Society of Medical Education & Research

2023, Volume 3, Page No: 66-80
ISSN: 3108-5059

Asian Journal of Ethics in Health and Medicine

A Comparative Study of Ethical Issues in the Egyptian Clinical Research Law

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Abstract

This study investigates the ethical dimensions of Egypt's newly enacted clinical trial legislation, employing the ethical framework of Emanuel *et al.* for evaluation and situating it within a comparative context alongside national and supranational laws. Given Egypt's emergence as a high-growth pharmaceutical market, the country has become a prime location for clinical research. Its extensive population, well-established healthcare system, and largely treatment-naïve patients provide a valuable setting for examining how bioethical regulations are applied in practice. We performed a comparative review of Egyptian law alongside regulations from Sweden, France, and the EU Clinical Trials Regulation. Using established criteria for ethical human subject research, a directed qualitative content analysis was conducted to systematically interpret the legal frameworks. The analysis was reinforced through rigorous peer review, repeated debriefing sessions, and consultation with legal experts experienced in international research law to ensure validity and depth. Across the seven ethical principles—social and scientific values, scientific validity, fair participant selection, risk-benefit ratio, independent review, informed consent, and respect for participants—the Egyptian framework displayed comparable alignment with French and EU regulations. Certain principles, including Social Value, Scientific Value, and Fair Selection of Participants, were difficult to assess directly due to their being addressed implicitly rather than through explicit legal statements. The study demonstrates that Egypt's clinical trial law broadly reflects internationally recognized ethical standards as outlined by Emanuel *et al.*, comparable to French, Swedish, and EU frameworks. Nonetheless, findings underscore the need for ongoing refinement, particularly regarding the definition and operationalization of social value and the expertise and neutrality of ethical review boards. These considerations suggest a continuing agenda for strengthening research ethics practices in Egypt and beyond.

Keywords: Social value, Ethical principles, Biomedical laws, Clinical trials, Egypt

Introduction

Progress in science fundamentally depends on research, which drives the expansion of knowledge. Various fields of research involve human subjects to differing degrees, ranging from qualitative, non-interventional studies to biomedical investigations and medical validation procedures. Although nearly all forms of research carry ethical considerations, clinical research demands particular scrutiny, as it is widely acknowledged that it must adhere to more stringent ethical standards than other research types [1]. To ensure research is ethically conducted, it is crucial that ethical regulations evolve in step with scientific advancements. The protection of participants' well-being is a cornerstone of research ethics, emphasized in landmark documents such as the Belmont Report (cited in [2]) and the Helsinki Declaration (see [3]). These guiding principles stress participants' right to have harm and discomfort minimized [2] and to be shielded from exploitation [4].

To evaluate compliance with ethical requirements and guarantee adherence to international standards, it is essential, as suggested by Artal and Rubenfeld [5] to consider established ethical principles in research. Practices that were once deemed acceptable in scientific circles may now be regarded as morally unacceptable [6].

Access this article online https://smerpub.com/

Received: 21 March 2023; **Accepted:** 19 June 2023

How to cite this article: Bratt A, Naimi-Akbar A. A Comparative Study of Ethical Issues in the Egyptian Clinical Research Law. Asian J Ethics Health Med. 2023;3:66-80. https://doi.org/10.51847/mjnPnkn27U

Ethical norms are also context-dependent; societies with unique cultural values and traditions may only partially align with the ethical principles embedded in international standards, creating potential gaps between local acceptability and global ethical compliance. Nevertheless, concerns about ethical colonialism and inherent biases are difficult to eliminate, as many international documents predominantly reflect Western perspectives [7].

Despite these challenges, some documents serve as widely recognized ethical benchmarks, including the Belmont Report and the Helsinki Declaration, both of which provide guidance for protecting human participants in medical research [8]. Another significant reference is the Ethical Framework for Biomedical Research by Emanuel *et al.* [9, 10], which has profoundly influenced ethics practices in institutions such as the South African Department of Health (DoH) and the Council for International Organizations of Medical Sciences (CIOMS). In research ethics, this framework has frequently been used to evaluate the performance of ethical review committees and assess the adequacy of legal regulations governing human subject research [11–13]. Rooted in major Western philosophical traditions yet not confined to any single school of thought, the framework establishes a set of principles designed to achieve broad consensus while accommodating diverse moral perspectives and beliefs.

The introduction of regulatory frameworks in new contexts provides a valuable opportunity to examine how contemporary bioethical laws are applied, as observed in studies involving BRICS countries [14]. In this light, Egypt's 2020 Bioethical Law represents an innovative model for other nations developing bioethical regulations and advancing bioethical education [15–17]. Recognized as a low- and middle-income country (LMIC) by the World Bank [18], yet classified as a "high-growth pharmaceutical market," Egypt has emerged as a prime location for pharmaceutical companies to conduct outsourced clinical trials. With a population exceeding 100 million, the country offers a notable setting to implement bioethical legislation in a context featuring predominantly treatment-naïve patients and a well-established healthcare infrastructure, including public hospitals and professional representation.

The present study aims to provide an ethical analysis of Egypt's new clinical trial law. This analysis is conducted using the Ethical Framework for Biomedical Research by Emanuel *et al.* [9, 10] and includes a comparative examination with selected national and supranational legal frameworks.

Egypt

Egypt is among the latest countries to implement formal bioethical legislation governing clinical research involving human subjects. Its inaugural law on clinical trials was published in the official journal on December 23, 2020. Although this law had been in preparation for several years, the urgency created by the COVID-19 pandemic—particularly the need to conduct vaccine trials among the Egyptian population—accelerated its adoption [19]. The legislation forms part of broader efforts to strengthen respect for civil and human rights within the nation. However, US Embassy reports in 2022 highlighted ongoing challenges [20], signaling concerns about equity and fairness in society, which can affect ethical practices in healthcare and research. As a United Nations member since 1945, Egypt has participated in international initiatives aimed at promoting human rights [21]. Like other Arab nations registered in the UN Watch Database, including Jordan and Saudi Arabia, Egypt has had to demonstrate its commitment to implementing human rights principles [22].

