



CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA

Report-Opinion 15/CNECV/95

On

## **Experimentation on the Human Embryo**

### **REPORT**

#### **Experimentation on the human being**

1. Modern medicine, in its quality as a biological science, does not dispense with experimentation as a method which enables it to advance scientific knowledge and derive conclusions that might guide the introduction of new treatments, thus corresponding to its mission of preventing, healing or attenuating symptoms or diseases. Although great part of such experimentation is carried out on animals, research activity is being extended more and more onto the human being – fundamentally, because it is recognised that in some situations using an animal model proves to be insufficient or even impossible, and that the extrapolation to the human being of results obtained from animals often leads to gross errors. On a parallel with this, ancillary though it may be, the growing outspokenness and significant impact of animal protection groups has led effectively to reduced investment of efforts in animal experimentation.

The attitude that an increasing number of societies and governments have been adopting towards defending the life, integrity and dignity of the human being, is well known: they lay down principles, often anchored in national constitutions, of respect for such values; and they introduce legislation that clearly defines the principles, objectives, limits and rules of experimentation on human beings. The great principles at stake are the inviolability of human life, the respect for the dignity of each being, informed consent, and the just balance between risks and benefits. In Portugal, the observance of those principles was set down in Decree-Law no.97 of 1994, dedicated to these issues – an opinion by the National Council of Ethics for the Life Sciences was requested prior to its billing (Bill no.193 of 1993 and Opinion 4/CNECV/93).<sup>1</sup>

#### **Experimentation on the embryo: respect and informed consent**

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<sup>1</sup> Decreto-Lei 97/94; Projecto de Decreto-Lei 199/93; Parecer 4/CNECV/93.



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2. Though the principles enunciated above have proved to be sufficient for the ethical and juridical elucidation of research projects where the subjects have been adult and competent human beings – and though practice has shown that difficulties arising from incapacity or extreme youth or old age can be circumvented – it is indisputable that ethical evaluation and juridical opinion become rather delicate when it comes to experimentation on the unborn human being, that is to say, on the human embryo or foetus. First of all, because the terminology itself is debatable. Indeed, some consider that the product of conception goes through different phases in its evolutionary process, i.e., first as a pre-implantation embryo (the embryo has not yet encrusted itself in the uterine membrane, a phenomenon occurring around the 10<sup>th</sup> to 14<sup>th</sup> day); then as implanted embryo (encrusted in the uterine membrane, a phase corresponding to the 2<sup>nd</sup> through to the 8<sup>th</sup> week); then as foetus (from the 8<sup>th</sup> week until birth, which usually occurs by the 38<sup>th</sup> week). Biology has shown, however, that such divisions are arbitrary, for the process is continuous; and that the distinction between embryo and foetus, for instance, is entirely artificial, for no morphological or functional event marks the supposed passage from embryo to foetus. For that reason, we shall employ the terms *embryo* and *foetus* throughout this text without any exact chronological connotation, even though we refer at more length to the embryo, that is to say, to the first stages of human life.
3. One difficulty with wider implications is that concerning the nature of the embryo, for in society there are markedly differentiated currents of thought regarding this issue: ranging from those who defend that as from conception we are in the presence of a human being endowed with full dignity and the consequent rights, to those who maintain that the process is quite diverse, with no humanisation<sup>2</sup> until the beginning of extra-uterine life. More widespread than the latter (most extreme) position, is that of conceding respect to the embryo since the first stages of development, because it is of human origin and a potential person, nevertheless establishing limits to that same respect, which, in the opinion of those who think thus, cannot be as complete or as absolute as that due to a person already born.
4. The third difficulty lies in obtaining informed consent, given the patent impossibility of its being accorded by the subject of the experimentation. The mother, both parents, or whoever represents them – can they decide freely and amply in this matter, ought they to? If no one is the owner of anyone else's life, how can we bestow on the parents (or, in the majority of views, exclusively on the mother) the power of decision over the utilisation, for experimental purposes, of the embryo or foetus they generated, most especially if such experimentation should lead to

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<sup>2</sup> In the original text: "hominização".



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rendering it unviable, that is to say, if it be destructive? The answers to these questions diverge, according to the stand assumed as to the nature of the embryo or foetus.

