Beyond the permissibility of embryonic and stem cell research: substantive requirements and procedural safeguards

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This report provides a comparative analysis of the regulation of embryonic stem cells and cloning research in 50 countries. The development of international stem cell consortia involving the exchange of materials, data and knowledge presumes ‘policy know-how’ on the varying positions and governing regulations of the various partners; knowledge is essential for the feasibility of such international collaborative projects. Across the spectrum of restrictive-to-liberal policies, requirements regarding the justification for or the setting of substantive limits on (i) embryo use and/or (ii) destruction in research are often present. These goals justify the regulation, the control and even the prohibition of embryonic stem cell and cloning research. Moreover, irrespective of whether a country adopts a restrictive or a liberal approach, there is significant symmetry in both the substantive and the procedural requirements. Procedural safeguards provide another layer of protection and control over the research. In reality, such safeguards may have a greater systemic impact than the substantive requirements. They can be subdivided into three broad categories: (i) safeguards relating to the stage of embryonic development, (ii) safeguards relating to the donors of blastocysts, gametes, embryos and somatic cells and (iii) requirements for research governance.

Key words: cloning/ethics/policy/stem cells

Introduction

The approaches that countries worldwide have taken to develop policy in the area of embryo and stem cell research have varied enormously. They range from constitutional and legislative to administrative approaches and differ in degree from liberal to intermediate, to restrictive. To interpret their permissibility with any degree of accuracy, it is crucial to take into account the respective policy frameworks, ethical principles, substantive requirements and procedural safeguards that inform and shape them significantly. Certainly, these policy frameworks would be better understood by referring to their sociocultural, religious, economic and historical contexts.

Perhaps the most prevalent criterion for policy development in this area, albeit via different conceptualizations, is the moral (and legal) status of the human embryo. Often, this criterion is used to inform provisions regarding the justification for embryo protection, use and destruction as well as the requirements surrounding the relevance of research goals and its scientific rationale.

By setting political and ethical boundaries, substantive requirements aim to demonstrate that a society is capable of both making ethical assessments and establishing priorities. At the same time, they balance the diverse if not conflicting interests and values at stake. Several dimensions for justification and assessment are present in the substantive requirements; they all relate to the importance of the research goals and the need for embryo use to attain those goals. Across jurisdictions, these requirements are approached and interpreted in diverse ways; hence, they can result in flexible controls or stringent regulations.

Common goals are needed in the advancement of important human interests, such as the improvement of (collective or individual) human health and well-being. These goals are often reflected in policies with the general aim of preventing and treating diseases, of developing therapies to aid in medically assisted reproduction or to benefit the embryo’s healthy development. Furthermore, the promotion of scientific research and the generation of knowledge (e.g. in basic scientific research or biological development in human beings) have been widely identified as critical objectives. Substantive requirements demand that those interests be realized by relying on alternative approaches, including the use of different sources, before resorting to the instrumental use of human embryos.

Finally, provisions regulating the stages of embryonic development and the protection of the donors of reproductive materials (e.g. informed consent, confidentiality, privacy), and policies mandating research governance that are found in accompanying procedural safeguards, are vital to support and
make effective the substantive requirements. Indeed, these procedural safeguards determine the manner and means of enforcing the policy framework enshrined in and defined by the substantive requirements.

