

Scientific research

## Scientific research is a moral duty

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### Biomedical research is so important that there is a positive moral obligation to pursue it and to participate in it

Science is under attack. In Europe, America, and Australasia in particular, scientists are objects of suspicion and are on the defensive.<sup>1</sup>

“Frankenstein science”<sup>5-8</sup> is a phrase never far from the lips of those who take exception to some aspect of science or indeed some supposed abuse by scientists. We should not, however, forget the powerful obligation there is to undertake, support, and participate in scientific research, particularly biomedical research, and the powerful moral imperative that underpins these obligations. Now it is more imperative than ever to articulate and explain these obligations and to do so is the subject and the object of this paper.

Let me present the question in its starkest form: is there a moral obligation to undertake, support and even to participate in serious scientific research? If there is, does that obligation require not only that beneficial research be undertaken but also that “we”, as individuals and “we” as societies be willing to support and even participate in research where necessary?

Thus far the overwhelming answer given to this question has been “no”, and research has almost universally been treated with suspicion and even hostility by the vast majority of all those concerned with the ethics and regulation of research. The so called “precautionary approach”<sup>9</sup> sums up this attitude, requiring dangers to be considered more likely and more serious than benefits, and assuming that no sane person would or should participate in research unless they had a pressing personal reason for so doing, or unless they were motivated by a totally impersonal altruism. International agreements and protocols—for example, the *Declaration of Helsinki*<sup>10</sup> and the *CIOMS Guidelines*<sup>11</sup>—have been directed principally at protecting individuals from the dangers of participation in research and ensuring that, where they participate, their full informed consent is assured. The overwhelming presumption has been and remains that participation in research is a supererogatory, and probably a reckless, act not an obligation.

Suspicion of doctors and of medical research is well founded. In the modern era it stems from the aftermath of the Nazi atrocities and from the original Helsinki declaration prompted, although rather belatedly, by the Nazi doctors’ trial at Nuremberg.<sup>12-13</sup> More recently it has been fuelled by further examples of extreme medical arrogance and paternalism. The Tuskegee Study of Untreated Syphilis<sup>14</sup>—for example, in which 412 poor African/American men were deliberately left untreated from 1932–1972 so that the natural history of syphilis could be determined.<sup>15</sup> Even when it became known that penicillin was effective against syphilis they were left untreated. More recently in the UK a major scandal caught the public imagination and reflected serious medical malpractice, it involved the unauthorised and deceitful post-mortem removal and retention of organs and tissue from children.<sup>16</sup> (For a commentary on some of the major issues concerning this case see my paper, Law and regulation of retained organs: the ethical issues.<sup>17</sup>)

These and many other cases seem to provide ample justification for the presumption of suspicion of, and even hostility to, medical research. Vigilance against wrongdoing is, however, one thing; the inability to identify wrongdoing with the result that the good is frustrated and harm caused is quite another.

This paper challenges and seeks to reverse the presumption against medical research.

When we ask whether there is a moral obligation to support and even to participate in serious scientific research we need first to be clear that we are talking of research directed toward preventing serious harm or providing significant benefits to humankind. In all cases the degree of harm or benefit must justify the degree of burden on research subjects, individuals, or society. This balance will be explored below. Of course the research must also be serious in the sense that the project is well designed and with reasonable prospect of leading to important knowledge that will benefit persons in the future.<sup>ii</sup>

Two separate but complementary lines of argument underpin a powerful obligation to pursue, support, and participate in scientific research.

#### DO NO HARM

The first is one of the most powerful obligations that we have, the obligation not to harm others. Where our actions will, or may probably prevent serious harm then if we can reasonably (given the balance of risk and burden to ourselves and benefit to others) we clearly should act because to fail to do so is to accept responsibility for the harm that then occurs. (I set out arguments for and the basis of this duty in *Violence and Responsibility*.<sup>18</sup>) This is the strong side of a somewhat weaker, but still powerful duty of beneficence, our basic moral obligation to help other people in need. This is sometimes called “the rule of rescue”.<sup>19</sup> Most, if not all diseases create needs, in those who are affected, and in their relatives, friends, and carers and indeed in society. Because medical research is a necessary component of relieving that need in many circumstances, furthering medical research becomes a moral obligation. This obligation is not limited to actual physical participation in research projects, but also involves supporting research in other ways, for instance economically, at the personal, corporate, and societal levels and indeed politically.

