Instituts thématiques

Inserm

Institut national
de la santé et de la recherche médicale

CHARTER FOR DATA ACCESS
MEDIT-AGEING PROJECT (C16-38 AND C16-61)

VERSION N°1.0 DU 30/06/2020

The charter and the SRP form can be download from the MEDIT-AGEING Project website (www.silversantestudy.eu).

TABLE OF APPROVALS			
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SOMMAIRE

PREAMBLE

The European MEDIT-AGEING project, involving 6 European countries and funded by the European Commission (program H2020-PHC22), is based on the increasingly documented concept of a negative effect of stress on mental and physical health, particularly the elderly. Following the recommendations of the European Commission, the project is organized into work packages (WP) which correspond to working groups with specific tasks around a specific theme. The governance of this project is based on its executive committee (ExCom) made up of the coordinator, the management team and those responsible for scientific WP and is in charge of monitoring the project and validating strategic choices, but also on the general assembly of the European MEDIT-AGEING consortium.

The main objectives of the MEDIT-AGEING project are to improve the understanding and early diagnosis of Alzheimer's Disease (AD), gain insights on the impact of lifestyle factors, and to assess comprehensively the effects and mechanisms of action of meditation training on mental health and wellbeing in older people, including on AD risks and highlighting sex and gender specificities.

This document describes the policy for Data access of AGE-WELL and SCD-WELL studies of the MEDIT-AGEING project for which Institut national de la santé et de la recherche médicale (Inserm) is the sponsor.

All groups participating in the H2020 MEDIT-AGEING project must therefore comply with the present policy before any access using AGE-WELL or SCD-WELL trials data.
This includes the following academic partners from the Medit-Ageing Consortium:

- Institut national de la santé et de la recherche médicale (Inserm)
- Université de Liège (ULG),
- University College of London (UCL),
- Klinikum Der Universitaet Zu Koeln (UKK),
- Hospices civils de Lyon (HCL),
- Consorci institu d'investigations biomediques august pi y sunyer (IDIBAPS),
- Université de Genève (UNIGE)
- University of Exeter (UNEXE)

This document is also applicable for any scientific team which requires a Data access of AGE-WELL and SCD-WELL studies.

This document is approved by the Executive Committee (ExCom) of MEDIT-AGEING project.

It is recalled by the ExCom, no biological transfer is planned. The present charter is focused on Data access.

CONTACTS

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DEFINITIONS

In this document, the terms beginning with a capital letter shall have the meaning defined below:

Academic	Refers to legal persons under public law having a research mission as well as legal persons under private law having a research mission and not primarily engaged in industrial and commercial activity.
Administrative Manager of the SRP or AMSRP	Designates the legal person responsible for the SRP, in particular in charge of formalities with the Authorities in accordance with the regulations in force. In the event of a SRP involving several legal persons, the latter must designate among them the Administrative Manager of the SRP; the concept of AMSRP includes, for the purposes of this Charter, also all of these legal persons.
Authorization	Refers to (1) all of the opinions and authorizations issued by the Competent Authority prior in particular to carrying out the SRP and for which the acquisition is necessary for the implementation of the SRP, as well as (2) the declarations and more generally the whole formalities to be carried out before the implementation of the Project or a part of the Project.
Competent Autority	Refers, but is not limited to, all of the agencies, departments and ministries with which formalities must be completed prior to the completion of the SRP in accordance with the laws and regulations in force, in particular in order to obtain authorization. In France, the competent authorities may be in particular, depending on the legal qualification of the SRP, the National Agency for the Safety of Medicines (ANSM), the Personal Protection Committee (CPP) and the National Commission for Information Technology and Freedoms (CNIL).
Confidential Information	Refers to all information and / or data in any form and of whatever nature, including in particular any written or printed documents, any samples, models and / or knowledge which is patentable or not disclosed by a Party to one or more other Parties to the title of the Agreement. Own Knowledge and Results are considered Confidential Information.
Consortium Agreement	Means the agreement concluded between Inserm, ULG, UNIGE, UCL, UKK, HCL, IDIBAPS, ECRIN, Inserm Transfert and Minerva.
Counter / Referent	Means the counter in which a referent will be chosen to be in charge of presenting the applicant's file before the ExCom and of interacting in a privileged manner with the latter.
Data	**Data**: Refers to the data collected by the Sponsor or under the responsibility of the Sponsor within the framework of the Project or prior to the Project and necessary for it. This Data may be personal data within the meaning of Law No. 78-17. Data is excluded from the concept of Results. Derived Data are also considered as Data, i.e. data derived from biological analysis (including genetic analysis) or imagery analysis. A distinction is made between Data, Accessible Data and Mobilizable Data. **Accessible Data**: Designate a category of Data which may be directly accessible within the framework of SRP. Accessible Data does not constitute personal data within the meaning of Law No. 78-17, as amended.

	This Accessible Data is Aggregated Data or, subject to the aforementioned reservation, Individual Data or Derived Data. The recipient of such Accessible Data undertakes not to seek, by any means whatsoever and in particular by cross-checking the database, the identity of the person from whom the Data has been collected. **Raw Data**: Designate a category of Data consisting of raw data from the Project which can be mobilized within the framework of SRP, within the meaning of Law No. 78-17, as amended.
Material	Means the Data, as well as the copies of the SRP Data integrated into the MEDIT-AGEING Database.
MEDIT-AGEING Project	Refers to the MEDIT-AGEING project composed of two projects: AGE-WELL (C16-38) and SCD-WELL (C16-61).
Partner establishments	Means in particular a clinical investigation center, a research unit, a service, without legal personality, placed under the supervision of one or more Parties and, where applicable, third parties to this agreement, also designated by "Partner establishments", in charge of carrying out part of the project.
Specific Agreement	Means the agreement drawn up and signed by Inserm or its agent for the needs of the SRP specifying in particular the methods of mobilizing the Equipment within the framework of a SRP.
Sponsor	Designates the legal person ensuring the role of a sponsor, within the meaning of article L1121-1 of the public health code. The Project Sponsor is Inserm.
SRP	Means the specific research project requiring in particular the mobilization of Data from MEDIT-AGEING Project, and which must be submitted for authorization to the competent committees set up by the Consortium Agreement and this Charter.
SRP carrier	Designates the physical person and main contact with scientific responsibility for the SRP.
SRP protocol	Refers to the document describing the objectives, design, methodology, statistical aspects and organization of the SRP. The term covers successive versions of the protocol as well as its modifications.
Results	**Results**: Means any new result obtained, in application of the Statistical Analysis Plan by one or more Parties during the implementation of the Project of any kind and in any form whatsoever, in particular knowledge, experience, know-how, patent, method, tool design, process, specific component, software, whether or not it is protected or protectable by a right and / or an intellectual property title, with the exception of improvements in Own Knowledge, Data. Data, Raw Data, Accessible Data, and Derived Data do not constitute Results. **SRP results:** Means any new result obtained by the AMSRP during the realization of the SRP of any kind and in any form whatsoever, in particular knowledge, experience, know-how, patent, method, tool design, process, specific component, software, whether or not it is protected or protectable by a right and / or an intellectual property title, to the exclusion of SRP Data.

