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Πρωτότυπη Εργασία

Ethics & Governance of Research: Focus on Research Ethics Committees globally, disparities across regions and the understanding of the structures and systems in place for publicly available information

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Abstract

This publication presents the findings of the Research submitted for the degree of MRes in Bioeconomy Biotechnology & Law that was conducted in May 2022 at the International Hellenic university in Thessaloniki, Greece. The original research purpose was to gather information on the coherence or disparities that exist in the current environment within the established ethics committees on the country or regional level. Several elements were taken into consideration on their structural systems in place in terms of: governance, standard operating procedures, trainings, and reporting systems (internal but as well as external)] but the outcome of this research serves also as a baseline as "the outcome of a person's understanding (author) on the current environment based on publicly available information" to reach to the desired result which is to establish a clear understanding on the current procedures of the ethics committees from a person without extensive knowledge or constant exposure to their inner environment. Therefore, there are two elements that were simultaneously under research.

This article presents the results based on the findings of this research but as well the barriers (limitations and restraints) contributing to their understanding. The author provides closing recommendations on the organizational level but as well on a fundamental level to provide alignment but as well as a request for clarity on the existing publicly available information in a manner that is easy to understand to the simple reader which contributes to transparency on research.

Keywords: governance of research, ethics research, ethics committees, understanding of the current procedures of ethicσ committees.

Δεοντολογία και Διακυβέρνηση της Έρευνας: Εστίαση στις Επιτροπές Δεοντολογίας της Έρευνας παγκοσμίως, ανισότητες μεταξύ περιοχών και η κατανόηση των διαδικασίων και συστημάτων απο πληροφορίες δημοσίως διαθέσιμες στο κοινό

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Περίληψη

Το παρόν άρθρο παρουσιάζει τα αποτελέσματα της έρευνας που υποβλήθηκε για την απόκτηση του μεταπτυχιακού τίτλου: Έρευνα στη βιοοικονομία: βιοτεχνολογία και δίκαιο τον Μάιο του 2022 στο Διεθνές Πανεπιστήμιο της Ελλάδος στη Θεσσαλονίκη. Ο αρχικός σκοπός της έρευνας ήταν η συλλογή πληροφοριών σχετικά με τη συνοχή ή τις ανισότητες που υπάρχουν εθνικό/τοπικό ή περιφερειακό επίπεδο των επιτροπών βιοηθικής και δεοντολογίας. Υπόψη ελήφθησαν διάφορα στοιχεία σχετικά με τα διαρθρωσή τους και λειτουργικό τους συστήμα όπως: τη διακυβέρνηση, τις τυποποιημένες διαδικασίες λειτουργίας, τις εκπαιδεύσεις και το συστήμα υποβολής εκθέσεων (εσωτερικών αλλά και εξωτερικών εκθέσεων)]. Το αποτέλεσμα αυτής της έρευνας χρησιμεύει επίσης ως βασική γραμμή πληροφοριών ως προς "το αποτέλεσμα της κατανόησης ενός ατόμου (συγγραφέα) προς το τρέχον περιβάλλον με βάση δημόσιων διαθέσιμων πληροφορίων" προκειμένου να φτάσουμε στο επιθυμητό αποτέλεσμα το οποίο είναι η σαφής κατανόηση για τις τρέχουσες διαδικασίες των επιτροπών δεοντολογίας από ένα άτομο χωρίς εκτεταμένη γνώση ή συνεχή έκθεση στο εσωτερικό τους περιβάλλον. Ως εκ τούτου, υπήρξαν δύο στοιχεία που ήταν ταυτόχρονα υπό έρευνα.

Στο παρόν άρθρο παρουσιάζονται τα αποτελέσματα με βάση τα ευρήματα αυτής της έρευνας, αλλά και τα εμπόδια που συμβάλλουν στην κατανόησή τους. Ο συγγραφέας παρέχει τελικές συστάσεις για την οργάνωση των επιτροπών σε θεμελιώδες επίπεδο για την ευθυγράμμιση τους και θέτει αίτημα για σαφήνεια σχετικά με τις υπάρχουσες δημόσια διαθέσιμες πληροφορίες με τρόπο ο οποίος να είναι εύκολα κατανοητός στον απλό αναγνώστη, το οποίο συμβάλλει στη διαφάνεια στην έρευνα.

Λέξεις κλειδιά: διακυβέρνηση της έρευνας, ηθική της έρευνας, Επιτροπές Ηθικής και Δεοντολογίας, κατανόηση των τρεχουσών διαδικασιών των επιτροπών.

Introduction

This chapter contains an introduction to the world of bioethics, the history, the dilemmas, and presents the need for Ethics Commissions around the world to establish collaborative trust in order to support research.

1.1 Research Ethics Committees - Role, structure & function around the world

Our world is a unique and diverse place. With the evolution and expansion of scientific knowledge, new technologies, discoveries, inventions and treatments have emerged. In parallel, new national governmental policies and strategies, national regulations, and international agreements, have been set in place in response to these emerging trends resulting in new professional attitudes while societal culture and norms provoke discussions which escalate to new bioethical debatable dilemmas.

