NUFFIELD COUNCIL ON BIOETHICS

Novel neurotechnologies: intervening in the brain

CONSULTATION

March 2012

How to respond

We would prefer it if you could send your response to us electronically. Responses can be sent via email to Varsha Jagadesham: vjagadesham@nuffieldbioethics.org, with ‘Novel neurotechnologies’ in the subject line. Please ensure that you also include a completed response form with your submission, which can be found at the end of this document or downloaded from www.nuffieldbioethics.org/neurotechnology.

If you would prefer to respond by post, please send your submission to:
Varsha Jagadesham
Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

Telephone: +44 (0)20 7681 9619
Fax: +44 (0)20 7323 6203
Website: www.nuffieldbioethics.org/neurotechnology

Closing date for responses: 23 April 2012, 5pm.

Terms of reference of the Working Party

List of Working Party members

Terms of reference of the Council

List of Council members

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Novel neurotechnologies: Introduction

Humans have intervened directly in the brain for a long time. Archaeological evidence shows that people in the late Stone Age in Europe, pre-Incan civilizations, the Ancient Egyptians, the Romans and Byzantines all performed brain surgery for medical, spiritual and magical purposes. During the last century, brain intervention experienced a steep rise and fall: electroconvulsive therapy (ECT), 'split-brain' surgery and lobotomy were each first heralded as a wonder cure for epilepsy, depression, schizophrenia and many other illnesses in the first half of the 20th century. But each was to some extent discredited only a few decades later as they came to be seen as treatments that were often inappropriate and sometimes harmful, leading to the view that their uncritical and widespread use arose from the hubris of a medical profession bound by too few rules. Far more targeted applications of these treatments, and other treatments that intervene directly into the human brain, are only slowly being re-introduced to medical practice, with very strict risk-benefit assessments and strong consent and oversight procedures in place.

Intervening in the brain has always raised both hopes and fears in equal measure: hopes for curing crippling neurological conditions or improving human capabilities beyond normal limits vs. fears of harmful manipulation with unforeseen consequences or the wilful destruction of what it means to be human, or a person. Currently, technologies are emerging that intervene in the brain which seem to promise significant benefits to people with neurological conditions. Such neurotechnologies could also potentially be used in non-medical settings. For example, brain computer interfaces (BCIs) which connect the brain to a computer system could help people who have a locked-in syndrome[1] to communicate or even interact with the outer world, by using thoughts to direct a bed, wheelchair or speech computer. BCIs can be used in non-medical ways for computer gaming, where games are 'thought-controlled', and there is growing interest in using BCIs in the military, to enable military personnel who have lost limbs to control their prosthetic devices directly from their brain, or to improve soldiers' capabilities or employ though-controlled, remote weaponry. Neurostimulation such as deep-brain stimulation (DBS), where electrodes are implanted into the brain, has been used to treat illnesses such Parkinson's and severe depression, Transcranial direct current stimulation (tDCS), where areas of the brain are stimulated directly with low electrical current, is being used to treat some psychiatric disorders, to aid rehabilitation and in some cases in the hope of enhancing cognitive performance. Non-invasive transcranial magnetic stimulation (TMS), where the brain is stimulated from outside using a magnetic field, is used to treat patients with depression and is also being researched for improving cognitive skills both in patients and healthy subjects. Finally, neural stem cells, inserted into the brain, are being investigated for treating people with stroke and dementia.

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[1] Patients in a locked-in state are aware and awake but cannot move or speak due to paralysis of all muscles in the body (except for, in some cases, the eyes).

While the clinical benefits of some of these treatments are thought to be significant for particular groups of patients, they nevertheless raise questions not only about safety, but about, for example, possible effects on personality and personhood, about responsibility, about enhancing human capabilities, and about how we secure beneficial uses whilst avoiding the dangers. Most of this is still being researched, but it is important that we address the ethical considerations at this early stage.

