Constances charter

This document sets forth the rights and responsibilities of the research teams authorized to access the Constances cohort. It reviews the institutional environment of Constances and its governing bodies and then specifies the stages and requirements of research projects associated with the cohort. Access to Constances includes a declaration of acceptance of the operating rules detailed in this document.

- Procedures for project selection
- Conditions for using cohort data
- Procedures for the collection and use of and access to data collected in additional investigations
- Funding of research projects associated with the cohort
- Scientific responsibilities
- Data protection
- Dissemination of research results

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FOREWORDS

The Constances project is conducted as a partnership between the National health insurance fund (Caisse nationale d'assurance maladie, Cnam) and its Health screening centres (HSC), the National old-age insurance fund (Caisse nationale d'assurance vieillesse, Cnav), the National institute of health and medical research (Institut national de la santé et de la recherche médicale, Inserm) and Paris Cité University, Paris-Saclay University, Versailles Saint-Quentin-en-Yvelines University, and supported by the French ministry of health. The cohort is implemented and conducted by the *« Epidemiological Population Cohorts Unit »* (UMS 11). The directors of this Unit are the scientific and technical leads of Constances, hereafter referred to as the Constances principal investigators (PIs). The team responsible for implementing the cohort is known as the 'Constances team'. The Constances data controller, with regard to the French data protection act, is Inserm.

Since 2012, Constances has been certified as a 'National infrastructure for biology and health' as part of the Investments for the future program and, as such, receives funding from the French national Research Agency. Since 2020, Constances has benefited from a public service subsidy awarded by the Ministry of Research (programme 172). The sampling methodology used by Constances has been awarded the Label of general interest and statistical quality by the National council for statistical information (Cnis). Constances has also established public-private partnerships, set up by Inserm Transfert and managed by Inserm, with companies and start-ups in the health and well-being sector.

This Charter has been approved by the Constances Institutional steering committee and forms an integral part of the consortium agreement between the partners.

RULES FOR OPENING THE CONSTANCES COHORT

1 GOVERNANCE OF THE CONSTANCES COHORT

The governing bodies of the Constances[1] cohort are the International scientific committee (ISC) and the Institutional steering committee which brings together the Constances cohort's partner institutions. Their operating procedures are defined by a consortium agreement.

2 SCOPE OF THE CONSTANCES COHORT

The Constances general-purpose cohort is intended to serve as an epidemiological research infrastructure open to the health research and public health studies. Its use is therefore restricted exclusively to work of interest for biomedical research and / or public health.

The Constances cohort is an observational study, and has received legal and regulatory authorizations for this type of study and research. Interventional studies are therefore excluded a priori from the scope of the Constances cohort.

3 PROCEDURES FOR RESEARCH PROJECTS ASSOCIATED WITH THE CONSTANCES COHORT

3.1 ELIGIBLE ACCESS REQUESTS

The procedures described in this document concern French and foreign research teams as well as organizations in the field of public health who wish to use the Constances cohort. After an initial discussion with the Constances PIs, they must submit an application for each project of their projects, via an online system[2]. It may involve the use of available data as well as the biological materials collected, and/or the collection of additional data for a specific objective.

Broad research programs or projects involving very long-term monitoring must be the subject of several access requests, each addressing a specific and clearly defined primary objective (or purpose of personal data processing).

Special case: National bodies responsible for public health or social protection missions are also entitled, as part of their remit, to rely on Constances for their own needs. The procedures for accessing data applicable to these bodies are defined in section 3.9.

[1] https://www.constances.fr/en/scientific-area/international-scientific-committee-2/
[2] https://www.constances.fr/en/scientific-area/access-to-constances-2/

3.2 SELECTION OF RESEARCH PROJECTS BY GOVERNING BODIES OF THE CONSTANCES COHORT

It includes the following steps:

1 - Receipt of requests for access to Constances by the scientific secretariat of the Constances team. It checks that each file is complete and correctly filled in.

