

## **A DISCUSSION PAPER: NEUROETHICS AND THE BRITISH PSYCHOLOGICAL SOCIETY RESEARCH ETHICS CODE**

Prepared by: Dr Carl Senior, Professor Patrick Haggard and Professor John Oates

This is a discussion paper prepared for the British Psychological Society (BPS) which is about to publish its Code of Human Research Ethics. The aim of this paper is to generate dialogue around the potential neuroethical risks that society members may encounter during their research and recommend potential avenues to alleviate such risk. It is not meant to be a definitive text on neuroethical risk rather a starting point for such discussions. It is hoped that feedback can be incorporated back into the document and then ultimately back to the society for subsequent inclusion into the revised code. The paper is divided into four sections, which correspond to the general structure of the nascent BPS Code of Human Research Ethics. These four sections are i): Respect for the autonomy and dignity of persons, ii) Scientific value iii): Social responsibility and iv): Maximising benefit and minimising harm.

Cognitive neuroscientific techniques are commonplace in psychology laboratories across the UK, with functional magnetic resonance imaging (fMRI) being particularly popular (Bandettini, 2007). Alongside fMRI there are a number of other approaches that could be used by society members however a description of these techniques is outside the remit of this paper and readers are directed to more specialised texts for details (e.g., Senior, Russell & Gazzaniga, 2006; Senior & Rippon, 2007). Technological advances of this kind often develop extremely quickly so it is not surprising that 'neuroethics', the forum for identifying and evaluating ethical issues in neuroscience, has recently emerged from biomedical ethics several years after the technology became available (Farah, 2002). At this stage of its development neuroethics can be defined in two parts, these are the 'ethics of practice' and the 'ethical implications of neuroscience'. In the former category potential risks could include issues like implicit coercion, informed consent and even the possibility of anxiety or claustrophobia in participating in MRI procedures etc. This is the more traditional aspect of neuroethics.

However in the latter category potential risks could include issues surrounding cognitive enhancement, lie detection in organisational settings and even the use of brain imaging techniques in education (See e.g., Roskies, 2002). It should be worth noting that significant risks also exist with high magnetic field associated with MRI scanners. Bringing ferromagnetic objects into close proximity of MRI scanners can result in the object being drawn into the centre of the magnetic bore

– which can have lethal consequences. These risks do not fall under the neuroethics umbrella and should be considered in the safety guidelines at the local institution.

Following on from a review of the literature and discussions with colleagues at Aston University, Queen Marys, University of London, Kings College London, University of Zurich and with delegates at the Ethical Management of Research Imaging meeting held at the Wellcome Trust, London (1<sup>st</sup> July 2010) the following areas of potential risk plus possible solutions to alleviate such risk were identified as being relevant to society members.

## **RESPECT FOR THE AUTONOMY AND DIGNITY OF PERSONS**

The central principle for all ethical consideration is that the autonomy and dignity of the individuals involved in the research process is respected. Yet there are times when researchers study certain areas of the brain that directly impacts the autonomy of the participants. Take for example, the ventromedial prefrontal cortex (VMPF), an area towards the front of the brain implicated in a range of ethical decision-making processes (Casebeer & Churchland, 2003; Damasio 1995). Indeed this well replicated finding has lead some researchers to consider the VMPF as playing an essential role in morality processing (Green & Haidt, 2002, Hauser, 2006). The ability to assess the morality and ethicality of an experimental procedure is an important stage that participants undergo when deciding whether or not to take part. Individuals whose capacity to make autonomous assessments about the ethical nature of a proposed paradigm would not be able to make a fully informed decision as to the provision of consent. Of relevance is the fact that neuropsychological evidence has shown consistently that patients suffering from damage to the VMPF are impaired in making ethically charged judgments about themselves and also the environment that they interact with (Damasio, et al 1990). Such a deficit would have an immediate and significant effect on the ability to provide informed consent. Here, researchers should consider the use of an independent third party to assess the ability to provide consent in these cases. (See the Mental Capacity Act, 2007 : <http://www.dca.gov.uk/legal-policy/mental-capacity/mca-summary.pdf> and BPS guidelines: [http://www.bps.org.uk/document-download-area/document-download\\$.cfm?file\\_uuid=AC678329-1143-DFD0-7E20-4EE07191A785&text=pdf](http://www.bps.org.uk/document-download-area/document-download$.cfm?file_uuid=AC678329-1143-DFD0-7E20-4EE07191A785&text=pdf)).

