

Going high and low: on pluralism and neutrality in human embryology policy-making

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ABSTRACT

Formulating sound and acceptable embryo research policy remains challenging especially in a pluralistic world. This challenge has acquired a new dimension of complexity with the advent of so-called embryo models, which are derived from stem cells. In this article, we present a normative strategy to facilitate the process of sound policy-making in the field of human embryology. This strategy involves seeking neutral agreements on higher level theories and doctrines as well as seeking agreements on the level of concrete policy proposals. We call this strategy: going high and low. By going high and low, the plurality of reasonable moral and epistemic convictions of stakeholders involved in the domain of human embryology is respected while the process of policy-making in this area is improved.

INTRODUCTION: HUMAN EMBRYOLOGY POLICY IN A PLURALISTIC WORLD

The road to sound human embryology policy is paved with ethical challenges. On the one hand, the study of human embryos offers promising avenues into better understanding the biological underpinnings of human development as well as the improvement of medical practices including artificial reproductive technologies (ARTs), the therapeutic management of early pregnancy and regenerative medicine. These considerations offer grounds for permissive law and policy for embryo research.

On the other hand, the hoped-for scientific insights and clinical benefits should not be pursued at any cost and by any means. The use of human embryos has raised pervasive and intractable disagreement on whether these embryos should be awarded some form of moral value, what the grounds are for this value are and to which extent this value should restrict their creation and manipulation for research purposes. This discussion is typically subsumed under the heading of the moral value or status of the embryo.¹

The ethics of human embryology has acquired a new dimension of complexity with the advent of embryo models that simulate early human development. These embryo models form in a dish as a result of the spontaneous organisation of stem cells. The potential supply of scalable and manipulable embryo models is, at first sight, most welcome given the scarcity of and research restrictions on human embryos.² The question, however, is whether and if so, to which extent these embryo models deserve moral and legal protection and whether and to which extent the grounds for these protections should be based on the protection we award human embryos.³

These questions are certainly not new and have yielded a plurality of views on how desirable and acceptable human embryology research (HER) should take shape.⁴ This plurality of views reflects the academic and societal pluralism in which these questions have evolved and are being addressed. Put differently, the plurality of views on the desirability and acceptability of HER mirrors the plurality of ethical, philosophical, cultural and religious doctrines on which they are based.

Our aim is not to put forward a new position regarding the moral status of the embryo or the desirability and acceptability of HER. Nor is it to scrutinise the normative bases of the different existing moral positions regarding these issues. Our aim instead, is to offer criteria for policy makers to navigate this plurality of views so to base HER policy on grounds that are ethically sound and respect the plurality of views on this subject matter. Or to put in a question: how should ethically sound HER policy in pluralistic societies take shape?

To answer this question, we will (1) start by elaborating on the role of the state, which gives policy makers their mandate to shape HER policy. In most countries, the state or other institutions of power (from here on state) have the mandate to regulate HER, for example, by awarding or limiting subsidies for research or by curtailing certain scientific liberties such as the liberty to create embryos or embryo like structures for research purposes. These regulations warrant justification. The central 'justificatory question' we will address is: which grounds serve to justify HER law and policy? This question is particularly pertinent as in a pluralistic society, different stakeholders will find different justificatory grounds satisfying.

To respect this plurality, we take as an imperative that all citizens must be treated as free and equal members of society. This entails that HER policy should not be based on views, ideals, values or doctrines that can be reasonably rejected. The view that for policy to be legitimate it should be 'reasonably non-rejectable' to those to whom it applies is also known as the doctrine of 'justificatory neutrality'.^{5 6} The justificatory neutrality criterion is buttressed on the requirement that the normative and epistemic grounds of policy have to be 'reasonably non-rejectable'. That is, the justification (as opposed to the policy itself) for HER policy should be reasonably non-rejectable.

¹To be sure, this justificatory neutrality does not yield neutral policy rather it ensures that the reasons underpinning law and policy are reasons that no one can reasonably reject.



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(2) We will continue by discussing what makes a ground reasonable and non-rejectable. (3) Subsequently, we will discuss how these justificatory demands can be specified in the case of HER policy-making. According to the neutrality doctrine, controversial comprehensive views should be avoided when state power is used to formulate policy. Rawls has famously asserted that in pursuit of political conceptions that all reasonable persons are willing to accept, controversial comprehensive doctrines should be avoided, and political stakeholders should ‘retreat’ towards neutral grounds that all have reason to accept. He coined this political strategy, the search for ‘overlapping consensus’.⁷ In the spirit of this idea(l), we will present two justificatory grounds on which HER policy can be based that respect stakeholders as free and equal persons, which are: neutral higher-level agreements and neutral lower-level agreements.

The former refers to the demand that the normative principles that underpin HER policy should be reasonably non-rejectable to all to whom that policy applies. These agreements alone might be insufficient as they can still lead to too much reasonable disagreement in practice. For example, based on a manifold of ethical theories it can be argued that harm should be avoided, and liberty promoted. How the prevention of harm and the promotion of liberty should take shape, and what these principles should entail in terms of the weighing of values and the formulation of reasonably non-rejectable policy, may remain unclear.