#### FAIRNESS

Second, the obligation also flows from an appeal to basic fairness. This is sometimes expressed as an appeal to the unfairness of being a “free rider”. We all benefit from the existence of the social practice of medical research. Many of us would not be here if infant mortality had not been brought under control, or antibiotics had not been invented. Most of us will continue to benefit from these and other medical advances (and indeed other advances such as clean drinking water and

<sup>i</sup>In this paper I use arguments developed for a paper I wrote with my colleague Søren Holm. See our paper, *Should we presume moral turpitude in our children?*; my chapter, *Research on human subjects, exploitation and global principles of ethics*,<sup>2</sup> and my paper, *Ethical genetic research*.<sup>3</sup> Recently these themes have been taken up by Martyn Evans. See his paper, *Should patients be allowed to veto their participation in clinical research*.<sup>4</sup>

<sup>ii</sup>Here the argument is restricted to research projects that are not merely aimed at producing knowledge. Unless an increase in knowledge is a good in itself (a question I will not discuss here) some realistic hope of concrete benefits to persons in the future is necessary for the validity of our arguments.

sanitation). Since we accept these benefits, we have an obligation in justice to contribute to the social practice which produces them. We may argue that since we could not opt out of advances that were made prior to our becoming capable of autonomous decision making we are not obliged to contribute. It may, however, still be unfair to accept their benefits and implies also that we will forgo the fruits of any future advances.<sup>20</sup> Few, however, are willing to do so, and even fewer are really willing to forgo benefits that have been created through the sacrifices of others when their own hour of need arises!

It should be clear how what I am claiming relates to the principle which is sometimes called the “principle of fairness” developed by Herbert Hart and later used by John Rawls.<sup>21 22</sup> That principle may be interpreted as saying “those who have submitted to...restrictions have a right to similar acquiescence on the part of those who have benefited from their submission”.<sup>23</sup> Here I am not suggesting an *enforceable* obligation to participate based on fairness although such an enforceable obligation would, as we shall see, certainly in some circumstances be justified by the argument of this paper. Nor am I proposing any *right* possessed by those who participate, to similar acquiescence on the part of those who benefit. Being a free rider *is*, however, unfair and people always have a moral reason not to act unfairly. This moral reason is probably enough to justify an enforceable obligation but we do not have to use compulsion as a strategy of first resort. It is surely powerful enough, however, to rebut some of the presumptions against an obligation to support and participate in research.

There may be specific facts about me and my circumstances that absolve me from the obligation to be a research subject in a given situation. This could be the case if I have just participated in other burdensome experiments and there are other potential research subjects who have not done so, or if participation would create excessive burdens for me that it would not create for other potential participants. This does not show that the general obligation we have identified does not exist, just that it, like most other or perhaps all moral obligations, can be overridden by other moral considerations in specific circumstances.<sup>iii</sup>

**THE MORAL IMPERATIVE FOR RESEARCH**

We all benefit from living in a society, and, indeed, in a world in which serious scientific research is carried out and which utilises the benefits of past

research. It is both of benefit to patients and research subjects and in their interests to be in a society which pursues and actively accepts the benefits of research and where research and its fruits are given a high priority. We all also benefit from the knowledge that research is ongoing into diseases or conditions from which we do not currently suffer but to which we may succumb. It makes us feel more secure and gives us hope for the future, for ourselves and our descendants, and for others for whom we care. If this is right, then I have a strong general interest that there be research, and in all well founded research; not excluding but not exclusively, research on me and on my condition or on conditions which are likely to affect me and mine. All such research is also of clear benefit to me. A narrow interpretation of the requirement that research be of benefit to the subject of the research is therefore perverse.<sup>24</sup>

Moreover, almost everyone now living, certainly everyone born in high income industrialised societies, has benefited from the fruits of past research. We all benefit—for example, either from having been vaccinated against diseases such as polio, smallpox, and others or because others have been vaccinated we benefit from the so called “herd” immunity; or we benefit (as in the case of smallpox) from the fact that the disease has actually been eradicated. To take another obvious example, almost at random, we all benefit from the knowledge of connections between diet, exercise, and heart disease. This knowledge enables us to adopt preventive strategies and gives us ways of calculating our level of personal risk.

