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## **The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015**

### **Scottish Council on Human Bioethics Submission:**

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the **United Nations Universal Declaration of Human Rights** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10<sup>th</sup> of December 1948.

#### **Executive Summary:**

1. The SCHB is of the opinion that the law should not be changed to allow Maternal Spindle Transfer (MST) and Pro-Nuclear Transfer (PNT) to take place for Scotland under the **Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015**. This is because, the proposal is:
  - A matter which may be devolved to the Scottish Parliament in the very near future
  - Misleading the general public through the use of the term 'mitochondrial donation'
  - Contrary to international legal instruments
  - Unclear with respect to consequences
  - Genetic engineering which alters the gene line irrevocably
  - A precedent that will eventually and inevitably lead to the further engineering of prospective babies
  - Misleads parents to believe that they are having a child 'of their own' when in reality they may have to share parenthood with another woman (the egg donor)
  - Undermines the manner in which children born from these procedures may understand their sense of identity since they may not accept that they only have two parents
2. Moreover, the possibility of promoting MST and PNT in order for parents to believe that they can have 'children of their own' while addressing mitochondrial disorders should not be envisaged until the two following questions have been satisfactorily addressed:
  - The wish most couples express for a child 'of their own', and
  - The important bonds that exist between the biological parents and the child.
3. If it remains unclear why parents want to have a child of their own, then it remains unclear why the considerable risks related to MST and PNT should even be contemplated when other procedures already exist which enable couples to have a healthy child.

4. Finally, the SCHB notes that new alternatives to both MST and PNT are already being pursued by scientists in the treatment of mitochondrial disorders which can be considered as far less controversial.<sup>1</sup> These should be examined and developed instead of considering MST and PNT.
5. **Note:** The SCHB has asked UNESCO's International Bioethics Committee (ICB) for an opinion on MST and PNT. In this regard, because of its international responsibilities, it would be appropriate for the UK Department of Health to support the development of an ICB report on the procedures. It would also be inconsiderate of the UK Department of Health to contemplate legalising MST and PNT before the ICB's report on the subject has been published.

### **Definitions:**

6. Though the expression 'Mitochondrial Donation' is used in the **2008 Human Fertilisation and Embryology Act**, the SCHB believes that the UK Department of Health's characterisation of MST and PNT as 'mitochondrial donation' is scientifically deeply misleading and reflects a manipulation and misunderstanding of what is really being suggested. It represents a lack of professional discernment in the UK Department of Health as to its role in the context of a democracy in helping the general public understand what the procedures actually mean from a biological perspective.
7. The SCHB would like to question why the UK Department of Health is continuing to use the ambiguous term of 'mitochondrial donation' when this has already been shown to potentially mislead the general public.<sup>2</sup> This can have very serious repercussions and undermine the democratic process.
8. Certainly the more detailed biological description of both these procedures provided by the Human Fertilisation and Embryology Authority (HFEA) as part of its public consultation made it abundantly clear that it is the chromosomes that are transferred during both procedures, and not the actual mitochondria.<sup>3</sup>
9. Moreover, it is noted that it is not just new mitochondria that are being used in a defective unfertilised or fertilised eggs but a whole new unfertilised or fertilised egg emptied of its maternal spindle or pronuclei, respectively. Mitochondria only form a small part of these new eggs.<sup>4</sup>
10. The mitochondria are certainly not taken out of one egg and safely transplanted into another egg, from which all or most of the latter's mitochondria have already been removed. It is, therefore, not so much a process of 'mitochondrial donation' or 'mitochondrial transfer' but of 'chromosomal transplantation'.
11. The UK Department of Health mentions in its consultation that:

*"2.1 On 28 June 2013 the Government announced that it intended to move forward with regulations to allow mitochondrial donation to prevent the transmission of serious mitochondrial disease between mother and child. The Chief Medical Officer for England, Professor Dame Sally Davies, said: Scientists have developed ground-breaking new procedures which could stop these diseases being passed on, bringing hope to many families seeking to prevent their future children inheriting them. It is only right that we look to introduce this life-saving treatment as soon as we can."*

12. Again, the SCHB believes, that this is an inappropriate distortion of the facts since there is no question of 'saving lives' through the procedures. Instead, it is only certain lives that are brought into existence through MST and PNT. This reflects an unacceptable lack of discernment and even misinformation on behalf of the Chief Medical Officer.

