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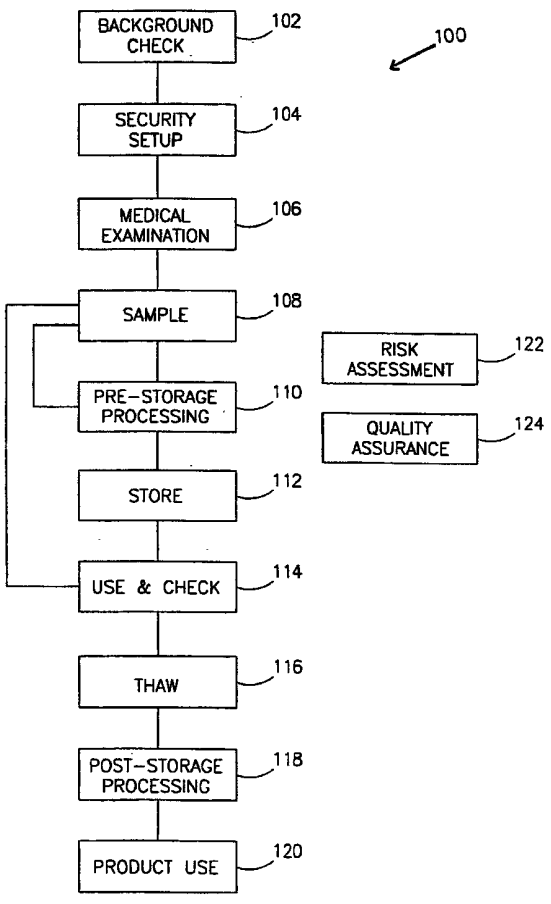
(54) Title: BIOLOGICAL DEPOSIT SYSTEM AND METHOD



(57) Abstract: A tissue depository for a large number of people, comprising: at least one cryogenic storage container; and a plurality of samples, comprising at least three different tissue types for a same person, stored in said at least one container, using at least one set of storage parameters for a same tissue type for a same person, for at least 5,000 different people.

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BIOLOGICAL DEPOSIT SYSTEM AND METHOD

FIELD OF THE INVENTION

The present invention relates to the storage of body tissues for large populations, for example storage of autologus tissue.

BACKGROUND OF THE INVENTION

A property of all living creatures and especially human beings is that as time goes on the creature sustains damage. In the example of humans, the damage can be on a macroscopic level, for example cuts and cirrhosis of the liver. Additionally, microscopic damage, such as damage to the DNA of the constituent cells of a human body, may be sustained, for example by cosmic rays, by viruses and by various environmental poisons.

It is known in the art to store and cultivate stem cells and other cells, for example as described in US patent 5,192,553 and in PCT publications WO 97/39104, WO 95/11659 and WO 97/33470, the disclosures of which are incorporated herein by reference. US patent 5,559,022, the disclosure of which is incorporated herein by reference, describes the isolation and culturing of liver reserve cells, such that new liver tissue can be cultured from the reserve cells. PCT publication WO 92/04978, the disclosure of which is incorporated herein by reference, suggests storing an umbilical cord and/or a portion of a placenta as a source of stem cells for certain tissue types and as a source of tissue to be used for identification purposes. The storage methods described include short term storage, suitable for a few days or weeks and long term storage, in particular cryogenic preservation, suitable for storing tissue for years or decades.

Repairs to body organs and cells are currently performed using many different techniques, including surgery, artificial organs, organ implantation, pharmaceuticals, gene therapy. cell therapy and natural healing techniques. Each of these techniques has its own limitations, for example, implanting of organs requires a viable donor organ and a continuing regimen of anti-rejection drugs, to prevent rejection of the organ by the patient. Growing new organs and tissues from body tissues is an emerging technology, which is hoped to be more widely available within the next few years or decades. Skeletal myogenesis is described, for example, in E. Guussoni, et al, Nature 401,390 (1999), the disclosure of which is incorporated herein by reference. Blood vessel growth is described, for example, in T. Ashara, et al, Science 275,964 (1997), the disclosure of which is incorporated herein by reference. Skin growth is described, for example, in F. M. Watt, Philos.Trans.R.Soc.London Ser.B 353,831 (1998), the disclosure of which is incorporated herein by reference. Neurogenesis, is described for example in R.A. Fricker,et al, J. Neurosci.19, 5990 (1999), the disclosure of which is

incorporated herein by reference. Liver development, is described for example, in B.E. Peterson, et al. Science 284, 1168 (1999), the disclosure of which is incorporated herein by reference.

Various types of tissue sample banks are known for example for use in the Budapest convention for depositing micro-organisms.

SUMMARY OF THE INVENTION

An object of some exemplary embodiments of the invention is to provide a system for increasing the probability of the successful repair of body damage, especially for large numbers of people. Optionally, this system is managed as an insurance scheme, however, this is not required. In an exemplary embodiment of the invention, this assurance system does not depend on any particular storage, treatment or tissue regeneration technology. Rather, in an exemplary embodiment of the invention, the system aims to maximize the probability that a body damage repair technique will be available to an insured person, when needed. Thus, even if a particular repair technique is only in the realm of "wishful thinking", it may be worthwhile to maintain a storage of tissue suitable for the technique, in case a viable repair technology is developed.

An object of some exemplary embodiments of the invention is to have suitable tissue samples on hand, when advanced tissue manipulation techniques are developed and/or in a sufficient quantity and/or immuniological matching. In an exemplary embodiment of the invention, this aim is achieved by storing tissue samples from persons while it is still possible to harvest viable tissue samples from those persons, for example, prior to damage from pharmaceuticals, viruses, toxins and/or age.

An object of some exemplary embodiments of the invention is to have, on hand, a plurality of tissue and/or non-tissue material which may be used to modify a person's body and/or psyche, as desired, and especially to allow reconstruction of past states of the person, for example, a previous external look of the person's face.

An aspect of some exemplary embodiments relates to preparing, storing and/or maintaining in storage, tissue samples for use in medical techniques which do not exist. In an exemplary embodiment of the invention, a decision to store a tissue sample of a certain type is made responsive to an expectation that a medical technique will be available for using the sample, preferably within the expected life time of a person from whom the sample is harvested.

An aspect of some exemplary embodiments of the invention relates to storing a plurality of different stem cell types and/or tissue samples for a single person. In an exemplary

embodiment of the invention, at least 5 samples of different tissue types are stored per person. Alternatively at least 10 different samples are stored per person. Possibly, several different samples are stored for a same tissue type. The multiplicity of samples may be stored at a single location or they may be distributed in several locations, for example to lower the probability of all the samples being damaged by a single accident. Possibly, same samples are stored using a same technique. Alternatively or additionally, different techniques are used for different samples. Not all the clients need have the same amount of samples, for example, the above sample numbers may be correct only for a portion of the clients, for example for about 5%, 10%, 20%, 40%, 80% and/or lower, higher or intermediate percentages of the samples and/or clients in a database.

Alternatively or additionally, different cell culture complexity levels may be stored, for example, single cells, small organ sections and complete organs lobes, in anticipation of different needs. Alternatively or additionally, different differentiation levels may be stored, for example, fertilized ova, cell cluster, stem cells, progenitor cells and completely differentiated cells.

An aspect of some exemplary embodiments of the invention is maintaining a storage facility in which tissue samples of different types are stored for a large plurality of persons, for example, over 100,000, 500,000 or over 1,000,000 persons. In some embodiments, a single depository is distributed, so that each sub-depository contains only a few tens of thousands of samples. However, all the depositories are linked together, for example, by robotic tissue transport mechanism.

An aspect of some exemplary embodiments of the invention relates to maintaining secrecy and/or controlling availability of biological information, to avoid misuse. In an exemplary embodiment of the invention, the association of a tissue sample with another tissue sample and/or with a person is encrypted. Possibly, the identity of the person is secret to the storage facility.

An aspect of some exemplary embodiments of the invention relates to using stored tissue cultures during the period of time when they are not needed for body repair. In an exemplary embodiment of the invention, the tissue samples are used for statistical assays, for example for pharmaceutical efficiency or toxicity. Alternatively or additionally, the tissue samples are used to test, treat and/or prepare for treating the tissue sample owners. In one example, the stored tissue is analyzed to determine EST distribution, to sequence the genome of the donor and/or to screen the tissue for mutations. Alternatively or additionally, the tissue samples are traded between tissue owners.

An aspect of some exemplary embodiments of the invention relates to a tissue storage depository including a cross-tissue matching index, which indicates the suitability of tissue from one donor for implantation or for other use by other donors. In an exemplary embodiment of the invention, cross-matching is generated and maintained for tissue culture owners who so desire. Alternatively, cross-matching may be checked on demand or it may be checked in advance, but the cross-matching information not provided to other donors unless they ask and/or pay. Thus, a single replacement organ can be prepared ahead of time which can be used for a plurality of tissue donors.

In an exemplary embodiment of the invention, tissue samples are processed to create familial stem cell line, of embryonic and/or non-embryonic type. These cell lines may then be stored, for used in later organ regeneration.

An aspect of some embodiments of the invention relates to preparing tissue and/or organs ahead of time, so that they are ready when required. The preparation may include, for example, thawing, regeneration and/or modification. In an exemplary embodiment of the invention, the preparation of tissues may be prompted by an advancing disease or by a medical checkup. Alternatively or additionally, the preparation may be based on statistical considerations, for example based on known disease statistics, so that tissue are generally available when needed. Optionally, prepared tissues which are unused may be frozen, disposed of, sold and/or used for non-matching patients, for example as a temporary measure. Optionally, the tissues are prepared for a group of donors, possibly without an exact immuniologic match to all those donors, however, that the organ may be used as a temporary measure.

An aspect of some exemplary embodiments of the invention relates to continuously updating tissue samples in a depository. Thus, the viability of samples can be maintained. Alternatively or additionally, changes over time, in the tissues can be tracked, for example, the accumulation of damage and/or the effect of gene therapy treatment in tissues. The changes can be taken into account during tissue repair.

An aspect of some exemplary embodiments of the invention relates to a tissue storage depository containing tissues having different viability expectancies, for a single donor. In an exemplary embodiment of the invention, short, medium and long term viable tissues are all stored for a same donor. Typically, but not necessarily, the short term-viability samples have a better chance of being used for tissue repair.

An aspect of some exemplary embodiments of the invention relates to storing medical and/or other information in association with the tissue samples. In an exemplary embodiment

of the invention, the information is of a type useful for body repair, for example, external body contours and images, for example for reconstructive surgery or internal body images, for example for measurement of desirable organ size.