Against this background, the Nuffield Council on Bioethics, an independent body examining ethical issues in the biomedical sciences, has set up a Working Party on *Novel neurotechnologies: intervening in the brain*. This project focuses on non-pharmacological technologies that directly intervene in the brain, often through the use of some kind of device. The Working Party aims to identify and explore the ethical, social and legal issues raised by such novel neurotechnologies and to develop policy recommendations where appropriate. In the process of writing its report, the Working Party wants to invite comments from as many interested parties as possible.

The Working Party places great value on having feedback from people and organisations in diverse locations with different interests and perspectives. We would like to hear from anyone with either a personal or professional interest in novel neurotechnologies that intervene in the brain. We also invite those who have direct experience with these technologies, either because they work with them or have used them as patients or in recreational settings. Below are a few general questions about neurotechnologies that intervene in the brain. Following this, there are three sections with questions about examples of technologies: 1) brain-computer interfaces, 2) neural stimulation and 3) neural stem cells. Please feel free to answer whichever questions interest you. In each section, some of the more specialist terms appear in *italics*. Additional information on these terms can be found in footnotes at the bottom of the page.

General questions

1. Have you ever used a technology that intervenes in the brain, and with what consequences? Please describe your experience.

2. If you have not used a technology that intervenes in the brain before, would you do so if you were ill? Why / why not?

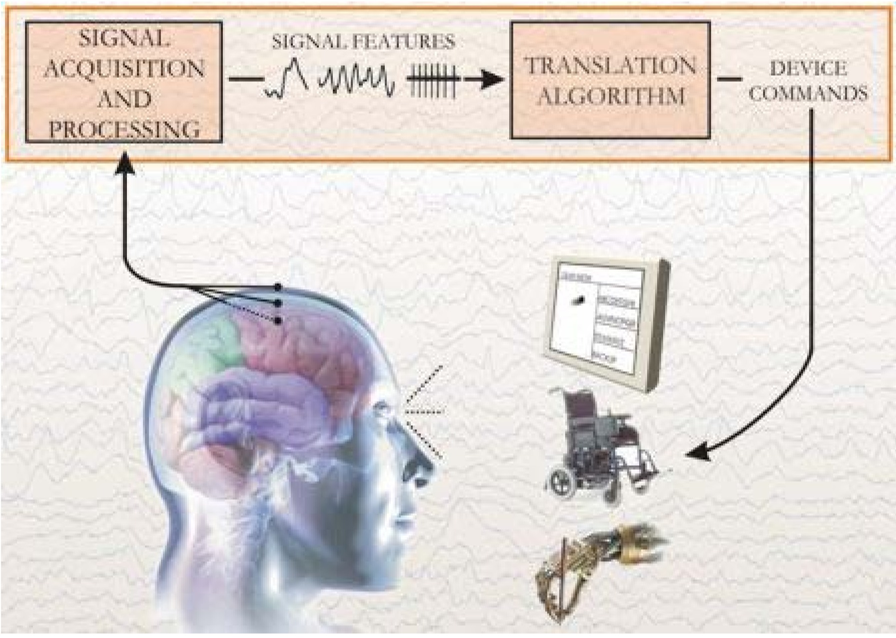
3. Would you use a technology that intervenes in the brain for non-medical purposes, such as gaming or improving your cognitive skills? Why / why not?

4. What are the most important ethical challenges raised by novel neurotechnologies that intervene in the brain?

5. In what ways, if at all, should the development and use of these technologies be promoted, restricted and/or regulated? Please explain your reasons.

1) Brain computer interfaces (BCIs)

A brain-computer interface, or a BCI, is a system that measures and analyses an individual's brain signals, and converts these into an output such as a movement, but without making use of the individual's own body. For example, with a BCI connected to a motorised bed, the BCI could measure an individual's intent to adjust the incline of the bed and translate this into the desired action, or the BCI could translate the desire to move into action and operate a BCI wheelchair.