Special care in determining the ability to provide informed consent needs to be considered in these instances where the participant may be suffering from a neurodegenerative disorder (Jaworska, 2006). For research that carries more than minimal risk but does not have the prospect of direct medical

benefit, the use of a consensus model of consent requiring the agreement of a number of parties such as the participant's legal guardian, general practitioner, and/or a lay subject advocate etc should be considered (Fins & Miller, 2000).

Involving participants who are suffering from such various lesions or neurodegenerative disorders is consistent with the ethical principles described in the Belmont Report. Belmont sought to ensure the just distribution of research ethics risks across all populations and to safeguard the vulnerable amongst us (1978). Modern day regard for distributive justice (Rawls, 1975) urges the inclusion of marginalized communities and fair access to research for those with neuropsychiatric disorders (Michels, 1999). The ethics challenge for society members is to study this population to learn more about their cognitive capabilities and to include these subjects, as they are able, in the consent or assent process, recognizing that participants may reveal a greater capability to engage with the investigative team.

Notwithstanding the effects of neurological status the technology itself may invoke coerced behaviour and thus impact on informed participation. The technologically intensive environment associated with a modern day psychology laboratory could encourage research participants to take part in experiments just 'to see what it is like'. The implications of such over-use in clinical studies are emotively argued in a BMJ personal review entitled, "VOMIT (victims of modern imaging technology) – an acronym for our times", which describes instances of 'confirmatory' neuroimaging procedures which can cause unnecessary distress to patients and relatives with little diagnostic benefit (Hayward, 2003).

We previously reported that research participants also experience raised anxiety prior to undergoing a neuroimaging procedure (Cooke et al, 2007). High noise levels, confinement inside the magnet bore, concerns about diagnosis and patient control have been identified as anxiety provoking in clinical settings and may also lead to an increase in anxiety in research participants. Yet even with participants reporting anxiety before engaging with an experimental procedure very few opt to withdraw participation. The ethical framework imposed by most local research ethics committees ensures that express coercion does not occur in the contemporary psychology laboratory. We have previously reported that research participants consider such procedures as benign clinical investigations that confirm the absence of a neurological pathology (Shaw et al, 2008). Given that MRI scans conducted for research alone serve a very different purpose to those in a clinical context, it is important to examine whether this phenomenon could mediate indirect or implicit coercion to

participate and carry an additional risk of reducing participants' motivation to seek clinical examination if neurological symptoms subsequently occur (a real effect noted in the Whitehall longitudinal study).

In order to exclude the possibility of implicit coercion in cognitive neuroscientific investigations it is recommended that researchers not only provide information about the paradigm but also the technique and the experience that the participants may undergo should they decide to take part. Where possible individuals interested in participation should be invited to the laboratory before the experiment to see the equipment and have the opportunity to ask questions prior to consent being sought.

However, it is when discussing the possibility of inadvertently revealing a previously undiagnosed malignancy that the implications for personal autonomy remain unclear. Can a volunteer choose in advance not to know about some or all incidental findings? For the sake of this discussion paper an incidental finding is defined as being 'a finding that has potential health or reproductive importance which is discovered in the course of conducting research, but is beyond the aims of the study' (Wolf et al, 2008). With regards to neuroimaging the prevalence of such incidental findings is quite high with studies reporting between 18 to 40% prevalence (Katzman et al, 1999; Orme et al, 2010) however the manner in which incidental findings are managed varies considerably.

Currently, some UK units will scan volunteers only if they consent in advance to their GP being told of any potential incidental finding. An interesting corollary of this policy would be that a person determined to maintain their autonomy could not participate in the research. In other research areas, notably genetic research, the situation is exactly the opposite: participation is allowed only on the understanding that no information about the participant's data will be fed back to them or their doctor under any circumstances.