An aspect of some embodiments of the invention relates to linking insurance programs to the type, extent and/or storage method of tissue samples. In an exemplary embodiment of the invention, more expensive programs merit a wider variety of storage methods. Alternatively or additionally, the insurance program and/or its cost is linked to usage of the samples while the tissues are stored. Different programs may cover, for example different organs, different procedures and/or different costs of procedures.

An aspect of some embodiments of the invention relates to software and computers programmed using the software, for supporting trade and/or investment in stored tissues. In an exemplary embodiment of the invention, a person can sell tissue and/or the use of tissue. Alternatively or additionally, a person may purchase a ready (stored) organ from another person. In an exemplary embodiment of the invention, the software shows current prices, finds buyers and/or sellers and/or performs transactions and money exchange. Alternatively or additionally, functions as known in the art of stock markets, may be provided. It is noted that tissue has some aspects unlike money. In one example, if the tissue has a better match for a person, it may be more valuable to him. In another example, the tissue availability/viability window may not match a time window in which a procedure may be performed using the tissue.

An aspect of some embodiments of the invention relates to software and computers programmed using the software, for managing insurance schemes in which a person is provided with treatment or money for treatment, providing the person deposits tissue samples. In an exemplary embodiment of the invention, the software monitors payments to offset the cost of storage of the tissue and/or development of tissue manipulation techniques. Optionally, the software calculates premiums and/or payoffs based on a treatment package and/or based on a lump sum payment.

An aspect of some embodiments of the invention relates to a method of predicting and/or recording suitability of tissues for future repair use. In an exemplary embodiment of the invention, various parameters of tissue that is sampled, are recorded. These parameters are later matched with actual success rates in various procedures using these tissues. Consequently, sampling procedures and/or thawing procedures may be modified. Alternatively or additionally, active research is used to quantify the effect of various parameters, after the tissue is sampled. Exemplary parameters of cells or tissue include one or more of EST profiles,

markers on cell surfaces, protein profiles, cell or donor age and/or medical history, gene mutations and/or variations and/or response of the tissue or cells to various physical and/or chemical or biochemical stimulation and/or environments, for example, hormones, toxins, heat, nutrients and/or lack of nutrients. Profiles may be general and/or directed to particular molecules. Alternatively or additionally, profiles may relate to absolute and/or relative values. Exemplary effects of the parameters, include, for example, one or more of storage life, desirable storage parameters, suitability and/or success rates for one or more procedures, sample volume and/or geometry required, growth time, viability of resulting grown tissue and/or flexibility of sample for producing multiple tissues types and/or geometries.

There is thus provided in accordance with an exemplary embodiment of the invention, a tissue depository for a large number of people, comprising:

at least one cryogenic storage container; and

a plurality of samples, comprising at least three different tissue types for a same person, stored in said at least one container, using at least one set of storage parameters for a same tissue type for a same person, for at least 5,000 different people. Optionally, the samples are for at least 10,000 people. Alternatively or additionally, the samples are for at least 50,000 people. Alternatively or additionally, the samples are for at least 100,000 people. Alternatively or additionally, the samples are for at least 500,000 people. Alternatively or additionally, the samples are for at least 1,000,000 people. Alternatively or additionally, the samples are for at least 10,000,000 people.

In an exemplary embodiment of the invention, at least six tissue types are provided, for a percentage of at least 10% of the persons. Alternatively or additionally, at least ten tissue types are provided, for a percentage of at least 10% of the persons. Alternatively or additionally, at least fifteen tissue types are provided, for a percentage of at least 10% of the persons. Alternatively or additionally, at least two sets of storage parameters are provided, for a percentage of at least 10% of the samples. Alternatively or additionally, at least four sets of storage parameters are provided, for at least 10% of the samples. Alternatively or additionally, at least one of the samples for a person is of a fully differentiated tissue. Alternatively or additionally, at least one of the samples for a person is of a partially differentiated tissue. Alternatively or additionally, at least one of the samples for a person is of a stem cell tissue. Alternatively or additionally, at least one of the samples for a person retains its original structure. Alternatively or additionally, at least one of the samples for a person is of cellular tissue. Alternatively or additionally, at least one of the samples for a person is cultured.

Alternatively or additionally, a client ID of the person for who the samples are stored, is encrypted from the depository management.

In an exemplary embodiment of the invention, the depository comprises a data store containing a plurality of records associated with a plurality of individuals of said persons. Optionally, an associated record comprises at least one medical history record. Alternatively or additionally, an associated record comprises at least one medical image record. Alternatively or additionally, an associated record comprises at least one external image record. Alternatively or additionally, an associated record comprises at least one personal information record. Alternatively or additionally, an associated record comprises at least one personal recording record. Alternatively or additionally, said depository includes a cross-match table matching immunilogic properties of at least two persons having samples stored in the database. Optionally, the depository comprises a matching engine for generating said table.

In an exemplary embodiment of the invention, said at least one storage container comprises a single storage container. Alternatively or additionally, said at least one storage container comprises multiple storage containers in a single location. Alternatively, said at least one storage container comprises multiple storage containers in multiple locations, and including a database linking the contents of said containers.

In an exemplary embodiment of the invention, said at least one storage container comprises at least one robotic manipulator for removing a selected sample form said container, under computer control.

In an exemplary embodiment of the invention, said at least one storage container comprises at least one tissue-manipulator for processing a sample in said storage container, under computer control.

There is also provided in accordance with a method of maintaining a tissue depository, comprising:

automatically generating a request for an updated sample, based on at least one of direct and indirect feedback; and

providing an updated sample per the request. Optionally, said direct feedback comprises a failure in a viability testing of a related sample. Alternatively or additionally, said indirect feedback comprises a statistical analysis of viability testing of similar samples. Alternatively or additionally, said indirect feedback comprises a time table for updating. Alternatively or additionally, said indirect feedback comprises an indication that the source of the sample is deteriorating. Alternatively or additionally, providing comprising removing a

sample from a person. Alternatively or additionally, providing comprising generating new tissue from an existing sample.

There is also provided in accordance with an exemplary embodiment of the invention a method of generating a database of suitability information, comprising:

recording a plurality of parameters of samples provided for storage;

recording behavior of the sample during at least one of storage, regeneration, usage and after-use;

analyzing statistical significance of said behavior; and

generating a linkage between parameters and behavior. Optionally, said behavior is success in regenerating a viable tissue from the sample. Optionally, said viable tissue is an organ grown from said sample.

In an exemplary embodiment of the invention, said behavior is long term viability of the sample or its progeny after it is used in a medical procedure. Alternatively or additionally, said behavior comprises a growth rate. Alternatively or additionally, said plurality of parameters comprise matching with a plurality of cell surface markers. Alternatively or additionally, said plurality of parameters comprise a geometry. Alternatively or additionally, said plurality of parameters comprise a volume.

There is also provided in accordance with an exemplary embodiment of the invention, a method of timing tissue regeneration, comprising:

determining an expected profile of tissue requirements;

determining an expected regeneration duration and viability of regenerated tissue; and

generating an instruction to regenerate said tissue responsive to said requirements, based on said expected duration and viability, so that it matches said expected profile. Optionally, said expected profile is for a single client. Alternatively or additionally, said expected profile is for a plurality client, which use a same, not-matching tissue.

In an exemplary embodiment of the invention, said generating comprises continuously assuring the availability of said tissue.

In an exemplary embodiment of the invention, different tissues are generated at different assurance rates of availability.

There is also provided in accordance with an exemplary embodiment of the invention, a method of offsetting at least a portion of storage costs of a plurality of tissues stored in a depository, comprising:

receiving from a client permission to use a tissue associated with the client;

using said tissues; and

crediting an account of said user based on at least one of said permission and said using. Optionally, using comprises drug screening using said tissues. Alternatively or additionally, using comprises experimentation in tissue regeneration using said tissues. Alternatively or additionally, using comprises experimentation in tissue storage using said tissues. Alternatively or additionally, using comprises using said tissues for other clients.

There is also provided in accordance with an exemplary embodiment of the invention, a method of remotely accessing a tissue stored at a depository, comprising:

connecting to a computer controller of said depository using a remote connection;

entering authorization information associated with samples of a particular client; and

receiving from said computer at least a status of a sample associated with said authorization. Optionally, the method comprises manipulating said sample, using commands entered via said remote connection. Alternatively or additionally, said authorization information does not comprise identification of the client.

There is also provided in accordance with an exemplary embodiment of the invention, a circumcision sampling kit, comprising:

a rinse vial;

a bacteria-static storage vial; and

instructions for use of said vials. Optionally, said rinse vial comprises a cleaning fluid. Alternatively or additionally, said storage vial comprises a sterilizing fluid. Alternatively or additionally, said storage vial comprises a cryogenic storage fluid. Alternatively or additionally, said storage vial comprises a cooler. Optionally, said cooler comprises a significant pre-chilled thermal mass. Alternatively, said cooler comprises an active cooler.

There is also provided in accordance with an exemplary embodiment of the invention, software for managing a combined tissue deposit and insurance scheme, comprising:

a database for associating deposit information with insurance information; and

a calculator for determining at least one of a premium and an insurance sum responsive to the deposit information. Optionally, said calculator calculates different premiums for different deposit schemes. Alternatively or additionally, said calculator updates a coverage of said insurance based on costs of medical procedures.

There is also provided in accordance with an exemplary embodiment of the invention, a trading software, comprising:

a user interface adapted for presenting information regarding available tissues; and

a user input for receiving a request to trade in said available tissues. Optionally, said user interface presents current values of said tissues. Optionally, said value is a monetary value. Alternatively, said value is a barter value for another tissue.

Alternatively or additionally, said user interface presents a matching of said tissue to a user entering said request. Alternatively or additionally, said user interface presents an estimated availability time of said tissue. Alternatively or additionally, said user interface presents an estimated life duration of said tissue.

There is also provided in accordance with an exemplary embodiment of the invention, a method of assaying of a given material, comprising:

providing a library of tissue samples from at least 10,000 different donors;

selecting a plurality of tissue samples which are near an end of an expected viability for the samples;

applying the material to the selected samples;

analyzing the selected samples after said application; and

determining at least one property of the given material based on said analysis. Optionally, the library contains samples from at least 100,000 donors. Alternatively or additionally, the library contains samples form at least 1,000,000 donors. Alternatively or additionally, the plurality of samples comprises at least 10,000 samples. Alternatively or additionally, the plurality of samples comprises at least 100,000 samples.

In an exemplary embodiment of the invention, the material comprises a toxin. Alternatively, the material comprises a pharmaceutical.

