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**“Genetic Manipulation and Gene Therapy”**

## **Presentation of the Chairs**

### **Distinguished delegates,**

I warmly welcome you to VIMUN 2016! It is my great honor and privilege to serve this conference as chairperson of the International Bioethics Committee of UNESCO.

My name is Ekaterina Rogacheva and I come from Russia. Currently I am studying international law at the Moscow State Institute of International Relations of the MFA of Russia also being Assistant Coordinator of the Moscow International Model UN.

The Committee, whose work we will be simulating in the course of the model, is quite exotic and remarkable. It was established in 1993 as a response to the rapid advances in the scientific understanding of the human genetic code comprising, by the way, 3.6 billion letters. In recent years, a number of spectacular achievements in the field of genetics have been made, which are truly revolutionary, and, in the present situation, observance of the ethical norms and human rights in this field becomes precondition of the survival of all mankind.

This year such a relevant and pressing agenda as «Genetic Manipulation and Gene Therapy» is offered for discussion of the IBC. In this regard, you have a unique chance to transform into diplomats and decide the destinies of the world, presenting your own vision of the situation and possible ways of its resolution.

I sincerely wish you a successful conference, fruitful and heated debates, adoption of worthy and comprehensive resolutions. As for my part, I promise that I will do my best to make the work of the committee effective and constructive.

Looking forward to meeting you all in Vienna!

Sincerely yours,

Ekaterina Rogacheva

## **1) Introduction**

*«The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.»*

-Article 1, UDHGHR-

*«No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.»*

-Article 10, UDHGHR-

Starting with the adoption of the Universal Declaration on the Human Genome and Human Rights (UDHGHR) by the General Conference of UNESCO in 1997 and in 2003 with the International Declaration on Human Genetic Data (IDHGD), the field of genetics has been marked by a number of spectacular achievements that paved the way for genetic screening and diagnosis for the presence of genetic diseases, gene therapy, use of embryonic stem cells in medical research and the possibility of cloning and genome "editing" for medical and non-medical purposes.

Sequencing DNA has become easier, faster and cheaper. Direct-To-Consumer tests, precision/personalized medicine, biobanks, non-invasive prenatal testing are some of the most challenging developments of today. New techniques such as human cloning for research purposes, spindle and pronuclear transfer, gamete formation from somatic cells and genome editing have evolved.

However, all these achievements have evoked new debates and awareness of both new opportunities and obligations created by them.

Among the main concerns arising therefrom we observe the lack of ethical awareness, as well as of effective legislation frameworks in this field at the international and national levels, resulting in the fact that unregulated actions, even though only in some countries, become automatically allowed.

These fundamental and urgent problems have been reflected in many reports of the experts of the International Bioethics Committee. The IBC experts argue that gene therapy could be a watershed in the history of medicine, while genome editing is undoubtedly one of the most promising undertakings of science for the sake of all humankind. At the same time, their reports also contain a warning that such development seems to require particular precautions and raises serious concerns.

## **2) General background**

### **2.1) Current State of Genetics**

In 2000, following the completion of the international research project "The Human Genome Project", started in 1990 by James Watson under the auspices of the US National Health Organization, an unprecedented technological development has led to reduction of the price of human genomic sequence determination (sequencing) by several orders of magnitude. The speed of obtaining a complete human DNA sequence has also increased dramatically.

The combination of lower cost and increased speed have led to the fact that the genome sequencing of individual patients became part of clinical medicine as diagnostic procedures to identify mutations responsible for some diseases.

Concomitant development of genome analysis bioinformatic tools and also the possibility to link this information with the data on human health, on the impact of environment and lifestyle, have created the problem of big data (the phenomenon of «Big Data»).

Functional analysis of genome sequences has also revealed patterns of epigenetic inheritance - changes in activity (expression) of genes throughout life of the individual without changing the genome DNA sequence and contributing to complexity and human diversity.

A particularly troublesome result of rapid progress in the field of genome analysis is the creation of a **global**

**web market for direct-to-consumer (DTC) tests** for medical and non-medical applications, created to promote these services in various countries. This market is based on the right of people to know information regarding them and undergo genetic testing for any purpose they consider valid, for example, in order to determine their origin or the origin of their children.

In many cases, results of the tests advertised on the Internet are not based on scientific evidence. Yet such analyses are offered to suggest tailored diet, exercise program, face cream, and etc.

In some countries appropriate authorities can intervene when these tests address matters related to health, although offers of the international market are difficult and often impossible to regulate at the national level.

Moreover, there are so far no effective approaches to regulate the sequencing applications area according to consumer protection law. An important matter of concern is the fact that the companies carrying out testing, collect personalized information, that they can later make use of for their own benefit with little guarantee on the respect of individual privacy.

The progress of genetic and biomedical research has introduced a new concept, '**precision medicine**' (PM) or '**personalized medicine**' which is gradually being introduced into health care.

This development is faced with the problem of integration and interpretation of the huge amount of data (the «Big Data» phenomenon), derived from genetic and other molecular analyses, and from health records, including medical imaging, as well as different types of information related to environment and human lifestyle. Research has revealed that in most cases diseases result from an interaction of several, and sometimes (even hundreds of) factors.

