Collection and Management of Samples

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Abstract

A number of sample access policies from member biobanks and also from domestic biological repositories were considered during the development of the UAB Model Tax Receipt Policy. Developing a SAP was well-thought-out and required delicate negotiations within the UAB. Human genetics research is an

Access Policy in the Ukrainian Biobank Network

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important area when it comes to biobanks. Also within the UAB working group, it was clear that one of the most important benefits is the establishment of member biobanks and their specific collection of samples and data. This is important in order to work with modern applications in biomedical research at an international level and to study the range of human genetic variations. SAP systems were reconsidered based on the sample access ordered by the Ukrainian biobanks. An important step within the Ukrainian Biobank Association was the establishment of a multidisciplinary steering committee. Experts from each research group form the SCUAB sample access committee. SCUAB consists of physicians, scientists, and biobanking specialists who can provide information on regional, general, and international biobanking queries.

Keywords

Sample access policies (SAPs) · SCUAB · Management and collection of samples · Sample input · Sample output · Sample distribution · Sample access committee

Several sample access policies (SAPs) from member biobanks of the UAB and also from international biorepositories were reviewed in formulating of the UAB's sample access policy. The development of an SAP has been very deliberate and has required delicate negotiations within the UAB. They detained differentiations of eligibility factors for the access of samples and corresponding data. Also important was that the consensus on the priority for the Ukrainian research groups was time-consuming, corresponding with active discussions and opinion exchange. A comprehensible SAP is a pivotal milestone for a well-functioning association as for any other consortia and must represent and provide a simple and transparent instrument for accessing samples for researchers.

The development of a multidisciplinary Steering Committee of the Ukraine Association of Biobanks (SCUAB) was the next major step. The SCUAB reviews applications for accessing samples and assisted data from biomedical research groups from academia and industry. Representatives from each research group of collecting sites are nominated for the SCUAB.

The SCUAB is a multidisciplinary and multi-professional active team of clinicians, scientists, and specialists in biobanking, which is recognizing local, but also national, and international significance and an impact on biobanking. The most important task of SCUAB is reviewing applications from researchers, not only from academia but also from the industry, also from national and international groups for approval (or rejection) of sample access. Also within the UAB, the conduction of large-scale research studies is based on reviewing of the SCUAB, which necessitates involvement of all partners and recruitment of samples from multiple hospitals within the association.

Nevertheless, it has become obvious that an associated partner biobank which constantly shows a preference for local researchers in their own host organization rather than national or international researchers coming from outside of the given site faces complications for requests of human biological samples from other partner biobanks of the association. For that reason, it was mutually agreed that for all member biobanks of the UAB, it is indeed beneficial to facilitate all kinds of collaboration projects.

As was already reported in the introduction section, research on human genetics is one of the noticeable fields where biobanking is involved; sometimes biobanks carry out the research themselves. Also within the working team of the UAB, it was clear that one of the most significant benefits comes from the establishment of the member biobanks and their specific research aimed collections of human biological samples and related data. The work with modern applications in biomedical research on an international level and to study the extent of human genetic variations is very relevant to the members. These biobanks intended to accomplish a potentially very significant role in biomedical and human genetics research, as long as the epidemiologically relevant pool of samples and management of those samples and corresponding data are standardized and suitable for requirements of internationally recognized investigators.

If at all possible, the human biological material should be collected and stored as best as possible to suit and meet the needs of future developments in human genetics and molecular biology research, which can be foreseen from today's perspective. It would be disastrous, given the situation that after a decade, it would be realized that the human biological material, which was collected and stored at the UAB, is not adequate for research. Consequently, understanding the importance of this decision and intending to develop potentially potent resources, the SCUAB is continuously performing literature research to find hits and trends in biomedical research and recommendations and/or providing detailed guidance to members, before a new major sampling effort and/or profile building specimen collection begins.

As soon as a study under the scope of the UAB is started, it is vital that the banking of samples, and, if applicable, transport to the central biobank in Kharkiv, is carried out in a structured, robust, and reliable manner. For this purpose, the active team of the UAB works with each member site and each collecting unit through an IT system called "SMART" to guarantee that all sites use suitable collection methods, harmonized and agreed for the given specific study. Also important is to monitor that they use the same supplies of consumables and the same consumables in all participating sites and that the processing is made at a safe and timely frame.

Under the scope of the UAB, in all member biobanks for a given collection, the same principles and systems are implemented for sample management: shipping samples, clinical collection of samples, sample registration, research sample management, client correspondence communication, sample distribution, research sample qualification, sample preparation, and sample storage (see Fig. 9.1).