In view of these considerations there is a clear moral obligation to participate in medical research in certain specific circumstances. This moral obligation is, as we have seen, straightforwardly derivable from either of two of the most basic moral obligations we have as persons.

This entails that there are circumstances where an adult, competent person ought to participate in research, even if participating is not in his or her best interests narrowly defined. If I am asked to give a blood sample for a worthwhile research project, or if I am asked if tissue removed during an operation may be retained for research or therapeutic use, I may have to think in the following way: in the case of giving the blood sample I may say to myself: “I hate needles and the sight of my own blood!”. Equally with retained tissue or organs I may feel that since I understand little of the future uses for my tissue it would be safer to say “no”.

In each case we will suppose that the disease being investigated is not one that I or anyone I know is likely ever to get, so giving this blood sample or allowing the use of excised tissue is not in my best interests narrowly conceived. In this situation doing what is best, all things considered, therefore seems to entail not doing what is best for myself, not pursuing my own best interests. However, this is not really so. Some of my main interests have not been identified and taken into account in this hypothetical train of thought. One of these is my interest in taking myself seriously as a reflective moral agent, and my interest in being taken seriously by others. Identifying my moral obligations, and acting on them is not contrary to my interests, but is an integral part of what makes me a moral agent.<sup>iv</sup>

More importantly, however, as we have seen, I do have a powerful interest in living in a society and indeed in a world in which scientific research is vigorously pursued and is given a high priority.

**DO UNIVERSAL MORAL PRINCIPLES DENY THIS CLAIM?**

A number of the most influential international protocols on science research seem to contradict the claims so far made and we must now examine these more closely.<sup>25</sup> One of the most widely cited principles is contained in a crucial paragraph of the World Medical Association’s *Declaration of Helsinki*, adopted by the 52nd General Assembly, in Edinburgh, Scotland, in October 2000.

In medical research on human subjects, considerations related to the wellbeing of the human subject should take precedence over the interests of science and society (WMA,<sup>10</sup> para 5).

This paragraph is widely cited in support of restrictions on scientific research and is interpreted as requiring that all human subject research is in the narrowly conceived interests of the research subjects themselves. This article of faith has become almost unchallengeable.

We need first to examine more closely the idea of what is or is not in someone’s interests. (Here the argument

<sup>iii</sup>It is perhaps also worth pointing out that there is a separate question about whether this moral obligation should be enforced on those who do not discharge it voluntarily. This is not a question I will discuss here.

<sup>iv</sup>I owe this formulation of the interest I have in being a moral agent to Søren Holm.

echoes that of my paper, Ethical genetic research.<sup>3)</sup> In this paper I shall neither follow nor consider what other commentators have made of this idea but attempt a rigorous analysis of the meaning of the concepts involved. We should note at the outset that what is or is not in a particular individual's interests is an objective matter. While subjects have a special role to play in determining this, we know that human beings are apt to act against their own interests. Indeed the idea of respect for persons which underpins this guideline has two clear and sometimes incompatible elements, namely, concern for welfare and respect for autonomy. Because people often have self harming preferences (smoking, drug abuse, selfless altruism, etc) they are sometimes bad judges of their interests.

The interests of the subject *cannot* be paramount nor can they automatically take precedence over other interests of comparable moral significance. Such a claim involves a straightforward mistake: being or becoming a research subject is not the sort of thing that could conceivably augment either someone's moral claims or, for that matter, her rights. *All* people are morally important and, with respect to one another, each has a claim to equal consideration. No one has a claim to overriding consideration. To say that the interests of the subject must take precedence over those of others, if it means anything, must be understood as a way of reasserting that a researcher's narrowly conceived professional interests must not have primacy over the human rights of research subjects. (The researcher may also have specific contractual duties to them.) As a general remark about the obligations of the research community, the health care system, society or indeed of the world community, it is not, however, sustainable.

