LifeGene Access and IP Policy

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1. LifeGene - Purpose and Overview

LifeGene is a national collaborative project designed to build up a resource for research in all medical disciplines but also behavioral and social sciences, enabling new and groundbreaking research on the relationships among heredity, environment and lifestyle and its impact on disease. The LifeGene project will include studying a quarter of a million Swedes mainly aged 0-50 with the aim of creating new tools to prevent, diagnose and treat our most common diseases.

A quarter of a million Swedes will be included for collection of information concerning their health, lifestyle and exposures, and donation of biological samples. LifeGene will be longitudinal with repeated contacts with our study participants. LifeGene will seek active engagement with participants, researchers and society in general throughout the lifetime of the resource. Data and samples will only be used for ethically and scientifically approved research consistent with the above purpose. Safeguards will be maintained to ensure the confidentiality of the participants' data and samples.

LifeGene will constitute a platform for a myriad of biomedical research projects. Researchers not only in biomedicine and biotechnology but also behavioral and social sciences may benefit from access to LifeGene. By combining a biological perspective with e-epidemiology, LifeGene will open up new possibilities for a greater understanding of the interplay between heredity, lifestyle and the environment as regards to our most common diseases, possibilities strengthened by the longitudinal aspects of the study.

The data access policy of LifeGene will conform to international recommendations. The open-access resource will provide new information about the causes of diseases that holds a good chance of leading to their prevention, refined diagnostic methods and therapeutic opportunities.

LifeGene will serve as the steward of its resource, maintaining and building it for the public good in accordance with its purpose. This implies both the judicious protecting and sharing of the resource. It also extends to the careful management of any transfer of parts or all of the database or sample collection.

In this document, the Access and IP Policy of LifeGene and the process for applying for access is presented.

2. Stewardship of Data and Samples

LifeGene will serve as the steward of its resource, maintaining and building it for the public good in accordance with its purpose. This implies both the judicious protecting and sharing of the resource. It also extends to the careful management of any transfer of parts or all of the database or sample collection. Participants will not have property rights in the samples.

LifeGene will act in accordance with the Personal Data Act and all other relevant legislation, including the Biobank act. Compliance with the Personal Data Act together with the Swedish Act on Secrecy and the Genetic Integrity Act is necessary to ensure the confidentiality of the participants in LifeGene. LifeGene has received all necessary approvals that are required for the planned invitation, assessment and follow-up procedures (e.g. from relevant ethics committees, the National Board of Health and Welfare and other relevant bodies). LifeGene will also require that all research projects gaining access to LifeGene data and biobank samples are approved of by the Independent Regional Boards of Ethics in accordance with the Ethical Review Act. Although the current Biobank Act does not strictly apply to LifeGene, as part of Karolinska Institutet, LifeGene commits itself to act in accordance with the higher standards of the Biobank Act. LifeGene will also comply with international conventions, such as the World Medical Association Declaration of Helsinki and relevant European international guidelines. LifeGene will respect domestic laws and beyond that conform to the principles with highest ethical standards. The monitoring will be done by LifeGene itself as well as by LifeGene's Data Access Committee.

3. The LifeGene Resource

LifeGene has currently, as of beginning of 2015, recruited more than 41000 participants, of whom 34000 have fully completed our online questionnaire and more than 22000 participants who have visited one of our test centers. LifeGene's baseline assessment involves an extensive range of questions and measures as well as the collection of biological samples that allow many different types of assays and analysis.

A detailed description of the resource can be found at www.lifegene.se.

4. Access to Data and Samples

4.1 General principles of access

LifeGene will retain full control of all access to, and uses of, the resource. LifeGene will not proscribe any medical or other health related research uses at the outset. However, all proposals will be reviewed by LifeGene to ensure they are consistent with the participants' consent and the Ethics Policy, and that they have relevant ethics approval. All users, whether employed by universities, government, charities or commercial companies, will be held to the same scientific and ethical standards.