Egypt has also focused on enhancing ethical competence among healthcare professionals. For example, EL-Khadry *et al.* [23] examined the impact of targeted educational programs on Egyptian paramedical and administrative staff, assessing knowledge and attitudes toward research, research ethics, and biobank management. Reflecting a trend seen across many developing countries, Egypt has experienced rapid growth in medical research driven by an urgent need to improve healthcare [24]. In 2023, Egypt ranked 37th globally in publication output [25]. Despite this growth, in 2020 Egypt had only 838 researchers per million inhabitants, compared with 4,821 per million in the USA (2019) and 2,443 per million in the UAE [26]. Within the BRICS nations, Egypt occupies a mid-range position, above South Africa (484 researchers per million) but below China (1,585 researchers per million).

National examples: France and Sweden

France and Sweden were selected as national points of comparison due to their longstanding ethical regulatory traditions. France has historically influenced the Egyptian legal system, beginning with the 1875 legal structuring and later through reforms led by French legal

expert Édouard Lambert during the 1930s and 1940s [27]. This historical linkage makes France a relevant comparator for evaluating Egypt's regulatory framework. Sweden, by contrast, was chosen as a high-income European country with a strong research profile but no historical connection to Egypt.

Northern European countries remain global leaders in research. Sweden, for instance, ranked third worldwide in research and development expenditure as a percentage of GDP in 2020, after Israel and Korea [28]. These countries also maintain a long-standing focus on bioethics, including adherence to the Helsinki Declaration in 2000 [29]. Sweden exemplifies a Nordic nation with an evidence-driven approach to health policy [30] and a strong emphasis on ethical oversight for under-researched and vulnerable populations [31–33]. Sweden's 2004 enactment of "The Act concerning the Ethical Review of Research Involving Humans" (SFS nr: 2003:460) introduced comprehensive ethical review procedures for biomedical research well before similar laws in France (Loi Jardé, 2012) or Egypt (2020), representing an early benchmark for innovative legislation.

Regarding research workforce and output, France had 4,926 researchers per million inhabitants in 2020, similar to the USA's 4,821 in 2019, representing a medium European benchmark. Sweden, however, had 7,930 researchers per million, with Norway (6,699), Finland (7,527), and Denmark (7,692) also showing high researcher density [34]. In terms of publication volume, France ranked 6th globally, while Sweden held the 18th position [35].

Supra-national entity: the EU regulations in the context of France and Sweden

Supra-national European regulations play a pivotal role in shaping the legal frameworks of EU member states, although no comparable supra-national authority exists in Egypt. At the EU level, the EU Regulation on Clinical Trials on Medicinal Products for Human Use (CTR) provides the overarching governance for the ethical review of clinical trials. However, the specific organization and operation of ethics committees are determined by national legislation within each member state. Consequently, despite the CTR establishing general standards for ethical review, significant variation exists across Europe regarding how committees are structured and how they carry out their responsibilities.

The CTR mandates that all clinical trials undergo ethical review (Article 4) and outlines key elements of this process. Nonetheless, the modalities of ethics committee functioning are left to the discretion of each member state. Typically, a clinical trial authorization application is divided into two sections: Part I addresses the technical and scientific aspects, while Part II focuses on ethical considerations, which are reviewed by the relevant member state. Within the CTR framework, an ethics committee is defined as an independent body established under the national law of a member state. This committee must be empowered to provide opinions for CTR purposes, incorporating the perspectives of laypersons, particularly patients and patient organizations (Art. 2(2)(11)).

Recital 18 of the CTR emphasizes that member states should ensure that the necessary expertise is available for ethical review. Mechanisms must exist to include laypersons in the process, with their input considered in the review (Art. 2(2)(11)). It is common for multiple ethics committees to operate within a single member state, and how their involvement is organized to meet CTR requirements is left to national authorities (Recital 18). Nevertheless, the ethical review process must be coordinated to comply with the CTR's stipulated timelines for clinical trial approvals (Art. 4).

Methods

Design and data analysis

This study analyzes Egyptian law in comparison with the ethical and regulatory frameworks of France and Sweden, taking into account the obligations arising from the CTR regarding clinical trials. Additionally, these regulations are evaluated using the Ethical Framework for Biomedical Research by Emanuel *et al.* [9, 10], with particular attention to how EU regulations influence French and Swedish practices.

A directed qualitative content analysis was employed, using the seven principles of the Ethical Framework for Biomedical Research as pre-defined analytical themes [36]. Two independent coders reviewed each regulation in its original language for France (MA, SM), Sweden (MA, AM), and the EU (MA, AM), while the Egyptian law was assessed in its English translation (AM, SM). The coders engaged in critical discussions during debriefing sessions, and coding decisions were finalized through consensus, with input from an international legal

expert specializing in ethical regulations (SS), who provided clarification regarding EU, Swedish, and French frameworks.

Theoretical framework

The analysis is guided by seven principles that serve as the criteria for comparison: "(1) (Social) value—enhancements of health or knowledge must be derived from the research; (2) scientific validity—the research must be methodologically rigorous; (3) fair subject selection—scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; (4) favorable risk-benefit ratio—within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review—unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent—individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects—subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored." (Emanuel et al., 2000, p2701 [9]).

Material

For this analysis, we focused solely on the primary legal texts of each regulation, without referencing connected laws (for example, the Code de la Santé and Code Penal for France, or "Law No. 151 of 2019, the Egyptian Medicines Authority" for Egypt). The latest available version of each law, including amendments, was used. These are as follows:

1. Egypt – Law No. 214 of 2020 Regulating Clinical Medical Research, enacted on December 23rd, 2020, with no amendments.
2. France – the "Loi Jardé" (LOI n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine) as amended by "Décret n° 2016-1537 du 16 novembre 2016," with the 2022 amendment considered in this analysis.
3. Sweden – Lag (2003:460) om etikprövning av forskning som avser människor, including amendments: 2018:147, 2018:1092, 2019:1144, 2021:611, and 2022:48.
4. EU – Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC, with EEA relevance, OJ L 158, 27.5.2014, p. 1–76.

These regulations were selected as the primary legal texts governing biomedical research, particularly studies involving human subjects. National and supra-national regulations were chosen based on their significance in international pharmacological and biomedical research. The EU regulation is considered complementary, supporting the analysis of Swedish and French legal frameworks, as both countries are EU members.