This is not of course to say that human rights are vulnerable to the interests of society whenever these can be demonstrated to be greater. On the contrary, it is to say that the rights and interests of research subjects are just the rights and interests of persons and must be balanced against comparable rights and interests of other persons. In the case of medical research the contrast is not between vulnerable individuals on the one hand and an abstract entity such as "society" on the other, but rather between two different groups of vulnerable individuals. The rights and interests of research subjects are surely not served by privileging them at the expense of the rights and interests of those who will benefit from research. Both these groups are potentially vulnerable, neither is obviously *prima facie*

more vulnerable or deserving of special protection.

It is important to emphasise that the point here is not that there is some general incoherence in the idea of sometimes privileging the rights and interests of particularly vulnerable groups in order to guarantee to them the equal protection that they need and to which they are entitled. Rather I am suggesting two things. The first is that all people have equal rights and entitlement to equal consideration of interests. The second is that any derogation from a principle as fundamental as that of equality must be justified by especially powerful considerations.

Finally, although what is or is not in someone's interests is an objective matter about which the subject her (or him) self may be mistaken, it is usually the best policy to let people define and determine "their own interests". While it is of course possible that people will misunderstand their own interests and even act against them, it is surely more likely that people will understand their own interests best. It is also more respectful of research subjects for us to assume that this is the case unless there are powerful reasons for not so doing—for example, in cases of research on young children, mental patients, and others whom it is reasonable to assume may not be adequately competent.

### IS THERE AN ENFORCEABLE OBLIGATION TO PARTICIPATE IN RESEARCH?

It is widely recognised that there is clearly sometimes an obligation to make sacrifices for the community or an entitlement of the community to go so far as to deny autonomy and even violate bodily integrity in the public interest and this obligation is recognised in a number of ways.<sup>26</sup>

There are a perhaps surprisingly large number of cases where we accept substantial degrees of compulsion or coercion in the interests of those coerced and in the public interest. Numerous examples can be given: limiting access to dangerous or addictive drugs or substances; control of road traffic, including compulsory wearing of car seat belts; vaccination as a requirement—for example, for school attendance or travel; screening or diagnostic tests for pregnant mothers or for newborns; genetic profiling for those suspected of crimes; quarantine for some serious communicable diseases; compulsory military service; detention under mental health acts; safety guidelines for certain professional activities of HIV positive people, and compulsory attendance for jury service at criminal trials. Some societies make voting compulsory,

taxation is omnipresent, universal education for children, requiring as it does compulsory attendance in school, is another obvious example. All these involve some denial of autonomy, some imposition of public standards even where compliance is not based on the competent consent of individuals. These are, however, clearly exceptional cases where overriding moral considerations take precedence over autonomy. Might medical research be another such case?

### MANDATORY CONTRIBUTION TO PUBLIC GOODS<sup>V</sup>

The examples cited above demonstrate a wide range of what we might term "mandatory contribution to public goods". I will take one of these as a model for how we might think about participation in science research. (For use of this principle in a different context see my paper, Organ procurement—dead interests, living needs.<sup>27</sup> Taxation is of course the clearest and commonest example.)

All British citizens between 18 and 70<sup>vi</sup> are liable for jury service.

They may be called, and unless excused by the court, must serve. This may involve a minimum of 10 days but sometimes months of daily confinement in a jury box or room, whether they consent or not. However, although all are liable for service only some are actually called. If someone is called and fails to appear they may be fined. Most people will never be called but some must be if the system of justice is not to break down. Participation in, or facilitation of, this public good is mandatory. There are many senses in which participation in vaccine or drug trials involve features relevantly analogous to jury service. Both involve inconvenience and the giving up of certain amounts of time. Both are important public goods. It is this latter feature that is particularly important. Although jury service (or compulsory attendance as a witness) is an integral part of "due process", helping to safeguard the liberty and rights of citizens, the same is also true of science research. Disease and infirmity have profound effects on liberty and while putting life threatening criminals out of circulation or protecting the innocent from wrongful imprisonment is a minor (numerically speaking) product of due process, life saving is a major product of science research. If compulsion is justifiable in the case of due process the same or indeed more powerful

<sup>v</sup>I use this term in a non-technical sense.