<sup>1</sup> Anonymous, Correcting human mitochondrial mutations, 13 March 2012, e! Science News, <http://esciencenews.com/articles/2012/03/13/correcting.human.mitochondrial.mutations>, (Accessed on 20 August 2012).

<sup>2</sup> Calum MacKellar, Questions relating to 'mitochondrial replacement', BioNews, 741, 10 February 2014, [http://www.bionews.org.uk/page\\_395064.asp](http://www.bionews.org.uk/page_395064.asp)

<sup>3</sup> See: HFEA, New techniques to prevent mitochondrial disease, <http://mitochondria.hfea.gov.uk/mitochondria/what-is-mitochondrial-disease/new-techniques-to-prevent-mitochondrial-disease/> (Accessed on 27 January 2014)

<sup>4</sup> Mitochondria only constitute 15 to 35 per cent of a cell's total mass. See: Mitochondria, Wellcome NEWS, Spring 2012, p. 24.

## **Devolution of Human Embryology to Scotland under the Smith Commission**

13. In the light of the referendum vote on the 18th of September 2014 and the commitment expressed to strengthen the powers of the Scottish Parliament within the UK, the Smith Commission<sup>5</sup> has indicated with respect to Health and Social Affairs that:

*“61. The parties are strongly of the view to recommend the devolution of abortion and regard it as an anomalous health reservation. They agree that further serious consideration should be given to its devolution and a process should be established immediately to consider the matter further.*

*62. The devolution of xenotransplantation; embryology, surrogacy and genetics; medicines, medical supplies and poisons; and welfare foods (i.e. matters reserved under Sections J2 to J5 of Head J – Health and Medicines, Schedule 5 to the Scotland Act 1998) should be the subject of further discussions between the UK and Scottish Governments. Those discussions are without prejudice to whether or not devolution takes place and in what form.”*

14. Because of the above, the Scottish Council on Human Bioethics would like to ask the UK Parliament to not enact the **Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015** for Scotland.

It would be appropriate for the Westminster Parliament to put all new legislation on hold concerning these subject matters for Scotland until it has been established which elements will be devolved to the Scottish Parliament.

In the UK, it is only natural that the complex nature of devolved responsibilities in this range of policy areas should be delayed for Scotland in consideration of the full enactment of new legislation.

## **Human Procreation**

15. Traditional human procreation does not take place out of thin air. It takes place through the participation of the man and the woman as whole persons. More specifically, this participation takes place through the means of reproductive cells (sperm and egg cells). In this regard, it is important to consider how these reproductive cells can be understood in the context of reproduction. This is not an easy matter but, generally, each reproductive cell may be considered as a kind of representative of each of the partners in the procreative process. As such, each sperm cell becomes a representative of the whole man and each egg cell becomes a representative of the whole woman.
16. Of course, sperm and egg cells have no moral value of their own but when they come together to form an embryo, their representative wholeness cannot, in any way, be dismissed as unimportant. On the contrary, it is fundamental since it is the reproductive cells that are the means for procreating another specific ‘whole’ living child.
17. This also means that if the sperm and egg cells were significantly modified in a technical manner, such as with MST, questions can be asked whether they would still represent the wholeness of the partners from whom they originated. Would they not be seen, instead, as being foreign in the same way as if the reproductive cells of a foreign man or woman (i.e. from outside the couple) were used? The procreative process may then be taking place with reproductive cells that no longer represent the partners and could be seen as an intrusion into the exclusive relationship of the couple.

## **Kinship and Personal Identity**

18. It is noteworthy that as soon as persons become aware of their existence and are not affected by any serious mental disorders, they usually ask themselves questions about who they are. Of course, the answer to such questions may continually be changing and the quest for identity may never really reach a final conclusion.