How do BCIs work?

Patterns of electrical activity in the brain that accompany an individual's thoughts and intentions give rise to characteristic brain signals which can be detected. For example, the activity of an individual's intention to press a button is associated with a certain pattern of electrical activity. These electrical signals can be analysed and converted, with the help of a computer, into various commands and appropriate actions. The BCI devices used vary in terms of their invasiveness. Some electrical brain signals can be recorded from the scalp with an *electroencephalogram* (EEG)[2], and this is not invasive. Other BCIs measure electrical signals directly from the brain. They are invasive, as they require the surgical placement of electrodes on the surface of the brain, or the implantation of electrodes into the brain (*ECoG*[3] *and*

[2] An electroencephalogram (EEG) is a recording of electrical activity along the scalp.

[3] Electrocorticography (ECoG) is the practice of using electrodes placed directly on the exposed surface of the brain to record electrical activity from the cerebral cortex. It requires brain surgery.

intracortical[4] *BCIs*). Compared with EEG-based BCIs, they are more sensitive at picking up signals.

Uses in medicine

In medicine, BCIs are being considered for individuals who have lost the ability (or have severely reduced abilities) to carry out basic actions such as speech or movement. An example of this is an individual who, in medical terms, is 'locked in'. This is when a person is unable to communicate or move due to the loss of all muscle function (except for, in many cases, the eyes). However, she is aware of her surroundings and what is going on around her. People who are paralyzed due to spinal injuries or those who have extreme difficulties moving and carrying out relatively simple tasks following e.g. a stroke could also benefit from a BCI. Finally, there are efforts to restore lost functions, such as vision or action, through BCIs which control prosthetic devices. Such devices could greatly improve patients' quality of life and enable them to participate more fully in family, work and social life.

Uses outside of medicine

Outside of medicine, BCIs are being considered for application in gaming and in the military. Computer games today require increasing numbers of inputs by the user in order to interact with the game and this is associated with increased user effort. Game developers and researchers are therefore interested in achieving rich user-interaction in a way similar to the real world – that is, quick and simple, ideally translating thoughts into actions without much additional effort or the use of devices such as joysticks and keyboards. BCIs could be used so that an individual is able to express themselves directly in the game world, both in terms of mood and beyond what is physically possible in the 'real world' (e.g. flying). In addition, BCI use in gaming could make individuals more relaxed and focused and result in higher 'gaming intelligence'.

Military applications are largely speculative at present, but could include BCIs for controlling prosthetic limbs, and BCIs for the modification and/or optimisation of combat performance, such as 'super-human' strength through a BCI-skeleton that supports the human skeleton and augments muscle strength and movement. BCIs also aim to enhance perception and enable remote control of vehicles and machinery. For example, using EEG signals, a BCI device could enable soldier-to-soldier communication in the battlefield and other settings where speech is restricted or undesirable. Other approaches include BCI binoculars, which would be capable of responding quickly to a subconsciously detected threat or target. Finally, 'telepresence' is where a soldier, whilst physically present elsewhere, has the ability to sense and interact in a removed and real-world location, such as with a demolition robot or unmanned vehicle (drone), through a BCI connection.

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[4] Intracortical BCIs involve the implantation of electrodes into the brain. They require brain surgery.

Current availability

Interest in BCIs is growing, and whilst most of the things that are currently being discussed have not yet been demonstrated, or have only been demonstrated in the laboratory, a number of devices are already commercially available and a lot of research and development is ongoing. Non-invasive BCIs using EEG in medicine are currently being developed, with some successful studies and demonstrations. For example, a BCI-controlled wheelchair has been developed and some paralyzed individuals have been able to operate remotely household devices such as TVs and motorised beds. However, these applications are not yet available in regular clinical practice. There have been few studies with regards to longer-term use; and the devices are currently very expensive. Nevertheless, it is expected that the field will grow significantly.

