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GUIDELINES -

Biological Samples and Human Genetic Data: Collection, Processing, Use and Storage

These Guidelines are based on principles set out in the UNESCO **International Declaration on Human Genetic Data** adopted at the 32nd session of the General Conference on 16th October 2003.

PREAMBLE

Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics alone since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.

Human genetic data have a special status because they can be predictive of genetic predispositions concerning individuals; they may have a significant impact on the family, including offspring, extending over generations and even the whole group to which the person involved belongs. They may have cultural significance for persons or groups and may contain information the significance of which is not known at the time of collection of the biological sample. On account of the sensitivity of human genetic data an appropriate level of protection for these data and the biological samples from which the data are derived should be provided.

A. GENERAL PROVISIONS

1. Aims and scope

- 1.1. These guidelines aim to ensure the respect of human dignity and the protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data¹, human proteomic data and of the biological samples from which they are derived².
- 1.2. These guidelines shall not apply in the investigation, detection and prosecution of criminal offences and in parentage testing³.
- 1.3. These guidelines aim to help eliminate possible corruption.

2. Purposes

Biological samples and genetic data may be collected, processed, used and stored only for the purposes of:

- 2.1. diagnosis and health care, including screening and predictive testing;
- 2.2. medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as 'medical and scientific research';

¹ See Appendix I for an explanation of terms used.

² 'Human genetic data and human proteomic data' are referred to hereafter collectively as 'genetic data.'

³ Collection of biological samples and use of genetic data for such purposes should be as provided by Sri Lanka law and should be consistent with the international law of human rights.

- 2.3. forensic medicine and civil, criminal and other legal proceedings, as provided for by Sri Lanka law⁴ and consistent with the international law of human rights;
- 2.4. or any other purpose, including pure research, consistent with the Universal Declaration on the Human Genome and Human Rights, and the international law of human rights.

3. Procedures

- 3.1. All procedures concerning the collection, processing, use and storage of biological samples and genetic data should be transparent and ethically acceptable.
- 3.2. Ethical Review Committees (Research Ethics Committees) at institutional or local level should be consulted and approval obtained before the commencement of medical and scientific research projects that include the collection, processing, use and storage of biological samples and/or genetic data.
- 3.3. The collection, processing, use and storage of biological samples and genetic data for medical diagnosis and healthcare programmes, such as screening and predictive testing, shall be consistent with guidelines that deal with such topics.
- 3.4. A National Bioethics Committee, or in the absence of such an entity a bioethics committee with wide representation of a national character, shall be consulted on matters that are not addressed in these guidelines or when there is no relevant Sri Lanka law as required by these guidelines.
- 3.5. When collection, processing, use and storage of biological samples and genetic data are carried out in Sri Lanka and one or more other countries, Ethical Review Committees (Research Ethics Committees) of all countries concerned should review the proposal (be it for research, diagnostic or healthcare purposes) and give their approval⁵.
- 3.6. Clear, balanced, adequate and appropriate information should be provided to the persons from whom biological samples and genetic data are to be collected, processed, used and stored prior to obtaining their free, informed and express consent. It is important to specify the purpose (e.g. pure or applied research, diagnosis, etc.) for which genetic data are being derived from biological samples, used and stored. (See also clauses 5 & 6: Consent and Withdrawal of consent)

4. Non-discrimination and non-stigmatisation

- 4.1. Genetic data should not be used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatisation of an individual, a family, or a group or community.
- 4.2. In this regard appropriate attention should be paid to the findings of population based genetic studies and behavioural genetic studies and their interpretation.

⁴ See Appendix II

⁵ The provisions of the SLMA Guidelines on International Collaborative Research also apply.

B. COLLECTION

5. Consent

- 5.1. Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for collection of biological samples and genetic data, whether through invasive or non invasive means, and for their subsequent processing, use and storage, whether carried out by public or private institutions.
- 5.2. When a person is incapable of giving informed consent, authorization should be obtained from the guardian or 'legal representative', who should have regard to the best interest of the person concerned.⁶
- 5.3. An adult not able to consent (e.g. due to poor educational attainments or mental retardation) should nevertheless, as far as possible, take part in the authorization procedure. The opinion of a minor too should be taken into account, in proportion to age and degree of maturity.
- 5.4. In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when it has important implications for the health of the person and has regard to his or her best interest.