Finally, what if the incidental finding is potentially harmful to others? For example a bus-driver who is informed that he has an aneurysm: ignoring an incidental finding, or respecting a volunteer's right to autonomy, could then threaten the lives of other road users if the aneurysm were to rupture at the wrong moment. Such a 'ticking bomb' scenario could have potential implications for a significant number of people and obviously needs to be considered.

It is with the possibility of an incidental finding that the autonomy of the individual and the scientific value of the research at hand needs to be carefully considered. As noted above, it has been shown

that some participants consider neuroimaging procedures as a form of benign medical investigation even when the procedures are clearly described as being a research based only. However, as Pickard & Gillard (2005) highlight there are those individuals who become serial participants in neuroimaging studies so as to repeatedly confirm the absence of any underlying pathology and MR exposure rates should also be monitored in all cases.

It is clear that to protect the autonomy of the individuals as well as the scientific value of the research a number of steps are possibly needed. First, informed consent should include a statement that clearly highlights that possibility that an incidental finding may occur and the implications of such a findings. Secondly, to ensure that the research procedure is not associated with a medical context in any way clinical and research governance should be explicitly separated. This should serve to highlight the fact that the researchers do not have a duty of care to report such incidental findings, which, on the other hand is a responsibility of the members of the clinical governance committee. As Pickard & Gillard (2005) suggest all structural MR images should be confidentially reviewed by a medically qualified individual. If an abnormality is found that may impact the validity of the research then the principal investigator is informed the specific individual should no longer be invited to participate. The participant is informed that there may be an abnormality and a full clinical MRI scan should be arranged if necessary. At every stage the participant should also be informed that no communication with the family doctor would be made without express permission.

As a further suggestion the society should consider the generation of standard consent text to be included within individual institutional consent forms so that the correct information regarding the potential to reveal incidental findings is communicated to participants.

## **SCIENTIFIC VALUE**

As is the case with any research endeavor the implications should not be taken out of context. This may seem a straightforward assumption however it is not the case with brain imaging where the complex processes that mediate the fMRI signal are still not completely understood. Given this lack of understanding researchers should be cautious about making inferential leaps from the data (be it predicted or revealed). Previous commentaries have urged for simple experimental designs (Kosslyn, 1999). However there is rising interest in the use of brain imaging technologies for more and more complex investigations with one such application being the study of lying. Indeed, in the recent Harvard Business Review 'Breakthrough List' – an annual list of innovations that are predicted to make an impact in the preceeding year. An article Lies, Damn Lies and Lie Detectors by Langleben

and Wolpe (2008) presents the possibility that brain imaging technologies may be used in contemporary polygraphy. They go on to mention two start up companies (Langleben is the Director of one) that have been approached by ‘...law enforcement agencies, defence and business communities [my underline].’ While the (very real) limitations of applying contemporary polygraphic techniques in an occupational setting have been discussed elsewhere (Senior et al, 2008) the drive to develop more and more effective polygraphic techniques is not new.

Event related potentials (ERPS) have previously been used to detect differences in the P300 wave (which is thought to be the signature for novelty detection) between guilty and innocent people in an approach termed ‘Brain Fingerprinting’ (Farwell & Smith, 2001). Like Langleben, Farwell also has ties to American security agencies; in fact the paper cited here is coauthored with a special investigator from the FBI. While both approaches have generated much interest in the media they both suffer from a significant oversimplification of the cortical response to a complex social phenomena. Farwell himself states that ‘brain fingerprinting doesn't have anything to do with the emotions, whether a person is sweating or not; it simply detects scientifically if that information is stored in the brain’ (Source <http://news.bbc.co.uk/1/hi/sci/tech/3495433.stm>). Yet a lie is rarely so simplistic and almost never a binary response with either a ‘yes’ or a ‘no’ response that requires minimal cognitive effort. This is especially relevant when placed in the context of a criminal case where the accused would probably be in a very nervous, confused and emotional state with a lot going through his/her mind (see Wolpe, Foster & Langleben, 2005 for a further discussion of this emerging field).

