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# GUIDELINES FOR USERS

## Database and Biobank of the Quebec Longitudinal Study on Nutrition and Successful Aging (NuAge Database and Biobank)

The NuAge Database and Biobank are compiled for academic research purposes to store the data and biologic samples of the NuAge Study ("Quebec Longitudinal Study on Nutrition and Successful Aging") cohort, within a platform that allows their content to be shared with investigators[1], co-investigators, collaborators, students, interns or other qualified academic research staff (hereinafter referred to as users), whether or not they have contributed to the NuAge Study. No sharing of data or biologic samples for private companies is eligible.

These guidelines aim to valorize the use of data and biologic samples of the NuAge Database and Biobank in a co-ordinated, transparent, ethical and secure way, and to implement interdisciplinary collaborations through the completion of research projects consistent with the mission of the NuAge Database and Biobank. Strict and rigorous procedures govern the access and use of these Banks, as described in the *NuAge Database and Biobank Management Framework* approved by the Centre intégré universitaire de santé et de services sociaux de l'Estrie – Centre hospitalier universitaire de Sherbrooke (CIUSSS-de-l'Estrie-CHUS) Research Ethics Committee (REC).

This document contains a description of the NuAge Study and NuAge Database and Biobank, the guidelines to follow to obtain access to the Banks, and the expectations toward users regarding what use they will make of the data and samples transferred by the NuAge Database and Biobank, as well as toward the expected benefits of their study.

## EFFECTIVE DATE

These guidelines have been in effect since March 8, 2019 (see version history in Attachment A).

[1] To simplify the text, the masculine gender is used in the context where the person concerned is not determined.

## WHAT IS THE PURPOSE OF THESE GUIDELINES?

A research bank is a systematic collection of data or biologic material that may be used for research purposes and that may be used for more than one current or future project, whether the data or biologic material are shared or not. The research Banks are registered with a Research Ethics Committee (REC). The REC ensures the compliance of the management framework of the bank, in particular regarding the procedures that ensure the security, confidentiality and integrity of the bank, approves the usage agreement and ensures participants' consent for the banking.

The NuAge Database and Biobank are registered with the CIUSSS-de-l'Estrie-CHUS REC, a health institution of the Province of Quebec. The NuAge Database and Biobank are not public. Management of the Banks and the processing of the access requests are ensured by the NuAge Steering Committee, and the members of its team, in compliance with the management framework approved by the REC. These guidelines, therefore, inform users of what is expected of them (responsible conduct of research) and the procedures to follow for access requests, for the receipt, preservation, processing, return and destruction of the data and biologic samples of the NuAge Databank and Biobank, as well as the dissemination of the research project results. All users must read these guidelines and comply with them.

The research projects that make use of the data and biologic samples of the NuAge Database and Biobank contribute to ensuring its funding and sustainability, notably through its enrichment. Therefore, it is in the interest of the NuAge Database and Biobank users and team to work cooperatively to ensure the quality of the research projects as well as the success of everyone's professional path.

## MISSION AND OBJECTIVE OF THE NUAGE DATABASE AND BIOBANK

### *Mission*

The mission of the NuAge Database and Biobank is to provide high quality data and biologic samples to the scientific community to carry out research projects to characterize the heterogeneity of trajectories of aging as well as the multiple underlying factors, in particular nutritional factors, with the aim to improve the overall health and quality of life of the elderly.

### *Principal objective*

The principal objective of the NuAge Database and Biobank is to create, maintain and enrich a platform that allows for the sharing of data and biologic samples of participants in the NuAge Study with the scientific community for the purpose of

research projects whose objectives align with the mission of the NuAge Database and Biobank.

## DESCRIPTION OF THE NUAGE DATABASE AND BIOBANK

### *Recruitment and characteristics of participants of the NuAge Study*

The NuAge Study is a longitudinal observational study of a cohort of 1,793 men and women recruited in the regions of Montreal, Laval and Sherbrooke, between 67 and 84 years of age and in good health at the time of recruitment[2]. These participants were recruited from a random sample stratified for sex and three age groups. To be eligible for the study, the participants had to be French or English speaking, willing to participate for a 5-year period, able to walk without help (cane acceptable), free of disabilities in activities of daily living, not cognitively impaired (3MS >79), able to walk 300 meters or climb 10 stairs without rest, and able to provide written informed consent. People suffering from class II heart failure, chronic obstructive pulmonary disease, inflammatory digestive diseases, or cancer treated either by radiation therapy, chemotherapy, or surgery in the previous 5 years were excluded. Recruitment and selection of participants took place by telephone and by medical examination at the first visit.

### *Data and biologic sample collection methods*

The annual interviews for the NuAge Study took place at one of the two Research Centres of the Montreal or Sherbrooke Geriatric Institutes. The participants completed nutritional, medical, anthropometric, functional and social assessments initially, and then annually for three years, by questionnaires or direct measurements. Data were collected by research dieticians and nurses using computer-assisted personal interview methodology and standardized procedures. Brief telephone interviews took place 6 months after each annual interview. Recruitment of participants took place between November 2003 and June 2005 and all follow-ups were completed in June 2008.

For 1,657 participants, biological sample collection (blood, urine, saliva) took place at recruitment and annually for three years. Blood analyses on fresh blood samples (total blood count, albumin, fasting glucose) were performed during the study and the results were immediately integrated into the NuAge Database and Biobank. The results of other biomarker assays were progressively integrated into the NuAge Database and Biobank according to the procedures described below, and following approval of the

[2] Gaudreau P, Morais JA, Shatenstein B, et al. Nutrition as a determinant of successful aging: description of the Quebec longitudinal study Nuage and results from cross-sectional pilot studies. *Rejuvenation Research* 2007;10(3):377-86.