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<sup>5</sup> Report of the Smith Commission for further devolution of powers to the Scottish Parliament, 27 November 2014, [http://www.smith-commission.scot/wp-content/uploads/2014/11/The\\_Smith\\_Commission\\_Report-1.pdf](http://www.smith-commission.scot/wp-content/uploads/2014/11/The_Smith_Commission_Report-1.pdf)

19. But one of the most important aspects of this identity is related to a person's understanding of his or her origins of existence. For example, individuals may want to identify who caused them to exist (and their ancestors) as well as their biological, social and cultural origins in seeking to recognise, understand and make sense of who they really are.
20. When parents, children or other relatives, who have been separated for some reason, eventually seek to re-connect with each other, their reasons for doing so are often difficult to articulate. They frequently struggle themselves to understand what they are actually looking for though they do recognise that it is something which, to them, is very important. In some cases, of course, they would like to know if they are at risk of having a genetic or other biological disorder but many studies indicate that they are also doing this out of 'curiosity' which may reflect a deeper reason such as a search for identity, to know more about themselves or 'emotional significance'.  
It is indeed recognised that people, who do not have any genealogical roots, may often experience a deep sense of genealogical void or bewilderment; of being cut off from the causes and reasons for their existence which helps them build their identity.
21. As a result, individuals usually regard these ancestors and family relatives as being a single community who are 'cemented' together. For example, children realise that their existence originated from the personal existences of their ancestors and that their own existence is inherently tied to these previous existences. Without these parents or ancestors they would not exist. As a result they begin to understand that a long chain of ancestors resulted in their existence. It is as if one large communion between the child and his or her ancestors was present, in a kind of single block, who are all the cause of each other's existences down the ages (the cause may be genetic, gametal such as an emptied egg or something else). People appreciate that because they actually exist because of all their forefathers they owe their existence to them in some way. There is a sense of being dependent on, and even belonging to, these earlier existences. That all these past existences are seen, in some way, as part of the 'whole' existence of the child. The child knows that he or she only exists because of his or her ancestors and the prior continuum of descent.
22. In some form, all these existences come into a kind of communion in which there are deep relationships of unconditional acceptance but also responsibility. And this communion does not only exist between parents and their child but with grandparents, siblings, cousins and other family members.

### **Parents want children of their own**

23. The desire by parents to have children 'of their own', or at least as much as possible 'of their own', is the driving force behind the interest in procedures such as MST and PNT.
24. In addressing the issues raised by the regulation of MST and PNT, it is very important to examine the deep bonds that exist between parents and their offspring. For example, many parents, as the responsible partners in the creation of life, know intuitively that they belong to the child and that the child, in receiving life, belongs to them, i.e., there exists a sort of mutual belonging. The deep sense of loss or incompleteness felt by parents who are unable to be directly responsible for the creation of life in their child is one of the underlying reasons why many seek assisted reproduction rather than adoption. In other words, the fact that prospective parents even consider, let alone undergo, expensive procedures for artificial reproduction indicates the importance they attach to the biology of creation. Such parents are aware, even if subconsciously, that the lack of biological connection may prevent them from feeling a sense of belonging with the child or the child with them.
25. One of the most fundamental questions which arises from the use of MST and PNT is the fact that at least three individuals are participating in the creation of human life. From this perspective, and although chromosomal DNA is extremely important in the creation of a being, it is impossible to just reduce the concept of parenthood to the persons who contributed to this chromosomal DNA. This is because without an enucleated egg or fertilised egg from another couple, no new life would ever have existed. From an ethical perspective, chromosomes by themselves have no real value as such. They only become ethically meaningful if they are transferred into an enucleated fertilised or unfertilised egg and left to develop. In this regard, all those participating in the process of bringing a life into existence may be considered, in some form and to varying degrees, as the 'real' creators of

the creature. They may then also experience some or all the corresponding aspects of parenthood bonds and mutual belonging which arise between creators and their creatures.