5. Finally, the binomial benefit-risk raises problems, too, for, given the lack of knowledge about the later consequences of early interventions on the embryo, the preventive rule in the legislation of those countries that authorise (subject to certain conditions) this type of research, has been a formal prohibition of the implantation in the uterus of any embryos subjected to experimentation – and this necessarily entails their destruction.
6. Faced with the above difficulties and dilemmas, the attitude most in keeping with simple common sense seems to be the absolute prohibition of any experimentation on the embryo and on the foetus – an attitude actually adopted by some legislations. Those opposing such a stand claim that experimentation on the embryo is neither futile nor in any way dispensable, for in several areas within the medicine of reproduction and development significant advances cannot be made without resorting to experimentation on the human embryo (cf. e.g. the lists mentioned in the reports by the European Commission's Work Group on Human Embryos and Research - HER, and by the Panel on Human Embryo Research of the US National Institute of Health - NIH). To counter this kind of argument one might point that, because of its utilitarian allegiance, it lacks legitimacy as an ethical basis for the *praxis* of research, for science does not in itself represent a value that may be compared to human life and dignity, which it is meant to serve.
7. We must not fail to note yet another conceptual difficulty: what is meant by *experimentation*. In discussions of the licitness of experimentation on the embryo, such as the present one, what is generally meant is a programmed research, following a previously stipulated protocol, carried out on series of embryos that are as far as possible at the same stage of development (or at comparable stages). But it must be pointed out that another type of experimentation exists and has been practised systematically: that which occurs when fortuitous observations are made that are not integrated in a programmed series – when the physical and chemical characteristics of a culture are altered so as to find which might offer the optimum conditions for the development of the embryo *in vitro*, etc. This type of experimentation cannot be regulated, nor do we refer to it in this text.

### **Embryo, human life and person**



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The crucial question, as we have seen, is over the nature of the human embryo: on this will depend its status. It cannot be doubted legitimately that it is an initial stage of human life: when the necessary conditions are guaranteed, and if it overcomes the obstacles to its implantation and intra-uterine growth, the embryo cannot but originate a representative of the human species, and it will never turn out to be an individual of any other species.

So, a human life, beyond doubt. But a human person? To answer that is not so easy, for what is at stake are not only biological knowledge and facts but also philosophical concepts, cultural attitudes, religious beliefs; and juridical definitions, too.

A person, yes, as from fertilisation, insofar as the embryo has a genetic identity, which in itself is unique and not repeatable – so say many voices. Others will say: a potential person, insofar as it carries in itself the potential to become a person, though it is not imbued with a personality – a) because the embryo may originate not one but two, three or more individuals (monozygotic twins)<sup>3</sup> and because, conversely, two or more embryos at the morula stage may aggregate into one; b) because the number of embryos that do not actually become implanted is high, which means that nature disposes of embryos with manifest prodigality; c) because only the formation of the neural plate (around the 14<sup>th</sup> day) guarantees the beginnings of a nervous system, which is indispensable to the cognitive, sensitive and relational functions that constitute the essence of the human person.

8. A consensus among these doctrinaire positions does not seem possible. What is certain is the principle that the start of a new human life is marked by fertilisation. By the latter, we mean syngamy – that is to say, the fusion of the two pronuclei (one maternal the other paternal) – and not the penetration of the ovum by the spermatozoon. This distinction is not irrelevant, having instead practical importance, because, if it finds acceptance, it will permit experiments on the ovum, even when it has been penetrated by the spermatozoon (e.g. after micro-manipulation), for in the absence of the fusion of the pronuclei a human being can never develop. This point of view is not shared by everybody, however, because, even before syngamy, there would be all the conditions for the formation of a human being, and it would be illicit to stop such formation. On the other hand, nothing could be said against the activation of oocytes (experiments in parthenogenesis), since the resulting cellular divisions never lead to a human embryo but only to a structure known as a parthenote.

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<sup>3</sup> The term used in the original is “gémeos univitelinos”.



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9. In the impossibility of achieving a consensus, and knowing how significant strata of the plural community have adopted diverse and even opposing attitudes, it seems advisable not to attribute too much importance, for the present purpose, to the wider issue of the personal or non-personal nature of the embryo, restricting it the well secured principle of the presence of human life in the embryo from the beginning of its existence. In any case, the CDBI (European Council Bioethics Committee) reached the same conclusion, justifying its attitude in the memorandum attached to the Bioethics Convention Project it elaborated. If there are arguments against the character of the embryo as a person, the only one that carries weight is based on the possibility of division into twins: according to it, there cannot be a person without individuality. Nevertheless, it appears to be fallacious, seen from the point of view of respect for human life: is life less deserving of respect because we do not know whether it will be expressed, phenotypically, into one or more persons?