1. GENERAL PROVISIONS

1.1. General principles

The Material can be mobilized, under the conditions and modalities defined in the Charter, by any research team belonging to an Academic signatory to the Consortium Agreement concluded for the needs of the Project or by any research team belonging to an Academic outside the Consortium Agreement, French or foreign, for carrying out SRP relating to the scientific theme of mental health and wellbeing in older people.
The Material may also be mobilized, by non-academic third parties for the realization of SRP relating to the scientific theme of mental health and wellbeing in older people, under conditions, in particular financial, which will be established by separate agreement between Inserm and by the said third party.

The Mobilisable Data cannot be subject to any transfer or authorization of direct access. The Mobilisable Data is subject for the purposes of a SRP to processing carried out by INSERM, or under the responsibility of INSERM through a service provider, the result of which is communicated to the AMSRP or SRPC.

The mobilization of the Material provided for in the first paragraph of this article is done only within the framework of SRP.

There are 2 types of SRP:

1. SRP involving Material (without further investigation).

In this case, the SRP may involve Data from a part of the MEDIT-AGEING database

2. SRP requiring additional collection, from human persons included in the MEDIT-AGEING Project, of data for the needs of the SRP constituting SRP Data.

The AMSRP can be Inserm or another academic. In addition, the MEDIT-AGEING Project Results may be used, under the conditions and modalities defined in this Charter, for the benefit of any research team belonging to an Academic signatory of the Consortium Agreement for the needs of a SRP under the scientific thematic of mental health and wellbeing in older people, carried out alone by the Academic concerned or in collaboration with third parties, excluding industrial third parties, with the exception of SRP conferring a right of exploitation on the Results of the Project to the third party.

1.2. Details related to the administrative organization of the MEDIT-AGEING Project

1.2.1. The signatories of the Consortium Agreement

The MEDIT-AGEING project is the subject of a Consortium Agreement involving Inserm, ULG, UNIGE, UCL, UKK, HCL, IDIBAPS, ECRIN, Inserm Transfert Minerva and UNEXE.

1.2.2. The Executive Committee (ExCom)

- to propose this Charter aiming to define the conditions and modalities for data access for the needs of SRP;
- to assist in the examination of SRP requests, according to the procedure defined in the Charter;
- to assess the scientific and methodological relevance of the SRP requests;
- to validate this Charter;
- to select the SRP after examination.

2. Funding

It is specified that the provisional budget of the MEDIT-AGEING Project is dedicated to the collection of Data according to the AGE-WELL (C16-38) and SCD-WELL (C16-61) protocols.

The cost linked to a SRP is not covered by the Project budget.

The AMSRP and the SRPC must, before any mobilization of Data for a SRP, guarantee that they have the necessary funding to pay the cost related to the mobilization of the Equipment and the realization of the SRP.

As part of SRP requests to the Executive Committee, the terms and conditions of SRP funding and in particular the case of industrial funding of a SRP carried by an academic partner, must be brought to the attention of the Executive Committee.

3. Modalities of mobilizing Data of the MEDIT-AGEING Project

The SRP request assessment flowchart is described in the appendix entitled « SRP request assessment flowchart » and repeats all of the steps described below.

3.1.1. Submission schedule

The submission schedule is available on the website (www.silversantestudy.eu).

The form to complete can be download or fill directly on the website with an explanatory notice of the procedure for the applicant to follow (i.e. SRP request assessment flowchart). Once completed, this form is sent directly to the appropriate referent (designated by the applicant by checking the appropriate box on the form).

3.1.2. Preparation of a SRP request file

Any SRPC who wishes to submit a SRP request can request the ExCom to obtain the following information:

- specific information (quantity of Data available on a given date, number of patients included in the Cohort meeting the specific selection criteria for SRP requests, etc.) necessary for the conception of the SRP request;

- the price list for the mobilization of Data within the framework of the SRP. The price modality will be discussed on a case-by-case basis in ExCom based on the elements presented by the referent;

- the list of services likely to be performed by the signatories of the Consortium Agreement for the purposes of the SRP request, as well as the associated price list;

- a quote for services not included in the price list.

The request for access to this information will be precisely described and justified and addressed to the ExCom. It will be studied by the ExCom on a case-by-case basis.

Any request sent to the ExCom is answered **within sixty (60) days**. Repetitive or deemed abusive requests will be denied.

The information communicated via the ExCom must be considered by the SRPC and the AMSRP as confidential information; they constitute a descriptive statement of the progress of the MEDIT-AGEING Project on a specific date. They are communicated in order to allow the SRPC to prepare the said request. Any other use is prohibited and all of this information must be destroyed as soon as possible in the event that the SRPC renounces the filing of the said request or that the said request was not accepted.

Contact for the ExCom: poisnel@cyceron.fr

3.1.3. *Contents of the SRP application form*

The list of necessary documents and the forms to be provided will be kept up to date on the website dedicated to the Project (www.silversantestudy.eu).

A request for all of this information will be possible by email (poisnel@cyceron.fr) if the website is unavailable.

3.1.4. *Submission of the complete SRP request file by the SRPC (before M0)*

The complete file model is available on the website (www.silversantestudy.eu).

The ExCom recommends that the SRPC submits the complete file in a period of **sixty (60) days** even there is not limited period to complete the file.

Regarding the letter of intent, it must be completed via the website dedicated to the MEDIT-AGEING Project. The 1st version of the letter of intent form is appended to this charter (SRP request submission form) and may be used in the event of the unavailability of the website dedicated to the Project. This letter had to be submitted with the other requested files to the ExCom on the website or at the following address: poisnel@cyceron.fr.

An email confirming receipt of the SRP draft of the complete file will be sent by the ExCom to the SRPC.

3.1.5. *Assessment of the complete SRP project file (M0 to M2)*

The ExCom has a period of **sixty (60) days** from the deadline for sending the complete SRP request file by the SRPC (schedule indicated on the website dedicated to MEDIT-AGEING Project) to examine the admissibility and feasibility of the request:

• By checking the completeness of the elements to appear in the request,
• By assessing the relevance and methodological admissibility (feasibility, operational methods and consistency with the project),
• By examining the possible regulatory admissibility without commitment of the Authorizations to be obtained,
• By identifying any redundancies or overlap between the different requests for SRP expressed in the letters of intent or in progress and also on the analysis the MEDIT-AGEING project team had planned to do;
• By verifying that the budgetary elements have been transmitted.

