VITILIGO BIOBANK ETHICS POLICY

INTRODUCTION

Human biological specimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetic insights, scientists have greatly increased their use and demand for properly prepared and clinically annotated tissue samples that yield valuable insights into the mechanisms and pathways of human disease.
Research on human tissue samples has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of human biological material (HBM) in basic and translational research in general. These guidelines have been applied to dealing with issues related to collection, study, storage, transfer and disposal of tissue specimens and associated patient data.
In view that HBMs are becoming a valuable and irreplaceable resource and society's interest in the advancement of medical knowledge, a consistent and coherent ethical framework should govern specimen use.

1.0 PURPOSE

The Vitiligo Biobank (VBB) is committed to high ethical standards and practices in the collection and storage of patients information and human tissue for research purposes. The purpose of this policy is to outline general principles that can be used in most situations to ensure that the interests of the patient are safeguarded.

2.0 SCOPE

The policy applies to major ethical considerations that arise in the conduct of HBM banking research. The issues concern ownership and custodianship, risk, confidentiality, consent and quality of research.

3.0 RESPONSIBILITY

This policy applies to VBB member repositories and to personnel involved in all aspects of the patients information and HBM repository program.

4.0 DEFINITIONS

Custodianship: Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the Research Ethics Board. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.
Existing or historical collections: Collections comprising samples that were collected and stored before guidelines came into operation.
Human Biological Material: All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA and RNA.
Participant: An individual (patient or healthy volunteer, if applicable) who participates in the Vitiligo Biobank Program. The terms patient, participant, subject and potential donor may be used interchangeably.

Research Ethics Board (REB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research program participants. In the case of VBB REB's functions are performed by VR Foundation Scientific Advisory Board and Board of Directors.
Standard of Minimal Risk: If potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.
Translational Research: Integrated clinical-laboratory investigations designed to improve the prevention, diagnosis and/or treatment of disease. Involves both clinical and laboratory investigations, or laboratory investigations on clinical material.
Vitiligo Biobank or Repository: Regional, state or local repositories that coordinates the collection, processing, storage and distribution of tumor tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term 'bank' and 'repository' is used interchangeably.

5.0 POLICIES

The use of HBM and accompanying data is critical for medical research. The public and program participants should have confidence that repositories and researchers will use and handle such material with sensitivity and responsibility. It is important to ensure that collections of HBMs are used ethically and optimally for the research to benefit health and knowledge. The interests of the participants should always take precedence over the interests of research, science and society. The following principles in areas requiring ethical consideration should guide the VBB repositories in collecting, maintaining and managing the resource it controls:

5.1 Ethics Review

- To ensure that the interests of the patient are safeguarded, processes such as consent, collection, storage and proposed research should be reviewed and approved by Research Ethics Board (REB) consisting of VR Foundation Board of Directors and Scientific Advisory Board members.
- The standard of "minimal risk" should be considered in the review process. The physical risks in donating tissue samples for research may be minimal, but the risk that information from research on the sample and annotated data could harm the privacy and confidentiality of the participant should be considered.
- REB approved informed consent should be obtained from participants of the VBB program. Participants should be informed and understand what the biosample and medical data is to be used for and how the results of potential research might impact them.

5.2 Confidentiality

- Personal and medical information and research results relating to the participant and tissue sample should always be treated as confidential. The participant should be made aware of the type of personal and medical information that will be used by researchers, and what safeguards will be in place to protect their confidentiality.

5.3 Economic Factors

• Economic factors may provide motivation for participants to provide biosamples but this could compromise the quality and safety of the collection. Subjects should not be offered or receive any financial compensation for participation in the program. HBMs collected from participants should be treated as gifts.

• HBMs should not give rise to financial gain. The VBB repositories should not sell (for a profit) samples of HBMs that they have collected. A reasonable payment from users of the repository to recover costs of managing, maintaining, processing and handling the repository collection is however acceptable.

5.4 Custodianship of tissue and data

• The concept that repositories have "custodianship" over the samples and data in their collection implies that repositories should direct storage and controls to safeguard the interests of the participant.
• Custodians of the tissue samples should bear responsibility for keeping proper records of all uses that have been made of the materials, whether by themselves or others. If transfer of material occurs, appropriate material transfer procedures should be followed and documented.
• Custodians of Existing Collections should ensure that they make optimal use of the resource they control and seek the advice of the established REB through periodic (for example, annual) review.

5.5 Commercialization and Intellectual Property Issues

• The development of new drug therapies and diagnostics to a point where they can be made available to universally benefit society is very dependent on commercial involvement. Access by the commercial sector to HBMs within the repositories should be facilitated if consistent with the goals of the repository. However, no one commercial enterprise should be given exclusive rights of access to the collection. Patients should be informed in the consent process, that samples or their products may be used by academic researchers as well as researchers in the commercial sector and that they will not be entitled to a share of the profits that may ensue from research. Disclosure that there is the possibility or intent to commercialize research might help alleviate ethical concerns that participants are not aware of intended uses of their tissue.
• Intellectual property (IP) rights arising from research using human samples may be sold or licensed in the same way as other IP rights. Before allowing access to samples by either academic or commercial sector researchers, the repository or "custodian" of the HBMs and data should make clear (by contractual agreement) its policies on ownership of IP.

5.6 Genetic Testing

• The ability to study samples stored in biorepositories and to generate information about genetic disease and susceptibility to disease has raised concerns over risk to participants associated with discrimination and stigmatization of individuals. Privacy of research results should never be breeched, as the consequences for the participant are likely to be social, economic and psychological.
• Much genetic information received for research purposes is of unknown or uncertain predictive value. Results should never be disclosed to the patient or added to medical records unless consent is obtained. If consent is sought, then appropriate counseling should be available. During this counseling, participants should be advised of the potential risks and implications of genetic information on family members and relationships, employment and insurance.

6.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3
http://www.wma.net/e/policy/b3.htm
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org
http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
3. USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. http://www.fda.gov/oc/gcp/default.htm or www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
4. Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent.
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm
5. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series.
6. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
7. National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.
http://bioethics.georgetown.edu/nbac/hbm.pdf
8. Meslin, E. and Quaid, K. Ethical issues in the collection, storage, and research use of human biological materials. J Lab Clin Med. 2004;144:229-34
9. Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505.