26. In the case of MST or PNT, it is not only what is being used that is important (and whether DNA, cytoplasm or any other material is considered) but the amount of individual participation in the creative process, be it at a biological or even manipulatory level. A participation which could then also give rise to creator-creature (parent-child) bonds.
27. In this regard, the UK government is arguing that any child resulting from MST or PNT would not be interested in knowing the identity of his or her egg donor. This is because it is just her emptied egg, and not her chromosomes, that is being used to generate the future child. Thus, in contrast to the donation of whole eggs, the government does not want children born from these two new procedures to be able to identify their egg donors.<sup>6,7</sup>
28. This is, however, very unfortunate and seriously misunderstands the concept of causal parenthood which may be seen as very important to the resulting child who may want to know which individuals were the actual cause of his or her existence.
29. Probably the best example of causal parenthood in which biological parenthood, including genetic parenthood, was seen as being less important than other considerations was reflected in the famous Californian Buzzanca case which took place in 1997. The case arose when an infertile couple, Luanne and John Buzzanca, contracted three separate adults, a sperm donor, an egg donor and a surrogate woman, to help them bring their child into existence through IVF. As a result, a baby girl was subsequently born in 1995. But before the birth took place, and after the Buzzancas signed a contract with the surrogate, John Buzzanca decided to leave his wife and filed for divorce. After a lengthy legal battle over who should pay child-support for the little girl, judges eventually decided that both John and Luanne were to be considered the legal parents even though they did not have any biological, including chromosomal, connections to her. This was because the baby girl would never have been born had not Luanne and John both agreed to have a donated egg fertilised with donate sperm implanted into a surrogate mother. Thus, the court found that the child's very existence was every bit as much their responsibility as if things had been done the traditional way. This decision acknowledges that it was the persons who were the primary cause for the child's existence who had parental priority over any other individuals who had caused the child to come into being.
30. This, of course, does not mean that any of the other persons who had caused Luanne and John's daughter to exist cannot be considered as some kind of parent, such as a genetic or gestational parent. It just means that when any person is partly responsible for the very existence of a child, through any means, then this is sufficient to qualify this person as a causal parent. As such, the daughter of Luanne and John Buzzanca actually has five causal parents whom she may possibly want to identify and with whom she may even want to begin relationships. Similarly any child born from MST or PNT may also want to identify his or her egg donor (even if her egg's chromosomes had been removed) since he or she would be aware that without this woman's emptied egg he or she would not exist.
31. Another example is the hypothetical experiment where two identical twin women are being treated at the same IVF clinic and there is some mix up with their eggs. Assuming, for the sake of the hypothetical experiment, that the women's eggs were exactly the same from a genetic perspective, there would be no genetic test to tell from which woman the eggs originated. If a son, for example, was born from one of these eggs, could it not be assumed that, when he grows up, he may want to know which twin's egg was fertilised to bring him into existence? This would happen even though both women produced identical eggs from a genetic perspective. It would surely be important for the child (and the mother) to know which of the eggs was actually used. This means that it is not only the chromosomes or what is found in the genes that matters but also the fact that a certain person brought

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<sup>6</sup> Sarah Knapton, Three parent babies banned from knowing 'second mother', The Telegraph, 23 July 2014, <http://www.telegraph.co.uk/science/science-news/10984068/Three-parent-babies-banned-from-knowing-second-mothers.html>

<sup>7</sup> UK Department of Health, Mitochondrial Donation: government response to the consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child, 22 July 2014, p. 30.

into existence a certain child through cause and effect.<sup>8</sup> In other words, that a certain life brought into existence another life.

32. This is important since it also reflects the manner in which, historically, individuals have understood who their ancestors or offspring were in matters, for example, of the inheritance of a crown. At that time, no one knew of the existence of chromosomes nor did anyone understand the manner in which biological heritage functioned but they did comprehend that a certain life brought into existence another life.

Again, it was never so much chromosomes or genes that mattered in a historical context but the fact that a certain person brought into existence another person through cause and effect.

33. With MST and PNT the same understanding would exist. In other words, parenthood cannot just be reduced to chromosomes. Instead it is all those who are the cause, including from a biological perspective, of the existence of a child (including the egg donor) who can be considered as causal parents.

### **Kinship in Relation to MST and PNT**

34. With natural reproduction, the 'real' creators and the chromosome providers are the two same persons. However, with a number of new fertility procedures, such as with MST and PNT, the involvement of the causal creators becomes very complex and may vary quite considerably. Thus, a real risk exists that the future child may be confused as to the manner in which he or she understands who his or her causal (creator) parents really are. This may be important for him or her to establish a healthy sense of identity.

