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ANCILLARY STUDIES CHARTER

University of Bordeaux / i-Share study

Version table

Version	Date	Edited by	Reason for update
1.0	30/07/2015	Clothilde Pollet *Operational project manager*	
2.0	26/102017	Catherine Fagard *Inerm research engineer;* *Research/quality expert*	Update of quality documents for ancillary studies

Ancillary study N°	**EA _ _ _**
Title	
Acronym	

Contents

The purpose of the ancillary studies charter for the i-Share cohort is to establish the operating rules for ancillary studies of the cohort from project phase to evaluation.

It is based on the general principles of the generic charter for opening to researchers health cohorts within the scientific community established by the Institut de Recherche en Santé Publique (IResP). It has been written under the guidance of the executive committee and validated by the board of trustees.

The lead researcher of the ancillary study must sign the declaration accepting the operating procedures for ancillary studies of the i-Share cohort which can be found on page 11 of this document.

1. THE I-SHARE COHORT

1.1 General introduction

As part of the "Cohorts" section of the "Investissements d'Avenir" program launched by the Commissariat Général à l'Investissement (CGI) in 2010, the French ministry of higher education and research, Agence Nationale de la Recherche (ANR), and various other research organizations (University of Bordeaux, Université de Versailles Saint-Quentin en Yvelines (UVSQ), Institut national de la santé et de la recherche médicale (Inserm), Institut Pasteur, Le Centre National de Recherche Scientifique (CNRS), Centre Hospitalier Universitaire (CHU) de Bordeaux and Commissariat à l'énergie atomique et aux énergies alternatives (CEA)) joined forces to create a program entitled "Student health cohort study" (*Étude de cohorte sur la santé des étudiants*), also known as "i-Share".

The consortium agreement signed between the various parties in October 2014 specifies the governance bodies of the cohort, their roles and responsibilities. This project is led by the University of Bordeaux (coordinator). The board of trustees, comprising a representative of each institution in the consortium and presided over by the coordinating institution, is responsible for validating strategic direction and general budget, distributing specific allocated resources, and monitoring modifications to the cohort and associated documents (agreement, charter, etc.).

The i-Share cohort is an epidemiological study that aims to evaluate the health of students as well as changes in their health throughout the study, and also to explore the risk factors for certain diseases in this population of young adults, an age group for which little information is available, including specific risks (mood disorders and suicide, risky behavior and accidents, exposure to alcohol and drugs).

i-Share is a collaborative research platform open to the scientific community. It pursues two main types of objectives:

- public health objectives linked to student health: evaluating the frequency and consequences of diseases, trialing interventions to test the effectiveness of preventative, screening, and treatment strategies for certain diseases...
- biomedical research objectives on the determinants of diseases: testing scientific hypotheses on physio/psycho-pathological mechanisms.

1.2 Governance

The i-Share cohort is carried out under the scientific supervision of Pr. Christophe Tzourio (Inserm U1219/University of Bordeaux), lead research coordinator.

The cohort is managed and coordinated by the i-Share **coordination team** comprising project leads, data manager, statistician, clinical research associate and manager, the list of which is included in the document entitled "List of persons involved in the cohort" (ENR-PERS). The operational project manager coordinates the team.

The operational project manager and the relevant people in the coordination team (according to the needs of the ancillary study) manage and coordinate ancillary studies of the cohort.

The role of the **executive committee**, comprising the lead research coordinator and co-researchers, is to monitor the operation of the i-Share cohort, select ancillary research projects, and decide on access to data or biological samples for collaborating research teams. The composition of the executive committee is detailed in the ENR-PERS document.

The **ethics committee** is responsible for deciding ethical issues raised by the cohort or ancillary studies.

2. PROCEDURES FOR COLLABORATION WITH THE I-SHARE COHORT

2.1 General principles

i-Share, an open study. The data collected as part of the i-Share cohort is accessible to any researcher or research team, public of private, French or overseas.

