

CALL FOR RESEARCH PROJECTS WITHIN THE CONSTANCES COHORT

The objective of the Constances epidemiological cohort is to contribute to the development of epidemiologic research and surveillance, and to provide information useful for public health. Constances is a random sample intended to include 200 000 adults aged from 18 to 69 years covered by the National Health Insurance Fund (CNAMTS). At inclusion, the participants complete a questionnaire and undergo a very complete medical examination in one of the CNAMTS health screening centers (HSC) in one of 20 administrative districts. A biobank is being set up from samples taken at this initial examination. The very long follow-up planned for this cohort will include an annual questionnaire and regular linkage to the national health insurance fund databases via the Interfund National Health Insurance Information System (SNIIRAM), the National retirement Insurance Fund for work-related events, and the CepiDc-Inserm database of causes of death. The participants will be regularly invited for new health examinations. All research teams, whether French or foreign, that want to use the Constances cohort structure can submit an application. It may involve the use of data already collected as well as of biological materials collected, and/or the collection of supplementary data for a specific objective.

March 2017



CFP

Constances Cohort

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The aim of this call for projects (CFP) is to allow research teams to propose projects to be nested in the Constances cohort. The CFP is permanent and open to both French and foreign teams. They must submit a scientific application, which will be examined by the scientific and institutional governing bodies of Constances.

1. THE CONSTANCES COHORT

1.1. Background

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 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). Its scientific and technical direction is provided by the Joint INSERM-UVSQ "Population-based Epidemiologic Cohorts" Unit (Cohortes épidémiologiques en population, UMS 11). Constances is accredited as a « National Research Infrastructure in Biology and Health » and has received as such funding from the French governmental « Investissements d'avenir » program since 2012. Constances received also the "Label of general interest and statistical quality" from the French National Council for Statistical Information – CNIS.

Constances is a large-sized cohort composed of a random sample of the adult general population covered by the National Health Insurance Fund (CNAMTS); it is characterised by broad coverage of health problems and their determinants. It is a "general-purpose" cohort, designed to help analyse a wide range of scientific problems and is accessible to the community of researchers and public health.

1.2. Essential aspects of the Constances cohort

Constances is a prospective epidemiological cohort comprising a representative sample of the population covered by the CNAMTS National Health Insurance Fund aged 18 to 69 years at study inception ; the goal is a total of 200 000 persons. The cohort will be assembled over a 5 year period beginning in 2012. The principal stages in setting up and following the cohort are the following.

Selection of eligible persons by random drawing (with stratified sampling and unequal probabilities) overrepresenting the individuals with a higher probability of not volunteering, as a function of the usual variables: age, sex, socioeconomic/occupational category. The random drawing is conducted by the National Old-Age Insurance Fund - Caisse nationale d'assurance vieillesse (Cnav) from the comprehensive National Registry of Health Insurance Beneficiaries (RNIAM).

Invitation to participate, sent by mail, together with an invitation to a health examination in one of the Health Screening Centers (HSCs) participating in the project, located in administrative districts of various regions.

Calling of participants in their HSC by a letter specifying the date and place of their examination. Before coming to the HSC, participants have to complete two self-administered questionnaires (Health and Lifestyle questionnaire, and a full "Job history" questionnaire).

Inclusion of the participants: they undergo a medical examination that will enable the collection of health data (details below), additional questionnaires (questionnaire by interview

about lifetime occupational exposures, self-administered questionnaire for women to complete at the HSC). Participants have to sign an informed consent form to be included in the cohort.

Active follow-up: a self-administered questionnaire will be sent each year to the participants' homes; they will also be invited to attend a medical examination every 5 years in their HSC.

Passive follow-up of work-related events and health data: the principal work-related events will be regularly extracted from the databases of the National Old-Age Insurance Fund - Caisse nationale d'assurance vieillesse (Cnav) (current job, unemployment, sick leave, welfare allocations, and maternity leave...). Health data includes vital status and causes of death, as well as principal health events and healthcare utilisation information extracted from the SNIIRAM and the national hospital database-PMSI.