35. The UK Department of Health mentions in its consultation that:

*“1.24 The dominant DNA (the nuclear DNA) in any child born from these new techniques would be that of the mother and the man providing the sperm (usually the father). Although it would be the case that DNA from three people (the mother, the man providing the sperm and the egg donor ) would be present in the child, only a tiny percentage of the child’s DNA would come from the egg donor. Most importantly, the residual DNA from the donor would only be mitochondrial DNA so would not affect the resulting child’s personal characteristics and traits. This is because mitochondrial DNA only contains genes that are essential for normal mitochondrial function; personal characteristics and traits are derived from the nuclear material.*

*1.25 This was reflected in the HFEA’s report of its public dialogue, in which most contributors rejected the “three parent IVF” idea for these reasons. The Nuffield Council on Bioethics report similarly said that “mitochondrial donation does not indicate, either biologically or legally, any notion of the child having either a third parent or a second mother”.*

*1.27 The proposed mitochondrial donation techniques only allow for unaltered nuclear DNA to be transferred to an egg or embryo that has unaltered healthy mitochondria. The key consideration is that these techniques only substitute, rather than alter, a very limited number of unhealthy genes in the “battery pack” of the cells with healthy ones. Most importantly, mitochondrial donation techniques do not alter personal characteristics and traits. As the aim is that children born as a result of mitochondrial donation, and their offspring, would be free of serious mitochondrial disease, it would though be a form of germ line modification or germ line gene therapy, as recognised by reports produced by the HFEA and the Nuffield Council on Bioethics.”*

36. In response, the SCHB notes that the HFEA and Nuffield Council on Bioethics were mistaken to suggest that *“mitochondrial donation does not indicate, either biologically or legally, any notion of the child having either a third parent or a second mother”*. They misunderstand the very concept of kinship

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<sup>8</sup> Another example is if an adoptive child seeking out his biological father discovers that there is a match for paternity with a certain man but then discovers that this man is not his father but the twin brother of his biological father. The discovery that this man is, in fact, his uncle will be a matter of great significance even though the genetic heritage of both twin brothers is the same. What the child in search of his biological identity is seeking is not merely genetic information of a certain kind but also the truth about the manner of his conception, information about the relationship between his biological father and mother, his kin, siblings, grand-parents, and a great deal more. Jacqueline A. Laing, *Artificial Reproduction, Blood Relatedness, and Human Identity*, *The Monist*, Vol. 89, No. 4, (p 548-566). p. 551-552.

which cannot be reduced to the personal biological characteristics and traits of a person but must also include the manner in which a child constructs his or her personal identity. An appropriate appreciation of the meaning of kinship, and how this strongly influences the manner in which a person understands his or her identity, is reflected in the above discussion.

37. Part of the identity of a person is based on knowing his or her origins including who was responsible for bringing him or her into existence (i.e. the parents). This cannot be reduced to the origins of the chromosomes but must also take into account all those who were the original cause of a person's life and existence.
38. From a sociological perspective, MST and PNT are being proposed because couples want children of their own. But that is precisely not how the resulting children may see it. The children born from these procedures may not accept that they only have two parents. Instead they may want to know and have parental relationships with all the 3 or 4 persons who brought them biologically into existence. The SCHB has a lot of sympathy and compassion for persons affected by mitochondrial disorders since they are experiencing a lot of very real suffering. It believes, however, that they are being misguided about the ability of MST and PNT to give them children 'of their own' and this is extremely unfortunate and concerning.
39. It may also be the case that parents who use MST and PNT may be bringing a child into the world for their own sakes without fully considering the eventual wishes of the future child. That is, the child may want to know and/or have a relationship with all his or her biological parents. Though the social or chromosomal parents may concede to tell their child the truth when they are older, they would then have to understand that the child may wish to see and know his or her gametal parent(s) (the donor(s) of the eggs or the fertilised eggs) and express a sort of affection which he or she may already experience.
40. A broad societal discussion concerning the relationship between 'being a creator' and parenthood while trying to understand these parent-child bonds is, therefore, necessary when the creation of human life by novel means is contemplated. After all, it is because these creator-creature bonds are seen as extremely important by many couples that they are seeking fertility treatment and making sure that they have a child 'of their own'.
41. Thus, the HFEA should provide in response to a request from a person born from MST and PNT identifying information for all the individuals responsible for bringing him or her into existence. This includes all the egg donors as well as the man who participated in creating the healthy embryo in PNT. This is because the person born from MST and PNT may consider all these 3 or 4 persons as his or her biological parents and he or she may want to know, or even have a relationship with, them in order to develop a healthy psychological identity.
42. Moreover, framing the concept of 'genetic modification' so that a comparison is made to organ donation, as was done by the UK Department of Health, is false and misleading. This is because with organ donation a life is already in existence whereas in the case of chromosomal transplantation between unfertilised or fertilised eggs, the very creation of life is being considered which is completely different from a philosophical and ontological perspective.