Some commercial BCI developments in computer gaming are already available to purchase, for example devices that aim to replace functions of the joystick and enhance game control through wearing a wireless headset which reads and interprets brain signals. Military applications are currently being researched and tested. So far they are not in wide use but it is expected that this might soon be the case. In both fields, advances are expected in the near future and there will likely be more BCI devices available for purchase soon.

Technology-related risks

Potential benefits of BCIs could be very substantial in some patient groups. Being able to communicate again would be a major breakthrough for locked-in and other severely paralyzed patients, as would being able to move independently for those unable following brain or spine injury, and those with amputations would most likely welcome the option of being able to control a prosthetic with their thoughts. However, BCIs also carry some significant risks. Invasive BCIs require brain surgery and the integration of the technology into live brain matter. Apart from the general risks of surgery, which include anaesthesia complications, bleeding, blood clots, infection, and pain, this carries the risk of damaging healthy brain tissue. The electrodes could induce the growth of scar tissue in the brain that might lead to seizures or loss of function, and there are also concerns over the long-term stability of such invasive electrodes. There are few studies available about the long term outcomes of BCI implantation and how the benefits and risks compare.

BCIs which measure signals non-invasively make use of certain *neural circuits*[5] repeatedly and in a repetitive fashion. Again, little information is so far available whether this could be hurtful to brain function; there may be a risk that this repetitive activation changes brain structure and functioning in unpredictable ways.

Commercially available EEG-based BCIs are not very convenient to use. Also, most BCI approaches require large amounts of training, involving

[5] A neuronal circuit is a functional entity of interconnected neurons that influence each other.

significant investments of time and effort. Therefore, there is the risk of patients becoming extremely tired by use. Reliability of BCIs also needs to be further improved upon. If the BCI system does not function as hoped, and perhaps does not deliver the benefits expected, patients might become frustrated, disappointed or bitter. Safety, reliability, convenience of use, as well as speed of reaction, are also concerns in non-medical BCI applications.

We would also like to hear views on wider concerns and questions about the use of BCIs, such as whether their risks (as described above) are in an appropriate relation to their benefits, particularly in non-medical applications; whether they could be used in a malicious way; how their use in military settings should be evaluated (especially given the need for secrecy in military research and development); what societal impact BCI use in non-medical settings could have; and whether research efforts and public money should be devoted to this technology. In general, some have suggested that BCIs, in extending the power of the mind beyond the body, might blur the distinction between humans and machines and thus could change our understanding of human beings.

Questions

Please be specific with regards to the type of BCI you are referring to in your answer

6. Have you used a BCI, and if so, with what consequences? Please describe your experience.

7. If you have not used a BCI before, under what circumstances would you do so?

8. What are your expectations and concerns for BCIs?

9. Are there any particular ethical or social issues associated with BCIs?

10. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.

2) Neurostimulation

The term 'neurostimulation' broadly refers to the application of an electric or magnetic stimulus to nerves. There are several types of neurostimulation in use and some of these intervene in the brain. The best-known types of neurostimulation used on the brain are transcranial magnetic stimulation (TMS), and deep brain stimulation (DBS).

How does neurostimulation work?

TMS is non-invasive. An electromagnet is positioned on or near the scalp to induce electrical currents in selected regions of the brain in order to change the activity in these regions. The exact mechanism by which TMS operates is uncertain. TMS is today mostly applied through a hand-held device. Apart from usually slight local discomfort, subjects do not feel any physical effect of the treatment and no anaesthesia is necessary. Earplugs are typically worn to block the noise caused by the magnet.

DBS is invasive and requires brain surgery. It involves the placement of an electrode directly onto or into the brain with a wire running down the neck, under the skin, that is connected to a battery pack/pulse generator in the chest or abdomen (sometimes called a 'brain pacemaker'). The electrode is implanted under general anaesthesia using stereotactic microsurgery, a type of keyhole surgery. In the six months following implantation, the device might need adjustment by the treating clinician and follow up visits may be necessary for this.