Research that is carried out in collaboration with outside agencies should always be encouraged however when such collaborations may lead to the incarceration of the individual special consideration should be given to the proposed research. Such consideration should focus (but not be restricted to) any conflict of interest between the scientific interests of the research process and security agencies that may be funding the research. Furthermore, the very fact that so little is understood of the human cognitive system means that cognitive neuroscience (at this stage) should not be used within any interrogational setting (Senior, 2008; Rippon & Senior, 2010).

Another area where there may be a potential neuroethical risk is the emerging field of neuromarketing (the study of the neural correlates of market behaviour; Lee, Broderick & Chamberlain, 2007). In the early days neuromarketing was considered to be the erroneous and quite fanciful search for the mythical ‘buy button’ in the brain - a cortical region that, when active would

signal the start of unstoppable consumer behaviour. The identification of such a region would allow for 'supermarketing' campaigns, hyperefficient advertising campaigns that consumers would not be able to resist! Such an outcome has clear moral and ethical concerns that are similar to the early work of Jose Delgado who inserted 'stimocievers, small radio controlled electrodes, into the brains of mammals, including humans, to control their behaviour (Delgado, 1969). However, it is worth noting that brands such as Coca Cola and Apple maintain a global domination of the consumer market without recourse to brain imaging.

Contemporary neuromarketing now stands as a valid, rigorous and relevant sub discipline of social cognitive neuroscience and is essentially the study of the cognitive neuroscience of applied social influence (Senior & Lee, 2008). Notwithstanding the caveats noted above one question that is worthy of consideration is whether or not researchers are justified to ask participants to undergo a procedure without any kind of therapeutic implication or intention and also whether or not research is permitted that may be funded by companies whose vested interest is purely to make profit?

## **SOCIAL RESPONSIBILITY**

Given that most cognitive neuroscientific techniques require access to a relatively large laboratory setting at some point the issue of the social responsibility that Society members could play may not be clearly evident. However, cognitive neuroscience does raise some unique issues and one of these issues is embedded in the persuasive power of brain scan imagery. Observers are more likely to believe an explanation when it is presented alongside a picture of a brain scan compared to most other images (McCabe & Castel, 2008). The persuasive power of brain scan imagery occurs due to the 'neurorealism' effect (Racine et al, 2005). In other words brain scans are highly persuasive images because they allow observers to realise the physical entity of complex cognitive problems. They are influential because they provide a physical basis for abstract cognitive processes that appeal to people's preferences for reductionistic explanations of cognitive phenomena (Weisberg et al, 2008).

In light of the persuasive power of brain scan imagery its use to illustrate any fact should be restricted as much as possible. Brain scan imagery should not be included on recruitment posters for participation in experiments. Furthermore, in order to alleviate any undue influence in understanding explanations Society members have an additional responsibility to communicate the implications of their findings to the widest population and in straightforward language.

## MAXIMISING BENEFIT AND MINIMISING HARM

The ability to enhance cognitive function is now a real possibility with a variety of enhancements available (see Burkhardt, 2007 for general discussion on this area). For the sake of this paper only neuropharmacological enhancements will be discussed (see Farah, 2002). Such enhancements are surprisingly common with a recent commentary in *Nature* even highlighting their usage in academic staff (Sahakian & Morien-Zamir, 2007). The Sahakian paper highlights how drugs such as Modafinil (used to treat daytime sleepiness associated with narcolepsy) and Ritalin (used to treat sufferers of attention deficit disorder) are being used to increase concentration and memory in the healthy population. But some of these drugs do indeed have potentially harmful side effects and it may be important to control access. While most people would agree that to better oneself is a good thing and should be encouraged, the field of cognitive enhancement raises concerns of distributed justice, the fair allocation of resources among diverse members of a community, and this deserves consideration (Rawls, 1975).

Modafinil and Ritalin (and any other type of cognitive enhancement) cost money and are therefore only available to people who have money to spend on it. Accordingly any drug that brings benefit to someone's worklife would also bring an unfair disadvantage to those who don't have access to it who may then start to address the unfair distribution of these resources. At the societal level the recourse to a natural distributed justice can see a rise in crime in sections of society. However, at the level of the individual research experiment participation in experimental procedures where the effects of these drugs are being examined for any reasons would be one such way that distributed justice can occur. More specifically research examining the effects of drugs such as Modafinil on sleep patterns would provide an opportunity for healthy individuals to gain the enhancement in concentration that the drug indirectly provides. In some experimental procedures healthy individuals are recruited as control participants and as such researchers need to be aware of the fact that recruitment to their procedures may be biased in certain instances with participants who wish to gain some form of cognitive enhancement.