In an exemplary embodiment of the invention, the samples are remains of thawed samples. Alternatively or additionally, the samples are recorded as approaching an end of a viable life.

BRIEF DESCRIPTION OF THE FIGURES

Exemplary, non-limiting embodiments of the present invention will now be described, with reference to the following drawings, in which:

Fig. 1 is a flowchart of a process of acquiring, storing and using tissue samples, in accordance with an exemplary embodiment of the invention; and

Fig. 2 is a schematic block diagram of elements of a facility for medical treatment insurance, in accordance with an exemplary embodiment of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Many regeneration-based healing techniques are currently under development. In an exemplary embodiment of the invention, a depository is provided for storing tissue sampled in

anticipation of the availability of just such healing techniques. The present invention, in some embodiments thereof, relates not only to the provision of such a depository but also to methods and apparatus for administering such a depository and for making such a scheme financially and/or socially viable. In particular, in an exemplary embodiment of the invention a method and apparatus for insurance of availability of future health treatment is provided, in which statistical considerations applicable to relatively large populations are used to increase the practicality of the depository.

OVERVIEW OF MAINSTREAM PROCESS

Fig. 1 is a flowchart of a process 100 of acquiring, storing and using tissue samples, in accordance with an exemplary embodiment of the invention. Fig. 2 is a schematic block diagram of elements of a depository facility 130 for medical treatment insurance, in accordance with an exemplary embodiment of the invention. For clarity, the mainstream process 100 and exemplary depository facility 130 will be described in general lines first, followed by details.

As with other insurance transactions, a background check 102 is optionally performed on a client 132 (Fig. 2). Then, a security setup is optionally agreed upon (104), to assure the privacy of the client 132 and/or that his tissue samples are not manipulated against the client's wishes. A medical examination 106 is optionally performed, for example to assist in choosing a suitable insurance plan and/or as a preamble for the acquisition of samples.

One or more samples are acquired during one or more sampling sessions 108. The acquired samples may be processed for preparation for storage or for other reasons (110), for example to determine if the tissue is viable or otherwise suitable for storage and/or for future use. As a result of the processing, it may be determined that additional samples are necessary, for example if a sample is damaged or if it appears to have a low viability or require multiple exclusive types of storage and/or processing. Possibly multiple samples are acquired and/or a single sample is cut up, for example, for use for suitability testing, risk assessment, screening multiple storage and/or R&D.

The samples are then stored (112). The storage may be short term, however, most insurance schemes in accordance with an exemplary embodiment of the invention optionally include a long-term storage component as well, especially cryogenic storage. Optionally, a plurality of tissue samples are provided, for example, to support testing, storage and experimentation, three instantiations of a sample may be desirable. For reasons of later use of the sample and/or for redundancy, more than one sample may be used for storage. While the samples are in storage, they are optionally checked (114) for viability or other reasons, for

example as described below. Alternatively or additionally, the samples may be put to use during their storage, for example to aid in offsetting the storage costs.

The checking and/or later use of the tissue may include transporting the frozen or thawed tissues from a tissue storage facility to a separate tissue processing facility.

When the tissue samples are required, they are optionally thawed (116). Thereafter the tissues may be processed (118), for example to undo the effects of storage or to prepare them for use. The tissues are then used (120), thereby fulfilling one of the objects of many clients 132, namely, having tissue available when needed. The very existence of the tissues fulfills another object of many clients 132, namely peace of mind which comes from knowing the tissues will be available when needed.

In an exemplary embodiment of the invention, a step of risk assessment (122) is performed. Although risk assessment may be performed only at particular steps in the above described process 100, in an exemplary embodiment of the invention, risk assessment is an ongoing process, which can be continuously applied to substantially all the steps of process 100, to enable the proper level of insurance to be provided, at a reasonable cost, to client 132. A particular type of risk to be assessed is a determination of the expected life time and viability of a tissue sample, which can depend on the client and on the sampling method, as well as on the inherent characteristic of the tissue sample.

Another type of risk to be assessed in the probability of successful and/or low cost treatment options being generated. In an exemplary embodiment of the invention, such a risk is assessed, for example, based on a number of publications, the author of the publications (number and identity), academic or corporate institute that publishes, novelty of treatment method, success reports and/or success of similar treatments. Such as assessment may be manual, semi-automatic or possibly even automatic, for example, by automatic searching of databases of publications. Manual or automatic searching can also suggest changes in the sampling and/or storage procedures and/or statistical distribution of various parameters thereof, for example, to provide better, more dependable and/or lower cost service.

In an exemplary embodiment of the invention, a step of quality assurance (124) is performed. Although quality assurance may be performed only at particular steps in the above described process 100, like risk assessment, quality assurance is optionally an ongoing process, which can be continuously applied to substantially all the steps of process 100, to assure that the quality of tissue samples and the resulting insurance, it at least at a required level. The results of this step may, for example, be useful for a particular sample and/or they may have bearing on the procedures for other samples.

Referring to Fig. 2, an exemplary depository facility includes a sampling unit 134, for acquiring samples, one or more storage units 138, for storing the samples and one or more biological processing stations 136 for preparing the tissue samples for storage or for processing samples retrieved from storage. In some cases, processing of the samples is by an outsource unit 146, for example a laboratory which specializes in organ regeneration form stem cells. The entire process is optionally managed by a data processing and control unit 142, which, in some embodiments of the invention, may be a distributed system. A health care unit 144 may be provided as part of the facility for providing other medical care. Alternatively, the health unit may provide medical data and/or may use the depository facility as a health service. A data store 140 is optionally provided for electronic storage of data for each of a plurality of clients 132. Exemplary data includes medical history and information regarding the body structure. This information may be useful not only for risk assessment but also for guiding the processing of the biological samples, for example as described below.

The above process 100 will be described in more detail below, however, some steps are described out of order, to facilitate the understanding of the interrelationship of the steps.

ENROLLMENT

A person may enroll in a sampling and storage program at various times of his life, for example, as part of a requirement for a life or medical insurance program, as part of an employer-sponsored program, on his own accord and/or when performing surgery (elective or non-elective) or other invasive medical procedures. A typical enrollment procedure will include explaining the process to the enrollee, collecting various information (described below) and signing of various legal forms, for example, consent for extra sampling procedures, consent for use of tissue while in storage and/or various liability forgiving forms. In an exemplary embodiment of the invention, an access code, for accessing the storage information, is provided during or soon after enrollment.

BACKGROUND CHECK AND REQUIREMENTS COLLECTION

When applying for availability insurance, as in an exemplary embodiment of the invention, matching of the protection plan to the needs and financial ability of a client may be an important factor in the overall quality of service. The service supplied can be defined by several parameters, including, for example, one or more of:

(a) the number of overlapping treatment and therapy schemes for which tissue samples are stored and/or other preparations made;

(b) the estimated probability that various treatments schemes (e.g., organ growth from stem cells) will be viable and their breadth of application;

(c) the cost of applying the schemes;

(d) the type and extent of activities and/or quality control taken to assure the viability and/or suitability (at sampling time) of the stored samples; and

(e) the type and/or extent of usage and/or manipulation of the storage samples during storage.

Generally, but not necessarily, values for the above service parameters are selected to match one or more of the following client variables:

(a) the level of assurance desired by the client;

(b) the type of activities contemplated by the client in the future, which can affect the viability of future tissue samples from the client;

(c) the type of situations for which the client desires treatment (e.g., pancreas replacement yes, heart replacement no);

(d) the financial abilities of the client, including both the available cash and the future expected cash flow;

(e) client characteristics, which can be determined from the medical examination, which affect the practicality of certain procedures;

(f) degree of invasiveness allowed for tissue sampling; and

(g) a temporal and/or body profile of expected procedures. Such a profile may be updated manually and/or automatically, for example when a client provides the results of tests or reports changes in life style. Alternatively or additionally, the updating may be based on statistics of procedures performed on other clients and/or new medical knowledge. Optionally, a periodic update is performed and/or required from the client.

As indicated above, the final matching of an insurance plan to a client may depend on the results of the medical examination, and, to some extent, on the tissue sampling steps.

MEDICAL EXAMINATION

The medical examination can have several purposes, including one or more of:

(a) to assist in selecting a sampling program;

(b) to assess the medical condition of the client for risk assessment purposes;

(c) to assess the medical condition of the client for determining which insurance options are required and/or expected to be needed;

(d) to obtain a baseline of medical information for future use;

(e) to assess if there any viability problems can be expected with the tissue samples; and

(f) to set a baseline medical condition to which the health level that the insurance is committed to maintain (at a level equal or otherwise related to it).

SAMPLING

There is a wide range of levels of invasiveness in the different types of sampling. As indicated above, the willingness of a client for invasive sampling may affect the types of insurance available.

Although the sampling can be done as a stand alone procedure, in an exemplary embodiment of the invention, the sampling is done as part of a different surgical procedure already planned for the client, for example elective or non-elective surgery. Thus, the risk associated with possible local or general anesthesia during sampling are reduced. Possibly, the fact that a patient is undergoing surgery is used as an incentive for the patient to join an insurance plan.

One or more of the following sampling methods may be used, however, other methods may also be used:

(a) Open surgery. This may be least desirable, unless the patient is already undergoing open surgery.

(b) Endoscopic or catheter based surgery. This method is less invasive, but still poses some risks and discomforts. However, it is noted that some endoscopic procedures, such as colonoscopy, are routinely performed on many people.

(c) Needle and other biopsy procedures. For some tissues this option is not available, however, the benefit is that the procedure is very straight forward. Blood letting, although performed using a needle is both very common and generally considered minimally invasive.

(d) Autopsy, on extracted tissue or on a dead human, especially a relative.

(e) Non-invasive tissue sampling, for example, sampling of body fluids or sampling of surfaces of the body, such as the mouth, skin or other tissues easily reachable through an existing orifice in the body.

In an exemplary embodiment of the invention, prior to sampling, a list of required samples is draw up and a plurality of storage vials are pre-printed with suitable labels. When the samples are taken, they are inserted in the vials and transported to the biological processing unit, for preparation and then storage.

Some samples may require cleaning or separation of one cell type out of the sample. In other sample types, such procedures may be applied after the sample is retrieved from storage.