6. Withdrawal of consent

- 6.1. When biological samples and genetic data are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. Withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.
- 6.2. When a person withdraws consent, the person's biological samples and data should no longer be used, unless they are irretrievably unlinked to the person concerned.
- 6.3. If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.

7. The right to decide whether or not to be informed about research results

- 7.1. When biological samples and genetic data are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results.
- 7.2. The right to decide whether to be informed or not does not apply to research on data that are irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in the research.
- 7.3. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.

⁶ 'Incapacity to give informed consent', 'guardian' and 'legal representative' need defining. UNESCO declaration provides 'in accordance with domestic law'.

8. Genetic counselling

- 8.1. It is imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate manner. Such genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned.

9. Collection of biological samples for forensic medicine or other legal proceedings (including parentage testing)

- 9.1. The collection of biological samples for obtaining genetic data for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, *in vivo* or post-mortem, should only be made in accordance with Sri Lanka law.

C. PROCESSING

10. Access

- 10.1. No one should be denied access to his or her genetic data unless such genetic data are irretrievably unlinked from that person as the identifiable source.
- 10.2. However, access to his or her genetic data may be denied if Sri Lanka law limits such access in the interest of public health, public order or national security.

11. Privacy and Confidentiality

- 11.1. The privacy of individuals and the confidentiality of genetic data linked to an identifiable person, a family, a group or a community should be protected.
- 11.2. Biological samples and genetic data linked to an identifiable person should not be disclosed or made accessible to third parties, in particular employers, insurance companies, educational institutions and the family.
- 11.2.1. However, biological samples and genetic data linked to an identifiable person **may** be disclosed or made accessible to third parties for an important public interest reason **if** provided for by domestic law **or** where prior, free, informed and express consent has been given.
- 11.3. Biological samples and genetic data collected for the purposes of scientific research should not normally be linked to an identifiable person.
- 11.4. Biological samples and genetic data collected for medical and scientific research purposes can remain linked to an identifiable person only if necessary to carry out the research provided privacy of the individual and confidentiality of the data is protected.
- 11.5. Data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.

12. Accuracy, reliability, quality and security

- 12.1. Persons and entities responsible for the processing of biological samples and genetic data should have adequate facilities, knowledge and experience to ensure accuracy, reliability, quality and security in processing biological samples and genetic data.

- 12.2. They should exercise rigour, caution, honesty and integrity in the processing and the interpretation of genetic data, in view of their ethical, legal and social implications.

D. USE

13. Change of purpose

- 13.1. Data collected for one of the purposes set out in Clause 2 (Purposes) should not be used for a different purpose that is incompatible with the original consent, unless fresh consent is obtained **or** unless the proposed use, decided by Sri Lanka law, corresponds to an important public interest reason.
- 13.2. When prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an unidentified person, human genetic data may be used in accordance with provisions of Sri Lanka law or in accordance with the provisions of Clause 3.4 i.e. consulting a national ethics committee.

14. Stored biological samples

- 14.1. Stored biological samples collected for purposes other than set out in Clause 2 (Purposes) may be used to produce genetic data with the prior, free, informed and express consent of the person concerned.
- 14.2. However, Sri Lanka law may provide that if such data have significance for medical and scientific research purposes e.g. epidemiological studies, or public health purposes, they may be used for those purposes, following the consultation procedures set out in Clause 3.4 i.e. consulting a national ethics committee.

15. Circulation and international cooperation

- 15.1. Cross-border flow of biological samples and human genetic data should be in accordance with Sri Lanka law.
- 15.2. In the absence of relevant provisions in law, the onus of fostering international medical and scientific cooperation and ensuring fair access to this data lies with the Ethical Review Committee (Research Ethics Committee) reviewing the research proposal.⁷
- 15.3. Such a committee should seek to ensure that the receiving party provides adequate protection for the persons who provided the biological samples and the genetic and other data derived from them in accordance with the principles set out in this guide.
- 15.4. In order to foster the sharing of scientific knowledge, researchers should endeavour to publish in due course the results of their research.