Results

A complete overview of the coding procedure for all regulations is provided in the supplementary material **(Tables 1 and 2)**. **Table 1** summarizes the assessment using a scoring system indicating compliance with each principle. A score of 0 denotes minimal or no compliance, while an X indicates satisfactory or full compliance with the principle.

Table 1. Comparative coding summary

Emanuel's criteria	Egypt	France	Sweden	EU
1 Social values and scientific value	0	0	0	0
2. Scientific validity	x	x	x	x
3. Fair selection	x	x	0	x
4. Favorable Risk-benefit ratio	x	x	x	x
5. Independent review	x	x	x	x
6. Informed consent	x	x	x	x
7. Respect for participants	x	x	x	x

0= partial or no compliance with the criteria, X=satisfactory or full compliance with the criteria

Table 2. Coding table short form

Emanuel *et al.*, 2000 [9]	French Law	EU regulation	Egypt	Sweden
Social and scientific value	Article L1121-2 Modifié par LOI n°2012-300 du 5 mars 2012 - art. 1 (V) Article L1121-16	Article 3 General principle, Article 6, See art.78 and 79.	Art 10, Chapitre 5, art 18. Chapitre 8 art 20. Art 7; 2 - Ch 2 Art 10. Executive regulations art 24	No provisions..
Scientific validity	Art. L 1121-3, Article L.1121-8-1, Arti. L1123-7	Article 4 Prior authorization, Article 6	article 1, #2, art 1, #24, Art 7; 2, Ch 2 Art 10 Ch 5 art 22. Chap 3 art 6, §2 Chap 4 art 9.	11 §, Verksamhetsregioner och avdelningar av Etikprövning 25§, Beslutsförhet 26 §
Fair selection of study population	Articles L. 1121-5 to (Articles L. 1121-5 to L. 1121-8 of the Code de la santé Code – CSP. article L. 1122-2, article L. 1122-2 of the CSP, article L. 1122-1-2 of the CSP, art. L. 1122-2 II, §3, art. L.1122-2 PHC, Art. L. 1121-6 PHC, art. L.1121-8-1 PHC, art. L.1122-1-2 PHC, art. L.1122-1-3 PHC, art L.1131-1-1 PHC, art. L1131-1-1 PHC, art. L.1122-2 II PHC, art. L. 1122-2 II PHC.	Article 10 Specific considerations for vulnerable populations, Article 35, Article 31 Clinical trials on incapacitated subjects, Article 28 Article 29(2), Article 32 Clinical trials on minors, Article 33 Clinical trials on pregnant or breastfeeding women, Article 34.	Art 17; 7 (PI resp), art 3, Chap 5 art 13.14:	14 §
Favorable risk-benefit ratio	article L1123-10 (R. 1123-46),Article L1121-2)	Article 6	Art 18; 6 (PI duties), Chap 5 art 10, Chap 7 art 18 §9, Chap 11 : requirements of research organization	8 §, 9 §, 10 §
Independent review	L. 1114-1, Art. L1123-1	Article 4, Article 9	- YesArt1; 24, law art 8., Chap 2 article 4: REC, Chap 3 artile 1 to 4 about setting up protocols	6 §, 25 § SFS 2018:1091 Act with supplementary provisions on ethical review to the EU regulation on clinical trials of human medicinal products Ethical review of the application for permission for clinical drug trials § 2 The ethical review must be carried out by the Ethics Review Authority.
Informed consent	Article L1121-2, Article L1121-14, Chapter II: Informing and obtaining the consent of persons undergoing research involving the human person (Articles L1122-1 to L1122-2). Chapitre V : Dispositions particulières applicables aux investigations cliniques de dispositifs mentionnés à l'article premier du règlement	Article 7, Article 29, Informed consent, Article 76(1); Article 81 (the 'EU database'), Article 37(4), Article 30 Informed consent in cluster trials	Art 1; 21, Art 12; 3 Chap.5 arti 12 § 3, law Art 3, Chap 7 art 17 § 2: obtaining IC is mandatory, Chap 10, art 23 §2 Informed consent for data usage for further research	!6 §, 14 §, 17 §, 18 §, 20 §, 21 §, 22 § All the sections in the law from 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22.

	(UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 (Articles L1125-1 à L1125-31)			
Respect for recruited participants and study communities	art L 209–5,. art. L.1122-1 PHC, art. L.1122-1 HPC, art L1126-1 PHC Concerning interventional researches (category 1): art. L.1122-1-1 PHC, art. L. 1122-1-1 PHC, art. L.1122-1-1, §2, PHC.	Article 28 General rules, Article 29(2) Article 29(1), (7) and (8), Chapter 5	Art 12; 2., Art, 15; 2.Chap 5, Art 15;3, Art 12 (1), art 18:5, Art 20:9, 10, Art 14	1§, 7 §, 19 §, 8 §

Social value

Egypt

Egyptian legislation does not explicitly define the social value of a research proposal. However, this principle is implicitly addressed through the mandate of the national Research Ethics Committee (REC) (Supreme Council), which evaluates protocols in light of the "national interest" (Ch. 3, Art. 7(2)).

Sweden

In Sweden, the Ethical Review Act similarly lacks direct clauses targeting social value assessment. Nonetheless, the idea that research should serve societal benefit is indirectly reflected in the composition of the departmental REC, where five of fifteen members are designated to represent societal perspectives (Section 25). Moreover, Section 8 prioritizes participants' welfare above societal objectives, highlighting the balance between individual protection and social considerations.

France

French law does not clearly articulate social value either. References to "social" aspects are generally tied to the Code de la santé (CS) or the social security framework, without directly addressing research value for society. Elements of social and scientific significance appear in the statement: "Research organized and carried out on human beings to develop biological or medical knowledge shall be authorized" (Art. L1121-1 CS).

EU

Within the CTR, the enhancement of health embodies social value, even if not explicitly named. Articles 3 and 6 establish that research must protect the rights, safety, dignity, and well-being of participants, while ensuring trials generate robust and reliable data. Additionally, both member state and EU inspections (Arts. 78–79) function as safeguards, reinforcing that compliance with CTR standards reflects research benefiting both science and society.