***A single point of contact*.** Researchers wishing to work on data from the i-Share cohort must submit a request to the lead research coordinator or to the operational project manager of the cohort. The submission procedure is described below.

***Types of ancillary study*.** The various types of ancillary study are presented in **Appendix 1**. It may include analyzing the available data, collecting additional data, carrying out an interventional study, collecting additional data from existing samples or collecting new biological samples.

Contribution to costs. i-Share is a study with cost contribution and access to the data, biological samples, and their analyses, must be funded by the requester.

2.2 Regulatory framework

The regulatory framework for each study type is presented in **Appendix 1**. The lead researcher of the ancillary study consults with the i-Share operational project manager on the regulatory framework for the ancillary study in accordance with its specificities and they define the roles of each in the regulatory procedures. The distribution of tasks and responsibilities is detailed in the "Ancillary study quality plan" document ENR-EA-PQUAL.

2.3 Submission process for proposing an ancillary study

The submission process for proposing an ancillary study begins with the lead researcher sending a letter of intent, followed by an application package, to the operational project manager of the cohort.

2.3.1 Letter of intent

A letter of intent, including a synopsis detailing the reasoning and objectives of the ancillary study, and a brief summary of the planned means and options for funding, must be sent by the lead researcher of the ancillary study to the operational project manager of the cohort.

The executive committee examines the request and the lead research coordinator sends a response to the requester by email within 15 working days: principle agreement, request to reformulate the application or for further information, refusal with reasons.

In the event of a positive response, the operational project manager of the i-Share cohort contacts the ancillary study lead researcher for the submission of a full dossier. The operational project manager provides the lead researcher with all the documents needed to prepare the application package, and the necessary documents from the cohort (protocol, questionnaires, status and characteristics of the population, etc.).

2.3.2 Application package

The complete application package must be sent to the operational project manager. It comprises the following documents:

1. Completed "Ancillary study proposal form"
2. Ancillary study protocol
3. Data collection questionnaires (if applicable)
4. This "Ancillary studies charter", signed

2.4 Evaluation process for an ancillary study proposal

This process is carried out as follows:

- **Operational and regulatory evaluation by the i-Share project leads which will consider the following:**
  - regulatory framework and adherence to regulations (access to data, confidentiality)
  - operational feasibility in terms of human resources, planning of the study, consistency with the cohort, procedures for data management and analyses, management of biological samples (if applicable) and evaluation of budget.

- **Scientific and methodological evaluation by the executive committee, with emphasis on the following:**
  - scientific and methodological quality of the project
  - relevance of the project in relation to the overall consistency of the cohort in the long term (soliciting respondents, redundancy of certain current or future projects/questionnaires, etc.,)
  - complementarity or competition with a project that is planned or currently underway
  - ethical aspect (an ethics opinion may be requested if needed)
  - partnership

- budget and planned funding

The executive committee is also informed of the operational and regulatory assessment in order to make its decision.

- **Issue of a decision by the executive committee**

The executive committee issues a decision (favorable/favorable with conditions/unfavorable) by completing the "Results of evaluation of the ancillary study by the i-Share executive committee" section on the application form. The decision is sent to the requester of the ancillary project within 20 working days of receipt of the application package.

If the ancillary study is accepted, the specifics of collaboration will be formalized in the ancillary study quality plan (ENR-EA-PQUAL). An agreement is drawn up on contribution to costs.

The cycle for submission and evaluation of the project is summarized in Appendix 2.

2.5 Funding of proposed ancillary research

Ancillary studies may be financed either by the team leading the project with their own funds, or through a specific request made to a funding body (ANR, etc.).

The i-Share operational project manager must be consulted before the submission of any funding application for an ancillary study using i-Share data in order to verify the feasibility. Any funding obtained will not be considered as a guarantee to access to i-Share data if this process is not followed.

The i-Share operational project manager consults with the lead researcher of the ancillary study to calculate the costs incurred through the ancillary study. A provisional budget is then drafted.