Even though stem cell lines can be harvested from a variety of sources (e.g. umbilical cord blood, bone marrow, fetuses), this paper focuses on embryonic research and the procurement of stem cell lines from human embryos. This choice is based on the continual ethical controversies surrounding this particular type of research and the scientific community’s general agreement regarding their greater scientific potential. This article provides an overview of (i) the regulatory frameworks in 50 countries concerning embryonic stem cells and cloning research, (ii) the substantive requirements for embryo use and (iii) the procedural safeguards. (The countries surveyed are Australia, Argentina, Austria, Belgium, Brazil, Bulgaria, Canada, China, Colombia, Costa Rica, Cyprus, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Latvia, Lithuania, New Zealand, Norway, Panama, Peru, Poland, Portugal, Singapore, Slovenia, Slovakia, Spain, Romania, Russia, South Africa, South Korea, Sweden, Switzerland, The Netherlands, Tunisia, Turkey, Ukraine, UK, USA and Vietnam. The criterion for selection was based on the adoption of policy on embryo, stem cell and/or cloning research.) Even in countries that span the range from restrictive to liberal approaches, there is remarkable symmetry in both the substantive requirements for embryo use and the procedural safeguards. Restrictive policies, in general, aim to strongly protect the human embryo by adopting tight regulations or blank prohibitions of many techniques (e.g. reproductive and therapeutic cloning, embryonic research). Restrictive policy frameworks can be further subdivided into three types: policies prescribing the impermissibility of human embryonic stem cell (hESC) derivation, the impermissibility of using hESC lines or their products (though some exceptions exist for imported hESC lines) and lastly, policies prescribing the impermissibility of government funding for such research. Most countries surveyed in this article fall under the intermediate policy approach. Hereunder, a wide range of techniques is allowed but the techniques are controlled and monitored by modest government intervention. Under an intermediate policy framework, stem cell research on supernumerary IVF embryos is permitted, whereas both therapeutic cloning and reproductive cloning are prohibited. Finally, in a liberal policy framework, a wide range of research activities is allowed. For instance, the creation of embryos for either research purposes, for the derivation of stem cells lines and for therapeutic cloning is permitted, provided procedural rules and governance are observed (for a detailed analysis of regulatory approaches regarding embryonic and stem cell research, see Isasi and Knoppers, 2006).

The regulation of embryonic stem cell research

Most countries that have adopted public policies on embryonic, stem cell and cloning research can be labelled intermediate, whereas a minority of countries are at the edge of the spectrum, meaning they adopt either a restrictive or a liberal public policy approach. (The intermediate countries are Australia, Brazil, Bulgaria, Canada, Cyprus, Latvia, Greece, Estonia, Finland, France, Hungary, New Zealand, Spain, South Africa, Switzerland, The Netherlands, Portugal, India, USA, Argentina, Peru, Mexico, Thailand, Turkey, Ukraine, Tunisia and Vietnam. The countries that have adopted a restrictive public policy approach are Iceland, Lithuania, Denmark, Slovenia, Germany, Ireland, Georgia, Taiwan, Austria, Italy, Norway, Poland, Costa Rica, Colombia, and Panama. The countries that have adopted a liberal public policy approach are Belgium, China, Japan, Israel, Singapore, South Korea and UK.)

In relation to human embryonic research, generally, where public policy has been adopted, most countries allow research on human embryos or gametes under strict conditions [16 countries by national laws (see, e.g. legislation in Iceland, Latvia and Lithuania) and seven by guidelines (see, e.g. legislation in India and Taiwan)], whereas a few countries explicitly prohibit research on embryos by law (Austria, Ireland, Cyprus, Costa Rica and Italy). The remaining countries surveyed have no explicit policy on embryonic research.

An interesting pattern is evident in the regulation of hESC research: where public policy has been adopted, most countries allow the procurement of hESC lines and research on supernumerary embryos [16 countries by law (Australia, Brazil, Canada, Denmark, Estonia, Finland, France, Greece, Hungary, Latvia, New Zealand, Slovenia, South Africa, Spain, Switzerland and The Netherlands) and five by guidelines (China, India, Portugal, Taiwan and USA)]. In addition, only eight countries explicitly prohibit by law the procurement of hESC from surplus embryos and subsequent research (Lithuania, Norway, Poland, Italy, Austria, Ireland, Costa Rica and Slovakia). Only two countries prohibit research on embryos to create hESC lines but allow the importation of hESC lines under strict conditions set forth in the law (Germany and Italy). In Germany, the importation of hESC lines from surplus embryos is allowed under strict conditions set forth in the Act Ensuring the Protection of Embryos in Connection with the Importation and Utilization of Human Embryonic Stem Cells (Stem Cell Act) (28 June 2002). Even though in Italy the Medical Assisted Procreation Law (2004) prohibits research on embryos (other than observational studies), embryonic stem cell research takes place through the backdoor. Given the lack of specific regulations regarding stem cell research and in the absence of an explicit prohibition on the importation of stem cell lines, hESC research is conducted on imported stem cell lines derived from surplus embryos (subject to approval by a local research ethics committee). The remaining countries surveyed have no explicit policy on hESC research.