In an exemplary embodiment of the invention, a client is provided with a home kit, which can be used, at home and/or by a local physician and/or at a hospital, to obtain updated

samples. An exemplary kit includes one or more storage vials and a cooling device for maintaining a low temperature and preventing putrefaction of the samples during transport. Also, the kit may include sampling tools, or the vials themselves may operate as sampling tools (e.g., include a hollow needle). Depending on the type of cooling device (e.g., dry ice, electronic, gas-expansion), the sample kit may be mailed using regular mail, courier or the depository may arrange for a pickup just shortly after the sampling. In a home-type kit, a client will typically sample only non-invasively, for example, skin, hair, mucus and sperm. In a physician-office type kit, simple biopsies may be performed. In a hospital type kit, the kit may be adapted to interact with certain types of common surgery or with a particular surgery expected by the patient, for example providing sampling means which match the tools used by the surgeons.

In an exemplary embodiment of the invention, a vial label includes, for example, one or more of a client ID or random code assigned to the client, a code indicating the sample type, a code indicating the sampling method, a general code and/or a code indicating a type of storage for the sample.

In an exemplary embodiment of the invention, a sampling process using a biopsy needle includes excising between 100 and 500 mg of tissue and placing the tissue in a pre-chilled sterile tube with 1-2 ml of phosphate buffered saline or Ham's F-10 medium with heparin (1U/ml) and penicillin-streptomycin (10U/ml). The tube is put on ice put on ice and frozen within an hour.

An exemplary surgical sampling procedure comprises removing 0.5-2 cubic centimeters of tissue and continuing as in the biopsy example. Smaller or larger sample sizes may be used as well. In some cases, healthy tissue is sampled. Alternatively or additionally, diseased tissue is sampled.

A kit for sampling during circumcision can include, for example, two vials, one for rinsing, for example by immersion and/or agitating and a storage vial with a bacteria-static fluid. In an exemplary embodiment of the invention, the storage vial is self cooling, for example, by means of compressed gas release, a compartment for dry ice and/or by including a thermal mass which is pre-chilled.

It should be appreciated that the sampling does not have to be done all at once. Rather, it might be performed over a lengthily time period, for example averaging one sample a month. In addition, some samples are renewed, for example periodically. Alternatively or additionally, sampling may be prompted by various events, for example, changes in life style, the detection of a developing disease and/or responsive to results of a medical checkup.

Updating of experience or medical information (described below) may also utilize a kit form, for example a questionnaire or an interactive program (or internet site) which queries the client. Such a kit may be personalized for a particular client, for example attempting to obtain information on points that are determined to be unclear or problematic from an analysis of a previous response to such a questionnaire or from an analysis of samples. Alternatively or additionally, such an updating of experience may be performed over the Internet or by telephone. Medical data from medical databases may be transmitted electronically from a health care provider to the depository. Possibly, a client can OK one or more queries, records or fields of the stored data for the depository to ask the medical database provider without additional permission. Alternatively, a complete permission may be supplied. In some cases, the client will desire to send some information from the depository to the health provider. However, in many cases the client will desire to keep such information secret.

PRE-STORAGE PROCESSING

Many different types of pre-storage processing are known in the art and may be used. Alternatively or additionally, pre-processing methods dedicated and/or adapted for the uses herein, may be used. In an exemplary embodiment of the invention, a sample is identified by a pathologist or histologist, cut up, for example into 3-5 sample parts and then snap frozen in liquid nitrogen. The storage location may be, for example pre-assigned or may be determined on the spot, for example based on -available locations in tank. Vials for testing purposes may be frozen then thawed, or kept at a constant cool temperature, such as 4 degrees Celsius.

Various sample geometries may be used. Exemplary sample volumes are 0.01, 0.1, 0.5 and 1 cubic centimeters and intermediate, smaller or greater volumes. The storage sizes may be the same, or smaller, for example, 10%, 30% 80% smaller or any greater intermediate or smaller size. Alternatively, several samples are stored in a single storage compartment. The tissue sample may be shaped to fit the storage compartment or geometry suitable for freezing, thawing, maintenance and/or usage, for example, into the shape of a cylinder, flat sheet, ball or cube.

In another exemplary pre-storage process, the different cell types of the sample are separated. The sample may also be cultured and/or treated before storage.

In another exemplary pre-processing method, a placenta is analyzed to determine which hormones are generated by which parts of the placenta, the placenta may then be divided and the differently acting parts thereof stored and/or labeled differently. If the placenta is not divided and/or for other tissues, staining and/or other marking techniques may be used to mark landmarks and/or different zones in the tissue. Alternatively or additionally, tissue is

marked, for example with radioactive materials or non-biodegradable markers, so that it can be identified after it is implanted, at least for a while.

In an exemplary embodiment of the invention, warm storage is used instead of cold storage, for example, the sample is kept alive in a culture. Processing may include preparation for such a culture. Alternatively, a sample may be encapsulated and implanted in a host (human or animal) so that the sample is kept alive by the natural physiological processes of the host.

TYPES OF CELL SAMPLES

Many different types of tissue samples are suitable for practicing exemplary embodiments of the invention. A main reason for this is that each type of tissue sample may have different characteristics with regard to viability, storage term and suitability as a raw ingredient of a treatment process. In some cases, the tissue sample itself is cultured, prior, during or after storage, to provide the raw ingredient. The following described tissue sample types are only examples of suitable tissue samples. Of course, as new types of tissue sampling, storage and/or preparation techniques are developed, they may also be used in accordance with exemplary embodiments of the invention.

(a) Embryo or portions thereof. Especially for female clients, there is the ability to provide an embryo having a genetic relation or identity with the client. In some cases, an embryo may be created by cloning the client. The developmental stage of the embryo can vary, for example, 1 day, 1 week, 1 month or 5 month embryo. Additionally, a plurality of differently aged embryo parts may be provided, for example, a six month heart and two month brain cells. An embryo may be partitioned, for example, at storage, during storage or when thawed. "Human pluripotent stem cells derived from fertilized eggs", in J.A.Thomson et al, Science 282,1145(1998) and M.J. Shamblott et al., Proc.natl.Acad.Sci.U.S.A.95, 13726 (1998), the disclosures of which are incorporated herein by reference, describe the generation of embryonic cell lines.

(b) Sperm and/or ova (fertilized or unfertilized).

(c) Progenitor stem cells and/or partially differentiated stem cells, possibly derived from different tissues.

(d) Extracted DNA, chromosomes or parts thereof. This material may have the advantage of extended storage periods.

(e) Complete cell nuclei.

(f) Cell organelles, for example mitochondria.

(g) Small body portions containing heterogeneous mixtures of cells, to be processed during or after the storage, for example at the thawing stage.

(h) Immune cells, for example cells that respond to certain stimuli.

(i) Genetically altered host cells, unnatural differentiated host cells or otherwise processed cells, for example cells created for a gene therapy session. Thus, in one embodiment, such cells can be available when required later.

(j) Cells, in culture, in suspension and/or attached to a surface. Typical cultures are mono-cell cultures, however also hetro-cell cultures may be created and stored.

(k) Organ portions, for example, lobes of the lungs and the liver and skin segments. Such portions may be stored in one piece or they may be cut up and assembled when the organ portion is to be used.

(l) Post-storage products, such as regenerated and/or tissue-engineered organs and/or tissues.

Alternatively or additionally, the storage may include samples which represent the body state, for example, blood samples, urine samples, metabolite samples and other body fluids. These samples may be used, for example, to determine that a regenerated and implanted organ is functioning as well as the original organ did at a previous time and/or to assure that the balance of the body is maintained, at a same level as in the past.

In an exemplary embodiment of the invention, the samples in storage are updated over time, for example by periodic or other resampling. Thus, the extent and effect of damage can be tracked. Additionally, if a patient is treated using gene-therapy or other treatments that affect the genetic makeup or other low-level behavior of his cells, such changes can be reproduced and/or detected. The availability of periodic updates, to which a tissue sample can be compared, allows also more complex analysis of the tissue. For example, what-if scenarios can be checked, possibly over a large group of clients to sees if a particular treatment affects the tissues in a desired manner, as compared between the clients and/or as compared against a stored and optionally manipulated baseline culture. As described below, a client may obtain some sort of compensation for allowing these effects to be tracked and/or reported to data customers.

It should be noted that a plurality of tissue samples are optionally stored for each client, for example more than 5, 10, 20, 40, 50 or even 100 or more. Additionally, as new tissue storage, treatment and sampling techniques develop, additional samples may be required, or old samples dropped. Thus, the total number of samples stored over a lifetime can exceed 100, 400 or even 1000 or more. In addition, it is noted that a plurality of samples for a single tissue

may be stored, possibly utilizing different ones of the above types of tissues and/or different preparations, for example storage media of a single type. For example, 2, 4, 5 or even 10 distinct samples of a single tissue may be stored.

In an exemplary embodiment of the invention, the tissue samples are stored in a cryogenic fashion. However, other storage techniques, such as dry freezing, and fixing (e.g., using formaldehyde), may also be used in some exemplary embodiments of the invention. In some samples, the tissue may be maintained in a live culture.

Examples of body tissues for which tissue samples are stored and/or taken from include: heart, lungs, muscles, intestines, stomach, kidneys, brain (neurons and/or support structures) skin, gonads, nerve cells, cornea, retina and other structures of the eye, tendons, bone, bone marrow, nail-base cells, cartilage, non-fetal maternity related tissues such as placenta, fetal blood cells and an umbilical cord, foreskin, mucus, muscle biopsy samples, body fluids, surfaces of internal lumens, tongue and cheek scrapings, blood, dead skin, hair follicles, skin, vascular tissue, pancreas, spleen and/or glands, such as the adrenal, thyroid and pituitary glands.

STORAGE LAYOUT

Many types of storage devices for storing tissue samples are known in the art and will not be described here in detail, as, in general, all such storage devices are suitable for using in exemplary embodiments of the invention. In an exemplary embodiment of the invention, the storage facility used includes means for or is adapted for automated robotic retrieval and/or manipulation of samples. Alternatively or additionally, the facility includes micro-manipulation devices, for processing such samples.

It is noted however, that a facility for storing small tissue samples can be quite small, yet still store many samples for a very large number of people. In an exemplary embodiment of the invention, tissues that are stored for long term, are compressed together more than tissues stored for short term. Tissues may also be moved from more compressed storage to less compressed storage, as their expected usage date nears.

In an exemplary embodiment of the invention, a plurality of storage units 138 are provided, each at a different location, to increase the reliability in face of a local disaster which would destroy one storage unit. Multiple copies of same samples for a same client may be stored at each of the units. Alternatively, different samples types of a same tissue may be stored at different locations. It is noted that a same tissue may be stored a plurality of ways, for example 2, 3, 5 or more, to allow different usage of the tissue when it is thawed. The probability of catastrophic failure of the storage can be calculated and used, in conjunction

with the general risk/cost plan for a client and/or a client's personal worries, to decide how to distribute the samples and how many copies of each sample type to obtain. Thus, the amount of effort in storage can be made dependent on the expectancy and on probability of damage, and on providing a desired utility to the insured client. The geographical distribution of storage and/or processing facilities may be prompted, for example, based on statistics of tissue need, client distribution or probability of accidents happening to the storage facility.