Scientific validity

Egypt

Regarding scientific validity, Egyptian law assigns the REC the duty to guarantee ethical and scientific quality of approved research (Arts. 1, 2, 24). It also sets standards to ensure methodological rigor (Ch. 2, Art. 10; Ch. 3, Art. 7(2)) and requires principal investigators to possess the necessary competencies for conducting research (Ch. 5, Art. 22; Ch. 3, Art. 6 §2; Ch. 4, Art. 9).

Sweden

Swedish legislation stresses that research must be scientifically sound. Section 11 mandates that only researchers with the required scientific expertise, or those under their supervision, may conduct research. Section 9 further requires that the expected scientific value of a study justifies any risks posed to participants' health, safety, or personal integrity, ensuring proportionality.

France

Article L1121-2 emphasizes the combined need for social and scientific validity. L1121-3 specifies that research must be carried out by "qualified personnel" and approved by a REC. RECs operate regionally and may collaborate with the Commission nationale de l'informatique et des libertés (CNIL) for data security issues and the Committee of Experts for Research Study and Evaluation in Health. EU regulations (Art. L1121-1

CS) also govern the conduct of research, while discipline-specific rules are contained in the CS (L1121-3), though not explicitly in the Loi Jardé.

EU

At the EU level, Article 4 mandates prior authorization of clinical trials. Research must undergo both scientific and ethical review in compliance with CTR requirements. Article 6(1)(b)(i) stresses that trials must produce reliable, robust data, accounting for methodology, statistical analysis, sample size, randomization, comparators, and endpoints.

Fair selection of study population

Egypt

The Egyptian law guarantees the unbiased recruitment of an appropriate number of research participants. Specific guidance is provided to the REC regarding the inclusion of particular subgroups or vulnerable populations. For example, the law prohibits research participants from enrolling in multiple studies simultaneously and forbids coerced participation (Ch. 5, Arts. 13–14).

Sweden

Although the Swedish law does not contain explicit clauses emphasizing fair selection of the study population, protections are included for minors and individuals unable to provide consent. These are described in Sections 18, 20, 21, and 22 (see Informed consent section for details).

France

French regulations stipulate that study participants should be beneficiaries of the Social Security system, or treated as such if they are not. The Code de la santé (CS, Arts. L1121-5 to L1121-8) ensures fair selection of participants. Special protections are applied to adults in coma, patients with dementia or psychiatric conditions, frail individuals, persons deprived of liberty, foreigners, minors, and pregnant or nursing women. In certain "urgency" situations, consent requirements may be overridden.

EU

Article 10 specifies "specific considerations for vulnerable populations," including minors (Art. 32), incapacitated subjects (Arts. 28–31), and pregnant or breastfeeding women (Art. 33). When considering participation of particular groups or subgroups, the evaluation of the trial authorization must take into account expertise relevant to the population in question. Article 34 addresses additional categories, including participants performing mandatory military service, persons deprived of liberty, individuals barred by judicial decision, or residents of care institutions.

Favorable risk-benefit ratio

Egypt

Egyptian law clearly requires that the Principal Investigator take all necessary measures to evaluate the risk-benefit ratio, considering both physical and psychological aspects, while ensuring participants' dignity and health (Arts. 18, 6). Risk reduction is further supported through evaluation of preclinical research (Ch. 5, Art. 10), provision of health insurance for participants (Ch. 7, Art. 18 §9), and ensuring that the research organization can properly address any adverse effects or health risks arising from the trial (Ch. 11).

Sweden

Swedish legislation specifies that research may only be approved if it respects fundamental personal freedoms and human rights. Section 9 allows approval when the scientific value justifies the risks to participants, Section 8 prioritizes participant welfare over societal and scientific interests, and Section 10 requires that research should only be conducted if its objectives cannot be achieved through methods posing less risk to health, safety, or personal integrity.

France

The Loi Jardé strengthened the favorable risk-benefit ratio by introducing consideration for "new facts." Crucially, the sponsor assumes responsibility for care and costs arising from severe adverse effects, covering both biomedical research (R1) and minimal-risk interventional studies (R2).

EU

Article 6 of the CTR mandates that risks and inconveniences to participants be minimized, with safety measures in place to ensure interventions are no more hazardous than standard clinical practice. Suspected unexpected serious adverse reactions (SUSARs) and annual reporting are strictly regulated. Committees are required to be informed of SUSARs and annual reports submitted to the European Medicines Agency (Art. 44.3).

Independent review

Egypt

In Egypt, independent review is carried out by a REC (Arts. 1, 24), which is responsible for safeguarding participants' rights, evaluating research protocols, deciding on approvals, amendments, or renewals, and monitoring the progress of studies, all in accordance with the executive regulations (Art. 8). The law provides further details on the review process across several articles (Ch. 2, Art. 4 for REC; Ch. 3, Arts. 1–4).

Sweden

Swedish law (Section 6) mandates independent review whenever research involves a physical intervention or presents potential physical or psychological risks to participants. This also applies to studies using biological material from living individuals that can be linked to them. The same section highlights the Principal Investigator's duty to prevent research from being conducted in violation of the law. Section 25 outlines the structure of the Ethics Review Authority, organized into operational regions, each comprising one or more departments aligned with specific areas of expertise. Departments include a chairman, who is or has been an ordinary judge, and fifteen other members: ten with scientific expertise and five representing public interests, including at least one from a patient organization. The government appoints the chairman and deputy, while the Ethics Review Authority selects the remaining members and their deputies.

France

In France, independent review is well established through the Committee for the Protection of Persons and the 39 RECs organized across seven inter-regional committees. RECs are structured into two colleges—one scientific and one patient-oriented—to support independent review. However, the criteria for appointing REC members at national or local levels remain somewhat unclear. At the local level (Art. L1123-1), the Health Minister appoints members of the CPP for a fixed or indefinite term based on need, with members designated by the Director General of the regional health agency hosting the committee. These committees are fully independent in carrying out their duties, have legal status under public law, and receive state funding. Ethical approval may also be granted by institutional committees within hospitals or universities. Members of the National Commission for Research Involving Humans must declare conflicts of interest (Art. L1123-1-1), but the law does not explicitly clarify this for CPP members, especially when promoters apply to their own in-house committees.