To address this point, we will also propose to aim at achieving agreement on more concrete levels. Consider, for example, that people may agree on a concrete level, that doing research with human embryos that are sentient is morally impermissible, while disagreeing on the reasons as to why this research is impermissible. They may be ‘theoretical enemies’ and yet be ‘policy friends.’ The merit of more concrete outcome agreement in the face of more abstract theoretical disagreement has also been described by Cass Sunstein in terms of ‘incompletely theorised agreement’.⁸ This merit is furthermore reinforced by the consideration that in the face of intractable disagreement, agreement about policy based on compromise rather than on shared substantive reasons can be desirable over leaving issues unregulated altogether.⁹

We call agreement on concrete policy level in spite of disagreement on higher levels of abstraction, neutral lower-level agreements. For HER policy to be legitimate, it should be based on neutral higher-level and/or lower-level agreements. We will explain why higher-level and lower-level agreements have the same justificatory status, that is, why there is no lexicographical ordering of agreements to be made. Our approach of going high and low shows some similarities with recently developed reflective equilibrium frameworks that can be used to formulate policy around novel technologies informed by public preferences.^{10 11} Similar to these reflective equilibrium frameworks, a lack of coherency in preferences about policy offers grounds to reasonably reject these preferences, that is, grounds to jettison these preferences when formulating HER policy. An important distinction however is that ultimately it is agreement and not coherence that offers justification for including preferences as a basis for policy. Coherence is only of derivative importance in our approach. In addition, our approach does not give a priori weight to how well preferences cohere with established ethical theories such as Kantianism, utilitarianism and contractualism. The weight of established ethical theories is determined a posteriori, that is, based on how much agreement they can generate among reasonable and well-willing stakeholders.

We conclude by stating that in formulating and evaluating HER policy that is suited for a pluralistic world, policy makers should aim to go high and low.

Embryo research and the importance of liberty and equality

The Warnock report is the landmark document in the discussion on ethically permissible embryo research.¹² The foreword, which has a strong philosophical bent, mentions the necessity of having moral principles for governing embryo research. It continues by stressing the importance of respecting the pluralism of views that exist within society when formulating these guiding moral principles. Or in the words of the Warnock committee: ‘But in our pluralistic society it is not to be expected that any one set of principles can be enunciated to be completely accepted by everyone.... The law itself, binding to everyone in society, whatever their beliefs, is the embodiment of a common moral position. It sets out a broad framework for what is acceptable within society (emphasis added).’¹²

This important observation will also be our point of departure. Against the backdrop of pluralism as is mentioned in the Warnock report, we ask the question: given that there is a plurality of views on the desirability and acceptability of HER available among reasonable and well-willing researchers, policy makers and other stakeholders, how should policy-making that respects this plurality take shape? We adopt as our most fundamental ethical demand that whatever the state does in terms of policy-making, it has the stringent duty to treat its citizens as free and equal members of society. We argue that this respect for liberty and equality is the normative precondition for justified HER policy-making in a pluralistic world

How can law and policy makers respect the liberty and equality of citizens? This question has been a central subject of concern in the domain of political philosophy. The question asked from the viewpoint of political philosophy is: how can the state respect its citizens as free and equal members of society?¹³⁻¹⁵ To answer this question, we will unpack what it means for the state to treat citizens in general and HER stakeholders in particular as free and equal. We start with the former.

The philosophy of liberty and equality

In general, when citizens are treated as free members of society they are treated as persons who are bound by moral requirements that are acceptable from their own point of view. Moreover, in principle, no justification is warranted when they exercise their right to liberty, but justification is warranted when their liberty, such as cultural, political, religious or scientific liberty, is interferedⁱⁱ with. Therefore, the burden of justification always falls on the side that proposes some interfering policy. Applied to HER, this entails that the burden of justification falls first of all on the state, which is considering, for example, interfering with HER. In practice, the burden of justification for HER, currently falls on either national committees (e.g., the Warnock committee) and/or on international scientific societies (e.g., the International Society for Stem Cell Research, ISSCR) that write guidelines serving as a ground for state policies. Consider, for example, that one of the recommendations of the Warnock report was to subject research with human embryos to legal licensing. This recommendation was based on the argument that the human embryo should be awarded some form of moral and legal protection. This is an example of the demand to offer justi-

ⁱⁱInterference can involve restricting funds for research, submitting research to criteria of permissibility or barring certain research practices altogether.

fication so that the proposed interference with HER is legitimate. The exercise of scientific liberty in this context should not be equated with unbridled or exaggerated claims to freedom. There are often sound and compelling reasons to regulate and curtail liberties. The prevention of harm and the respect for morally valuable life for example, constitute good reasons to do so. Still, to meet the demands of liberty, the grounds for restricting scientific freedom should be explicit and acceptable by the researchers' own reasonable moral standards.

Consider for example the 14-day rule, which follows the advice of the Warnock committee and which was established as a law in the UK through the Human Fertilisation and Embryology Acts of 1990 and 2008. This rule stipulates that 'in vitro culture of the human embryo is not allowed to proceed beyond the equivalent of day 14 of embryonic development, or the approximate time at which the primitive streak appears'.¹⁶ One of the arguments that underpins this rule is that the founding cells of the nervous system have not been specified prior to this stage. This entails that at this stage, the embryo must be incapable of experiencing any kind of suffering but that, after the nervous system is established, it might. The experience of needless suffering, or suffering which cannot be justified by benefits which are substantial and can only be brought about through research which involves suffering and for which no morally less problematic alternative exists (suffering which does not meet the demands of proportionality and subsidiarity) constitutes an impermissible harm. Performing research that brings about harm through unjustifiable suffering is morally impermissible. Do no unjustifiable harm, is a moral principle that reasonable researchers can agree on.ⁱⁱⁱ Therefore, it is reasonable to assert that, by their own lights, researchers agree with the argument underpinning the 14-day rule. Although this principle curtails the liberty of researchers by limiting their possibility to assess whether embryo models are functional, it clearly prevents the formation of embryonic structures in a dish that could experience suffering.^{iv 17 18}

Overall, to respect the liberty of researchers in this case thus entails that policy makers provide a ground—harm as a result from suffering—to limit embryo research which is acceptable by the researchers' own professional moral standards.