2 - Technical and scientific evaluation of applications by the Constances team and the ISC. This covers the following aspects: authorized purposes, feasibility of the project with Constances data, accuracy and scope of objectives, consistency of the protocol and minimization of the data requested, permanent status of the person in charge, financing arrangements, etc.

If the project has already been the subject of a scientific evaluation by a public body or a non-profit research foundation, the opinion of the scientific body that examined the project must be attached to the application; the ISC of Constances does not carry out a new scientific evaluation (except in the case of additional data collection and/or access to the Constances biobank), but it takes into account various criteria such as compatibility with the general objectives of Constances, consistency with any projects already in progress, etc. If incompatibility is identified, the project will be rejected.

Particular attention is paid to projects involving the collection of additional data and/or access to the Constances biobank, in order to verify that they are of major scientific interest and that the planned collection procedures comply with current recommendations and state-of-the-art practices.

If the project involves collecting additional data, the complementarity with already available data and the need to contact volunteers will be assessed to avoid excessively frequent contact with participants (see point 3.7). Where applicable, the questionnaire is reviewed and, if the project is accepted, the Constances team provides support for the operational implementation of the collection and validates both the information provided to the volunteers in the cohort (collection documents) and the schedule for implementing the collection.

If the project involves access to samples from the biobank, given the "non-reusable" nature of this material, the quantities and qualities requested are assessed so that only the samples strictly necessary for the achievement of the validated project objectives are made available.

Important note

The ISC may reject a project even if it has been funded (ANR, Europe, etc.). It is advisable to contact the Constances PIs before submitting any funding application.

3 - For projects that require it, the Inserm Ethics committee may be consulted.

4 - For projects accepted by the ISC, the scientific evaluation and, where applicable, the opinion of the Ethics committee shall be forwarded to the Institutional steering committee. The Cnam and Cnav may employ a right of refusal, giving reasons, on the provision of data from the databases they manage.

3.3 LEGAL AUTHORIZATIONS

Constances personal data become accessible once the legal and regulatory formalities have been completed by the project Principal Investigator (PI, in conjunction with their affiliated organization, the project data controller).

Important note

It is essential to obtain the favorable opinion of the ISC before initiating legal and regulatory formalities. Otherwise, the Constances team will not make any data available.

3.4 DATA PROTECTION

It is the responsibility of each project data controller to ensure data security and confidentiality, and to take all precautions to prevent the direct or indirect identification of volunteers in accordance with the GDPR.

Important note

From October 2025, data for projects accepted by the ISC are available in a highly secure bubble at the CASD (Centre d'accès sécurisé aux données[3](Secure Data Access Center)).

The teams responsible must enter into a contract directly with the CASD, and access to the data is subject to verification by the CASD of the following:

1. a formal contract between the team responsible for the project and the CASD;
2. validation of the project by the Data Protection Officer of the project's data controller, where applicable, by the Cnil;
3. confirmation by the Constances team of the project's validation by the ISC, including in particular the definition of the authorization period and its duration.

This infrastructure complies with the SNDS Security Reference Framework, as defined by the decree of 22 March 2017 and updated by the decree of 6 May 2024.

3.5 FORMALIZATION OF THE COLLABORATION

The specific terms and conditions of the collaboration between the Constances cohort team and the project PI are formalized in a contractual document that specifies the following points in particular:

- Commitments of the parties;
- Terms and conditions for the provision of data;
- Financial clauses;
- Intellectual property;
- Publication and communication of results;
- Confidentiality clauses;
- Project duration and contract term;
- Project monitoring procedures, including the possibility of the project PI terminating the project before it is completed and, where applicable, the obligation to transmit any additional data collected by the project PI to Constances;
- Where relevant, clauses concerning additional data collected as part of the project, including in particular the conditions for making it available to the Constances team, the format of the documentation that must accompany it, the definition of the period of exclusive use after the end of data collection, intellectual property and results rights, the conditions for their reuse by other projects within the Constances infrastructure (see 3.7);
- Appendices: declaration of acceptance of the rules of operation of the Constances infrastructure (Constances Charter) signed by the project PI, project research protocol (including the identity of the project PI, the definition of the sample concerned, the categories of data authorized, the duration of the project, and data protection procedures) as assessed by the ISC, favorable opinion of the ISC, legal and regulatory opinions and authorizations.