### **MST and PNT Contravenes International Law**

43. The SCHB notes that the techniques on offer are not about treating people who are ill but about shaping future children and generations. It is also of the opinion that there are serious social and ethical implications to changing the germ line in the way proposed by MST and PNT.
44. Because parents would be intervening, with intent, into the genome (i.e. the complete set of genes, including chromosomal and mitochondrial genes) of their prospective children in MST and PNT, the procedures could be considered as germline interventions. This means that genetic modifications may be passed on to a child and all subsequent descendants. It would be the first time such intentional genetic modifications of descendants is considered and would open the door to further genetic alterations of human beings with unforeseeable consequences.

Thus, for the UK to go it alone, without consulting its international partners, and allow both these procedures would create a very serious precedent.

45. The SCHB notes that any intervention seeking to modify the human genome of a person before he or she is created is contrary to international law, including the three following legal instruments:

**(A) The United Nations Education, Scientific and Cultural Organization (UNESCO) - *Universal Declaration on the Human Genome and Human Rights (Adopted on 11 November 1997)* indicates that:**

*Article 24: That 'germ-line interventions' could be considered as a practice that would be 'contrary to human dignity'.*

In this regard, the **UNESCO's International Bioethics Committee** explained in 2003 that "*Germ-line interventions aim at the correction of a specific genetic abnormality in the germ cells or early embryo or at the introduction of genes that may confer to the embryo additional traits like increased resistance to certain diseases.*"<sup>9</sup>

**(B) Council of Europe (47 Countries) - *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To The Application of Biology and Medicine (ETS – No. 164, Entered into force on 1 December 1999)* indicates that:**

*Article 13 – Interventions on the human genome*

*An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.*

In this regard, the **Explanatory Report** for Article 13 mentions that:

*"91. Interventions seeking to introduce any modification in the genome of any descendants are prohibited. Consequently, in particular genetic modifications of spermatozoa or ova for fertilisation are not allowed. Medical research aiming to introduce genetic modifications in spermatozoa or ova which are not for procreation is only permissible if carried out in vitro with the approval of the appropriate ethical or regulatory body.*

*92. On the other hand the article does not rule out interventions for a somatic purpose which might have unwanted side-effects on the germ cell line. Such may be the case, for example, for certain treatments of cancer by radiotherapy or chemotherapy, which may affect the reproductive system of the person undergoing the treatment."*

**(C) The EU (28 Countries) *Directive on clinical trials (2001/20/EC)***

This states in Article 9(6) that:

*"No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity."*

46. Bearing in mind the UNESCO, Council of Europe and European Union Statements it would be very important to define the international implications for the UK to unilaterally pursue germline genetic engineering. For any female offspring conceived using such techniques in the UK, questions may arise relating to the necessary limits placed on her reproductive freedoms should she choose to eventually live in other countries in order to prevent germline alterations being transmitted beyond national borders.

47. Furthermore, for the UK Department of Health to consider allowing MST and PNT without undertaking any clinical safety investigations so that it does not come under the definition of a clinical trial (and

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<sup>9</sup> UNESCO International Bioethics Committee. Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention, 24 April 2003; UNESCO *International Bioethics Committee (IBC)* Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention, 2003, [http://portal.unesco.org/shs/en/files/2397/10554294261ReportfinalPGD\\_en.pdf/ReportfinalPGD\\_en.pdf](http://portal.unesco.org/shs/en/files/2397/10554294261ReportfinalPGD_en.pdf/ReportfinalPGD_en.pdf)



therefore not regulated by the EU Clinical Trials Directive) would very likely be seen as irresponsible and even reckless by the general public.