<sup>vi</sup>Those over 65 may be excused if they wish.

arguments would surely justify it in the case of science research.

Of course “compulsion” covers a wide range of possible measures. Compulsion may simply mean that something is legally required, without there being any legal penalties for non-compliance. Such legal requirement may of course also be supported by various penalties or incentives, from public disapproval and criticism, fines or loss of tax breaks on the one hand, to imprisonment or forcible attendance or participation further along the spectrum. To say that it would be legitimate to make science research compulsory is not to say that any particular methods of compulsion are necessarily justified or justifiable. While it seems clear that mandatory participation in important public goods is not only justifiable but also widely accepted as justifiable in most societies, as the examples above demonstrate, my own view is that voluntary means are always best and that any form of compulsion should be a last resort to be used only when consensual means had failed or where the need for a particular research activity was urgent and of overwhelming importance. If the arguments of this paper are persuasive, compulsion should not be necessary and we may expect a climate more receptive to both the needs and the benefits of science. However, to point out that compulsion may be justifiable in some circumstances in the case of science research establishes that a fortiori less stringent means are justifiable in those circumstances.

I hope it is clear that I am not here advocating mandatory participation in research, merely arguing that it is in principle justifiable, and may in certain circumstances become justified in fact. There is a difference between ethics and public policy. To say that something is ethical and therefore justifiable is not the same as either saying it is justified in any particular set of circumstances, nor is it to recommend it nor yet to propose it as a policy for either immediate nor yet for eventual implementation. I believe that consensual participation is always preferable and that persuasion by a combination of evidence and rational argument is always the most appropriate way of achieving social and moral goals. This paper is an attempt to do precisely this. I believe—for example, that conscription into the armed forces is justifiable, but I am not recommending, still less advocating its reintroduction into the UK at this time. The distinction between ethical argument and policy proposal is crucial but is almost always ignored, particularly by the press and news media that report on these matters. In this paper I am

intending to do ethics; this is not a policy proposal although it contains one policy proposal, which we will come to in due course.

If I am right in thinking that medical research is a public good, that may *in extremis* justify compulsory participation, then a number of things may be said to follow:

- It should not simply be assumed that people would not wish to act in the public interest, at least where the costs and risks involved are minimal. In the absence of specific evidence to the contrary, if any assumptions are made, they should be that people are public spirited and would wish to participate. (I talk here of minimal risk in the sloppy fashion usual in such contexts. “Risk” is, however, ambiguous between “degree of danger” and “probability of occurrence of danger”. Risk may of course be minimal in either or both of these senses.)
- It may be reasonable to presume that people would not consent (unless misinformed or coerced) to do things contrary to their own and to the public interest. The reverse is true when (as with vaccine trials) participation is in both personal and public interest.
- If it is right to claim that there is a general obligation to act in the public interest, then there is less reason to challenge consent and little reason to regard participation as actually or potentially exploitative. We do not usually say: “are you quite sure you want to” when people fulfil their moral and civic obligations. We do not usually insist on informed consent in such cases, we are usually content that they *merely* consent or simply acquiesce. When—for example, I am called for jury service no one says: “only attend if you fully understand the role of trial by jury, due process, etc in our constitution and the civil liberties that fair trials guarantee”.

If these suggestions are broadly acceptable and an obligation to participate in research is established, this may well become one of the ways in which research comes to be funded in the future.

We must weigh carefully and compassionately what it is reasonable to put to potential participants in a trial for their free and unfettered consideration. Provided, however, potential research subjects are given full information, and are free to participate or not as they choose, then the only remaining question is whether it is reasonable to permit

people freely to choose to participate, given the risks and the sorts of likely gains. Is it reasonable to ask people to run whatever degree of risk is involved, to put up with the inconvenience and intrusion of the study, and so on in all the circumstances of the case? These circumstances will include both the benefits to them personally of participating in the study and the benefits that will flow from the study to other persons, persons who are of course equally entitled to our concern, respect, and protection. (If they are.) Putting the question in this way makes it clear that the standards of care and levels of protection to be accorded to research subjects who have full information must be, to a certain extent, study relative.