Funding documents (estimates, funding request) must be included in the ancillary study application package.

3. ACCESS TO COHORT DATA AND COLLECTION OF ADDITIONAL DATA

The various types of ancillary study and the collection and management of the data concerned are summarized in **Appendix 1**.

Any exchange of data must follow the data exchange procedure (POS-A_ECH). The data transfer form (ENR-EA-TRF) must be completed then validated and signed by the lead researcher of the ancillary study and the lead research coordinator of the cohort. It includes all the information needed for the exchange, storage, and destruction of data after the expiry of the permitted period.

Specific provisions for genetic data: this type of data is subject to specific legal and regulatory provisions, and projects using such data must adhere to the specific conditions which apply from the time of the project request.

3.1 Ancillary study on existing data

Subject to issues of confidentiality, ethics, or ownership, all data collected in the i-Share cohort may be accessible to researchers if the study is approved.

In collaboration with the applicant, the i-Share coordination team prepares the selected data and makes it accessible in the most suitable technical format. Access through a secure data server is preferred in the majority of cases and particularly in the case of data transfer, provided by the cohort coordination team.

Analyses must relate only to that which has been declared in the ancillary study application package. Consequently, access to data will be limited to that specified in the package. In the event of major expansion of the initial project, a new package will need to be submitted.

Transfer of data, provided by the i-Share cohort coordination team, to any person other than those specified in the application is prohibited.

At the end of the study, the requester is prohibited from any further use of the data files which were transmitted to them by the i-Share cohort coordination team and agrees to destroy this data. A certificate of data destruction will be required.

3.2 Ancillary study involving the collection of additional data

3.2.1 Collection methods and storage of new data

Additional data may be collected as part of an ancillary study:
- through questionnaires directly sent to participants by the ancillary study lead researcher
- by including questions or questionnaires in the i-Share cohort database and online platform.

If the ancillary project involves direct access (interview, examination, etc.) to i-Share cohort participant, the operational practices for this access must be clearly defined in the project protocol.

The lead researcher of the ancillary study is responsible for the quality of the data collected. All precautions regarding any authorizations, confidentiality, and ethics must be considered and described in the application package.

No other information may be requested from cohort participants other than those explicitly authorized as part of the agreed research. A copy of the correspondence to be sent to i-Share cohort participants must be transmitted to the i-Share cohort coordination team for approval before sending.

3.2.2 Period of exclusive use of the data collected in an ancillary study

The data directly collected by ancillary study researchers is exploited and stored under their responsibility for a fixed period of exclusive use of 12 months (this duration may be discussed with the lead research coordinator of the cohort).

For the purposes of backup and archiving, a copy of the data files collected by the lead researcher of the ancillary study, accompanied by adequate documentation (data catalog based on the i-Share model), must be sent to the i-Share cohort coordination team as the data is consolidated. The i-Share cohort coordination team will not exploit this data during the period of exclusive use, nor transmit it to anyone whatsoever without the formal agreement of the ancillary study lead researcher.

At the end of the exclusive use period, the lead researcher of the ancillary study agrees to transfer the data, accompanied by adequate documentation, to the cohort team and make them available for any future collaboration. After the transfer, the lead researcher who collected the data renounces all rights to the data. They will however be offered the opportunity to be associated with any scientific development relating to the results of any future analyses based on the data collected in the ancillary

study. The lead research coordinator of the i-Share cohort may choose not to include this data in the i-Share database for quality reasons.

3.2.3 Data confidentiality and security

The data collected as part of an ancillary study may include personal data as defined by the French data protection directive 95/46/CE, law no. 78-18, amended, of January 6 1978 on information technology and civil liberties and other applicable French regulations, referred to hereinafter as personal data protection regulations.

The lead researcher of the ancillary study agrees to comply with personal data protection regulations when carrying out the ancillary study, when writing reports, and when storing records relating to this study.