CIUSSS-de-l'Estrie-CHUS REC. A summary description of the biomarkers, which were added to the NuAge Database, is available in Attachment D.

In addition to the data collected for the NuAge Study, other data were collected for specific research project purposes involving recontacting NuAge Study participants. These new data were integrated into the Database according to the procedures described below, and following approval of the CIUSSS-de-l'Estrie-CHUS REC. A summary description of these new data integrated into the NuAge Database and Biobank is included in Attachment D.

## ***Participants included in the NuAge Database and Biobank***

In total, 1,753 of 1,793 participants of the NuAge Study are part of the NuAge Database and Biobank. This number has been defined based on participant consent, as approved by the CIUSSS-de-l'Estrie-CHUS REC.

## ***Collection practices used to ensure quality***

### Clinical data

Rigorous collection and inputting of data are ensured through the implementation of standardized procedures, the development of tools and the initial and continuing training of the NuAge Study research teams. The quality of the data inputted in the files was ensured by verifying the validity (plausibility), duplications, coherence and statistical distribution. This verification was also carried out for the new data generated by the research projects before their integration into the Database.

### Biologic samples

All biologic samples, collected from participants who had fasted from the night before the collections, were treated, aliquoted, and stored according to standardized procedures and on the basis of the desired analyses in the NuAge Study. Inventory of the samples is carried out with the GIEB software (Gestion d'Inventaire d'Échantillons Biologiques [Biologic Sample Inventory Management in English]). Individuals authorized to receive samples for research projects must follow the instructions described in the *Procédure à suivre par les laboratoires experts pour assurance qualité* [*Procedure to Follow by Expert Quality Assurance Laboratories* in English] sent by the Biobank Coordinator.

## ***Content of the NuAge Database and Biobank***

The list and description of the individual data may be provided to users by contacting the NuAge Database and Biobank (NuAge-cdrv@usherbrooke.ca) or by consulting our website (http://www.nuage.recherche.usherbrooke.ca/). A summary of their content is presented below.

**Database**

The NuAge Database includes nutritional (dietary intakes, eating habits), anthropometric (height, weight, skinfold thicknesses, circumferences), functional (functional autonomy, physical performance, muscle strength), medical (chronic conditions, health events, physiologic conditions, mental and cognitive health), and body composition (DXA, bioelectrical impedance analysis) data and analysis results of different biomarkers of various kinds (e.g. markers of nutritional status, inflammatory status). Sociodemographic information about lifestyle habits, physical activities and social functioning (resources, support, activities, participation) are also part of the data collected.

In compliance with the consent granted by the NuAge participants, other data will possibly be integrated into the Database, including genetic (integration planned in 2022-2023), epigenetic, transcriptomic, proteomic and metabolomic data. The request for medico-administrative data access from the *Régie de l'assurance maladie du Québec* (RAMQ) and the Minister of Health and Social Services (MSSS) and their matching with NuAge data using the Research Data Access Services of the *Institut de la statistique du Québec* (ISQ; https://statistique.quebec.ca/recherche/#/accueil) is currently under evaluation.

**Biobank**

The NuAge Biobank includes serum, plasma, red blood, peripheral blood mononuclear cell (and their DNA and RNA content), urine and saliva samples.

## GUIDELINES FOR SUBMITTING A REQUEST TO ACCESS THE BANKS

### *Eligible people*

Any user who holds research privileges in a recognized academic institution to manage research funding may submit a request to access data or biologic samples from the NuAge Database and Biobank. This user is referred to as the "requesting investigator". No sharing of data or biologic samples for private companies is eligible.

### *Types of access requests*

Three types of access requests are possible:

- **New access request:** Applies to a new project requiring data or biologic samples to carry out the project. The requesting investigator must specify the funding source that will support the project. New requests are evaluated by two

reviewers. They may be approved as such, approved conditionally to certain amendments, or refused. **An initial response from the Steering Committee should be expected within 2 months.**

- **Attestation for a grant application:** Applies to a project that must be submitted to a funding body with the aim of obtaining the funding required to carry out the project. The NuAge Database and Biobank may provide a letter attesting that the data and biologic samples are available to carry out the project, as well as an estimate of the access fees, if funded. Obtaining the attestation letter could take up to 2 weeks. If the project is funded, the requesting investigator must submit a new access request and provide the scientific evaluation by the funding body. The attestation for a grant application does not constitute approval of a project.
- **Addition or amendment to a previously approved request:** Applies to a project that was previously approved by the Steering Committee, but requires a protocol amendment, **whether or not** additional data or biologic samples are requested. **Between 1 to 2 months should be expected to obtain an initial response from the Steering Committee**, depending on the extent of the additions or amendments made to the protocol.

***Deadline for submitting an access request***

There is **no deadline** for submitting an access request. Thus, researchers can submit their request to the NuAge Database and Biobank at any time.

***Guidelines for submitting an access request***

To submit an access request, the following documents must be completed and submitted to the Steering Committee by email at NuAge-cdrv@usherbrooke.ca or via our website (https://nuage.recherche.usherbrooke.ca/en/faire-une-demande-dacces/). The form templates are available by contacting the NuAge Database and Biobank team, as well as on our website.

- ***"Access Request Form"*** describing the protocol and individuals involved in the project (a summary of the content is provided below);
- ***"Data Form"*** listing the variables requested for the project according to the dictionary of variables;
- ***"Biologic Sample Form – Component 1"*** if biologic samples are required for the project.

The NuAge Database and Biobank dictionary of variables is available on request (NuAge-cdrv@usherbrooke.ca) and via our website in order to properly fill out the "*Data Form"*. The NuAge Database and Biobank team offers support to researchers in the preparation of their research protocol (choice of variables and biologic samples,

study design, feasibility, etc.). It should be noted that data and biologic sample access fees apply and may be subject to periodic revision. Details regarding fees are available by contacting the NuAge Database and Biobank team. The requesting investigator is responsible for all costs associated with carrying out the research project, including biomarker assays and statistical analyses.