During this period, the ExCom may request any additional information or any document it deems necessary from the SRPC, specifying the response times. In the absence of an answer or an answer after the deadline, the file will be considered inadmissible.

For each SRP which have been judged admissible, besides the referent chose by the applicant during the submission, the ExCom may enlist, in an advisory capacity, the skills of any third party whose expertise appears necessary for assessment by the referent.

The referent sends his report to the Coordinator of the ExCom (Gaël Chételat) who summarizes the responses and prepares the meeting of the ExCom. For the examination of the complete file, the ExCom meets validly by physical meeting or, subject to the possibility of ascertaining the identity of the interlocutors, by videoconference or teleconference. Likewise, the ExCom may validly consult by e-mail; for this purpose, the principles mentioned in decree n ° 2014-1627 of December 26, 2014 relating to the methods of organizing remote deliberations of administrative bodies of a collegial nature are applied.

The ExCom ensures the scientific and methodological relevance of the request for SRP on the basis of the following evaluation criteria:

• Scientific and technical quality of the project

• Methodology

• Ethical dimension

The Coordinator of the ExCom will prepare a summary of the assessments and recommendations made by the members of the ExCom for each SRP request submitted.

The final decision is taken by the ExCom unanimously by the members present or represented. It is specified that INSERM, in charge of collecting and / or managing Data mobilized for a SRP, has a veto right to the use of data in the context of a SRP. This veto right must be justified and motivated in particular by technical and regulatory issues (embargo period, non-compliance with regulations, non-compliance with the will of human persons, etc.).

At the end of this 60-days period, the ExCom has **thirty (30) days** to formulate the summary and the recommendations.

3.1.6. Formalization of the decision (M3)

The decision of the ExCom is notified in writing (email and / or mail) to the SRPC by the Coordinator of the ExCom within one month of the meeting. The decision will contain technical, scientific and methodological comments.

It is specified that the refusal of a request for SRP does not prevent the HPRC from presenting a new request for SRP after integration of the recommendations formulated by the ExCom.

In case of approval of the SRP request, contractualisation aspects and the timeframe of the data availability are discussed. After the fulfillment of the goal described in the SRPC request, a certificate of data destruction must be sent by the SRPC to the ExCom.

3.1.7. Additional terms payable by AMSRP

Before the establishment of the SRP, the AMSRP undertakes to:

- make sure you have funding for the realization of the SRP and inform the ExCom

- ensure that you have the regulatory authorizations necessary to carry out the SRP and inform the ExCom.

4. CONDITIONS OF THE IMPLEMENTATION OF THE MATERIAL

4.1. Regulatory and legal terms

The AMSRP can be INSERM or another research organization, as the case may be.

4.1.1. Regulatory terms

The regulatory procedures are ensured by the AMSRP.

Regulatory formalities must be completed with the Competent Authorities before carrying out a SRP, in accordance with the laws and regulations in force.

The SRP can only be set up after obtaining the Authorizations.

In the event that the AMSRP is not INSERM, the SRPC must first transmit the authorizations obtained to the ExCom, and may thus have access to the equipment of the MEDIT-AGEING Project.

As a reminder, the SRP submission form must specify all the regulatory provisions taken, and if necessary provide the deadline for regulatory procedures before any SRP Data and are collected.

4.1.2. Legal terms

A specific agreement will be signed between INSERM and the AMSRP.

4.2. Procedures for carrying out and monitoring the SRP and associated analyzes

4.2.1. In case of exceeding the planned schedule, adding analyzes

It is recalled that the AMSRP undertakes to carry out the analyzes on the Material in accordance with the SRP validated by the ExCom. Any other analysis that was not initially planned must be validated by the ExCom of MEDIT-AGEING Project.

In the event of a modification of the SRP, the SRPC informs the referent before any implementation of the modification of the SRP.

The ExCom will receive the modified SRP and will decide on the follow-up to be given to this modification, specifying if necessary a timetable for examining the modification by the Competent Authorities. In the event of a substantial change, the SRPC will be invited to file a new request for SRP.

4.3. Conditions and duration of use of the Material

Limit of use

When the SRP is associated with a transfer of Material, the AMSRP which benefits from it (the "Recipient Party"), undertakes that all or part of the Material transmitted by or under the responsibility of INSERM ("Issuing Party"):

• Be used only for the purposes of conducting the SRP, to the exclusion of any other application, in particular commercial;

• Is not distributed to a third party for any purpose whatsoever, this restriction does not, however, prohibit the transmission of the Material to a third party as part of a service performed by the third party and provided that this is identified. in the SRP submission file and that the contract which binds it with the Beneficiary Party contains clauses in accordance with the provisions of the Charter;

• Be used in accordance with the laws and regulations applicable to this type of Material, and;

• Either used exclusively on the premises of the Receiving Party and by scientists working on the premises of the Receiving Party or under its direct responsibility.

The Recipient Party recognizes that the Material is a research tool provided "as is", without warranty of any kind, express or implied, in particular as to the possibility of using it for a given purpose. The Issuing Party will communicate to the Receiving Party all the information at its disposal relating to the storage and use of the Material.

In the event of termination of the Specific Agreement, upon its expiration or at the request of the Transmitting Party, the Receiving Party must cease all use of the Transferred Material still in its possession and must return or destroy it on the instructions of the Emitting Party and shall justify this destruction in writing.

A template of Data Transfer Agreement is attached in appendix.

5. RESPONSABILITIES - Guarantees

5.1. INSERM Responsability

Inserm guarantees that all the Data mobilized for a SRP are collected in accordance with the regulations in force.

6. INTELLECTUAL PROPERTIES AND EXPLOITATION

6.1. SRP requiring the use of the Material and/or a complementary collection

6.1.1. Data, MEDIT-AGEING Database

Furthermore, it is recalled that, within the meaning of article L 341-1 of the Intellectual Property Code, the producer of a database is understood as the person who takes the initiative and the risk of the corresponding investments. As such, said producer benefits from the protection of the content of the database defined by the Intellectual Property Code. This protection is independent and is exercised without prejudice to those resulting from copyright or another right in the database or one of its constituent elements. Inserm is producer of the MEDIT-AGEING Database and owner of this MEDIT-AGEING Database and of the Data and copy of the SRP Data which will be incorporated therein.

6.1.2. SRP Data, SRP Database

6.1.2.1. Property

The SRP Database and the SRP Data gathered therein are the property of AMSRP.