As for the other two arguments, it does not seem that they can stand: the embryo's fragility, shown by the significant percentage of those that do not reach full term as a born infant, does not in any way authorise us to value it less, just as an elderly ninety-year old deserves no less respect despite having minute probabilities of living much longer. As for the onset of the neural plate, it is only one link in the chain of events that mark the process of maturation; with the same degree of credibility we might advance the proposition of establishing as a limit the formation of the heart or any other event during organogenesis. We must keep in sight that the argument based on the neural plate can be manipulated for pragmatic purposes: since it appears around the 14<sup>th</sup> day, that being the maximum survival time of an embryo in a *in vitro* culture, the coincidence of dates would provide grounds for the licitness of *in vitro* research during those 14 days, a time-limit imposed anyway by the impossibility, in present-day conditions, of the embryo continuing to divide *in vitro* beyond that period.

In any case (and as the CNECV properly emphasised in its Report on Medically-Assisted Reproduction),<sup>4</sup> the existence of one insoluble doubt as to the nature of the embryo (person, human life, potential person, cellular aggregate undergoing a process of humanisation) would suffice to render seriously illicit any experimentation on the embryo (which is, as we have seen, necessarily destructive).

### A legal status for the embryo?

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<sup>4</sup> *Relatório-Parecer sobre Reprodução Medicamente Assistida (3/CNECV/93)*, in CNECV - *Documentação*. Vol. I (1991-1993). Lisbon, Imprensa Nacional-CM, 1993.



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10. Human life is inviolable – so establishes, in exemplary fashion, Article 24 of the Portuguese Constitution. Thereby, and since it seems impossible to deny the existence of a new human life in the embryo as from syngamy, the embryo cannot be the object of any experimentation that leads, or might lead, to its destruction.

Notwithstanding this, it must be remembered that the Constitutional Court, by a majority of express votes, did not discern unconstitutionality in the text of Law no.6/84 (May 11th), which excludes illegality in some cases of voluntary interruption of pregnancy. That finding does not imply in any way that the principle of the inviolability of human life is not applicable to the embryo, since the grounds invoked by the majority of the Constitutional Court judges specifically refer reasons relating to health, eugenics or gestation due to rape, reasons which obviously do not apply to healthy, viable embryos.

Two practical conclusions would seem to prevail at once: all experimentation carried out on gametes is ethically and juridically unassailable (including studies of cryopreservation, maturation and parthenogenesis using oocytes), the same possibly applying as well to experimentation bearing on the penetration by the spermatozoon prior to syngamy.

On the other hand, all experimentation carried out on the embryo, at least following syngamy, is out of bounds, for it is at present always destructive (as stated before, the most permissive legislations in this regard formally prohibit the implantation of embryos subjected to experimental manipulation, which is equivalent to saying that all permitted experimentation is destructive, even when the intervention *per se* does not result in the death of the embryo).

An exception should be opened to experimentation carried out with the intention of benefiting the embryo. However, in the present state of our knowledge and techniques, such experimentation appears to be unfeasible – presently, the genic therapy of the embryo is not possible (it would result, anyway, in germinal line therapeutics);<sup>5</sup> besides which, being an experimentation, the end result is unknown at the start, whence follows a disproportionate risk of implanting a non-viable or seriously defective embryo. The preceding does not in any way preclude *therapy*, particularly that of the foetus, even if it be *experimental*, for what distinguishes the latter from experimentation is the existence of a sizeable accumulation of scientific proof of its utility and reasonableness.

11. Should this be the position adopted – and to us it seems to be in consonance with the prevailing sensitivity of Portuguese civil society – there should be no apparent need to produce legislation especially

<sup>5</sup> In the original: “terapia da linha germinal”.



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directed at experimentation on the embryo and foetus; instead, efforts should be directed at grounding this conclusion solidly, at divulging it widely, and at recommending to scientists the respect imposed by the constitutional principle.

It would be impossible, then, to speak of a legal vacuum allowing adventurous incursions into the field of experimentation on the embryo, nor would it be necessary to confer a legal status upon the embryo, as so many have proposed. Accretion of reasons would make it unnecessary to prohibit expressly the production of embryos for experimental purposes, since the very act of their production towards an end unrelated with the treatment of infertility hurts principles of human dignity, and since their ultimate destiny (destruction) seriously offends the principle of respect for life. We reaffirm, therefore, what has been stated with greater emphasis and better substantiation in the CNECV Report on Assisted Human Reproduction.