Exclusive access to the fully developed resource will not be granted to any party. Use of the biological samples will have to be carefully coordinated and controlled since they are limited. While the resource is being developed, LifeGene may use the early data and samples to validate and improve methods of data collection and analysis. There will be frequent calls for research project proposals needing biological materials in order to prioritize the use of the biological samples. The general criterion for such a priority is the scientific and potential health value of the research projects in question. Applications will be subjected to peer-review and the final decision to grant access to the material will be made by NSAB.

Researchers will only be given access to coded data and samples. The concept of coded information means that all identifying information, such as personal identity number, is removed and is replaced with a designated number. Researchers will not be able to identify individual participants from the data or samples that are provided to them. Only a few people within LifeGene have permission for re-linking the participants' identifying information with their data and samples. It is necessary to retain this link with identifying information to allow follow-up of participants' health; to eliminate redundant data (e.g. duplicate cases); to verify correctness and completeness of data against original records.

4.2 Decisions on access

The LifeGene Data Access Commitee will have the overall decision-making authority over access to and use of the resource. LifeGene will explain, to participants, the public and the scientific community, the policies and procedures for research access. The Access and IP Policy addresses fairness and transparency of decision-making, the handling of conflicts of interest and the prioritization of use of samples.

In cases of international researchers applying for access to LifeGene resources, LifeGene will act in accordance with the Swedish Biobank Act [chapter 4, §3] and require a Swedish research institution to file for approval for sharing samples outside Sweden. International researchers will be held to the same standards as Swedish researchers regarding access and usage of LifeGene resources. All researchers (Swedish and international) need to sign a contract.

LifeGene commits itself to act in accordance with the Ethics Policy and this Access and IP Policy, in order to assure others that the resource is being used in the public interest.

4.3 Licenses for specific uses

Access to data and/or samples will be granted under license for scientifically and ethically approved research consistent with LifeGene's purpose. Licenses will be for specific uses under strict terms and conditions in standard access agreements, including compliance with the consent given, the provisions of this Ethics Policy and other policies.

4.4 Sharing of data and findings

LifeGene seeks to augment the value of the resource in order to ensure that the greatest potential benefit for public health may be realized from it.

All researchers will be required to deposit data and results from analyses made on participants' data and samples, and any relevant supporting information, in the LifeGene database so that they are subsequently available to all researchers with appropriate scientific and ethics approval. It is highly desirable that any such deposit is done within six months of the completion of the study. LifeGene will require results to meet a standard of quality for incorporation into LifeGene's database.

There will also be a requirement on researchers to place the findings (whether positive or negative) from research based on LifeGene data/samples in the public domain so that people can benefit from them. Publication should be in the peer reviewed scientific literature whenever possible. LifeGene will also explore further strategies for dissemination of findings (such as through accessible electronic archives).

Researchers will only be permitted to keep results based on LifeGene confidential for a limited and reasonable period (for example, while they prepare papers for publication, file patent applications or otherwise pursue reasonable competitive advantage for their efforts). This policy will apply to all researchers, whether non-commercial or commercial.

Researchers should acknowledge LifeGene in publications, presentations, and patents filed. LifeGene will provide researchers using its resources detailed guidance on the manner in which it wishes to be acknowledged.

4.5 Intellectual Property

Intellectual property and access policies have been developed to help ensure that the LifeGene resource is accessible to all *bona fide* research users, but is not exploited improperly or used in any way that inappropriately constrains use by others. Terms of access will be embodied in legal transfer agreements that reflect LifeGene's objectives.

LifeGene is not expected in itself to lead to patentable inventions that return significant income either to researchers or LifeGene, but it is expected to become a valuable common resource for research. Nevertheless, there is a significant chance that research conducted using the resource (which might be conducted by researchers in the public or commercial sector, as well as the academic and charity sector) will subsequently support the development of an invention that returns a profit. As long as the research project using LifeGene's resource is approved in the standard manner, filing for IP rights by Swedish or international researchers are allowed.