It is recalled that the SRP Database and/or are created for research purposes.

For clarification and notwithstanding any provision to the contrary in the Charter, it is recalled that the Material, the MEDIT-AGEING Database is the property and/or are the responsibility of Inserm. In the event of termination of the Specific Agreement, upon its expiry or at the simple request of Inserm, the Material, whether or not it has been integrated for the needs of the SRP into the SRP Database must be returned to Inserm or destroyed in accordance with the provisions of article 4.3 of this Charter.

6.1.2.2. Use and Exploitation

Subject to the provisions of this article, the AMSRP is free to use and exploit, directly or indirectly, its SRP Data and the SRP Database which bring them together, as it sees fit.
When the SRP involves the collection of SRP Data, after the freezing of the SRP Database unless otherwise stipulated in the Specific Agreement, the AMSRP undertakes, after agreement from Inserm, to transfer a copy of the SRP Data to the MEDIT-AGEING Database. The said copies of SRP Data thus extracted and integrated into the MEDIT-AGEING Database will be at the responsability of Inserm, Project Sponsor, and may be made available by Inserm and the governance bodies of the Project for the purposes of research, alone or in collaboration with third parties, within the framework of SRP following the procedure described in this Charter, or in separate agreements in the case of non-academic third parties. To this end, the AMSRP will cede to Inserm the ownership of the copies of the SRP Data considered and any related intellectual property rights, and undertakes not to assert any rights of producer of the SRP Database for annihilate these rights. It will be up to AMSRP to take all measures, and in particular to put in place the relevant information and consent documents and to obtain the Authorizations necessary to allow this use for the purpose of searching for copies of SRP Data. It is understood that this use will not give rise to any financial payment or any right in favor of AMSRP in return for the provision by Inserm of copies of SRP Data from its SRP.
The AMSRP and the SRPC benefit from an exclusive period of use of the copies of the SRP Data integrated into the MEDIT-AGEING Database for academic research purposes within the framework of a HPR which, unless otherwise agreed by the AMSRP and Inserm, is one (1) year from the date of collection of the last SRP Data. At the end of this period of one year, and unless otherwise agreed by the AMSRP and INSERM, this period of exclusivity will end and Inserm may freely make available the copies of the SRP Data integrated into the Database for research purposes.

Unless otherwise stipulated in the specific agreements, the following guarantees apply:

The AMSRP guarantees that all SRP Data transferred to Inserm have been collected in accordance with the laws / regulations and that the expression of the will of the people from whom the SRP Data are taken allows Inserm to use the SRP Data for scientific purposes within the framework of SRP.

Inserm guarantees the AMSRP, including its directors and its staff of the said Party, against any recourse, formed by the persons sampled or their dependents, which would be based on the non-compliance by Inserm of the laws and regulations in or the provisions of the Specific Agreement regarding the terms of use of the SRP Data.

The AMSRP may call Inserm as a guarantee in the event of an action brought against the AMSRP, including its managers and staff, due to the non-compliance by the AMSRP of its obligations.

The AMSRP guarantees Inserm , including its managers and its staff, against any recourse, formed by the persons sampled or their dependents, which would be based on the non-compliance by the AMSRP of the laws and regulations in force, of the stipulations of the Charter or the provisions of the Specific Agreement, in particular with regard to the procedures for collecting and SRP Data, the procedures for informing the persons sampled and for collecting the expression of their wishes for the use of this SRP Data as these terms are defined in the Specific Agreement. Inserm may call the AMSRP as a guarantee in the event of a recourse brought against Inserm, including its managers and staff, due to the non-compliance by the AMSRP of these obligations.

Notwithstanding any contrary provision, it is understood that if Inserm is AMSRP, Inserm will be free to use and exploit its SRP Database, its SRP Data.

6.1.3. SRP Results

6.1.3.1. Property

The SRP Results are owned equally by the AMSRP and any third party involved in the realization of the SRP on the one hand, and INSERM on the other hand. It is understood that AMSRP will be in charge to distribute with third parties the share of co-ownership due to them under this stipulation.

6.1.3.2. Use

Inserm and AMSRP have a non-exclusive, non-transferable and free right to use the SRP Results for educational, academic and research purposes, regardless of who owns them.

Notwithstanding the above, in the event that an industrial third party is involved in the above-mentioned educational, academic and research activities, Inserm and the AMSRP agree immediately that Inserm, through Inserm Transfer where applicable, will be in charge of developing, negotiating and signing, in the name and on behalf of Inserm and AMSRP, the agreements governing the design and implementation of the said research activity as well as their possible endorsements. For clarification purposes, these agreements include confidentiality agreements, research, collaboration, service contracts or consortium agreements.

Notwithstanding anything to the contrary, it is understood that if Inserm is AMSRP, Inserm will be free to use its SRP Results as it sees fit.

6.1.3.3. Exploitation

Inserm and the AMSRP, including third parties involved by it in the realization of the SRP if necessary, will sign, by separate act and before any exploitation, an agreement defining the terms of management of the co-ownership between the co-owner parties concerned.

It is already planned that Inserm and AMSRP hereby designate Inserm to act on their behalf and for their accounts, through Inserm Transfert, its valuation subsidiary, for the search for partners, negotiating and signing with them any contract for the exploitation of all or part of the SRP Results, and for the execution of the latter while ensuring their financial and administrative management. For clarification purposes, the said contracts include the co-ownership regulations - exploitation with a manufacturer, license contracts, option contracts on license or any other contract aimed at the exploitation of all or part of the SRP Results.

The separate agreement defining the terms of management of the co-ownership between Inserm and AMSRP will take over the stipulations of the previous paragraph.

Notwithstanding anything to the contrary, it is understood that if Inserm is AMSRP, Inserm will be free to use its SRP Results as it sees fit.

6.2. SRP requiring the use of the Project Results

It is understood that in application of the provisions of the Consortium Agreement, the Academic signatories of the Consortium Agreement, with the exception of Inserm INSERM, have a non-exclusive, non-transferable and free right to use the Results of the Project for the realization of SRP, alone or in collaboration with third parties, excluding SRP made in collaboration with industrial third parties or with or on behalf of a third party conferring a right of commercial exploitation on the Results of the Program third party audit.

The SRPs thus led by the Academic signatories of the Consortium Agreement are subject to the provisions of this Charter.

It is recalled that Inserm owns the Project Results and is free to use and exploit them as it sees fit, subject to the provisions of the Consortium Agreement.

6.2.1. Property

The SRP Results from the Results of the Project led by an Academic signatory of the Consortium Agreement, with the exception of Inserm, are owned in equal parts by AMSRP and any third party involved in the realization SRP on the one hand, and Inserm on the other. It is understood that AMSRP will be in charge to distribute with third parties the share of co-ownership due to them under this stipulation.