This of course leaves room for debate on whether the prevention of harm by suffering is best served by the 14-day rule proper. The presence of neural progenitors is not sufficient to experience suffering, which requires functional neural networks. Perhaps a new demarcation is called for between 14 days and the acquisition of sentience, which is unlikely to occur before the embryo forms a functional central nervous system.¹⁸ It is uncertain whether ethical scrutiny alone can ever yield sharp demarcations of this kind. Still reasonable agreement on the impermissibility of harm through suffering is an ethical value that all reasonable citizens, including researchers have good reason to accept. From this it follows that a demarcation is called for and that this demarcation is not in conflict with

ⁱⁱⁱThere are limits to this claim. Consider for example, the permissibility of animal research. There is wide disagreement on whether this research meets the demands of proportionality and subsidiarity. The discussion on the distinction between harm to humans and harm to animals is however, beyond the scope of this article.

^{iv}Of note, this restriction on human embryology passes the burden onto animals, especially non-human primates, with important ethical concerns as well. A question to address is whether growing human embryos issued from IVF in a dish is ethically more acceptable than sacrificing non-human primates.

scientific liberty. This may sound paradoxical; the freedom to perform research is curtailed but scientific liberty is preserved. Yet, as long as infringements imposed by the state are based on reasons (such as the prevention of suffering) that are acceptable to stakeholders to whom these infringements apply, their liberty is sufficiently preserved.

We move now to the second moral value: equality. In general, when citizens are treated as equal members of society, they are awarded the same moral standing. Unequal treatment of these citizens is only justified when it is reasonably acceptable by those who are worse off for being treated unequally.^v Applied to HER this entails that policy cannot be based on grounds that some stakeholders accept but others have reasonable grounds to reject. Consider, for example, a second argument underpinning the 14-day rule namely that: '14 days is the last stage in development at which twinning can occur and therefore represents the point of individuation'.¹⁶ This argument is also known as the 'ontological individuation argument'.¹⁹ As Pereira Daoud *et.al.* rightly point out: '[a]s ontological individuation establishes numerical identity between the embryo and the human individual it may grow into, reaching the stage where twinning is no longer possible seems relevant only for those subscribing to the idea of active potentiality. In fact, only for those linking this idea [ontological individuation] with the ascription of full moral status, would it seem obvious that ontological individuation poses an absolute limit to the moral acceptability of human embryo research'.²⁰ We agree that the argument from ontological individuation is only persuasive for those who subscribe to the idea of active potentiality. In short, the argument from active potentiality is that (1) human subjects have moral status; (2) Although an embryo is not like a human subject in terms of, for example, sentience and rationality, it has the active potential to become a human subject, that is, it is not yet a human subject and (3) this temporal distinction between an embryo (human subject-to-be) and a human subject is not fundamental and therefore offers no moral reason to not award the latter (weak) moral value or (strong) moral status.²¹ The individuation argument is a derivative argument in which it is stated that moral value (or status) should be awarded to an entity the moment that this entity has the capacity to become the individual human subject it is destined to be (because of the active potentiality argument). This entity is the embryo from 14 days onwards as from there on the possibility for twinning is lost and the individual subject-to-be has emerged.

There is a peculiar jump here from ontology 'the individual human' and biology 'twinning' to morality 'moral status'. If for example, we entertain for a second the wildly unscientific thought that the possibility of twinning never disappears in humans, we never become individual human beings(-to-be) and one could wake up to find a perfect copy of herself lying next to her in bed, why would this (bizarre) ontological fact have any bearing on the moral status of either person? It seems that there is fallacy here. From the conjunction (a) 'all human subjects are individuals' and (b) 'all human subjects have moral status' we cannot infer the necessary condition 'because all human subjects are individuals, the emergence of individuality is the threshold for (eventual) moral status'. $(a \wedge b) \neq (a \rightarrow b)$ So, at the very least, the arguments from potentiality and from ontological individuation are open to reasonable disagreement. To underscore the reasonable disagreement which can arise on

^vThis is the Rawlsian interpretation of equality tied to the difference principle

this matter consider the following citation by Williams. individuation is: ‘not uniquely reasonable it is nevertheless reasonable to draw a line there’. (emphasis added)²² In other words, among reasonable persons the chips may fall on both sides of the argument.

The individuation argument becomes even more open to reasonable disagreement when it is applied to current embryo models. Why is the threshold of individuation morally relevant for embryo models that are, at least for the time being, incapable of developing into persons? Embryo models, lack the capacity to develop into persons, even when they surpass the threshold of individuation. This pulls the rug under the individuation argument applied to embryo models, or at least those which lack the capacity to develop into persons. And these are exactly the embryo models under current moral scrutiny.