It is crucial that the powerful moral reasons for conducting science research are not drowned by the powerful reasons we have for protecting research subjects. There is a balance to be struck here, but it is not a balance that must always and inevitably be loaded in favour of the protection of research subjects. They are entitled to our concern, respect, and protection to be sure, but they are no more entitled to it than are, say, the people whom—for example, HIV/AIDS or other major diseases are threatening and killing on a daily basis.<sup>vii</sup>

It is surely unethical to stand by and watch three million people die this year of AIDS<sup>viii</sup> alone and avoid taking steps to prevent this level of loss, steps, which will not put lives at risk and which are taken only with the fully informed consent of those who participate.

Fully informed consent is the best guarantor of the interests of research subjects. While not foolproof, residual dangers must be balanced against the dangers of not conducting the trial or the research, which include the massive loss of life that possibly preventable diseases cause. These residual dangers include the difficulties of constructing suitable consent protocols and supervising their administration in rural and isolated communities and in populations which may have low levels of formal education.

<sup>vii</sup>Of course the historical explanation of the *Declaration of Helsinki* and its concerns lies in the Nuremberg trials and the legacy of Nazi atrocities. We are, however, I believe, in real danger of allowing fear of repeating one set of atrocities to lead us into committing other new atrocities.

<sup>viii</sup>Figures are for 2003, with an estimated five million people newly acquiring HIV in that same year.<sup>25</sup>

An interesting limiting case is that in which the risks to research subjects are significant and the burdens onerous but where the benefits to other people are equally significant and large. In such a case the research is both urgent and moral but conscription would almost certainly not be appropriate because of the unfairness of conscripting any particular individual to bear such burdens in the public interest. That is not of course to say that individuals should not be willing to bear such burdens nor is it to say that it is not their moral duty so to do. In fact the history of science research is full of examples of people willing to bear significant risks in such circumstances, very often these have been the researchers themselves. (For one prominent example, that of Barry Marshall's work, in which he swallowed *Helicobacter pylori* bacteria, thereby poisoning himself, to test a bacterial explanation for peptic ulcers, see his website.<sup>29</sup>)

### BENEFIT SHARING

I have so far said nothing about the public/private divide in research funding and about the fact that much of the research we have referred to has been carried out in the private sector for profit. This has inevitably led both to a concentration on what the comedian Tom Lehrer memorably called "diseases of the rich" and on diseases and conditions where, for whatever reason, a maximum return on investment is to be expected. In this paper there is room simply to note that the duty to participate in research is not a duty to enable industry to profit from moral commitment or basic decency, and that fairness and benefit sharing as well as the widest and fairest possible availability of the products of research is, as we have seen, an essential part of the moral force of the arguments for the obligation to pursue research. Benefit sharing must therefore be part of any mechanisms for implementing the arguments of this paper.

### A NEW PRINCIPLE OF RESEARCH ETHICS

A new principle of research ethics suggests itself as an appropriate addition to the *Declaration of Helsinki*:

Biomedical research involving human subjects cannot legitimately be neglected, and is therefore both permissible and mandatory, where the importance of the objective is great and the risks to and the possibility of exploitation of fully informed and consenting subjects is small.

For an earlier version of this principle applied in the context of genetics see my paper, *Ethical genetic research on human subjects*.<sup>3</sup>

Thus while fully informed consent and the continuing provision to research subjects of relevant information does not eliminate all possibility of exploitation,<sup>30</sup> it does reduce it to the point at which it could no longer be ethical to neglect the claims and the interests of those who may benefit from the research. It should be noted that it is fully informed consent, and the concern and respect for the individual that it signals, which severs all connection with the Nazi experiments and the concerns of Nuremberg, and which rebuts spurious comparisons with the Tuskegee study.<sup>30</sup> It is this recognition of the obligation to show equal concern and respect for all persons, which is the defining characteristic of justice.<sup>31</sup> The recognition that the obligation to do justice applies not only to research subjects but also to those who will benefit from the research must constitute an advance in thinking about international standards of research ethics.

### ON WHOM DOES THE OBLIGATION TO PARTICIPATE IN RESEARCH FALL?

*The Declaration of Helsinki* (paragraph 19) states:

Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research (WMA,<sup>10</sup> para 19).