6.2.2. Use

Inserm and AMSRP have a non-exclusive, non-transferable and free right to use the SRP Results for educational, academic and research purposes, regardless of who owns them.

Notwithstanding the above, in the event that an industrial third party is involved in the above-mentioned educational, academic and research activities, Inserm and the AMSRP agree immediately that Inserm, through Inserm Transfer the case where applicable, will be in charge of developing, negotiating and signing, in the name and on behalf of Inserm and AMSRP, the agreements governing the design and implementation of said research activity as well as their possible endorsements. For clarification purposes, these agreements include confidentiality agreements, research, collaboration, service contracts or consortium agreements.

Notwithstanding anything to the contrary, it is understood that if INSERM is AMSRP, Inserm will be free to use its SRP Results as it sees fit.

6.2.3. Exploitation

Inserm and the AMSRP, including third parties involved by it in the realization of the SRP if necessary, will sign, by separate act and before any exploitation, an agreement defining the terms of management of the co-ownership between the co-owner parties concerned.

It is already planned that Inserm and AMSRP hereby designate Inserm to act on their behalf and for their accounts, through Inserm Transfert, its valuation subsidiary, for the search for partners, negotiating and signing with them any contract for the exploitation of all or part of the SRP Results, and for the execution of the latter while ensuring their financial and administrative management. For clarification purposes, the said contracts include the co-ownership regulations - exploitation with a manufacturer, license contracts, option contracts on license or any other contract aimed at the exploitation of all or part of the SRP Results.

The separate agreement defining the terms of management of the co-ownership between Inserm and AMSRP will take over the stipulations of the previous paragraph.

6.3. *Availability of the data*

The data are made available for the duration defined at the start in the form filled out by the applicant and then the possibility of renewal every year on justification; an automatic justification request will be sent.

Data destruction had to be done once the article is published or before it if the applicant does not continue his project. The applicant cannot share the data. Indeed, the data comes from the MEDIT-AGEING project and can be share to the applicant only on request to the ExCOM. Besides, any data collected by the SRPC can be added to the MEDIT-AGEING database and accessible to partners and new applicants.

7. DISSEMINATION AND DEVELOPMENT OF THE RESULTS

7.1. Scientific communications of SRP results

The SRPC will send the draft publication (scientific article, abstract and poster or oral presentation) (hereinafter the "Communications") of the SRP Results for submission to the ExCom, 30 days before the submission to the editor or the conference. The latter will have 15 days to make any objections or requests for changes.

7.2. Press Communication Rules

In the event of Communications linked to an SRP, Communication to the media may only relate to data validated by peers (within the framework of a scientific journal or a conference) and must comply with the embargo rules set by journals or symposia, as well as all the applicable stipulations of the Consortium Agreement.

Communications on the Project, including on its objectives or on the Results of the Project are ensured by Inserm and the Academics signatories of the Consortium Agreement and in accordance with the stipulations of the Consortium Agreement.

Communications on SRP Results and intended for the media will be sent to Inserm for communication, Inserm will be free to decide will do so in consultation with Inserm, which will decide whether or not to join the communication.

7.3. Rules for scientific publications

7.3.1. SRP Results Communications

The rules for signing Communication projects from SRPs are the responsibility of the ExCom and the SRPC. The ExCom recommends the application of the Vancouver rules which are recalled below:

• An "author" is generally considered to be a person who has made a significant scientific contribution to a published study,

• The qualification of “author” must be reserved for people meeting the following three conditions:

1) be involved in a substantial way in the study design, data analysis and interpretation,

2) have participated significantly in the writing of the article or in the critical review of its scientific content,

3) have approved the version submitted for publication.

• Obtaining funding, collecting data or general supervision of the research group does not qualify as an author,

• Each author must have participated enough in the work to assume responsibility for part of the published results.

• Inclusion of authors in the list should be discussed in ExCom on a case-by-case basis

Systematic mentions on abstracts, displayed or oral communications and publications:

- Mention of the collaboration with the MEDIT-AGEING research group at the end of the authors list according to the involvement/collaboration with the MEDIT-AGEING research group.

- Mention "Inserm is the sponsor of the MEDIT-AGEING Project (C16-38 and / or C16-61)".

- Mention of the origin of funding "The" SRP "is conducted with the support of .... " and also mention that the MEDIT-AGEING project was funded through the European Union's Horizon 2020 research and innovation program (grant agreement N°667696), Inserm, Region Normandie, and Fondation d'entreprise MMA des Entrepreneurs du Futur. Funding sources of the MEDIT-AGEING project were not involved in the study design, data acquisition, analysis, interpretation or manuscript writing.

- For SRPs using the data of patients participating in the MEDIT-AGEING Project :

mention in the acknowledgments the title of Inserm acronym MEDIT-AGEING (if the newspaper allows it)

- For SRP involving the collection of SRP Data from patients of the Project :

mention in the acknowledgments the personnel involved (principal investigators, laboratory personnel…) of the investigative centers of MEDIT-AGEING having included at least one patient in the SRP analysis.

8. Appendices

8.1. *SRP request assessment flowchart*

Before M0

- **Submission of the complete project:**
  - Who: The SRPC
  - How: Submission of the complete file on the website www.silversantestudy.eu or if the website is unavailable by email to poisnel@cyceron.fr

M0 à M2

- **Assessment of the complete SRP request files:**
  - Who: The ExCom
  - How: - by assessing the admissibility and the relevance of the files (scientific, methodological, regulatory, budgetary) and possible redundancies or overlap between SRP and the MEDIT-AGEING project
    - then by selecting the SRP proposals

M3

- **Notification to SRPC:**
  - Who: The ExCom
  - How: information by email of the outcome of the assessment process of the SRP

M4

- **Contractualisation:**
  - Who: The SRPC and the ExCom
  - How: the ExCom send a contract to sign to the SRPC who had a granted access to the data. Also, the Data Management team will inform the SRPC the deadline for sending the data requested. The sponsor had to grant the data transfer after validation of the Data Access Request form and receiving the signed Data Transfer Agreement contract.

M16 (then each year if applicable)

- **Information from SRPC on the availability of the granted data:**
  - Who: The ExCom to the SRPC
  - How: The ExCom asks the SRPC if the SRPC is allowed for a renewal of the availability of the granted data (Is the SRPC analyzing it ? Do the SRPC still need the data ? Is the SRPC still working on the same project with the data sent, otherwise they must make another request.)

