

**Access to Memento data and Publications Charter**  
**2<sup>nd</sup> September 2013, version 3.1**

**MEMENTO COHORT:** Cohort of outpatients from French Research Memory Centers in order to improve knowledge on alzheimer's disease and related disorders

**PURPOSE OF THIS DOCUMENT:**

To describe Memento general principles and path to follow for data access, ancillary project and publication submission.

**KEY POINTS FOR INFORMATION AND DEFINITIONS**

**Memento Study Group**

The different components of the Memento Study Group (or Memento network) are the following:

**Memento Principal investigators**

Geneviève Chêne – Memento Principal Investigator (CIC-EC7)

Carole Dufouil – Memento co-Principal Investigator (CIC-EC7)

**Memento Executive Committee**

Philippe Amouyel – General Director (Fondation Plan Alzheimer)

Pierre Ducimetière – co-Chair Memento Scientific Strategy Committee

Françoise Forette – Chair Memento Scientific Strategy Committee

Geneviève Chêne – Memento Principal Investigator

Carole Dufouil – Memento co-Principal Investigator

**Memento Main Funder**

Fondation Plan Alzheimer

**Memento Sponsor**

Bordeaux University Hospital (CHU Bordeaux)

### **Memento Scientific Strategy Committee**

Independent scientific members: Françoise Forette (Chair), Pierre Ducimetière (Co-chair), Annick Alpérovitch, Lisa Berkman, Hugues Chabriat, David Clayton, Mony de Leon, Yves Lévy, Ronald Petersen, Philip Scheltens

Non independent members: Philippe Amouyel, Geneviève Chêne, Carole Dufouil

Permanent observers: Joël Ménard, one representative from Sponsor, Memento project manager, Jean-François Mangin (director of Center for Imaging analysis, CATI), one representative of French Federation of Memory Clinics

### **Memento Steering Committee**

Geneviève Chêne (GC) - Chair, alternatively with CD

Carole Dufouil (CD) – Chair, alternatively with GC

Coordinating Center: Project manager (Olivier Marcy, CIC-EC7). Other staff members are permanent observers.

Investigating centers: one representative from clinical site of participating CMRRs

Amiens, Hôpital Nord et Hôpital Sud (Pr Olivier Godefroy); Angers, CHU d'Angers (Pr Olivier Beauchet); Besançon, Hôpital Jean Minjoz, Hôpital Saint Jacques (Pr Pierre Vandell); Bobigny, Hôpital Avicenne (Dr Catherine Belin); Bordeaux, Hôpital Pellegrin (Pr Jean-François Dartigues), Hôpital Xavier Arnoz (Dr Sandrine Harston) ; Brest, Hôpital de la Cavale Blanche (Pr Armelle Gentric) ; Clermont -Ferrand, Hôpital Gabriel Montpied (Pr Isabelle Jalenques) ; Colmar, Hôpitaux civils de Colmar (Dr François Sellal) ; Dijon, Hôpital général, Centre de gériatrie de Champmaillot (Dr Olivier Rouaud) ; Grenoble, Hôpital de la Tronche (Dr Olivier Moreaud) ; Lille, Hôpital Roger Salengro (Pr Florence Pasquier) ; Lyon, Hôpital des Charpennes (Pr Pierre Krolak-Salmon) ; Marseille, Hôpital La Timone (Pr Mathieu Ceccaldi) ; Montpellier, CHU Gui de Chaulliac (Dr Audrey Gabelle) ; Nantes, hôpital Nord Laënnec (Dr Martine Vercelletto) ; Nancy, CHU de Nancy (Pr Athanase Benetos) ; Nice, Hôpital de Cimiez (Pr Renaud David) ; Paris, Hôpital de la Salpêtrière (Pr Bruno Dubois) ; Hôpital Broca (Pr Olivier Hanon) ; Groupe Hospitalier Lariboisière (Pr Jacques Hugon) ; Poitiers, CHU La Milétrie (Pr Marc Paccalin) ; Rouen, Hôpital Charles Nicolle (Pr Didier Hannequin) ; Saint-Étienne, Hôpital Nord (Dr Marie-Odile Barrellon), Hôpital la Charité (Dr Catherine Girtanner) ; Strasbourg, Hôpital de Hautepierre, Hôpital de jour Saint François (Dr Frédéric Blanc) ; Toulouse, Hôpital Casselardit (Pr Bruno Vellas) ; Toulouse, Hôpital Purpan (Dr Jérémie Pariente) ; Tours, Hôpital Bretonneau (Pr Caroline Hommet).