[3] https://www.casd.eu/en/

3.6 Access to Constances: research projects requiring only data already available in the Constances database

3.6.1 General case

Subject to legal and regulatory provisions, the favorable opinion of the ISC and the non-opposition of the Institutional steering committee all data may be made available to researchers. The Constances team prepares, in collaboration with the project PI, the selected data and makes it available in the most appropriate form according to the technical possibilities at the time.

Analyzes must only cover what has been described in the research protocol evaluated and accepted by the Constances ISC and then by the bodies involved in the legal and regulatory processes. Consequently, only data included in this protocol may be requested from the Constances team. In the event of an extension of the initial project, a new request must be submitted to the Constances governance bodies and new legal and regulatory formalities must be completed; an amendment to the initial contractual document must be drawn up.

Only those responsible for an approved project are authorized to request data from the Constances team, unless explicit prior agreement has been given. The access to Constances data to any person other than those specified in the access request is prohibited.

At the end of the study, access to data within the CASD is closed. In accordance with the agreements concluded with the CASD, the latter is authorized, in particular at the request of the Cnil, the Constances governance bodies or the Constances PIs, to carry out any checks to verify compliance with contractual commitments and regulatory requirements, in particular the processing of data made available exclusively for the stated and authorized research objectives, as well as the prohibition of any extraction of individual data outside the secure environment.

3.6.2 Particular case of DNA access requests

Projects that use this type of data must comply with legal and regulatory provisions applicable at the request for access.

3.6.3 Fast-track procedure

If the project corresponds to a request from the health authorities that requires rapid completion, the ISC and Institutional steering committee of Constances are informed and possibly consulted. The response time is defined in conjunction with the Constances PIs at the time of referral to the said committees.

3.7 Access to Constances: research projects requiring the collection of additional data

3.7.1 Methods for collecting and storing additional data

Beyond the data routinely collected by the Constances team for the cohort's core activities, additional data may be collected by the PI of an approved research project. Such data collection may involve the administration of specific questionnaires to volunteers in the Constances cohort or any other methods authorized by the relevant regulatory authorities (CESREES/Cnil, CPP, etc.), subject to the consent of the volunteers concerned. If the research project entails direct interaction with Constances cohort volunteers beyond questionnaires (interview, clinical examination, etc.), the operational procedures governing such interactions must be precisely defined in the submitted access request file.

The possibility of collecting additional data from Constances volunteers is assessed by the ISC on the basis of scientific and financial criteria and the additional burden placed on volunteers and the Constances team, taking into account the overall functioning of the cohort.

Important notes

It is essential to contact the Constances team before submitting an access request involving the collection of additional data.

Any medium used to collect additional data (questionnaire or other) must be validated by the Constances PIs and the ISC as part of the project review process.

Once the project has been approved:

• No information other than that explicitly described in the approved project may be requested from volunteers in the Constances cohort.

• All collection documents (requests, reminders, information notes, etc.) sent to volunteers in the Constances cohort must be previously submitted to the Constances team for approval. Correspondences are co-signed by the Constances PIs and the project PI.

• The ISC may refuse a project involving additional data collection, even if it has been funded (ANR, Europe, etc.). It is recommended that you contact the Constances PIs before submitting any funding application.

During the collection period, additional data collected directly by the project PI is stored under his or her responsibility. After a period of exclusive use of this data, the project PI agrees to accept its integration into the Constances database, in a usable form and accompanied by adequate documentation. Constances PIs may decide to waive this requirement for reasons related to data quality. The rights to additional data collected directly by the project PI, in particular intellectual property rights, and the duration of the period of exclusive use are specified in the contractual document referred to in point 3.5.