It is often difficult to apply to an individual results of the studies, having a statistical value, as they are imprecise and limited to the provision of one type of information - whether a person is exposed to an increased or lower than normal risk for a disease.

This type of information is difficult to interpret and apply in everyday medical care. Some mutations are directly life-threatening, while others only increase or decrease the risk of development of a disease (e.g. sickle cell anemia and malaria). Many other variants currently can not be interpreted properly due to the fact that they have only rarely been found or are new, and so no one yet knows what they mean.

The fact that the same companies are offering their services through different subsidiaries, contributes to convergence of "Big Data" and PM.

Technological developments in the context of genomics are not limited only to sequencing. A number of technologies, such as

- human somatic cell nuclear transfer into an enucleated oocyte,
- spindle or pronuclear transfer for preventing mitochondrial diseases in offspring,
- derivation of gametes from induced pluripotent stem cells (IPSC),

can be involved (already or potentially) in the process of human reproduction. What was only a theoretical possibility a few years ago is now a scientific reality, and can enter the area of clinical use in the near future.

New experimental tools allow scientists to insert, remove and correct the sequence of genes, opening up the possibility of treating, or perhaps even curing, certain single-gene disorders (such as beta-thalassemia, sickle cell disease and certain forms of cancer).

Further improvement of these procedures and establishment of security for patients would enable the long-awaited success of **somatic gene therapy**, owing to the fact that genetic changes induced are not passed on to the next generation.

In several countries somatic gene therapy has already received ethical and regulatory acceptance. However, the potential application of these technologies to germline modification for therapeutic purposes or for enhancing particular characteristics of an individual has led to dramatic increase of concerns of scientists and ethicists.

As a result, there have been calls for a moratorium on the application of such technologies, at least for as long as their safety and long-term consequences are not better understood.

Some countries have imposed legal bans on germline modifications in humans whereas others have only introduced administrative or ethical rules ("soft law") prohibiting such experiments on embryos and gametes.

**Nuclear transfer of somatic cells** is a technique that has been used for cloning numerous species of

animals. The best known case in connection herewith was the sheep Dolly in 1997.

This method is based on extracting the nucleus from a normal somatic cell (not a germ cell) and introducing it into an oocyte (egg cell) of the donor from which the nucleus has been previously removed, and on the implantation of the reconstructed oocyte stimulated to develop into the uterus of a female mammal of the same species.

The success rate of this technique is not high. Of almost three hundred attempts only Dolly was a successful outcome. For mice, on which research is carried out more than on any other mammals, success is about 1%. Since the birth of Dolly, somatic nuclear transfer has been successful for many mammals, but using this technique for humans was largely a theoretical possibility and ethical problem than anything else.

So two terms were introduced: cloning for research purposes and cloning for reproductive purposes.

Aim of the former is obtaining embryos at earlier stages, which would never be implanted but could serve as the source of embryonic stem cells, which could be used for various purposes in regenerative medicine.

The second term is self-explanatory: the aim of the process would be to obtain an embryo that would be implanted and would lead to the birth of a baby being the exact genetic copy of another human being in other words the clone. **The first human cloning for research purposes was conducted in 2013.**

The discovery of a new method for producing stem cells capable of producing any cell of the human body without having to destroy embryos raised great excitement.

**Induced pluripotent stem cells (iPSCs)** are produced by introducing several specific genes into normal somatic cells. However, the capacity of iPSCs to be a substitute for normal embryonic stem cells (ESCs) is a topic of constant debate.

Comparisons between ESCs, iPSCs and embryonic stem cells obtained by cloning for research purposes, has shown that there are still quite a number of differences between iPSCs and ESCs and fewer differences between ESCs and the cells obtained after somatic cell nuclear transfer.

In recent years special attention is paid to mitochondrial diseases and techniques to avoid passing them to next generations.

Mitochondria are organelles of human cells, which have their own DNA (mitochondrial DNA) and are passed only from the mother to her children, as paternal mitochondria are destroyed at the very early stages of embryonic development.

The mitochondrial DNA does not contain a large number of genes (37 genes compared with more than 22,000 of genes in the nucleus), but it can contain mutations (mostly in nervous tissue and muscle) causing the disease that can lead to the development in humans of a number of diseases such as blindness, deafness, diabetes, etc. No treatment for these diseases has been found yet.

It should be noted that not all the mitochondria bear a mutated gene within the given cell. Most mitochondrial diseases become symptomatic when the percentage of mutated mitochondria exceeds a certain threshold.

Unfortunately, the presence of diseases caused by mutations in nuclear genes, prenatal and pre-implantation diagnosis does not always give fully reliable results. Moreover, for one of the most common mitochondrial diseases (a type of blindness) in most persons suffering from the disease, the percentage of mitochondria carrying a mutated DNA is 100%, i.e. the disease is always passed on to the next generation, though women are often asymptomatic for this particular disease.

**Maternal Spindle Transfer (MST) and Pro-Nuclear Transfer (PNT)** are two techniques on the basis of in vitro fertilization, which have the potential of preventing transmission of inherited through the maternal line mitochondrial disorders caused by mutations in mitochondrial genes.

For MST, nuclear DNA from an egg cell, being the carrier of the mutation, is transferred into an egg of the donor from which the nucleus is removed beforehand and therefore bringing healthy mitochondria, and then reconstructed cell is fertilized.

For PNT, egg of the woman with defective mitochondria is fertilized first, then the nuclear DNA is removed and transferred into a donor's fertilized egg after the removal of nucleus from the latter.

MST hereby, as opposed to PNT, does not involve the destruction of embryos as transfer is performed before fertilization.

Recently another method of **mitochondrial genomes modification** in oocytes, not resorting to donor eggs, has been tested on mice.

Several laboratories performed a successful derivation of egg and sperm precursor cells from embryonic stem cells (ESCs) of a mouse, the so-called "artificial gametes". In consequence the same has also been achieved with human cells.

It is now considered already proven that the artificial gametes can also be produced from induced pluripotent stem cells (iPSC) of mice.

These findings demonstrate that iPSCs are not only developmentally similar to ESCs, but also that the somatic cells from adult tissues can produce gametes in vitro, i.e. if they are reprogrammed into iPSCs.

These procedures promise many new opportunities for stem cell research and development of the new methods of assisted reproductive technology. For couples, using in vitro fertilization, it would be possible to have a genetically related child, without the need for gamete donors. However, now it is almost impossible to predict whether this method would be successful in humans, as there are still major technical problems unsolved.

Current findings offer only the opportunity of primordial germ cells production (created in vitro from stem cells) which must later be converted into mature sperm or in eggs by transplanting them respectively back into testes and ovaries. During culture both, iPSCs and ESCs, frequently pick up chromosomal abnormalities, genetic mutations and epigenetic disorders.

A new genome editing technique using a bacterial system, called **CRISPR-Cas9**, has been recently introduced offering the possibility of inserting, removing and correcting DNA with relative simplicity and effectiveness, unparalleled so far. Application of this technology to the germline raised serious concerns within the entire scientific community.

In April 2015 a group of scientists from China published the results of applying this technique. All human embryos obtained from IVF carried abnormalities preventing their further development as the technique, appearing to be not so effective, caused numerous errors in insertion.

## **2.2) Impact of Genetic Interventions on the Intensification of Ethical Issues and New Protection Requirements of Individuals**

When considering the impact of genetic interventions on ethical issues one should bear in mind that none of them is new. However, technical progress in the field of genetics brings deeper challenges and new requirements for regulations to protect individuals. At the same time freedom of research and freedom of the individuals should not be inhibited by too many strict regulations.

Experts underline and consider the following five principles of the ethical and social issues as major:

### **2.2.1) Respect for Autonomy and Privacy**

Genetic data of an individual is considered to be among the most important personal data, so it must be protected from unauthorized access and possible misuse.

Only the person tested has the right to decide, whether she or he wants to know or not to know about her or his genetic make-up, whether someone else may get access to this information and for what purposes genetic data are to be processed and used.

Information about one's own genetic make-up can be helpful for the prevention and treatment of diseases. However, in some cases it can cause anxiety, uncertainty and become a significant moral burden. In order to really make decisions independently, a person has to receive confirmed and reliable information about the test, its possible outcomes and consequences.

Counseling without the influence of commercial interest is an essential prerequisite for fostering adequate awareness. Particularly serious challenges in this case are caused by DTC-tests.

Giving informed consent for genetic testing, a person must understand the potential impact of the results on her or his life. Due to increasing use of high-throughput sequencing in medical practice the problem of random findings and results that are difficult to interpret is becoming significantly important.

The question of whether the right to know encompasses the right to be informed about the incidental findings raises a lot of discussions.

Autonomy in the field of genetics can not only take into account the interests of the person being tested. There are inevitable implications for relatives and communities as well, who may share the same or similar

genetic status. In this regard, a question arises, whether there is an overarching right not to know and/or not to disclose, or can there be situations where family members have to be informed?

Further problems arise with regard to individuals who can not give consent to be genetically tested. A lot of legal instruments exist to protect the welfare of such persons, one of which is the institute of legal representation. However, all these instruments can not protect an unborn child from being genetically tested in a comprehensive way, as the unborn child has a different moral and legal status in different countries. There is a lively controversy about the right of the child, especially the unborn child, to have his or her future right not to know, his/her right to an open future and his/her right to privacy preserved.

### 2.2.2.) Justice and Solidarity

Undoubtedly, genetics contributes to a better health care. For example, personalized medicine promises better outcomes and lowers the burden for specific diseases like some types of cancer.

However, genetic methods are costly, being not affordable for the health systems of some countries. The huge inequality in the distribution of wealth is an obstacle for accessing the achievements of scientific progress and its application in accordance with the basic human rights.

The lack of justice in health care and participation in progress remain a major challenge within and among countries. Discrimination and stigmatization on genetic grounds can also occur outside of the health sector (e.g. non-medical insurance or work place). Even racism could be fostered, but only on the basis of erroneous or even unintentionally misinterpreted data.

Effects of stigmatization and discrimination can also occur with regard to prenatal and pre-implantation genetic testing. Very often for the unborn child the consequence of detecting a genetic abnormality is not a therapeutic intervention, but resorting to abortion or discarding the embryo. Erroneous or misinterpreted results may lead to the destruction of healthy and normal embryos or foetuses.

The introduction of non-invasive prenatal diagnosis is being increasingly implemented as a routine measure in the early stages of pregnancy, especially in countries with an established system of technique-based pregnancy care. This could have a significant impact not only on reproductive freedom, but also on the perception of disability and societal solidarity with disabled people and women who give birth to them.

Justice and solidarity between countries is a priority in this field as well as in many others. This is especially true for lower and middle-income countries which might contribute to scientific progress through participation in scientific and medical research without having the possibility to benefit from the results.

This kind of scientific knowledge is directly related to what has been defined as "heritage of humanity" in Article 1 of the UDHR. In this regard, the question of understanding it as a common good, to which *open* access should be therefore guaranteed, immediately arises.

This question involves obviously the rethinking of the scope of informed consent (how broad or narrow the consent should be as both may have major implications), and raises the issue of confidentiality and data protection, as well as the problem of equitable sharing of research results between all participants.

At the same time, the international community, governments, and researchers need to address the very complex issue of the looming conflict between the right to have access to scientific knowledge and other relevant principles, starting with the patents for protection of intellectual property.

### 2.2.3.) Understanding of Illness and Health

The individual's knowledge of his or her genetic endowment may be emotionally relieving or, on the contrary, upsetting. At the same time, behavioural, social, and environmental determinants of health play a crucial role. Underestimation of the complexity of factors influencing health should be avoided.

It is the responsibility of scientists and physicians to explain to the general public the importance and limits of the opportunities of genetics.

As whole it becomes significantly easier to perform genome sequencing. However, often, the healthy individuals, learning about a higher risk of developing certain diseases, immediately begin to perceive themselves as being ill. This can be especially burdensome when there is no available preventive or therapeutic intervention and it has detrimental effects on the individuals and their family.

#### 2.2.4.) Cultural, Social and Economic Context of Science

Globalization, access to information and growing pluralism strengthens the necessity of deeper reflection on the value, meaning, and direction of science as well as of a legal framework complying with the respect of fundamental human rights.

When technical and scientific capacity reaches a new threshold (for instance, the possibility of introducing a genetic mutation into the genome of a human being), the ethical problem arises: what to do or not do, so that human beings remain human beings and achieve the best of their development?

Science tends to become more accessible to citizens. New media, the internet and free access to medical publications contribute to amplify this change, which has been called 'participatory medicine'.

However, this involvement entails great opportunities and some concerns associated with the quality of the information they provide. The wide accessibility of the Internet, even beyond national borders, is its advantage and at the same time its pitfall.

#### 2.2.5.) Responsibility Towards Future Generations

Reproductive choices with regard to genetics are an issue of ongoing controversy. Some people claim that parents have the right to make far reaching choices concerning their offspring, including the use of genetic information obtained from the early stages of pregnancy. Others believe that they should refrain from genetic testing of their future children if it is not necessary for their health.

Some people emphasize the responsibility of parents to ensure the best possible health for their children even by intervening in their genes, whereas others stress the right of every person to have an unmanipulated genetic makeup, so that nobody could make choices of other human beings with respect to their biological starting configuration if it poses no risk of developing a disease of particular severity.

The responsibility to future generations is extremely important because it respects the rights of those coming into life later on. It is also important for our social relationships, for a society in solidarity and for justice between all peoples to keep in mind that the respect for the dignity of every human being entails the duty to refrain from making her or him a mere instrument for the fulfillment of the wishes and preferences of others.

Germline genetic interventions were the subject of science-fiction novels and scientific theoretical debate, but considered non-executable. Everything has changed recently.

Today, due to the fact that the effectiveness, safety and harmlessness of these procedures are far from being warranted, this new reality calls upon experts, governments and all citizens to consider all the possible consequences on human rights and fundamental freedoms as well as on the future of humanity itself.

Here it is very important to be aware of the uncertain and highly variable functional state of the genome. We cannot be sure of the long term effects of the introduced changes.

### **3) Past Committee Action**

Since 1970s UNESCO has been actively involved in some aspects of bioethical issues, and, the first of its kind, the **International Bioethics Committee (IBC)** was established in **1993**.

Today the IBC is composed of **36** independent experts from different areas. According to the Charter, its main **objectives** are:

- developing international dialogue on ethical and legal aspects of biology and medicine and promotion of information exchange;
- support of the initiatives to improve awareness of the general public, as well as experts and authorities, regarding research projects in bioethical sphere;
- cooperation with international governmental and non-governmental organizations, supervising issues of bioethics, and others.

In **1998**, in accordance with Article 11 of the IBC Statute, the **Intergovernmental Bioethics Committee (IGBC)** was established. This committee comprises **36** members - representatives of **36 countries**. These representatives are elected **every four years** at the General Conference of UNESCO.