It is striking that a negligible number of countries have adopted national laws (Belgium, Japan, Singapore, South Korea, Sweden and UK) or guidelines (Israel) specifically allowing embryo cloning for therapeutic or research purposes. Nevertheless, a significant number of countries worldwide have no explicit policy on research cloning. All of the countries surveyed forbid cloning for reproductive purposes.

Finally, since 2002, an emerging pattern in the legal landscape reveals a move towards the liberalization of national policies across the restrictive–liberal spectrum (e.g. Australia, Belgium,
Denmark, France, Germany, Greece, Brazil, Japan, Netherlands, New Zealand, Singapore, South Korea, Spain, Switzerland and UK). This trend towards the liberalization of policies is also noted in proposed legislation currently under debate (e.g. Czech Republic, Malta, Mexico and Ukraine). However, some countries have still opted to pass very restrictive laws (e.g. Italy, Panama and Colombia), and many policy debates show resistance against this movement towards liberalization.

Substantive requirements

Across the spectrum of restrictive-to-liberal policies, requirements regarding the justification for or the setting of substantive limits on (i) embryo use and/or (ii) destruction in research are often present. These justify the regulation, the control and even the prohibition of embryonic, stem cell and cloning research. Substantive requirements are multidimensional; they qualify not only the importance of the research goals but also their reference and rationale. Likewise, the means used to achieve those aims are of great importance. However, artificial boundaries are often drawn between the legitimate purposes and goals of research, embryo origin and sources of stem cell lines. All of this leads to policies that are internally inconsistent from a legal and ethical standpoint.

Most policies adopted in the countries surveyed underscore the importance of the research goals to advance human interests, such as the alleviation of human suffering and the improvement of human health and well-being, as well as the generation of scientific knowledge. Additionally, respecting the freedom of scientific research has been widely identified as an important objective.

Requirements for embryo use in research

The substantive requirements for embryo use can be further regrouped according to two criteria: (i) proportionality and (ii) subsidiarity or necessity (in a strict sense, the criterion of subsidiarity can be considered as a different dimension of the principle of proportionality). We opted for subdividing these two principles for methodological purposes.

Proportionality

The principle of proportionality refers to constraining embryo research to practices that serve important and worthwhile goals and purposes. Defining what those goals of great importance varies greatly across jurisdictions, and in some instances, policies are salient or quite unsettled and therefore, a great amount of interpretation is required.

Moreover, the criterion for permissible purposes of research is frequently contingent on the purpose for which the embryo was created and/or the individual categories of research (e.g. general embryo research, research on supernumerary or cloned embryos). [For instance, compare the different criteria of acceptable research goals for embryos created for reproductive or research purposes contained in The Netherlands Embryos Act (The Netherlands, 2002a) or in German law regarding research on human embryos (Embryo Protection Law, 1990) and research on imported stem cell lines (Stem Cell Act, 2002).]

In countries adopting a restrictive policy framework, the only ethical justifications for embryo research are to achieve pregnancy (Austria, 1993) and to maintain or promote the embryo’s healthy development (Italy, 2004; Germany, 1990).

For instance, Lithuania’s law permits research on supernumerary embryos only when ‘medically indicated’ and ‘when the medical risks for the embryo are not disproportionate to the potential benefits’ (Lithuania, 2000). By allowing only research that ‘directly benefits the embryo’ (Germany, 1990) and leaving aside other scientifically and ethically important goals, these policies are tantamount to conferring on the early human embryo a full moral/legal status. However, in some jurisdictions, the rationale put forward for conferring greater protection to the embryo in vitro (as opposed as in utero before nidation) is allegedly based on the in vitro embryo’s higher exposure to misuse, rather than its moral and legal status (Beckman, 2005).