Biobank personnel may prepare biomaterials for transport only based on approved SOPs from vendors of trust of the UAB. This is of primary importance to all UAB biobank sample logistics. For human biological material shipping

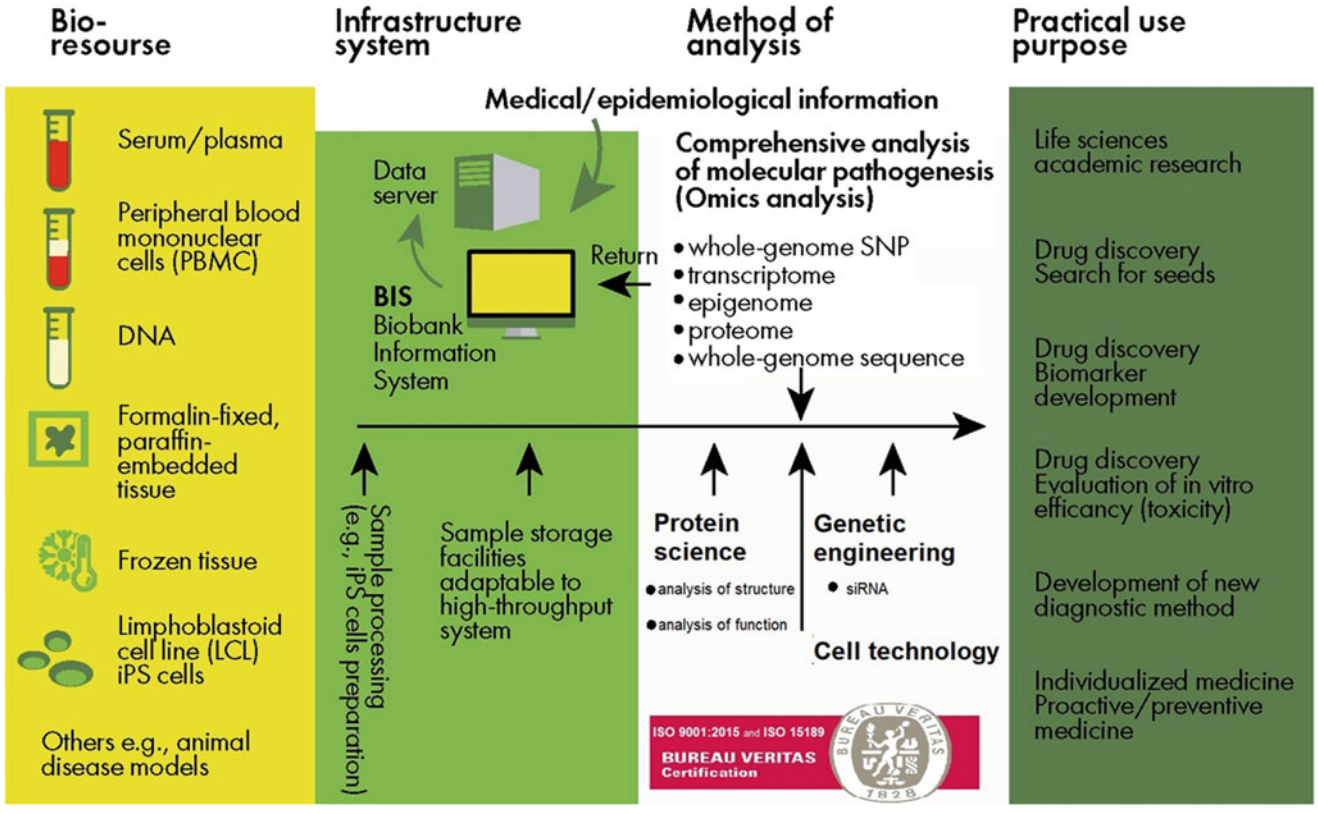

Fig. 9.1 Schematic representation of management and collection at UAB. Ukraine Association Biobank

services, several companies have as a prerequisite the safe and timely transport of biological material within, but also from or to Ukraine from all over the world. To ensure compliance with international standards, various delivery conditions can be used, while vendors and companies support the network to minimize temperature deviations during the transit of samples in the Ukraine, to the Ukraine, and from the Ukraine. The UAB is getting requests for shipment of a variety of materials from the storage site, such as liquid nitrogen, dry ice, wet ice, and samples of temperature storage between 2 and 4 °C to meet the needs of each type of sample.

As already described, the UAB provides detailed SOPs for all procedures in the member biobanks including the collection of samples. The protocols of collection are part of the UAB's shape of sample logistics for all research projects. Standard operating procedures include instructions of specific steps of collection, the tube types, the order in which they are collected and aliquoted, quality control, and the handling and dispatching of mail items. The steps to follow are precisely described (see Annex).