EU

Article 4 establishes the requirement for prior authorization according to the law of the Member State. Ethical review may cover aspects outlined in Part I (Art. 6) and Part II (Art. 7) of the assessment report for clinical trial authorization, depending on the Member State. Article 9 emphasizes that individuals validating and assessing applications must be free of conflicts of interest, independent from sponsors, clinical trial sites, investigators, funders, and other undue influences. At least one layperson must participate in the assessment process.

Informed consent (IC)

Egypt

Egyptian law introduces a definition of IC early in its articles (Arts. 1, 21), emphasizing its integration into ethical research practices: "the written expression based on complete voluntary freewill of the person with full legal capacity, and it includes his explicit consent as a signature and a fingerprint to participate in clinical medical research, after all aspects of the research are explained to him, and in particular the potential effects or harms that may impact his/her decision to participate[…]". Exceptions to obtaining IC are outlined in the executive regulations (Ch. 5, Arts. 12, 3). Additional provisions emphasize its necessity, including Ch. 7, Art. 17 §2, which mandates IC, and Ch. 10, Art. 23 §2, which requires IC for data usage and future

research. The law also provides specifications regarding consent for data use.

Sweden

Swedish legislation (Section 17) establishes that research can generally only proceed if the participant has voluntarily and explicitly consented in a documented manner after receiving adequate and detailed information. Section 16 identifies the essential information to be provided. Special attention is required where participants are in a dependent relationship with the research team or are otherwise unable to assert their rights (Section 14). Provisions for minors, particularly participants aged 15 and older, are outlined in Section 18. Sections 20–22 describe circumstances under which research may be conducted without consent, including cases of illness, mental disorder, compromised health, or similar conditions that prevent the participant from giving consent.

France

French regulations state: "Consent is free, informed and (voluntary)" and stress the necessity of explicit agreement across various legal contexts. Written IC is required for category 1 studies, while oral IC may be permitted for category 2 studies but must be documented in the medical file. For category 3 research and studies using data from routine care, the rule is that the patient "must not object." No research listed in 1° of Art. L. 1121-1 can proceed without the person's free IC, given in writing after receiving relevant information. When written consent is impossible, it may be attested by a trusted support person (Art. L. 1111-6), a family member, or a close relation, provided they are independent of the investigator and sponsor. Specific provisions apply for minors (under 18). Article 4 further clarifies situations where the participant cannot express consent and is not under guardianship. Options for "collective consent" are allowed only for minimal-risk interventional research, such as epidemiological studies.

EU

Article 7 emphasizes compliance with IC requirements as specified in Art. 29, detailing rules for written IC. Article 30 addresses cluster trials, stating: "Where a clinical trial is to be conducted exclusively in one Member State, that Member State may, without prejudice to Art. 35, and by way of derogation from points (b), (c), and (g) of Art. 28(1), Art. 29(1), point (c) of Art. 29(2), 29(3), (4) and (5), points (a), (b) and (c) of Art. 31(1) and points (a), (b) and (c) of Art. 32(1), allow the investigator to obtain IC by the simplified means set out in paragraph 2 of this Article, provided that all of the conditions set out in paragraph 3 of this Article are fulfilled."

Respect for participants

Egypt

The Egyptian law ensures participant protection through several measures, including safeguarding privacy and data (Arts. 12, 2), providing adequate information to research participants (Arts. 15, 2; Ch. 5, Art. 18:5), and preventing exposure to publicity (Art. 15, 3). It also clearly outlines procedures to respect withdrawal of consent (Art. 2, 1) and specifies compensation mechanisms (Art. 20:9, 10). Provisions against induced participation, such as enrolling participants solely for monetary or other rewards, further reinforce respect for participants (Art. 14).

Sweden

The Swedish law emphasizes protection of the individual and respect for human dignity in research (Sections 1 and 7). Section 40 allows certain exceptions regarding consent or data processing if requested by the government or another authority, provided the research poses no significant risk to participants' health, safety, or personal integrity.

France

In French legislation, respect for study participants is less explicitly articulated, with greater emphasis placed on fair selection and risk protection. One notable provision addresses protection for "a deceased person, in a state of brain death, without his or her consent expressed during his or her lifetime or through the testimony of his or her family" (Art. L1125-13).

EU

Article 28 sets out general requirements for lawful clinical trials, including participant benefit, IC, protection of mental and physical integrity, minimal pain or risk, guaranteed medical care, and absence of undue influence (including financial). Regulation (EU) No

536/2014 ensures that withdrawal of consent is free of constraints, does not impact participants' rights or care, and does not affect data collected prior to withdrawal (Art. 28; Art. 2).

Discussion

Our findings indicate that the Egyptian law meets ethical standards for human subject research and is largely comparable to French, Swedish, and EU regulations. Detailed analysis shows that most regulations exhibit a relatively vague approach to "social values and scientific values" (principle 1). Regarding fair selection of participants, Swedish law appears the least explicit (principle 3), although overall, this principle is reasonably addressed. All other principles—favorable risk-benefit ratio, independent review, IC, and respect for participants (principles 4, 5, 6, 7)—are well represented in Egyptian law, similarly to the French, Swedish, and EU frameworks. For clarity, results are discussed under two broad themes: 1) Values and validity (principles 1, 2, 5, with 5 being the mechanism to achieve value and validity), and 2) Participant protection (principles 3, 4, 6, 7).

Values and scientific validity

Principle 1: Social values and scientific value

Egyptian regulations share a common challenge with French, Swedish, and EU frameworks in clearly defining the social value of research. Assessment of social value indicates that most regulations lack precise specifications regarding the circumstances under which research should serve a social purpose. Social value is often considered through cost-effectiveness metrics, making standardization across countries and cultures difficult, as it involves "the general concept and practice of measuring social impacts, outcomes, and outputs through the lens of cost" [37]. In Emanuel *et al.*'s framework, social value is defined by: a) ensured benefit, b) value for prospective beneficiaries, c) dissemination of results via long-term collaborative strategies, and d) avoidance of undermining existing community healthcare [38]. These findings also raise questions about the prioritization of social value in research, particularly in areas where it may not serve as an overarching guideline. Recent discussions have examined justice and egalitarian considerations arising from evaluating the social value of research [39, 40], depending on its societal innovation and impact.