The main **objectives** of the IGBC are:

- expression of their opinions with regards to the activities of the IBC;

examination of the advice and recommendations provided by the IBC;  
submission for consideration of its proposals and amendments to the IBC documentation.

Today the basic instruments adopted by UNESCO relating to the sphere of bioethics are:

the Universal Declaration on the Human Genome and Human Rights (UDHGHR), adopted by the General Conference 11 November 1997 and approved by the UN General Assembly in 1998;  
International Declaration on Human Genetic Data (IDHGD), adopted by the General Conference 16 October 2003;  
the Universal Declaration on Bioethics and Human Rights (UDBHR), adopted by the General Conference 19 October 2005.

The Universal Declaration on the Human Genome and Human Rights (UDHGHR), adopted in **1997** in the framework of the UNESCO's Bioethics Programme, was the first legal instrument regulating this sphere. This declaration consists of a preamble, 7 chapters and 25 articles.

Seven chapters cover the following topics:

Human Dignity and the Human Genome,  
Rights of the Persons Concerned,  
Research on the Human Genome,  
Conditions for the Exercise of Scientific Activity,  
Solidarity and International Co-operation,  
Promotion of the Principles Set Out in the Declaration,  
Implementation of the Declaration.

The greatest number of articles is in the chapter: "Rights of the persons concerned." This chapter is the most important, as it establishes the principles of human rights protection.

The UDHGHR largely reflects the principles set out in the Nuremberg Code (1947). For example, Art. 5, paragraph «b» of the Declaration refers to the fact that patient's consent has to be prior, free and expressed. Undoubtedly, this Declaration lays emphasis on human genome and the rights of its research. For example, Article 5, paragraph "a" states the following: "Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto in accordance with any other requirement of national law.»

Another important principle of this declaration is set out in Article 6 : "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.»

In other words, this declaration proclaims the following **principles**: the principle of equality, justice, solidarity and responsibility, as well as the principle of respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and freedom of expression, including freedom of research, as well as the right to privacy and security of the person, which must underlie the collection, processing, use and storage of human genetic data activities.

The Declaration also sets a sort of restrictions on the medical intervention into the genetic heritage of humanity. In addition, the UDHGHR is crucial for the development of national legal frameworks of many countries.

The **International Declaration on Human Genetic Data (IDHGD)**, adopted in 2003 under the auspices of UNESCO is another important legal instrument in this sphere. The IDHGD consists of a preamble, 7 chapters and 27 articles. Chapters are divided into: General Provisions, Data Collection, Data Processing, Use of Data, Data Storage and Promotion & Implementation.

Art. 1 reveals the aims of this declaration, which are «to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived, referred to hereinafter as "biological samples", in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles which should guide States in the formulation of their legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for the institutions and individuals concerned.»

In addition, Art. 7 of this Declaration, as well as the Universal Declaration on the Human Genome and

Human Rights, highlights the importance of non-discrimination and stigmatization. Besides, Art. 10 considers a human right to decide whether or not to be informed about research results.

Art. 13 of the IDHGD is also an important point, which stipulates that «no one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security».

Another important Declaration adopted under the auspices of UNESCO is the **Universal Declaration on Bioethics and Human Rights (UDBHR)**.

The aim of this Declaration is to provide assistance to States in the creation of national legislation frameworks in the field of bioethics meeting all the necessary requirements.

This document also regulates research in this area by controlling observance of the fundamental principles set forth in it. In addition, the UDBHR also aims to "foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge."

The innovative character of this Declaration lies in the fact that it proclaims the obligation of governments to comply with a number of bioethical principles.

Adoption of the UDBHR also shows that to date there is agreement on the principles underlying the international multicultural bioethics, which, in turn, is firmly based on the internationally-recognized human rights.

Thus, thanks to the cohesive work of the IBC and the IGBC, a lot of effort was put towards the creation of a full-scale legislative framework on the issues of bioethics.

In the development of relevant standards UNESCO is currently focusing on providing support for implementation of these standards at regional and national levels, laying particular emphasis on developing countries.

#### **4) Conclusions and Recommendations**

In a symbolic sense, as stated in Article 1 of the UDHGHR, the human genome is "the heritage of humanity". Abiding by this definition, it acknowledged that the advancements of science and technology in this field entail a global responsibility, which has to be met not simply by States and governments, but by the entire international community.

Otherwise, the 'demand' for some product, service or achievement will always find a space where the corresponding 'supply' remains or becomes legal.

It is also important to emphasize the risk that it could be essentially the market, which is as global as science, which would decide what possibilities are worth realizing and draw the line on what is 'acceptable' or not. Genetic diagnosis and interventions should always be guided by ethical principles.

States and governments, especially in relation to editing the human genome so that genetic modifications would be passed on to future generations, should renounce the possibility of going into it alone within their own legal system.

Retaining their freedom to adopt more detailed and even stricter national regulations, they are called on to boost the idea of establishing common global standards and regulations, building on the universally accepted principles enshrined in the UDBHR:

- human dignity;
- autonomy and individual responsibility;
- respect for vulnerable people and personal integrity;
- privacy and confidentiality;
- equality, justice and equity;
- non-discrimination and non-stigmatization;
- respect for cultural diversity and pluralism;
- solidarity and cooperation;
- social responsibility for health;
- sharing of benefits; protection of future generations;
- protection of the environment, the biosphere and biodiversity.

