Neuroethics and The British Psychological Society
Research Ethics Code: An updated discussion paper

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Executive summary

- The use of neuroimaging and related techniques of neuroscience has become widespread in psychological research, generating new ethics issues and the new field of neuroethics.

- The present document analyses these ethics issues in terms of the four principles of research ethics that form the foundation of the Society’s Code of Human Research Ethics.

- New advances in neuroscience have raised questions about the relation between variations in capacity for autonomous decision-making linked with variations in cortical structure and function, challenging traditional notions around the concept of valid consent.

- The technical sophistication of neuroimaging potentially invokes a coercive effect from the point at which potential participants are initially contacted and throughout the data gathering process.

- The recognised probability of incidental findings from imaging raises new issues of confidentiality, disclosure, and competence to interpret data, mandating specific protocols to safeguard participants.

- Because it is known that arguments containing neuroscience terminology have greater persuasive value, it is especially important for researchers to beware of over interpretation or overgeneralisation from their data.

- Researchers engaged in work that focuses on enhancing mental functioning through medical means should be aware of the ethics issues around potential encouragement for members of the public to engage in the use of substances that may carry elevated risks of harm.
This is an updated version of a discussion paper that was originally published by the British Psychological Society (BPS) in 2007. The aim of this paper was to generate dialogue around the potential ethics issues associated with neural imaging and related fields of neurological and psychological research (described as ‘neuroethics’ from here on) that Society members may encounter and to recommend potential avenues to alleviate such risk. It is not meant to be a definitive text on neuroethics risk, but rather a starting point for such discussions. It was hoped that feedback would be incorporated back into the document and then ultimately back to the Society for subsequent inclusion into the revised code. This paper has undergone a revision to ensure that it continues to reflect a contemporary position on the potential neuroethics risks that Society members may face during their research activities. As before, the paper is divided into four sections, which correspond to the general structure of the 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 neuroscience techniques are commonplace in psychology laboratories across the UK, with functional magnetic resonance imaging (fMRI) being particularly popular (Bandettini, 2007). Alongside fMRI there is a number of other approaches that are used by Society members, however a description of these techniques is outside the remit of this paper and readers are directed to more general texts for details (e.g., Senior, Russell & Gazzaniga, 2006; Senior & Rippon, 2007). Technological advances in this field often develop extremely quickly so it is not surprising that ‘neuroethics’, the forum for identifying and evaluating ethics issues in neuroscience, has recently emerged from biomedical ethics several years after the technology became available (Farah, 2002). Over the course of the last five years (2009–2014) the growth of interest in neuroethics has been significant – merely entering the phrase ‘neuroethics’ into Google Scholar returns over 6000 articles on this area alone. The formation of the International Neuroethics Society (http://www.neuroethicssociety.org/) in 2011 as well as centres such as the Oxford Centre for Neuroethics.
Neuroethics (http://www.neuroethics.ox.ac.uk/home) in the UK have helped to drive the consolidation of this approach to identify risk. Coupled together with the formation of annual international conferences (http://www.neuroethicssociety.org/2014-annual-meeting) and various other fora as well as the publication of *Neuroethics* – a journal dedicated to the study of this topic has ensured that this branch of bioethics is now an established approach in its own right.

Within the previous draft of the discussion paper the development of neuroethics was defined in two parts; the ‘ethics of practice’ and the ‘ethical implications of neuroscience’. In the former category potential risks could include issues like implicit coercion, failure to gain valid consent and the possibility of anxiety or claustrophobia in participating in MRI procedures. 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 (viz. e.g., Roskies, 2002). It is worth noting that significant risks also exist with the high magnetic fields associated with MRI scanners. Inadvertently bringing ferromagnetic objects into close proximity with 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.

Originally, the initial discussion paper was developed following a review of the literature and discussions with colleagues at Aston University, Queen Mary University of London, King’s College London, University of Zurich and with delegates at the Ethical Management of Research Imaging meeting held at the Wellcome Trust, London (1 July 2010). The following areas of potential risk plus possible solutions to alleviate such risks were identified as being relevant to society members. To update the initial document the literature (from 2009–2014) within the various sections below was reviewed and incorporated into the current revised document where appropriate.
Readers are reminded that this paper should not be considered a definitive text on neuroethics; rather it is a starting point for further discussion in the field.
A central principle for all ethical consideration is that the autonomy, dignity and privacy of the individuals involved in the research process are respected. This may seem to be quite a straightforward assumption yet it is its centrality that has driven most debate. Moreno (2003) – in what some may argue to be a provocatively titled article ‘Neuroethics: An agenda for neuroscience and society’ provides a number of examples to illustrate the potential for the loss of autonomy and dignity in some instances. Moreno’s debate provided a clear foundation for the subsequent discussions into this very important field that was developed further into a standardised theoretical framework that would allow directed investigation and consideration (Hayry, 2010). But perhaps most importantly the theoretical framework that was originally developed by Moreno, Hayry and others was encapsulated and operationalised within a recent report by the International Bioethics Committee of UNESCO which clearly states that the ‘Reinforcement of the need to protect an individual patient’s integrity … Appropriate clarification for the legal relevance of the views of relatives of incompetent patients should be provided to health care professionals as part of their professional education’ (p.21)1.