Any and all intellectual property rights derived from LifeGene samples and data are the sole and exclusive property of LifeGene or its licensors. Subject to the above, LifeGene waives all rights to any intellectual property developed by Researchers whilst using data and samples in accordance with the Material Transfer Agreement.

4.6 Profits and Royalties

The biotechnology and pharmaceutical industries can play an important role in realizing health benefits in a practical sense by developing and improving the use of biomedical products. Commercial companies and other research endeavors that stand to make a profit will, therefore, be allowed access to LifeGene if their proposal falls within the LifeGene purpose and complies with the usual scientific and ethics requirements.

5. Terms and Conditions for Access

Before access to the collection is granted, applicants must agree to the conditions of access set out in this policy and return a signed material transfer agreement (MTA) or data transfer agreement (DTA) to LifeGene.

These conditions will be included in the transfer agreement to be signed by the Scientific Director of LifeGene and the principal investigator (PI). The main elements are set out in the access policy so that researchers are aware of them at the time of application. MTA and DTA templates can be downloaded from www.lifegene.se.

5.1 Limitations of usage

Data or samples supplied from the collection must only be used for the purposes stipulated by LifeGene and described in the research plan in the transfer agreement.

5.2 Recipient warranties

The recipients warrant that all work in relation to the samples will be carried out in compliance with all applicable laws, regulations, guidelines and any approval from an Ethics Review Board.

5.3 Onward transfer

Data or samples from the collection may not be transferred to any third party not approved by LifeGene. The recipients are forbidden to transfer their rights or obligations according to the transfer agreement without prior, written approval from LifeGene.

5.4 Protection of integrity

The identity of provided samples and datasets are coded to protect the integrity of the donors and recipients must not attempt to identify any individual from the data or samples provided.

Should recipients believe that they have inadvertently identified any individual, they must not record this, share the identification with any other person or attempt to contact the individual.

If recipients believe that they have inadvertently identified any individual from the data or samples provided they must inform LifeGene and provide details of the circumstances under which this occurred.

No attempt to contact donors should be made by the recipient.

The recipients are responsible for taking the necessary technical and organizational measures to protect the samples and information from unauthorized access. Any user should be bound by professional secrecy

Recipients must agree not to link the coded data or samples provided with any other data set not mentioned in the application without the prior permission by LifeGene.

5.5 Transparency

Study titles may be published on the LifeGene website or in other public documents, together with lay summaries and the names of the institutions where the work is taking place. Contact details for the principal investigator of each study may be provided by LifeGene upon request.

5.6 Dissemination of data and results

The recipients of data and samples own the results of their research. Other researchers or companies wishing to use the results must first obtain permission from the recipients.

Recipients are expected to submit their results to a peer reviewed publication within 6 months after completing their study. If the researchers wish to have this period extended to protect IP, they should discuss this with LifeGene.

Generally, recipients who have satisfied the requirements for accessing the collection should be considered competent and free to publish their results without restriction, although they may benefit from discussing their results and interpretation with LifeGene's scientific staff before publishing.

Researchers who do not wish details of their study to be openly available should state this in their application to Lifegene and give the reason.

5.7 Record of publications

Recipients should provide a copy of any publications based on data or samples from the resource to LifeGene.

5.8 Acknowledgement of the resource

The applicants will ensure that any publication or presentation that is based (in whole or in part) on any samples or data obtained from LifeGene will include an acknowledgement of LifeGene and its funding sources.

5.9 Reporting data and results to LifeGene

On completion of their study, recipients should provide any results or data arising including derived data, calculation models and any relevant supporting information from the use of the samples to LifeGene within 6 months for possible inclusion in the resource database unless a delay is required to protect IP.

Submission of results to LifeGene does not affect the requirement for recipients to maintain their own research records.