To be clear, the point here is not to deliver a final blow to the individuation argument. We are quite sure no such blow has been dealt here. What we do hope to have accomplished however, is to show that reasonable disagreement can arise among reasonable and well-willing stakeholders who seek to regulate HER in a sensible manner. Given this reasonable disagreement, a 14-day rule that is justified by reference to the ontological individuation argument would constitute an illegitimate policy act as policy makers would be unfair arbiters, favouring those who adhere to this view over those who hold different yet reasonable views. This amounts to an impermissible form of unequal treatment for it is in conflict with the duty of equality as described above. In more general terms, in formulating HER policy the state has the duty to treat in an even-handed manner researchers and other stakeholders who hold different yet morally (and epistemically) acceptable views. Consequently, in their justification of HER policy, the state is barred from favouring one reasonable view on the moral significance of embryos or embryo models over another. In sum, we propose that HER policy makers should always respect those to whom the policy applies as free and equal persons.

Libertarianism is itself open to reasonable disagreement

This emphasis on liberty and equality may be construed as a form of libertarianism. This is the doctrine that liberty and equality are paramount substantive values which are typically interpreted in terms of a strong right to self-ownership of citizens and corresponding strong duties of non-interference and non-coercion of the state.²³ These rights and duties typically hold even in the face of possible societal gains in terms of health, well-being or a more equal distribution of goods. Libertarianism is itself comprehensive doctrine and therefore, of course, open to reasonable disagreement. Our position, however, is closer to what is known as Rawlsian political liberalism than it is to libertarianism. That is, rather than considering liberty and equality as actual substantive values, we take these values to be the preconditions for identifying the substantive norms and values that should underpin HER policy. For example, free and equal stakeholders might reasonably accept that gastruloid embryo models that do not develop the anterior part of the embryo, which is the precursor of the central nervous system, are not harmed when they are maintained in a dish even after 14 days. They might also accept that this research may produce significant scientific and therapeutic gains. This justification for not applying the 14-day rule to research with gastruloids is not based on libertarian liberty but rather on the principles of ‘do-no-harm’ and ‘beneficence’ which were identified by free and equal persons who are involved or invested in human embryology policy-making. In other words, liberty and equality are like the ‘rules

of engagement’ for policy-making that respects the plurality of values of different stakeholders.

It is, however, true that these rules of engagement are biased towards more permissive views on embryo research. This is inescapable in any approach in which stakeholders are seen as free and equal as the burden of justification will always fall on those who desire to interfere with, in this case, scientific freedom and equality. This is not an argument in favour of permissive ethics of embryo research but an explanation as to why restrictions on research for example based on religion, ideology or any other substantive doctrine warrant justification which is reasonably acceptable to other stakeholders. We do think however, that this penchant towards liberty and equality is fair and desirable as it offers, as far as we can see, the best opportunities to invite stakeholders with different ideological commitments to debate on the basis of the most suitable values (liberty and equality) on which agreement can be achieved. That is, open and fair debate is biased towards liberty and equality because it requires liberty and equality.

We would also like to add that a sole appeal to principles such as liberty and equality can never achieve what discussion and deliberation among disagreeing free and equal persons cannot. An appeal to these principles sets the stage for a discussion, it cannot replace the discussion itself. Or to describe it in Habermasian terms, freedom and equality among stakeholders are necessary to achieve an egalitarian ideal speech situation in which agents can exercise their communicative rationality, that is, their capacity to engage in discussion under these ideal speech conditions. As such, our approach offers no guarantee to solve intractable disagreement—no approach could. It is however an adequate normative tool for those who see merit in achieving agreement.

In the next section, we will explain how liberty and equality as preconditions for formulating HER policy manifest in a pluralistic world.

Pluralism and neutrality in embryo model research

HER is a multidisciplinary and international endeavour in which researchers from different backgrounds cooperate to achieve scientific aims that all and each from their own evaluative perspective, have reason to value. This research has become a nexus in which multiple forms of pluralism, for example, pluralism of scientific, ethical and cultural views, intersect. Pluralism in scientific research and in HER in particular is a fait accompli.²⁴ This pluralism is, for example, reflected in the variety of the legal definitions of the embryo, but also in the variety of perceptions of the moral status of the human embryo. Although pluralism adds significant value to scientific research, it poses a challenge for policy makers burdened with formulating ethical and legal limits to this research. Confronted with a plurality of views on the desirability, acceptability and value of HER, policy makers are hard pressed to formulate policy which does justice to this pluralism that is, which respects all stakeholders as free and equals. A turn towards political philosophy and the work of philosopher John Rawls in particular is instructive here.

Political philosophy is among other things concerned with the justification of state policy. Political philosophers have traditionally justified their policy by appealing to their theory of choice such as utilitarianism, contractualism, Kantianism and the like. One of Rawls’s contributions in this field was to argue that this strategy of ‘selecting the best theory’ to justify state policy is mistaken. Reasonable and well-willing citizens who strive to lead lives they have reason to value, will inexorably subscribe to different and even conflicting doctrines. Rawls calls this the ‘fact

of reasonable pluralism'.⁷ The justification of state policy should not rely on comprehensive doctrines. 'For doing so would be unfair to those who subscribe to a conflicting reasonable doctrine; it would mean that the coercive power of the state would not be justified to them in terms they can accept, even while they were forced to abide by its terms.'²⁵ Rather, Rawls proposes to identify the principles that reasonable and well-willing citizens who adhere to conflicting comprehensive doctrines can agree on and use those as the basis for state-governed policy. In this way policy-making is based on impartial that is, neutral grounds which are justifiable to all to whom said policy applies. In other words, the neutral justification of policy is a necessary prerequisite for value pluralism as citizens are in this way respected as free and equal members of society.