48. The UK Department of Health mentions in its consultation that:

*1.30 It is important to note that the UK Parliament has expressly provided for the possibility of regulations enabling mitochondrial donation and that it is our view that this power is compatible with the European Convention of Human Rights.”*

49. In this regard, the SCHB disagrees that MST and PNT is compatible with the **European Convention on Human Rights**. Indeed, should a case be brought to the European Court of Human Rights (ECHR) related to MST and PNT, it is inevitable that the judges of the ECHR will base their decision on Article 13 of the **European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To The Application of Biology and Medicine** (see above).

### **MST and PNT Represent Eugenic Practices**

50. Both MST and PND could be considered as different forms of eugenic practices since the genome of future children are being intentionally modified through the procedures. Eugenic procedures are generally defined as strategies or decisions aimed at affecting, in a manner which is considered to be positive, the genetic heritage of a child, a community or humanity in general. As such they would contravene Article 3 of the **Charter of Fundamental Rights of the European Union** (Proclaimed in Nice on 7 December 2000) which indicates that “*In the fields of medicine and biology ... the prohibition of eugenic practices, in particular those aiming at the selection of persons*” must be respected.

51. When a eugenic choice between bringing into existence a disabled or non-disabled person is being considered, it is impossible to separate these persons from their physical characteristics. Any choice in this regard which then becomes public will be seen as very significant by the disabled community since it would suggest that they should also not exist.

Even once they are born, the very identity of persons and the manner in which they understand themselves as individuals cannot be dissociated from their physical characteristics.

In summary, there is a real danger of discrimination to suggest that disabilities, which cannot be separated from persons, should not be brought into existence. This is because the disorder's existence cannot be dissociated from a person's existence. Instead, it is all persons with or without a disability who should be able to be brought into existence without favouritism, discrimination or bias. In other words, saying that a disorder should not exist, should never mean that a person with such a disorder should not be brought into existence.

52. In this respect, the SCHB is of the opinion that making sure that only certain persons are brought into existence in a eugenic manner significantly undermines the very basis of human equality and human dignity.

### **MST and PNT Involves the Destruction of Embryos**

53. The SCHB notes that a significant ethical question would arise if human embryos are destroyed during this procedure.

54. In this regard, the **UK Human Fertilisation and Embryology Act 2008** defines an embryo in Article 1: (1) (b) as: “*an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.*”

55. For MST and PNT to be accepted for clinical use, it is unavoidable that many human embryos will be created solely for research purposes that will, eventually, be destroyed. This creates a serious ethical problem since the **Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To The Application of Biology and Medicine**<sup>10</sup> indicates that:

*Article 18: The creation of human embryos for research purposes is prohibited.*

<sup>10</sup> This is a legally binding document when ratified by a country. So far, 29 Member States have ratified this Convention with another 5 signing their intention to ratify. The UK has not signed or ratified this Convention.

56. In this regard, the Explanatory Report for Article 18 mentions that:

*“116. The article does not take a stand on the admissibility of the principle of research on in vitro embryos. However, paragraph 2 of the Article prohibits the creation of human embryos with the aim to carry out research on them.”*

57. At present, out of the 47 countries of the Council of Europe only **two member states** (the United Kingdom and Belgium) have publicly indicated that they have no intention, at present, of signing or ratifying this convention. This is because, amongst other things, it would prohibit the creation of human embryos for research through cloning or other procedures (which the UK has already legalised) so that experiments can take place on them for up to 14 days after their creation.

58. Furthermore, if PNT were to be accepted as a form of routine treatment and because UK law defines an embryo as *“an egg that is in the process of fertilisation”*, the procedure would require that at least two embryos are destroyed, each time, to reconstruct a third embryo with new healthy mitochondria. This would be seen as deeply offensive and unacceptable to the millions of people in the UK who believe that personal life begins at the moment of creation of the embryo.

### **Further Risks with MST and PNT**

59. It should also be noted that assisted reproduction is not risk-free for the woman giving the eggs since egg retrieval procedures may risk ovarian hyperstimulation syndrome following aggressive hormonal treatments.