Countries adopting a more flexible framework identify as an important objective the alleviation of human suffering as well as the decrease of morbidity and mortality in human beings (as opposed to human embryos). Indeed, most jurisdictions interpret this substantive requirement—whether for embryonic, stem cell and/or cloning research—as equivalent to medical therapy (e.g. for diagnostic and preventive purposes). For instance, in Belgium (Belgium, 2003) and Spain (Spain, 1998a), embryonic, stem cell and cloning research is restricted to ‘therapeutic purposes’. In Brazil (Brazil, 2005), Hungary (Hungary, 2003), France (France, 2004), Switzerland (Switzerland, 2004), Iceland (Iceland, 1996) and Japan (Japan, 2001a), research on embryos in vitro (supernumerary or not) is allowed ‘for the prevention or treatment of disease’ or for ‘major therapeutic advances’. Furthermore, Finland (Finland, 1999a,b), France (France, 2004) and the UK (United Kingdom, 2004) incorporate additional qualifiers, such as requiring that the disease under study using surplus or cloned embryos be ‘serious’, ‘grave’ and/or ‘hereditary’. Canadian (Canada, 2004) legislation allows research on supernumerary embryos where there are ‘potential health benefits’ with no further justification.

The proportionality principle could also be expressed by characterizing the knowledge to be obtained from the research activity. Belgium (Belgium, 2003), the UK and Iceland allow ‘embryo in vitro research for advancing knowledge on fertility, sterility’, and Denmark for improving ‘treatment concerning human diseases’ (Denmark, 1997). Likewise, legislation in Switzerland (Switzerland, 2004) stipulates that the research project from which hESCs would be used or derived should have the goal of obtaining ‘essential knowledge’. Japan’s guidelines (Japan, 2001a) refer to ‘the study of the biology of development of human beings’, and Germany’s (Germany, 2002) laws ‘serve eminent research aims to generate scientific knowledge in basic research’ and ‘increase medical knowledge’.

Subsidiarity or necessity

The requirement of subsidiarity or necessity aims to identify the circumstances under which embryonic, stem cell and/or cloning research is ethically justified. This principle requires demonstrating how essential the use of human embryos is for the research goals and the absence of alternatives for such use.
It further establishes a hierarchy among embryos used for research (Pennings and Van Sterteghem, 2004).

The most common dimension of this requirement is found in the context of policies allowing embryonic stem cell research where research is limited to supernumerary embryos (embryos created but no longer needed for reproductive purposes; e.g. in Israel, France, South Africa, Estonia). Likewise, for embryos specifically created for research purposes (including cloned embryos), this principle requires the absence of an adequate alternative (e.g. in UK and Sweden).

Illustrative examples of the latter are found in legislation adopted in Belgium (Belgium, 2003), for example, where cloning for research purposes is permitted if there is ‘no alternative research method having comparable effectiveness’ or when ‘no adequate stem cells (are) available’. In Latvia (Latvia, 2002) and Singapore (Singapore, 2002), this requirement is expressed in allowing research on surplus embryos in the ‘absence of alternative methods’. Moreover, policies adopted in Belgium, Japan and Singapore require researchers to demonstrate or justify that existing embryonic or adult stem cell lines cannot be used before research cloning is allowed, whereas South African guidelines (South Africa, 2002) recommend conducting therapeutic or research cloning ‘in a manner that eliminates the need for the use of human embryos’.

Alternately, France (France, 2004) and Germany (Germany, 2002) recognize certain exceptions and allow research on imported embryonic stem cell lines when such research cannot be conducted appealing to an ‘equally efficient alternative method’ of research or when the ‘scientific knowledge to be obtained cannot be expected to be gained by using other cells’.