In an exemplary embodiment of the invention, the cost of insurance is determined, at least in part, by the volume, number and/or type of samples. However, associated costs may have a greater part, for example, the cost of sampling, testing, preparing for storage or regenerating an organ.

In an exemplary embodiment of the invention, multiple samples of a single client are stored together. In some cases, each sample may be stored at a different temperature or require different thawing procedures. Suitable storage devices are known in the art. Further, it is noted that different samples will have different viabilities, expected lifetimes and/or required treatment during storage. Thus, it may be useful to group together, in storage, tissues requiring the same handling. Alternatively or additionally, different parts of a storage container may have different properties, for example, different heat dissipation properties or different temperature fluctuations or values. In an exemplary embodiment of the invention, statistical sampling for testing tissue viability also takes into account the location of the tested sample. Alternatively or additionally, less sensitive samples are stored at areas with greater fluctuations.

In some embodiments of the invention, storage facility 138 is emulated or enhanced by collective management and/or association of samples of individual storage facilities, such as existing blood, skin, liver and umbilical cord storage facilities.

ACCESS TO STORED SAMPLES

In an exemplary embodiment of the invention, the storage and/or biological processing utilizes robotic apparatus, for example robotic arms and/or storage retrieval actuators (such as used, for example, on a larger scale in warehouses) for retrieving and manipulating the samples. As described below, the use of robotic manipulation allows remote access to the stored samples. Manipulating the samples may be performed before or after the samples are thawed. In non-cryogenic storage, other storage retrieval tasks may be required, for example separation from a tissue culture. Optionally, when a sample is retrieved, instead of using the entire sample, only a portion of the sample is excised, for example by removing part of the sample in the storage or by removing the sample from storage, excising a portion and returning

the balance to storage, possibly after some further processing. Alternatively, an unused part of the sample may be used for backup or for experimentation or quality assurance purposes. Possibly, the remaining sample portion or other sample copies are regenerated, to make up for the missing sample portion. Alternatively or additionally, a new sample may be acquired from the client, once he has healed.

In an exemplary embodiment of the invention, each samples is assigned an ascension number, for retrieval. In some security schemes, as described below, any person lacking the proper security keys will not only be unable to match a sample with a client, but will also be unable to match two samples from a same client with each other. Possibly, even the identification of the tissue sample type will also be obscured.

ASSOCIATED DATA STORAGE

In an exemplary embodiment of the invention, certain information is stored in association with the stored samples.

The information may be associated with a particular or group of sample, for example, description and maintenance information. Alternatively or additionally, the information may be associated with a particular client, for example, an identification of related samples or a timetable matching samples to a medical history. Alternatively or additionally, the information may be associated with a group of clients, such as a family. Alternatively or additionally, the information may be database information, for example statistics of various characters (e.g., viability) of a certain tissue sample type. Medical information in general may, as for example, acquired during the medical examination 106 may be stored.

The following are examples of information, one or more of which may be stored in data storage unit 140, in accordance with an exemplary embodiments of the invention:

(a) Medical history. Optionally, the history is continuously updated, for example using a computer connection to a medical database of the client's health-care provider.

(b) Internal images, for example acquired using MRI, CT or ultrasound. These images may be used, for example to reconstruct organ sizes and layout of organs, for major reconstructive work.

(c) Body statistics, for example blood test results, capillary density and average blood pressure. This information may be of use, for example when regenerating an organ and the regeneration needs to match certain characteristics of the client's body.

(d) External images, for example 3D images, surface contours and 4D images (showing motion). These images may be useful for plastic and/or other reconstructive cosmetic surgery.

Also, it allows a client to specify a particular age to which the body is to be sculpted, thus simulating "rewinding" of time.

(e) Functional information, such as lung capacity and heart stroke. This information may be used, for example, to assure that a regenerated or otherwise treated organ has reached its prior capacity.

Alternatively or additionally, in an exemplary embodiment of the invention, life experience is stored in association with the tissue samples. As people age, and/or as a result of trauma, people tend to forget facts and experiences which may be important. It is expected that future advances in hypnosis and/or other types of mind, brain and/or memory control, will enable memories and/or experiences to be injected into a person's mind relatively easily. Although both synthetic and natural experiences can be thus added, it is expected that a significant number of experiences to be added will comprise personal experiences and natural experiences of other persons.

In an exemplary embodiment of the invention, the life experiences are stored in electronic means. The life experiences may be acquired in many ways, including, for example:

(a) a video and audio recorder carried around by a person;

(b) a transcript of a hypnotic recall session with a person;

(c) recording of nerve action potentials of visual and audio perception system nerves; and

(d) home made recordings, such as videos.

In an exemplary embodiment of the invention, the memories may be tailored, for example by removing portions, enhancing them or changing them, to a client's specification, before being implanted n his mind.

In an exemplary embodiment of the invention, the recordings may be accessed by Internet, for example for sampling wares, instead of implantation in a memory and/or for a client to revive fond memories periodically. In an exemplary embodiment of the invention, the depository maintains an index of the stored memories, for example, based on a time line, content of the experience and/or general atmosphere of the experience (e.g., sad, happy, uplifting).

It should be noted that any of the associated information (e.g., (a)-(e) and life experience) may be periodically updated. The comparison between the updates may also yield important medical or other information.

SECRECY AND SECURITY

There are several reasons why a client could want his tissue samples maintained in secrecy, including, for example, one or more of:

(a) maintaining his medical history and problems secret, especially from employers, prospective dates;

(b) avoiding enemies obtaining the client's genome and possibly using it against him, for example in tailoring poisons;

(c) preventing unauthorized use of his body tissues;

(d) preventing pressure on the client if his tissues are desired by a second person; and

(e) prevention of unauthorized cloning.

In an exemplary embodiment of the invention, the samples are stored using a double blind encrypting system, in which each sample is identified by an ascension number and the association between ascension numbers and clients is encrypted. Further, also the identifying client information may be secret. Thus, any manipulation of the samples cannot be connected with a particular client. Different insurance schemes can have associated with them different security and/or secrecy levels, for example depending on payment by the client and/or depending on technical difficulties involved with accessing and manipulating the stored samples.

In an exemplary embodiment of the invention, reports are not sent directly to a client, as that would require a computer which can match the clients and the reports. Instead the reports may be posted, or be available for access by the client, using an anonymous or encrypted login. Alternatively, two computers may be provided, one for generating the report and one which associates an encrypted report with a particular client and sends the report to the client.

Alternatively or additionally, the tissue samples may be physically separated and/or mixed-up, so that adjoining tissues do not belong to a same client.

When tissue samples are sent to an outside vendor, such as outsource 146, the samples are optionally provided with an anonymous code, so that their source cannot be identified.

In an exemplary embodiment of the invention, when the stored samples and/or other information are used as part as studies, care is optionally taken to prevent the statistical data gleaned from the information from inadvertently identifying a particular client and/or health information thereof. In some cases, a client may be precluded from having his tissues take part in certain activities, responsive to a security level requested by the client.

TISSUE SUITABILITY AND QUALITY ASSURANCE

As indicated above with reface to step 124, quality assurance is optionally an on-going process. Two exemplary types of quality assurance are per-sample quality checks, which test the quality of every sample and statistical quality assurance, which use test populations, to detect statistical quality problems. The type of quality assurance performed may be a function of the particular insurance plan of a client.

In an exemplary embodiment of the invention, one or more of the following quality assurance techniques are applied, however, other techniques may be applied as well or instead. In an exemplary embodiment of the invention, suitability testing is applied when the tissue is sampled or about to be used. Quality assurance testings are applied all through the process, to ensure the process (and/or storage) are proceeding properly.

(a) testing of tissue samples to assure their viably and/or their ability to be used as a raw ingredient for a particular treatment;

(b) checking for mechanical and DNA damage, for example that caused by cosmic radiation and/or DNA screening; and

(c) test regeneration, to test the entire storage-restoration cycle.

In an exemplary embodiment of the invention, the checks are performed on a statistical basis, as they may be destructive. However, at least for some types of tissue samples, the removed tissue may be regenerated from the original sample, by culturing, resampled from the patient or be one of several available samples. Optionally, new samples are acquired before destructive testing of old samples.

In an exemplary embodiment of the invention, the size of the test population as well as other parameters of the quality assurance testing are determined as an ongoing process, for example, by tracking the number of failures and the number of testes, for each particular tissue sample type.

In an exemplary embodiment of the invention, if the quality of a sample is in doubt, more in-depth testing may be done. Alternatively or additionally, a new sample may be requested from the client.

In an exemplary embodiment of the invention, the success and failure rates of all parts of process 100 are utilized to drive the quality assurance program.

In an exemplary embodiment of the invention, the suitability of tissue for various uses is estimated by matching various tissue characteristics to a database including an association of tissue characteristics with sample suitability parameters.

In an exemplary embodiment of the invention, the database is generated by research. Alternatively or additionally, the database is generated by monitoring the results, for example

for tissue reconstruction, medical procedures and long-term follow up, for a plurality of clients. Thus, many parameters of sampled tissues may be recorded even if their meaning is not known and/or they turn out to have no meaning. Alternatively or additionally to suitability information, the associated information may be used , for example, to suggest other samples to be taken, desirable sample size, suitable storage conditions, tissue generation and/or tissue usage procedure parameters and/or medical follow-up, such as pharmaceuticals.

Exemplary parameters which may be measured include, for example, one or more of: responses to physical, chemical and biochemical environment, size, geometry, medical history of patient and location where sample is from, sampling method, preparation parameters, storage method, temperature and/or other parameters, biological properties of the tissue, such as cell type, cell arrangement, EST and protein profiles, rate of cell division, cell surface markers and/or cell metabolic input or output, and/or visual parameters, such as color or texture.

TISSUE MANIPULATION DURING STORAGE

In an exemplary embodiment of the invention, the stored tissue is manipulated during storage, possibly without connection to the client's needs. In an exemplary embodiment of the invention, one or more of the following optional manipulations are practiced:

(a) Testing the viability of tissue samples and/or of regeneration methods (e.g., is the tissue sample alive and/or is it still suitable for use for certain treatments). Also, the expiration curve of tissues can be assessed.