Given the fact of reasonable pluralism in HER, we also subscribe to a neutral mode of justification for its policy. Basing HER policy on a comprehensive ethical view on, for example, the moral worth of embryo models would amount to a form of indefensible ethical hubris; the idea that there are some who have privileged access to uncontested ethical truths. Moreover, without neutrality, reasonable and well-willing stakeholders are coerced to abide by policy that is based on ethical views they do not subscribe to and may even vehemently disagree with on reasonable grounds. The task for policy makers is not to convert -say- utilitarians into Kantians or vice versa. It is to formulate policy which is acceptable to both. Only then are they respected as free and equal individuals.

In the next section, we will further explain what 'reasonableness' entails. Before doing so however, it is important to note that the distinction between what is reasonable and unreasonable and consequently between what is neutral and non-neutral (ie, perfectionist) is gradual rather than dichotomous. It is therefore more appropriate to understand reasonableness and neutrality as normative benchmarks that can be approximated to a lesser or greater extent. To illustrate these positions however, we discuss these concepts as if they are attainable aims, knowing very well that unqualified reasonableness and neutrality are out of reach.

Reasonableness and non-rejectability in HER policy-making

Reasonableness in the context of HER can be defined as: 'the demand that the reasons underpinning public policies have to be answerable before epistemic and ethical standards that rational citizens, willing to cooperate with fellow citizens on terms that are acceptable (ie, non-rejectable) to all, have reason to accept'²⁶ In other words, the pluralism we wish to put forward is not an unbridled acceptance of different views on what constitutes good HER policy. In the previous paragraphs, we have already argued that policy-making should respect stakeholders as free and equal persons by not forcing them to accept justifications that are reasonably rejectable. We add here that stakeholders should base their position on HER policy on arguments that meet epistemic and ethical standards. Without these standards, pluralism can collapse into arbitrariness. Starting with the former, epistemic standards pertain to the minimal standards of logical consistency, argumentative coherence and scientific soundness.

Consequently, views which are logically inconsistent, incoherent or scientifically unsound should not inform HER policy. The first two are uncontroversial. If one puts forward that it is morally permissible to do research with human embryos up to 14 days but it is impermissible to do research with liver organoids, then, *ceteris paribus*, this claim raises suspicions of a logical nature (it seems that the law of transitivity is not respected). Without further explanation such a view need not to inform HER policy-making. The same goes for incoherent claims, for

example, believing that sentience cannot occur before 14 days but disallowing HER altogether because of harm as a result of (sentient) suffering. Logical consistency and argumentative coherence are necessary requirements for rationality and basing HER policy on irrational views is unreasonable; stakeholders have grounds to reasonably reject these views. The more challenging requirement is scientific soundness. Modern day science is in its very nature non-categorical, open to revision and based on expert consensus. The unquestionable belief in science as the right way to uncover the Truth about the world is known as scientism and is itself a comprehensive view which should be avoided in HER policy-making. Still, whenever moral claims are based on scientific insights, insights that have to do, for example, with the benefits of HER, the developmental potency of stem cells or the developmental stages of the embryo, these insights should be scientifically sound. That is, based on the insights which have, as yet, passed the test of serious scientific scrutiny.

Reasons that are logically inconsistent, incoherent, or scientifically unsound are reasonably rejectable and HER policy that is based on these epistemic errors can rightfully be challenged by those who disagree with said proposed HER policy.

Take for example the 14-day rule. The scientific insight which is mentioned in the context of the 14-day rule is that: 'not even the founding cells of the nervous system have been specified prior to this stage'¹⁶ Until falsified, this is a scientific matter of fact (whatever a scientific matter of fact may mean). In the case of embryo models however, the development of cells and structures responsible for sentience can differ depending, for example, on the medium that is used to culture them that might favour or impede the appearance of specific neural structures. An example is the gastruloid model. Under certain culture conditions or genetic manipulations of the stem cells used to form gastruloids, it will not be able to form the anterior part of the embryo, which is the part that is the precursor for the central nervous system.²⁷ Similarly, experimental conditions can also restrict the appearance of tissues associated with sentience in more complete embryo models such as blastoids. Consequently, basing the 14-day rule to gastruloid or blastoid research would not be reasonably non-rejectable as sentience is not adequately capturable in terms of 'days of development'. That is, although sentience is morally relevant, the link to a number of days of development (14 in this case) is epistemically speaking questionable.

In addition to epistemic standards, ethical standards should also be taken into consideration. The 14-day rule, for example, is based on the ethical standard that harm caused by suffering is impermissible and should therefore be prevented. This ethical standard is uncontroversial as most normative outlooks converge towards the idea that it is impermissible to subject sentient beings to suffering in general and within research in particular. The impermissibility of disproportionate and non-subsidiary suffering brought about by research is an ethical standard that can be supported by or subsumed under many different ethical theories and cultural as well as religious doctrines; no sensible normative outlook teaches the promotion of needless suffering. Therefore, the ethical standard underpinning the 14-day rule is reasonable for both human embryo research and embryo model research.

To sum up, reasonableness requires on the part of policy makers to adhere to epistemic and ethical standards that are non-controversial, and therefore, in principle, non-rejectable. We have provided an example of both standards.