Finally, an additional dimension of the principle of subsidiarity exists in establishing a hierarchy among embryos used for research and in requiring the traceability of hESC lines with respect to their source. For instance, in some jurisdictions, research must first be performed on embryos of low quality, ‘not suitable to be placed in the body’ (e.g. Australia, Slovenia) or lacking ‘biological fitness for implantation’ (e.g. Australia) before conducting research on other human embryos (Australia, 2002a).

Requirements for embryo destruction

The substantive requirements for embryonic, stem cell and cloning research aim to provide an ethical (and legal) justification for the instrumental use of an embryo, as well as for its creation and eventual destruction in research, in order to respect the embryo’s special status. However, attempts to create a moral separation between embryo destruction and use (e.g. for medically assisted procreation, to derive embryonic stem cell lines or to study cell lines already derived) are often artificial and lack moral consistency.

Probably the most ethically coherent—albeit contentious—policy regarding embryo use is found in countries adopting a very restrictive policy framework. Under this approach to embryo research, cryopreservation and destruction are prohibited (e.g. Austria, Ireland, Italy). Certainly, this assessment does not take into account the medical (e.g. health) and broader social consequences arising from these policies. Indeed, in all three countries, embryos created through ART must be implanted, regardless of medical indication or the couples’ wishes.

In most of the jurisdictions surveyed, regardless of their policy design, there are provisions mandating the destruction of cryopreserved embryos (created for reproductive and/or research purposes) after the expiration of the statutory storage period [the length of storage varies widely, ranging from 5 years (e.g. Iceland, Norway, South Korea, Sweden and UK) to 15 years (e.g. Finland)], or at the embryo donor’s request (e.g. Canada, Switzerland and UK). Moreover, as an additional safeguard to the prohibition on developing a human embryo beyond 14 days from fertilization or until the formation of the primitive streak, in the procedural safeguards, a number of jurisdictions require the destruction of the embryo after the aforementioned period (e.g. Estonia, Finland, Sweden and Switzerland).

Although the destruction of embryos after long storage periods is often inevitable due to safety concerns, the ethical consistency of provisions that forego their donation for reproductive purposes or for use in research, while at the same time conferring ‘special respect’ to the human embryo, is questionable. Allowing childless couples to receive such embryos for procreative purposes or using embryos for important scientific research would be the most coherent way to grant ‘serious moral consideration’ to human embryos already created for reproductive purposes.

Regardless of attempts to legislate it away, direct or indirect inducement and complicity are necessarily involved in the research enterprise. The special respect or moral value attributed to the human embryo in most of the public policies surveyed would be considered morally consistent when such policies also require a scientific and ethical justification for embryo use and destruction [e.g. Israeli guidelines require that ‘the research and possible applications (of the research) be justified in terms of the benefit that it offers to humanity’ (Israel, 2001)]. Indeed, the rationale for the two conditions of proportionality and subsidiarity, as well as positions on embryo destruction, are often sadly lacking. Is it really the moral status of the embryo that underscores these positions? It could well be issues of feasibility, safety and liability for unknown long-term effects or even fear of public perception—the government condoning ‘potential persons’ remaining indefinitely frozen—that drive such limits, albeit without explicit discussion. These fundamental, philosophical and political shortcomings may however be mitigated by the procedural safeguards, including quality control, licensing and ongoing ethical oversight and governance.

The substantive requirements adopted in policy frameworks across the restrictive–liberal spectrum seek to prevent research from being conducted for its own sake or for research goals that are deemed trivial. They demand that research conducted upon human embryos serves a sufficiently important purpose (however ‘important’ be defined). The absence of adequate alternatives outweighs the moral concerns relating to the instrumental use of human embryos.

Substantive requirements recognize that at the core of our attitudes towards human life is the symbolic significance we confer to the human embryo. They also recognize how contentious and sensitive these attitudes and meanings are for any given
society, and the need to balance them with other important societal values. Overall, substantive requirements seek to promote scientifically and ethically sound research.