### ***Eligible research projects***

The proposed research projects must be written in French or English and be aligned with the mission of the NuAge Database and Biobank. The study plan may be cross-sectional or longitudinal depending on the nature of the research question and availability of the data and biologic samples. Including a student member in the research team is strongly encouraged.

**It should be noted that an approval of the research project by the REC of the requesting investigator's institution is required before transferring any data or biologic samples. The transferred data are de-identified; they are not anonymous or public data.**

### ***Content of the Access Request Form***

**New Access Request and Attestation for a Funding Request:**
The form contains the following headings, including 5 pages for the research project itself:

- Names and affiliations of the people involved in the research project;
- Title, key words and abstract;
- Context and relevance of the project;
- Objectives and hypotheses;
- Method: study plan and proposed methodology, data analysis plan, sample analysis method (if applicable), and statistical power calculations;
- References;
- Project feasibility: description of the expertise and role of the research team members, project funding (if applicable) and project timeline;
- Expected milestones: scientific communications that may result from the project, student training, research grants awarded, etc.;
- The security measures planned to ensure the security and integrity of the data (e.g.: secure institutional server);

**Addition or amendment to a previously approved request:**
In order to speed up the approval process, the Access Request Form initially approved by the Steering Committee may be resubmitted with "tracking changes" mode and accompanied by a letter detailing and justifying the additions or amendments that have been made since the last version.

## ACCESS REQUEST APPROVAL PROCESS

### *Assignment of requests to reviewers*

The evaluation of the access requests is done in close collaboration with the requesting investigator to ensure the suitability of the project in the context of the NuAge Database and Biobank and to optimize its chances of success. The Database Coordinator and two independent reviewers of the project will evaluate the request submitted (see criteria below).

### *Evaluation criteria*

The requests are evaluated according to the criteria listed below:

- Relevance and originality of the project in view of current knowledge;
- Relevance in view of the NuAge Database and Biobank mission;
- Originality in view of research projects already completed with NuAge;
- Quality and scientific rigour of the proposed methodology;
- Match between the research project proposal and the data and biologic sample forms;
- Availability of the data and biologic samples requested;
- Adequate statistical power and sample size available;
- Available resources in terms of expertise (proposed research team, available support staff) and funding;
- Realistic timeline;
- Planned security measures to ensure data security and integrity;
- (Asset) Contribution of the project to student or intern training;
- (Asset) Potential contribution of the research project to the enrichment of the NuAge Database and Biobank (e.g. addition of new biomarker analysis results).

### *Possible decisions from the Steering Committee*

Three types of decisions are possible:

- **Positive, accepted as submitted**
  Some minor suggestions may nonetheless be made to the requesting investigator who may, at their discretion, integrate them into their research proposal. An approval letter for the project will be sent by email to the requesting investigator with the summary of the minor comments, as well as the details about the next steps leading to obtaining the data and biologic samples required to carry out the project.

- **Negative, with an invitation to resubmit a revised proposal**
  In this case, the reviewers have identified issues that require amending the research proposal to make it acceptable. The requesting investigator is then invited to resubmit a revised research project proposal in accordance with the issues identified, **by clearly specifying the amendments made to the protocol and by responding to each issue raised in a *Response to Reviewers*.**
- **Negative, without an invitation to resubmit a revised proposal**
  In this case, the reviewers have identified major issues that mean that the proposed research project cannot be carried out in the context of the NuAge Database and Biobank. The requesting investigator then receives a letter presenting the issues that justify the negative response.

## PROCESS FOR SENDING DATA AND SAMPLES

After the Steering Committee has approved authorization to access the NuAge Database and Biobank, the following steps must be completed before the data and biologic samples are sent:

- Obtain a REC approval for the project to be carried out: The NuAge Database and Biobank are not public and although the data and samples are de-identified, they are not anonymous. This step is a requirement of the policies and procedures that govern Research Banks for which the CIUSSS-de-l'Estrie-CHUS is the trustee. No exemption will be granted. Subject to exceptions, it is generally the REC of the requesting investigator's institution that grants the ethics approval. The approval letter for the research proposal issued by the NuAge Steering Committee is helpful for supporting the ethics approval request;
- Sign the *Collaborative Agreement* (legal contract): The *Collaborative Agreement* must be signed by the requesting investigator, the designated administrator of the NuAge Database and Biobank, and the representatives of the trust organization of the NuAge Database and Biobank. The agreement describes the legal provisions that govern access to the NuAge Database and Biobank, including the commitment of the requesting investigator to pay the access fees to the NuAge Database and Biobank, if applicable;
- Sign the *Usage Agreement* (moral contract): The *Usage Agreement* must be signed by the requesting investigator. The requesting investigator undertakes to inform everyone involved in the research project (the users) of the guidelines and expectations towards them, in particular complying with the rules of good conduct that govern access to the NuAge Database and Biobank.

Once these steps are completed, a project-specific data file, as approved by the Steering Committee, will be prepared and sent to the requesting investigator via a site that is secured by an access code. For data quality assurance purposes, all users have the responsibility to report to the NuAge Databank and Biobank any suspected error in the data file that was provided to them. It is forbidden to make any changes to the data transmitted.

The biologic sample access procedures are established by the Biobank Administrator and Coordinator (patricia.larcher.chum@ssss.gouv.qc.ca) according to the type of analyses required by the research project and the expert-laboratories identified.