Reasonableness requires on the part of citizens, that is, the stakeholders of HER that the policy they accept or reject are also

acceptable or rejectable from the perspective of peers who hold different yet epistemic sound and ethically defensible views. Take, for example, the consideration that the creation of human embryos for reproductive ends is morally less problematic than the creation of human embryos for research ends. Proponents argue that the latter subjects embryos to a higher degree of instrumentalisation than the former.²⁸ As FitzPatrick frames it, it is merely foreseeable that some embryos created for reproductive ends will be destroyed whereas embryos created for research ends are intended to be destroyed. The moral weight of this argument depends on whether one accepts that intending to treat morally relevant subjects solely as a means to an end is more wrongful than only foreseeing that this might occur. Steinbock, for example, disagrees with the moral relevance of this distinction.²⁹ For one, she argues that respect for persons as ends in themselves is not owed to embryos (and a fortiori to embryo models). Moreover, she argues that what justifies the use and destruction of embryos for reproductive ends is the value of reproduction. If it is the value of reproduction that justifies the foreseeable destruction of embryos then equally valuable projects, such as the improvement of ARTs and regenerative medicine, should by the same token justify the use and destruction of embryos for these aims.

If we accept, for the sake of argument, that neither argument is decisively superior to the other then it would be unreasonable on the part of ‘Fitzpatrickians’ to demand from ‘Steinbockians’ to submit to policy that is based on their ethical commitment (or vice versa). Reasonableness thus demands that the reasons underpinning policy are acceptable or rejectable not only from one’s own perspective but also from the perspective of others who hold different yet epistemic sound and ethically respectable views.

In sum, to arrive at justifiable HER policy, policy makers have to strive for presenting reasonable grounds that underpin their policy proposals and stakeholders should strive to assess these grounds in a reasonable manner in order to either accept or reject them. In the following section we will specify our neutrality criterion for HER policy in terms of neutral higher-level agreement and neutral lower-level agreement.

Neutral her policy, going high and low

We have argued that in a pluralistic world, legitimate HER policy requires agreement on neutral grounds which conceptually speaking amounts to the demand that policy should be reasonably non-rejectable. To flesh out this demand in terms of what we will call ‘neutral higher-level agreements’ and ‘neutral lower-level agreements’, we will first shortly present Rawls’s idea of an overlapping consensus as it is the philosophical root from which our two neutral grounds sprout.

Rawls grappled with the reconciliation of the need for justification of the exercise of political power and the desirability of value pluralism which entails that no comprehensive theory, doctrine or set of values should be used to base this legitimacy. His solution to this conundrum was to point towards normative elements that otherwise competing normative outlooks share and use these as freestanding ethical principles on which the legitimate exercise of political power can be based. That is, his solution was to seek an ‘overlapping consensus’. For example, liberty as a value is present in several religious doctrines as well as in several ethical theories. Therefore, liberty can be used, in Rawls’s words, as a ‘freestanding module’, which is derived from different comprehensive normative outlooks to base legitimate policy on. In other words, policy that respects or promotes the liberty of citizens is -in principle- justified as the importance of

liberty is (A) not dependent on any single comprehensive normative outlook yet and (B) it can be affirmed by different competing normative outlooks. The merit of this justificatory approach is that the values that are identified as the result of an overlapping consensus are broadly supported and thus respect the plurality of values. There are however, two possible demerits. First, the scope of values that are identified as the result of an overlapping consensus is limited and may be too limited to base policy on. Second, there will be many reasonable interpretations and specifications of the values that are the product of an overlapping consensus which in turn will yield insufficient consensus on rules and policies.

In the case of HER policy for example, some of the values that can be endorsed as a result of an overlapping consensus, probably, are: ‘non-maleficence’, ‘beneficence’, ‘fairness’ and ‘equity’. Most HER stakeholders from different parts of the world with differing ethical commitments will most likely converge on the importance of these abstract values. The challenge for policy makers, however, is to translate these abstract values into concrete policy. We can both agree on ‘do no harm’ as a value that should underpin HER policy but disagree on whether this amounts to the acceptance of creating blastoids for research purposes. This becomes even more challenging when we disagree, for example, on whether an embryo has a soul. What would, in the face of intractable disagreement on metaphysical or empirical matters be the added value of having a higher level agreement such as ‘do no harm’ when aiming to formulate HER policy?

The claim that ‘embryos have souls’, is reasonably rejectable by those who do not believe that embryos have souls as there is no empirical evidence provided for its existence. Therefore, the part that can be reasonably rejected (embryos have a soul) offers no basis for agreement based on consensus (but agreement based on compromise is still open). (To be sure this does not settle the question about whether embryos have souls) But other higher-level agreements (e.g., do no harm) can still pave the way towards concrete policy. For example, a stakeholder of Jewish faith will not reject a 14-day rule because ensoulment has not taken place yet, but he might reject the creation of embryo like structures which can (for the sake of argument) be manipulated in such a way that they develop rudimentary sentience around 14 days. He will agree with the secular stakeholder that the higher level agreement ‘do no harm’ should lead to HER policy which forbids the creation of these manipulated embryo like structures. This is to say that stakeholders who agree that harm is to be avoided (higher level) can explore the multiple ways in which this principle can be specified into concrete policy even in the face of intractable disagreement on concrete matters or matters of faith. (e.g., about the soul).

We call the search for values that should underpin HER policy ‘going high’ and the overlapping consensus reached on these values ‘higher-level agreement’. Ensuring that HER policy is based on values such as ‘non-maleficence’, ‘beneficence’, ‘fairness’ and ‘equity’ would follow from the demands of going high. Notwithstanding the above-mentioned demerits, reaching higher-level agreement remains crucially important to formulate HER policy in a pluralistic world.