8.2. *SRP request submission form*

Data access request form

Applicant	
First Name	
Last Name	
Name of Organisation	
Unit or Department	
Address	
Postal Code	
City	
Country	

Project		
Title of the Project		
Acronym		
Select the contact person[1] according to your area of interest in the context of this project. If your project overlaps on different areas, please select only one, the most central to your project		
Contact person: Domain & Researcher	☐	**Meditation & Age-Well Expert study :** Antoine Lutz antoine.lutz@inserm.fr
	☐	**Lifestyle** : Julie Gonneaud gonneaud@cyceron.fr
	☐	**Attention** : Fabienne Collette f.collette@uliege.be
	☐	**Emotion** : Olga Klimecki Olga.Klimecki@unige.ch
	☐	**Cognition & Wellbeing + SCD-Well trial + SCD-Well blood biomarkers**: Natalie Marchant n.marchant@ucl.ac.uk
	☐	**Neuroimaging biomarkers + Age-Well trial :** Gaël Chételat chetelat@cyceron.fr
	☐	**Sleep :** Géraldine Rauchs rauchs@cyceron.fr
	☐	**Age-Well blood biomarkers :** Géraldine Poisnel poisnel@cyceron.fr
Background and rationale (max 120 words) including the main scientific publications (5 max) justifying the project		

[1] Contact person: Member of the Medit-Ageing/Silver Santé Study consortium in charge of presenting the applicant's project to the Executive Committee for review and validation.

Main Objective (max 50 words)	
Other Objectives (max 100 words)	
Project Design (method, analyses and hypotheses, max 300 words)	
Originality and innovative aspects (max 200 words)	
Expected results (max 150 words)	
Start and Completion dates	
Project leader and contributing researchers and their roles	Statistical analyses : Paper drafting and editing : Design and conception : Coordinator : Other collaborators expressing their interest :
Study population	
Study Sample size and Characteristics (sex, age, intervention arm, number)	☐ SCD-WELL ☐ AGE-WELL TRIAL ☐ AGE-WELL EXPERT STUDY
Ethical approval (only when the study cover a topic not already submitted to the ethical committees)	
Did you already obtain ethical approval from an Ethics committee or Institutional Review Board for this specific project? (specify) If not → when doing so Medit-Ageing (Age-Well/SCD-Well) should be mentioned	

SCD-WELL (SCD patients) Study 1				
	Description of table	**V1**	**V2**	**V3**
	Demographics	☐		
	Vital signs	☐		
	Concomitant treatments	☐		
	Family history	☐		
	Medical history	☐		
	Significant life event	☐		
	Serious Adverse Event	☐	☐	☐
	Intervention groups (Meditation, Health Self-Management (control) groups)	☐		
Blood Data	**Blood biological data :** Genetic and epigenetic Proteomic	☐ ☐	☐ ☐	☐ ☐
Behavioral Data	**Monitoring of interventions**	☐	☐	☐
	Subjective Cognition : SCD Interview (screening only), McNair cognitive difficulties scale	☐	☐	☐
	Cognition : Mattis dementia rating scale, Coding, Stroop, Trail making test, Rey Auditory verbal learning, Visual object separation, Verbal fluency	☐	☐	☐
	IQ : Matrix reasoning, vocabulary		☐	
	Personality : The Big five inventory	☐		
	Sleep questionnaires : Sleep quality index	☐	☐	☐
	Quality of Life and Well-being : Well-being, 3-item loneliness scale, Quality of life questionnaire	☐	☐	☐
	Lifestyle : Automedication, AUDIT, Physical activity for elderly The lifetime of Experiences, CAQ, MAQ, Diet	☐ ☐	☐	☐
	Meditation, Compassion and support : Trait mindfulness, Drexel defusion, Multidimensional assessment of interoceptive awareness, self-compassion, compassion for others, COPE, social support	☐	☐	☐
	Emotion : Anxiety, depression, worry, rumination, emotion regulation abilities	☐	☐	☐
	Partner: Compassion for others, social support and mindfulness, prosocialness, depression, anxiety, COPE	☐	☐	☐

V1 = Baseline, Data collected during the inclusion visit, before randomization of the participants into two groups.
V2 = Assessments taken after the 8-week interventions (post-intervention evaluation).
V3 = Long-term assessments taken 6 months after the start of the interventions.
Importantly, there was no intervention between V2 and V3.

AGE-WELL TRIAL and EXPERT STUDY (Study 2)						
		Expert meditators	**Cognitively unimpaired seniors**			
	Description of table	**Baseline (V1)**	**V1**	**V2**	**V3**	**V4**
Clinical Data	**Demographics**	☐	☐			
	Vital signs	☐	☐			
	Concomitant treatments	☐	☐			
	Medical history	☐	☐			
	Family history	☐	☐			
	Significant Life event	☐	☐			
	Serious Adverse Event (SAE)	☐	☐			
	Intervention groups (Meditation, Language learning (active control), no intervention (passive control) groups)		☐			
Biological Data	**Blood biological data**: Global health, ageing and Alzheimer, inflammation, stress, emotion…	☐	☐		☐	☐
	Lymphocytic immunotyping	☐	☐		☐	☐
	Genetic and epigenetic	☐	☐		☐	☐
	MRI sessions *(if yes, please specify which sequence.s)*	☐	☐		☐	☐
	Structural MRI (T1w)					
	- Raw imaging data	☐	☐		☐	☐
	- Extracted ROIs (anterior cingulate, insula, hippocampus)	☐	☐		☐	☐
	Hippocampus high resolution (T2weighted; raw imaging data)	☐	☐		☐	☐
	Activation fMRI - Emotion (SoVT).					
	Raw imaging data only	☐	☐		☐	☐
	Raw imaging + behavioral data	☐	☐		☐	☐
	Activation fMRI - Attention (AX-CPT).					
	Raw imaging data only	☐	☐		☐	☐
	Raw imaging + behavioral data	☐	☐		☐	☐
	Resting-State fMRI (rs-fMRI; raw imaging data)	☐	☐		☐	☐
	Meditators resting state fMRI					
	Mindfulness rs-fMRI (raw imaging data)	☐				
	Compassion rs-fMRI (raw imaging data)	☐				
	Diffusion imaging (DKI; raw imaging data)	☐				
	FLAIR (raw imaging data)		☐		☐	☐
	T2-weighted (raw imaging data)	☐	☐		☐	☐
	T2* (raw imaging data)	☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐
		☐	☐		☐	☐