### 12. Yet another word must be said concerning respect for human life.

As we have seen, the reasoning of the proponents or supporters of the licitness of experimentation on the embryo does not in any way deny that the embryo is deserving of respect, never considering it as an object nor even as being at the level of any animal (thereby already commanding respect). What they do affirm is that it does not merit the same degree of respect accorded to a human being endowed with a nervous system, a cardiovascular apparatus or the capacity to live without the maternal womb (these three stages of development are repeatedly invoked in this kind of discourse). Now, it is difficult to establish degrees of respect, to quantify nuances and to point out criteria that might permit, at any determined and concrete situation of development, the attribution to that situation of degree of respect 1 or 2 or eventually 5.

Thus, also in this regard, it seems preferable not to distinguish gradations: human life merits respect, whatever its stage or phase, due to its essential dignity. The embryo, at any phase and from the start, constitutes the physical and biological support indispensable to the development of the human person, and we anticipate in the embryo what it will become: wherefore there are no reasons leading us to establish a scale of respect. This statement is not contradicted by the fact that the juridical system sets gradations in the penalisation of attempts on life – the penalties attending suppression of life become harsher from abortion to infanticide to homicide, for the legislator cannot ignore that the consequences of such crimes are unequal in relevance.

### **Particular situations: surplus embryos, foetal tissues and experimental therapy**



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13. Three concrete situations are given special relevance by circumstances, thereby deserving particular analysis, which now follows.

1) The existence of numerous embryos in cryoconservation. It is general knowledge that the practise of fertilisation *in vitro* (FIV) led to the fertilisation of a number of ova exceeding the number of embryos that it would be reasonable to implant (not more than 3 or 4, as a rule). It became customary to freeze the surplus or reserve embryos, once those destined for implantation had been selected. Thus arose considerable deposits of cryopreserved embryos, some of which do not present health conditions that render them apt for implantation. There is no reason to doubt, however, that others are just as viable and healthy as those actually implanted, becoming surplus simply because they were not needed.

To circumvent this problem, with very high human, ethical, social and juridical impact, it has been recommended that, as far as possible, the existence of surplus embryos be avoided, either through the restriction of the number of fertilised ova; or through recourse to techniques that do not require their production (e.g. intra-tube transfer of gametes); or through a prior selection of gametes and micro-injection of the selected spermatozoon or spermatozoa. Whatever the solution, the problem of the embryos already in storage persists. The adequate solution would be to implant them in later cycles of the same woman in whom the original treatment was performed, or to make them available for intra-uterine adoption. It has long been evident that such a solution is unfeasible, besides which it can never resolve the problem of those embryos of doubtful health.

Once all hope of ever implanting them is exhausted (for instance, after several years have elapsed), the surplus embryos can be disposed of in two ways only: they can be unfrozen and allowed to die, or they can be put to use in experimentation. The utilitarian criterion does not supersede the principle of respect for life.

The difficulties referred regarding surplus embryos are sufficient illustration of the convenience of prohibiting the production of embryos for experimental ends, since such production would always raise the problem of their ultimate fate.

That was, in any case, the position taken by the *Commission for the Legislative Framework of the New Technologies*,<sup>6</sup> appointed in 1968 by

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<sup>6</sup> Comissão para o Enquadramento Legislativo das Novas Tecnologias.



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the Minister of Justice (at the time Dr.Mário Raposo, later the first President of the CNECV), elaborated among others a bill on the utility of the techniques of assisted procreation (Article 36). This bill admitted exclusively the utilisation of surplus embryos in research, under very restrictive conditions.

14. (2) The second concrete situation pertains to the utilisation of foetal tissues for experimental or therapeutic ends (for instance, in transplants). So long as they are obtained from spontaneous miscarriages or from abortions induced within the legal dispositions restricting their illicitness, there are apparently no fundamental objections to the utilisation of foetal tissues or organs for medical purposes, especially of a therapeutic nature (e.g. transplants of neuronal cells or of the foetal stria<sup>7</sup> for the experimental treatment of Parkinson's disease or Huntington's chorea). Equally reasonable seems to be the utilisation of foetal cells for the production of cellular strains in cultures, allowing the rapid diagnosis of viral infections.

Likewise, purposes that are purely diagnostic or serving scientific research may justify recourse to these tissues, organs or cells. All the preceding considerations have as their basis the principle – always defended by the CNECV and fundamentally important for all legislation on transplants – that a corpse is not a person, nor does it possess human life, obviously, although it deserves respect.