Registration of Samples

The registration of samples at the member biobanks of the UAB is carried out continuously in an IT system called SMART. The SMART system was developed in the Ukraine, taking the economic component and the national and scientific features into account. SMART is creating a unique record at each time when registering samples.

The human biological material is tracked in the system for storage and for receipt regardless of the storage method (tubes, FFPE, fresh frozen, etc.). SMART uses 2D barcodes with a scanner that can identify the information of individual aliquots of the main sample, the donor and collection, even the tube type, and the sample type or tissue, which was entered in the web interface.

Input of Samples

The process of including each sample in the common UAB biobank system is carried out and controlled by the SMART IT system. If the samples are delivered to the central biobank storage facility in Kharkiv, each parcel is scanned upon arrival, and the collection forms and individual samples are checked for accuracy.

During input, samples are automatically assigned to specific projects. All samples have data on the site of collection, the donor (pseudonymized), the clinical and pathology report, and the quantity of material.

Communication of Project Management

The project managers of a given project routinely correspond with sites and researchers to ensure all needs are met and all sample-processing workflows are followed. The clinical and pathology reports are generated in a given time frame. Relationships are built with each research group/client to ensure the projects' needs are being satisfied: parameters of inclusion and exclusion, single parameters of clinical information, the volume of aliquots, the amount of material required, etc.

Distribution

Human biological material provided from members of the UAB has been disseminated worldwide. Members of the UAB are obtaining broad education in international guidelines including International Air Transport Association (IATA)/ shipping regulations. Due to different courier contacts, the UAB is able to ship at any required condition: room temperature, dry ice, etc.

Sample Qualification and Processing

All samples that enter the biobanks are checked for compliance with volume and quality. Samples that do not pass quality control and do not meet the criteria of scientific projects receive a code for rejecting the registration before processing the sample and transferring it to the repository.

At first, the samples arrive in the laboratory department of the biobank; they are allocated to the relevant material department of the laboratory. The lab technician of the biobank processes the material according to the validated standard protocols in accordance with the type of specimen. The processing protocol differs in relation to the type of sample: blood and tissue samples may be used for the isolation of subsamples: buffy coat, mononuclear cell, specific immune cell, and DNA/RNA.

Storage

The storage of samples in accordance with research project-specific conditions of the UAB member biobanks is performed as long-term storage at liquid nitrogen (−180 °C), −80 °C, −20 °C, 4 °C, and room temperature.

The variety of temperature storage facilities is offered by both individual members and the central storage capacity in Kharkiv. All storage systems are maintained and monitored manually, and some important infrastructure units have automatic alarms.

The SMART IT system continuously monitors the temperature in the system, and its programmed freeze/thaw cycle limits the flow of moisture to maintain sample quality. The UAB member biobanks have a number of semiautomated and fully

automated analyzers and aliquot systems for processing blood, tissues, and other biological samples while maintaining the eligibility criteria and research project criteria. Most analytical procedures used in UAB member biobanks involve several SOPs.

The automated system of sample tracking with 2D technologies used at the UAB guarantees the elimination of errors with the labelling and sample identification data. These new states of technological innovations provide data that can be tracked and presented through online processes. Stages of sample preparations include automated or manual sample aliquoting, such as blood fractionation (plasma, serum, etc.), aliquoting biomaterial, and preparing tissue. Manual sampling retrieval may involve simply picking a sample from an automated system. The customized service of a biobank is provided for all sample types, volumes, and concentrations. Clients are offered a system for direct interaction with project managers based on research project needs.

SAPs were reconsidered in the sample access policy, commissioned by the Ukrainian biobanks. The disclosure of an SAP required extensive trading with the UAB. Defining illegibleness for specimen admittance and comprehend agreement on antecedence for the Ukraine study assembly was conclusive. A cleaving SAP contributes researchers with an unmingled and diaphanous movement for the admittance of specimens.

The construction of a multidisciplinary steering committee was an important step within the framework of the Ukraine Association of Biobanks. The SCUAB analyzes applications for samples from medical research groups. Specialists from each research group constitute the sample access committee (SAC) for the SCUAB.

The SCUAB is composed of clinicians, study scientists, and specialists for biobanking who are able to learn about regional, general, and international solicitations of biobanking. The SCUAB analyzes applications, submitted both by the nation and the investigators, providing comprehensive-separate pondering that describe specimens from manifold hospitals within the network.

On the other hand, a hospital site consistently prefers local projects to national or international projects, which may cause difficulties during the process of obtaining samples from other biobanks in the frames of the network. However, there are benefits for each place within the network to support collaborations with the members of the UAB and the network having a priority.