		☐ ☐	☐		☐	☐
	Perfusion/Amyloid - PET-AMYVID ***Perfusion (early frames)*** - Raw imaging data - Extracted ROIs (anterior cingulate cortex, insula) ***Amyloid (late frames)*** - Raw imaging data - Extracted ROIs (neocortex)	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐		☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
	FDG - PET-GLUCOTEP - Raw imaging data - Extracted ROIs (anterior cingulate cortex, insula)	☐ ☐	☐ ☐		☐ ☐	☐ ☐
	Actigraphy	☐	☐		☐	☐
	Polysomnography	☐	☐		☐	☐
	Somno-art	☐	☐		☐	☐
Neuropsychological and Behavioral Data	**Monitoring of interventions** : Meditation and language learning; quantitative and qualitative data from participants and teachers			☐	☐	☐
	Global cognition: Mattis dementia rating scale	☐	☐		☐	☐
	IQ: Matrix reasoning, vocabulary	☐			☐	
	Attention and executive functions: Flanker task, Stroop, Coding, Trail making test, selective attention, Digit span forward and backward Attentional style	☐ ☐	☐ ☐	☐	☐ ☐	☐
	Episodic memory : California verbal learning, Short-term recall, Long-term recall Visual object separation	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐
	Autobiographic memory : Fluency	☐	☐		☐	
	Language: Verbal fluency	☐	☐		☐	
	Emotion: STAI, GDS, IRI, PANAS-NOW, depression death, Penn-state worry, emotion regulation abilities, rumination response, satisfaction with life Cyberball, Empathic dictator	☐ ☐	☐	☐	☐ ☐	☐
	Mental imaging: 2D-mental rotation test, Visual mental Imaging battery	☐	☐	☐	☐	
	Personality: The Big five inventory	☐	☐	☐	☐	
	Lifestyle: Lifetime Experiences Questionnaire, Cognitive activity questionnaire	☐	☐			

	Modifiable activity questionnaire (i.e. physicial activity)	☐	☐			☐
	Automedication/alcool/smoking, Mediterranean Diet (MEDAS)	☐	☐		☐	
	Physical activity for elderly, current Cognitive activity questionnaire	☐	☐	☐	☐	☐
	Quality of Life and Well-being : McNair cognitive difficulties scale, Well-being, Quality of life questionnaire	☐	☐	☐	☐	☐
	3-items loneliness scale	☐	☐	☐	☐	
	Meditation, Compassion and support: Trait mindfulness, Drexel defusion, Multidimensional assessment of interoceptive awareness, self-compassion	☐	☐	☐	☐	☐
	Partner: Other compassion, Social support, COPE, prosocialness, mindfulness, depression, anxiety	☐	☐	☐	☐	☐
	Sleep questionnaires: Leeds sleep, sleep quality, Epworth sleepiness, insomnia severity, St Mary's hospital	☐	☐		☐	☐

V1 = Baseline, Data collected during the inclusion visit, before randomization of the participants into three groups.
V2 = Assessments taken 9 months after the start of the interventions, only behavioral test.
V3 = Assessments taken at the end of the 18-month interventions (post-intervention).
V4 = Long term assessments taken 21 months after the end of the interventions.
Importantly, there was no intervention between V3 and V4.

Feasability of the project	
Funding aspects	☐ Available ☐ Expected
Funding source(s)	☐ Public funding ☐ Other(s)
Others aspects to ensure the feasibility of the project	

Key information for applicants :

- Use of MEDIT-AGEING data is subject to full ethical approval. Some requests may fall under existing MEDIT-AGEING approvals. Please contact the relevant contact person (at the beginning of the document) to further discuss this aspect.
- This application will be reviewed by the MEDIT-AGEING Executive Committee to ensure the request is appropriate to the data, and does not conflict with existing research and analysis within the MEDIT-AGEING portfolio.
- The MEDIT-AGEING investigators ask that any publications or outputs arising from the use of MEDIT-AGEING data include authorship for MEDIT-AGEING investigators (, i.e. “the MEDIT-AGEING Research Group” at the end of the author list and the corresponding list attached to the publication to be provided by your contact person).

Document to be submitted to the contact person selected at the beginning of the form.

Name : Date : Signature of the applicant …… …….	Name : Date : Signature of the data provider …… ……..

8.3. Price list for Material access

The price list below is presented for information only and is not exhaustive.

The price list will be free for academics and the costs for the requests emanating from private companies will be discussed on a case by case basis in agreement with the IT team experienced on this type of discussions.

8.3.1. Access cost:

Administrative manager of the SRP	**Access cost**
For profit / industrial organization	*Access right to be defined + Real costs*
For non-profit / academic organization	*Access right to be defined + Real costs*
MEDIT-AGEING Consortium Agreement partners	*Real costs*

8.3.2. Costs related to the extraction of data from the eCRF and the statistical analysis carried out by the Data management team:

Expertise profile	**Daily rate (excluding additional costs*)**
Data-manager	To be defined €
Developer	To be defined €
Bio-statistician	To be defined €

8.3.3. Cost related to the implementation of the SRP (regulatory, organization, logistics, etc.) and monitoring:

Expertise profile	**Daily rate (excluding additional costs*)**	
Project manager	To be defined €	
CRA/CST	To be defined €	
	PU (euros)	unité
Information / consent note (printing and distribution)	€	/ document
Protocols (printing and distribution)	€	/ amendment
Travel / monitoring costs	€HT	/ year (CRA ou CST)
Travel expenses for meetings	€HT	/ person
Operating costs (sending documents, supplies, etc.)	€HT	/ year
IT / equipment costs	€HT	/ person

*These additional costs represent in particular:
-environmental costs of research organizations corresponding to recurrent costs such as costs of supervision (management), assistance, human resources, accounting, etc.; structural costs related to staff: buildings, furniture, etc.;
- structural costs linked to other expenses such as management costs (administrative service)
The personnel and operating costs are given for information purposes and are not exhaustive. They must be adjusted according to the needs of the PRS and depend on the structure of the administrative manager of the PRS.

8.4. Charter adhesion form

SRP MEDIT-AGEING Charter adhesion form

……
(Surname, First name of the SRP Carrier)

……
(Function)

……
(Research unit)

……
(Administrative affiliation)

Hereby, I engage myself in the framework of the Specific Research Project "MEDIT-AGEING":

1. To comply with the terms and conditions of the Charter annexed to this commitment, and for which a copy can be obtained at any time on request to INSERM;

2. To use the data that will be communicated to me for the sole purposes of the SRP and in compliance with the Charter;

3. To make myself available to respond to any request from the Executive Committee and to respect the advice of the Executive Committee as planned by the Charter;

4. To considered confidential, any information, of whatever nature or form whatsoever, oral or written, brought to my attention within the framework of the SRP, and to not disclose it to a third party without the prior written authorization of INSERM.