In the reflection at the global level of the impact of new technologies relating to the human genome a key role is played by the discussions involving scientists and bioethicists.

The United Nations, through its several agencies and bodies and other possible procedures of consultation and evaluation of the advancements of research, should be responsible for making fundamental normative decisions.

The precautionary principle must be observed to ensure that substantial consensus of the scientific community on the safety of new technologies is the premise for any further consideration.

Against this background, the necessity of introducing a ban on human cloning for reproductive purposes and a moratorium on genome editing of the human germline can be traced.

There is no medical or ethical argument to support the former. As to the latter, the concerns about the safety of the procedure and its ethical implications are so far prevailing.

Particularly controversial debates are evoked by the novel techniques for the prevention of mitochondrial DNA disorders. Once again, it should be noted that it is important that the safety and effectiveness of procedures "are adequately proven to be acceptably safe and effective as treatments" by reliable international scientific fora before considering them for use in human beings.

Many issues, particularly those related to the respect for human life at its very beginning, remain controversial. In this regard, the method of the largest possible inclusion seems to be the most appropriate to be applied : those procedures should be encouraged that are ethically 'non-controversial', that is respectful as much as possible of the different sensitivities and cultural traditions. National legislations and international regulations and guidelines ought to be framed accordingly.

DTC-tests and new generation sequencing techniques, including sequencing of the whole genome, require raising awareness and higher levels of health literacy and education for professionals, patients, research participants and all citizens.

Protection is no longer possible only through rights and duties in the patient-doctor-relationship, but requires an independent empowerment of the user, who needs to have sufficient information and access to appropriate counseling.

Service delivery in genetics should always be accredited according to high quality standards and officially certified. The same requirement applies to websites that provide information about genetics.

A regulatory agency framework should be implemented for DTC tests to ensure autonomy, privacy and unbiased information, and the absence of misleading advertisement for the sake of financial gain.

Having in mind the difficult nature of the results of genetic analyses, especially in the case of diseases with multifactorial traits or new variants with unknown impact on the individual, special training is needed for people communicating them. Doctors should know about the role of genetics in diagnosis, therapy and prevention of diseases.

The difference between medical and non-medical use of the new technologies remains the decisive factor. Any future work, research, and research application in the non-medical fields should respect human rights and dignity. In this connection, improvement techniques, which have long since been a matter of special concern in sports, also deserve deep reflection and precaution.

Benefits stemming from advancements in human genetics, inasmuch as they have an impact on health protection and health care, for instance through precision and personalized medicine, should be considered as content of the fundamental right of every human being to enjoy the highest attainable standard of health and the right to have access to quality health care and medicines.

However, scientific and technological progress should not deepen inequalities within and among countries nor be used for discrimination against individuals or groups.

Taking into account the growing implementation of biobanks and the problem of "big data" security measures, biobank safeguards should be provided at the international level and international guidelines and standards continually updated to protect research participants from violation of their autonomy and privacy to foster preparedness to participate in research.

States must give priority to public biobanks and must enforce laws and contracts between private biobanks and citizens that take into account justice and equity in benefit sharing.

It is necessary to implement an international public registry of DNA mutations and variants.

Those who can not decide that they wish to know the results of genetic testing, including for example healthy children, should not be subject to the imposition of this information. Children should only be tested when it is for the purpose of their better medical care or that of their close relatives.

The widespread use of genetic screening in particular of NIPT may foster a culture of "perfectionism" or "zero-defect" and even renew some trends of "eugenics". As a result, it could become more and more difficult to accept imperfection and disability as a part of *normal* human life and a component of the diversity we are all called on to acknowledge and respect.

The anxiogenic effect is also to be considered. The right of an individual to make autonomous choices is to be made consistent with the right not to be discriminated or stigmatized on the basis of genetic characteristics and the duty to respect every human being in her or his uniqueness.

In the near future new genetic technologies may not become available on a large scale in lower and middle-income countries. However, in order to be able to take advantage of genomics in the future, LMIC governments should begin to develop national genomics policies that will address human and technology capacity within the context of their national economic and sociocultural uniqueness now.

Due to the rapid development of genetics, the process of deepening and updating of its ethical reflection is a never-ending commitment. Probably, some revision of existing declarations should also be considered. The cogency of the principles is untouched. The scope of possible applications is changing and widening every day.

This is a task to perform for UNESCO, building on its well-established, pivotal role as a global forum for global bioethics and relying on the contribution of its institutional and expert bodies. At the same time, this responsibility should be taken on by all international agencies working in the field.

We are human because of the interplay of many biological, historical and cultural determinants, which maintain the feeling of our fundamental unity and nourish the richness of our diversity.

The international community, States and governments, scientist, actors of civil society and individuals are called upon to consider the human genome as one of the prerequisites of freedom itself and not just as a raw material for manipulation at leisure but at the same time to keep in mind that scientific advancements in this field are likely to offer unprecedented tools against diseases, so it is extremely important to acknowledge that these opportunities should never become the privilege of few.

