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3.4. GEORGIA
(G.Kiknadze, G.Dgaviashvily, T.Kurtanidze)

Like many other developing countries, Georgia experiences considerable difficulties. One may suggest that it is not time to speak about research ethics when you hear everyday, that fundamental rights of citizens, including right to life, are violated (e.g. in terms of regional conflicts). However, it is never too early or too late to speak about the rights and freedoms of individuals, particularly in the field of health and biomedical research as far as various biomedical researches are being carried out currently in those countries. So, we have to do something to ensure the safety of people in this sphere.

Georgia has made considerable step forward in establishing legal framework for human rights protection in the field of health care and biomedicine, including specific legislation on protection of research subjects. Georgia has signed and ratified all major documents of the Council of Europe in this sphere and endorsed various international texts. Moreover, national legislation has been brought in harmony with internationally accepted standards of human rights protection. These steps have been followed by educational activities to raise awareness of the society.

However, there is a lot of work to be done to effectively implement aforementioned legislation, particularly in the field of biomedical research. The most topical issue for Georgia now is the development of effective system of ethical review of research projects. Although, certain type of system is operating, it needs improvement in terms of accessibility and quality.

3.4.1 Historical and Cultural Background

Georgia is situated on the border of Europe and Asia. It occupies the Central and Western parts of the Caucasus. The Western part of the country is washed by the Black Sea. The Northern boundaries of Georgia run along the Great Caucasian Range. Citizens of Georgian nationality comprise about 70% of the whole population. Other nationalities are Russians, Osetians, Abkhazians, Azerbaijanis, Armenians, Greeks.

Georgia is a newly independent Republic (It restored its independence in April 1991). At the same time it has a long history of Statehood.

Georgian slave-owning kingdoms Kolkheti and Iberia emerged in the 6th-4th centuries BC. The unification of Georgia in the form of the united kingdom started in XI century. In 1801 Georgia lost its independence as a result of the expansive policy of Russian Empire. In 1918 independence of Georgia was re-announced (Republic of Georgia), which lasted only up to 1921, when intervention of Russia resulted in incorporation of Georgia in the Soviet Union.

Georgia has little experience in building the civil society. However, it has definitively moves towards the integration with the Western World and harmonisation with the western law. The legislative basis apparently is one of the most important points in the process of establishing common anthropocentric values and viewpoint of the civil, open society.

The history of the Georgian state and law dates back to ancient times. Due to the historical misfortunes Georgia never participated in the process of great codifications. In this connection legislative activity of the King Vakhtang VI (XVII-XVIII cc) deserves major attention. Chronologically this period coincides with the epoch of creation of the basis for the modern law and state in Western Europe. Drafting of King Vakhtang's Law Book can be considered to be an attempt to get closer to the cultural world, at which Georgia aspired during its whole history. In some regions of Georgia the code of Vakhtang's Laws was in force up to the second half of the XIX century.

An attempt to build a modern independent state in 1918-1921 was not successful due to the expansion of Russia. As a result Georgia became the part of the communistic space for the next 70 years. Thus, formation of the civil society in Georgia started within the borders of another country (Soviet Union), making Georgia unable to develop its own legislation independently.

During aforementioned 70 years legislative activity in Georgia was restricted to the slight alteration or, at best, adaptation of the frame laws, provided by the central authorities (Moscow). As well as in other republics of the Soviet Union there was no tradition of training the legal professionals for the health care system in Georgia. Before re-establishment of Georgia's sovereignty, the Law on Health Care, adopted in 1972 by Soviet Government, was in force. This document showed significant negligence of individual rights of patients. Almost none of the basic principles of ensuring patients'

autonomy and self-determination (except the right to keep personal data confidentially) were even declared.

The creation of national legislation is an essential condition for building the national and democratic state and a civil society. Adoption of Georgian Constitution (24 of August 1995) and Georgian Civil Code (26 of June 1997) is definitely significant step toward establishment of national state.

3.4.2 Legal Regulations

Legislation of Georgia related to health, biomedicine and human rights comprise laws which regulate various aspects of medicine/health care: rights of patients and research subjects (including vulnerable groups; such as minors, persons with mental disorders, patients with HIV/AIDS etc.), duties and responsibilities of health care professionals, human organ transplantation, assisted reproductive technologies etc.

From the above-mentioned laws the Law of Georgia on Health Care (adopted by the Parliament of Georgia in 1997) is considered to be the framework law, which determines the priorities and sets out fundamental principles of the health care legislation of Georgia. It covers full range of problems related to health, including issues related to protection of research subjects.

In general, there are three major documents serving the legal basis for biomedical research involving human subjects. These legal texts are:

- Convention on Human Rights and Biomedicine (Signed by Georgia in May 2000; Ratified by the Parliament in September 2002; Entered into force on 1 of March 2001);
- Law of Georgia on Health Care (Adopted by the Parliament of Georgia in December, 1997);
- Law of Georgia on Drug and Pharmaceutical Activity (Adopted by the Parliament of Georgia in 1995; Updated in 2001).

The draft of specific law on biomedical research –"Law on Biomedical Research Involving Human Subjects" will be the fourth and the most comprehensive document regulating research on human subject. Draft "Law on Biomedical Research Involving Human Subjects" (originally drafted in 1999) has been reviewed by the expert appointed by the Council of Europe in 2000 and updated according to the comments provided.

It was submitted to the Government in 2000 and to the parliament of Georgia by the President in 2002. However, in 2005 it was taken back by the Government for further consideration against the background of the latest developments of the Council of Europe. In 2006 the draft law was reviewed by the working group based on the comments of the experts, including experts appointed by the Council of Europe. The draft law was the subject of debates during the international conference "The Council of Europe and Promotion of Research Ethics in East European States" organized by the Council of Europe and the Government of Georgia in Tbilisi in October 2006.

Since the Convention on Human Rights and Biomedicine entered into force in Georgia it becomes the integral part of Georgian legislation, taking precedence over other laws and coming after the Constitution in the hierarchy of law. So, provisions of the Convention related to the research on human subjects is applicable to all relevant research projects being carried within jurisdiction of Georgia. However, more specific impact on biomedical research and its ethical evaluation will have its Additional Protocol on Biomedical Research, which has been signed by Georgia but is not yet ratified.

The law of Georgia on Health Care includes separate chapter – Chapter XIX "Biomedical Research", in which basic principles regulating biomedical research are set out. Particularly according to the above-mentioned law:

- aims, objectives, methods and possible outcomes of the research should be specified in the research protocol; research should be carried out only within the frames of the research protocol;
- research protocol should be reviewed by independent body and ethics committee;
- risks and benefits of the research should be assessed; risk associated with the research should not be disproportional to the expected benefits;
- research subject should be fully informed about the details of the research (objectives, methods, potential benefits, risks, alternatives etc.);
- research should not be started without informed consent of the research subject;
- research subject has the right to refuse to participate in the research or withdraw from the research at any time despite already given written informed consent.

The law also outlines general principles for the protection of incapable persons and minorities in the context of biomedical research.

The law on Drug and Pharmaceutical Activity sets out the rules for organizing drug trials including trials in clinical phase when human beings are involved in the research programme. It requires that ethics committee to be created at the institution where the trial is to be carried out. Interestingly, this law specifically mentions recommendations set out in WMA Declaration of Helsinki to be the basis for conducting clinical trials on human beings.

As already mentioned the most specific law on the protection of the research subjects will be the Law on Biomedical Research involving Human Subjects, which is being submitted to the Government this year. The aim of the draft law is protection of the rights, health and life of a research subject of biomedical research and provision of safety and respect for dignity during the research. The draft law concerns any type of research aiming at obtaining information and broadening knowledge in the sphere of biomedicine, which serves the interests of human health protection and implies:

- Physical intervention on human being;
- Research on biological materials which initially were taken and stored with other purpose;
- Intervention which doesn't imply physical intervention on human being but can pose danger to mental health or psychological condition of human being;
- Research on foetus and/or embryo in vivo (The Law does not apply to research on embryos in vitro.

The draft Law on Biomedical Research involving Human Subjects is based on the following core principles:

- Primacy of the human being;
- Autonomy of research subjects: information, informed consent, confidentiality and privacy;
- Scientific quality;
- Minimizing risks and keeping adequate risk-benefit ratio;
- Safety;
- Protection of vulnerable groups;
- Multidisciplinary review of ethical acceptability of research protocol and its approval by an ethics committee.

Side by side with legislation certain impact on the ethical conduct of health care providers as researchers has ethical regulations, which could be considered as soft legal instruments. In April 2003 the Congress of Georgian Physicians endorsed the Ethics Code of Physician of Georgia. The code was developed by Georgian Health Law and Bioethics Society (GHLBS) and the Health Legislation and Bioethics Department of the National Institute of Health. The first version of the Code was discussed by the participants of the Congress and was submitted to further considerations to the National Council on Bioethics. The letter considered the document during its three different sittings and finally published the final text of the Code, which was adopted at the last session of the First Congress of Physicians of Georgia.

The Ethics Code of Physician of Georgia is the first national code of ethics in the sphere of biomedicine. It includes specific provisions aiming at protecting research subjects. Particularly it says the following:

"Patient's interests are supreme in scientific research on human being. The research goals and its possible outcomes never interfere with the main mission of a physician – to serve for patient's health and life."

Although much has been done in building of the legal protection of the research subjects, many problems are remained to be addressed. Just to mention, no sanctions are yet introduced against violation of the rights of research subjects and infringement of the principles reflected in existing legislation on biomedical research. Also, existing ethics committees need be improved and the new system of research ethics committees is to be implemented. The draft regulation for the new system of research ethics committees has been already prepared. Its legitimisation will become possible after ratification of the Law on Biomedical Research Involving Human Subjects.

3.4.3 Education in Bioethics

Education in the field of Bioethics in Georgia has developed chiefly in two domains: on one hand, high medical education system at Tbilisi State Medical University; on the other hand, in the shape implementation of legislation related to human rights, health and biomedicine developed by Health legislation and bioethics group at National Institute of Health (former National Health Management Centre) and Georgian Health Law and Bioethics Society. Since its establishment GHLBS has been actively involved in educational programmes in the field of Bioethics and has been incessantly organizing various training courses aiming at rising awareness of, on one hand, patients and general public, and on another, medical society.

Currently, Tbilisi states medical university offers courses in Bioethics at different levels: on undergraduate level – for medical students, and on postgraduate level – for residents. Both courses are obligatory and constitute integral part of study curriculum.

Individuals who successfully enter residency-training program after graduation of high medical school are expected to take one-week obligatory program in bioethics during their residency training. The course focuses on raising awareness of residents about modern principles of bioethics/ medical ethics and of relevant legislation of Georgia and assisting them in developing skills for coping with various ethical problems/dilemmas which may arise during their professional medical activity. During the course the audience is introduces with the issues related to various ethical problems associated with development of new technologies in the field of health care/biomedicine: the role of ethics and law in health care; individual rights of patients, Georgian legislation on individual rights of patients; informed consent; competency and decision making capacity; specific groups of patients; genetics, ethics and law; ethics, law and biomedical research involving human subjects, etc.

Healthcare professionals have an opportunity to take short CME courses with credit hours. The course has been developed and submitted for accreditation by GHLBS. It offers the audience the variety of topical issues related to ethics inherent in doctor-patient relationship: basic principles of modern medical ethics; the rights of patients with the principles of modern medical ethics; active legislation of Georgia on patient's rights; ethical basis of informed consent, regulations about informed consent in Georgian legislation; necessity of obtaining a written informed consent and protection of dignity of a patient, protect confidentiality and privacy in the process of teaching students and residents, role of Ethics committees, etc.

There is one more programme specifically developed for doctoral students. This one day programme is focused on research ethics and covers all aspects of ethical and legal regulation of biomedical research.

3.4.4 The System of Ethical Review

Below is given unofficial data collected about the drug trials being conducted in Georgia.

In 1998-2002 12 internationally sponsored drug trials have been conducted in Georgia. About 15 medical centres participated in it and it included about two thousand people. As to the local trials, their total number is about 55, but number of participants is not so large.

On the other hand several hundred biomedical researches are being conducted unnoticed. They are not related to drug experiments (which usually attract more public interest), however many of these researches include human subjects. Just to give idea about their number - in only one academic institution 50 research plans are approved annually. Most of experiments conducted or to be conducted in the framework of these research plans, involve human subjects, but yet only scientific merit of these studies are assessed without evaluating its ethical acceptability.

It is expected that the number of international multi-centre biomedical research (mostly drug trials) will dramatically increase in this region and many thousand of people will participate in it. Therefore, the issue becomes very important and appropriate mechanisms should put on place to ensure that biomedical research involving human subjects is conducted in ethical manner and the rights and safety of research subjects are protected. The most effective and widely tested approach is mandatory ethical review of any research project that considers interventions on human beings. The first mention of ethics committee in legislation was appears in 1997 (the Law on Health Care). However, the first ethics committees were established in 2000.

Ethics Committees in Georgia

Three types of ethics committees exist currently in Georgia: National Council on Bioethics, research and clinical (medical) ethics committees. The table below schematically outlines all these ethics committees and the legal basis for their establishment and functioning.

Type of Committee	Title of Committee	Task of the committee	Legal bases (Laws, decrees, etc)
Central EC	National Council on Bioethics	To advise Minister on the ethical aspects of healthcare and biomedicine	Presidents Decree #15 of 12 January 98. Order #57 /m of the Minister of Health and Social Affairs. Regulation for the National Council on Bioethics was enacted by the Order # 157/0, of 5 July 2000 of the Minister of Labour, Health and Social Affairs.
Research EC	Biomedical Research Ethics Committees	Ethical review of research protocols	Law on Health Care (1997) Law on Drug and Pharmaceutical Activity (1995) Law on Biomedical Research Involving Human Subjects (before Parliament)
Clinical EC	Medical Ethics Committees	Ethics education and consultation for healthcare professionals, patients and their family members	Law on Health Care (1997) Regulation for the Institutional Medical Ethics committees was enacted by the Order # 128/n, of 2 October 2000 of the Minister of Labour, Health and Social Affairs.

National Council on Bioethics

National Council on Bioethics[17], which is advisory body to the Minister of Labour, Health and Social Affairs, prepared several recommendations during the last two years. However, it could not avoid discussion of certain specific cases upon request of the minister or other officials within the Ministry. On of the most interesting text of the Council is recommendation prepared for the government on the possible position of Georgia on international banning of cloning human beings. Based on this recommendation Government of Georgia took its position that all types of human cloning should be prohibited.

Clinical Ethics Committees

Although there are considerable legal developments related to the establishment and development of Clinical Ethics Committees (CECs) in Georgia[18], very few committees have been established. According to the survey (in total 22 HC institutions completed the questionnaire) carried out by the National Council on Bioethics and Georgian Health Law and Bioethics Society, only 9 health care institutions run medical ethics committees (CECs). Only 3 of the above 9 committees would have their own bylaw/regulation developed on the bases of the Charter. The number of members varies from 5 to 13. Most of the committees are established in 2003 soon after the National Council on Bioethics issued recommendation about establishment and development of CECs based on the Charter (approved by the order of the Minister of Labour, Health and Social Affairs).

At present intensity of the CECs work is quite law (each committee would hold 1-4 meetings since their establishment) and the competence (training, experience) of many members of the above committees is still under the question. For some members of the above-mentioned committees the cycle of workshops have been designed and carried out. However, it is not definitely enough and more intense training programs should be made available for the members of medical ethics committees.

At the moment it is not clear what the views of health care professionals and administrations of health care institutions (basically hospitals) are about

[17] Charter for National Council on Bioethics was approved with the Order of the Minister of Labour, Health and Social Affairs (Order # 157/0, 5 of July 2000).

[18] Law on Health Care, Law on Patient's Rights, Charter for Clinical Ethics Committees endorsed by the Order # 128/n of the Minister of Labour, Health and Social Affairs (2 of October 2000).

the value of CECs. Several projects are on their way of implementation aiming at intensifying clinical/medical ethics committee movement in Georgia.

First Research Ethics Committees

The first research ethics committees in Georgia were introduced about 5-6 years ago. The idea of their establishment at the first stage was related to the fact that well-known foreign medical journals do not publish the articles representing results of biomedical research, without prior approval of the research protocols by ethics committee. Therefore, only narrow circle of citizens (few scientists interested in publishing results of their research in foreign journals) was informed about the existence of the above-mentioned committees in the "western world".

The legal basis for the establishment of ethics committees, which would be in charge of reviewing protocols of drug-trials, was the Law on Drug and Pharmaceutical Activity enforced in 1996.

In 1995-97 the law regulating generally almost all fields of healthcare, was drafted. This document – The Law of Georgia on Health Care - was thought to be the framework law for ongoing healthcare reforming process in Georgia. The Law was enacted in 1997. It lays down the legal basis for the establishment of the research ethics committees, which shall carry out ethical review of all research protocols (not only research protocols related to drug testing). So, currently "a scientific research plan shall be considered and reviewed …by the ethics committee" (article 107; the Law of Georgia on Health Care).

At the first stage due to the lack of appropriately trained professionals it was considered wise to establish ethics committees bearing the functions of hospital ethics committees as well as research ethics committees. So the first version of the draft regulation for the so-called Medical Ethics Committees (prepared according to the Presidents Decree #15 on 12 of January 1998) was prepared.

In 1999 two separate documents were drafted – the first one lays down principles of establishment and operation of Medical (Hospital) Ethics Committees (already adopted by the Order of the Minister of Labour, Health and Social Affairs) and the second one will regulate the activity of Research Ethics Committees. According to latter document the two-tiered network of committees on the regional level will be created in Georgia. The central

research ethics committee shall coordinate the activity of regional research ethics committees.

Unfortunately the statute for the Research Ethics Committees has not been yet approved, because of the comments of the Ministry of Justice stating that establishment of the separate committees for research ethics is not required by existing legislation (law in force or the Presidents Order). Therefore, it is suggested to amend the draft law on "Biomedical Research Involving Human Subjects" (which is now before Parliament) by introducing in it basic statements from the above-mentioned draft statute.

About 15 research ethics committees were established during the last 5-6 years, from which about 6 would function at the moment. They have been created at the institutions that used to participate in the multi-centre trans-national drug trials. Without having such committees they would not have been able to participate in such trials. Only few of them would have their own regulation/bylaw. The number of the members would vary from 5 to 11 (mostly their number is 5 as it is defined in the Law on Drug and Pharmaceutical Activity).

Finally, the National Council on Bioethics would exceptionally review some research protocols that reflect international multi-central biomedical research, because still there is no central research ethics committee in Georgia that would be in charge of carrying out ethical review of multi-central studies.

Below is given brief schematic summary of what have has done and what is to be done in Georgia for the protection of research subjects in the sphere of biomedicine.

Has been done:

- General legal framework outlining basic principles for conducting biomedical research involving human subjects is created (law on health care; adopted in 1997) and requirements for organizing drug trials are specified (law on drug and pharmaceutical activity; adopted in 1995),
- Convention on Human Rights and Biomedicine is signed and ratified (entered into force in Georgia on 1.03.01); also, its additional protocol on Biomedical Research has been signed;
- First research (institutional) ethics committees for drug trials are established;

- Specific law on biomedical research involving human subjects has been drafted and submitted to the Government;
- Concept on the establishment of the two-tired network of research ethics committees on the regional level has been drafted (central research ethics committee and regional research ethics committees);
- National council on bioethics stresses the importance of strengthening the system of ethical review of research protocols and advocates for the speeding up of the process of adoption of the specific law on biomedical research;
- Teaching programmes in bioethics, including research ethics have been introduced on undergraduate as well as postgraduate level (programmes for residents and doctoral students as well as continuing medical education programmes for practicing physicians) of medial education/training.

Is to be done:

- Stimulation and speeding up the process of ratification of the law on biomedical research involving human subjects;
- Introduction of sanctions in administrative and criminal code of Georgia for the infringement of the principles set out in the legislation related to the protection of research subjects;
- Enforcement of the above mentioned concept on ethics committees (order of the minister of health or inclusion of the main statements of the concept in the draft law on biomedical research during the discussions at the parliament);
- Education: undergraduate, postgraduate education; education of potential members of research ethics committees;
- Establishment of central and regional ethics committees;
- Setting up quality assurance system for research ethics committees.

Finally, step-by-step we have to strengthen mechanisms, which will ensure that the rights and dignity of human research subjects are duly protected. This will be one more brick in the wall in the process of building democratic society, which doesn't allows injustice to take place among people.

3.4.5 Perspectives and Forms of International Cooperation

Georgia is the member of all international cooperation in the field of protection human rights in biology and medicine. Collaboration develops through the representatives of Georgia in international bodies and organisations, by following the international regulations, involving in educational and training programmes on bioethics and research ethics and by participation in scientific and practical conferences and workshops organized on global and regional levels. Scientific publication and common international projects help to share the experience and to build the harmonized relations in the bioethics in the frame of international informational, legal and research space.

3.5. REPUBLIC OF KAZAKHSTAN
(A.B.Sadykova, B.E.Sarymsakova)

3.5.1. Historical and Cultural Background

Kazakhstan is a country with very rich historical and cultural past time. Being geographically located in the Centre of Eurasia Kazakhstan was on the crossroad of ancient world civilizations, on the cross of transportation arteries, social and economic, cultural and ideological relations between East and West, South and North, between Europe and Asia, between the largest states of Eurasian continent. At different phases of the history states with original cultural history were organized and developed at the territory of Kazakhstan; the modern Kazakhstan is the inheritor of this cultural history. In the middle of XV century Kazakhs united in the unique khanate but after the death of khan Tauke and invasions of Djungars the country disintegrated and was divided into 3 “zhuzes” (sub-countries) each of which was practically independent of others. The khan of Jounger Zhuz applied to Russia for protection – so since that time the incorporation of Kazakh territories started.

In 1866 all Kazakh territories were under the political power of Russia but some part of Older Zhuz and Middle Zhuz was incorporated into the Czinn Empire.

In 1917 «Alash-Ordy» declared its autonomy.

In 1920 Kirgyz Autonomic Republic was organized as a part of the Russian Federation.

In 1925 the republic received the name of Kazakh Autonomic Republic with the capital in Almaty and in 1936 it was transformed into Kazakhskaya Soviet Socialist Republic.

In 1956 some part of republican territory was adjoined to Omskaya province and Altaysky krai.

On 16th of December 1991 Kazakhstan became independent republic. The official name of the country is the “Republic of Kazakhstan” (RK). Astana is the capital of the country, Almaty – the biggest city of the country. The territory of Kazakhstan is equal to 2,717,300 sq. km.

The population size of the country (data of 2006) is equal to 15.3 million citizens. Around 53% of the population is urban citizens. There are over