### ME AND MY KIND

It is sometimes claimed that where consent is problematic or, as perhaps with genetic research on archival material, where the sources of the material are either dead or cannot be traced, that research may be legitimate if it is for the benefit of the health needs of the subjects or of people with similar or related disorders. See—for example, the CIOMS guidelines (CIOMS,<sup>11</sup> guideline 6: p 22). The suggestion that research which is not directly beneficial to the patient be confined to research that will benefit the category of patients to which the subject belongs seems not only untenable but also offensive. What arguments sustain the idea that the most appropriate reference group is that of fellow sufferers from a particular disease, Alzheimer's—for example? Surely any moral obligation I have to accept risk or harm for the benefit of

others is not plausibly confined to those others who are narrowly like me. This is surely close to claiming that research should be confined to others who are "black like me" or "English like me" or "God fearing like me"? The most appropriate category is surely "a person like me". (I make a distinction between humans and persons which is not particularly pertinent in this context but which explains my choice of terminology.<sup>32 33</sup>)

### CHILDREN AND THE INCOMPETENT

What, however, about children?<sup>1</sup> Do they have an obligation to participate in research and if they have, is a parent justified in taking it into account in making decisions for the child?

If children are moral agents, and most of them, except very young infants are, then they have both obligations and rights; and it will be difficult to find any obligations that are more basic than the obligation to help others in need. There is therefore little doubt that children share the obligation argued for in this paper, to participate in medical research. A parent or guardian is accordingly obliged to take this obligation into account when deciding on behalf of her child and is justified in assuming that the person they are making decisions for is or would wish to be, a moral person who wants to or is in any event obliged to discharge his or her moral duties. If anything is presumed about what children would have wished to do in such circumstances the presumption should surely be that they would have wished to behave decently and would not have wished to be free riders. If we simply consult their best interests, (absent the possibility of a valid consent) then again, as this paper has shown, participation in research is, other things being equal, in their best interests. Because of the primacy of autonomy in the structure of this argument we should, however, be cautious about enrolling those who cannot consent in research and should never force resisting incompetent individuals to participate. It also follows from principles of justice and fairness that those who are not competent to consent should not be exploited as prime candidates for research. We should always therefore prefer autonomous candidates and only use those who cannot consent when such individuals are essential for the particular research contemplated and where competent individuals cannot, because of the nature of the research, be used—for example, because the research is into an illness which only affects children or those with a particular condition which affects

competence. In those extreme cases in which we might contemplate mandatory participation the same will hold. The incompetent should only be used where competent individuals cannot be research subjects because of the nature of the research itself.

**INDUCEMENTS TO PARTICIPATE IN RESEARCH**

Before concluding, a word needs to be said about inducements to research. Most research ethics protocols and guidelines are antipathetic to inducements. The CIOMS guidelines—for example, state that if inducements to subjects are offered “[t]he payments should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment (undue inducement)” (CIOMS,<sup>11</sup> guideline 7).

However, the gloss the CIOMS document offers on this guideline is perhaps confused. It states: “Someone without access to medical care may or may not be unduly influenced to participate in research simply to receive such care” (CIOMS,<sup>11</sup> pp 28ff). The nub of the problem is the question what is it that makes inducement *undue*? If inducement is undue when it undermines “better judgment”, then it cannot simply be the level of the inducement nor the fact that it is the inducement that makes the difference between participation and non-participation that undermines better judgment. If this were so, all jobs with attractive remuneration packages would constitute “undue” interference with the liberties of subjects and anyone who used their better judgment to decide whether a total remuneration package plus job was attractive would have been unduly influenced.<sup>ix</sup>

Surely, it is only if things are very different that influence becomes undue. If, for example, it were true that no sane person would participate in the study and only incentives would induce them to disregard “better judgment” or “rationality”, or if the study were somehow immoral, or participation was grossly undignified and so on, would there be a legitimate presumption of undue influence.