On a historical basis, there is a strong foundation in establishing and ensuring that research is conducted in an ethical manner deriving from the involvement of humans and experimentation that has taken place in the past. Few of the most well-known and large-scale examples are the atrocities and experiments done in concentration camp prisoners during World War II at Nazi, Germany (1933-1945) [1] resulting in the establishment of the Nuremberg Code (1947) [2]. Several years later The Nuremberg code was followed up with the rise of a research code of the World Medical Association that evolved into the Helsinki Declaration (1964) [3] which is the core of clinical research. Another example is the Tuskegee Syphilis Experiment (1932-1972) [4] that was carried out in Tuskegee, Alabama, by the United States Public Health Service which led to the Belmont report (1979) in the USA and the creation of the National Human Investigation Board [5].

The World Medical Association's Declaration of Helsinki and the Council for International Organizations of Medical Sciences' International Ethical Guidelines for Biomedical Research Involving Human Subjects (hereafter, CIOMS International Ethical Guidelines) (2002) [6] established the following requirement as the international standard for biomedical research: "All proposals out to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and Ethical Review Committees". The investigator must obtain the relevant approval or license or clearance before undertaking the research" (CIOMS, Guideline 2) [6]. This set the requirement for involving human subjects in research which established the need for the creation of Institutional Review Boards (IRBs) known also as Research Ethics Committees (RECs) and provided them with the authority and the responsibility for approving or disapproving proposals to conduct research.

RECs can be established in different structures and by different institutions, like Parliaments, Ministries, Universities, Authorities, Research Institutions, and others. RECs review study proposals that involve human participants in research or research done in the broader sense that involves humans and/or animals, or biological material to ensure with the intention to adhere to international, - but today mainly primary - national / local ethical guidelines that are acceptable by the norms, monitor studies once they have begun and, when is deemed necessary, follow-up and monitor beyond the end of the research. Additional functions that RECs serve are: setting policies, publish opinions on ongoing ethical issues in research and offer oversight and support (Research Ethics Consultation Services). The functions of RECs include identifying and measuring the potential risks and benefits of the research; evaluating the process and materials (printed documents and other tools or means) that will be used to ensure the informed consent of the participants (current main focus), assessing the recruitment process and any incentives that will be given to participants, evaluating risks and protect participants' confidentiality, any potential risk of discrimination, the adequacy of confidentiality and examining any other issues that may affect the ethical acceptability of the research. Ultimately, RECs have the authority to approve, reject, pause or even stop research that requires modifications to their protocols and operating

procedures in order to ensure that the research is conducted in an ethical manner [7,8].

Considering the last reference above "Ethical Manner" brings up the key question of "What constitutes a manner as "Ethical" or "Non-ethical" when our world is such a diverse place that includes different cultures, diverse perspectives, different religious believes, vast differences in political and governmental systems and finally different healthcare systems with different levels of structures, support and set societal responsibilities from each stakeholder's side across the world. As this question rests in the hands of our RECs globally, this research has mapped according to available information found the RECs and IRBs globally. The detailed findings from the research which is deposited to the repository of the International Hellenic University could potentially serve also as a guide to identify areas that potentially lack oversight and may assist on building further establishment or capacity in RECs or IRBs with the ultimate purpose to establish trust in research across the world.

1.2 Distinction between legal provision and ethics; guidelines and recommendations

International ethical standards for research involving human participants, as well as national / local laws in many jurisdictions, require review by Research Ethics Committees. This review is also essential if researchers intend to publish their findings, as most medical journals will not publish findings that have not been approved by a Research Ethics Committee. The primary role of a Research Ethics Committee is to protect potential participants in research, but it must similarly consider potential risks and benefits to the communities in which the research is conducted, promoting high ethical standards in health research [9]. International collaborative research may need to be validated under the laws of the research funding country, even if the host country's own laws do not require it [9].

Law is a set of rules created and enforced through social or governmental institutions to regulate behavior and sets a basis of minimum expectation of commonly expected behavior. Law follows certain practices and customs in order to deal with crime, business, social relationships, property, finance, and more. In the context of application of Biology and Medicine law is often referred as "Biolaw". The subject matter of biolaw can be defined as "the legal rules that govern the management of life as natural phenomenon, which includes the whole of the laws that regulate every kind of interference with the biological nature of species" [10].

The Oviedo Convention is the most widely known legally binding international instrument that contains provisions defining and protecting fundamental human rights in the medical field. The Oviedo convention incorporated into law the principles of modern medical ethics. It also contains provisions on human genetic and biotechnological applications, clinical research, transplantation and embryo research, and the prohibition of commercial use of humans [11].

In addition to laws established in each country that have the force to be mandated and are obligatory to follow there are the "soft law" instruments. Soft law is the term applied from instruments (UN, UNESCO, COE) which are sets of non-binding texts, as their purpose is not to compel to adopt enforceable rules inspired by common standards, but rather encourage them to do so [12]. This process allows countries to adhere to commitments that they would not otherwise enforce through their political system. Guidelines are a set of specific rules of good scientific, technical or ethical practice adapted to specific objectives and usually incorporated into "protocols" [10].

Over the years, with plenty of support from organizations and members of various scientific fields a number of existing international guidelines, statements and declarations relating to bioethics have developed, such as: The Declaration of Geneva [13], Declaration of Helsinki [3], Declaration of Tokyo [15], Declaration of Taipei [15], Declaration of Malta [16], Declaration of Lisbon [17], Declaration of Ottawa [18] CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) [6], WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) [19], Nuffield Council on Bioethics , The ethics of research related to healthcare in developing countries.

London, (2003) [20], The Universal Declaration on Human Rights and Bioethics, UNESCO (2005) [21], The Universal Declaration on the Human Genome (1997) [22], The International Declaration on Human Genetic Data (2003) [23], UN Declaration on Human Cloning (2005) [24], UNAIDS/WHO, Ethical Considerations in Biomedical HIV Prevention Trials (2007) [25] and more. An important part of the journey is also the operational procedures kept. This is referred to both operations throughout the research which is ensured by guidelines equally to operational procedures of the RECs that approve research. As such the WHO has published a set of operational guidelines for Ethics Committees That Review Biomedical Research (WHO Geneva 2000) [19].

These policy statements even though exist in the form of non-binding documents have set the founding stones, supported, or reinforced the establishment of the bioethics Commissions around the world. Additionally, they serve as an informal document council for the transformation of research morals into guidelines.

1.3 The importance of Bioethics in research; The four bioethics principles

All the declarations and guidelines mentioned above have a common denominator. The protection of the individual and placing ethics at the core of humanity. Ethics is based on well-founded standards of right and wrong and does not conform to a specific set of rules or policies. Rather, it provides a framework for evaluating problems and determining an appropriate course of action.

The term Bioethics places ethics in the particular context of medicine and biology. It a set of principles that define, uphold a minimum basis and defends basic human values, e.g. the right to life and health, respect for dignity and autonomy, examines ethical issues and dilemmas arising from health status, health care and research involving humans. Mutually recognized research ethics principles globally encompass not only the principle of minimizing harm while respecting autonomy and dignity, protecting privacy, ensuring informed consent, ensuring equality, inclusivity and diversity, while demonstrating social responsibility. Such as the UNESCO Universal Declaration on Bioethics and Human Rights (2005) recognizes the primacy of human values and fundamental rights, regardless of cultural differences (different ways of human life) [21].

Ethical dilemmas are highly taken into consideration from multiple perspectives, need to be open and diverse and find means to support innovation. Today, there are four principles that have been identified and have been commonly accepted by researchers, medical practitioners, and institutions: The principle of respect for *autonomy*, the principle of *Non-maleficence*, the principle of *Beneficence* and the principle of *Justice* [26]. Therefore, RECs in order to protection the individuals would need to uphold the set the four principles when evaluating any proposals and perform an analysis. In their core RECs are established for the protection the individuals and research done and not to impede research [27]. Any ethical analysis should reflect both internationally accepted norms and locally relevant cultures, nurture diverse perspectives and backgrounds and show respect, for our communities, for our planet and for all living beings. In addition, it needs challenge assumptions or unconscious bias to ensure that consequences are explored through a wider lens than ones'self and own perspectives. Cultural factors must also be taken into consideration in respect to the protection of one's beliefs and individuality [28]. Furthermore, there are vulnerable groups for which particular care should be taken. For example, people with physical or mental restrictions for that unable to consent, people in captivity, people enrolled in the military, subordinates to a researcher, minors, orphaned children, and the critically ill. Additional attention and special care is also to be provided to indigenous populations (eg. Oceania). In fact, it is supported that human research ethics in indigenous populations are to be informed by their indigenous principles and values for relevance and applicability [29]. The diversity of views, opinions and being able to withdraw impartial conclusions based on non-biased information requires adequate knowledge and training of the people taking decisions and assessing research. Ethics must be a radical

interdisciplinary endeavor, drawing and building up on knowledge from the humanities, social sciences, natural sciences, but also from other disciplines, as such, RECs must have a diversity in their members but also deep understanding and expertise in order to be able to assess and identify complex issues [30]. It is important to develop an awareness of the practical and philosophical issues of implementing ethical codes in research practice to support the needs of those engaged while ensuring that the integrity and implementation of fundamental ethical principles and guidelines are understood and practiced within the discipline as ethical research not only protects the research itself but also the future of research in itself and research that will be conducted based on previous research.

Although laws regulating research exist in several countries, many National Ethics Committees (NECs) mention/reported that research can be conducted without ethical review [31]. There are countries that lack the support to promote research and they are challenged seeking adequate funding and training on a fundamental level [31-36]. Therefore, a noticeable gap is observed in the referenced countries in research whether that is on funding or building frameworks. In addition to developing national frameworks in countries that lack such regulations, further efforts are needed to ensure compliance with existing laws. These challenges confirm the general concern that despite the existence of international research ethics standards, there is a need to develop policies that are sensitive and relevant to the local environment of emerging market countries as supported by the findings in the Eastern Mediterranean Region [37].

1.4 Complexity of current issues in healthcare that rise ethical dilemmas

There is an instilled and constant thinking about appropriate regulation and governance concerning new technologies that embrace innovation with deep uncertainty and unpredictability in the environment. This derives from unexpected situations such as epidemics or wars where ones' often confronted with puzzling questions of how to fit novel concepts into an old preset mindset or how to further develop and build on already established concepts when facing new insights and technologies that stretch beyond simple conflicts of principles. Such as digitalization, which has also contributed to the complexity of issues in this environment and has also accelerated new technologies even further [38]. In the context of these situations, one needs to consider our old concepts in new terms, accepting and be mindful of the past, translating the old into the new and discover terms connecting the past with the present. Few examples could be as to, what is autonomy in the digital age where artificial intelligence can build concepts of its' own. What is "natural" in the context of genome editing. What position are is society is holding on challenge studies and which is our responsibility when looking into the stakeholders but as well the rightsholders. There is also an additional layer of complexity that is shared from the above-mentioned questions when people are confronted issues of great societal importance with strong ethical dimensions. These problems are called "wicked problems". A wicked problem is a problem that is very difficult or impossible to solve because of shifting problem statements, disagreement about what counts as relevant expertise, diverging ideas about its causes, and incomplete, contradictory and changing requirements for solving the problem. Because the problem definition itself is contested or constantly shifting there is not a single solution to a wicked problem [39]. Emerging technologies in their first moments of conception are causing discussions which as seen as wicked problems.

Increased the complexity and additional ethical dilemmas rise when different types of conflicts exist when research is taking place. Besides the complexity in decision making that emit from ethical dilemmas, supporting research in practice also especially when funds are taken into consideration. Conflicts of interest from different stakeholders exists such as healthcare companies, patients, healthcare professionals, healthcare facilities and governments in the context of ownership of the data derived from the contribution of each in the process. For example, there are different conflicts on supporting research done that is based for a small group of people such as in rare diseases which

bestows a high cost of the treatment or cure of a disease to the individual or to society [30].

Our society is interconnected in many levels beyond our differences. For example, in the past, travel was a challenge. With the evolution of technology today the distance between two countries has been minimized more than ever. In a few hours you can be in another country and if you are willing to reach the further ends of the world you probably can. Over the years people have not only traveled and lived in other countries but also migrating to other countries living either as residents or seeking citizenship. In this diverse environment which has embraced the diversity in their society when technological innovations taken into consideration, the progress over the last years and the scientific discoveries, our world has become extremely dynamic. Our societies today are hyper-connected. A recent contributing factor that accelerated the environment was the Covid19 pandemic. This pandemic focused on the immediate need for vaccines with innovative methods that sparked extensive considerations on ethics in research for the protection of humanity that challenged our norms.

An additional layer that adds further ethical dimensional complexity is government funded research. Government funded research is using public funds, collected from taxpayers within the country from the laws that exist in that specific country. Therefore, there is the need of ethical consideration when it comes to research from the financial perspective ensuring the robustness and reliability but also from the ethical outcome of the research when it comes to ownership of data and data sharing and ensure transparency on the processes while safeguarding any personal information. Privacy breaches (access to data without the appropriate authorization through hacking, stolen equipment of data storage and more) can also occur, unauthorized transfers of data (accidental or unlawful destruction, loss, alteration, unauthorized disclosure of or access to, personal data transmitted stored or otherwise processed or transferred) and ethical considerations and additional clarity is needed when it comes to repurposing of data without having the consent for a specific use.

Violations of those requirements either perceived or actual, are considered unethical practices and can have significant and severe consequences for the public when it comes to our collective perception of trust in science and can initiate a rolling negative effect [41,42]. Lack of adherence to relevant laws and codes could result in criminal, administrative, and civil penalties including steep fines, prison time, and exclusion from participation in federal programs.

According to the European Group on Ethics in Science and New Technologies, society is viewed, in a socio-political context where citizens are at the center of inclusive and participatory governance, with innovative means of democratic participation and public participation and is structured by people who are interdependent, not atomistic individuals. Ethics is an integral part of all policy making, governance and management [31].

Throughout the complexities that innovation brings, the wicked problems, deep uncertainty that exists and unforeseen consequences that might occur, there must be a common denominator in order for research to advance and Ethic committees serve an important role that demands to be further supported.

2 Summary, findings and discussion

This research was conducted collecting available information across the globe from the world wide web which serves as the main source of easy access to publicly available information. The findings of the primary research are presented and analyzed in a form of discussion below. All data and information presented were collected using multiple online tools (Health research web, research gate, google search and google scholar) from as what could constitute as “trusted sources” selected by the author. The findings were all listed in detail in the extensive research which is published at the repository of the Hellenic University. The information gathered is categorized by country in an alphabetical order and divided across geographical regions in the following “chapters” format: Europe, North America, LATAM (Latin America), APAC (Asia-Pacific), Africa and Middle East (ME). The findings include a short summary of the available information

accompanied with the number of established RECs or IRBs and additional notes. The regional findings and collective efforts are presented and listed separately than the local findings and both call for a shift from informal efforts to formally supported actions. At the end the author provides recommendations based on these findings and the limitations imposed with the ultimate purpose enhance even further the strong foundation of trust in research.

2.1 Projects and Cooperative programs findings across the regions

As ethical awareness has risen across the globe over the last years, countries with no presence of RECs and IRB have found ways to support each other in terms of solidary and cooperation for research especially in early years of the establishment of RECs. Multiple global commitments have been made over the past years and even a dedicated body was established to support the development of health research systems capacity with a focus on low and middle-income countries known as the Council on Health Research for Development (COHRED) [43]. Likewise, UNESCO has established the "Intergovernmental Bioethics Committee" (IGBC) in 1998, under Article 11 of the Statutes of the International Bioethics Committee (IBC) which is comprised of thirty-six (36) Member States whose representatives meet one time every two years to examine the advice and recommendations of the IBC [44]. The IGBC informs the IBC of the opinions and submits them with proposals for follow-up of the IBC's work to UNESCO's Director-General which are distributed to the Member States, the Executive Board and the General Conference. The thirty-six (36) Member States are elected by UNESCO's General Conference upholding cultural diversity and balance in their geographical representation. The members serve for terms of about four years, from the end of the ordinary session of the General Conference in which they are elected until the end of the second subsequent ordinary session. States elected at the 40th session of the General Conference; members of the IGBC until the end of the 42nd session (Autumn 2023). The other States remain members until the end of the 43rd session (Autumn 2025) [44].

Another body that has formed is the Caribbean Network of Research Ethics Committees (CANREC). CANREC is an established network founded by the Caribbean Public Health Agency (CARPHA) with the cooperation of Research Ethics Committees RECs/IRBs across its their member states for which under this research limited information was available. In turn, CARPHA serves as the principal regional institution which is responsible for defining and responding to the public health priorities of its twenty-four (24) member states. The esbalished authority collects every information on all research projects every year which are approved by the RECs/IRBs in the member states of CARPHA and is stored in their research protocols registry. The requisite data must be submitted using their official Research Registry. The research registry serves as a portal that provides access to evidence-based research across the region, to assist bodies forming policies and related stakeholders in implementing their research findings [45]. CARPHA was initially the Caribbean Health Research Council (CHRC) which has developed the Health Research Policy for the Caribbean. The main subject of the Policy document includes the proposed structure for health research systems in the Caribbean (at the national and regional levels) and strategies to promote their strengthening. It is expected that it will be adopted (or adapted) by CHRC member countries and thus provide the necessary framework as they continue the process of developing/strengthening functional national health research systems [46].

In addition, there are several International organizations formed to support Ethics in research such as: European Group on Ethics in Science and New Technologies (EGE) [47], EU: Forum of National Ethics Councils (Forum NEC) [48], The Council of Europe: Bioethics Committee (DH-BIO) [49], OECD Internal coordination group for Biotechnology [50], UNESCO Bioethics Program Partnerships [51], WHO: Ethics and Health [52], European Network of Research Integrity Offices (ENRIO) [53], Regional "Think Tank" Supporting Health research in Latin America [54].

All the above-mentioned bodies are formed to support and advance research, educate the public and researchers in order to build trust and a strong unshakable foundation for health and protection for all the members involved.

2.2 In-country Findings and Discussion:

The outcome of this research based on the understanding of a person dedicated on searching information has shown that: There are three (3) types of ethic review systems that were found under the current research. Ethic reviews are performed on 1) National Bioethic Committees with a centralized system (such as: New Zealand, Iceland, Portugal, Congo, Malawi, South Africa). In many countries there is the presence of at least one National Bioethics Commission and in a few countries, there are even two National Bioethics Commissions (such as: Cameroon, Malawi, Tanzania and Ethiopia) established. 2) Governmental System for ethics review (such as: Korea, China) and further consideration in the above-mentioned countries where limited information was found where under the WHO the ministry of health was reported as a NBC with no further information of IRB/RECs established in the country 3) Most common system is the decentralized mix system where there is the presence of NBC and REC/IRB (most of the countries. The de-centralized system is developed as such as there oversee from the national bioethics commissions to the RECs/IRBs/ECs within the countries but there are also independent reviews and approvals from them with no oversight or monitor. In a number of countries there is a presence of Councils also which are independent organizations to support ethics in research, discuss and provide consultations and opinions when requested (Such as: Austria, Germany, Bulgaria, Czechia, Denmark, UK and more) but it is unclear under this research if ethic reviews are performed by the council or matters in ethics, are taken into consideration and under which level are factored. Although in Germany in the references, the importance of the Council was highlighted and there was a mention that the government is taking in high consideration the recommendations proposed by the council. Unique findings under this research were: 1) Poland, where no NBC exists, the WHO has listed the Ministry of health as a NBC even though there is the presence of IRB/REC in healthcare facilities and institutions. 2) USA where there was a NBC established in each state. 3) Small countries or islands where no Bioethics Commission was found or even no healthcare regulation system in place or at least limited information was found to report under the current research (ex. Djibouti, Equatorial Guinea, Guinea Bissau, Sao Tome, Mauritania, Swaziland, Togo and rest of non-listed or non-reported under the current research).

On additional communications efforts, in Austria, Sweden (and other countries) there is an annual conference held which is supported under the multidisciplinary approach and enriches the presence of diversity, inclusion, and support voicing of opinions which serves to the purpose of establishing trust, openness, transparency, and support in research. The author can also report that in many countries the NBC and the Councils were holding trainings either formal or informal to uphold the minimum or acceptable standards in research and support research in general, but this is not the case in most countries. There is very little information available on the training methods, consistency, competences or levels of proficiency.

In Canada, there is a well-developed system of ethical review board for funded projects and clear authority and distribution of the project that are being carried out to ensure the protection of the participants in research, same as in Finland, Sweden and UK.

In some European countries such as in Sweden, integrated portals and management application systems have been found where ethical processes are reviewed within the country and the researchers can apply and track their applications but also in non-European countries as well such as Thailand.

Digitalization efforts are observed and simplification in submissions and processes is seen. CANREC has found a way to establish a regional presence in the terms of solidary. Africa has developed considerably the last years with the assistance from multiple EU funded projects to assist research. Although as reported above there is a lack of training and infrastructure and

funds in order to be present. Europe has considerably the most information available.

An additional finding was that in El Salvador, there are no provisions that require legally approval of clinical trials by law but there are non-binding provisions that require approval that must be kept. As the findings were limited and possibly outdated, further research is recommended to the subject matter.

In the web from different sources digital tools have been developed that summarize the functions, legal provisions, guidelines across different countries. The information is spatial and, in many cases, outdated but it is open and free to the public or any party interested but this is another thing to take into consideration that effort has been given to uphold ethics and provide information widely to the public.

Noteworthy findings that contributed to this research are websites developed such as the: WHO research engine of national ethic commissions [55] and the European Network of Research Ethic Committees [57] and the Health Research Web powered by COHRED [58]. An additional useful tool that was found but not used under the current research was the "Committee finder" developed from the free online course Clinical Research Regulation in the Netherlands. This tool provides guidance to help researchers find a suitable committee or other organization to review their clinical trial applications in the Netherlands according to the type of research performed or the addressed population (adults, children, pregnant women etc.) [59].

An additional finding of this research was the fact that due to outdated information that exist on the web, search for relevant laws and regulations has an increased complexity and the author of this research recommends the development and association of outdated and speared information to be updated and then placed as sort of "archive information" from the web but distinct from the current setting.

Even though there is no mention individually per country in the country in the original research, most of the information available and found under the scope of this research was focused on the: 1) diversity of the members but in many cases without further explanation of their manner diversity (ethnicity and background) 2) meetings per years as an administrative procedure and 3) mentions on trainings taking place sporadically without consistency. Diversity, meetings held to ensure multiple functional procedures and visiting on the subjects and trainings that contribute to properly set the understanding and set expectations for the protection of the research ensure a foundation for the establishment and function of the RECs but more encouragement is given to expand the focus even further as now are moving from establishment to expansion. RECs could broadly share more information of their structural elements but as well as for processes kept within the organization (e.g. ethics review on the structural procedures of the review process, on the capabilities of the individual members who take part in the decision-making process or further support trainings throughout the country). The effort to communicate RECs processes will contribute to shifting informal procedures kept, rethinking functional (from an operational perspective) elements and ultimately reaching the governance structure. Simultaneously this action may elevate the standards of many countries as procedures kept and well-set principles could serve as a reference element and an example for other countries, to reach our aspirational goal and place also procedures as a functional element of the core value which is the protection and safeguard of everyone participating in the research process. If research is carried out in a uniformly and "ethical" way and builds a foundation with a base of trust, then further research upon the starting research can take place with no doubt that it may be shake one day. This builds on a strong foundation of trust for future research to take place.

A question that this research could raise is if there is an efficiency scale to determine if the establishment of too many Ethic Committees could be not functional. There is a strong foundation for ethic committees to be as many as possible, independent and multidisciplinary but as there is a clear lack of funds, trainings and unclearness of the process kept this brings up the question if the RECs/IRB are efficient and proficient to perform assessments.

Another finding of the research by the author was the fact that in almost all material found concerns were raised about the insuffiency and lack of funds as most RECs or NECs operate with minimum funds and are not recognized. Comparing the number of the RECs listed above, the collective knowledge of their members, the diversity and personal support of the members involved is real evidence that our society holds morals as the base. Looking for EC as a collective power and knowledge this research builds a strong business case which support the establishment of EC.

2.3 Limitations

Limitations are considered barriers in spreading knowledge and therefore an important part of this study was to also present the restrains found during this research. To begin with, a limitation imposed was to establish a clear understanding of the existing laws, regulations, functions, and systems especially when pre-existing, non-updated, limited information is available online and establish a clear roadmap on the developments that occurred in each country. As the findings were limited and possibly outdated, further research is recommended. In most countries there is not a systematic update of the status in the relevant field since there is not a systematic procedural disclosure of such information to the public especially from one single source. In fact, new legislations come into force and guidelines are updated but there is not a fixed period when the changes occur which increases the level of difficulty on obtaining updated information. Moreover, Bioethics Commissions in several cases are re-established and their scope of activities change and on occasions even the naming itself changes. In addition to the disrupting changes, there is the constant systematic change as well which is a natural occurring process (ex. rotation of the members or boards, the procedural updates). When both cases of changes occur (disruptive and natural) and at the same time there is not a clear roadmap and constant update of information or a track record for the Commissions and Councils then a procedural doubt for the clarity on the available information exists.

An additional barrier that contributed to this factor is the language barrier as a large number of the information was only available in the native language and even presented in documents especially in legal rules, provisions and decrees. For the comprehension of the documents found online translators were used (e.g. Google translate, DeepL. translate) even on the handwritten publicly available documents with text on camera method.

Furthermore, under the current research the distinction between the review scope of the ethic committees on clinical level and research level has been hard to determine. Findings under this research, but not reported in the summary of the countries, was that some countries had a system of evaluation levels on the type of clearance that each Bioethics Commission could provide. There is need for structure and clarity and for clear responsibilities to be assigned a lack of the responsibilities of each structure and processes kept in order to place in action, the core purpose that Bioethics Commissions hold which supports the claim that harmonization is needed in ethics in research. Researchers have done tremendous work behind supporting research and protect individuals with minimum funds in the past years.

Lastly, when describing the type of presence or entity that each advisory body holds, there were interchangeable references used such as: “association”, “organization”, “advisory body” etc. and limited reference or no reference to their formal type or presence.