Uses in medicine

The main clinical application for TMS is currently in the treatment of depression. Repeated TMS treatment has been shown to be effective in cases of major depression. There is also ongoing research into its therapeutic benefit for a variety of other disorders and diseases such as obsessive compulsive disorder, hallucinations in schizophrenia, tinnitus, Alzheimer's dementia and Parkinson's disease. TMS has been shown to temporarily decrease pain and is therefore being investigated for treating pain disorders including migraine. Its benefits in rehabilitation after stroke are also being explored.

DBS is used in the treatment of Parkinson's disease, neurological movement disorders such as *dystonia*[6], obsessive-compulsive disorder (OCD) and disorders of consciousness. In Parkinson's disease and dystonia, it has been shown to reduce tremor and involuntary movements quite dramatically, thus

[6] Dystonia is a neurological movement disorder involving sustained muscle contractions that lead to contorted body positions, twisting and repetitive involuntary movements. There is currently no cure for dystonia.

improving patients' quality of life. It is also being investigated for therapeutic application in epilepsy that is hard to control with drugs, in the treatment of stroke and severe pain, and in certain compulsive disorders such as *Tourette's syndrome*[7] and OCD, where it could help to manage symptoms that cannot be controlled in other ways.

Uses outside of medicine

TMS has been shown in some studies to improve cognitive skills and there is therefore some interest in developing non-medical application for enhancement. Enhancement aims to improve human traits and skills beyond a 'normal' level for educational, recreational or other non-medical purposes. Research is underway in using TMS to improve skills related to memory and learning, to further problem-solving capacities and creative thinking (a 'creativity cap'), to enhance mood, and to modulate social cognition (an individual's understanding of and relationship to other people).

Due to the need for brain surgery, there are currently no efforts to apply DBS in non-medical areas.

Current availability

TMS has been approved in several countries for treating depression and the equipment is commercially available. So far, TMS is not widely used in clinical practice, owing to the cost and complexity of the equipment and the availability of alternative treatments (i.e. drugs and ECT). However, it is expected that the equipment will become more convenient to use and cheaper in the near future. In that case, it might become more widely adopted when depression cannot be treated with drugs or other forms of therapy. Research into its use in other disorders, and into non-medical applications, is significant. Commercial interest can be anticipated particularly with regards to enhancement applications; clinics offering 'off-label' use have already appeared in some parts of the world.

DBS is now a routinely used treatment in severe cases of Parkinson's, dystonia and essential tremor, and increasingly in chronic pain conditions. In these conditions, DBS is applied if other treatments such as drugs are no longer effective in controlling symptoms. Benefits have been most clearly demonstrated in Parkinson's and in neurological movement disorders; outcomes vary in pain disorders. Using DBS to treat severe cases of depression or Tourette's syndrome is still mostly experimental.

Technology-related risks

While on the whole, TMS has few side effects, there have been reports of seizures when it is repeatedly applied. Based on this and the fact that the

[7] Tourette's syndrome is a neuropsychological disorder that involves a mix of repeated motor and vocal tics (involuntary movements and vocal expressions). It is inherited and starts in childhood.

exact mechanism is still unknown, some have questioned whether TMS might have long-term, negative results on the brain. There have also been reports that TMS might sometimes trigger unexpected behavioural responses, such as shouting obscenities, experiencing flashbacks or confessing to criminal offences.

DBS has side-effects and potential risks that are associated with all brain surgery, such as anaesthesia complications, bleeding, blood clots, infection, and pain, and also the risk of damaging healthy brain tissue. In addition to these, there have been reports that some patients who receive DBS treatment develop problems in word generation, attention and learning. There were also reports of hallucinations, apathy and some psychiatric side effects such as personality changes and compulsive actions (e.g. gambling, hypersexuality) and depression. These were often temporary or improved when electrodes were repositioned. Due to the group of patients treated (or potentially treatable) with DBS, there are questions of whether informed consent can be given in all instances.

