

Sample Management, Transportation and Transfer Agreement

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INTRODUCTION

Tissues are obtained either without consent of the provider or with consent, that does not specify possibility for future unknown research use. These practices raise ethical concerns about ownership of research samples. Ethics of stored samples and ownership issues in collaborative research is still gray in developing countries as most of the researchers have been on the receiving end with little autonomy to determine the terms of research.

Risks and benefits of use of human biological materials

- ◆ Genetic studies on human biological materials may pose social and psychological risks to the study participants especially if the materials bear identifiers
- ◆ On the other hand, there are huge financial gains when the materials are used to develop new drugs/vaccines, but research participants may not have access to the research products. Therefore the potential to exploit participants is high
- ◆ To correct the imbalance in the equitable of sharing benefits of post research products, research participants should develop capability to negotiate in fair terms. This would be easier if both the researchers and participants get involved right from the outset

Ownership of samples

- ◆ Ownership entails an individual or institution's right to possession of an object and thereby to have the right of its use, management, control, etc
- ◆ Ownership of human biological materials used in research has not been a subject of concern
- ◆ Most researchers in developing countries do not realize the value of co-owning the materials in collaborative research
- ◆ As a result, most of the researchers and institutions in these countries have given out samples and gained little or no tangible benefits compared to their counterparts who take and use the materials

Negotiation on sample use

- ◆ Human biological samples are not available for purchase from biological supplies, but obtained from human participants
- ◆ The participants are the inherent owners of the samples
- ◆ The owner can lend the samples to researcher/ sponsor for research.
- ◆ If this is the acceptable principle of exchange of human biological material, the exchange should be facilitated within a framework of legal contract that involves negotiation to ensure equity in sharing benefits of research and minimize exploitation of research participants

Material Transfer Agreement

- ◆ The most suitable type of contract between owner and borrower is the “Material Transfer Agreement” (MTA)
- ◆ It is a contract binding both the owner and the borrower
- ◆ The owner can be an individual or institution
- ◆ It can be simple and short, or complex, detailed and long, but the basic term remains to be similar

Components of Material Transfer Agreement

- ◆ Parties: lending and borrowing institutions
- ◆ Effective dates of the MTA
- ◆ Description of the material
- ◆ Purpose and usage: specific experimental test should be included
- ◆ Restriction: for the use of the material to retain control. E.g. “not to be used for human cloning”.
- ◆ Location: The sites where the material are used should be indicated
- ◆ Time period: date should be set to terminate the MTA
- ◆ Completion requirements: At the termination date the lender may ask for the return of the unused material or its destruction
- ◆ Ownership (derivatives): The lender should state whether it will allow the borrower to own the derivatives of the material

- ◆ Ownership (products): The MTA must state who owns any new products discovered through the use of the material
- ◆ Technology transfer: the MTA should emphasize the need for technology transfer
- ◆ Publication: the lender may wish the borrower to publish or not to publish under specified conditions the data obtained from the material
- ◆ Citation requirements: If the lender allows publication, it may decide the lending institution be acknowledged as the provider of the material
- ◆ Governing laws: an institution preparing the MTA will have it under the control of the country's governing laws

Mechanism for carrying out Material Transfer Agreement

- ◆ It is quite difficult for individual research participants to negotiate MTA.
- ◆ It is also not feasible for the PI to negotiate MTA with individual research participants
- ◆ The written and signed informed consent forms could represent agreement by individual research participants to the use of their samples
- ◆ Therefore, the local institution becomes responsible for negotiating the MTA for the exchange of the materials with foreign based institutions as well as third party institution within the host country

Sample Management

- ◆ All stored samples need to be handled properly till used or transferred
- ◆ Stored samples should be used only for the purpose indicated in the original proposal.

Sample exportation/importation

- Sample importation is controlled to avoid possible influx of hazardous materials to the country

Requirements for allowing sample to be exported

If:

- Its analysis needs hi-tech laboratory not available in the country
- It is collected for the research work of a student attached to an external advisor
- It is needed for forensic purposes in which the results require to be rechecked by a skilled expert
- It is to be sent for quality assurance of the work of any laboratory

It has to be made clear that the number of samples to be allowed for export should not exceed the number indicated in the original proposal of the research work

Requirements for sample importation:

- If it is proved to be safe and non-hazardous to the country
- If there is clear defined purpose

Types of samples requiring permit to be exported or imported:

- Human blood/serum samples
- Biopsy of human body tissues
- Human body fluids
- Viable or vegetative cellular colonies of microorganisms
- Lyophilized or freeze-dried whole cell materials

Types of samples which require permit to be exported or imported (cont.)

- Virulence factors of other purified cellular or surface components, essential enzymatic products, etc
- Any organic or inorganic products of animal or plant origin
- Sample of food products, water, waste matter, beverages and any other environmental and industrial products

Duties of researchers/institutes for the exported/imported samples

- They have to make sure that all exported/ imported samples are used only for the purpose of collection.
- They have to know that all exported/imported samples are properties of exporting institutions, unless there is an official agreement.
- They should know that all sample exportation/ importation require material transfer agreement.

Conclusion

- There are ethical, legal and managerial issues related to the obtaining and use of data and biological samples for collaborative research
- These issues need to be negotiated through MTA
- As much as possible, researchers/ institutions are advised to avoid sample exportation in order to build or strengthen capacity
- Prior to asking permission for sample exportation, one has to explore the possibility of undertaking the research in any of the institutes within the country
- Special attention should be taken by institutions which import samples, for the implication could be dangerous