2.4 Recommendations

The author of this research recommends to the National Bioethics Commissions established in each country to perform an evaluation of the status in research acting as centralized systems to align with international recommendations and expand their scope of activities with constant updates providing a of flow of information, ensuring legislation is aligned with the current international guidelines, respecting individual and cultural elements but challenging the norms and procedures kept in each country.

Call for clarity:

There is publicly available information but without coherence or structure there is no clarity. What constitutes as "publicly available information" expectation that is already set must encompass a data quality component (accuracy, completeness, timeliness) with a preset manner and establish the means to access the information.

Call for funds on ethics & research:

Today there are different structured ways and levels of maturity on ethics in research in each country. Several elements such as the organizational models/procedures, process of taking and enforcing decisions, a coherent reporting system, efficient trainings methods, rethinking the current operating procedures challenging and even minimizing unnecessary procedures encompass an additional form of contribution to research which is setting the appropriate structure to support research in various ways. Therefore a call must be made for bioethics commission to look more closely on their ways of working in a supported manner.

Moreover, NBC could possibly be encouraged to publish opinions on the status of the established IRBs/RECs, perform a gap analysis to detect potential areas where improvements could be made within the country but as well as with international recognized standards, provide support with trainings if needed (or additional outlets for support such as congresses) to create a stronger foundation of trust between researchers, governments, and institutions for the protection of participants and society as a whole. Therefore, this research could also prove to be a useful asset to international organizations (such as: European Commission) to issue guidelines on harmonization of RECs in Europe with other entities.

A final recommendation that could be collectively explored is for the bioethics commissions to be established under a new paradigm as a neutral independent presence in each country, acting as protectors of research for humanity in different countries. A new environment has formed due to the emerging needs in terms of collaboration among different structures. Setting and empowering bioethics commissions to serve their already preset duty for the protection of all participants in research may serve as the connective solution and as a reply to the needs for further collaboration between the preset systems and frameworks that clash in the current environment.

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BIBLIOGRAPHY

1. Holocaust online encyclopedia, developed by the United States Holocaust Memorial Museum, Accessible via: Nazi Medical Experiments, Holocaust Encyclopedia (Accessed: 26/05/2022).
2. The Nuremberg Code (1947) BMJ 1996; 313:1448.
3. Declaration of Helsinki, 6th revision WMA Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects - WMA - The World Medical Association (Accessed: 26/05/2022).
4. Thomas, S. B., & Quinn, S. C. (1991). The Tuskegee Syphilis Study, 1932 to 1972: implications for HIV education and AIDS risk education programs in the black community. American journal of public health, 81(11), 1498-1505.
5. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. Washington, DC, Department of Health, Education and Welfare, 1979.
6. Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization. 2002. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva, Switzerland.
7. Baumann- John R., Mullins-Owens H., Russell D., Waltz A., (2015) Chapter 1 - Human Subjects Research Protections, Editor(s):

Mark A. Suckow, Bill J. Yates, Research Regulatory Compliance, Academic Press, 2015, 1-20.
8. NIS - (2020) Research Ethics Committees overview, Accessible via: Research Ethics Committees overview - Health Research Authority (hra.nhs.uk) (Accessed: 26/05/2022).
9. Gelling L. (1999)Role of the research ethics committee. Nurse Educ Today. (7):564-9.
10. Vidalis T.C, (2022) The Emergence of Biolaw: The European Experience and the Evolutionary Approach, Springer.
11. Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) Oviedo Convention and its Protocols (Accessed: 26/05/2022).
12. Abbott, K., & Snidal, D. (2000). Hard and Soft Law in International Governance. International Organization, 54(3), 421-456.
13. World Medical Association (1948) Declaration of Geneva, Accessible via: Declaration of Geneva - WMA - The World Medical Association DECLARATION OF GENEVA The "Modern Hippocratic Oath" (Accessed: 26/05/2022).
14. World Medical Association (1947) Declaration of Tokyo, Accessible via: Declaration of Tokyo - WMA - The World Medical Association DECLARATION OF TOKYO Guidelines for Physicians to Prevent Torture (Accessed: 26/05/2022).
15. World Medical Association, Declaration of Taipei, Accessible via: Declaration of Taipei - WMA - The World Medical Association DECLARATION OF TAIPEI Research on Health Databases, Big Data and Biobanks (Accessed: 26/05/2022).
16. World Medical Association (1991) Declaration of Malta, Accessible via: WMA Declaration of Malta on Hunger Strikers – WMA – The World Medical Association WMA DECLARATION OF MALTA ON HUNGER STRIKERS (Accessed: 26/05/2022).
17. World Medical Association (1981) Declaration of Lisbon, Accessible via: WMA Declaration of Lisbon on the Rights of the Patient – WMA – The World Medical Association WMA DECLARATION OF LISBON ON THE RIGHTS OF THE PATIENT (Accessed: 26/05/2022).
18. World Medical Association (1998) Declaration of Ottawa, Accessible via: Declaration of Ottawa - WMA - The World Medical Association (Accessed: 26/05/2022).
19. World Health Organization. Product Research and Development Team. (2000). Operational guidelines for ethics committees that review biomedical research. World Health Organization. (Accessed: 26/05/2022).
20. Nuffield bioethics. The ethics of research related to healthcare in developing countries. London, (2003) (Accessed: 26/05/2022).
21. UNESCO (2005) Universal Declaration on Bioethics and Human Rights, Paris. Universal Declaration on Bioethics and Human Rights, UNESCO (Accessed: 26/05/2022).
22. UNESCO (1997) Universal Declaration on the Human Genome and Human Rights (Accessed: 26/05/2022).
23. UNESCO (2003) International Declaration on Human Genetic Data (Accessed: 26/05/2022).
24. GENERAL ASSEMBLY ADOPTS UNITED NATIONS DECLARATION ON HUMAN CLONING BY VOTE OF 84-34-37, Meetings Coverage and Press Releases (Accessed: 26/05/2022).
25. Joint United Nations Programme on AIDS. Ethical considerations in biomedical HIV prevention trials (Accessed: 26/05/2022).
26. WHO Ensuring ethical standards and procedures for research with human beings (Accessed: 26/05/2022).
27. Beauchamp T, Childress J. (2019) Principles of Biomedical Ethics, 6. New York: Oxford University Press.
28. Hudson, M., et al. (2010) Guidelines for Māori research ethics: A framework for researchers and ethics committee members, Te Ara Tika Health Research Council of New Zealand, 23.
29. UN General Assembly. United Nations declaration on the rights of indigenous peoples. UN Wash. 2007;12:1-18.
30. Tzermpinou A. (2022) Qalys, Dalys and value of life, Bioethica 8(1).
31. Abou-Zeid, A., Afzal, M., & Silverman, H. J. (2009). Capacity mapping of national ethics

