**Template - Material and associated Data Transfer Agreement**

**Instructions for use**

**Scope of use:**

This Material and associated Data Transfer Agreement template (“Template”) has been set up in conjunction with legal advisors of all the Dutch academic hospitals and serves to facilitate and regulate the transfer of human materials and sharing of associated personal data that were previously collected by a Dutch University hospital (“Provider”) from patients, participants and/or volunteers for the purpose of scientific research by an external not-for-profit party (“Recipient”).

This transfer/access is only permitted for *Recipient’s own* investigator-initiated research (single centre). The role of Provider in this Template is solely as provider of materials and data that are already in its possession. Provider does not (co‑)initiate the research, nor does the Provider participate in the performance of the research. For transfer of materials and associated personal data for the purposes of such a joint research project, a collaborative research agreement or another type of agreement with joint controllership will be the proper document to use. If Provider is asked to actively collect materials and/or data from subjects instead of providing existing material and data, a prospective study agreement may be the proper document to use. For such different documents, please contact your institution’s legal advisors.

For sake of clarity, the Template has been set up with the purpose of facilitating transfer among the scientific community; however, any Provider has no obligation to provide material and/or associate clinical data requested by any Recipient. And while Provider shall seek wide implementation of the Template for the interest of scientific research, it also the case that additional requirements may be imposed in light of: (i) circumstances under which the material and/or data may have been collected and/or (ii) the limitations considered by scientific committees custodian of data and/or material from cohort studies.

The Template and these instructions for use are provided for informational purposes. Please refer to your institution’s legal advisors for further advice and assistance when considering shipping human materials and data at the request of a third party. You may find the contact details of your institution’s legal advisors by using the buttons on page <…> of this ELSI Servicedesk.

**Coded data is personal data under the GDPR**

Since there will have to be a mechanism in place for donors to withdraw their samples from research, it is usual to code the shipped materials and data. Please note that coding personal data, for example by replacing direct identifiers with a number and storing the key in a different location, in itself will **not** result in anonymization under the General Data Protection regulation or GDPR (Dutch: AVG). The person shipping human material and associated data should therefore always assume that he/she is transferring *personal* health data unless the local Data Protection Office(r) has explicitly confirmed that the data qualifies as anonymous data. If the latter is the case, a different document should be used such as a Material transfer agreement for anonymous samples. For such a document, please contact your institution’s legal advisors.

**Legal and ethical preconditions**

The shipment of materials and (associated) personal data is subject to certain laws and regulations, which include for the Materials: ‘the Code of Conduct for responsible Use (2011)’ (in Dutch: ‘Code Goed Gebuik 2011’) and for the accompanying coded personal data: the GDPR. Since that coded personal data was most likely originally obtained for diagnosis or medical treatment, the articles 457, 458 and 467 of the WGBO (‘Beroepsgeheim’) will also apply.

Therefore, as stated in more legal detail in Article 6.2 of the Template, explicit consent from the relevant donor is required, or alternatively –if consent is not present and feasible- a documented assessment has to be made that the provision of samples is legitimate, based on the ground that it serves to enable sound scientific research. In all cases, the Institution’s Material and Data ethics committee should be involved and should approve the shipment. In the event that an institution has not installed a Material and Data ethics committee, that institution will have assigned the responsibility to approve shipments of materials and data to another entity or person within its organisation, whose contact details may be found by using the buttons on page <..> of this ELSI Servicedesk.

**Location of Recipient**

Laws on data protection in countries outside the EU/EEA will provide levels of data protection that differ from the GDPR.

Therefore, if the Recipient is established outside the EU/EEA territory, supplementary contractual safeguards and provisions may be necessary. In such an event please contact your institution’s legal advisors. For a list of EU and EEA countries, please follow: <https://www.netherlandsandyou.nl/documents/frequently-asked-questions/eu-eea-efta-and-schengen-countries>.

**Legal name and signatures**

For the correct legal name of your institution and the names of the authorised people to sign the agreement, please contact your institution’s legal advisors.