Principle 2: Scientific validity

Egyptian, French, Swedish, and EU regulations attempt to ensure scientific validity mainly through the selection of members for their respective RECs. However, the actual expertise and qualifications of these members, which are necessary to review research protocols and scientific methodology, are not clearly defined. There is no consensus on the specific competencies required to make balanced and unbiased ethical decisions. As highlighted by [41], different reviewers focus on different concerns: scientific reviewers more often raise questions about scientific validity, while ethicists emphasize ethical issues.

The impartial evaluation of scientific validity depends on both the REC structure and the broader societal context. In France, members of the National Ethical Committee, responsible for guiding all RECs, are "selected" or "designated" by the President of France. Similarly, in Egypt, Central intelligence members are part of the National REC (the Supreme Council). Political and social factors may influence decisions in a process that is ideally unbiased. Using preference studies to guide policy-making and including patient advocacy in decision boards can advance shared decision-making and support impartiality, but a unified definition of these processes is still lacking [42, 43]. Research also indicates that methodological standards are sometimes lowered to allow co-researchers access [44].

In general scientific practice, validity should be properly assessed across all areas of medical research. Tools such as systematic review scales are used to measure scientific quality, yet validity can be difficult to interpret for a heterogeneous group of REC members. The classical definition states: "The validity of a research study refers to how well the results among the study participants represent true findings among similar individuals outside the study. This concept of validity applies to all types of clinical studies, including those about prevalence, associations, interventions, and diagnosis." Even with this, specifying "The validity of a research study includes two domains: internal and external validity" shows the complexity involved, which may not be fully reflected in Emanuel's principles [45].

Further discussion on validity in biomedical research is necessary. Various types of validity, such as congruence

validity or criterion validity, may need to be considered to clarify what is meant by scientific validity [46]. Wages *et al.* (2021) [47] illustrated the use of operating characteristics to inform safety and accuracy in Phase I clinical trials, highlighting the potential for refining definitions of scientific validity in biomedical research. While some challenges arise from scientific communities, scientific validity should remain a priority for all REC members. Selection criteria for REC participants should address competency concerns, especially given ongoing debates about the representativeness of patients in shared decision-making within medical practice [48, 49].

Principle 5: Independent review

All ethical regulations, including Egypt's, guarantee that the review process is independent, granting RECs the authority to authorize, monitor, and terminate any research to safeguard participants [29]. A significant concern that remains unresolved across regulations is ensuring the effectiveness of RECs given some theoretical and structural deficiencies [50]. Opportunities to enhance the efficiency and effectiveness of ethics committees may rely more on researchers and the broader scientific community, as suggested by Hickey *et al.*, 2022 [51]. Establishing a clear collaborative framework between ethics committees and researchers could improve the efficiency of medical research.

Participant's protection

Principle 3: Fair selection

The Egyptian law actively promotes fair selection of research participants, representing an improvement over earlier proposals where vulnerable subjects' rights and welfare were not adequately protected [52]. However, questions remain about fairness in clinical trial recruitment. Ongoing debates highlight that fair selection raises complex ethical challenges, encompassing four key aspects: "(1) fair inclusion; (2) fair burden sharing; (3) fair opportunity; and (4) fair distribution of third-party risks" [53]. For instance, in 2022, French law incorporated EU requirements, enabling participants without social security access to take part in research [54]. While this broadens participation, it also raises questions regarding the fairness of selection.

Principle 4: Favorable risk-benefit ratio

Egyptian regulation, like the other comparative frameworks, treats "Risk-benefit" as a fundamental principle aligned with the clarity of the Helsinki Declaration [55]. Yet, none of the regulations explicitly address the potential under-reporting of harms, depending on how "harm" is defined. Psychological harm is frequently overlooked; even clinical trials often fail to report psychological adverse effects compared to physical effects from drugs, as noted in research by [56, 57].

Principle 6: Informed consent

Informed consent is broadly implemented, and Egypt aligns with this standard practice as do all the comparative frameworks. Although multiple forms of informed consent exist, the Egyptian law emphasizes written consent without explicitly addressing renewed consent, broad consent, or other approaches [58], including the potential use of "blanket consent."

Principle 7: Respect for recruited participants and study communities

Respect for participants embodies the principle of autonomy within healthcare and research systems, which is consistently applied across all four regulations. Egyptian law gives equivalent attention to this principle as French law and is comparable to Swedish and EU regulations. However, additional focus is warranted to ensure respect across different dimensions, including gender [59] and ethnicity [60, 61].

Limitations

This study has several limitations. First, our analysis focused primarily on expressis verbis statements, which may restrict the understanding of the full scope of how these laws are applied in practice. Implicit references within the legal texts could mitigate some of the conclusions drawn. For example, the CTR emphasizes the general aim of promoting social value through health enhancement, even if this is not explicitly articulated. At the clinical level, practitioners may not have complete access to all regulatory texts and may rely mainly on referenced documents relevant to ethical applications in their respective countries. Ambiguities or complex implicit references may impede understanding and complicate implementation. Additionally, using Emanuel *et al.*'s principles as an analytical framework

may be seen as a limitation, as these principles might not fully capture the nuanced features of the legal frameworks under examination. Another potential limitation is that the analysis may not entirely reflect the influence of cultural and social differences among Egypt, France, and Sweden. Future research should also examine the overall organization of ethical procedures within each country, including the roles of Supreme Councils, regional entities, and national unified procedures.

Conclusion

In conclusion, Egyptian law demonstrates alignment with Emanuel *et al.*'s principles when compared to French, Swedish, and relevant EU regulations. Nonetheless, shared challenges and areas for improvement exist across the ethical principles, highlighting opportunities for further research. A primary issue identified in this analysis is the need to clarify and standardize the concept of social value in research, which often relies on cost-effectiveness measures and, implicitly rather than explicitly, presents a complex concept for practical application [62]. A second key point concerns the expertise and impartiality of ethical review boards in decision-making. Additional research is necessary to examine the remaining principles in greater depth. Overall, these findings emphasize the importance of ongoing enhancement and refinement of ethical regulations to safeguard participant welfare and uphold the integrity of research in Egypt and comparable jurisdictions.