Procedural and ethical safeguards

Procedural safeguards provide another layer of protection and control over the research. In reality, such safeguards may have a greater systemic impact than the substantive requirements. They can be subdivided into three broad categories: (i) safeguards relating to the stage of embryonic development, (ii) safeguards relating to the donors of blastocysts, gametes, embryos and somatic cells and (iii) requirements for research governance.

Provisions regarding the sources of human embryos and of embryonic stem cell lines attempt to classify them based on the ‘ethical’ circumstances of their production. At the core of this ethical (and sometimes legal) requirement, we have seen the substantive principles of proportionality and subsidiarity often expressed as the requirement for the traceability of the embryo and of embryonic stem cell lines (e.g. Germany) with respect to their source (e.g. supernumerary embryos, cloned embryos and chimaeric embryos).

Stages of embryonic development

The stages of embryonic development have been conceptualized as the point where (ethically) responsible research must stop. Following international legal and ethical norms, most countries surveyed (e.g. Australia, Canada, Iceland, Singapore, Sweden, UK, Finland, Hungary, Spain, Slovenia, South Africa, Japan, France, India and Israel) include as an additional safeguard for embryo protection the prohibition of developing, implanting and conducting research on human embryos beyond 14 days from fertilization or until formation of the primitive streak (e.g. Australia, Canada, Estonia, Finland, France, Hungary, Iceland, India, Israel, Japan, Slovenia, Singapore, South Africa, Spain, Sweden and UK). However, some jurisdictions further this prohibition to include 5- to 7-day-old embryos (e.g. Switzerland). It should be noted that the 14th-day prohibition also applies to the harvesting of stem cell lines from human embryos.

Donors

Protection for patients’ rights and research participants are also commonly adopted in the jurisdictions under study. Safeguards for the donors of blastocysts, gametes, embryos and somatic cells include the requirement for free and informed consent (e.g. Australia, Canada, Latvia, Lithuania, UK, Estonia, Finland, Greece, South Korea, Sweden, Spain, South Africa, Switzerland, Belgium, Japan, Singapore, Germany, India, USA and Israel), the prohibition of conflicts of interest between the IVF medical staff and the researchers conducting hESC research (e.g. Israel) and the prohibition of financial gains or incentives for the donation, as well as safeguards for the protection of confidentiality and of the privacy of the donors (e.g. Canada, India, Lithuania and Switzerland).

In most jurisdictions, provisions regarding informed consent relate to the general rules for research participants and for donors of tissue and reproductive materials (e.g. gametes, sperm, ova and embryos). However, concerning the issue of requiring informed consent for the secondary use of reproductive materials and hES cell lines, the material information that should be disclosed (including researchers’ financial interests) and provisions for withdrawal of consent have seldom been addressed in the countries surveyed. Moreover, only in a few jurisdictions are there provisions specifically dealing with informed consent in the context of stem cell research [Canada, India, USA (state of CA), Singapore, South Africa, Switzerland and UK]. We recognize that this assessment is based on requirements enshrined in normative policies (e.g. laws and guidelines), and therefore, it might differ from best practices followed by researchers worldwide.

Linked to the principle of autonomy that underlies the doctrine of informed consent are the issues of conflict of interest, the timing of the consent for embryo donation (Ethics Committee of the American Society of Reproductive Medicine, 2002) and the prohibition of financial gains or incentives for such donation. As stated above, in some jurisdictions, procedural safeguards have been adopted to prevent conflicts of interest between embryonic and stem cell researchers and the medical personnel of an IVF institution. These provisions, in all their different conceptualizations, extend to regulating the timing of the consent process to prohibiting any financial compensation for embryo donation performed in the context of treatments for assisted reproduction.

Research governance

The establishment of a centralized, independent and transparent public authority empowered to grant licenses and strictly control or monitor the conduct of research is essential to ensure the good governance of science. The imposition of accreditation through licensing as a condition of operation is the one procedural mechanism with the greatest impact on embryonic research. Such an oversight mechanism, with its traditional requirements of certification, quality assurance, standard operating procedures, reporting procedures and ethics approval, can effectively frame and even curtail the introduction of technologies and influence the conduct of research itself.