(b) Preparing organs or other tissue products, ahead of time. In one example, a single organ may be regenerated for a group of matching or semi-matching clients. Thus, if any of the clients requires an organ, it will be available and the client will not need to wait. Thereafter, a self-tissue organ can be cultured at a relative leisure, and used when and if the first organ is rejected, for lack of perfect match. The grouping for organ regeneration can depend, for example, on statistics of type-matches, expected problems based on genetic or occupational analysis of the clients and/or on the client's medical history.

(c) Testing tissue properties, such as DNA sequencing and RNA EST mapping.

(d) Manufacturing and/or testing treatments and/or suitability of the client for treatment, for example transfecting and/or assessing the potential for transfection of certain tissue types of the client. In an extreme example, a client with a pre-disposition for cancer, can allow his tissue samples to be manipulated to determine which cancer fighting drugs will be most effective. In addition, the toxicity of certain pharmaceuticals can also be tested.

(e) Duplication of tissue samples, for example to make up for material used by the client or for other uses.

(f) Disease risk assessment, for example determining the sensitivity to toxins, pharmaceuticals, infection by viruses and/or cancer.

(g) Cloning, for example for generating new tissue samples, for a worried client or for acquiring tissue samples of a new type.

(h) preparing embryo lines from fertilized eggs or by cloning.

(i) differentiation of cell lines into tissue lines, as needed, or in preparation for a procedure.

(j) DNA screening for example, for mutations and cross-matching between clients.

(k) nuclei and DNA preparation and/or restoring.

(l) stem cell isolation (before, during or after storage), characterization, expansion and/or restorage (possibly in a different storage method).

(m) restorage of tissues, with or without thawing.

(n) stem cell indexing, for example using stem cell markers. CD34 is a known marker for some stem cell types. It should be noted that even if the matching of markers and cell types is unknown at the time of storage. If the tissue is characterized using enough markers, EST methods and/or other techniques, when the matching knowledge becomes available, the tissue samples can be properly labeled and/or more samples taken. The determined information may be used to generate an index of suitability of the tissue sample.

(o) cell preparation for cell therapy and/or gene therapy

These tissue manipulations may be done at a clients request. However, In an exemplary embodiment of the invention, the large store of tissue samples, complete with medical history and/or periodic updating, is used in assaying and/or for testing the efficacy of new pharmaceuticals or other treatments.

In addition, genetic simulations may be executed, to determine an expected effect of a certain treatment on a viability and/or other characteristics of a tissue. In some cases, the simulations are electronic. Alternatively, a biological model or a biological sample may be used, to test the effect of the treatment. In an exemplary embodiment of the invention, one or more test batches may be prepared and provided to a tester or to the client to try out. The result of such testing can show, for example, whether there are any side effects of the tissue implantation, the expected viability and/or the efficacy of the cell treatment. It is noted that long term effects for a particular client can be tested in this way, long before the client actually needs the treatment.

REMOTE ACCESS AND MANIPULATION

In an exemplary embodiment of the invention, a client 132 can access and/or manipulate his samples from a remote location. This access can be, for example, by telephone or using the Internet. Exemplary types of access and manipulation include:

(a) Viewing a viability status of the tissues, or any other information stored in data storage unit 140, which is not secret from the client. Possibly, the information is not sent in real-time, but as a report, via mail, e-mail or fax. One advantage of waiting is that the identity of the client can be better verified and/or protected.

(b) Requesting a manipulation, such as viability testing, thawing tissue or preparing an organ.

(c) Requesting an analysis based on the stored samples, for example a sensitivity to certain medication.

(d) Directly manipulating the tissue samples using the robotic actuators and/or a remote controlled biological processing station at the depository facility.

When a client orders a sample or a product, the preparation of the sample or product may be completely mechanized, with no human touch. Possibly, the sample is inserted into a refrigerated (or dry-ice including) envelope and mailed or couriered to an address requested by the client, by a machine.

REGENERATION OF ORGANS, CELLS AND/OR TISSUES

In an exemplary embodiment of the invention, when an organ is needed, a suitable tissue sample is thawed and a new organ grown from the sample. The techniques used may not exist or be practical at this time, but it is expected that in a few years they will be. As noted above, a temporary organ may be prepared for a plurality or even a single client and remain in stand-by. However, as growing organs is expected to be expensive and they are not expected to have a long life outside the body (although these both could change pending further research), such a technique may be expensive (but still covered by the insurance, in some cases).

Alternatively or additionally, a plurality of organs are grown, for example using a single or multiple processes and/or a single or multiple organ-growing vendors. Thus, a failure in any one method or a rejection or other failure of an organ need not be fatal.

In an exemplary embodiment of the invention, rather than grow a single organ, an entire body, optionally less part or all of the brain, is grown, so that many organs are available.

Any generated organ which is not used can be destroyed. However, it may be preferable to sell or donate such organs to un-insured individuals.

It is noted that not all treatments require organ growing. For example, some treatments may involve injection of genetically transfected cells, such as bone marrow cells, into a client.

The frequency of preparation of different organs and/or tissue may be different, for example, reflecting expected needs and/or growth times. In one example, skin and blood vessel tissue is always on hand, as these may be relatively easy to grow and/or likely to be needed. Alternatively or additionally, heart and liver tissue are maintained, as these are critical, non-replaceable, tissues.

Alternatively or additionally, the tissues may be prepared in anticipation of medical events, for example, as found in a medical check-up or base don changes in a client's life style.

INTERACTION WITH INSURANCE

The method or treatment insurance described herein may be integrated with other health insurance schemes in many ways. In an exemplary embodiment of the invention, treatment insurance is part of a complete insurance plan, for example as an option in regular health insurance or as a single policy. In an alternative embodiment, the treatment insurance may be considered a risk reduction option, for example allowing the health insurance provider, a disability insurance provider or a life insurance provider to assess a lower risk for people having tissue sample deposits and thus charge a lower premium.

Optionally, a client can withdraw a sample, for reconstruction, as part of a medical treatment that is not covered by the particular insurance scheme.

Although the term insurance is used to describe the treatment assurance methods described herein, a pure insurance scheme is not required, for example, a user may be required to pay for the deposit. Alternatively or additionally, the insurance provides a lump sum or a guaranteed treatment (or one or multiple available levels of treatment) when required. Alternatively or additionally, a user can receive a refund if the stored samples are not used.

In an exemplary embodiment of the invention, the some parts of the insurance have a time delay before taking effect, for example a time delay base on expected gain in the medical technology fields. Alternatively, milestones, such as the success rates of certain procedures, may be used as a trigger to putting the insurance into action.

Optionally, liability insurance is provided, for example, for a hospital or a doctor, by making replacement parts and/or costs for using the parts available.

CHANGING COSTS

Unlike traditional insurance, in treatment insurance the costs are not known in advance, especially if even the techniques are not fully developed. Thus, it can be expected that the cost for organ regeneration, tissue storage, viability testing and sampling will change (either

decline or increase). Also, the value of selling the use of the tissue samples may change. Thus, the actual cost to the client may not be set at the beginning. A no-frills insurance program may be provided, where the client pays only for sampling and storage, and, if organ regeneration is needed, it is paid for separately, as is viability testing if desired by the client. Optionally, some cap is provided on costs, for example, different caps for different programs.

In the example of organ regeneration, the cost of organ regeneration may be covered by the instant insurance. Alternatively, a client may be charged separately or may purchase a different insurance. It is noted that there is no current knowledge of the exact cost of regenerating an organ, inasmuch as the technique to be used is not decided either. Thus, any money paid towards future organ regeneration may be returned to the client or used for insurance plan upgrading, if the cost for organ regeneration (or other treatments) are lower than expected when the client was charged for the option. Alternatively or additionally, as the cost for storage and/or tissue regeneration declines, the quality of service may be upgraded automatically, for example by preparing more organs ahead of time.

Optionally, the cost of the insurance includes the cost of health care. Alternatively, two separate services may be provided, possibly with a discount if both services are purchased from a same vendor.

EXEMPLARY METHODS OF SELLING SAMPLE-USE

As indicated above, in an exemplary embodiment of the invention, the costs of creating and/or maintaining the depository may be large (although storage per-se is expected to be quite inexpensive). In accordance with exemplary embodiments of the invention, various methods are provided for generating income and/or providing additional benefits beyond insurance. Possibly, a client is directly reimbursed for using one of the following (or other) methods. Alternatively or additionally, the client is upgraded responsive to belonging to certain revenue generating plans. Alternatively or additionally, the insurance cost is reduced. Possibly, the benefit to the client is a function of the actual benefit derived from using his samples/information, rather than a function of agreeing to join certain programs.

In an exemplary embodiment of the invention, the use of cell samples, especially ones near expiration, and/or data associated with the samples can be sold to pharmaceutical companies for performing assays and determining populations characteristics. An additional advantage is the ability to provide treatment to the clients and/or track changes in the sample as the samples are updated.

Alternatively or additionally, knowledge of the special needs, medical situation and/or concerns of the clients can be used to target advertisements, for example for novel treatments

or healthcare items, to the clients. Alternatively or additionally, a client can receive warnings that describe personal health risks. Alternatively, these warnings may be provided for free.

TRADE CENTER

In an exemplary embodiment of the invention, the existence of a single depository (even if it is geographically distributed) is used to enhance trade between clients. It is noted that the depository can test the samples and ascertain their value, in complete secrecy to both sides. Alternatively or additionally, the depository can match up sellers and buyers, match up together clients with similar needs and perform tissue matching tasks to locate suitable tissue donors. Other stock market-like and/or market-like functions may be applied, for example, posting exchange rates and prices, providing options, and allowing investment. In an exemplary embodiment of the invention, if persons of a particular ethnic group (e.g., likely to match) are aware of a war or other calamity among persons of their ethnic grouping, they can start preparing replacement organs.

Exemplary wares which might be sold or traded include, organs, tissue samples, immune-receptors, genes, treatment schedules which are determined to work for a client with one makeup, genetically altered cells and information. An exemplary tradable information type is details regarding lifestyles which increase health or health risk for a particular client makeup.

In an exemplary embodiment of the invention, a person can be offered to receive insurance even if he has no samples deposited, for example if a sufficient number of similar people have deposited tissues. The cost may be high, and may include a disbursement to those that had deposited. In an exemplary embodiment of the invention, the system maps out the various immuniologic properties of the stored tissues, so that a more complete coverage of the different possibilities can be achieved.

In an exemplary embodiment of the invention, a organ or tissue loan center is provided, in which a client can receive a tissue and is required to provide tissue in return. The provided tissue may be, for example, the same tissue, after it is used. Alternatively or additionally, the returned tissue may be a different tissue, from the client's body or from a depository. Alternatively or additionally, the returned tissue may be, for example, the same type tissue.