Based on our analysis, the following actions are recommended to enhance research ethics regulations in the examined countries:

1. Clarify and Standardize Social Value: Establish precise criteria and standards to define and assess the social value of research in varying national and cultural contexts. This should include a detailed framework for evaluating how research contributes to societal benefits, its cost-effectiveness, and alignment with the long-term healthcare objectives of the population.
2. Strengthen Scientific Validity: Improve the selection process for Research Ethics Committee (REC) members to guarantee that they possess adequate scientific expertise and educational qualifications to critically appraise research protocols and methodologies. Implementing stricter competency requirements and offering ongoing training can help ensure objective and well-informed decision-making during ethical review.
3. Enhance Participant Protection: Prioritize fairness in participant selection by addressing ethical dilemmas and promoting equal access to research participation. Existing regulations should be revised to provide stronger protections for vulnerable populations and ensure equitable distribution of research opportunities.
4. Boost REC Effectiveness: Address structural and procedural gaps within RECs to improve their operational efficiency. Encouraging collaborative interactions between review boards and researchers, while guaranteeing sufficient independence, authority, resources, and expertise, can enhance the overall effectiveness of ethical oversight.
5. Promote Respect for Participants: Ensure that research practices consistently respect the autonomy, dignity, and rights of participants. Special consideration should be given to factors such as gender, ethnicity, and other personal characteristics that may affect participant experiences in research settings.
6. Encourage Further Research: Investigate additional dimensions of ethical principles beyond those outlined by Emanuel *et al.*, in order to better understand how cultural and social contexts influence the implementation of ethical guidelines across different jurisdictions.

Acknowledgments: None

Conflict of Interest: None

Financial Support: None

Ethics Statement: None

References

1. Dooly M, Moore E, Vallejo C. Research ethics. Research-publishing net. 2017.
2. Miracle VA. The Belmont Report: the triple crown of research ethics. Dimens Crit Care Nurs. 2016;35(4):223–8.
3. Halonen JI, Erhola M, Furman E, Haahtela T, Jousilahti P, Barouki R, et al. The helsinki declaration 2020: Europe that protects. Lancet Planetary Health. 2020;4(11):e503–5.
4. Johansen MV, Aagaard-Hansen J, Riis P. Benefit–a neglected aspect of health research ethics. Dan Med Bull. 2008;55(4):216–8.

5. Artal R, Rubenfeld S. Ethical issues in research. Best Pract Re Clin Obstet Gynaecol. 2017;43:107–14.
6. Paul H. The scientific self: reclaiming its place in the history of research ethics. Sci Eng Ethics. 2018;24(5):1379–92.
7. Thaldar D, Shozi B, Kamwendo T. Culture and context: Why the global discourse on heritable genome editing should be broadened from the South African perspective. BioLaw Journal-Rivista Di BioDiritto. 2021;4:409–16.
8. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. Jama. 2013;310(20):2191-4.
9. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? Jama. 2000;283(20):2701–11.
10. Emanuel EJ, Wendler D, Grady C. An ethical framework for biomedical research. The Oxford textbook of clinical research ethics. 2008. p. 123–35.
11. Rid A, Emanuel EJ. Ethical considerations of experimental interventions in the Ebola outbreak. Lancet. 2014;384(9957):1896–9.
12. Tsoka-Gwegweni JM, Wassenaar DR, Using the Emanuel, et al. framework to assess ethical issues raised by a biomedical research ethics committee in South Africa. J Empir Res Hum Res Ethics. 2014;9(5):36–45.
13. Mutenherwa F, Wassenaar DR, de Oliveira T. Ethical issues associated with HIV phylogenetics in HIV transmission dynamics research: a review of the literature using the Emanuel Framework. Dev World Bioeth. 2019;19(1):25–35.
14. Mantzaris E. Regulatory frameworks as a tool for ethical governance: drawing comparisons amongst the BRICS (Brazil, Russia, India, China and South Africa) countries. Afr J Public Affairs. 2017;9(8):91–104.
15. Sim JH, Ngan OMY, Ng HK. Bioethics education in the medical programme among Malaysian medical schools: where are we now? J Med Educ Curric Dev. 2019;6:2382120519883887.
16. de Lemos Tavares ACAL, Travassos AGA, Rego F, Nunes R. Bioethics curriculum in medical schools in Portuguese-speaking countries. BMC Med Educ. 2022;22(1):199.
17. Mukhamedzhanovna MZ, Akmalovna U, Nugmanovna M. The Uzbek Model of Bioethics: History and Modernity. Malim: jurnal pengajian umum asia tenggara (SEA Journal of General Studies). 2020;21.
18. Bank W. 2023a [Available from: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519.
19. Marzouk D, Sharawy I, Nakhla I, El Hodhod M, Gadallah H, El-Shalakany A, et al. Challenges during review of COVID-19 research proposals: experience of faculty of medicine, Ain Shams university research ethics committee, Egypt. Front Med. 2021;8:715796.
20. State USDo. 2022 [Available from: https://www.state.gov/reports/2022- country-reports-on-human-rights-practices/.
21. Migiro. [Available from: https://www.worldatlas.com/articles/when-did-egypt-gain-itsindependence.html.
22. H S. United Nations Human Rights Council and Israel: Comparative Analysis with Egypt, Jordan, and Saudi Arabia (Doctoral dissertation, University Honors College Middle Tennessee State University). 2021.
23. EL-Khadry SW, Abdallah AR, Yousef MF, M. abdeldayem H, Ezzat S, Dorgham LS. Effect of educational intervention on knowledge and attitude towards research, research ethics, and biobanks among paramedical and administrative teams in the National Liver Institute, Egypt. Egyptian Liver Journal. 2020;10:1-8.
24. Normile D. The promise and pitfalls of clinical trials overseas. Science. 2008;322(5899):214–6.
25. SJR [Available from: https://www.scimagojr.com/countryrank.php.
26. Bank W. 2023b [Available from: https://data.worldbank.org/indicator/SP.POP.SCIE.RD.P6?end=2017&locations=EG&start=2007.
27. Chaaban Y. Comparative law as a critical tool for legal research in Arab countries: a comparative study on contractual balance. Akkad J Law Public Policy. 2021;1(3):123–34.
28. Bank W. 2023c [Available from: https://data.worldbank.org/indicator/GB.XPD.RSDV.GD.ZS?locations=SE&most_recent_value_desc=true.
29. Guraya SY, London N, Guraya SS. Ethics in medical research. J Microscopy Ultrastructure. 2014;2(3):121–6.