Accordingly it is suggested that society members who are working in any area where participants can gain some form of cognitive enhancement via participation (e.g., examining the effects of Ritalin on visual attention etc) also employ a double blind placebo paradigm at the very least to ensure that the healthy participants have a 50% chance of receiving either the active drug or placebo. By reducing the chance that participants have to get the active drug the involvement of people who repeatedly

attempt to participate in such paradigms will be reduced.

It is hoped that this discussion paper will provide an opportunity to initiate consideration of the various factors that should be considered in contemporary cognitive neuroscience research and that this in turn will see itself becoming part of the Code of Human Research Ethics. **If you have any comments on this paper, please e-mail them to: [lisa.morrisoncoulthard@bps.org.uk](mailto:lisa.morrisoncoulthard@bps.org.uk).**

## REFERENCES

Bandettini, P. (2007). Functional MRI today. *International Journal of Psychophysiology*. 63. 138-145.

Belmont Report on the Ethical Principles and Guidelines for the Protection of Human Subjects of Research. (1978). DHEW Publication No. (OS) 78-0012 . Washington, D.C. US. Government Printing Office.

Burkhardt, TA. (2007). Operation Rebirth : Captain America and the ethics of enhancement. *Philosophy Now*. 64. 8-10.

Casebeer, WD. & Churchland, PS. (2003). The neural mechanisms of moral cognition: A multiple aspects approach to moral judgment and decision making. *Biology and Philosophy*. 18. 169-194.

Cooke, R., Peel, E., Shaw, RL. & Senior C. (2007). The neuroimaging process from the participants' perspective. *International Journal of Psychophysiology*. 63. 152-158.

Damasio, AR. (1995). *Descartes' error: Emotion Reason and the Human Brain*. New York, Avon Books.

Damasio, AR., Tranel, D. & Damasio, H. (1990). Individuals with sociopathic behaviour caused by frontal damage fail to respond autonomically to social stimuli. *Behavioural Brain Research*. 41. 81-94.

Delgado, JMR. (1969). *Physical Control of the Mind: Toward a Psychocivilized Society*. New York, Harper and Row.

Farah, MJ. (2002). Emerging issues in neuroscience. *Nature Neuroscience*. 5. 1123-1129.

Farwell, LA. & Smith, SS. (2001). Using brain MERMER testing to detect knowledge despite efforts to conceal. *Journal of Forensic Science*. 46. 135-143.

Fins, JJ. & Miller, FG. (2000). Enrolling decisionally incapacitated subjects in neuropsychiatric research. *CNS spectrums*. 5. 32-40.

Greene, J. & Haidt, J. (2002). How (and where) does moral judgment work ? *Trends in Cognitive Sciences*. 6. 517- 523.

Hauser, MD. (2006). The Liver and the moral organ. *Social Cognitive and Affective Neuroscience*. 1. 214-220.