I understand that :

- this commitment does not exempt from the preparation of a contractual document between INSERM and the Administrative Manager of the SRP according to the type of SRP;

- the terms, conditions and notices of the Charter are subject to change at any time and will be the subject of an information;

- INSERM strives to ensure, to the best of its ability, the accuracy of the information communicated;

- the data in the MEDIT-AGEING database are the exclusive property of INSERM.

This commitment is valid for the entire duration of the SRP.

Done at: ……., In two (2) original copies

Date: …….

Signature

8.5. Data Transfer Agreement Template

DATA TRANSFER AGREEMENT

In response to the Data Recipient's request for the Data

XXX

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

And:

YYY,

Hereafter referred to as the **"Data Recipient"**

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

PREAMBLE

Whereas XXX has scientific and technological expertise in the field of …….

Whereas YYY is active in the field of ….

Whereas the Parties, having considerable experience in the field concerned, have signed a consortium agreement (the "**Consortium Agreement**") relating to the Project entitled "MEDIT-AGEING**"**, hereinafter referred to as "**Project**".

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

Data (Short description)	
Format of the Data	
Personal Data (If applicable)	☐ Yes ☐ No
Intended Use of Data	General description of the study of the Data Recipient : Specific purpose of the use of Data by Recipient :
Foreseen period of Use of Data	
Mode of Transfer	

DEFINITIONS

Commercial Purpose	The sale, lease, license, or other transfer of the Data to a for-profit organization. Commercial Purposes shall also include publication and uses of the Data by any organization, including the Data Recipient, to perform contract research or to conduct research activities that result in any sale, lease, license, or transfer of the Data to a for-profit organization.
Effective Date	The date on which this Agreement becomes effective which is the date upon which the last Party to sign has executed this Agreement.

Data	any and all data part of a Party's Background included in the Project or generated under the Project, which is transferred by a Party to another in the frame of the Project, including personal data that is defined and protected as personal data under the European or national applicable legislation(s), and that shall be subject to terms and conditions specified in article 4 of this present Agreement. This term shall notably cover any personal health data, Clinical Data and Analysis Data.

TERMS AND CONDITIONS OF THIS AGREEMENT

1. PURPOSE

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

2. SUPPLY OF DATA

The Data Provider shall send anonymised Data to the attention of the Data Recipient, at the Data Recipient's expenses, and shall not provide the Data Recipient with any key to decode or identify the Data.

3. USE OF DATA

3.1 The Data Recipient agrees that the Data:
(a) Is to be used solely for purpose of the Project, in accordance with the Consortium Plan, to the exclusion of any other use of the Data thereof such as a use for Commercial Purpose, unless otherwise expressly agreed by the concerned Parties
(b) Is to be used only in compliance with all applicable laws and regulations applicable; and
(c) Is to be used only by scientists working in the Data Recipient's premises or under the Data Recipient direct responsibility and involved in performing the Project.

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

3.3 The Data Recipient undertakes that its use of the 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.

3.3 The Data Recipient acknowledges that the Data is or may be covered by intellectual property rights.

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

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

3.6 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 Data covered by this Agreement:

4.1 The Data Provider and the Data 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 Data.

4.2 The Data Provider represents and warrants the Data Recipient that:

- It has informed and obtained the consent from the persons (Hereinafter "Patients") who initially provided personal Data, to the full extent defined by the applicable law and regulation and in regards of the foreseen Intended Use of their Personal Data.
- Personal Data has been collected by fair means, in respect of all applicable legislation and regulation.
- When required by law or regulation, the personal Data have been encrypted before Transfer.

4.3 The Data Recipient represents and warrants the Data Provider that:

- Notwithstanding terms and conditions set out under section 3.2, personal Data shall be stored with relevant degree of security in order to protect the personal Data in regards of its specific nature, and that adequate maintenance procedures for the proper conservation of personal Data exist, pursuant to applicable laws and regulations, in order to prevent any misuse, involuntary change, loss or modification of the personal Data;
- Personal Data shall only be used for the Intended Use of the Data, which Intended Use is legitimate and lawful and necessary for the implementation of the Project,
- Personal Data will only be used to the strict extent that is necessary and during a reasonable period of time as regard to the Intended Use of Data,
- Personal Data shall not be used for Commercial Purpose,
- Personal Data will not be transferred to a third party including any affiliate of the Data Recipient, without prior written authorization from the Data Provider and in accordance with the authorization/declaration necessary for the transfer ,
- Subject to applicable laws and regulations, appropriate measures will ensure access to its own personal Data at any time upon request from the Data Provider, with no delay, notably in order to complete, modify or delete such personal Data upon request of Patients, in accordance with the applicable legislation(s),
- Any communication or publication of the results shall not allow, directly or indirectly, identification of Patients and shall in any case be compliant with all the provisions of the Consortium Agreement.

4.4 At any time, the Data Provider shall be granted access by the Data Recipient to the Place of Storage and information (including premises, compounds, websites, servers, files, authorizations, etc.), for the only purpose and to the only extent of controlling that terms and conditions of section 4.3 are respected.

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

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

5. PROPERTY

5.1 Data shall be treated as the sole property of the Data Provider between the Parties, subject to applicable laws and regulations, and in compliance with all the provisions of the Consortium Agreement.

5.2 The Data Recipient shall not file, or have filed in the name of third parties in any country, any patent application, or intellectual property rights (copyrights, trademarks,...) claiming the Data.

6. CONFIDENTIALITY

6.2 The Data Recipient undertakes to respect and maintain strictly confidential all Data received from the Data Provider.

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

7. WARRANTIES

7.1 The Data Recipient accepts the Data "as is". The Data Provider makes no representations and extends no warranties of any kind, either expressed or implied. No warranties, express or implied are offered by the Data Provider as to the fitness for a particular purpose of the Data. The Data Provider and their directors, officers, employees, or agents assume no liability and make no representations in connection with the Data use by the Data Recipient. The Data Recipient will defend, indemnify and hold harmless the Data 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 Data.

7.2 The Data Provider makes no representation that the use of the 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 […] from the Effective Date, or (b) upon completion of the Project, unless otherwise agreed by the Parties

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

It is understood that, as soon as the concerned Parties shall have agreed upon specific rules applying to the management and exploitation of the EHVA Database, it is understood that these particular rules shall prevail on the present Agreement .

In witness whereof, the Data Recipient and Data 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 Data Provider and the other for the Data Recipient.

XXX

Signature_____
(Authorized signatory of the Data Provider)

Name:
Title:
Date :

READ, UNDERSTOOD AND AGREED TO BY THE SCIENTIST:

Signature_____
Name:
Title:
Date:

YYY

Signature_____
(Authorized signatory of the Data Recipient)

Name:
Title:
Date: