CONSTANCES CHARTER

This document sets forth the rights and responsibilities of the research teams associated with 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.

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

PROCEDURES FOR ACCESS BY THE SCIENTIFIC COMMUNITY

January 2018

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FOREWORDS

The CONSTANCES project is conducted as a partnership between the National Health Insurance Fund (Caisse nationale d'assurance maladie, CNAMTS) 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 the University of Saint Quentin en Yvelines (Université de Saint Quentin en Yvelines, UVSQ), and supported by the Ministry of Health (Direction générale de la santé). The cohort is implemented and conducted by the "Population-based Epidemiologic Cohorts Unit", a joint INSERM-UVSQ Unit. The head of this Unit is the scientific and technical Director of Constances.

The Constances Cohort Study was supported and funded by the Caisse nationale d'assurance maladie des travailleurs salariés (CNAMTS). It also received a financial support from the Ministry of Health, the Council of the Ile de France Region, and by the Cohorts TGIR IReSP-ISP INSERM. The Constances Cohort Study is currently supported by the Investments of the Future governmental program as an « Infrastructure nationale en Biologie et Santé » and benefits from a grant from ANR (ANR-11-INBS-0002). It is also partly funded by MSD, AstraZeneca and Lundbeck.

PROCEDURES FOR ACCESS BY THE SCIENTIFIC COMMUNITY TO THE CONSTANCES COHORT

1 GOVERNANCE OF THE CONSTANCES COHORT

The governing bodies of the Constances cohort are the International Scientific Committee (ISC) and the Institutional Steering Committee which brings together all of the institutions that supports the Constances cohort. Operational 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 health 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 thus excluded from the scope of the Constances cohort.

3 PROCEDURES FOR RESEARCH PROJECTS ASSOCIATED WITH THE CONSTANCES COHORT

3.1 ACCESS REQUESTS

3.1.1 General principles

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. All research teams, French or foreign, that wish to use the Constances cohort must submit an application to the cohort Director. It may involve the use of available data as well as the biological materials collected, and/or the collection of supplementary data for a specific objective. Requests for access to Constances data are made in the framework of a widely circulated call for proposals (CFP).

3.1.2 Application deadline

The call for proposals is permanent. The ISC holds two sessions a year, usually in May and November. For a project to be reviewed by the ISC at one of its sessions, it must be deposited with the cohort Director at least 5 months before the session.

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

3.2.1 Types of projects

Proposals may be about “independent” or “consortium” projects.

- An independent project is a project with well-defined objectives and methods, concerning a sample of participants selected on the basis of specific criteria and using a limited and justified set of data to answer a specific research question. They can be proposed by a single research

group or by several associated teams. In both cases, the Principal Investigator is the contact person for Constances.

- A consortium project is a cluster of a limited number of research projects (workpackage) on a common well-defined scientific area and associating several teams under the responsibility of a coordinator. Each of the projects has its own objectives and methodology and concerns a sample of participants selected on the basis of specific criteria and using a limited and justified set of data to answer its specific research questions. Each research team heads by a Principal Investigator. The coordinator is the contact person for Constances.

An application describing the scientific and methodological aspects of the project, its potential implications in terms of confidentiality, ethics and good professional practices, as well as its funding, must be submitted to the Constances cohort Director. This application will include a preliminary study schedule, from its beginning. The Call for Projects can be downloaded from the Constances website (www.constances.fr).

3.2.2 Examination of the application

It includes the following steps:

1. Research proposals receipt by the Constances' Scientific Secretariat. It controls that proposals are curate and complete;

2. Technical examination by the Constances cohort team (of feasibility, confidentiality, consistency, etc.). The conclusions of the technical examination of the application are transmitted to the International Scientific Committee. If the project plans for the collection of supplementary data, special attention will be paid to the procedures for its collection, their compliance with existing guidelines and their complementarity with already recorded data and to the procedures for contacting cohort's participants. Where appropriate, the Constances team will provide technical support for setting up the project.

3. Scientific and methodological quality evaluation by the International Scientific Committee. The evaluation criteria and procedures are explained in the appendix to the document: "Evaluation of Requests for Access to Data or Material or Subjects". 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 which examined the project must be attached to the application. The ISC de Constances does not carry out a new scientific evaluation, but it takes into account various criteria such as compatibility with the general objectives of Constances, coherence with possible projects already underway, burden for the participants, etc. These points are specified in the attached document.

4. If needed the application may be transmitted to the INSERM Ethics Committee for its advice.

5. The evaluation of the International Scientific Committee is transmitted to the Institutional Steering Committee and, when appropriate, with the advice of the Ethics Committee.

Important note: CNAMTS and CNAV may refuse to allow the data coming from their own databases (SNIIRAM and SNGC) to be transmitted for a project; if that happens, they motivate their refusal.

3.3 LEGAL AUTHORIZATIONS

Personal data used in health research: Constances data will only be accessible once the legal and regulatory formalities have been carried out by the person in charge of the project. The Constances team can help the investigators to complete the legal and regulatory procedures.

Important note: *it is essential to obtain the consent of the cohort Director prior to any step. In addition, the Constances team will not provide the data requested if the realization of these legal and regulatory formalities has not been made in connection with it.*

Ethics: if the project includes items that might require the opinion of an Ethics Committee or of a "Committee for the Protection of Persons Involved in Biomedical Research-CPP", the applicant must request this Committee's approval and attach it to the application. If genetic data is to be transferred, authorization by the specific competent authorities must be obtained in advance and attached to the application.

3.4 DATA PROTECTION

It is the responsibility of the Constances Director and of each research project director to ensure the technical security of the data and compliance with confidentiality and to enumerate the precautions taken to avoid the direct or indirect identification of participants.

Important note: *if the project requires data from the National Health Data System (SNDS), a statement of compliance with the SNDS Security Standard must be provided. If the data file is sent to more than one team, a statement of compliance with the SNDS Security Standard must be provided by each team involved*.

3.5 MEMORANDUM OF AGREEMENT

When a research project is accepted, the specific modalities of the collaboration between the Constances cohort team and the applicant team must be recorded in the form of a memorandum. The Memorandum must specify the following points, in particular:

- definition of the sample concerned;
- list of the variables to be transmitted (made available by the Constances team from a data catalogue);
- duration of the project, frequency and modalities of transfer (name and contact information of recipient);
- procedures for data protection;
- confidentiality clauses;
- exclusivity-of-use clauses (if pertinent);

- clauses concerning the provision of supplementary data collected as part of the proposal, including the format of the associated documentation and the exclusive-use period (if pertinent);
- modalities of project follow-up, including the possibility to stop the project before its planned ending by decision of the investigators, or of the governing bodies of the Constances cohort; a clause may imply compulsory transmission to the Constances Director of already collected data;
- modalities of communication of results;
- rules concerning publication;
- financial clauses;
- appendices: copy of legal and regulatory opinions and authorizations; copy of the decision of the Scientific Committee and, when appropriate, of the Ethics Committee; declaration of agreement to comply with the Constances Charter; if applicable, declaration of conformity to the SNDS Security Standard.

3.6 ACCESS TO DATA: RESEARCH PROJECTS SEEKING TO USE DATA AVAILABLE IN THE CONSTANCES DATABASE

3.6.1 General case

Subject to problems of confidentiality, ethics, professional practices, or property, all data collected by the Constances team and contained in the cohort database can be transmitted to researchers whose proposal has been accepted, except in the case of a specific contrary decision by the Constances International Scientific Committee, Ethics Committee or the Institutional Steering Committee. The Constances team will prepare, in collaboration with the requesting team, the data selected and supply them in the most appropriate form, as a function of the technical possibilities at the time.

Important note: *In the absence of an explicit prior agreement, only the director of the research project that seeks to use Constances cohort is authorized to request data from the cohort team*.

Analyzes must relate only to what has been described in the proposal for a research project evaluated by the Constances ISC and then by the bodies involved in the legal and regulatory processes. Therefore, only the data described in the application can be requested from the Constances team. In case of a major extension of the initial project, a new application must be filed and new legal and regulatory steps be taken.

The transfer of data supplied by the Constances team to any person other than those foreseen in the application is forbidden. At the conclusion of the study, the research project director must no longer use the data file supplied by the Constances team and have to destroy these data. The Constances Director may consent to the use of the data beyond the planned study end date if the delay was justified.

3.6.2 Particular case of genetic data

Because this type of data is governed by specific legal and regulatory provisions, projects intended to use it must comply with the specific conditions applicable at the time of application; in particular, it may be necessary to obtain written informed consent specific to this project, signed by the subjects concerned (or their

representative). The application must enumerate all measures taken to comply with these dispositions.

3.7 ACCESS TO DATA: RESEARCH PROJECTS INVOLVING THE COLLECTION OF SUPPLEMENTARY DATA

3.7.1 Modalities for the collection and safeguarding of the new data

Beyond the data collected by the Constances cohort team during normal cohort operations, supplementary data may be collected by investigators whose research projects are accepted. These data may be collected by questionnaires sent to participants either by the associated project investigator or included in the annual questionnaires sent by the Constances cohort team, or by any other method authorized by the competent authorities, with the agreement of the participants concerned. If the research project requires direct access (interview, examination, etc.) to cohort members, the operational aspects of this access must be defined in detail in the research project protocol.

Additional measures are evaluated by the Scientific Committee based on scientific value, financial considerations and assessment by Constances investigators of the burden to the participant and balance to the Constances cohort as a whole.

Important note: *it is necessary that projects that require additional data collection be discussed in a preliminary way with the Constances Director before proceeding to a full application. Any data collection medium (questionnaire or other) must be approved by the cohort Director prior to the completion of legal and regulatory formalities for authorization of the by the French data protection authority ("Commission nationale de l'informatique et des libertés-CNIL").*

In the case of such a need, all precautions concerning potential authorizations, confidentiality, ethics, and professional practices must be complied with and described in the application form.

No other information can be requested from cohort members other than that explicitly authorized as part of the accepted research project.

A copy of all correspondence to the cohort members must be transmitted before it is sent to the Constances cohort team for its approval.

These correspondences will be co-signed by the Director of Constances and the person in charge of the project.

Data specific to the associated research project team and collected directly by its investigators belong to it, and it is responsible for conserving it. Nonetheless, after an appropriate period of exclusive use after the end of collection of data (set by written agreement in the above-mentioned agreement memorandum), the investigator of the research project associated with the cohort agrees that the new data will be incorporated into the overall Constances database, in a usable form and accompanied by adequate documentation. During this data transfer, the investigator who has collected these new data shall renounces its rights of exclusive use. The Constances Director may decide to not include these data in the cohort database if there is some concern with their quality. Rights on additional data collected directly by the investigator, including intellectual property, are specified in the agreement memorandum cited in § 3.5.

The Constances cohort team may also regularly request a copy of the data files collected by the investigator, accompanied by adequate documentation **for the sole**

purpose of safeguarding and archiving it. The Constances team agrees not to use these data in any way and not to transmit them to anyone else without the formal agreement of the principal investigator of the associated research project during the exclusive-use period. The Constances team will have no role in the management of these data, and the principal investigators of the associated projects shall remain solely responsible for them.

3.7.2 Modalities of access by other researchers to supplementary data collected by investigators of other associated projects

One of the advantages of the openness of the Constances cohort to the scientific community is the possibility of mutualizing the data about cohort members from the different research projects associated with the cohort. Access by researchers managing a project within Constances to new data collected by the directors of other associated projects is therefore encouraged. The rules of access will differ depending on the specific case.

3.7.3 Data catalogue

Each director of a project involving the collection of specific data agrees to create at the start of the project and regularly update a data catalogue modelled on that of the Constances cohort. The Constances team is keeping a regularly updated catalogue of exterior data, organized by project, to facilitate links between researchers.

3.7.4 Use of the new data during the exclusive-use period by investigators of associated research projects:

Two different situations may occur.

- Requested data are **not original** (published scales or questionnaires used in the project). Again, there are two situations:

- Data were collected by the Constances team (usually through the annual questionnaire): in such a case, the Constances Director takes the decision after informing the investigators who first introduced these data. He may ask an advice from the International Scientific Committee or of the Ethics Committee.

- Data were collected by the investigator of the research project (funding, data entry and validation…): in such cases, the rules are the same as if data were original (see below).

- Requested data are **original** (questionnaire elaborated by the investigator, medical exams…): during the exclusive-use period, only the investigators of the associated projects can decide whether or not to transmit the original data they collected or about any other arrangements they might want between themselves and another team requesting access. When they agree, a document must be drawn up specifying the data to be transferred and their planned utilization. A copy of this document must be transmitted to the Constances Director. Once the project team directors have made the decisions about data transfers, these transfers must go through the Constances team, which can thus keep the status of all the cohort data up to date. The intermediary role of the Constances team is also made necessary by the system chosen to protect the

subjects' anonymity in the database (assignment of subject's study numbers specific to each project which makes it impossible to directly share individual data between projects).

In all cases when a project uses data provided by another teams, the researchers who provided the data must be acknowledged in the publications.

Important note: *the transfer of individual data between different projects cannot be done without legal and regulatory steps*.

3.7.5 Use of the new data transferred to the Constances cohort team after the exclusive-use period has expired

On transfer of these new data to the Constances team, the investigator who collected them renounces its rights of exclusive use. These data can then be used by all researchers, according to the rules set forth above.

3.8 FOLLOW-UP OF RESEARCH PROJECTS

Project progress reports must be supplied to the Constances team. The format and timing of these rapports are specified in the memorandum of agreement cited in § 3.5. They may be transmitted to the International Scientific Committee, which can when appropriate recommend that the project be cancelled. In the latter case, the Constances Director can ask the transmission of already collected data to the investigator for integration in the cohort's database; these data can then be used by any researcher according to the same rules as the data collected by the Constances team.

Important note: *projects planning a very long follow-up will be assessed again very 5 years by the Scientific Committee*.

3.9 FUNDING OF RESEARCH PROJECTS ASSOCIATED WITH THE CONSTANCES COHORT

The implementation of projects using the Constances infrastructure implies a financial participation for the following reasons: the current funding of the Infrastructure is insufficient to cover all the costs of setting up and operating the cohort, including the salary of paid staff by the infrastructure, and it is essential to find additional resources; the funding obtained does not include any budget line to cover the work involved in the opening of the cohort; the financing of Investments of the Future extends over a limited period, and the rule is that the Infrastructure must be self-financing at the end of the current contract, which implies a financial participation of its users.

3.9.1 Research projects from academics funded only by public agencies

The costs of the work performed by the Constances cohort team to provide data to the investigator are assessed on a case-by-case basis and enumerated in the document describing the modes of collaboration between it and the research project team, as mentioned in § 3.5.

The specific costs related to the research project (potential collection of additional data, data analysis, etc.) shall be borne by the associated research project.

Where appropriate, the Constances cohort team can provide methodological support for obtaining funding from other sources.

Important note: *applications to funding bodies must include the costs of the work performed by the Constances cohort team, and no application can be made without the written agreement of the Constances Director*.

3.9.2 Research projects funded by private companies

Any funding from a private for-profit organization, or supported by a private for-profit organization, must be reported and accurately described. This applies at the time of the initial application and throughout the implementation of the project, whether proposed by an academic or private team.

For research projects funded by private companies, proposed either by an academic or by a private group, specific rules have been established. **In these cases, it is necessary to contact the Constances Director before submitting an application.**

3.10 SCIENTIFIC RESPONSIBILITIES

3.10.1 Scientific responsibility of the Constances team

The Constances cohort team agrees to comply with the cohort protocol as validated by the International Scientific Committee and the CNIL; modifications of the protocol must be approved by the International Scientific Committee. The team is the intellectual property holder of the conception and execution of the basic structure as well as the formulation of the scientific hypotheses that made it possible to set up and follow up this cohort. The Constances Director and team are also responsible for the methods used to transport and store the biological materials collected and for their use solely for research purposes.

The Constances cohort Director and team are responsible from a scientific perspective for the quality of the data collected and for the verification of its consistency. The quality assurance protocol and the procedures for implementation and management of the database are to be made available to all research teams that so request.

3.10.2 Scientific responsibility of research project teams

The directors of the various research projects hold the intellectual property relative to their projects. They are responsible for the statistical treatment and analyses of these data, their scientific publication and all other dissemination of the results, in compliance with good epidemiological practices. In the case of supplementary data collection, the director of each research project undertakes to comply with the good practices recommendations of international learned societies, when these exist, and to provide to the Constances Director all the information needed to assess the quality of the data in order to decide whether they can be included in the Constances database. The ownership of the data and the results are determined in the memorandum of agreement cited in § 3.5.

3.11 DISSEMINATION OF RESEARCH RESULTS

3.11.1 Scientific publications

The results from the projects using Constances data must be made public through publication in scientific journals, reports, thesis, etc. If needed, a confidentiality period can be defined in the memorandum of agreement.

Directors of research project can publish their results and thus provide the scientific community with this information in any form they choose. They are entirely responsible for such publication and must take into account the standard professional practice rules in this area.

Directors of research projects are required to provide a copy of each manuscript to the Constances Director at the moment of its submission; the Constances Director can require the inclusion in the manuscript of a statement that she is not responsible for the data analysis or the interpretation of the results.

Because of the very substantial scientific and technical activity of the Constances team in the development and management of the cohort, the signature of at least one member of the team must appear in any scientific publication or communication from these research projects, in compliance with the standard rules, as set forth in the *Recommendations for Professional standards and good epidemiological practices (see 3.12 for the reference)*; these modalities shall be specified on a case-by-case basis between the project director and the Constances cohort Director.

A statement that the research was conducted in the Constances cohort must be included in every scientific publication or communication and the word "Constances" must appear in the title of every publication.

After publication, research project directors are required to provide to the Constances cohort a copy of all publications and reports resulting from the project.

3.11.2 Acknowledgements

The standard acknowledgements concerning Constances as follows:

> Acknowledgements: The authors thank the INSERM-Versailles Saint Quentin en Yvelines University *"Population-based Epidemiologic Cohorts Unit" (Cohortes épidémiologiques en population*) which designed and manages the Constances Cohort Study. They also thank the National Health Insurance Fund ("*Caisse nationale d'assurance maladie des travailleurs salaries*", CNAMTS) and its Health Screening Centres ("*Centres d'examens de santé*"), which are collecting a large part of the data, as well as the National Old-Age Insurance Fund (*Caisse nationale d'assurance vieillesse) for its contribution to the constitution of the cohort,* ClinSearch, Asqualab and Eurocell, which are conducting the data quality control.
>
> Funding: The Constances Cohort benefits from a grant from ANR (ANR-11-INBS-0002). Constances is also partly funded by MSD, AstraZeneca and Lundbeck.

Nominative acknowledgements of the researchers who contributed to the development of the Constances cohort protocol may also be added, depending on the data used in the research project. Where appropriate, the specific role of one or several other partners may be specified.

Because the information included in the acknowledgements of publications may require modifications, it must be submitted in advance to the Constances Director.

3.11.3 Reference to the Constances project

Every publication must refer to at least one of the methodological articles presenting the study protocol and published by the Constances team. Currently, the references to be quoted are, according to the theme of the project, the following:

Zins M, Goldberg M, and the CONSTANCES team. The French CONSTANCES population-based cohort: design, inclusion and follow-up. Eur J Epidemiology. 2015, 30:1317-1328.

Goldberg M, Carton M, Descatha A, Leclerc A, Roquelaure Y, Santin G, Zins M; CONSTANCES team. CONSTANCES: a general prospective population-based cohort for occupational and environmental epidemiology – Cohort profile. Occup Environ Med. 2016 Nov 24. pii: oemed-2016-103678. doi: 10.1136/oemed-2016-103678.

Ruiz F, Goldberg M, Lemonnier S, Ozguler A, Boos E, Brigand A, Giraud V, Perez T, Roche N, Zins M. High quality standards for a large-scale prospective population-based observational cohort: Constances. BMC Public Health 2016 Aug 25;16(1):877. doi:10.1186/s12889-016-3439-5.

It is likely that other references might be cited later; it is thus useful to consult the Constances Director about this.

3.11.4 Dissemination to cohort volunteers and the public

The research project director is required to prepare, in liaison with the Constances team, documents intended to disseminate their results to the cohort volunteers and to both medical and non-medical audiences, especially via the Constances cohort website. At the request of the Constances Director, research project teams are also required to present the progress and results of their work during the annual scientific meetings of the Constances cohort.

Important note: *no use of these results for commercial purposes, by research project directors or their financial partners, is allowed without the written agreement of the Constances Director, after consulting the governing bodies of the Constances cohort*.

3.11.5 Constances cohort website

The Constances cohort website may make public some information about the director of associated research projects. This information will concern the project (title, description, keywords, publications, etc.) as well as the name and postal address of the researchers. According to French law (Law n° 78-17 dated 6 January 6, 1978, as modified in 2004), the directors of such projects have the right to access, modify, correct, and delete data concerning themselves. Given the nature of the Internet and specifically the free availability of the information provided and the inability to control use by third parties, project directors have a right to object to public dissemination of their personal data (name, address…).

3.12 GENERAL PROVISION

The directors of research projects related to the Constances cohort undertake to comply with the provisions about professional standards and good epidemiological practices defined in the Recommendations adopted jointly by ADELF, AEEMA, ADEREST and EPITER, approved by the French Data Protection Authority (CNIL), the National Council of Physicians, the French Advisory Committee on Ethics in Life Sciences and Health, and the Advisory Committee on Data Treatment in Health Research (version 2007, and subject to their modification. French and English versions: http://aeema.vet-alfort.fr/index.php/repository/Publications/Recommandations-de-D%C3%A9ontologie-et-bonnes-pratiques-en-%C3%A9pid%C3%A9miologie/).

4 APPENDIX: GOVERNING BODIES OF THE CONSTANCES COHORT (NOVEMBER 2017)

Institutional Steering Committee

Representatives of:

- CNAMTS, the National Health Insurance Fund (Caisse nationale d'assurance maladie)
- INSERM, the National Institute of Health and Medical Research (Institut national de la santé et de la recherche médicale)
- UVSQ, the University of Saint Quentin en Yvelines (Université de Saint Quentin en Yvelines)
- CNAV, the National Old-Age Insurance Fund (Caisse nationale d'assurance vieillesse)
- DGS, Direction Générale de la Santé of the Ministry of Health
- Paris Descartes University

International Scientific Committee

- Andrieu Sandrine
- Cambois Emmanuelle
- Clément Bruno
- Desenclos Jean-Claude
- Fortier Isabel
- Kaaks Rudolf
- Kogevinas Manolis
- Paccaud Fred
- Rodwin Victor
- Saracci Rodolfo
- Siegrist Johannes
- Siemiatycki Jack (President)
- Silberman Roxane
- Weiderpass Elisabete

Ethics Committee

The INSERM "Comité d'éthique pour la recherche médicale et en santé (Ermes)" acts as the Ethics Committee of Constances (http://www.inserm.fr/qu-est-ce-que-l-inserm/organigramme/comites/ermes).

5 APPENDIX: MODALITIES OF REVIEW BY THE INTERNATIONAL SCIENTIFIC COMMITTEE

INTERNATIONAL SCIENTIFIC COMMITTEE

EVALUATION OF REQUESTS FOR ACCESS TO DATA OR MATERIAL OR SUBJECTS IN CONSTANCES

GENERAL PRINCIPLES

The purpose of the Constances project is to create a uniquely comprehensive and high quality platform of health-related data that can be exploited by legitimate academic, government or industrial partners in France and elsewhere, to answer questions of scientific and public health relevance.

Besides the core statistical functions to be conducted by the Constances team, the exploitation of this resource will occur via initiatives and leadership of external investigators. There is no limit to the number of research projects that can be built on the Constances framework. However, there could be restrictions for projects implying supplementary data collection from the cohort participants, or using samples from the biobank. As Constances is a “general-purpose” cohort, any health research domain may be included.

While it is intended to provide data access to all legitimate requesters, there is a need to ensure that the uses to which the Constances data are put will be compatible with the objectives of Constances, including scientific validity and pertinence. The International Scientific Committee (ISC) plays a central role in screening requests.

It is an advisory body. Its and its advice and recommendations are transmitted to the PIs of Constances and to the Steering Committee (“Comité de pilotage institutionnel”).

DECISION RULES FOR EVALUATION

1. Supporting all valid proposals

All legitimate and scientifically valid applications should be approved and the main purpose of the scientific evaluation is to eliminate poor scientific projects, not to rank or prioritize the good ones.

2. Non-exclusivity

Apart from the possible exception of biologic material, data provided to investigators will not be exclusively for their use. The same data could be provided to different investigators and the different investigators would be free to use and analyze the data for the purposes and within the timeframe agreed to by the CSI.

Constances will not guarantee exclusive access and use related to research themes, variables or data. This policy holds irrespective of whether there may be an already-approved project dedicated to the same theme as the proposal under consideration.

3. Supplementary data collection and sharing of new data to be generated by investigators

Projects implying the collection of supplementary material will be considered provided they do not compromise the main Constances data collection and follow-up. If such data collection is not an integral part of the Constances project, the responsibility for procuring funding of such data collection will have to be assumed by the external investigator. The CSI will also consider possible burden for Constances participants, Constances team, or health screening centers. Further, the data thereby generated will become part of the Constances database, available to other investigators, after a mutually-agreed period of exclusivity for the investigators who proposed and organized and paid for the additional data collection.

4. Proposals already peer-reviewed

If a research proposal has already received a favorable funding decision from a recognized agency that has peer review of proposals, then the CSI will approve such projects quasi-automatically. There will be a brief review by the CSI and only the most egregious circumstances would justify a refusal to approve the proposal by the CSI. If a proposal has been reviewed by a recognized agency, and has received a favorable scientific review, but not at a priority level that led to approval for funding, then the applicant may submit the favorable review for information to the CSI, which would then take this into account in its deliberations.

5. Consortium proposals

Consortium proposals that consist of multiple projects led by multiple PIs will be evaluated and approved, or not, on a project by project basis, not as an entire package.

This does not contradict our support for the creation of consortia. Rather, the fact that a project is part of a meaningful consortium will enhance the attractiveness of each project.

The CSI decisions will be at the level of the projects. Thus, within a consortium proposal, it is possible that some projects will be approved and some rejected.

ISSUES CONSIDERED BY THE SCIENTIFIC COMMITTEE

- Scientific Quality
- Has it been previously reviewed by a recognized peer-review procedure, or not? (if yes, there should be a copy of the official summary or abstract of the previous application to the other agency, and a letter attesting that the previous peer review found the proposal to be meritorious, irrespective of whether it was ultimately funded)
- Legitimacy/quality of the applicant (academic research unit, or public health agency, or a private company in collaboration with an academic research unit)
- Potential health and/or socioeconomic and/or scientific benefits of the research
- Compatibility with the general orientation and aims of Constances
- Resources to conduct the study (funds, personnel, institutional support) already available or not
- If the project requires use of bio-material, has it been collected and stored?

- If the project requires additional contact with cohort members, what is potential implication for the participants?
- If the project is part of a research consortium does this project fit the general objectives of the consortium?
- Are there potential ethical issues?
- Potential harm to the participants
- Protection of participant confidentiality
- Conflicts of interest within the academic community
- Potential for misuse by industry or for private profit

COHORTE CONSTANCES
UMS 011 INSERM UVSQ COHORTES EPIDEMIOLOGIQUES EN POPULATION
HÔPITAL PAUL BROUSSE BÂT. 15/16 PORTE D 16 AVENUE PAUL VAILLANT-COUTURIER
94807 VILLEJUIF CEDEX