METHOD FOR LINKING A BIOLOGICAL SAMPLE IN A COLLECTION AND/OR INFORMATION RELATED TO A BIOLOGICAL SAMPLE IN A COLLECTION WITH INFORMATION FROM THE DONOR OF THAT BIOLOGICAL SAMPLE

DESCRIPTION

The present invention relates to a method for linking a biological sample in a collection and/or information related to a biological sample with information from the donor of that biological sample and furthermore relates to the use of said method for providing information related to a biological sample present in a collection to the donor of that biological sample.

It is common practice for hospitals, research institutes, universities, pharmaceutical or biotechnological companies, diagnostic laboratories, or biobanks to keep biological samples derived from human donors in collections. These collections can be relatively small comprising a limited number of biological samples or can be very large comprising millions of biological samples.

The biological samples can be any human material either directly derived after for example a biopsy, a surgical operation, a swab, an aspiration, or any other method for isolation of or obtaining human material, or indirectly derived after for example cell culture, tissue engineering, or in vitro fertilization.

Specific examples of such biological samples are body parts like an amputated limb; organs like a liver, a kidney, a spleen; tissues like parts of organs, muscles, skin, or retina; tumors or other malignancies; placenta; umbilical cord; blood or isolated fractions thereof; body fluids like lymph fluid; secreted fluids like saliva; cells

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like lymphocytes, sperm, egg cells, bone marrow cells,; intracellular organelles like the endoplasmatic reticulum or the mitochondria; intracellular components like DNA, RNA, or proteins; cell membranes; extracellular matrix; extracellular components; or cell culture products. The biological sample can also comprise combinations of the above examples.

In addition, often also data, either obtained before or during deposition of the biological sample or obtained thereafter, related to the biological sample like medical history data, genealogical data, lifestyle data, genomic data, expression data, nutritional data, environmental data, epidemiological data, sociological data, ethnic data, demographic data, an/or data derived from research on the biological sample and/or from analysis of the information related thereto, are stored in the collection.

These collections of biological samples and/or information related to the biological sample form a valuable resource of research tools in many fields of medical and pharmacological sciences, especially when a collection is statistically representative for a population or cohort. For example, these biological samples and/or information related to the biological samples enable the development of drugs; enable the elucidation of the underlying mechanisms of diseases like cancer, heart diseases, diabetes, hereditary diseases, or diseases associated with ageing; allow for epidemiological research; or enable the identification and/or isolation of pathogens.

However, in order to perform research on the collections of biological samples and/or on the information related to these samples or to use them for other purposes, often information is required, like a consent or objection of the donor to the use of the biological sample and/or information related thereto, or information is required like

additional medical information, of the donor of the biological sample. Obtaining such information from the donor can form a serious problem for the keeper or proprietor of a collection of biological samples because of the following reasons.

First, although in some collections identifying information of the donor, like a name and/or address, is linked to the biological sample and/or the information related to the biological sample, such information cannot be used because for example such information is no longer valid due to moving of the donor to another address, or a name change of the donor.

Second, in a number of collections such linked identification information of the donor is not available because it was never deposited with the biological sample and/or the information related to the sample; or the linked identification was present at the time of deposition of the biological sample in the collection, but was deliberately deleted for example to avoid the burden of privacy protection. Also, the linked identification information of the donor could be lost for example due to a computer malfunction.

The situation that the donor cannot be contacted also causes a problem when for example research on the biological sample reveals information which is important for the donor to known like for example information relating to possible diseases or a predisposition to certain diseases for which an early treatment could be life saving.

Thus, there is a need for a method enabling to link information from a donor with a biological sample and/or information related to that sample. In addition, there is a need for a method enabling to provide valuable information relating to a biological sample to the donor of that sample.

It is an objective of the present invention to provide such methods.

According to the present invention this objective is achieved by providing a method for linking a biological sample in a collection and/or information related to a biological sample in a collection with information from the donor of that biological sample, comprising:

- the public request or call for information from the donors of the biological samples in the collection;
- the determination of one or more biological characteristics of a donor responding to the request or call for information;
- the submission of the determined biological characteristics of the responding donor together with the information from the donor to a keeper or a proprietor of the collection;
- the comparison of the determined biological characteristics of the responding donor with the corresponding biological characteristics of the biological samples in order to identify the biological sample of the responding donor and/or information related to the biological sample; and
- the linking of the information of the responding donor with his or her biological sample and/or the information related to that sample.