What is heritage of humanity entails sharing both of responsibilities and benefits.

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## **How to Get Prepared**

You probably cannot wait until it is the end of July and VIMUN 2016 is about to start – at least we cannot! However, before the conference starts, there is still some work to be done.

You are the ones that fill the conference with life, that lead interesting discussions and fruitful debates and make innovative resolutions reality. This requires some preparation on your side. **While conducting research, try to keep in mind that your primary goal is to represent your country as realistically as possible.**

In advance to the conference we expect all delegates to research your state's position and become experts for the given agenda topic, to familiarize yourself with the rules of procedure (which you can find on our VIMUN homepage) and to practice your debating and writing skills.

Here are some useful hints on how to get prepared for the VIMUN conference:

### **Do Some Research**

The first step after you have been assigned your state and committee will be to do some research in order to prepare for the conference. These are areas you should look into:

- The structure and history of the UN
- Your assigned member state
- Research your committee
- Your member state's role in the committee
- Your agenda topics

### **Central Questions that Should Guide your Research**

- What sort of government does your country have?
- What types of ideologies (political, religious or other) influence your country's government?
- Which domestic issues might influence your country's foreign policy?
- What are some major events in your country's history? Why are they important?
- Which ethnicities, religions and languages can be found in your country?
- Where is your country located and how does its geography affect its political relationships?
- Which countries share a border with your country?
- Which countries are considered allies of your country?
- Which countries are considered enemies of your country?
- What are the characteristics of your country's economy?
- What is your country's gross domestic product (GDP)? How does this compare to other countries in the world?
- When did your country become a member of the UN?
- Does your country belong to any intergovernmental organizations outside the UN system such as the North Atlantic Treaty Organization (NATO) or the Organization of the Petroleum Exporting Countries (OPEC)?
- Does your country belong to any regional organizations such as the European Union (EU), the African Union (AU) or the Organization of American States (OAS)?
- Does your country belong to any trade organizations or agreements such as the North American Free Trade Agreement (NAFTA) or the Organization for Economic Cooperation and Development (OECD)?
- What are the key issues of your agenda topics?
- Why are these issues important?
- What are possible solutions?
- What is hindering those solutions?
- What has the UN (or other international agencies) done so far, in order to solve these problems?
- What should be done from the perspective of your state to resolve the issues?
- Which other states share your view, which are opposed to your position?

For further research apart from reading the study guide we greatly recommend:

- The UN homepage
- NGO (particularly those accredited by the UN)
- Country reports and data published by international or regional organizations such as the World Bank, WHO, OECD, APEC, etc.
- General socio-economic data: e.g. CIA World Factbook has served delegates in previous years in gaining a first overview of a particular member state
- Your country's government website
- Search for speeches made by your country on the topic
- Search for important resolutions regarding your topic

### **How to Write a Position Paper**

Writing a position paper might appear to be a daunting task, especially for new delegates. But with enough research, you will find that writing a position paper will be easy and useful.

Position papers are usually one to one-and-a-half pages in length. Your position paper should include a brief introduction followed by a comprehensive breakdown of your country's position on the topics that are being discussed by the committee. A good position paper will not only provide facts but also make proposals for resolutions.

Many conferences will ask for specific details in a position paper, so be sure to include all the required information. Most conferences will provide delegates a background guide to the issue. Usually, the background guide will contain questions to consider. Make sure that your position paper answers these questions.

A good position paper will include:

- A brief introduction to your country and its history concerning the topic and committee;
- How the issue affects your country;
- Your country's policies with respect to the issue and your country's justification for these policies;
- Quotes from your country's leaders about the issue;
- Statistics to back up your country's position on the issue;
- Actions taken by your government with regard to the issue;
- Conventions and resolutions that your country has signed or ratified;
- UN actions that your country supported or opposed;
- What your country believes should be done to address the issue;
- What your country would like to accomplish in the committee's resolution; and
- How the positions of other countries affect your country's position.

### **Position Paper Tips**

- **Keep it simple.** To communicate strongly and effectively, avoid flowery wording and stick to uncomplicated language and sentence structure.
- **Make it official.** Try to use the seal of your country or create an "official" letterhead for your position paper. The more realistic it looks, the more others will want to read it.
- **Get organized.** Give each separate idea or proposal its own paragraph. Make sure each paragraph starts with a topic sentence.
- **Cite your sources.** Use footnotes or endnotes to show where you found your facts and statistics. If you are unfamiliar with bibliographic form, look up the Modern Language Association (MLA) guidelines at your school's library.
- **Read and reread.** Leave time to edit your position paper. Ask yourself if the organization of the paper makes sense and double-check your spelling and grammar.

- **Speech! Speech!** Do you plan to make an opening statement at your conference? A good position paper makes a great introductory speech. During debate, a good position paper will also help you to stick to your country's policies.
- **Let the bullets fly.** Try not to let your proposals become lost in a sea of information. For speechmaking, create a bulleted list of your proposals along with your most important facts and statistics so that you will not lose time looking for them during debate.