## USAGE AGREEMENT (USER COMMITMENT)

By signing the *NuAge Database and Biobank Usage Agreement* and the *Collaborative Agreement,* the requesting investigator undertakes to inform all the users involved in the research project of the NuAge Database and Biobank guidelines and expectations towards its users. These expectations cover access fee payment, limitations of use, privacy and confidentiality, commercialization, intellectual property, deadlines granted for returning new generated data and biologic samples, destruction procedures for data transmitted by the NuAge Database and Biobank, as well as the dissemination of the research project results (manuscripts and scientific communications).

It should be noted that the NuAge Steering Committee grants itself the right to withdraw access privileges to the NuAge Database and Biobank to requesting investigators in the event **of non-compliance of commitments**.

### *Limitation of use*

Only the data and samples required to carry out the research project, as approved by the Steering Committee, will be transmitted to the requesting investigator. The users designated by the requesting investigator must use the data and biologic samples only for the objectives of the approved research project. The requesting investigator must inform the NuAge Database and Biobank Coordinator (NuAge-cdrv@usherbrooke.ca) of any new user being integrated into the research project, and is responsible for informing this new user of the expectations stated in the *Usage Agreement*. Therefore, sharing the data file with a non-authorized user and the use of data or biologic samples within the framework of a research project that has not been approved by the Steering Committee are not allowed. As needed, a research project amendment request may be submitted to the Steering Committee, which will evaluate its relevance.

## ***Protection of privacy and confidentiality***

### Privacy and confidentiality mechanism

The users receive de-identified data and biologic samples, which do not allow participants to be identified, and the user must not seek to directly or indirectly identify a participant, even by cross-referencing data. All users must comply with the rules regarding the confidentiality and protection of data and biologic samples pertaining to the NuAge Database and Biobank as listed in Attachment C. Under no circumstances will the identity or any information that may allow a participant identity to be determined or retraced, even by cross-referencing data, be disseminated.

### Physical security measures of data and other electronic information

The requesting investigator is responsible for ensuring the security and confidentiality of data transmitted by the NuAge Databank and Biobank (secure location and server, authorized personnel) and for informing all users involved in the project of the measures required. Data file exchange between the Databank Coordinator (NuAge-cdrv@usherbrooke.ca) and the requesting investigator is done via the secure *Transmission of Large Files*[3] site of the Université de Sherbrooke.

### Physical security measures of biologic samples

The requesting investigator is responsible for ensuring the security, confidentiality, storage (-80ºC) and proper handling of biologic samples transferred by the Biobank and for informing everyone involved in the project of these expectations. The samples must only be accessible to personnel authorized by the requesting investigator. The procedures for receiving and returning samples and results must comply with the instructions sent by the Biobank Coordinator (patricia.larcher.chum@ssss.gouv.qc.ca).

### Management of incidental findings

In the event that the conduct of the research project reveals abnormal results or incidental findings regarding one or more NuAge Database and Biobank participants, in particular in the context of projects performing complete genome sequencing, users of the NuAge Database and Biobank must inform the NuAge Steering Committee of this without delay. In this event, the Steering Committee will analyze the situation case by case. An expert clinician and/or the REC will be consulted, as needed.

[3] Secure transmission of files, https://cas.usherbrooke.ca/login?service=https%3A%2F%2Fwww.usherbrooke.ca%2Fenvoi-de-fichiers%2F, consulted on December 17, 2018.

## ***Commercialization and intellectual property***

### Commercialization of research results

An agreement must be authorized and signed between the NuAge Steering Committee (or its designated representative) and a user who wants to valorize any result, product, service, process, patentable technology, or any other work that may be subject to royalties, resulting from the use of the NuAge Database and Biobank. Resources available from the research valorization (e.g. SARIC[4]) and legal affairs offices of the Université de Sherbrooke will be used to protect the intellectual property of the parties concerned (including the affiliated institutions) in a discovery and to valorize these discoveries.

### Conflict of interest management

Users and Steering Committee members have the responsibility to declare or report, respectively, any real, apparent or potential conflict of interest, so that this situation may be reviewed by the CIUSSS-de-l'Estrie-CHUS REC and so that measures may be taken to manage and resolve these conflicts. Examples of conflicts of interest are available in the *Politique complémentaire sur les conflits d'intérêt* [*Additional Policy on Conflicts of Interest* in English] (2500-032)[5] of the Université de Sherbrooke.

### Return of new data generated and intellectual property

The requesting investigators have priority of use ("ownership") over the new data generated by the research project (e.g., blood test results) before the set time for transferring the new data to the NuAge Database and Biobank. The requesting investigator undertakes to transfer (via a secure site) all new data generated as part of the approved research project to the NuAge Database and Biobank as soon as one of the following criteria has been met:

- Twelve months after the publication of the results associated with the research project objectives, as defined in the research proposal approved by the NuAge Steering Committee; or
- Three years after the end of the research project funding, if no publication has resulted from this project.

If relevant, the **paper documents documenting the creation of the new data** must also be transferred to the NuAge Database and Biobank for references and archiving (the above deadlines apply).

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[4] Service d'appui à la recherche, à l'innovation et à la création (SARIC; Research, innovation and creation support service in English); https://www.usherbrooke.ca/gestion-recherche/outils/qui-fait-quoi/, consulted on December 20, 2018.

[5] *Politique complémentaire sur les conflits d'intérêt [Additional Policy on Conflicts of Interest in English];* https://www.usherbrooke.ca/a-propos/fileadmin/sites/a-propos/documents/direction/politiques/2500-032.pdf, consulted on January 18, 2019.

** At their discretion, the requesting investigator may transfer the data to the NuAge Database and Biobank before the above deadlines to make data available to other users.*

** The requesting investigator may request an extension of the deadlines mentioned by making the request to the NuAge Steering Committee. The reasons for the request must be clearly stated (e.g. parental leave, work stoppage due to illness of an essential research team member, technical problems that resulted in a significant delay in carrying out the project, etc.).*

In the event of potential financial benefits, the users must share the intellectual property rights of the project with the NuAge Database and Biobank (or a designated representative). A separate agreement must be authorized and signed by the parties concerned for the sharing of potential financial benefits. The potential financial benefits will strictly be used for purposes of financing NuAge Database and Biobank activities, the distribution of which will be defined by the NuAge Steering Committee and their affiliated institutions. Intellectual property does not apply to a research question or to participants.