The first step according to the method of the present invention is the public request or call for information from the donors of the biological samples in the collection. The request or call can, for example, comprise the reason why information of the donor is required, information regarding the collection, the preferred biological characteristics allowing identification of the biological sample and/or

information related thereto, which information from the donor is desired, or combinations thereof.

The public request or call can be made by or originate from the keeper or the proprietor of the collection but can also originate from any third party, like a research institute or a pharmaceutical or biotechnological company interested in the collection.

The request or call is made publicly. Publicly in this context means that the request can be made through communication channels open for anyone, but also that the request can be made through communication channels open for an authorized or restricted group of people such as for example physicians, or other medical professionals.

The communication channel for communicating the request is not restricted to a specific group of channels. According to the present invention any channel which enables the transmission of the request or call to donors either directly or indirectly is suitable. Examples of suitable communication channels are television, text TV, internet, specific intranet network(s), WAN, LAN, email, telephone, SMS, radio, newspapers, magazines, bill boards, folders, mailings, posters, advertisements, or combinations thereof.

After the public request for information from donors, the next step according to the present invention is that one or more biological characteristics of a donor responding to the request are determined.

The biological characteristics of a responding donor are those characteristics which correspond to or are equivalent to the characteristics of the biological sample originating from the donor and which are sufficient for identifying the biological sample as directly or indirectly originating from the responding donor. Although any biological characteristic can be used preferred are

biological characteristics relating to nucleic acids, proteins, cells, or to the composition of the blood or other body fluids since these characteristics can easily, reliably, and/or relatively cost effective be determined on human material obtained by relative non-invasive medical procedures such as blood collection or swabs, using standard and general available laboratory equipment.

Methods for determination of biological characteristics are well known in the art and therefore it is not necessary to further describe herein such determinations in detail.

Examples of biological characteristics are DNA fingerprinting patterns, Restriction Fragment Length Polymorphism (RFLP) patterns, Polymerase Chain Reaction (PCR) product(s), Real Time Polymerase Chain Reaction (RTPCR) product(s), gene expression patterns, protein expression patterns, Single Nucleotide Polymorphisms (SNPs), RNA structure(s), patterns of RNA levels, genomic mutations, genomic deletions, genomic insertions, genomic organization, cell composition, cell morphology, blood composition, body fluid composition, tissue composition, tissue morphology, extra-cellular matrix composition, extra-cellular matrix morphology, protein structure(s), protein level(s), lipid structure(s), lipid level(s), carbohydrate structure(s), carbohydrate level(s), proteoglycan structure(s), proteoglycan level(s), glycoprotein structure(s), glycoprotein level(s), glycolipid structure(s), glycolipid level(s), lipoprotein structure(s), lipoprotein level(s), nucleotide structure(s), nucleotide level(s) or combinations thereof.

After the determination of one or more biological characteristics, the information of the responding donor together with his or her determined biological

characteristics are submitted to the keeper or proprietor of the collection.

Subsequently, the biological characteristics of the responding donor are used to identify the biological sample of the responding donor. This can be done by comparing the determined biological characteristics of the donor with the corresponding or equivalent biological characteristics of the biological samples in the collection. Such comparison is well known in the art and therefore it is not necessary to further describe herein such comparison in detail.

After identification of the biological sample and/or the information related to the biological sample as originating from the responding donor, the information from the donor is linked to the biological sample and/or the information related to the biological sample.

The method according to the invention thus provides a solution for linking information from a responding donor to a biological sample and/or information related to this sample in all the above-mentioned situations wherein the identifying information of the donors cannot be used or is outdated, the identification of the donors is not recorded, or the identification of the donors is lost or deliberately deleted.

In addition, the method according to the present invention provides the possibility of opening a communication channel with a donor for subsequent information exchange regarding information relating to the biological sample.

An additional advantage of the method according to the present invention is that the method allows that the responding donor can remain anonymous while being able to provide information to the keeper or proprietor of a collection since identifying information, like a name or address, of the donor is not necessary for the identification

of his or her biological sample and/or information related thereto and the subsequent linking of the information from the donor with the biological sample and/or the information related to the biological sample.

According to one embodiment of the present invention, the information from the responding donor is an objection or consent to the use of the biological sample and/or the information related to the biological sample.

In some countries the use of the biological sample and/or the information related to the biological sample is legally not allowed unless the donor provides a consent. In other countries the use of the biological sample and/or the information related to the biological sample is only allowed when an opportunity for objection is offered to the donor.