**AGREEMENT**

**ON THE TRANSFER OF HUMAN MATERIAL**

**AND ASSOCIATED PERSONAL DATA**

**(for academic research)**

This agreement (hereinafter referred to as “Agreement”) is made and entered by and between:

**<…>**, the Netherlands, legally represented by the undersigned, hereinafter referred to as “Provider”

and

<…>, having its principal office at <…>, <…>, legally represented by the undersigned, hereinafter referred to as “Recipient”.

Provider and Recipient hereinafter also individually referred to as “Party” and together as ‘Parties’.

**Considering that:**

1. Provider has obtained Original Material and Associated Personal Data as described in further detail hereunder;
2. Provider has been requested to provide Recipient with its Original Material for use by Recipient’s Scientist for the purpose of the Recipient’s Research Project as described below;
3. The purpose and means of the Recipient’s Research Project have been determined by Recipient;
4. Provider agrees to provide its Original Material and Associated Personal Data and Recipient agrees to receive those subject to the terms and conditions specified below;
5. Provider furthermore has certain Confidential Information concerning its Original Material as specified hereunder;
6. Such Confidential Information of Provider is considered to be secret and confidential by both Parties and may constitute a valuable commercial asset to Provider;
7. Provider is willing, subject to the terms and conditions hereof, to respectively supply Original Material, Information and Associated Personal Data for no other purpose than the performance of the Research Project, as described below (the “Purpose”).

|  |  |
| --- | --- |
| Recipient's Scientist:  | Provider’s Scientist  |
| *Name: <…>**Address:* *Tel: +**Fax:+**e-mail:*  | *Name: <…>**Address:* *Tel:* *+**Fax:* *+**e-mail:* |

**Article 1. Definitions**

For purposes of this Agreement

* 1. *“Original Material”* shall mean human material, as provided by Provider to Recipient under this Agreement, and as further specified in Annex I to this Agreement.
	2. “*Material*” shall mean: Original Material, Progeny, and Unmodified Derivatives.
	3. “*Progeny*” shall mean unmodified descendant from the Material, such as cell from cell or organism from organism.
	4. “*Unmodified Derivatives*” shall mean substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material. Some examples include: Original Material or unmodified portions thereof fixed as tissue sections or in arrays, and unmodified proteins, RNA, or DNA extracted from the Original Material.
	5. “*Modifications*” shall mean substances created by the Recipient which contain/incorporate the Material but are not Unmodified Derivatives. Some examples include: genetic modifications or manipulation of cells extracted from the Original Material.
	6. “*Associated Personal Data*”: shall mean all coded personal information related to the Material, including clinical and pathological characterization of the Subject, provided by Provider to Recipient or developed by Recipient under this Agreement, as further specified in Annex I to this Agreement. The Associated Personal Data constitutes pseudonymized personal data under the GDPR.
	7. *”Recipient's Research Project”* shall mean the research project specified in Annex II to this Agreement.

1.8 *“Dependent Inventions”* shall mean any and all inventions that are conceived and reduced to practice by Recipient in the conduct of Recipient’s Research Project and that incorporate or claim the Material thereof, irrespective of whether such inventions are patentable or not.

1.9 *“Effective Date”* shall mean the date of the last signature on this Agreement.

1.10 *"Confidential Information"* shall mean all information -not being Associated Personal Data-, know-how, data, grant applications, method of work, techniques, expertise of Provider regarding the Material, its characteristics and Provider’s research concerning the Material, whether of a scientific, technical, engineering, operational, or economic nature, supplied to or obtained by Provider in written form, in the form of drawings or in the recording of oral conversation, or samples.

1.11 “*Unsolicited Findings*” shall mean the new finding that particular Material carries in it information that is considered of immediate importance for the future health of the Subject or its family-members.

1.12 “*GDPR*” shall mean the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation),

1.13 “*Applicable Data Protection Law”* shall mean the GDPR and any additional locally applicable data protection legislation.

