

Addressing the needs of research ethics system in Georgia through policy development

Study Report

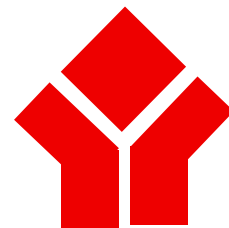
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Abbreviations

CDT - Clinical Drug Trial

CEE – Central and Eastern Europe

GCP – Good Clinical Practice

HBV- Hepatitis B Virus

HCW – Health care Workers

HIV – Human Immunodeficiency Virus

ICH – International Conference on Harmonization

IDACIRC -Infectious Diseases, AIDS and Clinical Immunology Research Center

IDU –Injecting Drug Use

IEC - Independent Ethic Committee

IRB – Institutional Review Board

LEPL- Legal Entity of Public Law

MOLSHA – Ministry of Labour, Health and Social Affairs of Georgia

NGO – Nongovernmental Organization

NCDC - National Center for Disease Control and Public Health

REC - Research ethic Committee

STD- Sexually transmitted Diseases

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I. INTRODUCTION

Georgia, since its independence from soviet system (1991), has gone through major social, economic and political transformations having immense influence on development of national legislation concerning human rights protection particularly in the field of health care and biomedicine. In spite of the facts that importance of ethical principles related to the field of health care was recognized and raised in the country even before gaining independence by local entities such as Georgian Medical Association (Registered by the Ministry of Justice in 1989 and considered as the first NGO/ professional union) there have not been introduced any modification of the “soviet” Law on Health Care (adopted by Soviet Government since 1972) neglecting basic ethical principles including respect and protection individual rights of patients for autonomy and self-determination (with exaction for right for confidentiality of personal data) [1-3].

Despite challenges faced by the country due to civil war and economic collapse following independence, Georgia managed to introduce reforms in national legislation in the area of human rights and health care and made significant progress in the development legal framework for fulfillment of fundamental ethical principle in the field of biomedicine. The process of the reform in the legislation of Georgia in the field of health, human rights and biomedicine started in 1990’s and was greatly influenced by strategies and principles developed in Europe [4,5].

In particular, Georgia adopted two new national and two international laws regulating the field of medicine and biomedical research.

1. Convention on Human Rights and Biomedicine (1.03.2001)
2. Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical research.(01.08.2010)
3. The Law on Health Care (adopted in December 10, 1997)
4. The Law on Drug and pharmaceutical Activity (adopted in December 25, 1996).

These four major legislative instruments regulate biomedical research involving human beings in the country addressing the most important issues: protecting the rights, safety and dignity of research participants. This includes establishing procedures and policies for the oversight of human subjects’ research by research ethics committees (RECs).

Current procedures for the review and oversight of biomedical research by Georgian are established by the two national laws mentioned previously, namely: (1) **The Law on Health Care**, which defines establishment of research ethics committees and general procedures of ethical review of any type of biomedical research on human beings; and (2) **The Law on Drug and Pharmaceutical Activity**, which defines establishment of research ethics committees and procedures of ethical review of drug trials [6,7].

Despite important steps made in establishment of legal framework for human rights protection in the field of health care and biomedicine, current legislation is very vague, lacks specificity and does not cover various aspects of biomedical research. Like in majority of developing countries absence of clear guidance at national level about the role and function of research ethics committees represents one of the main obstacles for the development of effective system of ethical review of research projects in the country [2, 8-11].

By the order of the minister of labor, health and social affairs in 2010 the next international guidelines were adopted as regulatory documents (standards) giving guidance for the preclinical and clinical studies of pharmacological agents:

1. International Conference on Harmonization ICH Guideline for Good Clinical Practice GCP E6 1996;
2. International Conference on Harmonization ICH Guidance on NonClinical Safety Studies M3 2009;

Development of *Draft Law on Biomedical Research Involving Human Beings* is considered to be another significant step forward addressing current issues in the field of research ethics regulation in Georgia by filling existing gap in legislation (including additional regulations on RECs structure and function) and creating effective framework for carrying out biomedical research on human beings according to current ethical and legal standards.

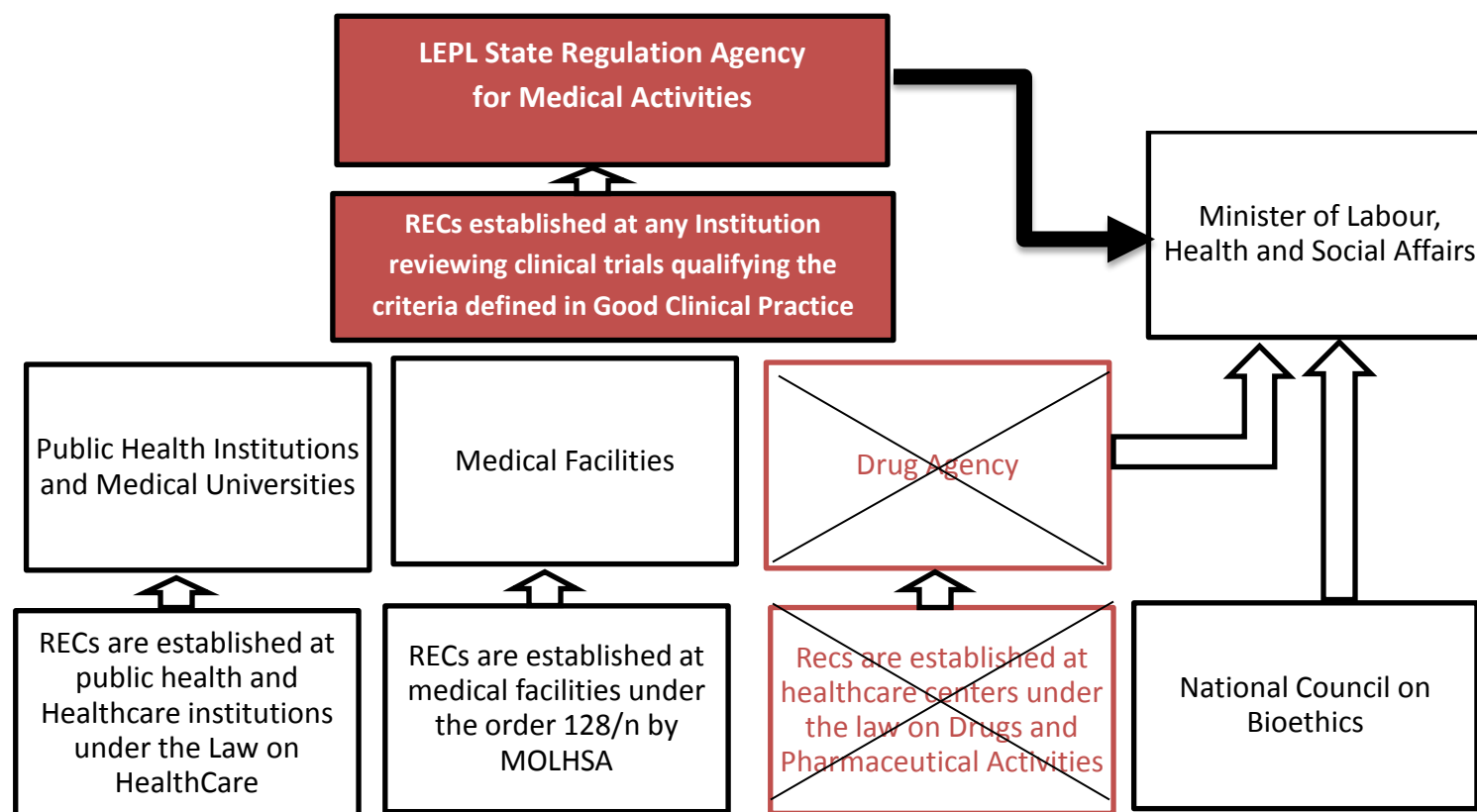
Institutionalization process of bioethics in Georgia started in late 90's and the first research ethic committees were established in Georgia in 2000. Till the year of 2012 there were three types of ethics committees functioning in the country, including: (1) National Council on Bioethics, (2) research ethic committee (often named as institutional review boards) and clinical (medical) ethics committees. National Council on Bioethics of Georgia was established in 2000 by Order of President and subordinate regulative act of the Minister of Labour, Health and Social Affairs. The council represent an advisory body to the Minister of Labour, Health and Social Affairs responsible to provide recommendations on wide range of ethical problems in the field of health, biomedicine and human rights. The primary purpose of establishment of the national council by the ministry was to develop the structure responsible for provision of expertized opinion and solution for complicated issues related to accessibility and quality of health services, professional competence and ethical conduct of health care providers [12]. In the table 1 is summarized information about all three ethics committees and the legal basis for their establishment and functioning to be available by 2012.[2]

Table 1. Research ethics committee system in Georgia. 2007

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.

RECs/IRBs and Clinical ECs at institutions are independent structures with no legal requirement for reporting to any other agency. Only the institution where such RECs/IRBs and clinical ECs are established serve as supervisor body. All researches on drugs till 2008 officially was held under the supervision of drug agency and Ministry of Labour, Health and Social Affairs (MOLHSA). In the year of 2008 drug agency was closed permanently and all the responsibilities were transferred to Legal Entity of Public Law (LEPL) State Regulation Agency for Medical Activities under the Ministry of Labour, Health and Social Affairs. As for National Council on Bioethics, it is responsible to report to the Ministry. Below is an organizational charts showing the hierarchical and reporting relationships among these bodies [Figure 1].

Figure 1. Hierarchical and reporting relationships in the research ethics committee system, Georgia, 2008-2013.



Currently there is no available up-to-date scientific data providing insight on major challenges in the field of research ethics in Georgia, neither there is the data suggesting reasons for possible barriers to ethical review system functioning in the country.

According to unofficial data more than hundred research studies on human subjects are carried out in the country without any review of their ethical acceptability [2]. The research planes approved at academic institutions usually go through assessment of their scientific merit and despite they involve experiments on human subjects no ethical evaluation is conducted.

In 2010-2011 there was conducted small scale study by Georgian scientists (Kristina Malkhasian under supervision of Givi Javashvili) on structure and functioning of the research ethics committees in Tbilisi (capital city) in the framework of Master Degree diploma work. According to the study results: (1) There is no centralized register for research ethics committees; (2) Majority of RECs in the country are established at hospitals based according to the Law on Drug and Pharmaceutical Activity; (3) More than 1/3 of RECs do not have their own bylaws and do not run registers of protocols reviewed; (4) Majority of RECs consider small number of protocols (<5 protocols a year) and approve them without changes or rarely ask for amendments or changes (1-5% protocols); (5) Most of RECs do not have experts in the field of bioethics/research ethics and biomedical research.

II. STATEMENT OF PURPOSE

Considering scarce scientific data about major challenges and barriers of effective functioning of the research ethic system in Georgia qualitative study was conducted in Tbilisi Georgia in 2013 as for assessment of stakeholders' attitude concerning challenges of effective functioning of RECs in the country and generation of related proposals from these stakeholders on potential responses from both the REC system and stakeholders themselves to address existing challenges and their causes. Results of proposed qualitative study as well as results of the critical analysis of Georgian legislation on research ethics (including both exiting legislation and its possible alternative the *Draft Law on Biomedical Research Involving Human Beings*) were utilized to develop recommendations for improvement the current system of research ethics review and oversight in Georgia.

III. PROJECT GOAL AND OBJECTIVES

The goal of the proposed project was to develop recommendations for improvement of the current system of research ethics review and oversight in Georgia. This was planned to be achieved by:

1. Identification of perceptions of different stakeholders about major challenges and barriers of effective functioning of RECs ethics in Georgia and receive their suggestions on measures to address them;
2. Assessment and Evaluation of existing local regulations in the field of research ethics in Georgia;
3. Development recommendations for enhancing research ethics capacity in the country;

4. Increase publicity of the issue by scientific paper in peer-reviewed academic journal, presentation for policymakers in parliament.

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IV. METHODOLOGY

To achieve the project goal and objectives we conducted:

- (1). Qualitative research among key stakeholders;
- (2). Survey on Georgian Education Institutions;
- (3). Critical analysis of exiting legislation and its possible alternative the Draft Law on Biomedical Research Involving Human Beings;
- (4). Developed recommendations,

** Based on project findings there is planned development of scientific paper and power point presentation for stakeholders.*

V. STUDY RESULTS

5.1. Qualitative Research

Qualitative study using individual in-depth interviews was conducted in Tbilisi (Capital city with 1/3 of Georgian population) to collect stakeholders' opinions, attitudes and perceptions about bioethics legislation, IRB structure, functioning, major issues in the review process at their local institution and recommendations for potential responses from both the REC system and stakeholders themselves to address existing challenges and their causes.

5.1.1. Data Collection and Ethical Consideration

Subject Population (Inclusion criteria):

Georgian RECs members (local RECs' chairs, leading members of National Council of ethics), experts of the field, researchers, policy makers, NGOs working on human rights and community/religious leaders were invited to participated in the study. To be eligible for participation in the proposed qualitative study, stakeholders were required to meet the following inclusion criteria:

- Age: Be older than 18 years
- Work Experience: 1 and more years in the field of bioethics, research, policy making and human rights.
- Education: bachelor's degree or more.

Recruitment and Consent Process:

Participants were recruited using purposive sampling method. Additional snowball sampling was conducted if necessary to reach the desired number of participants. Potential participants was conducted by phone, informed about research and asked if they were willing to participate. Participant's informed consent was obtained prior to inclusion them in the research. Consent for participation were obtained at private place either in National Center for Disease Control and Public Health (NCDC) or Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC) or their local institution (with consideration of participant's preference).