In both situations, this embodiment of the present invention provides the possibility to link a consent or objection to a biological sample and/or information related to this sample allowing the subsequent use of the biological sample for, for example, research or development.

In addition, when a responding donor objects to the use of the biological sample and/or information related thereto it is also possible that the objection of the responding donor comprises a request for removal and subsequent destruction of the biological sample from the collection and/or the deletion of at least a part of the information related thereto.

According to another embodiment of the present invention, the information from the donor is additional information relating to the responding donor and/or his or her biological sample.

Such additional information can be important or even essential for some research purposes or other use of the biological sample or the information related thereto. This

additional information is especially information which could not be derived from the donor at the time the biological sample was deposited or information which was deemed not to be necessary at the time the biological sample was deposited. Also, the additional information can be information confirming and/or updating the information which was already linked to the biological sample and/or the information related thereto.

Examples of additional information which can be provided by the donor and which can subsequently be linked to the biological sample and/or the information related to the biological sample are medical history information, genealogical information, lifestyle information, nutritional information, environmental information, epidemiological information, sociological information, ethnic information, demographic information, or combinations thereof. Other examples of information which can be provided by the responding donor are the circumstances under which the biological sample was collected and/or the methods used for this purpose.

According to yet another embodiment of the present invention, the information from the responding donor is a request for information related to the biological sample. By requesting such information a communication channel can be opened, for example by including an address with the request for information, through which information regarding the biological sample can be transmitted to the responding donor. It can also be envisaged that the information is requested by the responding donor using a secured Internet connection, making submission of an address redundant

Such information regarding the biological sample can already be known or can be derived after subsequent research

on or any other use of the biological sample and/or the information related thereto.

Examples of information related to the biological sample and/or the information related thereto are information about inherited diseases, information about inheritable diseases, (anthropo)genetic information, genomic information, other medical information, general information, or combinations thereof.

The method according to the invention is especially suitable to be used if the biological samples are deposited in the collection anonymously which means without any means which would enable identification of the donor.

Besides the above mentioned information from the responding donor, the information submitted to the keeper or proprietor of a collection can also comprise an authentication that the determined biological characteristics originate from the responding donor. Such authentication by for example a physician or a laboratory performing the determination of one or more biological characteristics of the responding donor could be important or even essential to legalize any other information like a consent or objection, additional information, or a request for information related to the biological sample submitted by the responding donor to the keeper or proprietor of a collection.

For similar reasons the above-mentioned information of the responding donor could also comprise an identification of the donor. Such identification can for example be a passport, a birth certificate, or a residence certificate. An additional advantage of submitting information comprising an identification is that any further requests or calls for information regarding the biological sample and/or information related thereto can directly be submitted to the donor.

According to one aspect of the present invention, the information of the responding donor can be submitted to the keeper or proprietor of a collection through an intermediary. Together with the already mentioned possibility of anonymously submitting information to the keeper or proprietor by the donor this additional step provides maximal protection of the responding donor.

Examples of such intermediaries are a physician, a family doctor, a nurse, a medical professional, a lawyer, a notary, or an authorized representative.

An additional advantage of submitting information from the donor through an intermediary is that the intermediary can guard the personal interest of the donor especially in situations wherein the donor is underage or not able to adequately understand the request or call. An example of guarding the personal interest of the responding donor is advising by the intermediary about consenting, objecting, providing additional information, requesting destruction of the biological sample, or requesting information about the biological sample and/or information related thereto.

The method according to the present invention as above described is especially suitable to be used for providing information related to a biological sample present in a collection to the donor of that biological sample. Such use would comprise performing the above method and providing to the responding donor information related to his or her biological sample.

As already outlined above the information provided to the responding donor could for example be information regarding predisposition to diseases, diagnostic information, prognostic information, information about inherited diseases, information about inheritable diseases, (anthropo)genetic

information, other medical information, general information, or combinations thereof.

In addition, such information can according to the present invention be provided to the responding donor through an intermediary such a physician, a family doctor, a nurse, a medical professional, a lawyer, a notary, or an authorized representative.

These intermediaries can, besides the already mentioned maximal anonymity, guarding of the personal interests and the protection of the responding donor, contribute to the medically responsible provision of the information related to the biological sample. Providing medically responsible information could also be providing no information, protecting the right of the responding donor "not to know", i.e., the right of the donor not to be informed about for example cancer or an predisposition thereto.