Published variables created using existing data from LifeGene should be reported back to LifeGene if it has been agreed upon. For each variable the code used to create this must be

enclosed together with documentation stating used variables, algorithm, codebook and data used.

5.10 Returning samples

The applicants agree to return all samples and unused portions of samples, including extracted DNA, to LifeGene within 6 months after the completion of the research project.

5.11 Withdrawn consent

If consent is withdrawn for issued samples, applicants will be informed of the relevant sample numbers and asked to return them. Results obtained from samples that have already been used for research need not be destroyed. Recipients may be contacted in case a participant requires destruction of all data from LifeGene.

5.12 Compliance policy

Recipients found to be in breach of the Transfer Agreement or the Access policy will be denied future access to the collection and their institutions and funders informed.

5.13 Fees

The recipient will be required to cover the costs of retrieving, processing and dispatching samples. Details about any fees that apply and invoicing procedure are available at www.lifegene.se and will be provided in an appendix to the transfer agreement.

5.14 Legal dispute

The transfer agreement falls under Swedish law. Conflicts arising from this contract will be settled in a Swedish court of law.

6. Applying for Access

6.1 Overview of the application process

The application process consists of four stages, which must be completed before samples and/or data are provided:

1. Submission of an initial application to determine the availability of samples and/ or data and the eligibility of the proposed study for access.
2. Submission of the main application and providing any supporting information required.
3. Scientific review of the application and decision whether to grant access (process shortened when no samples involved)
4. Agreeing to the conditions of access and signing the MTA.

The application process is outlined in figure 1. All applications should be sent applications@lifegene.se.

6.2 The initial application

Researchers who wish to access the resource should initially complete an intial application form giving a brief outline of the proposed study, the methodology to be followed and the number and type of samples required. The application form and instructions are available at www.lifegene.se. LifeGene staff will make a preliminary assessment of the availability of samples and the suitability of the application and respond to the applicant. If samples are not available the applicant will be notified with details of possible alternatives.