Before the commencement of the study, the lead researcher of the ancillary study agrees to implement all necessary measures to ensure the confidentiality, protection and security of the personal data collected or processed during the ancillary study, in accordance with applicable regulations.

The lead researcher of the ancillary study ensures that no data contains or constitutes directly identifiable personal data as defined by the data protection directive 95/46/CE, as transposed into French law by law no. 78-18, amended, of January 6 1978 on information technology and civil liberties, and/or any applicable regulations.

It is the responsibility of each ancillary study lead researcher to ensure the technical security and confidentiality of data, and to specify the measures taken to avoid direct or indirect identification of subjects, in accordance with Commission Nationale Informatique & Libertés (CNIL) recommendations.

4. MONITORING OF ANCILLARY STUDIES

The ancillary study lead researcher must provide regular progress reports on the ancillary study to the i-Share cohort coordination team.

Likewise, the operational project manager of the cohort must send a progress report on the cohort to the lead research of the ancillary study. They will also provide progress reports on the implementation of tools and the performance of project tasks which are the responsibility of the cohort coordination team and the ancillary study data when managed by the coordination team.

The regularity of these reports is defined by the two teams in the ancillary study quality plan (ENR-EA-PQUAL).

5. SCIENTIFIC RESPONSIBILITIES

5.1 Scientific responsibility of the i-Share cohort coordination team

The i-Share cohort lead research coordinator and coordination team hold the intellectual property rights for the design and implementation of the i-Share cohort, and the formulation of the scientific hypotheses which facilitated its establishment and continuation. They are responsible for the

procedures for creating the various digital, biological, and morphological databases and their use for research purposes.

5.2 Scientific responsibility of the lead researcher of the ancillary study

The lead researcher of the ancillary study is responsible for the ancillary study tasks list in the quality plan for the study. This could be the collection of additional data, statistical data analysis, scientific publication and dissemination of results.

The lead researcher of the ancillary study agrees to provide the lead research coordinator of the i-Share cohort with everything needed to judge the quality of the data collected, the analyses carried out, and promotion and communication documents.

The executive committee may choose to repeat the analyses carried out by the ancillary team at the request of a third party or of their own volition. The lead researcher of the ancillary study agrees to facilitate these re-analyses, such as by the transfer of analysis programs.

6. COMMUNICATION AND PROMOTION POLICY

6.1 Communication

In this charter, the term "communication" refers to the dissemination of information concerning an ancillary study for promotional purposes, including posters, leaflets, booklets, etc.

The lead researcher of the ancillary study must inform the i-Share cohort coordination team of any communication relating to the ancillary study prior to any such communication.

Any communication relating to an ancillary study will be subject to the i-Share cohort graphics charter.

The lead researcher of the ancillary study is also informed of the content of any communication materials regarding their ancillary study by the cohort project communications manager.

6.2 i-Share cohort website

Information regarding the managers of the cohort ancillary studies may be published on the i-Share cohort website. This information relates to the project (title, description, keyword, publications, etc.) and also the name and contact details of the researchers. Under the terms of the information technology and civil liberties law, the managers of ancillary studies have a right to access, modify, correct and remove information concerning them.

6.3 Publication of research results

6.3.1 Scientific publications

The rules of the publications below must be applied by any team or person with access to i-Share cohort data.

The executive committee is responsible for monitoring the proper application of these rules. It may, by consensus, authorize several exceptions. Furthermore, due to the time required for the

publication of all results from the cohort, certain rules may change in future years. Any modification will be subject to decision by the executive committee.

1. The publication procedure must comply with the agreements signed with the various i-Share cohort partners. This rule, as for some of the following rules, applies not only to publications involving multiple centers, but also to those based on data which would only have been collected by one center.

2. Any internal dispute over publications will be resolved by the executive committee. An internal dispute is a dispute between i-Share study teams, as opposed to a dispute between i-Share and one of its partners, which must be settled according to the procedure defined in the corresponding agreement.