National Database on Alzheimer: one representative (currently, Philippe Robert)

Center for imaging analysis (CATI): three representatives (Jean-François Mangin (director), Marie Chupin (MRI acquisitions), Marie-Odile Habert (PET-Scan imaging acquisition))

Centralised Biobank: one representative (currently, Nathalie Fievet)

Sponsor (CHU Bordeaux): one representative (currently, Laetitia Lacaze-Buzy)

*Any scientist in charge with an ongoing ancillary project may be asked to join upon the two co-PIs invitation.*

### **Memento coordinating Center**

CIC-EC7, Bordeaux: Dr Olivier Marcy, project manager; Vincent Bouteloup, Biostatistician; Virginie Richard, Data Manager; Isabelle Addra, Stéphanie Roseng, Nathalie Thiery, Clinical Research Assistants; Séverine Jallier, Scientific Assistant.

### **Memento secretariat**

memento\_scsecretary@isped.u-bordeaux2.fr

**For the purpose of this document,**

- **Sub-studies, ancillary studies, abstracts and manuscripts will be referred to as "proposals". Contrary to sub-studies, ancillary studies necessitate an extension of data collection and specific ethics approval should thus be obtained.**
- **Corresponding authors/applicants of a proposal will be referred to as the "authors".**
- **All data collected according to the most recent version of the protocol at the submission date is referred to as "Memento data". The list of variables is included in the "Memento variables catalog" and covers raw monitored data as contained in the central database managed at the CIC-EC7.**
- **As a general principle, core dataset corresponding to each follow-up wave will be made available within the 6 months after completion and cleaning.**
- **Moreover access to raw images (MRI and PET) centralised at the CATI or to any centralized biological material should require specific authorisations.**

**Memento co-principal investigators are responsible to advertise this policy by any means (presentation at meetings, website) and to provide all documents upon request (principles of governance; access to data and publications policy; submission forms; Memento questionnaire contents, Memento variables catalog).**

## 1. Background on Memento : principles of data sharing

Memento is a cohort funded by the Fondation Plan Alzheimer and sponsored by the Bordeaux University Hospital (CHU Bordeaux).

This cohort aims at studying the **evolution of a variety of potentially early signs** (cognitive complaints, deficit in some domain of cognition, psycho-behavioural disturbances, changes in imaging or biological markers) of Alzheimer's disease and related dementia and to estimate the **prognostic value of different markers** (neuro-psychological, vascular, psychopathological, socio-educational, genetic, biological, neuro-imaging) on the progression to clinical dementia or severe cognitive deterioration stages, and then to death.

The cohort is also a **translational research platform** open to sub-studies and ancillary studies proposed by any *bona fide* researcher. Memento scientific gain should aim at being maximised, while maintaining and promoting data confidentiality and security, cohort scientific integrity and high quality of publications. In addition, legitimate interests of Memento collaborators, and all Memento participants, in particular capacity-building among Memento collaborators' teams, should be promoted.

The approval process will be followed for all data collected or acquired within the Memento cohort, through the e-CRF, MRI (images and biomarkers), PET imaging (images and biomarkers), and biological specimen.

**No Memento proposal should be undertaken without prior discussion within the Memento study group and authorisation of the Memento Executive Committee.**

**Authors are encouraged to include Memento collaborators in their Proposal's Study Team for the sake of capacity building.**

## 2. General approval process of any proposal

- **Once the Memento Principal investigators have given input to the authors developing a full proposal, the Memento Secretariat is responsible for coordinating the approval process and for all circulations, and should be copied on all correspondence (memento\_scsecretary@isped.u-bordeaux2.fr).**
- **Authors are responsible for ensuring they start the approval process and contact the Memento Principal Investigators with enough time to meet any submission deadlines (for grant applications, communications to scientific congress...)**

- **Authors are responsible for all submissions and for keeping the Memento Secretariat informed at any time.**
- **The Memento Executive Committee is responsible for making sure that all relevant parties in Memento have been informed about and have no objection to the proposal. The Executive Committee is responsible for making the final decision and informing the authors.**

### **STEP 1 : INITIATION**

Ideas for all proposals should first be discussed (as early as possible and before drafting the document) with Memento Principal Investigators in order to identify any Memento data to be included in the proposal, and any need for data analysis. When imaging data are required, a representative of the CATI should systematically be involved in the discussions from the beginning. A brief outline of the proposal that authors would like to develop should be emailed to the Memento Principal Investigators and copied to the Memento Secretariat ([memento\\_scsecretary@isped.u-bordeaux2.fr](mailto:memento_scsecretary@isped.u-bordeaux2.fr)). At this stage, assessment criteria of the Memento Principal Investigators include: feasibility, absence of competition with ongoing research within Memento, potential for capacity-building within the Memento network.