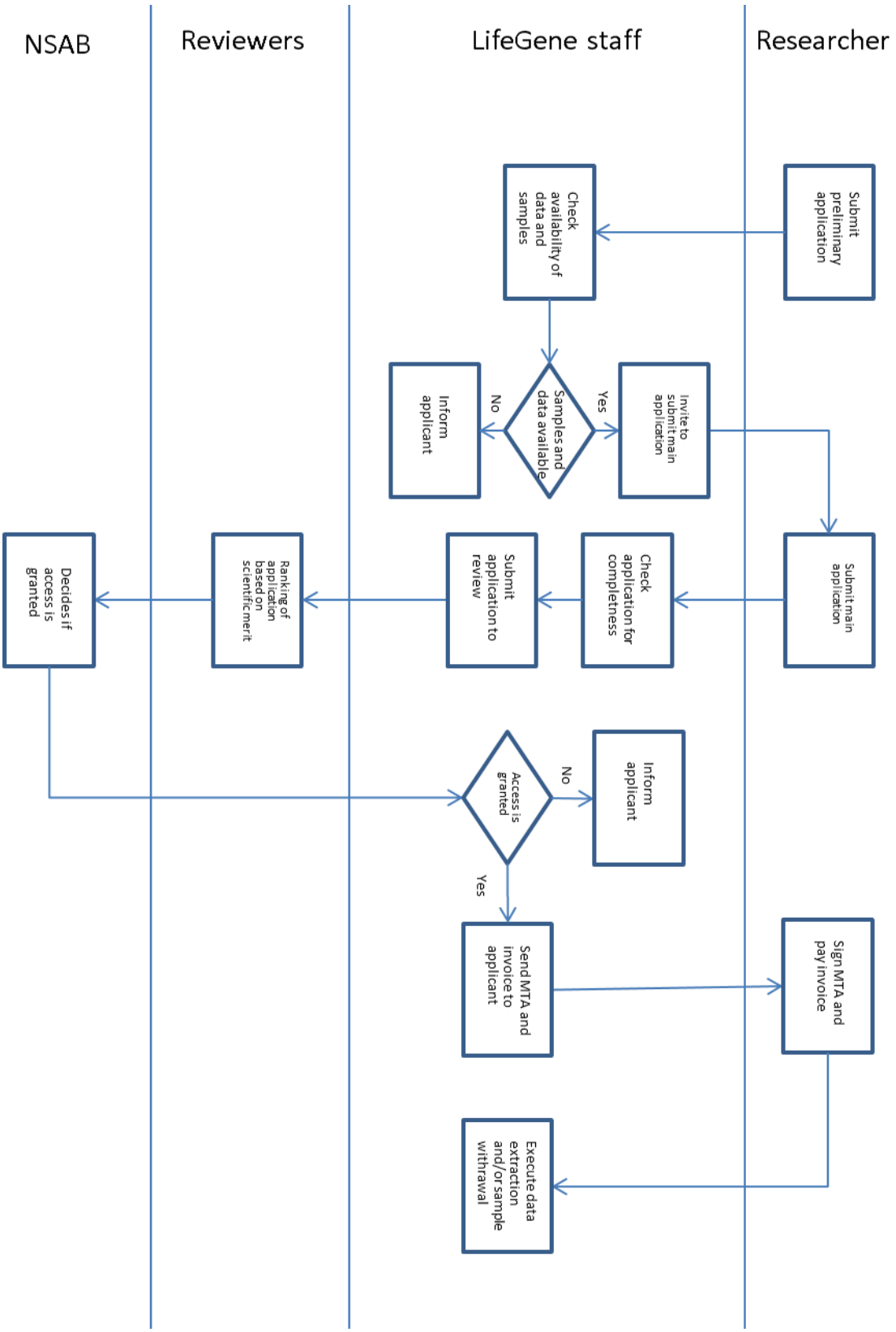

Figure 1. Overview of the application and review process.

6.2 The Main application

If the applicant PI has received an invitation to submit a main application, the applicant PI needs to complete a main application form (available at www.lifegene.se) and provide the following information:

Summary of the proposed study

Names of all applicant researchers

Project plan and scientific rationale of the study (background and any preliminary data, experimental details and design, expected value of results and relevant references), a maximum of 5 pages with minimum font size 11.

Required data and/or quantity and type of samples (updated if necessary from the preliminary application

Procedures for secure storage of data and/or samples

Proposed timetable (start, duration, availability of results and other deliverables, submission of publication)

Details of funding (or grant applications)

Assessment of potential risk to participants

The main application to LifeGene can be made before any ethical approvals are obtained. However, in these cases, the applicants will be asked to submit the decision from the ethical review board before any samples or data will be transferred.

6.3 Administrative checking

On receipt of the application, LifeGene staff will check that all required information has been supplied. If any information is missing from the application the applicant will be asked to supply this before the application is considered further for review.

6.4 Peer review

Due to the rare and depletable nature of the sample collection all applications for biological samples will be peer reviewed and graded on the basis of scientific and technical merit. Reviewers with appropriate scientific expertise will be appointed by the NSAB.

The final decision to grant access to biological samples will be taken by the LifeGene Data Access Committee based on the review report.

The review of applications only involving access to data will be handled differently from applications for biological samples. The whole process will be more straightforward and involves fewer reviewers. Final approval of access to data will be made by the Scientific Director of LifeGene.

6.5 Transfer agreement

If the research project is approved then LifeGene staff will send an MTA or DTA (with an invoice for any charges) to the applicant PI to be signed and returned before any data and/or samples will be transferred.

6.6 Provision of data

Data will be made available by issuing hyperlinks and passwords to the applicant PI so that the relevant data can be securely downloaded from LifeGene's servers.

6.7 Provision of samples

An order for retrieval of samples will be submitted to KI Biobank as soon as the MTA has been signed. KI Biobank will handle the whole process of sample retrieval and delivery to the applicant PI's laboratory.