1.14 “*Subject(s)*” shall mean the patient or other person who is the donor of the Original Material.

**Article 2. Ownership and use of Material, Confidential Information and Associated Personal Data**

2.1 The Original Material will be transferred to the Recipient, to be used in the Recipient’s Research Project. Recipient shall not acquire ownership rights to the Material under this Agreement. For the avoidance of any doubt, the control (in Dutch: zeggenschap) of the Material remains at all times with the Subject, with the Parties solely acting as a custodian of the Material.

2.2 Recipient shall use the Material, Confidential Information and Associated Personal Data solely for the non-commercial purposes of the Recipient’s Research Project specified in Annex II to this Agreement. All use of the Material, Confidential Information and Associated Personal Data by Recipient in the Recipient’s Research Project shall be under the direction of Recipient 's Scientist, and shall only be carried out by persons working under Recipient 's Scientist's direct supervision.

2.3 Without prior written approval of Provider, Recipient shall not transfer or otherwise make available or accessible the Material, Confidential Information and/or Associated Personal Data to any third party or entity. As an exception to the foregoing, such prior approval shall not be required for service providers who may have access to Associated Personal Data in the context of the standard business operations of Recipient, such as parties who supply ICT infrastructure maintenance. Recipient will safeguard that any data processors who have access to the Associated Personal Data, are instructed by a binding agreement to process the personal data in accordance with the requirements stated in the GDPR.

 [OPTION: Notwithstanding the restrictions on transfer given directly above, Recipient may transfer the Material and/or Associated Personal Data to academic third parties solely for the purpose of replication of the Recipient’s Research Project, in conformance with the data and replication policies of a journal that published the results of Recipient’s Research Project. Such transfers shall only be made by Recipient after the conclusion of a written agreement with terms at least as strict as the terms of this Agreement and without any further right of transfer.]

2.4 Recipient agrees in its use of the Material, Confidential Information and Associated Personal Data to comply with all applicable laws, regulations and guidelines, including any public policy, statutory or common law, or governmental or international regulations.

2.5 The Recipient shall not carry out any procedures with the Associated Personal Data, such as linking, comparison, processing, with which the identity of the Subject could be derived. Unless explicitly agreed under this Agreement as part of the Recipient’s Research Project description in Annex II, the Recipient shall not generate or perform analyses on genetic data. Genetic data for the purposes of this sub clause means: personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from genetic sequencing of a biological sample from the natural person in question.

2.6 In case any of the Subjects makes it known that he/she withdraws his/her permission to perform scientific research with the Material or Associated Personal Data provided by him/her, Provider will inform Recipient of that fact without delay. Provider shall provide sufficient coded information to Recipient, so that Recipient may identify the relevant Material or Associated Personal Data. That Material or Associated Personal Data shall either be destroyed by Recipient without delay with written confirmation of such destruction to be sent to Provider, or be returned to Provider. Recipient shall not retain any copy of the Associated Data and shall not use Material and/or Associated Data for further research or any other purposes.

2.7 The Material and Associated Data will be provided at no cost or with an optional transmittal fee solely to reimburse Provider for the collection, storage, preparation and/or shipment. If a fee is requested, the amount will be indicated here: <…>. Recipient will pay the transmittal fee within forty five (45) days from the date of receipt of a valid invoice thereto. Payment will be made to a bank account in the name of the Provider, as set out in the invoice.

2.8 Recipient will report any Unsolicited Findings to Provider.

**Article 3. Unmodified Derivatives, Modifications, Improvements, Inventions and Patents.**

3.1 Recipient shall be free to produce Unmodified Derivatives or develop Modifications only as part of, and only for the purposes of the Recipient’s Research Project specified in Annex II to this Agreement. The use of Unmodified Derivatives and Modifications by Recipient shall be subject to the same terms and conditions as specified in Article 2 of this Agreement.

3.2 Recipient shall inform Provider forthwith of any Modifications created by Recipient, and shall give Provider all relevant details concerning the said Modifications, which Provider shall treat as Confidential Information.

3.3 Recipient shall be the owner of the Modifications to the extent developed by Recipient but as stated above in Article 2.1, Recipient shall not obtain ownership rights on the Material that is contained in Modifications. Recipient shall not unreasonably refuse to make available to Provider a quantity of any Modifications for research purposes upon request.

3.4 Ownership of inventions shall follow inventorship. Where ownership of any inventions vests in Recipient, Provider shall have a perpetual nonexclusive royalty free license to use such inventions for its internal research and teaching purposes. In case of joint inventions, Recipient and Provider shall in good faith negotiate the terms of a separate agreement pertaining to the management of intellectual property and commercialization of such joint inventions. Until such agreement is effective, each Party shall be entitled to use the joint invention for research purposes, but neither Party shall be entitled to exploit, disclose, license or transfer its rights in connection with the joint invention.

3.5 When any Dependent Inventions are made by Recipient, Recipient and Provider shall in good faith negotiate the terms of a separate agreement pertaining to a reasonable share for Provider of the revenues obtained by Recipient from the commercialization of such Dependent Inventions.

**Article 4. Confidentiality and the protection of Associated Personal Data.**

4.1 Recipient shall treat all Confidential Information as confidential for the duration of this Agreement including any extension thereof and thereafter for a period of five (5) years following termination or expiry of this Agreement.

4.2 Excluded from the obligation of confidentiality contained in 4.1 above, shall be any Confidential Information of which the Recipient can reasonably demonstrate that it (a) was previously known to Recipient, or (b) is, and/or becomes, publicly available through no fault of Recipient, or (c) is independently and lawfully developed by the Recipient, or (d) was published or otherwise disseminated in accordance with the publication procedure set out below in article 5. However, the foregoing exceptions shall not apply to: (a) Confidential Information contained within more general information that may fall within one or more of the exceptions, or (b) any combination of features or items of Confidential Information where one or more of the relevant individual features or items (but not the combination itself) may fall within one or more of the exceptions.

4.3 The obligations of confidentiality contained in 4.1 above shall not apply to any disclosure required by law, provided that Recipient shall notify Provider of any disclosure required by law in sufficient time so that Provider may contest such requirement, if Provider so chooses.

4.5 Handling of Associated Personal Data

1. Associated Personal Data shall be provided by Provider in a sufficiently secure manner and Parties shall handle all Associated Personal Data in accordance with the Applicable Data Protection Law and shall keep such Associated Personal Data confidential without any of the exclusions contained in Article 4.2 above.
2. With respect to the Associated Personal Data, Recipient shall be considered to be a separate data controller under the Applicable Data Protection Law for the processing of the Associated Personal Data for Recipient’s Research Project.
3. Recipient shall implement appropriate technical and organizational measures to meet the requirements for data controllers of the Applicable Data Protection Law.
4. If Recipient becomes aware of a personal data breach, Recipient shall promptly notify Provider. In such a case Parties will fully cooperate with each other to remedy the personal data breach, fulfill the statutory notification obligations timely and cure any damages. The term ‘personal data breach’ refers to articles 33 and 34 of the GDPR.
5. In the event that a person from whom Associated Personal Data was obtained, withdraws his/her permission for the use thereof, Parties shall follow the procedures set out in 2.7 above.
6. Each Party’s shall add the contact details for inquiries regarding handling and protection of Associated Personal Data to Article 9.3 below.

**Article 5. Publication and acknowledgement.**

5.1 Parties acknowledge the importance of disseminating the results of the Recipient’s Research Project. Therefore, Recipient shall endeavor to publish or otherwise publicly disclose information, any data, results or information generated using the Material and Associated Personal Data (“Disclosures”), after review by Provider. The following shall apply to Disclosures:

1. Authorship of any publications shall follow the principles set out in the ICMJE recommendations ‘Defining the Role of Authors and Contributors’ as can be found on <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>.
2. At least thirty (30) days before Recipient submits a paper or abstract for Disclosure, Recipient shall provide such paper or abstract to Provider, who will have thirty (30) days to review proposed manuscripts and fifteen (15) days to review proposed paper or abstract to assure that its Confidential Information is protected. It is agreed that Recipient will fully comply with any reasonable written request by Provider to omit specified Confidential Information of Provider from such paper, abstract, press release or other disclosure prior to Disclosure.
3. In every Disclosure by Recipient based upon results obtained from the research through the use of the Original Material, Associated Personal Data and/or other contributions provided by Provider, Recipient shall acknowledge Provider’s scientists as contributor of the Material and the Associated Personal Data.

**Article 6. Representations and Liability**

6.1 Recipient acknowledges that any Original Material and Associated Personal Data delivered to it under this Agreement is experimental in nature. Other than those contained in this Agreement, Provider makes no representations nor extends any warranties of any kind, with respect to its Material, Confidential Information and Associated Personal Data. There are no express or implied warranties of merchantability or fitness for a particular purpose, nor does Provider represent that the Material, Confidential Information and Associated Personal Data and/or any use thereof will not infringe any patent, copyright, trade secret, trademark or other rights of third parties.

6.2 Regarding the Original Material, Provider warrants that a) it was collected from Subjects who were appropriately informed and who either explicitly consented to the use of their Material for scientific research or did not object, after having been given the opportunity to do so and b) that it shall be provided under approval from the relevant ethics committee –to the extent required-, all in accordance with locally applicable laws and regulations. Regarding the Associated Personal Data, Provider warrants a) that it has verified that there is an appropriate legal ground for the provision of the Associated Personal Data to Recipient in accordance with the Applicable Data Protection Law, such as Article 6 and/or 5.1 sub b GDPR b) that there is a valid exception to the prohibition for processing personal health data (Article 9 GDPR) and c) that it shall be provided under approval from the relevant ethics committee –to the extent required-.

6.3 The Recipient acknowledges that the Material is experimental in nature and may have hazardous properties and is supplied on an “as is” basis; to the extent allowed by law, Recipient assumes all liability for damages which may arise from use, storage, transport or disposal of the Material, except for damages that are caused by gross negligence or willful misconduct of Provider.

6.4 In regards to the Associated Personal Data and personal data breaches, Recipient shall be responsible and liable for any damages, losses and fines resulting from its own actions or failures to adhere to the terms of this Agreement and Applicable Data Protection Law and Recipient shall indemnify and hold harmless Provider for any of such damages. For the purposes of this sub clause, actions or omissions of data processors contracted by Recipient, shall be attributed to Recipient.

**Article 7. Duration and Termination**

7.1 This Agreement shall become effective on the Effective Date and will terminate […] years thereafter.

7.2 If Recipient or Provider wishes to extend the duration of this Agreement, it shall request the other Party in writing for such an extension.

7.3 It is understood that any extension of the duration of this Agreement pursuant to Article 7.2 shall not be unreasonably withheld by one of the Parties, other than for reasons of non-performance of any part of this Agreement by the other Party; for reasons of non-use of the Material by the other Party; and/or for reasons involving commercial considerations, including but not limited to the granting by one of the Parties to any third party of any royalty-bearing exclusive license relating to the Materials and/or being under any patents, patent applications and/or other property rights covering the Material.

7.4 Upon termination of this Agreement, Recipient shall immediately discontinue its use of the Material and any and all Modifications, Confidential Information provided by Provider, Associated Personal Data; and shall also, upon the written request of Provider, return to Provider or destroy any remaining Material as well as any and all Modifications, any Confidential Information provided by Provider and Associated Personal Data.

[OPTION: However, Recipient may retain one copy of Material and any and all Modifications and Associated Personal Data solely to comply with transfer requests that third party academic institutions may make for replication of the Recipient’s research Project, as described in Article 2.3 above.] If any Material and/or Modifications, Confidential Information provided by Provider or Associated Personal Data are destroyed by Recipient pursuant to this Article 7.4, Recipient shall, upon the written request of the other Party, provide Provider with confirmation thereof in writing.

