PROVIDER in confidence for review and comment no later than thirty (30) days prior to submission for publication. If no objection is made within thirty days stated above, the content is considered approved and the publication is permitted.

6.2 RECIPIENT agrees, in accordance with its established practice, to keep complete and accurate accounts, notes, data and records of the RESEARCH. If the RESEARCH PROJECT does not lead to any publication before the expiration of this contract, RECIPIENT provides PROVIDER with a summary

of any RESULTS obtained.

6.3 Upon completion of the RESEARCH or on PROVIDER's request, RECIPIENT will disclose to PROVIDER all RESULTS obtained from conducting the RESEARCH, which relate to the use of the MATERIAL or MODIFICATIONS. PROVIDER agrees to keep these RESULTS confidential until they are published

Art. 7 - Duration, withdrawal and termination

7.1 This Agreement will terminate an the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, through reagent catalogs or public depositories or (b) a completion of the RECIPIENT's current research with the MATERIAL, or (c) a thirty (30) days written notice by either party to the other, or (d) and the EXPIRATION DATE, if specified in Part I of this Agreement, provided that:

(i) if termination should occur under 7(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then available sources;

and

(ii) if termination should occur under 7(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS;

and

(iii) in the event the PROVIDER terminates this Agreement under 7(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODI FICATIONS.

Art. 8 - Fees and shipping costs

8.1 The RECIPIENT undertakes to meet shipping costs, including any applicable taxes. 8.1 Moreover, the RECIPIENT will pay the fee of (insert the cost) for any unit of sample (Describe the material)… to contribute to the biobanking costs.

Art. 9 - Confidentiality

9.1 Each party undertakes to keep "confidential information" strictly confidential (with this term we mean all information, data or knowledge of a technical-scientific, commercial or financial nature, in any form

expressed and/or on any stored medium, which are were communicated from one Party to another within the context of the relationship covered by this Agreement and because of it, even when not specifically and visibly qualified and regardless of the affixing on them of the wording "confidential" or "confidential" or "secrets") and not to disclose such information to third parties without the prior written consent of the other party for the duration of this agreement and for the following three (3) years.

Art. 10 - Modifications and amendments

10.1 Supplementary agreements, amendments and additions to this Contract shall be in writing.

10.2 If any provision or a part of any provision of this Contract is or shall become invalid, the validity of the remaining provisions shall remain unaffected thereby.

10.3 The Parties shall replace the invalid provision with one that most closely approximates the purposes of the Parties under this Contract.

Art. 11 - Applicable court and competent forum

11.1 Parties agree that any issues related to any matter which is not provided for in this Agreement, shall be preliminary discussed truthfully and in good faith for settlement purposes. In case of dispute this agreement shall be governed by the Italian Law exclusively and legal disputes, either judicial or not, shall be ruled by Bologna Courts or Authorities exclusively.

Art. 12 - Anticorruption rules:

12.1 The Parties undertake to comply with anti-corruption and transparency law rules, (for IOR L. 190/2012 and D. Lgs. 33/2013) and, in any case, to refrain from any behavior that is prohibited by the rules or other applicable regulations against corruption (collectively "Rules against Corruption"). In any case, Parties declare not to have (directly or indirectly) offered, paid, received, or authorised the offer, payment, or acceptance to/from anyone for cash, goods, or any utilities - and commit themselves not to offer, pay, receive, or authorise the offer, payment acceptance to/from anyone for cash, goods, or any utilities, or for performing any other activity - with the aim of improperly or unduly influencing the activity of a public official er any other person in order to obtain an undue advantage. In accordance with Italian law, IOR (PROVIDER) has a "Plan for the prevention of corruption" that can be found at the following link: http://www.ior.it/il-rizzoli/piano-triennalela-prevenzione-della-corruzione-e-della-trasparenza and RECIPIENT declares to be aware of it.

13. Registration expenses:

13.1 This Agreement shall be registered for use and at a fixed rate in accordance with artt.5 and 39 of DPR n. 131/86.

13.2 Expenses related to this Agreement shall be born by PROVIDER (stamps as set in Authorization prat. n. 4351/2018 - Bologna Tax Office)

24. Administrative contacts:

24.1 PROVIDER:

Amministrazione della Ricerca

Address: Via di Barbiano 1/10 - 40134 Bologna,

Phone: +39 0516366740, Email: sars@ior.it, certified mail: ufficio.ricerca@pec.ior.it

RECIPIENT:

xxxx

Address: xxx

Phone: xxx, Email: xxx, certified mail: xxx

24.2 Each person signing this agreement in any capacity is also, by his or her signature, representing that he or she has the authority to bind the party for which he or she is signing

RECIPIENT:

Signature: _____

Name: XXX

Title: XXX

Date: _____

PROVIDER:

Signature: _____

Name: Dr. xxx

Title: Legal Representative o its delegate

Date: _____

Seen and approved

RECIPIENT SCIENTIST:

Signature: _____

Name: XXX

PROVIDER SCIENTIST:

Signature: _____

Name: XXX

PROVIDER SCIENTIFIC DIRECTOR

Signature: _____

Name: XXX

ANNEX A

Description of MATERIAL

ANNEX B

Description of the PROJECT