In an exemplary embodiment of the invention, the availability of tissue is used for test driving or temporary tissue replacements. If the tissue is rejected, it can be removed.

ADDITIONAL EXEMPLARY USE SCHEMES

Once a depository is available, it can be used for other uses as well. In one example, the depository is used for animal, rather than human, patients and insured client.

In another example, when a person desires an integrated electronic interface to the body, a plurality of tissue sample scan be attached to electrical circuits and only those that work are attached to the person. The multiple samples may be provided, for example, using methods as described above.

In another example, tissue deposition may be supported by bodies that are responsible for persons performing dangerous acts. In one example, deposition of lung cells by a cigarette smoker may be supported and/or suggested by a cigarette company. Similarly, deposit of liver cells or lobes may be supported or suggested by an alcoholic beverage manufacturer (or a group thereof). Alternatively or additionally, a health care provider may require such a deposit. Alternatively or additionally, an employer may deposit samples of organs that may be damaged by industrial processes performed by an employee.

In another exemplary embodiment of the invention, the available tissues and indexes are used to generate family genetic maps, track possible relatives and/or suggest members of a family that are at genetic risk. These methods may be applied, for example, using well known genetic counseling tools and/or methods.

SOFTWARE RESOURCES

The above described operating is, in some embodiments of the invention, managed with the assistance of dedicated software. In an exemplary embodiment of the invention, the software manages, for example, enrollment, database management (with suitable, possibly dedicated databases), stock market management, storage monitoring, quality checking, timing of tissue regeneration, timing of sampling and sampling updates tracking premium payment risk levels and/or the progression of the state of the art and/or tissue manipulation. There may be single software. Alternatively, a plurality of separate software programs may be used. In some embodiments of the invention, the software comprises customized versions of known software, for example, insurance management software.

Various levels of automation may be implemented. In some cases, the software directly performs an activity, for example, calculation of initiating tissue regeneration so suitable tissue is available, yet not wasted or robotic tissue manipulation. Alternatively or additionally, the software may control a process, for example instruct a laboratory worker, for example by e-mail, by promoting letter or by work order, to thaw a certain tissue. Alternatively or additionally, the software may be used as a reference by a user, for example, providing a premium cost estimate on request for a particular insurance program and patient.

It should be noted that software for managing a particular procedure may exist even if the procedure is not viable. For example, software can have a time table and an alert

generation schedule suitable for body cloning, even if body cloning is not yet feasible, technically and/or economically.

Although the present invention has been described using certain exemplary embodiments having various features, it should be noted that in other exemplary embodiments of the invention not all the features are required. Alternatively or additionally, features from different exemplary embodiments may be combined. In a particular example, not all embodiments of the invention require multiple samples and/or both biological and data samples. In some embodiments, only one is required.

It should be noted that although many of the embodiments have been directed to multi-tissue storage banks, many of the features and/or embodiments, such as a trading center, may also be applied to "standard" banks, for example, organ banks and umbilical cord banks.

The present invention has been described with reference to exemplary embodiments thereof. It should be understood that various features of the exemplary embodiments may be combined in other exemplary embodiments and that other embodiments may omit certain features which have been shown. In addition, many of the embodiments are optionally embodied as software and/or hardware combinations. Both software and hardware programmed to perform the embodiments are included in the scope of the present invention. Further, in some embodiments, the description is that of a method, apparatus and/or software for carrying out the method are also considered to be within the scope. Section titles, where they appear, are not to be construed in limiting subject matter described therein, rather section titles are meant only as an aid in browsing this specification. As used herein the terms "comprise", "have" and "include" and their conjugates mean "include but not necessarily limited to."

CLAIMS

1. A tissue depository for a large number of people, comprising:

at least one cryogenic storage container; and

a plurality of samples, comprising at least three different tissue types for a same person, stored in said at least one container, using at least one set of storage parameters for a same tissue type for a same person, for at least 5,000 different people.

2. A depository according to claim 1, wherein the samples are for at least 10,000 people.

3. A depository according to claim 1, wherein the samples are for at least 50,000 people.

4. A depository according to claim 1, wherein the samples are for at least 100,000 people.

5. A depository according to claim 1, wherein the samples are for at least 500,000 people.

6. A depository according to claim 1, wherein the samples are for at least 1,000,000 people.

7. A depository according to claim 1, wherein the samples are for at least 10,000,000 people.

8. A depository according to any of claims 1-7, wherein at least six tissue types are provided, for a percentage of at least 10% of the persons.

9. A depository according to any of claims 1-7, wherein at least ten tissue types are provided, for a percentage of at least 10% of the persons.

10. A depository according to any of claims 1-7, wherein at least fifteen tissue types are provided, for a percentage of at least 10% of the persons.

11. A depository according to any of claims 1-7, wherein at least two sets of storage parameters are provided, for a percentage of at least 10% of the samples.

12. A depository according to any of claims 1-7, wherein at least four sets of storage parameters are provided, for at least 10% of the samples.

13. A depository according to any of claims 1-7, wherein at least one of the samples for a person is of a fully differentiated tissue.

14. A depository according to any of claims 1-7, wherein at least one of the samples for a person is of a partially differentiated tissue.

15. A depository according to any of claims 1-7, wherein at least one of the samples for a person is of a stem cell tissue.

16. A depository according to any of claims 1-7, wherein at least one of the samples for a person retains its original structure.

17. A depository according to any of claims 1-7, wherein at least one of the samples for a person is of cellular tissue.

18. A depository according to any of claims 1-7, wherein at least one of the samples for a person is cultured.

19. A depository according to any of claims 1-7, wherein a client ID of the person for who the samples are stored, is encrypted from the depository management.

20. A depository according to any of claims 1-7, comprising a data store containing a plurality of records associated with a plurality of individuals of said persons.

21. A depository according to claim 20, wherein an associated record comprises at least one medical history record.

22. A depository according to claim 20, wherein an associated record comprises at least one medical image record.

23. A depository according to claim 20, wherein an associated record comprises at least one external image record.

24. A depository according to claim 20, wherein an associated record comprises at least one personal information record.

25. A depository according to claim 20, wherein an associated record comprises at least one personal recording record.

26. A depository according to claim 20, wherein said depository includes a cross-match table matching immunilogic properties of at least two persons having samples stored in the database.

27. A depository according to claim 26, comprising a matching engine for generating said table.

28. A depository according to any of claims 1-7, wherein said at least one storage container comprises a single storage container.

29. A depository according to any of claims 1-7, wherein said at least one storage container comprises multiple storage containers in a single location.

30. A depository according to any of claims 1-7, wherein said at least one storage container comprises multiple storage containers in multiple locations, and including a database linking the contents of said containers.

31. A depository according to any of claims 1-7, wherein said at least one storage container comprises at least one robotic manipulator for removing a selected sample form said container, under computer control.

32. A depository according to any of claims 1-7, wherein said at least one storage container comprises at least one tissue-manipulator for processing a sample in said storage container, under computer control.

33. A method of maintaining a tissue depository, comprising:

automatically generating a request for an updated sample, based on at least one of direct and indirect feedback; and

providing an updated sample per the request.

34. A method according to claim 33, wherein said direct feedback comprises a failure in a viability testing of a related sample.

35. A method according to claim 33, wherein said indirect feedback comprises a statistical analysis of viability testing of similar samples.

36. A method according to claim 33, wherein said indirect feedback comprises a time table for updating.

37. A method according to claim 33, wherein said indirect feedback comprises an indication that the source of the sample is deteriorating.

38. A method according to any of claims 33-37, wherein providing comprising removing a sample from a person.

39. A method according to any of claims 33-37, wherein providing comprising generating new tissue from an existing sample.

40. A method of generating a database of suitability information, comprising:

recording a plurality of parameters of samples provided for storage;

recording behavior of the sample during at least one of storage, regeneration, usage and after-use;

analyzing statistical significance of said behavior; and

generating a linkage between parameters and behavior.

41. A method according to claim 40, wherein said behavior is success in regenerating a viable tissue from the sample.

42. A method according to claim 41, wherein said viable tissue is an organ grown from said sample.

43. A method according to claim 40, wherein said behavior is long term viability of the sample or its progeny after it is used in a medical procedure.

44. A method according to claim 40, wherein said behavior comprises a growth rate.

45. A method according to claim 40, wherein said plurality of parameters comprise matching with a plurality of cell surface markers.

46. A method according to claim 40, wherein said plurality of parameters comprise a geometry.

47. A method according to claim 40, wherein said plurality of parameters comprise a volume.

48. A method of timing tissue regeneration, comprising:

determining an expected profile of tissue requirements;

determining an expected regeneration duration and viability of regenerated tissue; and

generating an instruction to regenerate said tissue responsive to said requirements, based on said expected duration and viability, so that it matches said expected profile.

49. A method according to claim 48, wherein said expected profile is for a single client.

50. A method according to claim 48, wherein said expected profile is for a plurality client, which use a same, not-matching tissue.

51. A method according to claim 48, wherein said generating comprises continuously assuring the availability of said tissue.

52. A method according to claim 48, wherein different tissues are generated at different assurance rates of availability.

53. A method of offsetting at least a portion of storage costs of a plurality of tissues stored in a depository, comprising:

receiving from a client permission to use a tissue associated with the client;

using said tissues; and

crediting an account of said user based on at least one of said permission and said using.

54. A method according to claim 53, wherein using comprises drug screening using said tissues.

55. A method according to claim 53, wherein using comprises experimentation in tissue regeneration using said tissues.

56. A method according to claim 53, wherein using comprises experimentation in tissue storage using said tissues.

57. A method according to claim 53, wherein using comprises using said tissues for other clients.

58. A method of remotely accessing a tissue stored at a depository, comprising:

connecting to a computer controller of said depository using a remote connection;

entering authorization information associated with samples of a particular client; and

receiving from said computer at least a status of a sample associated with said authorization.

59. A method according to claim 58, comprising manipulating said sample, using commands entered via said remote connection.

60. A method according to claim 58, wherein said authorization information does not comprise identification of the client.

61. A circumcision sampling kit, comprising:

a rinse vial;

a bacteria-static storage vial; and

instructions for use of said vials.