## Sample Position Paper

Delegation of the **Republic of India**

Represented by **XXX**

Topic: Primary Education

The Republic of India acknowledges and has responded to the call of the United Nations for a universalization of primary education with fierce engagement and enthusiasm over the past 10 years. India firmly believes that the challenge of guaranteeing every child the opportunity to primary education can and shall be overcome by raising greater awareness among the public and by public involvement through respectful regional cooperation, e.g. the cooperation with Village Education Committees and Local Government substatal Bodies. Furthermore it is crucial not only to focus on the quantity of students, but on the quality of the education they receive.

The Republic of India recognizes the need and urgency to address universal primary education. Primary Education is of crucial importance to India. Although India is still facing difficulties in its efforts to guarantee every child the education it deserves, the Indian country will not succumb, but face the challenge with effective policies which have shown immersive and lasting effects in the past.

In 2010 The Right of Free and Compulsory Education Act was ratified, making the fundamental Right To Education Act the first of its kind in the world, which puts the responsibility of ensuring enrollment, attendance and completion of primary education to the government. To enforce implementation of this act, India strongly supports its governmental organizations, which have brought positive long-term effects, e.g. "The Education for All"- Movement, which has as a main objective the universalization of elementary education, making education free and compulsory for children between 6-14 years. In addition to this program, India launched the Mid-Day Meal Scheme in 1995, revised and improved it over the last ten years. Mid-Day Meal Scheme, as the world's largest school feeding program, reaches 1.2 million children across the country.

Furthermore a stronger emphasis is put on unprivileged and disadvantaged sections of the Indian society. As a result to the 10th five year plan of India the joined forces to tackle illiteracy, the number of elementary schools has increased by 216.054, the number of enrolment in the lower and upper primary school classes has increased about 30 million students, only in the period between 2000 and 2006.

In the 11th five year plan of the Republic of India, the focus is set on achieving an 80%- literacy rate, on reducing the gender gap in literacy rate to 10%, to reduce dropout rates of children at the elementary level from 52, 2% in 2003-04 to 20% by 2011-12, and to support low literacy States, disadvantaged groups, minorities and to reduce regional, social and gender disparities and on granting the quality of the given education.

However, universal education cannot be established in isolation, therefore the Indian government has successfully joined hands with the UN on this matter, as extensive cooperation within the United Nations Development Program prove. Together we can bring the MDGs in achievable and reachable range. Therefore the issue of primary education should be discussed realistically and on a basis, where not only providing quantity, but quality plays an immense and even more important role. Due to India's ideals which are Socialism, Democracy, Justice, Equality, Fraternity the Indian Republic believes that the question on how to provide and ensure qualitative education with well-equipped and modern schools and on the basic training of teachers should be raised.

In conclusion, India is striving to guarantee its pupils the universal access to education, regardless of their gender. Moreover it is of the main concerns to support tribal States, rural areas, disadvantaged groups, religious/ethnic minorities and to extinguish any kind of disparities which influence the access to education.

These main concerns remain to be: access, equity, quality, relevance, resources, planning and management of educational programmes.

Therefore the Republic of India highly approves of all expenditures which were made to tackle the problem of primary education and warmly welcomes every effort made on capacity building, modern education programmes, teacher training programmes and progressive use of instructional materials.

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## How to Make an Opening Speech

- First, you should thank the presiding official by saying "Thank you Mr./ Madame/ Honorable Chair/ President..."
- Then begin by providing a brief history on the issue as it relates to your country.
- Speak about how the issue is currently affecting your country.
- your country's position on the issue. Include an explanation for your country's stance, such as economic or security concerns or political or religious ideology.
- You may choose to give an explanation of how your country's position relates to the positions of other member states such as the major powers or countries in your regional bloc.
- You should discuss some of the past actions taken by the UN, member states and NGOs to address the issue.
- Present ideas for a resolution, stressing your country's objectives for the resolution.
- Talk about the role that NGOs or regional organizations have to play in addressing the issue.
- Indicate to the committee members whether your country is willing to negotiate.

## Vocabulary: Sample Preambulatory Phrases

|                      |                                |                            |
|----------------------|--------------------------------|----------------------------|
| Accept               | Notes Proclaims                | Designates                 |
| Affirms              | Reaffirms                      | Draws the attention        |
| Approves             | Recommends                     | Emphasizes                 |
| Authorizes           | Regrets                        | Encourages                 |
| Calls                | Reminds                        | Endorses                   |
| Calls upon           | Requests Solemnly affirms      | Expresses its appreciation |
| Condemns             | Strongly condemns Supports     | Expresses its hope         |
| Confirms             | Takes note of Transmits Trusts | Further invites            |
| Congratulates        | Encourages                     | Further proclaims          |
| Considers            | Endorses                       | Further reminds            |
| Declares accordingly | Expresses its appreciation     | Further resolves           |
| Deplores             | Expresses its hope             | Has resolved               |
| Designates           | Further invites                | Further recommends         |
| Draws the attention  | Deplores                       | Further requests           |
| Emphasizes           |                                |                            |