### **STEP 2 : SUBMISSION**

After discussion with the Principal Investigators, the authors should fill a proposal form (Appendix 1 for sub-study or ancillary study, Appendix 2 for abstract or manuscript information) to be sent to the Memento Secretariat ([memento\\_scsecretary@isped.u-bordeaux2.fr](mailto:memento_scsecretary@isped.u-bordeaux2.fr)) and examined by the Executive Committee. The Memento Executive Committee is responsible for ensuring that the proposal is scientifically original and not in conflict with the cohort development or results.

### **STEP 3 : CIRCULATION**

**In order to facilitate abstract submissions, this step is bypassed for any abstract proposal, approval being directly endorsed by the Executive Committee (see paragraph 4.)**

After queries have been satisfactorily dealt with by the authors and the proposal has been approved by the Executive Committee, the Memento Secretariat will circulate the full proposal for review, comment and formal approval among the Memento Steering Committee members and the Memento Scientific Strategy Committee members. They are responsible for ensuring that the content/ science of any proposal is suitably high to be

undertaken/published. Within the Memento Steering Committee, the co-PIs, the Fondation Plan Alzheimer and the Sponsor are specifically responsible for ensuring that any use of the Memento data is not in conflict with and does not compromise the integrity of the cohort. It can then be recommended: acceptance, rejection or that further work is needed. The proposal will be considered accepted if no comment is received within the given number of working days for approvals.

All substantive revisions/comments to the proposal from the Memento Executive Committee, and Steering Committee, must be addressed before approval/submission. Minor comments should be addressed, or responded to. Responses to comments and minor re-writing need not to be circulated. However, any major changes or re-analysis in response to reviewers should be re-circulated by the Memento Secretariat, to the Memento Executive Committee, and Steering Committee.

#### **STEP 4 : FINAL APPROVAL**

Once all the relevant parties have been consulted and have no more comment on the proposal, the Executive Committee makes a final decision regarding proposal acceptance that is circulated to the authors by the Memento secretariat.

The author of the proposal must report when requested to the Memento secretariat on proposal or publication progress at any time.

#### 3. Specific recommendations for any sub-study or ancillary study proposal

- 3.1. The **Executive Committee** has a **maximum of 5 working days** to give a go/nogo to a proposal.
- 3.2. The Memento Steering Committee considers the proposal at their next following meeting and makes recommendations. The **Scientific Strategy Committee** considers the proposal and makes recommendations within the same timeframe as the Steering Committee.
- 3.3. In any case, the need for contract agreement will be discussed at the Executive Committee level and the contract finalised before the sub-analysis or ancillary study can start.
- 3.4. PI of a sub-study or ancillary study could be asked to present progress of the study at any meeting of the Scientific Strategy Committee.

#### 4. Specific recommendations for abstracts proposal

- 4.1. A brief outline/idea for all proposed abstracts should first be discussed with Memento Principal Investigators and copied to the Memento Secretariat

([memento\\_scsecretary@isped.u-bordeaux2.fr](mailto:memento_scsecretary@isped.u-bordeaux2.fr)) at **LEAST 15 working days ahead of the submission deadline** .

Prior to developing the full draft abstract, an agreement on the concept and proposed authorship must be reached.

4.2. The **Memento Executive Committee** has a **maximum of 5 working days** to consider the proposal and make recommendations.

4.3. After queries have been dealt with by the authors, and the proposal has been reviewed and approved by the Memento Executive Committee, the author can submit the abstract. The corresponding author sends the submitted abstract to the Memento Secretariat for records tracking, as soon as possible.

4.4. The Memento secretariat will send the abstract to the **Memento Steering Committee** and the **Memento Scientific Strategy Committee** for information.

#### 5. Specific recommendations for manuscripts proposal

A list of all those collaborating in Memento (“Memento Study Group”) should be added as an appendix to all Memento publications. An up to date list and additional information regarding mentions on funding and sponsoring should be obtained from the Memento Secretariat ([memento\\_scsecretary@isped.u-bordeaux2.fr](mailto:memento_scsecretary@isped.u-bordeaux2.fr)).

5.1. The **Memento Executive and Steering Committees** have a **maximum of 15 working days** to consider the proposal.

5.2. After queries have been satisfactorily dealt with by the authors and the final version of the manuscript has been reviewed and approved by the Memento Executive Committee, the author can submit the manuscript. The author sends the submitted manuscript to the Memento Secretariat for records tracking, as soon as possible.

5.3. The Memento Secretariat will regularly send an updated list of manuscripts to the **Scientific Strategy Committee** for information.