We take note of the difference in aims between policy makers on the one hand and ethicist and philosophers on the other. With room for overlap, generally speaking, the latter is more interested in the soundness of moral judgements and the quality and consistency of moral arguments whereas the former is more interested in the legitimacy of policy, respect for those to whom policy applies and the stability and reciprocity that policy

should generate within a pluralistic context. These latter aims are served by basing HER policy on values that are espoused by the HER stakeholders. Going high alone, however, will most likely provide an insufficient indication on what concrete policy is desirable and acceptable.

To address this, we propose to also ‘go low’. This refers to the aim to identify agreement on a more concrete policy level. To illustrate this, consider the following examples. People can disagree on why a murderer must be punished (eg, retribution, deterrence, rehabilitation) but agree that a murderer must be punished. People can disagree on why rain forests are valuable (eg, intrinsic value, stewardship, symbolic value) but agree that they have value. People can disagree on what the moral status of human embryos is but agree that research with human embryos should be carefully regulated. In general terms, lower-level agreements such as agreements on actions or policy are not necessarily dependent on higher level agreement such as agreements on theory or doctrine. Sunstein has coined the term ‘incompletely theorised agreement’ for cases in which people diverge on abstract principles but converge on more concrete outcomes.⁸ We call the search for agreement on the level of concrete policy proposals ‘going low’ and the agreements that follow from this ‘neutral lower-level agreement’. The agreement reached is neutral and reasonably non-rejectable as it is not buttressed on any single comprehensive doctrine or theory which would require from some stakeholders to abandon or revise their deeply held morally respectable convictions.

In fact, concrete lower-level agreements can be supported from many different and even competing doctrines and theories. For instance, Kantians and utilitarians will have different reasons for wanting to adhere to policy that bans cloning for reproductive purposes. The disagreement on theory may pose a challenge for ethicists who are in pursuit of the most appropriate ethical reasons that should underpin this ban. For policy makers, however, this disagreement is not necessarily problematic as they are mainly concerned with broadly supportable agreement as the basis for policy. The ethical soundness should, in this context, be reflected in the agreement on the policy it generates. The lower-level agreement on the ban on cloning, for example, is satisfactory as the legitimacy for the ban is solidly based on multiple respectable ethical views^{vi} even though these views are conflicting on a higher level of abstraction. A more pertinent example is the difference in views on the moral status of the human embryo. It is for example typically thought that the ideological incompatibility between theists and atheist leads to intractable views on the permissibility of HER. This is not necessarily the case. Atheists and Muslims can, for example, perfectly agree on the 14-day rule (eg, HER policy of Iran) even if the former awards the embryo a lower moral status and the latter awards the embryo after ensoulment, which takes place after 40 days, full moral status.³⁰

HER policy makers are not concerned with converting stakeholders to some religious doctrine, especially not in a pluralistic social and academic milieu. What matters is that HER policy is acceptable to the stakeholders’ own reasonable ethical criteria, whatever these may be. In this way respect is shown to the moral convictions of different stakeholders. This will also contribute to the stability of the proposed HER policy as stakeholders will have, each from their own evaluative viewpoint,

reasons to support said policy. To ascertain the policy that stakeholders would converge on by ‘going low’ stakeholder analyses is required. It is therefore unfruitful to compile, here, a list of rules and regulations that HER should adhere to. Going low entails collecting, mapping and analysing the HER policies that stakeholders agree and disagree with, giving it a strong empirical dimension.

For example, agreement has been reached within the ISSCR that the level of completeness of the embryo model should be considered to establish the ethical oversight. The more complete the model, the more ethical oversight. The reasoning is that, because human embryos develop by being supported by extraembryonic tissues (eg, the placenta) and by a uterine environment, research on models that form analogues of these supporting elements have a potential to, one day, form into a fetus with sentience, whereas models that only form a limited part of the conceptus, do not. This agreement that biological completeness is an adequate indicator for ethical oversight can be reached, for example, via consequentialist ‘minimise harm’ as well as a deontological ‘maximise respect’ lines of ethical reasoning. Ample choice for a substantive theory is available to underpin the ethical oversight for research with embryo models.

An additional benefit of ‘going low’ is that it relaxes the justificatory demands of agreement by consensus and allows for agreement by compromise. For consensus, including Rawlsian overlapping consensus, some form of substantive agreement is required. That is, agreement by consensus requires that stakeholders agree on some value, principle, rule or policy even if they disagree on background reasons. We may for instance substantively agree on the adequacy of the 14-day rule, but for different background reasons. One may agree on its adequacy as the threshold of individuation has been reached whereas another may agree because the founding cells of the nervous system have not been specified prior to this stage. In this example, divergent background reasons lead to a substantive agreement on the 14-day rule. We may, however, also disagree on the 14-day rule, say, because the latter argues that there still is a significant gap between gastrulation and sentience and therefore the 14-day rule is disproportionately restrictive. In this case, there is no substantive agreement possible on the 14-day rule, that is, no agreement by consensus. Agreement as a result of compromise, however, is still possible. If one stakeholder holds that the 14-day rule is adequate and the other holds that it should be replaced by a 21-day rule, they could settle on a, say, 18-day rule. The 18-day rule does not follow from any substantive agreement backed up by diverging background reasons but by the consideration that it is better to have tolerable policy in place than to have no policy at all, even if said policy is not entirely desirable from one’s own point of view. In more general terms, even if there is no common ground to be found among stakeholders, they may still pursue, without resolving their disagreement, agreement through compromise as the benefits of agreement can outweigh the demerits of a situation of unregulated conflict. Arnsperger and Picavet describe this as ‘a transformation of unregulated conflict into negotiated conflictuality’.⁹ We subsume this search for compromise also under the strategy of going low.