Clearly, this position cannot fail to be accompanied by cautionary measures. Thus, the foetal material may only be derived from a dead foetus having no respiratory or cardiovascular support; no pregnancy shall be initiated, maintained or terminated for the purpose of obtaining foetal material; no organ or tissue shall be the object of transaction(s); the medical teams having under their care the woman who aborts or the team that perform the abortion must both be distinct from the teams that utilise the material; foetal material may only be used when there has been consent by the parents (or at least by the mother) or such consent may be presumed.

15. (3) As for experimental therapy (e.g. intra-uterine transfusions or surgery), no ethical objections are discernible, so long as the general principles that regulate, from an ethical point of view, such treatments are respected: namely, reasonableness, risk/benefit balance, informed consent. Somatic genic therapy is, at present, still unfeasible *in utero* but those principles are not contrary to its introduction, once the technical difficulties that oppose it have been surmounted.

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<sup>7</sup> "o estriado fetal", in the original text.



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It seems unnecessary to discuss here the ethical aspects of the recourse to techniques of prenatal diagnosis, habitually performed in Portugal in numerous health centres and generally acknowledged as having medical and social importance. It seems noteworthy, however, that the medical community managed, quite on its own, to find technical indicators and limits respecting fundamental ethical principles.

### Conclusions

Although the utility of scientific experimentation carried out on the human embryo is indisputable and, on that basis, it is possible to defend the production of embryos solely for experimental purposes, it must be made clear that it would be ethically unacceptable to permit such experimentation and the correlative production of embryos, for scientific interest cannot supersede the value of human life and dignity. In the absence of formal proof that the embryo is not a person and has not human life (it is highly improbable that such proof might be adduced in future), it is seriously illicit to conduct upon it experimentation from which it will not benefit and which, on the contrary, will lead to its destruction (since any embryo subjected to experimentation may not be implanted in the uterus).

There are no objections to the utilisation, for experimental purposes, of activated oocytes (parthenotes); nor, though with some reserve, to the recourse to fertilised oocytes, so long as the fusion of the pronuclei (syngamy) has not yet taken place.

The evolution of scientific knowledge, and the new and multiple capacities of intervention, make it advisable to study anew the questions relating to experimentation on the embryo and foetus within the scope of medically-assisted procreation, a study conducive to the elaboration of legislation regulating this sensitive and important issue – this legislative initiative may be classified as urgent.

The Reporter

sign.) Prof. Doutor **Walter Osswald**



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## Opinion

Having analysed and debated the *Report concerning Experimentation on the Human Embryo*, appended to this Opinion, CNECV has approved it and derives the following conclusions, which formulate its opinion:

1. While experimentation on and with Humans is indispensable to the progress of Medicine, having beneficial consequences for the community at large, such experimentation may be practised only when ethical standards are respected, among which are paramount the respect for human life and dignity, the subject's informed consent, and the possibility of benefit for the same subject.

2. Such principles are inapplicable to the human embryo, for there is an obvious impossibility of obtaining the subject's informed consent, or benefit for the subject, given that all experimentation performed on the embryo is presently of a destructive nature, either intrinsically or in consequence thereof, since there is universal consensus that no embryo subjected to experimentation may be implanted. Informed consent by the mother or both parents is not acceptable, for neither ethically nor legally may the parents dispose of the life of the being they originated.

3. As the matter stands, the licitness of experimentation on the embryo, whose scientific interest is not doubted, should be allowed only if there were sufficient proof that the embryonic structure is neither a person nor a human being. While acknowledging that conceptual and terminological difficulties do exist, yet one must accept that the embryo is endowed with human life, and that it evolves inexorably towards plenitude as a member of the human species, providing it survives the many obstacles that may confront it in the course of differentiation and growth.

4. Whence it follows that, in the light of consensual ethical principles and taking into account the human nature of the embryo, any systematic and planned experimentation on the embryo whatsoever must be prohibited, notwithstanding the scientific cost of such a prohibition.

5. The absence of national legislation regulating medically assisted procreation and the legal status of the *in vitro* embryo constitutes a serious loophole, which must be bridged urgently, for it leaves these sensitive issues in a legal limbo, allowing, at least apparently, every type of manipulation or



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experiment and even the implantation of manipulated embryos, with the author of such acts incurring in no illegality.

Lisbon, October 4<sup>th</sup>, 1995

The Reporter,

sign.) Prof. Doutor **Walter Osswald**

The President,

sign.) Bast. Dr. Augusto **Lopes Cardoso**