5.4. Revised manuscripts following any reviewer and editorial comments should be circulated by the Memento Secretariat to the Memento Executive and Steering Committees at least **10 working days** prior to re-submission to the journal or any other one.

## **Appendix 1. Memento Sub-study/ Ancillary study Outline**

Please complete the following form to allow the Executive and Steering Committees to evaluate your proposal – we encourage you to carefully read the guidance on the “Access to Memento data and Publications Policy Charter” (sections 2 and 3) and the following reminder to increase the acceptability of your proposal.

Please observe that proposals, in order to be endorsed, must comply with Memento principles:

1. Once the Memento Principal investigators have had input and have agreed to the authors developing a full proposal, the Memento Secretariat is responsible for co-ordinating the approval process and for all circulations, and should be copied on all correspondence.
2. Authors are responsible for ensuring they start the approval process and contact the Memento Principal Investigators with plenty of time to meet any submission deadline.
3. Authors are responsible for all submissions and for keeping the Memento Secretariat informed at any time.
4. Authors are encouraged to include Memento collaborators in their Proposal’s study team for the sake of capacity-building
5. The Memento Executive Committee is responsible for making sure that all relevant parties in Memento have been informed about and have no objection to the proposals. The Executive Committee is responsible for making the final decision and for releasing it to the authors.

Please send this proposal to:

- Memento secretariat ([memento\\_scsecretary@isped.u-bordeaux2.fr](mailto:memento_scsecretary@isped.u-bordeaux2.fr)) and
- Cc Memento co-PI (Genevieve Chene ([genevieve.chene@isped.u-bordeaux2.fr](mailto:genevieve.chene@isped.u-bordeaux2.fr)) and Carole Dufouil ([carole.dufouil@isped.u-bordeaux2.fr](mailto:carole.dufouil@isped.u-bordeaux2.fr)))



**Memento Sub-study/ Ancillary study Outline**

<b>Proposal title</b>	
<b>Submitted by</b>	
<b>Affiliation</b>	
<b>Collaborators of Memento involved in the proposal</b>	
<b>Study team &amp; roles</b>	
<b>Background and scientific hypotheses</b>	
<b>Justification for use of Memento</b>	
<b>Objectives</b>	
<b>Feasibility assessment</b>	
<b>Deliverables and timelines</b>	
<b>Significance</b> (added value compared to current scientific consensus and ongoing projects)	
<b>Possible limitations</b>	
<b>Standard Memento data items required</b>	
<b>Additional data items</b> (if biobank access, specify material needed)	
<b>Sample size/power calculations</b>	

<b>Estimated costs and sources of specific funding</b>	
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## Appendix 2. Abstract/Manuscript Information Form

Please complete the following form to allow the Executive and Steering Committees to evaluate your abstract or manuscript – we encourage you to carefully read the guidance on the “Access to Memento data and Publications Policy Charter” (sections 2 ,4 and 5) and the following reminder to increase the acceptability of your proposal..

Please observe that publications, in order to be endorsed, must comply with Memento principles:

1. Once the Memento Principal investigators have had input, the Memento Secretariat is responsible for co-ordinating the approval process and for all circulations, and should be copied on all correspondence.
2. Authors are responsible for ensuring they start the approval process and contact the Memento Principal Investigators with plenty of time to meet any submission deadline.
3. Authors are responsible for all submissions and for keeping the Memento Secretariat informed at any time.
4. Authors are encouraged to include Memento collaborators in their writing group for the sake of capacity-building
5. The Memento Executive Committee is responsible for making sure that all relevant parties in Memento have been informed about and have no objection to the publication. The Executive Committee is responsible for making the final decision and for releasing it to the authors.

Please send this form to:

- Memento secretariat ([memento\\_scsecretary@isped.u-bordeaux2.fr](mailto:memento_scsecretary@isped.u-bordeaux2.fr)) and
- Cc memento co-PI (Genevieve Chene ([Genevieve.chene@isped.u-bordeaux2.fr](mailto:Genevieve.chene@isped.u-bordeaux2.fr)) and Carole Dufouil ([carole.dufouil@isped.u-bordeaux2.fr](mailto:carole.dufouil@isped.u-bordeaux2.fr)))

**Memento Abstract and manuscript Information form**

<b>Abstract/manuscript proposed title</b>	
<b>Corresponding author</b>	
<b>Affiliation</b>	
<b>Collaborators of Memento involved,</b>	
<b>Language for publication/presentation</b>	
<b>Publication type</b>	
<b>Target Journal/Congress</b>	
<b>Planned date of Journal/Congress submission (for abstracts or journal submission) or presentation (for posters or oral presentations)</b>	
<b>Scope of intended audience</b>	
<b>Regulatory implications, if any</b>	