We would also like to hear views on wider concerns and questions about the use of neurostimulation, such as whether their respective risks are in an appropriate relations to their benefits, particularly in non-medical applications; whether they could be used in a malicious way; how we evaluate effects on mood, personality and responsibility; what societal impact their use in non-medical settings could have; and whether research efforts and public money should be devoted to this technology.

Questions

Please indicate which technology (TMS, DBS) you are referring to in your answer

11. Have you used neurostimulation and if so, with what consequences? Please describe your experience.

12. If you have not used neurostimulation before, under what circumstances would you do so?

13. Under what circumstances do you think it might be acceptable to use neurostimulation in non-medical context (that is to say, not for the treatment of a disease or disability)?

14. Are there any particular ethical or social issues associated with neurostimulation?

15. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.

3) Neural stem cell therapy

What is neural stem cell therapy?

Neural stem cells are cells that are able to give rise to any type of nerve cell. Researchers are examining whether neural stem cells could be used in treating diseases and conditions that involve the loss of nerve cells in the brain and/or spinal cord (e.g. Alzheimer's disease or stroke) and a subsequent loss of abilities. It is thought that by injecting neural stem cells into the brain and/or spinal cord, the effects of losing nerve cells could be reversed, therefore improving, and maybe one day restoring, the abilities affected.

Neural stem cells are injected into the brain while the individual is under general anaesthetic. Doctors find the correct location by studying 3D images of the brain that are taken continuously throughout the procedure. Once injected, the neural stem cells either replace the cells that were lost, or provide factors that improve brain function.

The neural stem cells for these studies are typically derived from the fetal nervous system. Similar cells can also be found in the adult brain, and some researchers are trying to discover how these adult cells could be directly activated in a patient to induce brain repair. Neural stem cells can also be derived from other sources, including from embryonic stem (ES), which can grow into any cell type. A new method uses cells in the body other than the eggs or sperm – such as skin cells – to produce induced pluripotent stem (iPS) cells. IPS cells behave like ES cells: they are able to produce all of the different cell types in the body. They have the potential therefore to produce neural stem cells, and may in the future have utility in brain repair.

In this consultation, we are not looking for views about stem cells as such, but for views on procedures that involve the injection of stem cells into the brain.

Uses in medicine

There is currently public and private research into neural stem cell therapy to treat diseases like Alzheimer's disease, Parkinson's disease and Huntington's disease, which involve the loss of nerve cells. Neural stem cell therapy is also being looked into as a treatment for conditions such as stroke. In Alzheimer's disease, where nerve cells are lost throughout the brain, the individual can experience progressive difficulties with memory, speech and thought. In stroke, where nerve cells can be lost in a particular brain region, the ability associated with that region – such as moving the left hand side of the body – can be significantly reduced. Neural stem cell therapy could benefit individuals with these diseases or conditions.

Uses outside of medicine

Some researchers in the field speculate that neural stem cell therapy could be used for human enhancement – i.e. the improvement of basic human capacities beyond 'normal functioning'. In the context of neural stem cell therapy, possible uses could include improving memory and learning. However, it is not evident that there is any current research into this, or any plans for research to be conducted in the future.

Current availability

Neural stem cell therapy is currently not available as a medical treatment in the UK; there are, however, some ongoing trials in humans. For example, the world's first fully regulated clinical trial of neural stem cell therapy to treat disabled stroke patients is currently taking place in Scotland. In other countries including China, India and Russia, there are some clinics which claim to offer stem cell therapy, including neural stem cell therapy. These clinics have caused concern with regards to the safety and efficacy of the stem cell therapies and the standard of care they provide.