**Article 8. Survival**

8.1 Articles 3.4, 3.5, 4, 5, 6, 7.4 and any such other provisions of this Agreement which shall be expected or intended by its nature to survive the termination or the expiration of this Agreement, shall survive the termination or the expiration of this Agreement.

**Article 9. Miscellaneous.**

9.1. This Agreement will be construed, governed, interpreted and enforced according to the laws of the Netherlands. Parties will first strive to settle any disputes amicably before taking legal action. All disputes arising out of or in relation to this Agreement that cannot be settled amicably will be brought before the competent court in the Netherlands, in the district in which the Provider resides.

9.2 Except as expressly provided under this Agreement, no rights or licenses are granted or provided to Recipient with respect to the Material, with respect to any information pertaining to the Material, and/or under any patents, patent applications, trade secrets or other proprietary rights of Provider.

9.3 Any notice or communication required or permitted to be given by any Party hereunder will be deemed sufficiently given if mailed by certified mail, return receipt requested, and addressed to the party to whom notice is given as follows:

If to Recipient, to:

*Name:*

*Address:*

*Tel: +*

*Fax: +*

*e-mail:*

If to the Provider, to:

*Name:*

*Address:*

*e-mail:*

The Parties’ contact details for inquiries regarding handling and protection of Associated Personal Data are as follows:

For Recipient, to:

*Name:*

*Address:*

*Tel: +*

*Fax: +*

*e-mail:*

For Provider, to:

*Name:*

*Address:*

*e-mail:*

9.4 This Agreement will be binding upon and inure to the benefit of the respective successors and assignees of the Parties hereto. However, Parties may not assign this Agreement in whole or in part without the prior written consent of the other Party.

9.5 This Agreement may only be altered or amended by an instrument in writing signed by both of the Parties.

9.6 If any portion of this Agreement is in violation of any applicable law, or is unenforceable or void for any reason whatsoever, such portion will be inoperative and the remainder of this Agreement will be binding upon the Parties.

9.7 If the lawful performance of any part of this Agreement by a Party is rendered impossible by or as a result of any cause beyond such Party's reasonable control, such Party will not be considered in breach hereof as a result of failing so to perform.

**IN WITNESS WHEREOF**, the parties have executed this Agreement, in duplicate originals or as a signed PDF, as of the Effective Date.

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| --- | --- |
| **For Provider**By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name: Title:Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name: Title:Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **READ AND ACKNOWLEDGED:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Provider’s Scientist**Attachments:** * **ANNEX I**
* **ANNEX II**
 | **For Recipient**By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name: Title:Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name: Title:Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **READ AND ACKNOWLEDGED:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Recipient’s Scientist |

**ANNEX I** Description of the Material and the Associated Personal Data, methods of transfer and storage, allowed processors

**MATERIAL:**

<…>

**ASSOCIATED PERSONAL DATA:**

|  |  |
| --- | --- |
| **Data subjects**The personal data transferred concern the following categories of data subjects: |  |
| **Purpose of the transfer(s)**The transfer is made for the following purpose: | See Annex II |
| **Categories of data**The personal data transferred concern the following categories (types) of data: | NB: All health information qualifies as sensitive data as meant in the field below |
| **Sensitive data** (if appropriate)e.g.: •racial or ethnic origin,•political opinions,•religious or philosophical beliefs,•trade union membership,•genetic data, biometric data,•health data,•sex life and sexual orientation |  |
|  **Method of transfer**e.g.: Soft- or hardware encrypted USB drive, database entry such as in Castor, etc.  |  |
| **Method of data storage and security measures (e.g. method of encoding)** |  |
| **Authorized processors, if applicable, as indicated in clause 2.3 of the Agreement** |  |

**ANNEX II** Recipient’s Research Project

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