3. Care will be taken to limit the number of authors. The note "on behalf of the i-Share study group" must feature after the list of authors. Some major publications may also feature "The i-Share Study Group" without a list of named authors. In these cases, the composition of the study group (and the composition of the "Writing Committee") must feature at the end of the article, before the list of participating researchers.

4. As with any large, multi-center study, each article has an appendix listing the participating researchers.

5. If possible, the name of the study must appear in the article title, potentially associated with the name of a center (e.g. i-Share-Bordeaux) for articles concerning i-Share data gathered by a single center.

6. In the case of collaboration between teams or disciplines, and if at least two teams were involved in writing the paper, the first and last author must not, if possible, belong to the same team or the same discipline.

7. The lead researchers responsible for coordination in the two founding universities of the i-Share cohort (D. Guillemot for UVSQ-Paris, C. Tzourio for Bordeaux) are co-signatories for all articles using data collected by their university. They may be replaced by a person from their team designated by them, depending on the theme. At the recommendation of the executive committee, this rule may be extended to cover other universities which have recruited a large number of participants.

8. The lead researchers responsible for the "Biobank and genetics" (S. Debette) and "MRi" (B. Mazoyer) technical platforms are co-signatories for all articles using data from these platforms. They may be replaced by a person from their team designated by them. At the recommendation of the executive committee, this rule may be extended to cover other technical platforms.

9. All the previous rules apply as long as new rules have not been defined and adopted by the executive committee.

6.3.2 Acknowledgments

Acknowledgments regarding i-Share must feature in the acknowledgments section of any article concerning data from the study. They must always mention funding by "Investissements d'avenir". The current version is available to the lead researchers of ancillary studies by the coordination team.

6.4 Dissemination to cohort participants and the public

In collaboration with the i-Share team, the lead researcher of the ancillary study is required to prepare documentation designed for the dissemination of results to cohort participants, and for a medical and non-medical public audience, including through the i-Share study website. At the request of the i-Share cohort managers, they may also be required to present the progress and results of their work when researchers gather at the annual scientific meetings of the i-Share cohort.

Declaration of acceptance of the operating procedures for ancillary studies of the i-Share cohort

I the undersigned, ...*Last name and first name of the ancillary study lead researcher*

Declare, as part of the project for which I am responsible, entitled:

Title	
Acronym	

□ Having read the i-Share cohort ancillary studies charter

□ Agree to abide by it

□ Agree to maintain the confidentiality of all i-Share cohort information transmitted to me

□ Agree to comply with research regulations (public health code, Jardé law) and personal data protection regulations (CNIL)

I accept that information on the title of the ancillary study, accompanied by my name, will appear on the cohort website (tick the corresponding box of your choice):

□ Yes □ No

Signed at ..... On.....

Signature

APPENDIX 1: Types of ancillary study

	Type of ancillary study (AS)	Project submission	Data collection	Data management	Analysis	Regulatory framework
❶	**AS of existing data**	Yes	NA	Transfer of cohort data ► AS	By AS Defined in the project	Research not involving humans (French INDS + CNIL)
❷	**AS with additional data from questionnaires or interviews**	Yes	**2a** Collection of data included in the cohort	By cohort	By AS By the cohort By both	Compliance with the cohort framework (non-interventional)
		Yes	**2b** Collection of data outside the cohort carried out directly by AS	By AS according to the methods defined in the cohort Transfer of cohort AS ► cohort	By AS By the cohort By both	According to questionnaire type: - non-interventional - intervention with minimal risk
❸	**AS with interventional research**	Yes	Collection of data outside the cohort carried out directly by AS	By AS according to the methods defined in the cohort Transfer of cohort AS ► cohort	By AS By the cohort By both	Interventional research
❹	**AS on biological samples**	Yes	**4a** Collection of additional data from existing samples	By AS Transfer of cohort AS ► cohort	By AS By the cohort By both	Evaluation of change of purpose
		Yes	**4b** Collection of additional data from new samples			Depending on samples: - Interventional research - Intervention with minimal risk