**Destruction of data and biologic samples**

The requesting investigator and all the other users involved in the research project must permanently destroy all the data that have been transferred by the NuAge Database and Biobank, including their copies, as soon as one of the following deadlines has been met:

- Seven years after the publication of the research project results; or
- Ten years after the end of the research project funding if no publication has resulted from this project;
- Without delay if a request to this effect is sent by the NuAge Database and Biobank.

** The requesting investigator may request an extension of the above deadlines to the NuAge Steering Committee, clearly explaining the reasons for this request.*

Users who have received biologic samples must (Attachment B) return all remaining material to the Biobank Coordinator within 6 months after the end of the laboratory analyses foreseen in the research project, and approved by the Steering Committee, so that the samples may be destroyed with proper procedures. The same procedures for returning samples apply in the case of the use of expert laboratory services identified by the NuAge Steering Committee, in collaboration with the requesting investigator, for the biomarker assays requested in the research project. When private or hospital laboratory services are used, proper destruction of the sample residues is assured by these services.

Data (in digital or paper format) and biologic sample destruction must comply with the applicable standards of the CIUSSS-de-l'Estrie-CHUS[6] (and those applied at the CRCHUM for the Biobank[7]). For digital data, they must be permanently deleted from the file server. IT support services may be called upon for this purpose. Paper documents must be shredded by a company specialized in this regard, according to the procedures used in the users' respective institutions. Biologic samples must be destroyed by a company specialized in the secure disposal of biomedical material.

**Dissemination of results and publications**

As highlighted in the *NuAge Database and Biobank Usage Agreement* (Attachment B), users must submit to the Steering Committee, for purposes of documenting benefits and prior to approval, any manuscript or scientific communication (abstracts, oral presentations, scientific posters) resulting from the use of the NuAge Database and Biobank before their submission for publication or dissemination. **This procedure remains compulsory even if some of the authors of the scientific communication are members of the Steering Committee**. The users must also undertake to identify the specific funding sources of the data transferred by the NuAge Database and Biobank. The section below describes in detail the manuscript and scientific communication approval process, as well as the expectations with regard to the list of authors, the official name of the NuAge Database and Biobank, the funding and acknowledgements.

## MANUSCRIPTS AND SCIENTIFIC COMMUNICATIONS

### Applicable documents

Article, conference abstract, oral and poster presentation, letter to the editor, conference proceedings or any other form in which the research results arising from the use of the NuAge Database and Biobank data and biologic samples are disseminated.

### Steering Committee approval process

The procedure is as follows:

1. The requesting investigator (or another designated user) sends an electronic copy of the scientific communication, revised and approved by all the co-authors, to the NuAge Databank and Biobank Coordinator at NuAge-cdrv@usherbrooke.ca.

[6] SOP in effect; http://cr.chus.qc.ca/clients/SanteEstrie/Sous-sites/Centres_de_recherche/CRCHUS/Services-outils/Politiques-reglements/Modes_Operatoires_Normalises_2018-10-31.pdf, consulted on December 19, 2018.
[7] *Biomedical Waste Management Procedures* (CRCHUM).

2. The NuAge Database and Biobank Coordinator ensures that the scientific communication stems from a **project that was approved by the Steering Committee** and that this project still has a **valid ethics approval**.

3. In addition, the NuAge Database and Biobank Coordinator and a member (or a representative) of the Steering Committee ensure that the scientific communication adequately presents the following elements: the NuAge cohort[8] and the NuAge Database and Biobank, the data and samples used, the selection of the study sub-sample (justified and explained), the NuAge funding sources and ethics approvals. The Steering Committee may not authorize the scientific communication if it does not correspond to the approved project. It also reserves the right to require amendments if the above-mentioned elements are not adequately presented. **It can take up to approximately 3 weeks to obtain an initial response from the Steering Committee.**

4. Following the submission, the requesting investigator (or a designated user) is encouraged to send the final version submitted and to inform the NuAge Database and Biobank Coordinator of any decision regarding the scientific communication (accepted, refused, revisions requested, etc.).

### List of authors

- The scientific communication authors' list must comply with the guidelines of the International Committee of Medical Journal Editors, 2018 (http://www.icmje.org/recommendations/).
- The authors' names appear in the order as agreed upon by the leading investigator of the research project with co-authors.

### Official name of the NuAge Database and Biobank

The official name to use in manuscripts and scientific communications is "Banques de données et d'échantillons biologiques de l'Étude longitudinale québécoise sur la nutrition comme déterminant d'un vieillissement réussi" or "Database and Biobank of the Quebec Longitudinal Study on Nutrition and Successful Aging". After having mentioned the official name in the text, the abbreviation "Banques NuAge" or "NuAge Database and Biobank" may be used.

### Declaration of funding sources and ethics approvals

All manuscripts or scientific communications resulting from the research project must mention the funding sources of the NuAge Database and Biobank and those related to

[8] As described in Gaudreau P, Morais JA, Shatenstein B, et al. Nutrition as a determinant of successful aging: description of the Quebec longitudinal study NuAge and results from cross-sectional pilot studies. Rejuvenation Research 2007;10(3):377-86.

the data transmitted by the NuAge Database and Biobank, as well as the NuAge ethics approvals, as stated in the *Usage Agreement* signed by the requesting investigator.

### Date of receipt of the data file

The date of receipt of the data file transmitted by the NuAge Database and Biobank must be added to any scientific communication resulting from each secondary project, as specified in the *Usage Agreement*.