committees in the Eastern Mediterranean Region. BMC Medical Ethics, 10, 8.
32. Abou-Zeid A, Afzal M, Silverman HJ. (2006) Informed Consent as an Ethical Requirement for Health Research in the Eastern Mediterranean Region of the World Health Organization. PRIM&R Conference, Washington, DC.
33. Abdur Rab M, Mamdouh R. Ethics in health in EMRO: practices and perceptions among health researchers in the Region. Global Forum for Health Research. 2004.
34. Hyder AA, Wali SA, Khan AN, Teoh NB, Kass NE, Dawson L. Ethical review of health research: a perspective from developing country researchers. Journal of Medical Ethics. 2004;38:68-72.
35. Benatar SR. Reflections and recommendations on research ethics in developing countries. Social Science & Medicine. 2002;54:1131-1141.
36. Dickens BM, Cook RJ. Challenges of ethical research in resource-poor settings. International Journal of Gynaecology and Obstetrics. 2003;80:79-86.
37. Abou-Zeid, A., Afzal, M., & Silverman, H. J. (2009). Capacity mapping of national ethics committees in the Eastern Mediterranean Region. BMC medical ethics, 10, 8.
38. Facca D, Smith MJ, Shelley J, Lizotte D, Donelle L (2020) Exploring the ethical issues in research using digital data collection strategies with minors: A scoping review. PLoS ONE 15(8): e0237875.
39. Lavery JV. (2018) 'Wicked problems', Community engagement and the need for an implementation science for research ethics, Journal of Medical Ethics;44:163-164.
40. European Commission (2021) European Group on Ethics in Science and New Technologies - Values for the Future: The Role of Ethics in European and Global Governance, Brussels.
41. Jennings, W.; (2021) Lack of Trust, Conspiracy Beliefs, and Social Media Use Predict COVID-19 Vaccine Hesitancy. Vaccines 2021, 9, 593.
42. P. R. Ward, K. Attwell, S. B. Meyer, P. Rokkas & J. Leask (2018) Risk, responsibility and negative responses: a qualitative study of parental trust in childhood vaccinations, Journal of Risk Research, 21:9, 1117-1130.
43. COHRED (2006) Supporting national health research systems in low- and middle-income countries. Annual Report 2005, Geneva.
44. Briefing note on the Intergovernmental Bioethics Committee (IGBC) - UNESCO Digital Library (Accessed: 26/05/2022).
45. Caribbean Network of Research Ethics Committees, CARPHA, Caribbean Network of Research Ethics Committees (Accessed: 26/05/2022).
46. Caribbean Health Research Council (2011) Health Research Agenda for the Caribbean ST. AUGUSTINE, TRINIDAD AND TOBAGO (Accessed: 26/05/2022).
47. European Group on Ethics in Science and New Technologies (EGE), European Commission (Accessed: 26/05/2022).
48. EU: Forum of National Ethics Councils (Forum NEC), European Commission (Accessed: 26/05/2022).
49. The Council of Europe: Bioethics Committee (DH-BIO) Bioethics at the Council of Europe (Accessed: 26/05/2022).
50. OECD Internal coordination group for Biotechnology (Accessed: 26/05/2022).
51. UNESCO Bioethics Programme Partnerships, Bioethics (Accessed: 26/05/2022).
52. WHO: Ethics and Health (Accessed: 26/05/2022)
53. European Network of Research Integrity Offices (ENRIO) (Accessed: 26/05/2022).
54. Regional "Think Tank" Supporting Health research in Latin America (2006) COHREDRP6 Health Research Systems Development in Latin America (Accessed: 26/05/2022).
55. World Health Organization (2022) National Ethics Committees Accessed: 26/05/2022).
56. National Bioethics and Technoethics Commission in Greece, Επιτροπές Βιοηθικής (Accessed: 26/05/2022).
57. European Network of Research Ethic Committees EUREC - National information (Accessed: 26/05/2022).
58. Health Research Web powered by COHRED (Accessed: 26/05/2022).
59. The Committee Finder tool (Accessed: 26/05/2022).