3.7.2 Access by other researchers to additional data collected as part of a project linked to the Constances cohort

One of the advantages of opening up the Constances cohort to the scientific community is the possibility of pooling data from different research projects supported by the cohort. Access to additional data collected by a project PI by other researchers who are themselves PIs of another project supported by Constances is therefore encouraged.

3.7.2.1 Use of additional data during the exclusive exploitation period

When a researcher wishes to use additional data that has been collected for a specific project by another team, an agreement must be sought between the teams concerned. If an agreement is reached, the requesting project PI must complete the legal and regulatory formalities in force and an agreement must be drawn up between the teams concerned, specifying in particular the data of interest, the purpose of their use, the method of provision, intellectual property rights and results; a copy of this document must be sent to the Constances PIs.

Once decisions have been made between project PIs, they must go through the Constances team because specific study numbers are assigned to the subjects included in each study, making it impossible to use individual data directly between projects.

3.7.2.2 Use of additional data transferred to the Constances team after the exclusive use period

After integration into the Constances database, the additional data can be used by all researchers according to the same rules as for data collected by the Constances team.

3.8 Access to Constances: research project requiring biological material from the biobank

The person responsible for an approved project requiring biological samples must prior to their transfer from the Constances biobank, complete all applicable legal and regulatory requirement as well as the specific contractual procedures governing the use of such material.

At the end of the project, they must:

- Complete, at the request of the Constances team, a questionnaire on the management of the biological samples transferred, specifying in particular the number of samples used, the average volume per aliquot used, their storage conditions, any incidents/accidents that may have occurred, where applicable, the availability of any remaining samples, their storage conditions and their availability for use in another Constances-backed project, information on the analyses carried out and the data produced.

Please note: In the event of a significant volume of remaining samples, cryotubes must be refrozen at -80°C and stored in the applicant's analysis laboratory. Constances PIs may request their transfer according to a protocol to be defined.

- Send the Constances team the data related to the sample analysis results in a usable format (accompanied by a dictionary of variables and documentation specifying, among other things, the analysis methods used).

Please note: The data transmitted becomes accessible to other researchers under the same conditions as those applying to data from additional collections (in point 3.7.2).

3.9 Access to Constances by national bodies responsible for public health or social protection

National bodies responsible for public health or social protection missions, in particular the Cnam, the Cnav, the DREES, the DGS, Santé publique France, other public health agencies or institutions such as the Court of Auditors, may, as part of their missions, access the Constances cohort according to a specific procedure and within the framework of an agreement with Inserm, in conjunction with the cohort PIs.

3.10 Funding for projects supported by the Constances cohort

The implementation of a project using the Constances infrastructure requires a financial contribution from its PI to cover the costs of access to Constances and the services provided the Constances team.

3.10.1 Academic team projects with solely public funding

The costs of accessing Constances and the work carried out by the Constances team to provide data to the project PI are specified in the contractual document referred to in point 3.5. The amount of this contribution is determined in consultation between the project PI and the Constances PIs.

The costs associated with implementing a research project (access to CASD, data analysis, open access publications, collection of additional data, etc.) are borne by the project PI.

The Constances team can provide support in obtaining funding from other sources.

Important notes

An application for funding may not be submitted to funding agencies without prior contact with, and approval from, the Constances PIs, who may, if appropriate, provide a support letter to be included in the application.

Any application to funding agencies must cover at least the costs of access to Constances and the services provided by the Constances team, data hosting and processing at CASD, open access publication of results and, where applicable, the costs of collecting additional data and/or accessing samples from the Constances biobank.

3.10.2 Projects with funding from private for-profit organizations

Projects with funding from private for-profit organizations are subject to specific management rules handled by Inserm Transfert.

Any funding (pending or obtained) from a private for-profit organization, or from an organization funded by a private for-profit organization, must be reported and described in detail in the application for access to Constances, whether proposed by an academic or private team. This also applies throughout the duration of the project.

A request for funding of this type cannot be made without first contacting and obtaining the agreement of the Constances PIs.

4 SCIENTIFIC RESPONSIBILITIES AND DISSEMINATION OF RESEARCH RESULTS

4.1 SCIENTIFIC RESPONSIBILITY OF THE CONSTANCES TEAM

Constances PIs are responsible for the quality of the data collected. The quality assurance protocol and the procedures for implementation and management of the database are to be made available on request.

4.2 SCIENTIFIC RESPONSIBILITY OF RESEARCH PROJECT PI

In accordance with good epidemiological practice, the project PI is responsible for the processing and analysis of the Constances data transmitted and, where applicable, any additional data collected. The same applies to scientific publications and any dissemination of results. Furthermore, in the event of additional data being collected, the person responsible for this data undertakes to comply with the best practices recommended by international learned societies, where these exist, and to provide the Constances PIs with all the information necessary to assess the quality of the data collected and decide whether this data can be included in the Constances database.

4.3 SCIENTIFIC INTEGRITY

The person responsible for a project supported by the Constances cohort agrees to comply with the ethical requirements established by the relevant national and institutional committees overseeing human research, as well as the Declaration of Helsinki (1964-2024). They also certify that adherence to the European Code of Conduct for Research Integrity[4]. For the sake of transparency, the methods employed should be documented to ensure scientific reproducibility and to enable evaluation by the ISC.

Authors of scientific publications based on the Constances cohort adhere to recommendations regarding transparency in the reporting of their work[5], the attribution of scientific authorship[6], and the transparent disclosure of conflicts of interest. They commit to exercising vigilance to avoid publication in predatory journals and to promoting the principles of open science by sharing, to the extent possible, their research protocols and analysis codes.

4.4 ARTIFICIAL INTELLIGENCE

The use of artificial intelligence methods, including but not limited to machine learning, deep learning, generative modelling and natural language processing techniques, is authorized within the framework of projects validated by Constances' governing bodies, subject to compliance with the following principles:

- Scientific purpose: artificial intelligence methods must be used exclusively for purposes that are validated and consistent with the cohort's field of use. Any use aimed at training generic models that can be reused outside the scope of the project, building commercial systems or feeding third-party databases is strictly prohibited, unless specifically agreed in writing.

- Data protection and minimization: models, scripts or systems developed must be designed in such a way as to avoid any direct or indirect re-identification of cohort volunteers. No individual information may be transmitted to external services, artificial intelligence platforms hosted in a public cloud or a commercial Application programming interface (API). Processing must strictly comply with the secure environment provided.

- Controlled dissemination: models or representations generated from Constances data may only be disseminated, shared or published if they do not in any way allow the individual data of cohort volunteers to be reconstructed, inferred or identified. Any dissemination of these derivative elements must be approved by the Constances team, which reserves the right to prohibit it.

- Destruction of sensitive derivatives: at the end of the project, in addition to the source data, any derivative representation likely to contain sensitive information must be destroyed (at the request of the

[4] https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf
[5] https://www.equator-network.org
[6] http://www.icmje.org

Constances team and depending on the data hosting environment, a destruction report must be sent). Only elements explicitly authorized by Constances and which cannot be re-identified may be retained.

4.5 DISSEMINATION OF RESEARCH RESULTS

All the rules to be followed are available on the Constances website:

- In French on the page: Vous allez publier[7].
- In English on the page: You're about to publish[8].

4.5.1 Scientific publications

The research results obtained using data provided as part of a project must be made public in the form of scientific publications, communications, reports, theses or dissertations, etc. Where applicable, a confidentiality period for the results may be specified in the contractual agreement formalizing the specific terms of the collaboration between the Constances team and the project PI.