Grant a number of assumptions: that research is well founded scientifically; that it has important objectives which will advance knowledge; that the subjects are at minimal risk, and that the inconvenience and so on, of participation is not onerous. Then surely it is not only in everyone’s best interests that *some* people participate but also in the interests of those who do. *Better judgment* surely will not indicate that

any particular person should not participate. Of course someone consulting personal interest and convenience might not participate “it’s too much trouble, not worth the effort, rather inconvenient” and so on. However, removing the force of *these sorts of objections* with incentives is not undermining *better judgment* any more than is making employment attractive.<sup>34–36</sup>

Of course inducements may be undue in a different sense. If, for example, a research subject were a drug addict and she were to be offered the drug of her choice to participate, or subjects were blackmailed into participating in research, then in such cases we might regard the inducements as undue. It is important, however, to note that here the influence or inducement is undue, not because it is improper to offer incentives to participate, nor because participation is against the best interests of the subject, nor because the inducements are coercive in the sense that they are irresistible, but rather because the *type of incentive* offered is illegitimate or against the public interest or immoral in itself.

If I offer you a million dollars to do something involving minimal risk and inconvenience, something that is good in itself, is in your interests, and will benefit mankind, my offer may be irresistible but it will not be coercive. If, however, I threaten you with torture unless you do the same thing, my act will be coercive even if you were going to do it whether or not I threatened you. I should be punished for my threat or blackmail or criminal offer of illegal substances, but surely you should none the less do the deed and your freedom to do it should not be curtailed because of my wrongdoing in attempting to force your hand in a particular way. The wrong is not that I attempted to force your hand but resides rather in the wrongness of the methods that I chose. This is the distinction between undue inducement and inducements which are undue. “Undue inducement” is the improper offering of inducements, improper because no inducements should be offered. It is this that is referred to in the various international protocols we have been examining and which is almost always wrongly understood and applied. “Inducements which are undue”, refer to the nature of the inducement, not to the fact of it being offered at all. This is an important but much neglected distinction. Here it is the nature of the inducement that is undue rather than the fact of inducements of some sorts (even irresistible sorts) being offered.

We can see that offering incentives, perhaps in the form of direct payment

or tax concessions to people to participate in research, or—for example, to make archive samples available for research would not be unethical. We tend to forget that law and morality are methods of encouraging and indeed enforcing morality. Approval and inducements are others. All are acceptable if the conduct they promote is ethical and worthwhile. Where science research is both of these, encouragement and, as we have seen, enforcement are justifiable.

**CONCLUSION**

There is then a moral obligation to participate in medical research in certain contexts.<sup>x</sup>

This will obviously include minimally invasive and minimally risky procedures such as participation in biobanks, provided safeguards against wrongful use are in place. The argument concerning the obligation to participate in research should be compelling for anyone who believes there is a moral obligation to help others, and/or a moral obligation to be just and do one’s share. Little can be said to those whose morality is so impoverished that they do not accept either of these two obligations.

Furthermore we are justified in assuming that a person would want to discharge his or her moral obligations in cases where we have no knowledge about their actual preferences. This is a way of recognising them as moral agents. To do otherwise would be to impute moral turpitude as a default. Parents making decisions for their children are therefore fully justified in assuming that their child will wish to do that which is right, and not do that which is wrong.

**ACKNOWLEDGEMENT**

The author acknowledges the stimulus and support of the European Project (EU-RECA)

<sup>ix</sup>The CIOMS gloss on their own guidelines creates a kind of Catch 22 which is surely unreasonable and unwarranted. Wherever the best proven diagnostic and therapeutic methods are guaranteed by a study in a context or for a population who would not normally expect to receive them, this guideline would be broken. The CIOMS guideline four therefore surely contradicts and violates not only the *Declaration of Helsinki* but also its own later guideline 14.

<sup>x</sup>This obligation has been partly endorsed by the Hugo Ethics Committee in its *Statement on Human Genetic databases*.<sup>37</sup> However, like so many statements by august ethics committees the Hugo statement contains not a single argument to sustain its proposals or conclusions. This paper and those referred to in references 1, 2, 3, and 4 above provide the missing arguments. For a critique of the operation of national and international ethics committees see the introduction to my book, *Bioethics*.<sup>38</sup>

sponsored by the European Commission, in the preparation of this paper. (DG-Research as part of the Science and Society research programme—6th framework.)

*J Med Ethics* 2005;**31**:242–248.  
doi: 10.1136/jme.2005.011973

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