1.3. Main data collected

The data collected routinely for all participants are intended to build a corpus that will enable us to describe and follow over time the changes in the subject's life, including health status, general morbidity and mortality, socioeconomic and occupational status, family, social and residential setting, and personal and environmental risk factors.

Social and demographic characteristics, social status: occupational position and activity, educational level, income level, marital status, household composition, socioeconomic status of parents and partner, material living conditions.

Behaviours: tobacco and alcohol use, dietary habits and physical activity, usage of cannabis, sexual orientation.

Occupational factors: job history, occupational exposure to chemical, physical, and biological agents, postural, gestural and organisational constraints, stress at work.

Health data:

Medical and medicosocial questionnaires and databases: self-reported health scales, diseases (list of reported diseases, diagnosis of chronic diseases, occupational diseases, and hospitalisations, sick-leave, handicaps, limitations, disabilities and injuries), date and cause of death.

In the HSC: personal and family medical history, weight, height, blood pressure, heart rate, vision, hearing, lung function, laboratory tests (fasting blood glucose, lipid work-up, liver function test, creatinemia, complete blood counts, urinalysis). For those aged 45 years or older: IADL (Instrumental Activities of Daily Living) scale, cognitive functions (MMSE, Trail Making Test A and B, Wechsler's coding subtest, Digital Finger Tapping Test, verbal fluency, formal lexical and semantic evocation, Grober & Busckhe's memory test), physical functions (gait speed test for 3 metres, balance test, Hand Grip Test).

At the health examinations, samples (DNA, serum, urine) will be collected for the planned biobank.

Health problems specific to women: reproductive history, infertility and delayed pregnancy, endometriosis and chronic pelvic pain, treatments for menopause, osteoporosis and osteoporotic fractures, sphincter disorders and perineal statics, and breast diseases.

Health-care utilisation and management: care networks, supplemental medical insurance for people on low incomes, date and type of services, including drugs (CIP code), devices and procedures, and lab tests; professionals who order and who fill the prescriptions, hospital discharge summaries.

1.4. Quality control and validation of health events

A routine permanent quality control system will be established in the HSCs to assess the validity of the data collected and to study the factors affecting their variability; epidemiologic research assistants will conduct regular inspections of each site.

Special attention will be paid to the validation of diagnoses extracted from health-related administrative databases : major disease-related events reported in the available sources will be systematically verified with the hospital or general practitioner.

1.5. Representativeness and selection effects

The population structure of the combined districts in which Constances will take place is almost identical to that of France as a whole for the principal demographic, social, and occupational characteristics. To obtain a representative sample of the target population and to minimise the bias due to selection effects at inclusion and during the follow-up, we will apply appropriate statistical methods, based primarily on the establishment of a random sample of non-participants. The CNAV and SNIIRAM files provide the same social, demographic, and health data for all of the participants and non-participants in the sample. Routine follow-up of the subjects in the national databases should result in a very low rate of loss to follow-up.

2. CALL FOR RESEARCH PROJECTS DESCRIPTION

Constances cohort constitutes a research infrastructure accessible to the scientific community. The research teams, whether French or foreign, that want to use the Constances cohort structure for their own study can submit an application. Detailed rules have been established for using the Constances database (see the Constances Charter [5.1.](#)).

2.1. Objective of the call for projects

Objective of the call is to allow research teams to propose associated projects with Constances.

2.2. Scope of the call for projects

Applications can be made in three research domains:

- The epidemiological research;
- The public health research;
- The epidemiological surveillance.

Only observational study designs are eligible. The call for research projects excludes the interventional studies.

2.3. Eligibility conditions

2.3.1. Who may submit projects

All organisations/institutions, regardless of their status, are eligible to propose research projects.

All research teams, whether French or foreign, that want to use the Constances cohort structure can submit an application.

Proposals involving several teams are strongly encouraged.