The first goal of a governance system should be to act in the public interest. Whether governance mechanisms rely on statutory bodies, professional organizations or a combination thereof, they should encompass regulatory structures with appropriate checks and balances. Moreover, they should be flexible enough to accommodate moral diversity and scientific advances, while maintaining effective scrutiny to maintain public trust. Probably the best-known model of effective oversight and licensing is the UK’s Human Fertilisation and Embryology Authority (HFEA) (United Kingdom, 1990). Other countries, such as Australia, Belgium, Canada, France, New Zealand, Japan and Sweden, also have statutory licensing and oversight mechanisms. In all, licensing is dependent on compliance with the proportionality and subsidiarity principles contained in the substantive requirements as found in each policy framework.

The stringency of regulatory responses is only one factor relevant to oversight and compliance. Adherence to ethical standards
in the conduct of scientific research is of key importance. For this reason, a great number of countries (e.g. Denmark, Estonia, Finland, France, Germany, India, Israel, Italy, Lithuania, New Zealand, Slovenia, Singapore, South Africa, South Korea, Spain and Switzerland), with a high degree of difference among their statutory and non-statutory provisions, foresee ethics review by local or national ethics committees. In fact, in many jurisdictions’ ethics review (if not ethics approval) has become part of the regulatory framework. The importance of this dual control mechanism is unquestionable. However, ethics review is often confined to the substantive requirements enshrined in the respective policies, eloquently described by one author as an ‘ethical assessment within the limits of the law’ (Beckman, 2005).

Moreover, good governance calls for provisions contemplating sanctions and enforcement mechanisms (countries with statutory provisions contemplating sanctions and enforcement mechanisms: Australia, Austria, Iceland, Lithuania, Brazil, Canada, Denmark, Estonia, Finland, Greece, Hungary, New Zealand, Spain, Slovenia, South Africa, Switzerland, the Netherlands, Belgium, Japan, Singapore, South Korea, Sweden, UK, Germany, India, Israel and Norway). In the countries under study, several statutory responses make engaging in the prohibited activities or violating their regulatory requirements a felony, punishable by severe prison terms, whereas others punish transgressions only with civil fines. Interestingly, most countries, across both sides of the policy spectrum, have opted for criminal sanctions: Iceland, Canada, Denmark, Estonia, Finland, New Zealand, Spain, Slovenia, South Africa, Switzerland, Belgium, South Korea, Sweden, UK, Germany, France, Israel, Austria and Italy. A negligible number of countries, such as Lithuania and Singapore, contemplate only civil sanctions (e.g. for malpractice or liability).

Finally, as national and international scientific collaboration have become a key feature in stem cell research, proper governance calls for policies regulating collaborative projects across diverse jurisdictions in order to ensure that equivalent standards for quality, safety and ethics are applied. In this context, provisions regarding the importation of human stem cell lines, data sharing and donors of reproductive materials are of major importance (The Hinxton Group, 2006).

Conclusion

The recent South Korean scandal regarding fraud and gross ethical violations in stem cell research illustrates that legislative responses are neither necessary nor sufficient. What are needed are authoritative regulatory oversight, scientific integrity, transparency and accountability (Knoppers et al., 2006). All these requirements must be integrated with less formal mechanisms, such as sociocultural norms and professional support and education.

Regulation indeed can be a positive force by upholding the values shared by a society and by fostering open discourse. However, countries are challenged to adequately reflect in their policies’ competing—if not conflicting—values. They must facilitate scientific research in view of its potential benefits for human health and well-being, as well as the generation of important scientific knowledge. While at the same time, they must set the legitimate boundaries of scientific inquiry by resorting to the scientific and ethical assessment of its justifiability.

This overview presents the diverse policy responses regarding the permissibility of embryo, stem cell and cloning research, as well as the substantive requirements and procedural safeguards enshrined in different jurisdictions. Obviously the historical, cultural and sociological context, the institutional framework and the mobilization of stakeholders are further factors that need to be examined in order to fully understand policy approaches.

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Supplementary material


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