Upon arrival the investigators confirmed that volunteers meet the criteria and again asked if the individuals were willing to be interviewed at a time and place chosen by them. Each potential participant read a letter explaining the purpose of the research and study benefits and risks, that participation was completely voluntary, and that they had the right to withdraw at any time. They also reassured that

participation or lack of participation would not affect their professional position (e.g. REC member, NGO worker, etc.), and that exact identity of participants would not be concealed to other participants and their colleagues (including the head of the institution as appropriate).

Confidentiality:

Interviews were conducted in Georgian and/or Russian. All interviews were recorded on audio tape. The participant's name was not included on the audio tape. The participant were able to review the content of the tape after the interview if she/he chooses and could delete any comment. The tapes were transcribed. The answers to qualitative questions were compiled and coded for emerging themes in the responses. Results of the research, stripped of any potential identifiers, were shared in the form of the recommendation document (Also is planned in PowerPoint presentation and published article).

5.1.2. Data analysis:

Transcripts, audiotapes and notes from the in-depth interviews will be reviewed independently by two investigators. All surnames and other specific identifying information that was inadvertently mentioned were deleted from the transcripts. Content analysis technique with deductive approach was utilized to develop coding categories and themes. Codes developed independently were compared and discussed, and differences were reconciled. A matrix was developed with rows for groups and columns for themes to summarize the data retrieved from the transcripts. The themes in the matrix were organized within free broad areas, including: (1) Awareness and perceptions; (2) Perceived challenges and barriers; and (3) Proposals. This provided opportunity to examine data within one theme and also explore relationship between themes by looking along the rows of the matrix. The iterative coding process resulted in a coding scheme with 7 main categories.

5.1.3. Results

Major Barriers and Issues

- **Policy: low political interest; national legislation inadequate and not enforced;**
- **IRB system: no coordination, no quality assurance mechanisms (i.e. registry, monitoring, evaluation, etc.) and no transparency;**
- **Education and awareness: no formal education for specialists, lack of public awareness;**
- **Financial support: no remuneration and low financial support for IRB activities;**

- **Legislation- Stakeholders' Perceptions, Barriers and Recommendations**

Overall perceptions regarding exiting national legislation on bioethics in Georgia did not vary significantly among different groups of stakeholders. Stakeholders believed that current national legislation was inadequate to address bioethical issues existing in the country nowadays mainly due to the fact that the bioethical regulations in legal documents have not been updated for almost two decades. As stated by the policymakers since adoption of the legislation on healthcare there have not been made any major amendments in the documents to address new challenges the country is facing and neither is considered up-to-date international recommendations in the field of bioethics.

Legislation is outdated. Since its introduction many changes has taken place in the country as well as in the field of bioethics. For instance there were no surrogate motherhood centers and the ethical problems related to these activities. [Policymaker]

While asked to evaluate the legislation on bioethics stakeholders mainly named those weaknesses and gaps they as professionals often find as the barrier to fulfill their duty. Institutional Review Board (IRB) members and policymakers complained that Georgian law on healthcare is very broad and vague document which does not provide bases for establishment of IRBs in the organization, neither does it provide clear guidance for the structure and function of the board.

The weakness of the national regulations on bioethics is that it is very vague, the strength is that thanks to God it exist. One of the problem is that there is no distinguished mechanisms for establishment of IRBs. The legislations does not provide such bases, neither does it give the adequate guidance for work to be carried out in IRBs. You have no choice but to refer to international regulations or use one of those adopted by the specific country. [Policymaker]

Researchers also complained about lack of comprehensibility and specificity of national legislation and argued that it represent important barrier for conducting high quality and effective research projects. One of the issues, according to the researchers is the lack of regulations for waiver of the consent obtaining requirements in minors.

Legislation does not provide adequate guidelines for involvement of participants under 18 without approval of legal guardians when the goal of the study is to collect confidential information on IDU, STD, HIV of minors. Inexistence of consent-waiver practice in the country results in low response rates due to unwillingness of participants to inform their parents about the issues and also unwillingness of parents to let their children being involved in such studies due to social stigma related to the issue. [Researcher]

Existing regulations defined in legal documents do not provide bases for development of adequate IRB system. Legal documents fail to equip local IRB boards with guidelines about procedures, quality control measures or any other issues. [IRB member]

Researchers and policymakers were also concerned about existing disproportion of regulations of different type of research. For instance ethics in drug trials was addressed in the Law on Drug and pharmaceutical Activity in details (more or less) while other types of studies including observational, sociological and etc. are neglected despite increased number and potential threat to the study subjects' wellbeing.

Imbalance in regulations of different studies. There is inadequate regulations for observational studies and almost no for sociological studies unlike drug-trials. [Researcher]

The regulations are vague and there are questions concerning what type of studies (sociological, bachelor and doctoral studies) should be reviewed by local IRBs. [Policymaker]

Though big majority of stakeholders criticized existing national legislation not all of them agreed on the need to adopt new law in bioethical research. Those against introduction of "stricter" regulations argued that such changes in legal document without following reforms in the system would be ineffective and even dangerous particularly considering corruption culture in the country. Some researchers and policymakers believed that currently there no demand on strengthening research ethics system considering the fact that observational studies do not possess big risk and as for pharmaceutical studies, they are better regulated and in big majority cases conducted by researchers from western countries with better regulations and stricter requirements.

Nowadays there is no need for stricter regulations or major changes in the IRB system considering the fact that most of the studies are observational and those which are clinical are carried out by western PIs. [Researcher]

Changes in legislation is not always a good idea. For instance introduction of sanctions for violation of patients' rights in clinical trials by government is a good initiative though there is a risk of using the sanctions by government officials without proper argumentation. [Researcher]

However all stakeholders agreed on the fact the major challenge nowadays represent inexistence of political interest and low enforcement of existing regulations.

Nowadays there is more problem with enforcement of regulations rather than the content of the regulations existed in the legislation. [Policymaker]

Adoption of new laws in bioethics though is a good initiative since it will be more detailed regulations of bioethical issues, still it will not be the guaranty of improvement of bioethical regulations in the country. There is need for enforcement of existing law rather than introduction new one. One of the reasons why current law does not work is inexistence of enforcement mechanisms. [Human Rights NGO member]

Considering difficulties in adoption of new national law stakeholders suggested first development of bylaws in forms of national guidelines which would be recommended document for local IRBs to use while carrying out their work.

Farther development of the legislation is important though details concerning structures, functions and etc should be defined in legislative acts, for instance in the orders by ministry of health. [Policymaker]

Development of national and local guidelines is important to provide IRB members with clear guidance concerning IRB function, responsibilities and it is also important to prevent disapproval of the studies with high potential though difficult ethical dilemma (i.e. clinical trials on the patients with Alzheimer's disease). [IRB member]

- **IRB work quality and human subject protection- Stakeholders' Perceptions, Barriers and Recommendations**

When asked to evaluate quality of the work carried out by local IRBs all stakeholders indicated that nowadays there is huge quality issue in most IRBs with exception for few boards. According to stakeholders there are 4 main reasons for low quality, including: (1) Lack of adequate policy in bioethics; (2) No quality control and monitoring system; (3) Lack of qualified and motivated workload; (4) Low public and scientific society education, awareness and involvement; (4) Low transparency of IRB activities; For policymakers viewpoint lack of adequate policy is the leading barrier for improvement of the quality of ethical review practices in the country.

Quality control is the key for improvement of local IRB work. However it cannot exist without adequate policy. It is difficult to evaluate efficacy and overall quality of local IRBs. If we use international partner's (donors, IRB and RECs of foreign universities and institutions, etc.) satisfaction as a parameter than we may conclude at least there were no ethical violations taking place in the country. There should exist monitoring system to assess the quality which again requires development of policy. [Policymaker]

Some stakeholders also stated that in generally quality of ethical review and control in case of clinical trials are considerably higher compared to other types of research. The main reasons for such phenomenon is more detailed regulations for clinical trials defined in national legislation and highly qualified management team from developed country with better bioethics policy.

Quality of IRB review in clinical trials are better considering the fact that it is initiated and managed by US or one of the European countries who have bigger experience and better regulations for ethical violations. Besides as local as well as foreign researchers are highly motivated to follow regulations considering the fact that usually in case of violation the study sites are closed. [Researcher]

Low qualification and experience of the IRB members is important issue. Due to gaps in high education system, short existence of IRBs and low workload result in the fact that even members with adequate bioethics training find it difficult to guarantee high quality of the IRB work since do not put in practice their knowledge for long period of time. No remuneration for the time and efforts allocated to the work in IRB result in low motivation among members particularly considering the social and economic problems existing in the country. Due to low awareness and lack of political support IRB membership is not prestigious either.

Problem is low willingness and motivation of IRB members and invited experts to allocate adequate amount of time from their busy schedule on the review of study protocol. [Researcher]

During the interviews stakeholders discussed other barriers for adequate human subject protection practice in the country, including: (1) Lack of informed consent culture; (2) Social-economic issues and risk for undue inducement; (3) Low protection of confidential information.

According to researchers and IRB members informed consent process is relatively new practice for both scientific and civil society. While the first group lacks the knowledge and skill to obtain informed consent, the second group due to long history of violation and ignorance of health rights in the country are resistant to provide oral or signed (particularly problematic) approval on the research.

There is need for qualified and dedicated staff who will be explaining content of Informed consent documents to the study subjects. There is lack of experience in obtaining informed consent from minors and people with disabilities. [IRB member]

Obtaining consent for participation in the research raises suspicion among potential participants since previously (during soviet system) patients were rarely involved in decision making concerning their health unless there was high risk for their life. The similar situation became one of the main reasons for low HBV vaccine uptake in maternity houses. Requirement to obtain Mother's approval was only introduced after introduction of HBV vaccine in national immunization schedule what increased suspicion among mothers that vaccine might be dangerous for their children and resulted in low vaccine uptake. [Researcher]

Economic hardship and low access to health care was named by stakeholder as important risk for undue inducement. Due to high unemployment, low remuneration and privatization of health care system became major barriers for adequate health care in the country. Patients often are well aware about the risks of having side effects due to or being treated by placebo

Economic and social status of the country and low access to medical services and expensive medication in big majority of the population creates base for undue inducement due to problems defining level of the incentives offered to the study population and having no alternative for the patients.[IRB member]

Enrolment of participants in clinical trials might be problematic considering low access to qualified medical care in the country. Though it is not unique issue, or something specific for Georgia. [Researcher]

Nowadays in Georgia there is not defined what an average salary is. I personally do not know how it is calculated in reality. So it is difficult to judge whether incentive is above the defined norms or not. This is problematic since participation is not altruistic anymore neither is guaranteed participants' honesty. In order to be qualified and "please" the researches participants usually provide socially acceptable responses on the questions. Another issue is that patients agree to participate in clinical trials due to having no alternative. [Policymaker]

Stakeholders also discussed the issue with low protection of confidentiality in the country.

Protection of confidentiality in Georgia represent an important issue. Particularly in the health care where information flow exists on many levels starting from administration, medical personnel, to patients, etc. Currently we could say that no information is confidential. [Human Rights NGO member]

Perceptions about transparency of IRB activities differed even among the same groups stakeholders. While some of the participants considered it important for farther development of the field and an important tool to increase public awareness and control over human rights issues, others considered increased transparency as the risk of discrediting scientific society.

Transparency of the information will support increase of population interest and awareness about bioethical issues and regulations. [Policymaker]

Transparency of the IRB activities carries risks of misinterpretation and violation of basic ethical principle – respect for the person, particularly considering high interest of media to publish information on medical errors. Like in case of HIV/AIDS and gay population (when first announced to be identified in gay population it became the stereotype and reason for stigma and discrimination) researchers and scientific society overall might be discriminated. Though transparency is crucial information should be provided with big caution. [Policymaker]

- **Research Ethics System - Stakeholders' Perceptions, Barriers and Recommendations**

While discussions on the country specific problems in the area of bioethics, majority of stakeholders named lack of organized bioethics research system as an important barrier for adequate human subject protection in the country.

Inexistence of the IRB system results in lack of standardized and unified research ethics regulations in the country [IRB member]

According to stakeholders the current tendency of chaotic establishment of the research ethic boards in the local institutions is the reason for number of problems country is facing in the area of research ethics. While there is an urgent need for development of the system due to increased number of international funded research projects, unfortunately there is evident lack of capacity for such rapid development.

Intensive Institutionalization of research ethics preceded the development of this scientific area in the country. From one side it was essential considering urgent need for existence of the system responsible for rights and well-being of research subjects, though on the other side it was challenging considering lack of qualified knowledge and experience in the field. [Church representative]

Low workload, short “life-expectancy” and only formal existence of ethic committees were another problematic outcomes of above mentioned process and main barriers for farther development of the ethics system in the country.

IRBs in Georgia are mainly created when the organization is receiving international scientific research grants and the board is existing mainly on the paper and for very short period of time. These all makes it impossible for the board members to gain experience and increase proficiency in the field. [IRB member]

Stakeholders also pointed on such issues as inexistence of accreditation, control and monitoring mechanisms in the country. Though consider it important majority of stakeholders considered introduction of such mechanisms problematic for several reasons: (1) No

political will; (2) Financial constraints; (3) Corruption culture; (4) Low involvement of civil society; (5) Difficulties in evaluation of ethics and quality of IRBs work.

I am against of the Control of the RECs'/IRBs' work, coordination is rather important and needed. Something like "consultation organ" which will be responsible for providing certificates, guidance. Control is difficult and connected with financial and human resources. I think it may be professional union or association for researchers. Researchers should ask for the consultation first, after given advice and recommendations, and then the association should check or control the work, like once in a month or year ask for the done work. But again, it will be better free exchange of information, coordination and agreement of RECs' and ensure their maximally union, but not control. [Policymaker]

Accreditation should be excluded, because who will be then in charge to provide or deny accreditation certificate? Or what kind of accreditation it will be? Ethics is rather difficult area for evaluation... ethical standards are sometimes even more questionable than the legal standards. Also please take into consideration that IRBs are created on the voluntary community basis, this is not governmental body. [Human Rights NGO member]

Perceptions regarding the agency or the body to be in charge of the control was different in policymakers and other groups of stakeholders. All groups of stakeholders except for policymakers saw government as the leading body for establishment and control of the bioethics system in the country.

Governmental organization should be in charge of control of IRB system: including registry, monitoring evaluation [IRB member]

Recommendations of central IRB should be disseminated both in scientific and in the civil society, and what is more important it must be provided to the decision-makers at top level. This can be guaranteed only by implementing central IRB in higher level of the governmental body (prime ministry, president office). [Human Rights NGO member]

There should exist at least some control mechanisms in bioethics at local governmental level since bioethics is part of human rights protection and thus one of the important duty of the government. [Researcher]

Policymakers were concerned about putting all responsibility of ethic system control on the government structure due to potential of turning the process into bureaucracy. Policymakers envisioned bioethics system in control of civil and scientific society for fulfillment of all three goals: (1) Protection of human subjects; (2) Enhancement of science and ethics; and (3) Guaranteeing of information transparency.

Central REC should become independent body and transform into association of bioethics which will not necessarily be associated with any governmental body, though its functions and competencies should be regulated by law. IRB should be part of social society to ensure better protection for study participants and access to study related information. [Policymaker]

Only light monitoring system should be implemented. Reporting requirements should be more for self-evaluation purposes and not for control and for sanctions. Monitoring should be performed by institution itself. Particularly ministry of health care should not be the control body, since it will lead to

unnecessary bureaucracy. Monitoring results should be used for quality improvement for the performing as well as other IRBs through information dissemination. [Policymaker]

- **Education and awareness about bioethics - Stakeholders' Perceptions, Barriers and Recommendations**

Lack of the competence in the area of bioethics in the country was named as one of the important issue. According to the stakeholders currently there is no formal education courses available for the people interested to receive degree in the field. Though currently in medical universities' bachelors, masters and doctoral students are provided with training in bioethics, those courses are very short, not specific and mostly concentrated on deontological issues than on the research ethics problems. They often fail to provide even basic knowledge in bioethics for researchers increasing risk of violations and resistance of researchers to follow existing regulations in bioethics. In addition there is no course for IRB members making it impossible for the specialists in the board to receive knowledge in the field to fulfil their duties.

Education about ethics is very short and carried out mostly on lower courses at universities, while it should be continues education. Particularly high attention should be paid to the courses learned on master and PhD programs. [University Representative]

Stakeholders also emphasized importance of introduction of education courses for specialists in other academic area who are also supposed to deal with human subjects.

Formal education is available only for medical faculty students or those pursuing high academic degree (MS, PhD) in medicine or public health, while there are number of other areas like law and sociology where is also high demand for bioethics since people of these direction are also involved in research on human subjects. There should be formal education available for students at faculties as well. [Policymaker]

Interestingly, willingness to enhance knowledge in bioethics and particularly in research ethics was low among both researchers and among most IRB members.

I do not see it necessary at least now (question: what do you think about farther trainings in bioethics?). Generally I think there is no need in long trainings in bioethics for researchers. Short trainings provide required basic knowledge for specialists involved in the research. [Researcher]

Education for IRB members in clinical trials in bioethics is favorable, though more import is that the member is well qualified and experienced in their areas like : law, nursing, research or specific medical specialty (hematology, neurology, etc). [IRB member]

Having diploma or certificate in bioethics should not be mandatory if person has experience and high moral standards. [IRB member]

Low public and science society awareness and resistance were named the reasons why still in the country there are studies on human subject which have never been submitted to any IRB and not only questionable in ethical viewpoint but also dangerous in national security viewpoint as well.

For instance: some clinical trials carried out by Georgian physicians as part of their dissertation are not reviewed by any IRB basically because health care and public health specialists in the country have absolutely no knowledge and information about existence for such requirements. [IRB member]

The researchers somehow should be informed and obliged to provide their studies to IRBs for review. Since some studies carry risks not only for study participants but also to national security (i.e. ethno-genetic studies) [Religious Leader]

Importantly when asked about the solutions to the existed problems in bioethics in the country all stakeholders prioritized two areas requiring urgent interventions, which from the other side would also be the most effective to address other issues in the field. According to stakeholders the interventions to address low education and awareness of specialists, policymakers and population must be the first important step to be made in this field. Suggested interventions included: (1) Public awareness campaign about health rights; (2) Conferences and workshops for all stakeholders; (3) Publication of scientific journals (4) Website;

Advocacy for reforms in research subject right protection regulations will be a first important step for development of the field and improvement of the quality of IRB review in the country. [Researcher]

Prioritization of the research ethics and bioethics in the country and putting it in our government officials' agenda is important for bioethics policy development and farther improvement. Big social campaign with participation of all stakeholders (i.e. public, patient groups, researchers, IRB members, journalists, etc.). The campaign should include development of qualified and motivated group of people and initialization of public discussions through bioethics in media channels. [Policymaker]

Improvement of the quality might be reach with:- increase public awareness about ethical issues (explain that it is not additional autocratic requirement and not the one introduced by foreign scientists but their own interest); - Develop education courses and master studies in bioethics. Addressing legislation issue is less important. [IRB member]

In order to increase awareness and interest in bioethics in the country there should be developed journal in bioethics where will be publishes articles about bioethics issue in Georgia and worldwide, violation identified in the country, etc. Also more conferences should be conducted to develop promote discussions on bioethics topics. [Human Rights NGO member]

Important is to organize trainings for stakeholders (for clinical administration, managers, lawyers) what is IRB, how it works, what are by laws, how they work, what will be results. The other issue is that IRB's should be very interested in having a strong bioethical team. [Human Rights NGO member]

It's a good idea to have website, which will be confidential and only for IRB's, it may contain statistical information or difficult issues. IRB's may interact with each other using this site. Bylaws of the IRB may state what kind of information and who would be responsible to put information on the site. Site also may contain names of someone who "broke the rules". [Human Rights NGO member]

- **Financial support - Stakeholders' Perceptions, Barriers and Recommendations**

Lack of the financial support for IRB activities was named by stakeholders as one of the important barriers for adequate quality of IRB activities and farther development of this field in the country. According to stakeholders considering existing socio-economic problems in the country IRB members are not motivated to allocate required amount of time the work in IRBs. However stakeholders' perception whether IRB members should be remunerated or not differed. While IRB members and policymakers were assured that remuneration of IRB members would improve work quality (through increased motivation and responsibility), researchers and human rights NGO members considered it as potential risk for corruption.

Remuneration for IRB members is the best way to increase their motivation as well as responsibility for the work carried out in IRB. [IRB member]

In the US like in case of blood donation, the volunteer donors are the best donors, those IRB members who are not receiving remuneration are the best one as well. However remuneration for IRB members in Georgia is a good idea and can may even improve quality of the review and support protection of patients' rights in Georgia. [Policymaker]

IRB member position should not be remunerated due to high risk of corruption and conflict of interest. [Researcher]

There should not be financial remuneration for ethic committee members. "Mercantile" (motivated only by money) mentality and motivation for those people should not be an issue. I think they must be people really dedicated to this work, who possess high ethical quality. [Human Rights NGO member]

According to stakeholders small country budget and no political interest in bioethics represent important issue for the field development in general and research subject protection specifically. Policymakers believed that if Georgian government was able to allocate such funds, there would be much higher interest from one side and power from another side to control the system and guarantee higher quality human subject protection practice.

The fact that nowadays government is unable to finance scientific projects due to difficult economic situation in the country represent important barrier to introduce strict human subject regulations and requirements by the government. In case government had resources to provide funds it would have more power and interest to introduce control mechanisms in the area of research ethics to guarantee that the government money is not allocated to scientific studies with violated human subject protection principles. [Policymaker]

5.2. Survey on Georgian Education Institutions

Short telephone and internet survey was conducted to assess existence of bylaws with requirements for ethical review, RECs/IRBs and standard operation procedures (SOP) at accredited high education institutions in Georgia.

Research instrument: short interviewer-administrated quantitative questionnaire.

Source of information: List of exiting accredited high education institutions (with Master's and PhD courses) and existing RECs to be obtained from the Ministry of Educations and Science of Georgia, And Office for Human Research Protections (OHRP) official website.

Main findings:

1. Out of 53 accredited high education institution 19 have medical, biological, pharmacology or public health department
2. Only 4 institutions had bylaw with requirement for PhD/MS research studies to be reviewed by REC/IRB (Although REC/IRB review requirement is not written in PhD/MS regulations, students projects of some institutions are reviewed by the scientific institution's or clinic's REC where the study is planned to carry out)
3. In almost all institutions (3 institutions did not have such info available) bioethics was included in MS and PhD curriculum.

5.3. Critical analysis of exiting legislation and its possible alternative the Draft Law on Biomedical Research Involving Human Beings

5.3.1. Objective of the research

Critical analysis of exiting legislation and its possible alternative the Draft Law on Biomedical Research Involving Human Beings was conducted, in the context of provision bases for development of adequate REC system, identify strengths, weaknesses (e.g. major gaps, inconsistencies, etc) and adequacy of those legislations to address issues existing in the country.

5.3.2. Methodology

Step I. Literature review of scientific papers on the REC systems (including both structure and functions of REC) and their regulation to develop evaluation criteria.

Step II. Analysis of exiting legislation and Draft Law to assess how the developed evaluation criteria are met in these two legal documents.

Step III. To check adequacy of the legal documents in local context. Evaluate appropriateness to address exiting challenges in the research ethics identified through qualitative research.

5.3.3. Results

Criteria #1 Requirement for ethical review of the research projects on human beings

Law of Georgia on Health Care: The Law of Georgia on Health Care indicates requirement for review of the biomedical research projects. “Any medical-biological research must comply with the norms of scientific research in Georgia...”[Chapter XIX, Article 106]. The term “Biomedical” became the reason for confusion and debates in the research society due to the uncertainty whether observational, sociological or other type of studies are required to obtain approval from IRBs/RECs or not. The definition of the term provided in the law leaves the question open whether studies with no experimental design are also required to be reviewed by the ethics committee. “medical-biological research- any experiments conducted on animals or human subject, which the only or the main goal is enhancement of knowledge in medical area”. [Article 3 Term definitions, Par23]

Law on Drug and Pharmaceutical Activity: The *Law on Drug and Pharmaceutical Activity*, (adopted by the Parliament of Georgia in December, 1996) till the year of 2009 by Articles 7 and 8 drug trials and protection of research subjects defined requirements for ethical

review for clinical drug trials: “the research subjects are protected by the Georgian Legislation based on the international principles of the research subject’s protection recognized by the Declaration of Helsinki.” (Article 8, par1)

From 2010 after amendment of the Law the Clinical Drug Trials (CDTs) are governed by the ICH guidelines adopted based on the order of the minister (Order# 233/N, August 2010) of MOLHSA. In the law the only place where is mentioned usage of international guidelines is chapter 1 (Terms Definitions), article 50 states, though there is not named specific guidelines to be used for the studies on Drug and Pharmaceutical Activity. This article just provides recommendation for adoption of CDTs’ guidelines in accordance of Georgian Law, international treaties and agreements.

Draft Law: The Draft Law – “Ethical Evaluation of Research Protocol and Biomedical Research Ethics Committees, “introduces requirement for ethical evaluation of *“Any research protocol with participation of human being is a subject of ethical review”* (Chapter VII, Art 34) and what is also very important (bearing in mind the notion that “ethical review should continuous process”) monitoring of ongoing research projects (Chapter VII, Art 34, Par. 1 and 3). The document clearly defines the types of bioethical research on which the regulation is assigned: *“The 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; ”* (Chapter 1 – General Provisions, Art.2)

Criteria #2 Legal bases for establishment of RECs/IRBs

Law of Georgia on Health Care: The *Law of Georgia on Health Care* (introduced in 1997) generally mandates the establishment of the “Special Independent” ethics committees, which can carry out ethical review of all biomedical research protocols. “A scientific research plan shall be considered and reviewed by the special committee independent from researchers and funding organization and by medical ethics committees” (article 107; the Law of Georgia on Health Care). The fact that there is not mentioned the name for this “Special Independent” bodies and on the other hand medical ethics committees are named as other entity to review the research protocols is problematic due to confusion of the role and responsibilities of these two entities. The medical ethics committees are established in the medical facilities with the purpose to address deontological issues (i.e. violation of patient’s rights, health personnel ethical misconducts, etc.) are functioning based on the order of the ministry of MOLHSA (Order#128/n October, 2000).

Law on Drug and Pharmaceutical Activity: The *Law on Drug and Pharmaceutical Activity*, till 2009 used to define establishment of research ethics committees and procedures of ethical review for drug trials (Articles 7 and 8: drug trials and protection of research subjects), including in the so called "Clinical phase" when assessing the drug efficacy is carried out on humans. In such cases the law required the institution (where the research was planned to be carried out) to establish an independent ethics committee during the time of the study process. However in the year of 2009 after amendment of the Law on Drug and Pharmaceutical Activity, the articles 6, 7 and 8 were removed from the document. On the other hand by the order of the minister of labor, health and social affairs in 2010 the next international guidelines were adopted as regulatory documents (standards) giving guidance for the preclinical and clinical studies of pharmacological agent's:

1. International Conference on Harmonization ICH Guideline for Good Clinical Practice GCP E6 1996;
2. International Conference on Harmonization ICH Guidance on Non-Clinical Safety Studies M3 2009;

These two international guidelines, which give very detailed guidance for ethical review of drug trials including establishment, function, responsibilities, operation of Institutional Review Boards (IRB)/ Independent Ethic Committees (IEC), became main documents for ethical review of CDTs harmonizing it with international standards. Adoption of these two guidelines was another important step in advancement of the regulations of clinical drug trials. However the mentioned changes in regulations are also problematic for the following reason: Lower power – The order of the ministry in the legislative hierarchy is on the lower level than the national law. Considering exiting problems (Including: resistance of society to follow the regulations from one side and low government power to enforce those regulations on the other side), replacing legal requirements defined in the national Law (articles 6, 7 and 8) by the ICH guidelines (Good Clinical Practice) represent important barrier for adequate control of drug trials in the country.

Currently clinical Drug Trials in the country, are reviewed by both IRB/IECs and LEPL State Regulatory Agency for Medical Activities, which is a part of Ministry of Labour, Health and Social Affairs of Georgia. Thus, the approval for the clinical drug studies also is given by the governmental agency (The Law on Drug and pharmaceutical Activity article 10 par.(g)), this agency is also responsible for the monitoring of ongoing drug trial and for the prohibitions for the infringements of the regulatory standards by the IRB/IECs as well as by study sponsor parties. It is important to mention that there is not such regulatory agency or well developed and strict regulations for other clinical trials (or other types of biomedical research) as it is currently for pharmaceutical research. Considering all above mentioned there is clear evidence of non-equivalent stringency in ethical regulations of different studies (similar to other CEE member countries).

Draft Law: The chapter VII of the Draft Law – “Ethical Evaluation of Research Protocol and Biomedical Research Ethics Committees,” also chapters VI, VIII, XIX are important sections of the document which provides clear and detailed guidance on establishment, structure, functions and operations of research ethics committees in the country and addresses main issues effecting quality of ethical evaluation of protocols often described in other CEE member countries.

Chapter VII article 34 p 1 states: “Research protocol shall be submitted for evaluation of its ethical aspects to ethics committee which is established on the basis of the present law and relevant normative act of the Ministry of Labour, Health and Social Affairs”.

The Draft Law defines organizational and structural issues of RECs dividing them by type: Central Research Ethics Committees and Local Research Ethics Committees. Both RECs are independent in their activities and guided only by ethical and professional standards defined by legislation of Georgia including the Draft Law.

Criteria #3 Defining responsibilities of ethics committees

Law of Georgia on Health Care: The Law only indirectly defines responsibilities of ethic committees by listing main international ethical principles and standards for ethical conduct of research.

Law on Drug and Pharmaceutical Activities: Before 2009 The Law defined main responsibilities of Independent Ethic Committee, which was created for the particular CD trial: “to evaluate ethical, moral and juridical aspects of clinical study of pharmacological agent.” [Article 8.2.] From 2010 responsibilities of IRB/IECs are defined by the international ICH GCP guidelines. Adoption of this guidelines brought another confusion in the research ethics system, specially: If before the law required establishment of ethic committees in the institution where study is undertaken for all period of this research, now any IRB/REC located in other institutions can conduct the review if qualifying for the requirements defined in the guideline (composition and qualification requirements). This might become the issue considering specificity of the work carried out by ethics committees on clinical trials, including higher frequency of meetings, trust and willingness for collaboration of the staff of the other clinic where drug trials are carried out.

The Draft Law: In the Chapter VII article 34, p 3 and 2 state that the responsibility of the REC is “to ensure compliance of research involving human beings with ethical and professional norms throughout the country, to ensure safety of a research subjects and protection of their rights, dignity, autonomy and welfare through examining research protocols and monitoring ongoing research projects”...”Research ethics committee is independent in its activities. It is guided only by ethical and professional standards recognized within the country as well as the norms reflected in this law”.

It is interesting that the article 41 Paragraph 7 of the Draft Law states that REC may review Drug trial, but the final conclusion is taken by the State Regulatory Agency for Medical Activities.

Criteria #4 Defining Composition of ethics committees

Law of Georgia on Health Care: No information about this topics.

Law on Drug and Pharmaceutical Activities: Before 2010, criteria for IRB/IECs composition for Clinical Drug Trials were established by the Law on Drug and Pharmaceutical Activity, according to the articles 8.3 and 8.4, the committee shall be composed of 5 members including qualified specialist (according to the topic of the research), nurse, pharmacist, lawyer and social worker or clergyman. It was very similar to newly adopted ICH GCP guidelines, which also recommend IRBs to be composed no less than 5 members (*Chapter 3.2 Composition, Functions and Operations*). The study results of K. Malkhasian, also showed that the most RECs in the country were established in accordance of the Law of Drug and pharmaceutical activities, composed by no less than 5 members.

There are no other national laws or regulation defining criteria for RECs' composition. No indication about the REC members' initial and continuing training in the field bioethics or research ethics.

The Draft Law: The law defines composition of Central REC (11 members) and local RECs (minimum 7 members). Approval for the composition of Central REC ensures the Ministry of Labor, Health and Social Affairs (article 46).

Despite strong sides of the document there are some discrepancies requiring careful consideration and farther clarification. For instance, though Draft Law defines the composition of REC (e.g. people of different professional background including: scientists in the field of biomedicine, ethicists and bioethicists, lawyers, physicians, nurses, representatives of church, human rights protection organizations/representative of broader society and minister of health care) and considers inclusion of lay persons in the central and local RECs' board it fails to indicated clear selection criteria (e.g. competence, qualification, basic knowledge in bioethics, etc) and also do not specifies maintenance of the "balance between biomedical and non-biomedical representatives" or gender balance.

Criteria #5 Defining system and functioning of ethics committees

Law of Georgia on Health Care: There are no specific provisions in the Law on Health Care specifying the functions and procedures or the statues of decisions of RECs in general. Neither is mentioned the organizational structure of the ethics committee system.

Law on Drug and Pharmaceutical Activities: The law mandates conduct of the preclinical and clinical studies on the basis of the Georgian legislation, international treaties and agreements, ICH guidelines for IRB/IECs, international standards, technical regulations and guidelines.

The Draft Law: The Law defines organizational and structural issues of RECs dividing them by type: Central Research Ethics Committees and Local Research Ethics Committees. Both RECs are independent in their activities and guided only by ethical and professional standards defined by legislation of Georgia including the Draft Law. By assigning central RECs coordinating role the Draft Law promotes establishment of effective system for quality assessment, supervision, coordination, educational activities and improvement of the work carried out by the local RECs. The mentioned mission is fulfilled by utilization of such instruments as: (1) requirement for accreditation of local RECs (Art.38, Par. 9); (2) Analysis of annual reports provided by local RECs and development of comments (for local RECs) and summary annual reports (for ministry of Health) on the base of those documents (Art. 37,Par.b and Par.8); (3) Evaluation and provision of approval on bylaws developed for local RECs (Art. 38, Par.7); (4) Development of guidelines and recommendations for local RECs (Art. 37, Par.a); (5) Provision education activities (Art. 37, Par.a) and finally (6) Organization of regular conferences of local RECs

The article 39 of the Draft Law give guidance for functions and procedures of the local research ethic committees: “Review of research protocol of the biomedical research, evaluation of its ethical aspects and the guarantees for protection of rights, dignity, autonomy and welfare of research subjects; ... Monitoring of ongoing research projects, ... Preparation of annual report and its presentation to central committee... Participation in annual conferences”

Articles 40 and 41 define procedural issues for Central and Local RECs: terms of appointment 4 years (A40,p1) and decision within 40 days (A41, p2, p6), submission of the protocol for appeal(A41,p5)

The Ministry of Labor, Health and Social Affairs ensure preparation of the bylaws of the Central and the Local Ethic Committees within 4 months of the enhancement of the Draft Law (chapter XIX article 46). The bylaw of Local REC is approved by the Central REC (article 38, p7)Difference in procedural clarity and the scope of ethical review for different types of the research as it is case for drug trials and other undefined groups of research (to be defined by the ministry within 4 month of enactment of the law) (Art.41 Par.4 and 7) is a clear indication of non-equivalent stringency of ethical review leading to inadequate level of protection of the human subjects in different types of bioethical research.

Criteria #6 Defining Remuneration and financing of research ethics committee activities

There are no regulation for remuneration procedures for REC/IRB members (RECs work for altruistic reasons) neither is such procedures defined for National Council on Bioethics of Georgia, as it serves as an advisory body to the Minister of Labour, Health and Social Affairs.

The Draft Law article 38, p8 mandates institution where the Local REC is establishing to ensure working settings (space, communication, stationery, technical personnel, etc).

Criteria #7 Defining Sanctions for violations

Law of Georgia on Health Care: Law of Georgia on Health Care: No information about the issue.

Law on Drug and Pharmaceutical Activities: From the existing legislation only the Law on Drug and Pharmaceutical Activity mentions about the sanctions for the illegal pharmaceutical activity of pharmaceutical product without permission of clinical research fined by 8000 GEL (4600 USD) and the same action committed repeatedly by 16000 GEL (9200 USD) (art. 37-2). The violation of conditions of permission of the clinical research is fined by 2000 GEL (1200 USD) (art.37-3)

The Draft Law: Regarding the problem of sanctions for violating legislation which regulates the field of biomedical research in Georgia, the Draft Law sends on the “prohibitions” in the chapter VIII articles 43, 44 and 45, prohibiting conduct of research which does not comply with provisions of this law and legislation of Georgia in general, including cases, when “research does not pose danger to the health and/or life of a research subject”. Also prohibits falsification of information with the aim of receiving consent and prohibits publication of materials if the research is against the provisions of this law, but do not specifies what are the sanctions for such violations.

Criteria #8 Defining Transparency

Though there is legally defined requirement for information transparency in public agencies, inadequate access to the information about regulations and rights is evident in almost all areas. Informational vacuum creates concern for scientific society, for researchers, for ethic committees, nothing saying for research participants. Since IRBs and RECs are independent bodies they do not have a requirement to provide information about their activities. As a results currently there is no information about RECs, except only few of them, which are available through the websites and there is no transparency of the work of ethic committees and no existed legal instrument mandates it. Even the information about the changes in the law (removal of the certain articles from the law and introduction of ICH guidelines) became available through website for several years later in 2013 after introduction in 2010.

The Draft Law: Chapter VII of the Draft Law introduces requirement for transparency of the information regarding the activities performed local RECs by publication of annual reports and also disseminates information about ethical aspects and problems in the society by central committee in cooperation with the National Council on Bioethics. (Art.37, Par.h and Art.39, Par.d)

Conclusions

Despite significant achievements in the development of the legislative basis on the protection of rights of the biomedical research subject, there is still considerable room for improvement. Creation of the *Draft Law on Biomedical Research Involving Human Beings* is another important step made toward development of effective REC system and improvement the quality of ethical review process. However there are aspects not addressed by Draft Law which should be considered before its final adoption by the parliament. In spite of the fact that provisions of the Draft Law are rather detailed than existing legislation of Georgia in the field of research ethics and gives very good guidance for RECs and researchers, it leaves the more detailed and specified guidance regarding RECs' technical issues to bylaws of Central and Local Research Ethics Committees, which as this law states, is the responsibility of Ministry of Labour, Health and Social Affairs of Georgia, to be prepared within 4 months of enhancement of this Law.

VI. RECOMMENDATIONS

Based on the revealed problems in the area of research ethics in Georgia there were developed following recommendations to address the issues and support farther development of the field in the country:

- Lobbying for bioethics policy development and changes in national legislation concerning bioethics issues including: (1) revision and lobbying of *Draft Law on Biomedical Research Involving Human Beings*; (2) Development and adoption of national guidelines on research ethics;
- Conduct awareness raising communication, education and advocacy campaigns;
- Development of website for specialists and general population for awareness raising, education and empowerment purposes;
- Development of the research ethics system in accordance to *Draft Law on Biomedical Research Involving Human Beings* (i.e. development of the registry, accreditation and reporting requirement, etc.);
- Increase of financial support from local institutions in the research ethics activities including: (1) administrative support; (2) trainings for researchers and IRB members; (3) organize workshops and conferences.
- Farther development of university education curricula and incorporation of bioethics subject in the curricula of non-medical faculties (i.e. Law, Sociology, Biology, etc.) and development of curricula specifically for IRB members.;
- Introduction of the requirement for ethics committees' members and researchers to obtain CITI certificate already available on Georgian Language.
- Introduction of the requirement for the IRB approval by all the local donor organizations including Rustaveli Science Foundation – the foundation which is responsible to use National budget for financing research activities in the country.
- Conduct more research on human subject issues to inform policymakers and public about existed gaps and violations;

Appendix # 1 Research Tools

INFORMATION AND CONSENT FORM

Title:

Addressing the needs of research ethics system in Georgia through policy development

Protocol Number:

1. Institutional Review Board of Albany College of Pharmacy and Health Sciences
2. Institutional Review Board of Georgian Maternal and Child Care Union # 2013/01

Sponsor (source of funding):

The Study is sponsored by Union Graduate College Bioethics Program (Schenectady, New York) in partnership with the Department of Medical History and Ethics of Vilnius University. It is supported by NIH Research Grant R25-TW 7085 funded by the Fogarty International Center, the National Institute of Environmental Health Sciences, the National Heart Lung and Blood Institute, and the National Institute on Drug Abuse.

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This consent form contains information about abovementioned research. To be assured that you are informed about your participation in the study, please read this document and signed it.

This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Purpose of the study:

Georgia, since its independence from soviet system (1991), has gone through major social, economic and political transformations having immense influence on development of national legislation concerning human rights protection particularly in the field of health care and biomedicine.

Considering scarce scientific data about major challenges and barriers of effective functioning of the research ethic system in Georgia qualitative study is considered as initial step for assessment of stakeholders' attitude concerning research ethics in the country and generation of related proposals from these stakeholders on potential responses from both the REC system and stakeholders themselves to address existing challenges and their cause

Results (without identifiers) of proposed qualitative study will be utilized to develop recommendations for improvement the current system of research ethics review and oversight in Georgia. To increase publicity of the results scientific paper will be developed for publication in peer-reviewed academic journal and presentation for policymakers in parliament.

Description of the study:

Qualitative study will involve up to 15 in-depth interviews (duration of interviews is approximately 30 minutes) with stakeholders residing in Tbilisi. After obtaining informed consent, each participant will be interviewed using semi-structured interview guide to obtain information on stakeholders' opinions, attitudes and perceptions about bioethics legislation, IRB structure, functioning, major issues in the review process at their local institution and recommendations for improvement.

Your role in the study:

After you sign the consent form, you will be interviewed approximately 30 minutes about your opinions, attitudes, and perceptions about bioethics legislation and will be asked about your recommendations to address the issues. This is one-time interview, you will not be contacted for further questions in future. The session will be recorded and a transcript of the discussion will be made. During the interview you are not expected to provide any names or other identifying information, and in case if such information still be mentioned please be assured that it will be deleted from the records. You may not give answer on all questions.

Interviews will be conducted in Georgian and/or Russian languages. All interviews will be recorded on audio tape. You will be able to review the content of the tape after the interview if you choose and can delete any comment. The tape will be transcribed within six months of the interview. The answers to qualitative questions will be compiled and coded for emerging themes in the responses.

Confidentiality:

Every effort will be made to ensure the confidentiality of the participants. The interview will be held at the place convenient for you to maintain confidential area (NCDC, IDACIRC or your institution). We will protect all the information you give us as best as we can. All records will be destroyed at the end of the study. You will be assigned individual identification number to keep the information confidential. No names will be included on audio-tapes and only the investigators will hold the key linking participants to interviews. All recordings will be deleted when the analysis is completed. Data will be kept in a password-protected encrypted file in the investigator's computers at National Center for Disease Control and Public Health without any specific identifiers. Results of the research, stripped of any potential identifiers, will be shared in the form of the recommendation document, PowerPoint presentation and published article.

Risks and Discomforts:

Risks of participation are minor and consist of breach of confidentiality which may have potential for causing damage to participants' reputation, career and/or employment if the administration, or co-workers, learned about their responses concerning the employing institution's REC activities. Though there are no sanctions or other legally binding procedures existing in Georgia for punishment (neither financial of any other form) of the research institutions for REC misconduct, institutions may still be unwilling to put at risk their reputation by making them publicly known.

Benefits:

There are no direct benefits for individual subjects participating in this research. However, this research project will provide valuable information for development of adequate recommendations for IRB system legislation, support IRB review process in the country and as a result improve human subject protection in the country.

Payment for participation:

You will not receive any payment for participating in this study.

Voluntary participation and withdrawal:

Your participation in this interview is voluntary. You may decide not to participate or you may leave the interview at any time. Your decision will not result in any penalty.

Questions and Study-related contact information:

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Contact the investigators on abovementioned contact information for any of the following reasons:

- if you have any questions concerning your participation in this study, now or later on
- if you have questions, concerns, or complaints about the research;
- If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research;

Or you may contact the Institutional Review Board of Albany College of Pharmacy and Health Sciences (IRB), between the hours of 9:00 a.m. and 4:00 p.m.:

IRB Chair:	Hassan El-Fawal, Ph.D.	+1 518 694-7137	
IRB Administrator:	Sunita Chowfin		+1 518 694-7144

The IRB chair and administrator will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Or contact Institutional Review Board of Georgian Maternal and Child Care Union

IRB Chair:	George Abashidze, Ph.D.	+995 322 392803
IRB Administrator:	Maia Kajaia M.D., M.S.	+995 599 703803
Address:	8 Nutsbidze str., Tbilisi 0177, Georgia	

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a copy of this signed and dated consent form for your records.

Informed Consent Statement:

I have read the document. I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction.

I voluntarily agree to participate in this study.

By signing this consent form I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

I will receive a signed copy of this consent form.

Signature of Subject

Date Signed
(Month/Day/Year)

Printed Name of Subject

As an investigator, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study, the alternative to being in the study; and how the information provided by the subject will be collected, protected, used, and shared with others:

Signature of Person
Administering This Consent

Date of Signature
(Month/Day/Year)

Printed Name of Person Administering This Consent

Addressing the needs of research ethics system in Georgia through policy development

In-depth Interview Guide

Participant identification N° |_|_|_|_|

Before the interview

I would like to invite you to participate in the project **"Addressing the needs of research ethics system in Georgia through policy development"**. You will be interviewed during which you will be asked questions to understand better what you think about certain kinds of issues related to effective functioning of RECs in Georgia and to hear your perception about possible solutions for major challenges and barriers existing in the REC system in the country;

This interview will take about 30 minutes. The session will be recorded and a transcript of the discussion will be made. During the interview you are not expected to provide any names or other identifying information and in case such information still be mentioned please be assured that it will be deleted from the records. We will protect all the information you give us as best as we can. All records will be destroyed at the end of the study.

I'm NOT going to ask you a personal question that you may find difficult to answer. However you may still feel uncomfortable answering some of the questions. You are free to refuse this interview. You will not be penalized in any way if you decide not to participate. You can refuse to answer any question. You may stop the interview at any time and I will oblige. May I continue?"

I. Experience and perceptions related to the field of research ethics

II. First of all please tell me little about yourself: education background, work experience and current position? Could you tell me more about your experience in the field of research ethics specifically?

For probing: Position, responsibility and type of activities?

III. Have you ever received formal training in the research ethics? Why yes/no? What role has the education played in your activities?

For probing: Source of information? Training provider? Perceptions about importance of the training in research ethics?

II. Knowledge and Perception about Georgian REC system and activities:

I. What do you know about research ethics system in the country? In your opinion approximately how many RECs are established in Georgia? Are any RECs established in regions? What is your perception about effective REC system in Georgia? What is the optimal number of RECs in Georgia? Please elaborate?

For probing: REC system strengths, weakness? Difference and similarities with REC systems existing in other countries?

II. What information do you have about REC system and activity control mechanisms in the country? What do you know about accreditation mechanism for local RECs? If RECs are to be accredited, what organization should carry out this accreditation?

For probing: What are the advantages/challenges of national accreditation system development?

III. What do you think about accountability of Georgian RECs? What documentation about REC activities is prepared by your REC (e.g. review meeting minutes, registry of reviewed protocols and approved protocols, etc.)? What is your opinion about RECs reporting of their activities to central agency (e.g. MOLSHA/ National Council on Bioethics)? What such reports should include? What is optimal frequency and content of the reporting?

For probing: reported information content: number and type of review (approved/not approved), information about reviewed protocols (e.g. project title, PI, organization, etc.), number of amendment, cases of violation of ethical principle by researchers, Statements of significant new findings provided to subjects, as required by 46.116(b)(5).?

IV. What information do you have about REC activities in the country? Is REC established at your institution? What can you tell about activities of your institution's REC? What type of researches is reviewed in your REC? What about REC workload? What is the optimal frequency of REC meetings/number of protocols to be reviewed? Please elaborate?

For probing: Type of researches: other types of clinical research (pathogenetical studies, research on diagnosis and treatment), epidemiological studies, master's/PhD thesis, international studies etc.? Number of meetings during a month/ a year? Number of protocols to be reviewed at meeting? Number of protocols reviews within one year?

V. What information do you have about regulations of clinical trials in Georgia? What is your opinion about review of clinical trials in Georgia?

For probing: Perception about adequacy of regulation mechanisms? Should clinical trials reviewed by specialized RECs or not?

VI. How do judgments about risks, benefits and informed consent differ between Georgia compared to developed countries? Could you bring an example of the study where risks to participants in Georgia are higher compared to other countries? What barriers are there to free informed consent compared to other countries? How can these barriers be minimized? If there is compensation paid to the participant, how much is this relative to the average living wage?

For probing: e.g. low literacy rate, non-Western beliefs about illness, different attitudes to contracts and signatures, the role of third parties in decision-making (e.g. husbands or village chiefs) undue inducement.

III. Perceived capacity to review research and Training

- I. How would you evaluate your REC capacities in your Institution? / Country? (1-4 scale) Could you list the major barriers of REC effective functioning in Georgia? Could you please elaborate?
For probing: How he/she evaluates REC ability to review and monitor approved protocols?
- II. How would you evaluate Georgian RECs' composition? What is the optimal composition of REC? What is your opinion about inclusion of lay person in REC? What is the optimal number of REC members? What is your opinion about choose "top management" individuals a REC member?
For probing: perception concerning specialty of REC members? Importance and optimal number of lay person in REC? Balance between biomedical and non-biomedical representatives ? gender balance?
- III. How would you evaluate REC members' competence to review protocol? What should be the minimal requirement for REC members (e.g. Age, education, work experience, specialization, etc.)?
- IV. What do you know about research ethics education capacity? What do you think about training of REC members?
For probing: Education programs and courses at universities and research centers? On-line, distant learning programs)?
- V. Recommendations for addressing the issues concerning REC qualification and composition? **For probing:** the frequency of training? Who should be provider of such trainings?

IV. Awareness and Perceptions about Legislation

- I. What information do you have about regulations of REC activities in Georgia? What regulatory documentation is available in the country (local international)? How appropriate are international ethical guidelines for use in review of research?
For probing: Challenges of using guidelines? Socio-political-economic-cultural context represent issue? Is the law and guidelines adequately sensitive to the context? Is there any need in popularization of laws and guidelines?
- II. What is your opinion about local legislation and regulatory documentation concerning research ethics? What are the major weaknesses in research ethics regulations in Georgia?
For probing: National standards for operation of committees? Disclosure and management of conflicts of interest? Process whereby research participants can register and complaint?
- III. What do you think about regulation of REC system structure and activities? How should be it regulated (Law, bylaw or guidelines)? Please elaborate? Who should be in charge? What is your opinion regarding national ethical guidelines/local standard operating procedures?
For probing: How do you evaluate importance of development of National guidelines? (1-4 scale) why it is important to have one? How it can support REC activities? Does your REC have local standard operating procedures? Importance of local standard operating procedures in REC activities?
- IV. What do you know about Georgian REC performance monitoring and evaluation regulations and practices? Who is in charge for assessment of REC performance in the country? Please list the major problems and gaps existed with assessment of REC performance?
For probing: How is assessed quality of REC performance in Georgia? Existed regulations () and common practices? Existed
- V. What is your opinion about existing prohibitions? Does prohibition provide enough bases for prevention of misconduct? Please elaborate? What information do you have about existing sanctions for violations of Georgian legislation by IRBs and researchers? What are the main barriers and challenges for implementation of sanctions?
For probing: What sanctions might be introduced for falsification of information with the aim of receiving consent and prohibits publication of materials? Types of effective sanctions?
- VI. Recommendations for addressing the issues concerning REC regulation?
For probing:

V. Financial and Material Resources

- I. What do you know about financing of REC activities in the country? How important do you consider REC member remuneration? How is covered other expenses: office space, computer equipment, stationery, administrative support? Who in your opinion should finance REC activities?
For probing: REC financing mechanisms? Who should be in charge for regulating REC finances? How important is administrative support (having the paid person, who will be in charge of all administrative work)? If REC review process is paid will type of research, financial source (local or international funding), or other information matters?

VI. REC Independence

- I. What do you think about transparency of Georgian REC activities? Why it is important? How it supports human subject protection? How can REC activities' transparency be increased in Georgia? What information should be transparent? Why?
For probing: website, central or local?
- II. What is your opinion about Institutional pressure –“culture of corruption”? Does such exist in the country? Please clarify? What mechanisms do exist for management of the conflicts of interests in IRBs?
- III. What is your opinion about political commitment to improve REC functioning (e.g. stigma associated with the disease being studied) ?

After completing the in-depth interview:

We have finished with the interview today. Thank you for your time.

You have the paper with the name of the people who manage the research, their phone number, if you have any questions or concerns, at any time you can contact us.

5.	Time at the end of the interview	_ _ _ h _ _ _ mn
	Comments:	
	Interruptions during the interview: no/yes (frequency)	

For the interviewer: after having concluded the interview, please complete the interview report.

Matrix – Awareness and Perception – Challenges and barriers – Proposals

Themes	Awareness and Perception	Challenges and barriers	Proposals
Legislation	<p>Legislation is outdated. Since its introduction many changes have taken place in the country as well as in Bioethics field as well. For instance there were no surrogate motherhood centers and the ethical problems related to these activities. (IRB_04) 07 10. Policymaker_03</p> <p>„სუსტი მხარე არის ის რომ ზოგადია, დამოღიერარისის რომ კიდევ კარგად არსებობს“.</p> <p>.....“შიდათვი თონი მქანი ზმირარის და ზვეწილი რომ ჩამოაყალიბო (ეთიკის კომიტეტებს გულს ხმობს). რომ ჩამოაყალიბორა და ცაუნდა და ეფუძნო, თავიდან უნდა შექმნა? რას უნდა დაეფუძნო?</p> <p><u>სახელმწიფოში არსებულ გარკვეულ კანონმდებლობას და სარეგულაციო დოკუმენტებს? ისინი გარარისს რულფას ღვანო, სამწუხაროდ მაინც გიწევს მიმართოს აეროთას მორისონი რომათა რსებობას ანიმრეკომენდაციებს რომელიც არსებობს“.</u></p> <p>საქართველოს კანონი ჯანმრთელობის შესახებ არის კონკრეტული, ზოგადია“ იცით რა, ცალკეული ნორმები გარსებობს, რომელიც ერთკანონში გარარის თავმოყ</p>	<p>1. Local IRBs are not aware about Georgian legislation concerning research ethics and mostly use only international (mostly US) regulations in bioethics while carrying out ethical review of the research protocols. (IRB_01)</p> <p>2. International regulations provide basic principle which could be applied in most of the countries. There are specific sensitive topics due to diverse cultural and religious views which cannot be addressed in such documentation. The board is in charge to discuss the topic and make decisions on an individual basis. (IRB_01)</p> <p>3. Religious viewpoints by local Orthodox church may raise dilemmas in ethical review (IRB_01)</p> <p>Low interest and awareness of the issue among policymakers are a leading reason for denial to adopt new legislation: IRB_04 and _01</p> <p>3. Sanctions for violation of patients’ rights in clinical trials by government is a good initiative though there is a risk of using the sanctions by government officials without proper argumentation. 03, 016</p> <p>4. No participation of civil society in the development of existing legislation on bioethics. 07</p> <p>5. Basic ethical principle and approaches are acceptable for Georgian context as well, though nobody is enforcing to copy their regulations. There is a problem of qualification of so called experts who due to low English proficiency are making incorrect interpretations and increasing resistance toward</p>	<p>1. Development of national guidelines will support works carried out by IRB since there would be considered peculiarities of local context which is not addressed in international regulations. Though all these measures are not enough to guarantee the quality of the work. _01</p> <p>2. Non-governmental organizations and specialists should lobby adoption of changes in legislation_04</p> <p>3. Both government funded and international organization funded projects should undergo ethical review. 05</p> <p>4. Bioethics regulations should be separate legal document and not be spread in different legislations like it is currently, Since specific topics/issues like the rights of vulnerable population could be addressed in more details with indication of responsible sides who will be responsible for making decision and weighting the risks and benefits. 06</p> <p>5. Development of national and local guidelines is important to provide IRB members with clear guidance concerning IRB function, responsibilities and to prevent disapproval of the studies with high potential though difficult ethical issues (i.e. clinical trials on the patients with Alzheimer’s disease). 06</p> <p>6. Further development of the legislation is important though details concerning structures, functions and etc should be defined in legislative acts, for instance in the orders by ministry of health. 016</p> <p>7. Development of the law as well as the discussions concerning such document should involve as many specialists as it is</p>

	<p>რილი , არამედსხვადასხვაკანონშიაგაზნეული. ამიტომთუკანონმდებლობასეთისეი ცი, თუსურვილიგაქვსრომიცოდამზრეც ველაფერი, იმასაგროვებ“.</p> <p>13. <i>Policymaker_04</i></p> <p>განუვითარებელიაკანონმდებლობა. რამდენადცმევიცი, ესკანონმდებლობაეხებამხოლოდექსპე რიმენტულკვლევებს, drug trials დაა.შ. ხოლო observational დამსგავსიტიპისკვლევებზერადაცმეც იფიურისაკანონმდებლობაზადარეგუ ლაციებიარარსებობს.11. <i>Researcher_02</i></p> <p>There should be legal base for conduct regulation of IRB system IRB_04</p> <p>Overregulation is as dangerous as incomplete regulation IRB_04</p> <p>(There should not be introduced regulations which would restrict existence of the IRB for low workload) IRB_02</p> <p>Nowadays there is no need for stricter regulations or major changes in the IRB system considering the fact that most of the studies are observational and those which are clinical are carried out by western PIs. 03</p> <p>Sanction systems practiced in clinical trials are very effective . IN clinical trials violation of human rights or any procedures are strictly monitored and if such identified the study site is closed</p>	<p>adoption of new regulations. While adoption of regulations in bioethics there is given particular attention toward religious, ethnic and cultural characteristic of the country since approach toward each bioethical issue difference among countries and within the same society. 07</p> <p>6. Existing regulations defined in legal documents do not provide bases for development of adequate IRB system. Legal documents fail to equip local IRB boards with guidelines about procedures, quality control measures or any other issues. 13. <i>Policymaker_04</i></p> <p>7. Ratified international documents in bioethics or other areas are important guidelines or recommendations though for adequate functioning of IRB system there should exist comprehensive legislation at national level.13. <i>Policymaker_04</i></p> <p>8.</p>	<p>possible. The process itself should be transparent and actively communicated to the society. 016</p> <p>8. Development of national guidelines and written procedures. 13. <i>Policymaker_04</i></p> <p>9. As to the Draft Law, better to include this law in The Law on Healthcare, not to have as a separate law on the issue, because the biomedical research is a health problem in general. Separate chapters may be repeated in other laws, like human rights protection or the law on patient rights. Or it may be the separate law, but the regulation mechanisms should be in other laws. (Sanctions in the criminal law or other).</p> <p>Georgian journals should not accept articles without IRB/REC approval, and National organizations who are donors and financing biomedical projects, also should demand approval from REC. The law should include this information and detailed instructions on the issue.</p> <p>10. <i>Policymaker_03</i></p> <p>11. „ამსფეროსთვისსაზოგადოებამვერმოცილა. პრიორიტეტშივერხედავს, ვერხედავსმისფასეულობას. იმიტომრომვევრირამეჯერკიდევარიციანუფლებების, თავისისტატუსისშესახებ“.</p> <p>„უფლებებისშესახებკანონისპოპულარიზაციააუცილებელ ია. სიტყვასაჭიროებაამასძირეულადგამოხატავს. სახელმწიფოსხვანაირადარშენდებდამითუმეტესსამოქალა ქოსაზოგადოება“. კანონისპოპულარიზაციააუცილებელია, რადგანაცუნდაიცოდერაარისშენიუფლება, რომშემდეგმიხვდესადდაირღვესუფლება. 13. <i>Policymaker_04</i></p> <p>12. უამრავისაერთაშორისონორმატიულიაქტებისდასტანდარ ტებისარსებობისმიუხედავადუნდაარსებობდესეროვნული დოკუმენტი, რომელიცკონკრეტულიდადეტალურიიქნება. „იდელურივიარიანტია, რომარსებობდეს.</p>
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	<p>forever. 03, 08- CTR Researcher _03</p> <p>Nowadays there is more problem with enforcement of regulations rather than the content of the regulations existed in the legislation. However there is vague regulations and questions concerning what type of studies (sociological, bachelor and doctoral studies) should be reviewed. 05</p> <p>Farther development of legislation is essential both to provide adequate protection for study population and to support development of science in the country (no to biased disapproval for scientific research)06</p> <p>Bioethical issues are numerous and sophisticated. It is impossible to fit all regulations concerning bioethics (i.e. reproductive health, abortion, surrogate motherhood, etc.) in the Law on Health Care. 07</p> <p>There should be more comprehensive approach to human rights issues. Nowadays Patients' rights protection is gaining high attention though approach toward the issue is not always correct. HCWs rights are absolutely ignored. Society due to dishonest media reporting lost trust toward Health care personnel what is risky both for the professional and most importantly for the patients. 07</p> <p>Adoption of new laws in bioethics though is a good initiative since it will be more detailed regulations of bioethical issues, still it will not be the guaranty of improvement of bioethical regulations in the country. There is need for enforcement of existing law rather than introduction new one. One of the reasons</p>		<p>დაამავედროსიციოსგაწერილირომარაკნინებდესრაიმეუფლებასრომელიცდაცულიასაერთაშორისოდონეზედაჩვენთანრატომდაცარიენებადაცული“.13. Policymaker_04</p> <p>13.</p> <p>თურელურადიარსებებსახელმწიფორეგულაციისმკაფიომექანიზმი. დაუნდაჩანდესვალდებულებები. ნუგარკვეულისანქციურობისხასიათიუნდაჰქონდეთმათდარღვევას.</p> <p>ამშემთხვევაშიმედილებაგარკვეულისანქციებიარსებობსმაგრამარასახელმწიფოსმხრიდან.</p> <p>არამედმანდატისგამცემისტრუქტურებისმხრიდან.</p> <p>„ზოგადადკვლევისჩატარებაარისაქმიანობა, რომელიცკარგიიქნებარომსახელმწიფოშილიცენზირდებოდეს. ანუჰქონდესსახელმწიფოსმხრიდანაკრედიტაციისვალდებულება“.</p> <p>13. Policymaker_04</p> <p>14. ზოგადადერთანკანონისაჭირარის, კვლევებისშესახებ, რომელიცველასაპექტსმოიცავსბიოსამედიცინოკვლევებს დასოციოლოგიურკვლევებსაც.</p> <p>აუცილებელიარასანქციები (დარღვევებისთვის) კანონშიიყოსმიითითებულისკანონქვემდებარეაქტებშიანრეგულაციებშიუნდაარსებოდეს.</p> <p>არსებულიკანონპროექტიბიოსამედიცინოკვლევებისშესახებმაღალდონეზეადვოკატირებასსაჭიროებს.</p> <p>11. Researcher_02</p> <p>15.</p> <p>კვლევისთითიკისსისიტემისწარმატებისთვისპირველრიგშიკანონმდებლობაუნდაარსებოდესდასრულდებოდესრაცდაარეგულირებსამსისიტემას.</p>
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	<p>why current law does not work is inexistence of enforcement mechanisms. 016</p> <p>Legislation does not provide adequate guidelines for involvement of participants under 18 without approval of legal guardians when the goal of the study is to collect confidential information on IDU, STD, HIV of minors. Inexistence of consent-viewer practice in the country results in low response rates due to unwillingness of participants to inform their parents about the issues and also unwillingness of parents to let their children being involved in such studies due to social stigma related to the issue. 08, 13. <i>Policymaker_04</i></p> <p>Imbalance in regulations of different studies. There is inadequate regulations for observational studies and almost no for sociological studies unlike drug-trials . - 11. <i>Researcher_02</i></p> <p>კვლევისეთიკისკომიტეტებისარარსებობასხვა, არასამედიცინოსფეროებში, მაგალითადსოციოლოგიურიკვლევებისთვის.</p> <p>„საქართველოშიგანსხვავდება, მაგალითადსოციოლოგიურიკვლევები არითვლებასამეცნიეროკვლევადმხოლოდბიო-სამედიცინოკვლევებითვლებასამეცნიეროკვლევად“.</p> <p>ბიოეთიკისკომიტეტებიძირითადადკვლევისუცხოურისპონსორისმოთხოვნის.13. <i>Policymaker_04</i></p>		<p>აკრედიტაციისსისტემაკარგიიქნებოდა, იმიტომრომყველაშემთხვევაშიუნდაიყოსრაღაცკონტროლისმექანიზმები. უცხოეთისმოდელისაღებაშიიღება. აქისეგვანონმდებლობასთანმივდივართ, არარსებობსკანონმდებლობა, შესაბამისადარგრეგულაციებიარარსებობს. სერთიფიცირებისგაკეთებაცსაჭიროიქნებაარაქმუნდაყველასთვის. ეგბელსშეუწოვსთვითონადგილობრივიტრენინგებისდან ერგვასიგვემკვლევაარებისათვის, ესყველაპროცესიიმასმოიცავსრომიყოსაკრედიტაცია, იყოსტრენინგიდაიყოსგანხილვახო? ესერთიანსისტემაშიუნდაგანიხილოს...</p> <p>ანგარიშებაცუნდაიყოს, რაღაცენტრალურორგანოში. მაგალითადჯანდაცვისსამინისტროშიანმსგავსდაწესებულებაში, სადაცმობდებამისიაკუმულირება.</p> <p>(შერჩევითიწესითშიიძლებაშერეგაკონტროლება, ვთქვათ, შეირჩესერთიკომიტეტისსამიკვლევადავნახოთროგორიარისმიმდინარეობაროგორიისარისდოკუმენტწარმოებაროგორიყოდაშესაბამისადმსგავსისახეშიიძლებაიყოსალბათ)იმემაჩნია, რომუნდაიყოსრაღაცმთავრობისდონეზე, სამინისტროსდონეზე, რაღაცადეპარტამენტთანრაღაცოფისი, რომელიცპასუხისმეგბელიიქნებაამისგანხორციელებაზედავალდებულებამასთანყოფიდაარარაღაცენტალურიკომიტეტთან.</p> <p>ცენტრალურიკომიტეტიიქნებაშიიძლებაარაღცრეგიონულიკომიტეტიყოს, თბილისისკომიტეტი, იმერთისკომიტეტიანრავიცირაღაცგეთითორემ...</p> <p>ცენტრალურიკომიტეტი...? იმისფუნქციებირაიქნებაამინ, ისიცგანიხილავსჩვეულებრივადდათანსხვასშეამოწმებს? რაღაცკოტარამგონიაეგსწორიიყოს.</p> <p>.11. <i>Researcher_02</i></p>
Respect for the person	Confidentiality	1. Unwillingness to sign consent document due to Fear of beak	

		<p>of confidentiality (IRB_01)</p> <p>2. Protection of confidentiality in Georgia represent an important issue. Particularly in the health care where information flow exists on many levels starting from administration, medical personnel, to patients, etc. Currently we could say that no information is confidential. 016</p>	
	Undue inducement	<p>1. Economic and social status of the country and low access to medical services and expensive medication in big majority of the population creates base for undue inducement due to problems defining level of the incentives offered to the study population and having no alternative for the patients.(IRB_01 and 06)</p> <p>2. Enrolment of participants in clinical trials might be problematic considering low access to qualified medical care in the country. Though not unique for Georgia IRB_02</p> <p>3. Risk with amount of incentives. Incentives in form of cash for IDU are the best motivation to be involved in the study and to bring others to recruit in the study. Amount should be low enough to prevent them purchasing drugs.08</p> <p>4.</p> <p>ჯერჯერობით საქართველოში სპარამეტრი გაუგებარი ათ ურარის საშუალო ხელფასი, მინიმალური არის, ვერ ვიგებთ საიდან დარგორით ვლუბადარეალობაში და არა ამ ციფრებთან მიმართებაში ის თანხა არის თუ არა იმ საზღვარს ზემოთ რომელიც შეიძლება ჩათვალოს როგორც ძირითადი მოტივაცია კვლევაში მონაწილეობის დახელი შეუშალოს მისალტრუის ტულომენტს და გულახდილობას ასევე.</p> <p>“რატომ გვაქვს ჩვენ სოციალურად მისაღები პასუხები ქვეყანაში, იმიტომ რომ თითოეულ ადამიანს არაქვს გაანალიზებული რამდენად მნიშვნელოვანია ეს თუ ის კვლევა მისთვის.</p> <p>„კვლევის სუბიექტმა იცის რომ ის პლაცებოჯგუფში შეიძლება მოხვდეს, მაგრამ მაინც იმიდით მიდის რომ სხვაალტერნატივა არაა ქვს. იმ ქვეყნებში სადა ცალტერნატივა არის,</p>	

		<p>პაციენტს რომ ჩაკეტილი ხოდა მონაწილე, აღმოჩნდება რომ მას გაანალიზებული აქვს ეს რისკი და შეგნე ბუღალდში დისამრისკებზე, იმიტომ რომ ფიქრობს იმიოზანზე რაც მომავალში შეიძლება“</p> <p>13. <i>Policymaker_04</i></p>	
	Informed consent	<p>Low informed consent culture:</p> <p>Researchers as well as patients express low interest in consent information. 02</p> <p>Patients afraid to sign consent document due to low security of confidential information. -02</p> <p>Obtaining consent for participation in the research raises suspicion among potential participants since previously (during soviet system) patients were rarely involved in decision making concerning their health unless there was high risk for their life. The similar situation became one of the main reasons for low HBV vaccine uptake in maternity houses. Requirement to obtain Mother's approval was only introduced after introduction of HBV vaccine in national immunization schedule what increased suspicion among mothers that vaccine might be dangerous for their children and resulted in low vaccine uptake. 05</p> <p>No practical experience in obtaining informed consent from minors and people with disabilities. 06</p> <p>There is need for qualified and dedicated staff who will be explaining content of Informed consent documents to the study subjects. 13. <i>Policymaker_04</i></p>	
	Not reviewed projects	1. Low awareness about bioethics among civil and scientific	1. Public is ready for changes in the IRB system_ increased axes

		<p>society_01</p> <p>2. Low scientific society and public awareness about research ethics and requirements for IRB review of research studies-0113. <i>Policymaker_04</i></p> <p>3. Most IRB applications are submitted by individuals and institutions with foreign funded grant projects and those with education in bioethics. IRB_01 05</p> <p>4. Some clinical trials carried out by Georgian physicians as part of their dissertation are not reviewed by any IRB basically because of the no information about such requirements among health care and public health specialists in the country. IRB_01</p> <p>5. International Clinical Trials are mostly approved and reviewed by foreign boards. While there is created boards locally they are either represented by incompetent people or exist formally only on the paper. 07</p> <p>6. Low political will to introduce changes_02</p>	<p>to information through internet_01</p> <p>2. National Programs should not require to be reviewed by IRB</p> <p>3. Public is unaware and not interested in ethical issues, more in politics -02</p> <p>3. Government should make it required for all international clinical trials to be reviewed by competent IRBs. Since some studies carry risks not only for study participants but also to national security (i.e. ethno-genetic studies) 07</p>
IRB system	<p>Inexistence of the IRB system results in lack of standardized and unified research ethics regulations in the country IRB_01</p> <p>There is no need for many IRBs in Georgia considering such low number of research studies carried out in the country. No big research market compared to developed countries. 05, 08 <i>CTR Researcher_03</i></p> <p>There is low need for IRG in regions due to almost no research activities carried out by local organizations. 06</p> <p>No coordination 016</p> <p>No information. 08 <i>CTR Researcher_03, 16, 14</i></p> <p>IRB system should have central agency as</p>	<p>1. There is no systems of mechanisms to monitor fulfillment of ethical requirements by researchers or identification of violations basically due to inexistence of financial resources - 01</p> <p>2. Development of Georgian accreditation system is problematic due to corruption culture in the country IRB_01 and -02</p> <p>3. Small country with Corruption culture and problem with identification of conflict of interest IRB-01</p> <p>4. Development of IRBs, RECs and similar committees usually depend on development active involvement of civil society in the country, which is less evident nowadays. 05</p> <p>5. Implementation of the system with central agency being in charge of motoring ethical review quality of all IRBs in the country will require big finances unrealistic for Georgian reality. 06</p>	<p>1. Introduction of the requirement for Reporting of IRB activities is a good idea, though not for control purposes but jut to have statistical data about IRB activities in the counytry-01, -02</p> <p>2. Development of registry in Georgia is the first step for implementation of monitoring system for local IRBs_01,</p> <p>3. There should be a registry for IRB and there should be common platform for register any scientific study -04, 06</p> <p>Central REC should become independent body and transform into association of bioethics which will not necessarily be associated with any governmental body, though its functions and competencies should be regulated by law. IRB should be part of social society. -04, 0713. <i>Policymaker_04-</i>, 10. <i>Policymaker_03</i></p> <p>Governmental organization should be in charge of control of IRB</p>

	<p>responsible body. 08 CTR Researcher_03</p> <p>ოღონდკარგიენებათუბიოსამედიცინ ოკვლევისკომიტეტიცალკეიენება, ხოლოსოციალურიმეცნიერებისკვლე ვებისცალკე.11. Researcher_02</p>	<p>6. Intensive Institutionalization of research ethics preceded the development of this scientific area in the country. From one side it was essential considering urgent need for existence of the system responsible for rights and well-being of research subjects, though on the other side it was challenging considering lack of qualified knowledge and experience in the field. 07</p> <p>7. IRBs in Georgia are mainly created when the organization is receiving international scientific research grants and the board is existing mainly on the paper and for very short period of time. These all makes it impossible for the board members to gain experience and increase proficiency in the field. 07</p> <p>8.</p>	<p>system: including registry, monitoring evaluation IRB_01</p> <p>Development of monitoring and evaluation procedures and mechanisms for scientific research projects to identify violations by site visits and study participant surveys. IRB_01</p> <p>Development of registry is important to develop data base about existing boards. However there should not requirement for recognition and licensing requirements for IRBs. 05</p> <p>Recommendations of central IRB should be disseminated both in the society and what is important provided to the decision-makers at top level. This can be conducted by implementing Central IRB in higher level of the governmental body (prime ministry, president office).07</p> <p>Only light monitoring system should exist. Reporting requirements should be more for self-evaluation purposes and not for control and for sanctions. Monitoring should be performed by institution itself. Particularly ministry of health care should not be the control body, since it will lead to unnecessary bureaucracy. Monitoring results should be used for quality improvement at that performing and other IRBs through information dissemination. 05, 06, 07, 14, 08 CTR Researcher_03,</p> <p>It is better if several research institutions have one IRB for number of reasons: adequate workload to gain experience and increase qualification in the field. 05, 07</p> <p>IRB should maintain as much independence as it is possible and prevention of violations from IRB members should be conducted by development of adequate criteria's for IRB members. 06</p> <p>Violations of regulations provided in Georgian legislation or ratified documents should be notified to ministry of health and also informed to civil society through broadcasting and particularly social media. 07</p> <p>Public health institutions should be in charge of regulation of ethical issues in the country. 014</p> <p>There should exist at least some control mechanisms in</p>
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			<p>bioethics at local governmental level since bioethics is part of human rights protection and thus one of the important duty of the government. 13. <i>Policymaker_04</i></p> <p>Accreditation system for researcher good quality control mechanism. Like in case of health care workers they would also be penalized with stopping the license and</p> <p>Accreditation should be excluded, because who will be then in charge and what kind of accreditation it will be? Ethics is rather difficult ... ethical standards are sometimes even more questionable than the legal standards. (Respondent means ethics in general, not only biomedical research). This is created on the voluntary community basis, this in not governmental . <i>Human Rights NGO Repr_02</i></p> <p>9. Vertical control and dependence is not a good solution. Control needs some rules, which may become blurred for Ethic committees. If you were to work with target groups, who would be responsible for REC creation: managers or medical personnel, invite religious representatives, lawyers, patient representatives, NGO representatives, than it would let community to control from one side, and medical personnel interest to solve ethical dilemmas on the other. <i>Human Rights NGO Repr_02</i></p> <p>10. It is a good idea to review difficult projects or issues by the “central” REC, but this “central” REC should not be responsible for control of other REC’s.</p> <p>IRB’s/REC’s should communicate and have conference in bioethics annually, to present their experience.</p> <p>Control may be done periodically by the team, who would check IRB’s randomly (how IRB’s solved some issues and so on).</p> <p>There should be sanctions for infringements, starting from the very light (warning) to the highest – deprivation of license or other. <i>Human Rights NGO Repr_02</i></p> <p>10. I am against of the Control of the RECs’/IRBs’ work, coordination is rather important and needed. Something like “consultation organ” which will be responsible for providing</p>
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			<p>certificates, guidance. Control is difficult and connected with financial and human resources. I think it may be professional union or association for researchers. Researchers should ask for the consultation first, after given advice and recommendations, and then the association should check or control the work, like once in a month or year ask for the done work. But again, it will be better free exchange of information, coordination and agreement of RECs' and ensure their maximally union, but not control.</p> <p>It is necessary to create the motivation; researchers should know that research means research subject and that there is the governmental regulation on the issue, or ethical standards that are recognized by the Government.</p> <p>It is reasonable to have just few RECs in the country formed by professionals.</p> <p>10. Policymaker_03</p> <p>11. ეთიკისკომიტეტებიანგარიშვალდებულიუნდაიყენენერთი სმზრემკვლევარის(ვისკვლევასაცაფასებს) დამეორესმზრისახელმწიფოსმიმართ. უნდაარსებოდესსახელმწიფოსკონტროლისმექანიზმი.ანგარიშვალდებულებამოითხოვსსტრუქტურებისარსებობას, რომელთასაქმიანობაცსახელმწიფოდონეზეუნდაიყოსმომოხილულიდაშეფასებული. ესმოითხოვსვალდებულებისგაცემისრეგულაციასდაშემდეგმონიტორინგისსქემას.</p> <p>13. Policymaker_04</p>
Education	<p>1. Bioethics training for IRB members is crucial particularly considering generally low Bioethics awareness and knowledge in the country. 04 and 01 and 02</p> <p>2. Online training courses are effective to update and increase knowledge in</p>	<p>1. No formal education courses available in Georgian universities-02, 03</p> <p>2. Low willingness, interest and even resistance of specialists in medical and biological sciences toward Bioethical education. 07</p> <p>3. Education about ethics is very short and carried out mostly</p>	<p>1. Qualification requirements for IRB members: CITI or other training in bioethics, experience and knowledge in scientific programs. .R02</p> <p>2. Criteria for IRB members should be defined in legal documents -01, 06</p>

	<p>bioethics IRB_01 and IRB_02</p> <p>3. Regular class trainings are interactive and thus considerably more effective to receive knowledge in bioethics. It gives opportunity to ask questions and receive response. IRB_01, IRB_03</p> <p>4. Good Clinical Practice trainings are very crucial for researchers involved in clinical trials. It contains modules on bioethics though more accent is made on study procedures. IRB_03 (CTR Researcher)</p> <p>5. Education for IRB members in clinical trials in bioethics is <u>favorable</u>, though more import is that the member is well qualified and experienced in their areas like : law, nursing, research or specific medical specialty (hematology, neurology, etc). 03</p> <p>6. There is no need long trainings in bioethics for researchers. Short trainings provide required basic knowledge for specialists involved in the research. 05</p> <p>7. IRB members should mainly represented by people with no medical, biological and research background since there is more risk for putting scientific interests higher than those of human subject. 05</p> <p>8. Training in bioethics, particularly concerning the rights of vulnerable population like those with mental disorders was helpful for development of legislation concerning mental health. 06</p> <p>9. Adequate bioethics and deontology trainings are important to implement in residency courses to address issues</p>	<p>on lower courses at universities, while it should be continues education. Particularly high attention should be paid to the courses learned on master and PhD programs. 07</p> <p>4. The terms bioethics and research ethics are often misleadingly considered same as Medical ethics. 07</p> <p>5. Formal education is available only for medical faculty students or those pursuing high academic degree (MS, PhD) in medicine or public health, while there are number of other areas like law and sociology where is also high demand for bioethics since people of these direction are also involved in research on human subjects. There should be formal education available for students at faculties as well.13. <i>Policymaker_04</i></p> <p>5. h</p>	<p>3.Bioethics education should be mandatory at graduate education programs at universities though not sure about adequacy-04 and 01</p> <p>4. At least 5 bioethicists should be educated in a year.02</p> <p>5. Short 1-2 weeks training in bioethics in major research institution is recommended in Georgia. 01</p> <p>6. Development of education materials: books on bioethics. 07</p> <p>7. Important is to organize trainings for stakeholders (for clinical administration, managers, lawyers) what is IRB, how it works, what are by laws, how they work, what will be results. The other issue is that IRB's should be very interested in having a strong bioethical team. <i>Human Rights NGO Repr_02</i></p> <p>8. It should be mandatory for REC members to have training in research ethics, certificate should be mandatory. Certificate should be given by national REC (central REC?). 10. <i>Policymaker_03</i></p>
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	<p>concerning low trust to health care workers and unawareness about patients' rights. 06</p> <p>10. Having diploma or certificate in bioethics should not be mandatory if person has experience and high moral standards. 014</p> <p>11. No formal education. self-educated 13. <i>Policymaker_04</i></p> <p>12. Trainings were very important to develop scientific research projects, taking into account issues for research subjects protection 11. <i>Researcher_02</i></p>		
Financial support	<p>IRB staff member remuneration is essential if the frequency of the review activities is more than 1 protocol a month. From the other side if a board does not review more than 1 protocol a month than quality of performed activities decreases. R-02</p> <p>Remuneration for IRB members is the best way to increase their motivation as well as responsibility for the work carried out in IRB.</p> <p>IRB_0113. <i>Policymaker_04</i></p> <p>In the US like in case of blood donation, the volunteer donors are the best donors, those IRB members who are not receiving remuneration are the best one as well. However remuneration for IRB members in Georgia is a good idea and can may even improve quality of the review and support protection of patients' rights in Georgia. 05, 07</p> <p>Financial remuneration for IRB members</p>	<p>1. Remuneration may become the source of corruption-02</p> <p>2. In Georgia most of grant project have very limited budget that may become reason for allocation money for IRB review_02</p> <p>3. No remuneration is the main reason IRB members and invited experts are less willing to allocate adequate amount of time from their busy schedule on the review of study protocol. 03</p> <p>4. The fact that nowadays government is unable to finance scientific projects due to difficult economic situation in the country represent important barrier to introduce strict human subject regulations and requirements by the government . In case government had resources to provide funds it would have more power and interest to introduce control mechanisms in the area of research ethics to guarantee that the government money is not allocated to scientific studies where is violated human subject protection principles. 05</p> <p>5. Low prestige of IRB membership status and lack of space for bioethics discussions for specialists and civil society. 06, 07,</p>	<p>1. Remuneration for IRB members should come from grant projects and in case of association there should be established member fees. -04 and 01,</p> <p>2. Financial support for IRB should be provided by government. At the beginning it could be provided in the framework of grant project. R-02</p> <p>3. No difference in amount of fees for local and internationally funded projects -04 and -01</p> <p>3. Partial financial support for IRB activities by government, institution and research project budget. 03</p> <p>4. Financial support should not be allocated from research projects since it may become the reason for conflict of interests. Institution should support its research ethics boards. 05</p> <p>5. Increase prestige of IRB membership status. To make bioethics and IRB membership popular in the country there should be developed journal in bioethics where will be publishes articles about bioethics issue in Georgia and worldwide , violation identified in the country, etc. Also more conferences should be conducted to develop promote discussions on bioethics topics. 06</p> <p>6. Financial support for IRB should come from the institution</p>

	<p>nowadays is not important considering low load of IRBs. However in the future when we will have increased number of studies with higher requirements for thorough ethical review remuneration should be evaluable for IRB members and invited experts. 05</p> <p>IRB member position should not be remunerated due to high risk of corruption and conflict of interest. 06</p> <p>Undecided 014</p> <p>Financial motivation is always good idea. 016</p> <p>There should not be financial remuneration for ethic committee members. Mercantile considerations for those people who would really be interested should not be an issue. "But the people dedicated to this, should possess high ethical quality." <i>Human Rights NGO Repr_02</i></p>		<p>itself.08</p> <p>7. RECs need financial resources, maybe Ministry of health will admit it and put the proposal into the budget, but no one will create a new structure for these purposes.</p> <p>მეცნიერობისუნდაიყოსსამინისტროსმიერადიარებული, გარკვეულიფუნქციაგადაცემული, კანონშიგაწერილიფუნქციაგადაცემული, დაწესებულებაში ____/გაუგებარია 21:12/, რომელსაცეცნებასაშუალება, პირველრიგში, ბიუჯეტიექნებაამისი, სახელმწიფოსმიერმიცემული</p> <p>If the RECs' work will be financed by the Government, then Government will be responsible for REC's control, (if the number of reviewed studies is much more than the budget? This is dilemma, so better to have financial support from the reviewed study budget, not from the government)</p> <p>Governmental budget should give financial support to the national REC, REC member's trainings, guidance, work of the committees, but review of the projects by the each REC should be financed from the project budget. This should be written in the law. 10. Policymaker_03</p> <p>მეზოგადადმომხრევაროესკვლევებითუფინანსდება, შესაბამისადბიუჯეტშიშეიძლებასულერთიპუნქტიჩაემატოს, რომელთანაცდაკავშირებულიაისხარჯებირომელიცუნდაგასწიამდასკვნისმიღებაზე.</p> <p>იცისადშეიძლებასახელმწიფოებდესთანხას? გარკვეულაღჭურვაზე, აიბაზაზე. ოფისიიქნება, ინტერნეტი, კომუნალურიხარჯიდაა.შ. დამეორეარისკვალიფიკაციისამაღლებისხარჯი. 13.</p> <p>Policymaker_04</p>
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Transparency	<p>Current situation – no transparency -01, 016</p> <p>Transparency of the information will support increase of population interest and awareness about bioethical issues and regulations. 05,</p>	<p>Total transparency of the IRB activity information carries risks related to misinterpretation and violation of basic ethical principle – respect for the person, particularly considering high interest of media to publish information on medical errors. Like in case of HIV/AIDS and gay population (when first announced to be identified in gay population it became the stereotype and reason for stigma and discrimination) researchers and scientific society overall might be discriminated. Though transparency is crucial information should be provided with big caution. 07. 13. <i>Polymaker_04</i></p>	<p>Results but not the process of the IRB review should be public 04</p> <p>For increase control over clinical trial subject's rights some information should be available for government and society, though it should be unidentifiable data (no names, last names or other personal data). Clinical TR researcher_03</p> <p>Central IRB should develop website with bioethics regulations and other required information for specialists. 08 <i>CTR Researcher_03</i></p> <p>It's a good idea to have website, which will be confidential and only for IRB's, it may contain statistical information or difficult issues. IRB's may interact with each other using this site. Bylaws of the IRB may state what kind of information and who would be responsible to put information on the site. Site also may contain names of someone who "broke the rules". <i>Human Rights NGO Repr_02</i></p>
Quality	<p>Quality of IRB review in clinical trials are better considering the fact that it is initiated and managed by US or one of the European countries who have bigger experience and better regulations for ethical violations. Besides as local as well as foreign researchers are highly motivated to follow regulations considering the fact that usually in case of violation the study sites are closed _02</p> <p>Most of research studies are given IRB approval with no actual review. 01, 06</p> <p>Local IRBs are flexible and almost never provide disapproval on the project protocol. "It never made researchers work difficult". That is important for</p>	<p>IRB though have documentation of conducted activities there is low load of applications for IRB review 02</p> <p>No bioethics specialists (low overall competence in bioethics + undefined criteria for membership) are available in the country (due to no formal education available at universities) what increases the risk of turning IRB into bureaucratic system. 02, 06, 07</p> <p>Low willingness and motivation of IRB members and invited experts to allocate adequate amount of time from their busy schedule on the review of study protocol. 03</p> <p>Quality control is the key for improvement of local IRB work. However it cannot exist without adequate policy. It is difficult to evaluate efficacy and overall quality of local IRBs. If we use international partner's (donors, IRB and RECs of foreign universities and institutions, etc.) satisfaction as a parameter than we may conclude at least there were no ethical violations</p>	<p>Improvement of the quality might be reach with:</p> <ul style="list-style-type: none"> - increase public awareness about ethical issues (explain that it is not additional autocratic requirement and not the one introduced by foreign scientists but their own interest) - Develop education courses and master studies in bioethics - legislation is less important.02 <p>3. Advocacy for reforms in research subject right protection regulations will be a first important step for development of the field and improvement of the quality of IRB review in the country 03</p> <p>საქართველოს იმ იმპორტის მქონე და დანახონრომების კანმასადგასრომლის მოთხოვნა შესასრულებელია. ორგანიზება უნდა სწორედ, კამპანია უნდა შედგეს. აბსოლუტურად სწორი,</p>

	<p>researchers. 0813. Policymaker_04</p> <p>თუშევაფასებთეთიკისკომიტეტებისმუშაობას 1 დან 4 ქულამდე - ვარშეცემდივერანაისციფრს, რადგანაც - „სახელმწიფომიჯერჯერობითესქაოტურსიტუაციშიადაარარისჩამოყალიბებული“ არცარსებობსინფორმაციამათიმუშაობისშესახებ.13. Policymaker_04</p> <p>რეგულაციებიდარწმუნებულისვაროკარგადარკედებაეფეულაფერი, იმიტოროგანათლებაარაქვთშესაბამისი ამეჩიბებსდამკველევარებს.11. Researcher_02</p>	<p>taking place in the country. There should exist monitoring system to assess the quality which again requires development of policy. 13. Policymaker_04</p>	<p>შესაბამისდროსშესაბამისიადამიანებიუნდაიყოსშეწუხებულნიდამათიდანტერესებამომენტშიუნდაიყოსაუცილებლობათავისიპოლიტიკურიქულებისდაწერისრა.13.Policymaker_04</p> <p>ლობისტებიუნდადაიქირავო, პარლამენტარილობისტები, რომლებიციმუშავენენიქპარლამენტშიდაწამოიწყებენამას.. . ლობიზმისაჰირო, ადვოკატირებადალობისტობასაჰიროამპროექტის, შეიძლებაფულიდამით... არცარავისარააქვსმაგისფულიმაგრამამოინახოსგზები, შეხვედრებიგამართოსპარლამენტშიუთხრანრომესმნიშვნელოვანია, შეხვედრებისამინისტროში. ვინცდისიქენმეიქერიამათუნდამიეწოდოსრაპრობლემარისდარამდენადაუცილებელია, რასკვრავავთ, ქვეყანარასკვრავსამითი... მედიაცშეიძლებაჩაერთოს, მთავარიდაარწმუნო (დისიქენმეიქერები) რომესმნიშვნელოვანია.11. Researcher_02</p> <p>4. უნდაარსებოდესერთიანიზაზა, სადაცშევაყველაკვლევისდაამკველევასთანდაკავშირებულ იდარღვევებიდაშესაბამისადინფორმაციამკველვარისშესახებ (ჰქონდათუარაიმედარღვევა).(მაგრამესარუნდაიყოსფართოსაზოგადობისთვის)</p> <p>მაგალითადმკველვარისმიერდარღვევისშემთხვევაში - მიეცესმასგაფრთხილება, ცუდშემთხვევაშილიცენზიისჩამორთმევად/ანხელახლაკვალიფიკაციისთუკრედიტაციისგავლა. თავიდანშეფასდესმისიციოდანდაუნარები, მეცესკიდევახალიშანსი.</p> <p>ეთიკისკომიტეტებისრაოდენობაარარისგადამწყვეტი, მნიშვნელოვანიაიმუშაობისხარისხიდაწევრებისკვალიფიკაცია, პასუხისმგებლობა, მოტივაცია.</p>
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			13. <i>Policymaker_04</i>
Public awareness	Low public awareness about rights IRB-03, 016		<p>To increase public awareness study results must be informed to them. 07</p> <p>Prioritization of the research ethics and bioethics in the country and putting it in our government officials' agenda is important for bioethics policy development and farther improvement. Big social campaign with participation of all stakeholders (i.e. public, patient groups, researchers, IRB members, journalists, etc.). The campaign should include development of qualified and motivated group of people and initialization of public discussions through bioethics in media channels. 13.</p> <p><i>Policymaker_04</i></p>