CLAIMS

1. Method for linking a biological sample in a collection and/or information related to a biological sample in a collection with information from the donor of that biological sample, comprising:

- the public request or call for information from the donors of the biological samples in the collection;
- the determination of one or more biological characteristics of a donor responding to the request or call for information;
- the submission of the determined biological characteristics of the responding donor together with the information from the donor to a keeper or a proprietor of the collection;
- the comparison of the determined biological characteristics of the responding donor with the corresponding biological characteristics of the biological samples in order to identify the biological sample of the responding donor and/or information related to the biological sample; and
- the linking of the information of the responding donor with his or her biological sample and/or the information related to that sample.

2. Method according to claim 1, wherein the information from the responding donor is an objection or consent to the use of the biological sample and/or the information related to the biological sample.

3. Method according to claim 1, wherein the information from the responding donor is additional

information relating to the responding donor and/or his or her biological sample.

4. Method according to claim 3, wherein the additional information is chosen from the group consisting of medical history information, genealogical information, lifestyle information, nutritional information, environmental information, epidemiological information, sociological information, ethnic information, demographic information, and combinations thereof

5. Method according to claim 1, wherein the information from the responding donor is a request for information relating to his or her biological sample.

6. Method according to claim 5, wherein the request for information relating to the biological sample comprises a request for information about predisposition to diseases, diagnostic information, prognostic information, information about inherited diseases, information about inheritable disease(s), (anthropo)genetic information, other medical information, general information, and/or combinations thereof.

7. Method according to any of the claims 1-6, wherein the biological sample is an anonymous biological sample

8. Method according to any of the claims 1-7, wherein the biological sample is selected from the group consisting of a body part, organ, tissue, placenta, umbilical cord, blood, body fluid, secreted fluid, cell(s), intracellular organelle(s), intracellular component(s), cell membrane(s),

extracellular matrix, extracellular component(s); cell culture product(s), and combinations thereof.

9. Method according to any of the claims 1-8, wherein the method for publicly requesting or calling information from the donors is chosen from the group consisting of television, text TV, Internet, specific intranet network(s), WAN, LAN, email, telephone, SMS, radio, newspapers, magazines, bill boards, folders, mailings, posters, advertisement, and combinations thereof.

10. Method according to any of the claims 1-9, wherein the biological characteristics are chosen from the group consisting of DNA fingerprinting patterns, Restriction Fragment Length Polymorphism (RFLP) patterns, Polymerase Chain Reaction (PCR) products, Real Time Polymerase Chain Reaction (RTPCR) products, gene expression patterns, protein expression patterns, Single Nucleotide Polymorphisms (SNPs), RNA structures, patterns of RNA levels, genomic mutations, genomic deletions, genomic insertions, genomic organization, cell composition, cell morphology, blood composition, body fluid composition, tissue composition, tissue morphology, extracellular matrix composition, extracellular matrix morphology, protein structures, protein levels, lipid structures, lipid levels, carbohydrate structures, carbohydrate levels, proteoglycan structures, proteoglycan levels, glycoprotein structures, glycoprotein levels, glycolipid structures, glycolipid levels, lipoprotein structures, lipoprotein levels, nucleotide structures, nucleotide levels, and combinations thereof.

11. Method according to any of the claims 1-10, wherein the information comprises an authentication that the

determined biological characteristics originate from the responding donor.

12. Method according to any of the claims 1-11, wherein the information comprises identification of the responding donor.

13. Method according to any of the claims 1-12, wherein the information is submitted to the keeper or proprietor of the collection through an intermediary.

14. Method according to claim 13, wherein the intermediary is chosen from the group consisting of a physician, a family doctor, a nurse, a medical professional, a lawyer, a notary, and an authorized representative.

15. Method for providing information related to a biological sample present in a collection to the donor of that biological sample comprising: performing the method according to any of the claims 1-14 and providing to the responding donor information relating to his or her biological sample.

16. Method according to claim 15, wherein the information is chosen from the group consisting of predisposition to disease(s), diagnostic information, prognostic information, information about inherited disease(s), information about inheritable disease(s), (anthropo)genetic information, other medical information, general information, and combinations thereof.

17. Method according to claim 15 or claim 16, wherein the information relating to the biological sample is provided through an intermediary.

18. Method according to claim 17, wherein the intermediary is chosen from the group consisting of a physician, a family doctor, a nurse, a medical professional, a lawyer, a notary, and an authorized representative.