Technology-related risks and concerns

While neural stem cell therapy could benefit people with diseases or conditions such as Alzheimer's disease and stroke, there are some concerns regarding the technology. Neural stem cell therapy involves surgery and transplantation, and it therefore carries risks that are common to such procedures, including: use of contaminated material; bleeding during surgery; side effects of general anaesthesia; catching infections after the operation; rejection of the transplanted cells by the individual's immune system. In addition, some argue that since the brain is the organ being operated on, these common surgical/transplant risks are of greater relative concern because the brain is home to the key elements of the 'self'. The nature of neural stem cell therapy also generates specific safety risks. As neural stem cells are able to multiply in numbers, there is a risk of tumours forming. The injected cells could also move to the wrong site in the brain, causing unwanted changes. There is also concern regarding the general risk of unwanted changes, for example in mood, behaviour and abilities. This could involve a loss in certain abilities, or possibly an enhancement. Neural stem cell therapies are understood less well compared to other brain interventions such as other types of brain surgery and drugs that target the brain, and some fear that through the use of neural stem cells that are not produced from the individual's own body the recipient could acquire donor traits or there could be at least some modification of personality traits.

There are also concerns associated with the practice of neural stem cell therapy in some instances. Clinics in China, India and Russia claiming to offer stem cell therapy, including neural stem cell therapy, has led to 'stem cell tourism', where patients travel to other countries in order to obtain stem cell treatment. However, it is unclear whether the therapy has gone through clinical trials, and whether there are adequate standards of medical treatment and care in place.

Questions

16. Under what circumstances would you use neural stem cell therapy?

17. What do you think of the risks and benefits of neural stem cell therapy?

18. Are there any particular ethical or social issues associated with neural stem cell therapy?

19. How do you feel about neural stem cell therapy being used for non-medical purposes one day, for example for human enhancement?

20. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.

Respondent's form

Please complete and return with your response by **23 April 2012, 5 pm**.

Your details:

Name:

Organisation (if applicable):

Address:

Email:

About your response:

Are you responding personally (on your own behalf) or on behalf of your organisation?

☐ Personal ☐ Organisation

May we include your name/your organisation's name in the list of respondents that will be published in the final report?

☐ Yes ☐ No, I/we would prefer to be anonymous

If you have answered 'yes', please give your name or your organisation's name as it should appear in print (this is the name that we will use for your response):

May we quote your response in the report and make it available on the Council's website when the report is published?

☐ Yes, attributed to myself or my organisation ☐ No
☐ Yes, anonymously*

*If you select this option, please note that your response will be published in full (but excluding this form), and if you wish to be anonymous you should ensure that your name does not appear in the main text of your response. The Nuffield Council on Bioethics cannot take responsibility for anonymising responses in which the individual or organisation is identifiable from the content of their response.

Obtaining consent to publish a response does not commit the Council to publishing it. We will also not publish any response where it appears to us that to do so might result in detriment to the Council's reputation or render it liable to legal proceedings.

Why are you interested in this consultation? (tick as many as apply)

- ☐ General interest
- ☐ Academic/research interest
- ☐ Work in/represent a professional body or government
- ☐ Work in/represent a charity, NGO or religious group
- ☐ Work in/represent industry
- ☐ Investor/Consultant
- ☐ Legal/regulatory interest
- ☐ Educational/teaching interest
- ☐ Work in/represent media
- ☐ Other (please state):

____

Please let us know where you heard about the consultation:

- ☐ Received notification by email
- ☐ Newspaper, radio or television
- ☐ Nuffield Council on Bioethics website
- ☐ Twitter
- ☐ Other website (please state):

  ____
- ☐ Other (please state):

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Using your information

We ask for your postal and email address in order that we can send you a copy of the report when it is published and notify you about activities related to this project. (Please note that we do not make your postal and email addresses available to anyone else and we do not include it with the list of respondents in the report.)

May we keep your postal and email addresses for these purposes?

- ☐ Yes
- ☐ No

Would you like to receive our newsletter by e-mail which provides you with information about all of the Council's activities?

- ☐ Yes
- ☐ No