16. Sharing of benefits

- 16.1. Benefits resulting from the use of biological samples and human genetic data collected for medical and scientific research should be shared with the society as a whole and with the international community in accordance with Sri Lanka law or policy and international agreements.

⁷ This is an area where a National Bioethics Committee should draw-up guidelines or regulations. Until such time it may be appropriate for the local committee to decide on the course of action.

- 16.1.1. If Sri Lanka law or international agreements stipulate limitations for the sharing of benefits, these should be given effect.
- 16.2. Benefits may take any of the following forms:
 - 16.2.1. Special assistance to the persons or groups who have taken part in the research;
 - 16.2.2. access to medical care;
 - 16.2.3. provision of new diagnostics, facilities for new treatments or drugs resulting from the research;
 - 16.2.4. support for health services;
 - 16.2.5. capacity-building facilities for research purposes;
 - 16.2.6. development and strengthening of the capacity to collect and process human genetic data;
 - 16.2.7. or any other forms consistent with the principles set out in the International Declaration on Human Genetic Data.

E. STORAGE

17. Destruction

- 17.1. The provisions of Clause 6 (Withdrawal of consent) apply in the case of stored biological samples and genetic data.
- 17.2. Biological samples and genetic data collected from a suspect in the course of a criminal investigation should be destroyed when no longer necessary, unless otherwise provided for by Sri Lanka law.
- 17.3. Biological samples and genetic data should be available for forensic purposes and civil proceedings only for as long as they are necessary for those proceedings unless otherwise provided for by Sri Lanka law.

18. Cross-matching

- 18.1. Consent is essential for cross matching of biological samples and genetic data stored for diagnostic and healthcare purposes and for medical and other scientific research purposes, unless otherwise provided for by Sri Lanka law.



Appendix I: Use of terms

For the purposes of these guidelines, the terms used have the following meanings:

Human genetic data: Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis;

Human proteomic data: Information pertaining to an individual's proteins including their expression, modification and interaction;

Consent: Any freely given specific, informed and express agreement of an individual to his or her genetic data being collected, processed, used and stored;

Biological samples: Any samples of biological material (for example blood, skin, bone cells, plasma or tissue cultures) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual;

Population-based genetic study: A study that aims at understanding the nature and extent of genetic variation among a population or individuals within a group or between individuals across different groups;

Behavioural genetic study: A study that aims at establishing possible connections between genetic characteristics and behaviour;

Invasive procedure: Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe;

Non invasive procedure: Biological sampling using a method which does not involve intrusion into the human body, such as oral smears;

Data linked to an identifiable person: Data that contains information, such as name, birth date and address, by which the person from whom the data were derived can be identified;

Data unlinked to an identifiable person: Data that are not linked to an identifiable person, through the replacement of, or separation from, all identifying information about that person by use of a code;

Data irretrievably unlinked to an identifiable person: Data that cannot be linked to an identifiable person, through destruction of the link to any identifying information about the person who provided the sample;

Genetic testing: A procedure to test the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change;

Genetic screening: Large-scale systematic genetic testing offered in a programme to a population or subsection thereof intended to detect genetic characteristics in asymptomatic people;

Genetic counselling: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences. It takes place before and after genetic testing and screening;

Cross matching: Matching of information about an individual or a group contained in various data files set up for different purposes.

Appendix II: Role of a National Bioethics Committee

Wherever these guidelines make reference to provisions of Sri Lanka law, if no such law exists, such matters should be referred to a National Bioethics Committee. If such a committee were to be unavailable for consultation on such matters, a bioethics committee with wide representation of a national character should be consulted.

Article 16 of the Universal Declaration on the Human Genome and Human Rights (February 2000) states thus ‘*States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications.*’ The Declaration on Human Genetic Data urges the establishment of ethics committees at national, regional, local or institutional levels. It goes on to recommend that committees at national level should be responsible for the establishment of standards, regulations and guidelines for collection, processing, use and storage of biological samples and genetic data as well as consultation on matters where there is no domestic law. On the other hand, ethics committees at institutional or local level should be consulted with regard to their application to specific research projects.

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