The call for research projects welcomes applications funded by private for-profit research centres, including industrial health laboratories, proposed either by an academic or by a private group. For that, specific rules have been established. It is necessary to contact the Constances PI before submitting an application.

2.3.2. 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 (work package) 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. More details about consortia are given in “Guidelines for Constances Research Consortia”. This document may be accessed electronically on Constances website at www.constances.fr.

2.3.3. Data concerned by the project

It may involve the use of:

- data already collected (see section [1.3.](#));
- biological materials collected;
- the collection of supplementary data for a specific objective.

3. SUBMISSION INSTRUCTIONS

3.1. Research project proposal

PIs should prepare a research project proposal to the technical assessment of the Constances team and the scientific evaluation of the International Scientific Committee.

A research project proposal must contain:

- Team description (PI, team members, affiliation, summary of expertise, accomplishments);
- Research project description (state of the art, background, objectives, methods, expected results, duration and schedule of the project, list of variables needed...);
- Funding of proposal (see [section 6.2](#)).

3.2. Submission

Prior to any submission, it is imperative to contact the Constances PI: Dr Marie Zins - marie.zins@inserm.fr.

Submission of an application must be done by using a web-based procedure. To know how to connect to the application website, contact: Céline Ribet and Sandrine Demarquay - celine.ribet@inserm.fr and sandrine.demarquay@inserm.fr.

An acknowledgment of receipt is sent to the applicant upon receipt of the application.

4. CFP EVALUATION PROCEDURE

4.1. Steps of evaluation procedure

The evaluation procedure includes the following steps:

1. Research proposals receipt (application website). The Constances' Scientific Secretariat controls that proposals are accurate and complete;
2. Technical examination by a Constances's epidemiologist (of feasibility, confidentiality, consistency... - Technical evaluation grid in the [Appendix](#)). The conclusions of the technical examination of the application are transmitted to the International Scientific Committee ;
3. Scientific and methodological quality evaluation by the International Scientific Committee (evaluation grid in the [Appendix](#)) ;
4. Final acceptance of projects.

4.2. The scientific and institutional governing bodies involved in the evaluation

The International Scientific Committee (ISC) is composed of 14 researchers, French and foreign (Canada, Germany, Italy, Spain, Sweden, Switzerland, USA) specialized in their main scientific topics (composition in the [appendix](#)). It evaluates the scientific quality of projects, teams, and the methodology. It judges ethical aspects and the relevance of projects in relation to the overall coherence of the cohort over the long term.

For plans that require additional data collection, the ISC also evaluates the burden to the participants, the Health Screening Centres and the Constances Team and the balance to the Constance cohort as a whole.

Each application is examined by two members of the ISC; they can ask an advice from external reviewers. After the entire procedure is complete there is a meeting in which each proposal is discussed and a decision made.

For consortium projects, the evaluation of the Scientific Committee will be both at the consortium and at the specific projects level; therefore it is possible that some work-packages will be approved and others will not.

The International Scientific Committee does not evaluate projects already evaluated by other scientific committees and which the feasibility is granted by the Constances team. Feasibility and compatibility with general orientations and purposes of Constances cohort are examined.

The Institutional Steering Committee brings together the institutions that supports the Constances cohort (CNAMTS, CNAV, INSERM, UVSQ). Within one month after receiving the decision of the ISC, the Committee may oppose access to specific data from the cohort for reasons of conflict of interest.

The application may be transmitted to the Ethics Committee for its advice.

4.3. ISC's decision

Applicants / consortium coordinator are informed of the ISC's decision and of the two reviewers comments.

Global assessments can be:

- favorable;
- favorable with some limits. Applicants will have to answer to the comments given by the reviewers and to describe the measures they intend to take. The revised proposals will be re-evaluated;
- unfavorable with required modifications. Applicants may submit modified projects which returns to the step 1 of the evaluation procedure.
- unfavorable assessment.

The responsables of projects which have received a favorable assessment are informed of the final acceptance within a period of one month.