# ATTACHMENT A – GUIDELINES VERSION HISTORY

| Version | Revision Date (effective; YYYY/MM/DD) | Description of the Amendment | Author/Person in Charge of the Revision |
|---|---|---|---|
| Nº1 | 2019/03/08 | Upgrading to meet with the *NuAge Database and Biobank Management Framework*, in keeping with the policies and standards in effect[a] | Valérie Turcot<br>Nancy Presse<br>Other members of the Steering Committee |
| Nº2 | 2019/11/29 | Revision of the number of participants excluded from the NuAge Database and Biobank and revision of procedures for the withdrawal of a participant. | Valérie Turcot<br>Nancy Presse |
| Nº3 | 2020/08/25 | Updating of guidelines for the submission of an access request, evaluation process for access requests and revision of scientific communications. | Valérie Turcot<br>Nancy Presse<br>Other members of the Steering Committee |
| Nº4 | 2020/10/28 | Attachment D update (integration of responses to the telephone pre-screening realised during CIMA-Q recruitment) | Valérie Turcot<br>Nancy Presse |
| Nº5 | 2021/06/01 | Attachment D update (IL-1 beta withdrawal for the NutCog substudy because not detectable during the assay) | Valérie Turcot |
| Nº6 | 2022/03/11 | Update of Attachment B (CCNA and CIMA-Q partnerships) and access request procedures (withdrawal of submission deadlines, addition of support for researchers). | Valérie Turcot<br>Nancy Presse |
| Nº7 | 2022/09/09 | Update of the access procedures provided for medico-administrative data (summary) and of the Attachment E (Table 3). | Valérie Turcot<br>Nancy Presse |

[a] *Politique sur les banques de recherche* by the CIUSSS-de-l'Estrie-CHUS [*Research Bank Policy* in English] (version dated January 10, 2019, transmitted by Dr. Annabelle Cumyn, Co-Chair of the CIUSSS-de-l'Estrie-CHUS REC). Standards in effect, MON30FR03;http://cr.chus.qc.ca/clients/SanteEstrie/Sous-sites/Centres_de_recherche/CRCHUS/Services-outils/Politiques-reglements/Modes_Operatoires_Normalises_2018-10-31.pdf, consulted on December 19, 2018.
Abbreviation: REC, Research Ethics Committee of the CIUSSS-de-l'Estrie-CHUS.

**ATTACHMENT B**

Centre intégré universitaire de santé et de services sociaux de l'Estrie – Centre hospitalier universitaire de Sherbrooke
Québec

Centre de recherche sur le vieillissement

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1036 Belvédère St. South
Sherbrooke, Quebec, J1H 4C4
819-780-2220, ext.: 45613
NuAge-cdrv@usherbrooke.ca

# DATABASE AND BIOBANK USAGE AGREEMENT

## Database and Biobank of the Quebec Longitudinal Study on Nutrition and Successful Aging (NuAge Database and Biobank)

As the requesting investigator in charge of the secondary project ***"Enter the title of the project" (enter the project number)***, I undertake to:

- Forward this usage agreement to everyone involved in the project so that they are informed and comply with the expectations towards NuAge Database and Biobank users, as described below;
- Read and comply with the procedures described in the document *"Guidelines for NuAge Database and Biobank Users"*;
- Use the data and biologic samples provided by the NuAge Database and Biobank for the sole purposes described in the project approved by the Steering Committee, on ***"Enter the date"***, and only to meet the following objectives: ***"Add the list of project objectives";***
- Obtain the NuAge Steering Committee's approval for any amendment to the initially approved protocol by submitting an amendment request to the NuAge Database and Biobank (NuAge-cdrv@usherbrooke.ca);
- Forward to the NuAge Database and Biobank any ethics approval renewal for the project concerned;
- Forward to the NuAge Database and Biobank the name and contact information of any new person involved in the project for follow-up purposes;
- Forward to the NuAge Database and Biobank any error suspected in the data records that were provided to me for quality assurance purposes;
- Follow the biologic sample collection, analysis and return procedures, as described in the documents forwarded by the persons in charge of the Biobank;
- Forward to the NuAge Database and Biobank all new data generated by the project, if applicable, according to the conditions, deadlines and procedures

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described in the *"Guidelines for NuAge Database and Biobank Users"*. The deadlines in effect are:

- Twelve months after the publication of the results associated with the research project objectives, as defined in the research proposal approved by the NuAge Steering Committee; or
- Three years after the end of the research project funding, if no publication has resulted from this project.

**The requesting investigator may ask the NuAge Steering Committee for an extension of the deadlines by clearly justifying this request*

- Permanently destroy the data files transferred by the NuAge Database and Biobank, and their copies, and to return the samples that were sent to me by the NuAge Database and Biobank according to the deadlines and procedures described in the *"Guidelines for NuAge Database and Biobank Users"*. The deadlines in effect are:
  - Seven years after the last publication of the project results; or
  - Ten years after the end of the project funding if no publication has resulted from this project; or
  - Immediately, if the NuAge Database and Biobank sends a request in this regard.

- Comply with the rules in effect regarding the confidentiality and protection of data and biologic samples transferred by the NuAge Database and Biobank, as well as for new data generated by the project, as mentioned in the "*Guidelines for NuAge Database and Biobank Users"*;

- Not to seek to directly or indirectly identify a NuAge Database or Biobank participant, even by cross-referencing data, in a project that does not require participants to be recontacted;

- Not to publish or disseminate any information that may lead to the direct or indirect identification of a NuAge Database or Biobank participant;

- Submit to the NuAge Database and Biobank any manuscript or scientific communication (abstracts, oral presentations, scientific posters) before their submission for publication or dissemination for approval from the Steering Committee;

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- Identify the funding sources of the NuAge Database and Biobank and of the data transferred by the NuAge Database and Biobank in all publications resulting from this project by indicating the following sentences:

  *[NuAge Database and Biobank]* "*The NuAge Study was supported by a research grant from the Canadian Institutes of Health Research (CIHR; MOP-62842). The NuAge Database and Biobank are supported by the Fonds de recherche du Québec* (FRQ; 2020-VICO-279753), the *Quebec Network for Research on Aging, a thematic network funded by the Fonds de Recherche du Québec - Santé (FRQS) and by the Merck-Frosst Chair funded by La Fondation de l'Université de Sherbrooke.*" / « *L'Étude NuAge a été financée par les Instituts de recherche en santé du Canada (IRSC; MOP-62842). Les Banques NuAge bénéficient d'un soutien financier des Fonds de recherche du Québec (FRQ; 2020-VICO-279753), du Réseau québécois de recherche sur le vieillissement, un réseau thématique financé par les Fonds de recherche du Québec-Santé (FRQS) et par la Chaire Merck-Frosst financée par la Fondation de l'Université de Sherbrooke.* »

  *[NutCog study] add: "supported by a research grant from the Canadian Institutes of Health Research (CIHR; MOP-82825)" / « financée par les Instituts de recherche en santé du Canada (IRSC; MOP-82825) ».*

  *[NutCog study – CCNA Biomarkers] add: « Analyses were made possible through funding provided by the Canadian Consortium on Neurodegeneration in Aging (CCNA; Team 5 – Diet and Prevention). The CCNA is funded by the Canadian Institutes for Health Research and many partners.» / « Les analyses ont été rendues possibles grâce à l'appui financier du Consortium canadien en neurodégénérescence associée au vieillissement (CCNV; Équipe 5 – Nutrition, exercice et style de vie). Le CCNV est financé par les Instituts de recherche en santé du Canada et plusieurs partenaires. »*

  *[Pre-screening for CIMA-Q study] add: « The Consortium for the Early Identification of Alzheimer's Disease (CIMA-Q) is supported by the Fonds d'Innovation Pfizer - Fonds de Recherche Québec – Santé sur la maladie d'Alzheimer et les maladies apparentées (Pfizer-FRQS; #27239), the Quebec Network for Research on Aging, the Courtois Foundation-NeuroMod project and the Fondation Famille Lemaire. » / « Le Consortium pour l'identification précoce de la maladie d'Alzheimer (CIMA-Q) est financé par les Fonds d'Innovation Pfizer - Fonds de Recherche Québec – Santé sur la maladie d'Alzheimer et les maladies apparentées (Pfizer-FRQS; #27239), le Réseau québécois de recherche sur le vieillissement, le Courtois Foundation-NeuroMod project et la Fondation Lemaire. »*

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- Indicate the consent status and ethics approvals obtained for the NuAge Database and Biobank in the publications resulting from this project based on the following sentences:

  *[NuAge Database and Biobank]:*
  *« All participants of the NuAge study provided informed consent. From the initial cohort of 1,793 participants, 1,753 (98%) agreed to the integration of their data and biological samples into the NuAge Database and Biobank for future studies. » / « Tous les participants de l'étude NuAge ont fournis un consentement éclairé. De la cohorte initiale de 1793 participants, 1753 (98%) ont accepté que leurs données et échantillons biologiques soient intégrés aux Banques NuAge pour des études ultérieures. »*

  *« The NuAge study protocol was approved by the Research Ethics Boards of the Institut universitaire de gériatrie de Montréal and the Institut universitaire de gériatrie de Sherbrooke (Quebec, Canada). The NuAge Database and Biobank have been approved by the Research Ethics Board of the CIUSSS de l'Estrie-CHUS (Quebec, Canada). » / « Le protocole de l'étude NuAge a été approuvé par les comités d'éthique de la recherche de l'Institut universitaire de gériatrie de Montréal et l'Institut universitaire de gériatrie de Sherbrooke (Québec, Canada). Les Banques NuAge ont été approuvées par le comité d'éthique de la recherche du CIUSSS de l'Estrie-CHUS (Québec, Canada). »*

  *[NutCog Study], add:*
  *« All participants of the NutCog Study provided informed consent. » /« Tous les participants de la sous étude NutCog ont fournis un consentement éclairé. »*

  *« The NutCog Study was approved by the Research Ethics Boards of the Institut universitaire de gériatrie de Montréal and the Institut universitaire de gériatrie de Sherbrooke (Quebec, Canada). / « L'étude NutCog a été approuvée par les comités d'éthique de la recherche de l'Institut universitaire de gériatrie de Montréal et l'Institut universitaire de gériatrie de Sherbrooke (Québec, Canada). »*

  *[Pre-screening for CIMA-Q study], add:*
  *« The CIMA-Q Study was approved by the Research Ethics Board of the Institut universitaire de gériatrie de Montréal (Quebec, Canada). » / « L'étude CIMA-Q a été approuvée par le comité d'éthique de la recherche de l'Institut universitaire de gériatrie de Montréal. »*

- Enter the date of receipt of the data file transmitted by the NuAge Database and Biobank in any scientific communication resulting from this project;

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- Declare to the NuAge Database and Biobank any real, apparent or potential conflict of interest situations between my personal interests (or those close to me) and my faculty obligations and responsibilities. In such a situation, a *"Conflict of Interest Declaration" form* must be filled out to assess and manage this situation, as described in the "*Guidelines for NuAge Database and Biobank Users"*;

- Declare to the NuAge Database and Biobank if the project aims to develop any patentable results, processes, or technologies or any other work that may be subject to royalties to obtain approval from the Steering Committee.

In the context where there is a possibility that the project may lead to patentable results, processes or technologies or any other work subject to royalties, steps will be taken by the NuAge Database and Biobank with the research valorization and the legal affairs offices of the Université de Sherbrooke to ensure the protection of the intellectual property and the sharing of royalties among the parties concerned.

For further information and follow-up concerning these commitments, please contact the persons in charge of the NuAge Database and Biobank via NuAge-cdrv@usherbrooke.ca.

**Full name and contact information of the requesting investigator:**
***"Enter here"***

**Signature:** _____

**Date:** _____

**ATTACHMENT C – LAWS, REGULATIONS AND GUIDELINES OF CANADIAN AND QUEBEC BODIES THAT APPLY TO THE ACTIVITIES AND USE OF THE NUAGE DATABASE AND BIOBANK**

**QUEBEC**

- Act respecting health services and social services:
  http://legisquebec.gouv.qc.ca/en/showdoc/cs/s-4.2

- Act respecting access to documents held by public bodies and the protection of personal information:
  http://legisquebec.gouv.qc.ca/en/showdoc/cs/A-2.1

- Act respecting the protection of personal information in the private sector:
  http://www.legisquebec.gouv.qc.ca/en/showdoc/cs/P-39.1

**CANADA**

- Personal information protection and electronic documents act*:*
  https://laws-lois.justice.gc.ca/eng/acts/p-8.6/

# ATTACHMENT D – LIST AND SUMMARY DESCRIPTION OF DATA FROM SECONDARY STUDIES INTEGRATED INTO THE DATABASE OF THE NUAGE DATABASE AND BIOBANK.

| **Name of the Secondary Project**<br>***Funding Source*** | **Number of Participants**<br>**Participant Selection Criteria** | **Summary Description of Data Integrated into the Bank**<br>**Method*, Data Collection Date** | **REC Approval Date** |
|---|---|---|---|
| **NutCog**<br>*Canadian Institutes of Health Research (CIHR; MOP-82825)* | • 464 of 1,793 NuAge participants were included in the NutCog study;<br>• 461 are included in the NuAge Database and Biobank;<br>• Criteria: no cognitive impairment, have accepted to be recontacted for future studies as per the initial consent form, French-speaking and with no clinical condition that may affect cognition (detailed in Presse et al., 2013). | Scores for 6 cognitive tests assessing 4 cognitive domains (Presse et al., 2013):<br>- Free recall/cued recall; 16 items at 0 and 20-min;<br>- Rey Complex Figure at 0, 3 and 20-min;<br>- Stroop test;<br>- Choice-Reaction Time;<br>- Adaptation of the Brown-Peterson procedure;<br>- WAIS-III Digit Symbol-Coding.<br>The tests were administered during 2 visits at the research centre, 2 years apart, i.e. in 2006-2008 (Visit 1) and in 2008-2010 (Visit 2). | July 5, 2019 |
| **NutCog**<br>*Canadian Institutes of Health Research (CIHR; MOP-82825)* | • 464 of 1,793 NuAge participants were included in the NutCog study;<br>• 461 are included in the NuAge Database and Biobank;<br>• Selection criteria: no cognitive impairment, have accepted to be recontacted for future studies as per the initial consent form, French-speaking and with no clinical condition that may affect cognition (detailed in Presse et al., 2013). | Results of biomarker assays that were performed on serum or plasma samples from the NuAge Biobank.<br>-long-chain fatty acid profile<br>-lipid profile (TG, HDL, Chol, LDL)<br>-us-CRP<br>-carbonylated proteins<br>-salivary cortisol<br>-insulin<br>-phylloquinone<br>-homocysteine<br>The assays were performed at different measurement times of NuAge according to the needs of the NutCog study and are available for the majority of the 462 participants. | September 11, 2019 |
| **NutCog**<br>*Canadian Consortium on Neurodegeneration in Aging (CCNA)* | • Same as above | Results of inflammatory biomarkers and from the somatotropic axis that were performed on serum or plasma samples from the NuAge Biobank.<br>- Tumor necrosis factor alpha (TNF-alpha)<br>- IL-6<br>- IL-10 | April 29, 2020 |

| **Name of the Secondary Project**<br>***Funding Source*** | **Number of Participants**<br>**Participant Selection Criteria** | **Summary Description of Data Integrated into the Bank**<br>**Method*, Data Collection Date** | **REC Approval Date** |
|---|---|---|---|
| | | - Insulin-like growth factor-1 (IGF-1)<br>- Insuline-like growth factor binding protein-3 (IGFBP-3) | |
| **Telephone pre-screening for CIMA-Q recruitment**<br>*Fonds d'Innovation Pfizer-FRQS sur la maladie d'Alzheimer et les maladies* apparentées (Pfizer-FRQS Innovation Fund on Alzheimer's Disease and Related Diseases, in English) | • 583 of 1,793 NuAge participants responded to CIMA-Q pre-screening questions;<br>• 577 are included in the NuAge Database and Biobank;<br>• Selection criteria: no cognitive impairment at the first NuAge follow-up, accepted to participate in further studies, still alive at the last NuAge follow-up and not a long-term care resident at the time of screening. | Results related to their general health based on three questionnaires:<br>-Elderly Nutrition Screening (ENS)<br>-Physical disability status (Nagi)<br>-Autonomy assessment in Activities of Daily Living (ADL)<br>Results related with memory and cognitive decline:<br>-Auto-perception of cognitive decline (Jessen et al. 2014)<br>-Adaptation of the Telephone version Mini-Mental State Examination (T-MMSE)<br>-Adaptation of the Telephone Interview for Cognitive Status (TICS; n = 367)<br>Telephone interviews with the 577 participants were conducted between January 2014 and March 2017. | October 28, 2020 |

*The protocols detailing the data collection procedure for the secondary studies are available upon request.

Abbreviations: CIMA-Q, Consortium for the Early Identification of Alzheimer's Disease; FRQS, Fonds de recherche du Québec – Santé.