62. A kit according to claim 61, wherein said rinse vial comprises a cleaning fluid.

63. A kit according to claim 61, wherein said storage vial comprises a sterilizing fluid.

64. A kit according to claim 61, wherein said storage vial comprises a cryogenic storage fluid.

65. A kit according to claim 61, wherein said storage vial comprises a cooler.

66. A kit according to claim 65, wherein said cooler comprises a significant pre-chilled thermal mass.

67. A kit according to claim 65, wherein said cooler comprises an active cooler.

68. Software for managing a combined tissue deposit and insurance scheme, comprising:
a database for associating deposit information with insurance information; and
a calculator for determining at least one of a premium and an insurance sum responsive to the deposit information.

69. Software according to claim 68, wherein said calculator calculates different premiums for different deposit schemes.

70. Software according to claim 68, wherein said calculator updates a coverage of said insurance based on costs of medical procedures.

71. A trading software, comprising:
a user interface adapted for presenting information regarding available tissues; and
a user input for receiving a request to trade in said available tissues.

72. Software according to claim 71, wherein said user interface presents current values of said tissues.

73. Software according to claim 72, wherein said value is a monetary value.

74. Software according to claim 72, wherein said value is a barter value for another tissue.

75. Software according to claim 71, wherein said user interface presents a matching of said tissue to a user entering said request.

76. Software according to claim 71, wherein said user interface presents an estimated availability time of said tissue.

77. Software according to claim 71, wherein said user interface presents an estimated life duration of said tissue.

78. A method of assaying of a given material, comprising:

providing a library of tissue samples from at least 10,000 different donors;

selecting a plurality of tissue samples which are near an end of an expected viability for the samples;

applying the material to the selected samples;

analyzing the selected samples after said application; and

determining at least one property of the given material based on said analysis.

79. A method according to claim 78, wherein the library contains samples from at least 100,000 donors.

80. A method according to claim 78, wherein the library contains samples form at least 1,000,000 donors.

81. A method according to claim 78, wherein the plurality of samples comprises at least 10,000 samples.

82. A method according to claim 78, wherein the plurality of samples comprises at least 100,000 samples.

83. A method according to any of claims 78-82, wherein the material comprises a toxin.

84. A method according to any of claims 78-82, wherein the material comprises a pharmaceutical.

85. A method according to any of claims 78-82, wherein the samples are remains of thawed samples.

86. A method according to any of claims 78-82, wherein the samples are recorded as approaching an end of a viable life.

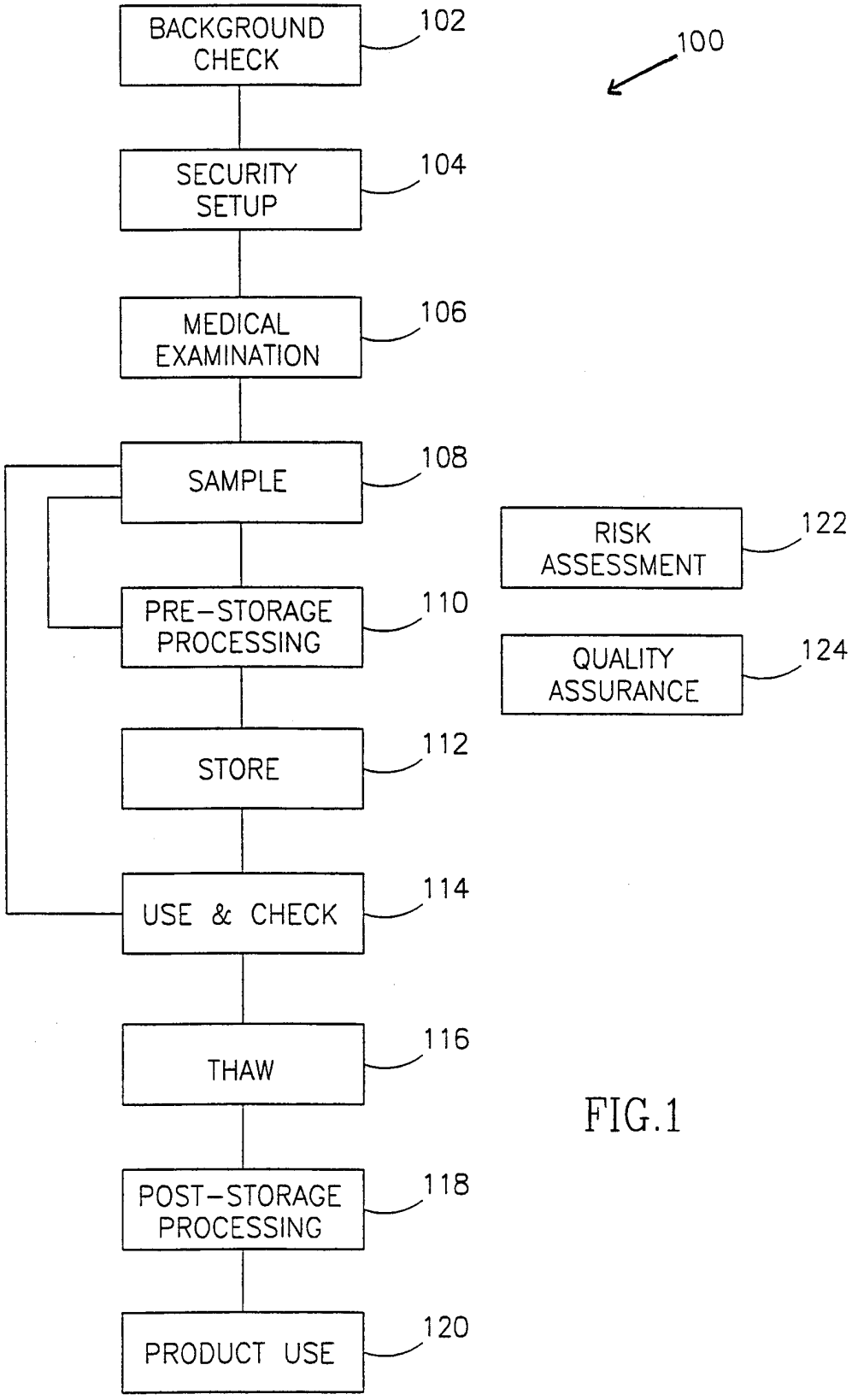
BACKGROUND CHECK
102
100
SECURITY SETUP
104
MEDICAL EXAMINATION
106
SAMPLE
108
RISK ASSESSMENT
122
PRE-STORAGE PROCESSING
110
QUALITY ASSURANCE
124
STORE
112
USE & CHECK
114
THAW
116
POST-STORAGE PROCESSING
118
PRODUCT USE
120

FIG.1

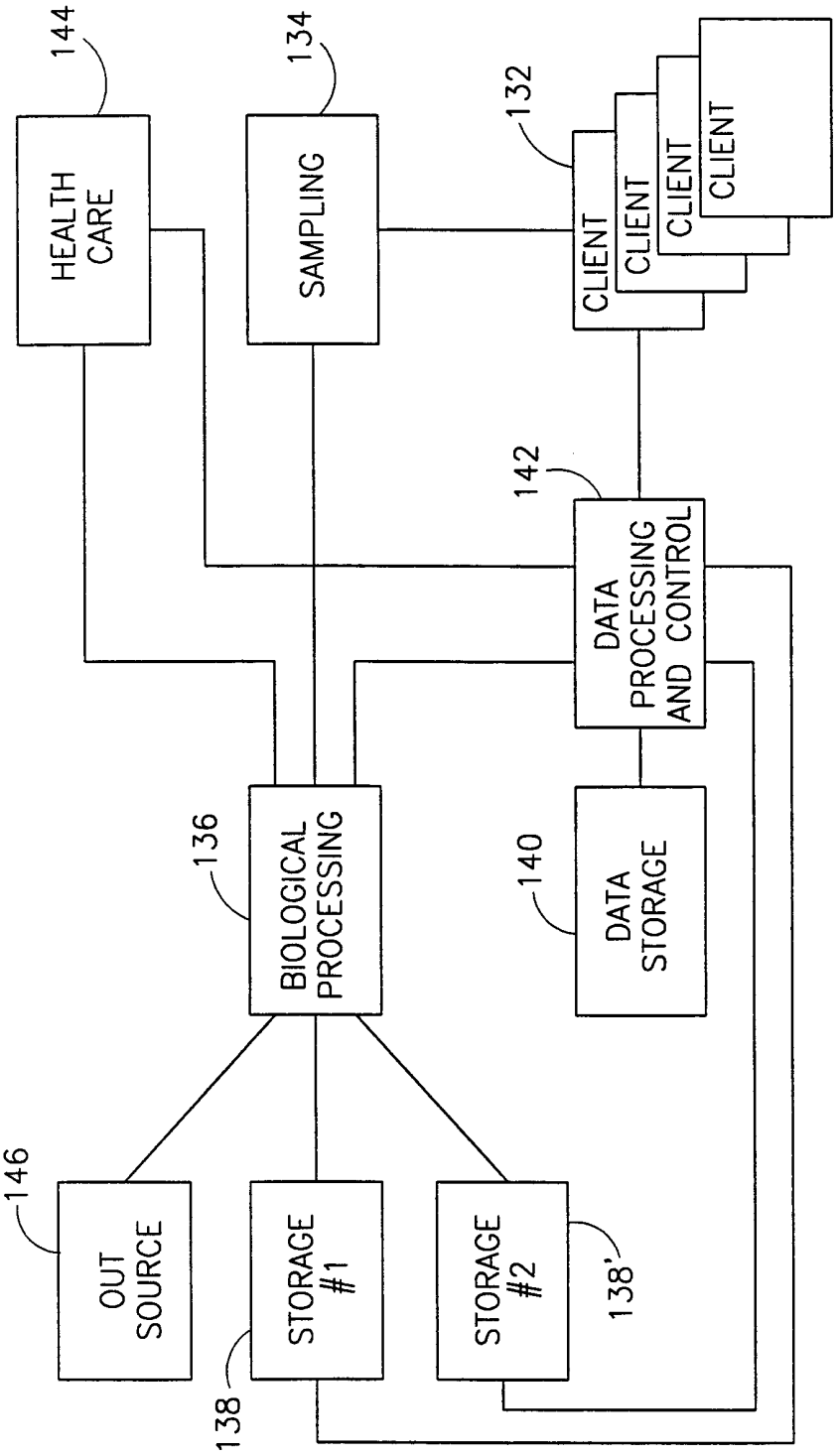
144
HEALTH CARE
134
SAMPLING
132
CLIENT
CLIENT
CLIENT
CLIENT
142
DATA PROCESSING AND CONTROL
136
BIOLOGICAL PROCESSING
140
DATA STORAGE
146
OUT SOURCE
138
STORAGE #1
STORAGE #2
138'
130

FIG.2