The project PI may publish the results obtained for scientific information purposes in any form they deem appropriate, under their sole responsibility, taking into account the usual ethical rules in this area.

The project PI is required to provide the Constances PIs with a copy of the manuscripts at the time of submission; the latter may request the inclusion in the manuscript of a statement disclaiming responsibility for the analysis of the data or the interpretation of the results.

Due to the scientific and technical contribution of the Constances team to projects using cohort data, at least two members of the team must be named in scientific publications or communications resulting from research projects, in accordance with the usual rules in the field of scientific research; these terms and conditions are specified on a case-by-case basis between the project PI and the Constances PIs.

Any scientific publication or communication must mention that the research was carried out as part of the Constances cohort, and the word "Constances" must appear in the title or at least in the abstract of any publication. Similarly, the DOI: doi.org/10.13143/inserm_constances must be explicitly stated, both as a reference in the methodology section and in the acknowledgements of the publication.

After publication, the project PI is required to provide the Constances PIs with a copy of any publications, communications, scientific and technical reports resulting from their project.

Important notes

Publications in scientific journals should be Open Access whenever possible.

Under French law, articles must be deposited in an open archive if the research from which they originate is at least half publicly funded. Research organizations and French universities use the HAL infrastructure[9].

European law also requires articles to be published in an open archive if at least half the research is financed by European funds.

4.5.2 Acknowledgements and Funding

Acknowledgements and funding information for Constances are available on the Constances website.

Acknowledgements naming the researchers who contributed to the development of the Constances cohort's scientific protocol may also be added, depending on the data used in the research project. Where applicable, the specific role of one or more other partners may be specified.

[7] https://www.constances.fr/espace-scientifique/vous-allez-publier/
[8] https://www.constances.fr/en/scientific-area/youre-about-to-publish/
[9] https://hal.science/

4.5.3 Standard reference to the Constances project

Any publication must cite at least one of the methodological articles describing the study protocol published by the Constances team. The references to be cited are available on the Constances website.

4.5.4 Dissemination to cohort volunteers and the public

At the request of Constances PIs, project PIs are required to work with the Constances team to prepare documentation for the dissemination of results to cohort volunteers and to medical and non-medical audiences, in particular via the website, the newsletter and the information journal sent annually to Constances cohort volunteers. They are also required to present the progress and results of their work at the annual Constances Scientific Days.

Important note

The results may not be used for advertising or commercial purposes by the project PI or any financial partners without the prior written consent of the Constances PIs, following consultation with the Constances governing bodies.

4.5.5 Constances transparency portal

Certain information regarding the PI responsible for a cohort-based project is published on the Transparency Portal of the Constances website, including their name and affiliation. In addition, information related to the project[10] (title, objectives, summary, publications[11], legal and regulatory status, and associated scientific outputs) is also made publicly available on the Constances transparency website.

4.6 BREACHES

Any dispute regarding the interpretation, validity, or execution of this Charter, or the contractual documents arising therefrom, shall first be subject to an attempt at amicable resolution between the project PI and the Constances PIs.

If no amicable agreement can be reached within a reasonable period of time, the dispute may, depending on its nature, be submitted, to the cohort's governing bodies (ISC, Institutional steering committee) or to the Inserm Ethics Committee, which will decide on the matter, taking into account the general interest of the infrastructure and compliance with scientific, ethical and regulatory requirements.

In the event of a breach of these requirements or the provisions of this Charter, authorization to access the data may be temporarily or permanently suspended. Access to the data will then be immediately blocked by the CASD at the request of the Constances team or the governance bodies. Furthermore, any serious violation of the principles of scientific integrity may be formally reported to the editors of the scientific journals in which the relevant results have been published or submitted.

[10] https://www.constances.fr/espace-scientifique/recherche-et-etudes/
[11] https://www.constances.fr/espace-scientifique/publications-scientifiques/

CONSTANCES
UMS 011 EPIDEMIOLOGICAL POPULATION COHORTS UNIT