4.4. Deadline

The call for research projects is continuous. Research project proposals can be submitted all year long. The ISC meets twice a year, usually in May and November. Research project proposal must be submitted five months before the ISC's meeting.

An expedited procedure will be established to examine the application of the health authorities which requires a period of rapid implementation.

4.5. Publications of results

As part of the Constances website, the list of selected projects will be made public. Moreover the Constances Team reserves the right to communicate information of selected projects to the Constances participants.

4.6. Documents available

The following documents can be downloaded from the Constances website:

- Call for research projects;
- Constances charter;
- Access guide to the Constances cohort data (in French, English version forthcoming);
- Guidelines for Constances Research Consortia;
- Constances' protocol;
- Questionnaires.

5. RECOMMENDATIONS

5.1. Constances charter

Before proposing a research project, it is essential to read the Constances Cohort Charter carefully; it can be downloaded from the Constances website (www.constances.fr). This document sets forth the rights and responsibilities of the research teams associated with the Constances cohort. It specifies the different stages of the research projects associated with the cohort:

- Procedures for project selection;
- Conditions for using cohort data;
- Procedures for the collection, 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.

5.2. Research projects funded by private companies

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 PI before submitting an application.**

5.3. Projects implying the collection of additional data from the cohort participants

The collection of supplementary data from the cohort participants must be:

- In conformity with existing guidelines;
- In complementarity with already recorded data;
- Compatible with the timing of contacts with cohort participants.

It is recommended that projects that require additional data collection be discussed in a preliminary way with the Constances PI before proceeding to a full application.

5.4. Personal Data Privacy

All processing of personal data is regulated by law. Therefore, the person responsible of a project must carry out the appropriate legal and regulatory formalities prior to the use of data collected in the context of the Constances cohort.

If the project involves treatment on human biological samples, it is necessary to carry out the appropriate regulatory procedures.

It is essential to obtain the agreement of the Constances Director and to await the decision of the ISC before starting these steps.

Important: the Constance team will not provide the requested data if the realization of these legal and regulatory formalities has not been made in connection with it.

6. GENERAL PROVISION

6.1. Memorandum of agreement

When a research project is accepted, the specific modalities of the collaboration between the research project team and the UMS 11 must be recorded in the form of a memorandum (further information in the Constances Charter).

All the documents justifying compliance of the legal and regulatory framework, particularly the security constraints related to the processing of personal data, must be appended to this document.

6.2. Funding

A financial contribution is required in accordance with the rules for access to the Constances Cohort data (refer to the Constances Chartes Constances). It covers:

- Cohort data access;
- Interventions performed by the Constances team to provide data.

The amount of the financial contribution has to be discussed with the Constances PI. For more information, contact Marie Zins at marie.zins@inserm.fr (copies for information Pr Marcel Goldberg and Céline Ribet: marcel.goldberg@inserm.fr and celine.ribet@inserm.fr).

The costs are enumerated in the document describing the modes of collaboration between the research project team and the UMS 11 (see section 6.1.).

The specific costs related to the research project (potential collection of additional data, data analysis, etc.) shall be borne by the associated research project. When appropriate, the Constances cohort team can provide methodological support for obtaining funding from other sources.

All proposal for funding must include the costs of the Cohort data access and the interventions performed by the Constances team; no funding may be submitted without the written consent of the Constances PI.

6.3. Publication and communication

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

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.

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 defined in the Recommendations adopted jointly by ADELFI, AEEMA, ADEREST and EPITER.

The results of research projects will be disseminated to participants of the cohort and to both medical and non-medical audiences, especially via the Constances cohort website.

For more information please read the Constances Charter.

7. CONTACTS

General inquiries regarding the submission procedure should be made to:

Céline Ribet and Sandrine Demarquay – UMS 11 Inserm-UVSQ, Unité Cohortes épidémiologiques en population, 3 bis passage de la Fontaine, 94 800 Villejuif, email: celine.ribet@inserm.fr ; sandrine.demarquay@inserm.fr

For questions related to the Constances’ protocol and other scientific information, contact:

Dr Marie Zins – Constances PI - UMS 11 Inserm-UVSQ, Unité Cohortes épidémiologiques en population, 16 avenue Paul Vaillant Couturier, 94 800 Villejuif, email : marie.zins@inserm.fr

For questions related to the financial contribution of PI projects, contact:

Dr Marie Zins – Constances PI - UMS 11 Inserm-UVSQ, Unité Cohortes épidémiologiques en population, 16 avenue Paul Vaillant Couturier, 94 800 Villejuif, email : marie.zins@inserm.fr

Annex 1. Technical evaluation grid

Grille d'analyse technique - Projet

Examen technique du dossier :

Relecteur dans l'UMS : _____

Date de validation de la grille : _____

A. GENERAL

Titre du projet : _____

Responsable(s) du projet : _____

Affiliation(s) du responsable du projet : _____

Catégorisation de l'affiliation :

- INSERM
- Autre EPST : CNRS, INED, INRA...
- Université ou autre EPSCP
- CHU, CHRU, APHP, APHM, Hospices civils de Lyon...
- Agence sanitaire : ANSES, INCa, INPES, IRSN, InVS, HAS, ANSM
- Autre organisme de recherche : INRS, IRDES...
- Direction / Département de ministère (DREES, DARES, Insee...)
- Organisme de protection sociale : Cnamts, Cnav, CNSA, Mutuelle...
- Fondation
- Organsime de recherche international
- Autre

Pays : _____

Type de projet :

- Projet Autonome
- Projet d'un consortium

Calendrier de mise en œuvre :

Date de début : _____

Durée du projet : _____

Type de dossier :

- | | |
|--|--|
| <input type="checkbox"/> Première demande | <input type="checkbox"/> Demande révisée |
| <input type="checkbox"/> Extension projet existant | <input type="checkbox"/> Non précisé |

Evaluation ou suivi scientifique du projet

En interne (comité pilotage, comité scientifique...):

- Oui, déjà en
- Oui, à venir
- Non
- Non précisé

Par un organisme indépendant¹ (ANR, Iresp ...):

Oui Non Non précisé

Si Oui, préciser organisme(s) : _____

Commentaires sur l'évaluation ou suivi scientifique du projet :

Moyens humains affectés au projet

Des recrutement(s) et/ou embauches (M2, doctorant, post-doctorant, cdd...) sont prévus pour la mise en œuvre du projet :

Oui Non Non précisé

Si oui, préciser (M2, doctorant, post-doctorant, cdd...) : _____

Si doctorant, préciser source de financement : _____

Commentaires sur les moyens humains affectés au projet :

Financement

Non précisé

Par l'organisme porteur du projet (hors salaire public des statutaires de l'équipe porteuse)

Par un organisme public :

Acquis :

Oui, pour toute la durée du projet. Préciser organisme(s) : _____

Oui, pour 1 partie du projet. Préciser organisme(s) : _____

Non précisé

En cours de demande :

Oui, pour toute la durée du projet. Préciser organisme(s) : _____

Oui, pour 1 partie du projet. Préciser organisme(s) : _____

Non précisé

Non précisé

Par une fondation :

Acquis :

Oui, pour toute la durée du projet. Préciser organisme(s) : _____

Oui, pour 1 partie du projet. Préciser organisme(s) : _____

Non précisé

En cours de demande :

Oui, pour toute la durée du projet. Préciser organisme(s) : _____

Oui, pour 1 partie du projet. Préciser organisme(s) : _____

Non précisé

Non précisé

¹ Les organismes tels que l'Institut de recherches scientifiques sur les Boissons (Ireb) sont à exclure.

- Par un organisme privé à but lucratif :
- Acquis :
 - Oui, pour toute la durée du projet. Préciser organisme(s) : _____
 - Oui, pour 1 partie du projet. Préciser organisme(s) : _____
 - Non précisé
 - En cours de demande :
 - Oui, pour toute la durée du projet. Préciser organisme(s) : _____
 - Oui, pour 1 partie du projet. Préciser organisme(s) : _____
 - Non précisé
 - Non précisé
- Autre. Préciser : _____

Commentaires sur le financement :

Aspects légaux

CTIRS (Comité consultatif sur le traitement de l'information en matière de recherche)

Nécessaire :

- Oui No Ne sais pas

Si oui :

- Avis Demande en cours Demande non Non précisé

Opportunité du CNIS (Conseil national de l'information statistique)

Nécessaire :

- Oui No Ne sais pas

Si oui :

- Avis Demande en cours Demande non Non précisé

CNIL (Commission nationale de l'informatique et des libertés)

- Autorisation Demande en Demande non Non

Si autorisation accordée, une copie a été réceptionnée par l'équipe Constances ?

- Oui No

CPP (Comité de protection des personnes)

Nécessaire :

- Oui No Ne sais pas

Si oui :

- Avis Demande en cours Demande non Non précisé

Commentaires sur les aspects légaux :

B. MÉTHODES

Participants

Critères de sélection spécifiques

- Non (prise en compte de l'ensemble de la cohorte)
- Oui. Préciser :

- Non précisé

Critères d'exclusion

- Non
- Oui. Préciser :

- Non précisé

Commentaires sur la sélection / exclusion :

Effectifs demandés disponibles dans la cohorte

- Oui, dès maintenant
- Oui, ultérieurement. Délai et compatibilité avec le calendrier du projet :

- Non, même ultérieurement
- Manque d'éléments pour évaluer

Commentaires sur la disponibilité des effectifs :

Données

La demande inclut :

- Questionnaires : Mode de vie et santé, Expositions professionnelles, Calendriers professionnels (non codés), Santé des femmes, Questionnaire(s) de suivi (Précisez la ou les années de suivi : _____)
- Examen de santé au CES (questionnaire médecin, examens paracliniques)
- Données de biologie recueillies au cours de l'examen de santé
- Bilan des 45 et + (tests fonctionnels physiques et cognitifs)
- SNIIRAM. Précisions indiquées dans le projet : _____

- CNAV/SNGC. Précisions indiquées dans le projet : _____
- Diagnostics validés :
- Cancers
 - Cardiopathies
 - AVC
 - Maladies neurodégénératives
 - Autre (financé par l'équipe demandeuse). Préciser : _____
- Calendriers professionnels codés
- Appariement avec des matrices emploi exposition (MEE)
- Géocodage (= X,Y sinon préciser dans « Autre »)
- Statut vital, date de décès, cause médicale de décès
- Pondération
- Indicateur d'accessibilité potentielle localisée (APL)
- Indice de défavorisation sociale (FDep)
- Autre. Préciser : _____
- Non précisé

Les données demandées dans la base Constances sont disponibles :

- Oui actuellement
- Oui ultérieurement. Préciser : _____
- Non

Le projet prévoit la collecte de données supplémentaires par questionnaire :

- Non Oui Non précisé

Si oui :

Données :

- non originales (questionnaires ou échelles publiés dans la littérature)
- originales (questionnaire développé par l'équipe demandeuse)

Intérêt d'introduire tout ou partie des questions dans un questionnaire annuel de suivi :

- Oui Non Ne sais pas

Nombre de questions (avec questions filtrées) :

- Non précisé
- 1-10 11-20 21-30 >30

Estimation de la durée de remplissage : _____

Une version « Internet » est envisagée : Oui Non Ne sais pas

Le(s) questionnaire(s) sont annexé(s) au projet : Oui Non

Le projet prévoit la collecte de données supplémentaires acquises hors Constances (appariement) :

- Non Oui Non précisé

Si Oui, préciser la source de données externe : _____

Pour les données de biologie, le projet prévoit :

Le recueil d'échantillons biologiques pour réaliser des analyses supplémentaires

Nature : Sang Urine Non précisé

Quantité : _____

Type d'analytes : _____

L'utilisation d'échantillons biologiques conservés dans la biobanque :

Nature : Sérum Plasma Sang total Urine Non précisé

Quantité : _____

Le recueil d'échantillons biologiques supplémentaires pour la biobanque (ARN, protéomique, phanères, cheveux, selles...)

Nature : _____

Quantité : _____

Le projet prévoit un recueil autre :

Non Oui Non précisé

Si oui, préciser : _____

Commentaires sur les données souhaitées, leur recueil, leur disponibilité :

C. ANALYSE D'ENSEMBLE

(Commentaires sur la faisabilité et les difficultés potentielles, le calendrier, la charge globale)

Faisabilité

Non Oui

Si Oui, préciser si difficultés potentielles :

Non

Oui, préciser :

Si problème de faisabilité lié au calendrier. Préciser :

Projet en concurrence avec projet en cours ou planifié

Non

Oui

Ne sais

Préciser :

Charge pour _____

les participants. Préciser : _____

les CES. Préciser : _____

l'équipe Constances. Préciser : _____

Commentaires des référents thématiques de Constances : _____

Autres commentaires _____

Annex 2. Constances International Scientific Committee (ISC) – Project Evaluation Grid

**EVALUATION OF PROPOSALS COMING FROM RESEARCHERS
WHO WISH TO USE THE CONSTANCES INFRASTRUCTURE**
Constances International Scientific Committee (CSI) – Project Evaluation Grid

This grid can be completed in French or English.

Principal investigator:

Project title:

CSI reviewer name:

Date of review completion:

Did you ask the advice of an external expert? Yes/No

If yes, specify name and affiliation of the expert:

Ranking: 5 = Excellent, 4 = Very good, 3 = Good, 2 = Acceptable, 1 = Unacceptable

One global score for each section (Items are listed as issues you might consider; you are free to give weight to these items as you see fit.)	Note (1 à 5)	Comments (if needed)
1. Quality of the research team Legitimacy-quality-expertise-productivity of applicants, including the PI and the team Complementarity of teams if appropriate Interdisciplinary approach if appropriate (Transversal teams)		
2. Scientific quality of the project Scientific quality of project Clarity and pertinence of the objectives Validity of design and methods Originality		
3. Feasibility (apart from the technical evaluation by the Constances team) Adequacy between human resources and stated objectives Realistic timetable Appropriate duration Burden on participants and/or health screening centers if appropriate		
4. Potential positive impact of the project For scientific knowledge For public health		

One global score for each section (Items are listed as issues you might consider; you are free to give weight to these items as you see fit.)	Note (1 à 5)	Comments (if needed)
5. Compatibility with general orientations and purposes of Constances (for instance outside the health field, intervention)		

General comments and feedback if any:
Strengths of the proposal (if any)
Weaknesses of the proposal (if any)
Recommendations for improving or modifying the project (if any)
Additional comments (if any) (for instance: competition with another project, conflicts of interest within the academic community, potential for misuse by industry or for private profit)

Global assessment	Grade (A-B-C-D)
Ranking A : Favorable B : Favorable, with some limits C : Unfavorable ; Invited to submit a revised protocol D : Unfavorable	

Annex 3. Members of the International Scientific Committee (ISC)

The 14 members of the International Scientific Committee (ISC) are :

- Andrieu Sandrine, Toulouse, France
- Cambois Emmanuelle, Paris, France
- Clément Bruno, Rennes, France
- Desenclos Jean-Claude, Saint Maurice, France
- Fortier Isabel, Montréal, Canada
- Kaaks Rudolf, Heidelberg, Germany
- Kogevinas Manolis, Barcelogne, Spain
- Paccaud Fred, Lausanne, Switzerland
- Rodwin Victor, New York, USA
- Saracci Rodolfo, Lyon, France
- Siegrist Johannes, Düsseldorf, Germany
- Siemiatycki Jack, Montréal, Canada (President of the ISC)
- Silberman Roxane, Paris, France
- Weiderpass Elisabete, Stockholm, Sweden