- Hayward, R. (2003). VOMIT (victims of modern imaging technology) – an acronym for our times. *British Medical Journal*. 326. 1273.
- Illes, J., Racine, E. & Kirschen, M. (2006). A picture is worth a 1000 words, but which 1000? In Illes, J. (Ed). *Neuroethics: defining the issues in theory, practice and policy*. Oxford, Oxford University Press, pp. 149-169.
- Jaworska, A. (2006). Ethical dilemmas in neurodegenerative disease: respecting patients at the twilight of agency. In Illes, J. (Ed). *Neuroethics: defining the issues in theory, practice and policy*. Oxford, Oxford University Press, pp. 87 –105.
- Katzman, GL., Dagher, AP. & Patronas, NJ. (1999). Incidental findings on brain magnetic resonance imaging from 1000 asymptomatic volunteers. *Journal of the American Medical Association*. 281. 36-39.
- Kosslyn, SM. (1999). If neuroimaging is the answer, what is the question? *Philosophical Transactions of the Royal Society of London (B)*. 354. 1283-1294.
- Lee, NJ., Broderick, AJ. & Chamberlain, L. (2007). What is Neuromarketing? A Discussion and Agenda for Future Research. *International Journal of Psychophysiology*. 63. 199-204.
- McCabe, DP. & Castel, AD.(2008). Seeing is believing: the effect of brain images on judgments of scientific reasoning. *Cognition*. 107. 343-352.
- Michels, R. (1999). Are research ethics bad for our mental health? *New England Journal of Medicine*. 340. 1427- 1430.
- Murphy, KJ. & Brunberg, JA. (1997). Adult claustrophobia, anxiety and sedation. *Magnetic Resonance Imaging*. 15. 51-54.
- Orme, NM., Fletcher, JG., Siddiki, HA., Harmsen, S., O'Byrne, MM., Port, J., Tremaine, WJ., Pitot, HC., McFarland, EG., Robinson, ME., Koenig BA., King, B. & Wolf, SM. (2010). Incidental Findings in Imaging Research: Evaluating Incidence, Benefit, and Burden. *Archives of Internal Medicine*. 170. 1525-1532.
- Owen, AM., Coleman, MR., Boly, M., Davis, MH., Laureys, S. & Pickard, JD. (2006). Detecting awareness in the vegetative state. *Science*. 313. 1402.
- Pickard, JD & Gillard, JH. (2005). Guidelines to reducing the risk of brain scan shock. *Nature*. 435. 17.
- Racine, E., Bar-Ilan, O. & Illes, J. (2005). fMRI in the public eye. *Nature Reviews: Neuroscience*. 6. 159-164.
- Rawls, J. (1975). *A Theory of Justice*. New York, Belknap.
- Rippon, G. & Senior, C. (2010). Neuroscience has no role in National Security. *American Journal of Bioethics*.1. 37
- Rosenfeld, PJ., Soskins, M., Bosh, G. & Ryan, A. (2004). Simple, effective countermeasures to P300-based tests of detection of concealed information. *Psychophysiology*. 41. 205-219.

- Rosenfield, PJ. (2005). 'Brain Fingerprinting' : A critical analysis. (2005). *The Scientific Review of Mental Health Practice*. 4. 20-37.
- Roskies, A. (2002). Neuroethics for the New Millennium. *Neuron*. 35. 21-23.
- Sahakian, B. & Morien-Zamir, S. (2007). Professors's little helper. *Nature*. 450. 1157-1159.
- Senior, C. & Rippon, G. (2007). Cognitive neuroscience : Contributions from psychophysiology ? *International Journal of Psychophysiology*. 63. 135-136.
- Senior C. (2008). The persuasive power of brain scan images. *The American Journal of Bioethics*. 8. 60-61.
- Senior. C., Lee, N. & Butler, MJR. (2008). The neuroethics of the social world of work. *The American Journal of Bioethics*. 8. 54-55.
- Senior, C., Russell, T. & Gazzaniga, MS. (2006). *Methods in Mind*. Cambridge, The MIT Press.
- Senior, C. & Lee, NJ. (2008). A manifesto for neuromarketing science. *Journal of Consumer Behavior*. 7. 263-271.
- Shaw, RL., Senior, C., Peel, EA., Cooke R. & Donnelly, LS. (2008). Ethical issues in neuroimaging health research: an IPA study with research participants. *Journal of Health Psychology*. 13. 1051-1059.
- Weisberg, DS., Keil, FC., Goodstein, J., Rawson, E. & Gray, JR. (2008). The seductive allure of neuroscientific explanations. *Journal of Cognitive Neuroscience*. 20. 470-477.
- Wolf, S.M., et al (+ 20 other authors) Managing incidental findings in human subjects research: analysis and recommendations. *Journal of Law and Medical Ethics*. 36. 219-248.
- Wolpe, PR. & Langleben, DD. (2008). Lies, Damn Lies, and Lie Detectors. *Harvard Business Review*. 86. 25.
- Wolpe, P.R., Foster, K. & Langleben, D. (2005). Emerging neurotechnologies for lie-detection: Promises and perils. *American Journal of Bioethics*. 5. 39-49.