Central to going high and low is ‘agreement’. We have identified two forms of agreement, agreement as a result of consensus, which is agreement on content and agreement as a result of compromise, which is agreement based on the strategic benefits of moving beyond disagreement and conflict. Our suggestion is to have no lexicographical ordering of justification with regards to going high and low and with regards to agreements based on consensus and compromise. The agreement of free and equal

^{vi} Although the question of what makes ethical views respectable is itself controversial, we would only require from such a view to be compatible with the basic view that persons are treated as free and equal.

stakeholders on a reasonably non-rejectable value, principle, rule or policy offers the necessary and sufficient justification for that on which agreement is reached. Given that agreement can only be reached if all stakeholders can support the outcome of the agreement each from their own evaluative space, justification follows from the agreement itself. One may call this a public reason approach³¹ to HER policy-making. For example, if one agrees with the 14-day rule because ensoulment hasn't taken place and another agrees on the 14-day rule because sentience is absent, then the agreement on the 14-day rule is its justification, even if the reasons for agreeing differ. This idea of justification by agreement would be impossible uphold if the different forms of agreement and the different levels at which they occur (higher and lower) are weighed differently. Therefore, there is neither a hierarchical relation of justification nor a difference in aim between going high and low. They aim for agreement and are worth the same.

CONCLUSION

What can be gained from going high and low? First, a focus on both neutral higher and lower agreements can be conducive to the process of HER policy-making that is acceptable to diverse stakeholders within a pluralistic context. In particular, agreements on all levels of abstraction can be considered as justificatory grounds for policy-making. Still, we recognise that the nature of this topic is controversial and divisive and that the stakeholders' positions may have become entrenched because of this nature. Alternatively, however, an appeal to a single ethical or philosophical doctrine, culture or ideology as a basis for justifying HER policy will yield equally disappointing outcomes with the added problem of not taking seriously, the plurality of sensible views that stakeholders may hold on this topic. The only way forward is through discussion which aims at finding some common ground or consensus. This discussion can be facilitated by going high and low.

Second, the demand that agreements are as neutral as possible can aid in the assessment of (entrenched) normative positions within the discussion. Rather than subjecting each other's position to substantive ethical and philosophical scrutiny it may prove to be more fruitful to assess positions in terms of their affinity with value pluralism. For example, if one's view on the (un)desirability of creating blastoids requires from most other stakeholder to abandon their deeply held and morally respectable views on the matter, then this view is uncongenial to the cooperative and reciprocal nature of policy-making, respectable as this view, on its own, may be. On occasion, standing on principle may be warranted but overall, seeking agreement is normatively speaking the best route towards policy that is acceptable to most if not all stakeholders. Thus, going high and low provides sensible rules of engagement for pluralistic HER policy-making.

Third, going high and low allows for agreement based on consensus (substantial agreement) and agreement based on compromise (strategic agreement). All avenues for reasonable discussion are open. Of course, this will not necessarily lead to agreement on HER all across the board. But the intractability of positions should also not be exaggerated, especially if we consider well-willing stakeholders not to be agents incapable of being moved by arguments, considerations and the benefits of shared policy-making but agents that are capable of adjusting their beliefs on multiple levels of abstraction in the face of good reasons. Cynicism about the willingness to cooperate and engage in public reasoning to arrive at sensible HER policy should be avoided.

Apropos religious views, which may be thought to manifest as entrenched positions, it is important to not treat these as a monolithic given. That is, with regards to the moral status of the embryo and the permissibility of HER, there are important differences both between religious views and within religious views. In fact, many dominant religious views including Islam, Judaism, Hinduism, and Buddhism do not award the embryo a full moral status at conception and offer significant leeway for HER if it serves the human good.³² Moreover even within religious views which hold that the inception of personhood coincides with the fertilisation of the egg, for example, the Roman Catholic view, there may be synchronic or diachronic interpretations available on the moral status of the embryo. For example, before 1869 in which the Pope Pius IX decreed that personhood occurs at fertilisation, there was no fixed interpretation of personhood within the Roman Catholic church and the views of Thomas on the three stages of ensoulment would locate the incipience of personhood at 40 days.³³ In addition, there are diverging views on the moral status of the embryo and the permissibility of HER to be found in our day and age as well. According to father McCormick the argument that a new human being comes into existence when a zygote forms should be rejected and he claims that: '(o)n view of the conviction that the preembryo is not yet a person and that its statistical potential for becoming such is small, it is not clear that nontherapeutic experiments can be excluded in principle.'³⁴ All this shows that although differences in beliefs on the moral status of the embryo can differ widely, these differences should not be exaggerated to the point that they are perceived as immutable categorical positions which are immune to evolving interpretations and insights.

Lastly, going high and low should be supplemented by procedural criteria in which it is stipulated that stakeholders should be able to participate in the shaping of HER policy; the process of policy-making should be publicly accessible and HER policy should always be revisable in light of new ethical reasons or scientific insights. The way to look for higher and lower level agreement is through open and fair and respectful discussion between stakeholders. Such a discussion could, for example, centre on the evaluation of current HER guidelines. There is real craftsmanship involved in organising and guiding fruitful discussion. This craftsmanship is beyond the expertise of the authors and beyond the scope of this manuscript. Our approach offers normative guidelines to have this discussion.

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