30. Hansson MG, Dillner J, Bartram CR, Carlson JA, Helgesson G. Should donors be allowed to give broad consent to future biobank research? Lancet Oncol. 2006;7(3):266–9.
31. Norberg Wieslander K, Höglund AT, Frygner-Holm S, Godskesen T. Research ethics committee members' perspectives on paediatric research: a qualitative interview study. Res Ethics. 2023;19(4):494–518.
32. Gallagher B, Berman AH, Bieganski J, Jones AD, Foca L, Raikes B, et al. National human research ethics: a preliminary comparative case study of Germany, Great Britain, Romania, and Sweden. Ethics Behavior. 2016;26(7):586–606.
33. Harcourt D, Quennerstedt A. Ethical guardrails when children participate in research: risk and practice in Sweden and Australia. Sage Open. 2014;4(3):2158244014543782.
34. Bank W. 2023d [Available from: https://data.worldbank.org/indicator/SP.POP.SCIE.RD.P6?end=2017&locations=EG&start=2007.
35. Scimago Journal and Country Rank [Available from: https://www.scima gojr.com/countryrank.php.
36. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res. 2005;15(9):1277-88.
37. Tuan MT. Measuring and/or estimating social value creation: Insights into eight integrated cost approaches: Bill & Melinda Gates Foundation Seattle, WA; 2008.
38. Emanuel EJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. J Infect Dis. 2004;189(5):930–7. https://doi.org/10.1086/381709.
39. Juth N. For the sake of justice: should we prioritize rare diseases? Health Care Analysis. 2017;25:1–20.
40. Juth N, Henriksson M, Gustavsson E, Sandman L. Should we accept a higher cost per health improvement for orphan drugs? A review and analysis of egalitarian arguments. Bioethics. 2021;35(4):307–14.
41. Haaser T, Bouteloup V, Berdaï D, Saux M-C. The multidimensional nature of research ethics: letters issued by a French research ethics committee included similar proportions of ethical and scientific queries. J Empirical Res Hum Res Ethics. 2022;17(3):242–53.
42. Groot BC, Vink M, Haveman A, Huberts M, Schout G, Abma TA. Ethics of care in participatory health research: mutual responsibility in collabo- ration with co-researchers. Educ Action Res. 2019;27(2):286–302.
43. Bomhof-Roordink H, Gärtner FR, Stiggelbout AM, Pieterse AH. Key components of shared decision making models: a systematic review. BMJ Open. 2019;9(12):e031763.
44. Malterud K, Elvbakken KT. Patients participating as co-researchers in health research: a systematic review of outcomes and experiences. Scandinavian J Public Health. 2020;48(6):617–28.
45. Patino CM, Ferreira JC. Internal and external validity: can you apply research study results to your patients? Jornal brasileiro de pneumologia. 2018;44:183.
46. Larsen KR, Lukyanenko R, Mueller RM, Storey VC, VanderMeer D, Par- sons J, et al., editors. Validity in design science research. Designing for Digital Transformation Co-Creating Services with Citizens and Industry: 15th International Conference on Design Science Research in Information Systems and Technology, DESRIST 2020, Kristiansand, Norway, December 2–4, 2020, Proceedings 15; 2020: Springer.
47. Wages NA, Horton BJ, Conaway MR, Petroni GR. Operating characteristics are needed to properly evaluate the scientific validity of phase I protocols. Contemp Clin Trials. 2021;108:106517.
48. Arora NK, McHorney CA. Patient preferences for medical decision making: who really wants to participate? Medical Care. 2000:335-41.
49. Lindsay SE, Alokozai A, Eppler SL, Fox P, Curtin C, Gardner M, et al. Patient preferences for shared decision making: not all decisions should be shared. J Am Acad Orthopaedic Surgeons. 2020;28(10):419.
50. Whitney SN. Institutional review boards: a flawed system of risk management. Res Ethics. 2016;12(4):182–200.
51. Hickey A, Davis S, Farmer W, Dawidowicz J, Moloney C, Lamont-Mills A, et al. Beyond criticism of ethics review boards: strategies for engaging research communities and enhancing ethical review processes. J Acad Ethics. 2021:1-19.
52. Silverman H, Edwards H, Shamoo A, Matar A. Enhancing research ethics capacity in the Middle East: experience and challenges of a Fogarty-

sponsored training program. J Empir Res Hum Res Ethics. 2013;8(5):40–51.
53. MacKay D, Saylor KW. Four faces of fair subject selection. Am J Bioeth. 2020;20(2):5–19.
54. Pace C, Miller FG, Danis M. Enrolling the uninsured in clinical trials: an ethical perspective. Crit Care Med. 2003;31(3):S121–5.
55. Association WM. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. Jama. 2013;310(20):2191–4.
56. Duggan C, Parry G, McMurran M, Davidson K, Dennis J. The recording of adverse events from psychological treatments in clinical trials: evidence from a review of NIHR-funded trials. Trials. 2014;15(1):1–9.
57. Jonsson U, Alaie I, Parling T, Arnberg FK. Reporting of harms in randomized controlled trials of psychological interventions for mental and behavioral disorders: a review of current practice. Contemp Clin Trials. 2014;38(1):1–8.
58. Hansson SO, Björkman B. Bioethics in Sweden. Cambridge Quarterly of Healthcare Ethics. 2006;15(3):285–93.
59. Cameron JJ, Stinson DA. Gender (mis) measurement: Guidelines for respecting gender diversity in psychological research. Soc Personal Psychol Compass. 2019;13(11):e12506.
60. Braddock CH III. Racism and bioethics: the myth of color blindness. Am J Bioeth. 2021;21(2):28–32.
61. Truong M, Sharif MZ. We're in this together: a reflection on how bioethics and public health can collectively advance scientific efforts towards addressing racism. J Bioeth Inq. 2021;18(1):113–6.
62. Habets MG, van Delden JJ, Bredenoord AL. The social value of clinical research. BMC Med Ethics. 2014;15(1):1–7.