This is clearly of importance when one considers the fact that there are times when researchers study certain areas of the brain that directly impact on 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; Moore et al., 2014). This well replicated finding has led some researchers to consider the VMPF as playing an essential role in

morality processing (Green & Haidt, 2002, Hauser, 2006). This has been supported by the finding that early lesions in this region of the brain can result in an inability to develop moral judgments (Taber-Thomas, et al., 2014). Assessing the morality and ethicality of an experimental procedure is an important process that participants engage in when deciding whether or not to take part. Individuals without capacity to make autonomous assessments about the ethical nature of a proposed experiment would not be able to make a fully valid decision as to their giving or withholding 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 effect on the capacity to provide valid consent. Here, researchers should consider whether the extent of impairment warrants the use of an independent third party to assess the ability to provide consent in these cases (see the Code of Practice (published in 2007) for the Mental Capacity Act, 2005 for England and Wales, the Adults with Incapacity (Scotland) Act 2000, Mental Capacity Act (Northern Ireland) 2016\(^2\) and BPS guidelines\(^3\)). Special care in determining the capacity to provide valid 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). Where there is sufficient evidence that capacity is impaired to the extent that valid consent is not possible, the provisions of the Mental

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Capacity Act should be complied with, in particular that there should be some prospect of benefit to the participant, or if not, to other persons suffering similar conditions, and that the research should have minimal risk. In addition, there should be compliance with the requirements of the Act to appoint a consultee to advise on whether or not the participant would have given consent if they had the capacity to do so.)

Involving participants who are suffering from such 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 marginalised communities and fair access to research for those with neuropsychiatric disorders (Michels, 1999). The ethics challenge for Society members is to study such populations to learn more about their cognitive capabilities and to include these individuals, as they are able, in the consent or assent process, recognising that participants may reveal a greater capability to engage with the investigative team.

Notwithstanding the effects of the neurological status of the patient 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). In fact a recent meta-analysis of studies examining the patient experience in and around such imaging technology concluded with the recommendations that radiographers must play a special role in ensuring that comprehension of all procedures is in place prior to seeking informed consent (Munn & Jordan, 2011). Indeed, it has
also been seen that one of the most reliable predictors of patient comprehension of the procedures prior to surgery is the length of time that radiographers spend discussing the various procedures (Fink et al., 2010).

It has been 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 should ensure that express coercion does not occur in the contemporary psychology laboratory. It has previously been reported that research participants consider such procedures as benign clinical investigations that are able to confirm the absence of 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 incidentally revealing a previously undiagnosed disorder 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 per cent prevalence (Katzman et al., 1999; Orme et al., 2010). To highlight the significance of such occurrences it is important to note that Hartwigsen et al. (2010) examined the MRIs of 206 healthy individuals and in 39 of them found an incidental finding that warranted further examination. Of this figure 21 individuals needed ‘further diagnostic interventions’ (p.596). Such prevalence has led to the formation of various recommendations and frameworks with which to ensure the availability of appropriate interventions prior to the discovery of incidental findings in the US (Rangel, 2010). However the manner in which incidental findings are managed still varies considerably in the UK.

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, there is a wide range of practice, in some cases 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. The variety of policies and procedures within the UK has been confirmed by a recent survey of principal investigators in the UK who were carrying out research with healthy volunteers (Booth et al., 2010). Here, the clarion call to a standardised procedure for the reporting of incidental findings was reinforced in the conclusion of this paper which states that ‘guidance on the management of research imaging is inconsistent, limited and does not address the interests of volunteers. Improved standards to
guide management of research images and incidental findings are urgently required’ (p.456).

Finally, what if the incidental finding is potentially harmful to others? For example consider the case of 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 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 also that MR exposure rates should 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 standardised and appropriate procedures are needed. First, the consent procedure should include a statement that clearly highlights the possibility that an incidental finding may occur and the implications of such a finding. Second, to ensure that the research procedure is not associated with a medical context in any way, clinical and research governance should be explicitly separated. As Pickard & Gillard (2005) suggest, there is an argument that all structural MR images should be confidentially reviewed by a medically qualified individual. If an abnormality is found that may impact on the validity of the research then the principal investigator should be informed that the specific individual should no longer participate. The participant should then be informed that there may be an abnormality and a full clinical MRI scan should be made available if necessary. At every stage the participant should be informed that
no communication with the family doctor would be made without express permission. Finally, standardisation of all procedures with regards to the reporting procedures for incidental findings should be carried out as matter of urgency.
As is the case with any research endeavour 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 preceding year – an article ‘Lies, Damn Lies and Lie Detectors’ by Wolpe and Langleben (2008) presents the possibility that brain imaging technologies may be used in contemporary polygraphy. They go on to mention two startup companies (Langleben is the director of one) that have been approached by ‘…law enforcement agencies, defence and business communities [our 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.

That said, their use within a judicial setting has not been smooth sailing throughout. In a review of her various experiences in the nascent field of forensic fMRI, Vendamia (2014) quotes several caveats to the successful interpretation of the results by jurors that emerge from the technological limitations of the approach used to decipher complex social information that may be held within a criminal’s mind. These limitations are significant yet Langleben and others have highlighted the need for a considered approach towards such applications that may yet see the regular use of fMRI in a forensic setting (Langleben & Dattilio, 2008; Langleben, 2008).
One of the central caveats that may impact on the ready assimilation of brain imaging technology into a forensic setting is the argument that we still know very little about the factors influencing structural changes within the brain, so a more guarded response to the adoption of forensic MRI is needed (but see Saad & Greengross, 2014 for an extended debate on the utility of the fMRI paradigm).

The overly persuasive effects of fMRI in swaying jury decisions should not be underestimated. In a study on jury bias McCabe, Castel, & Rhodes (2011) provided 330 potential jurors with three different types of vignette that included information pertaining to a specific lie detection test i.e., traditional polygraphy, forensic fMRI and thermal face imaging. Each vignette described a crime in a deliberately ambiguous setting and the potential jurors were asked to provide an outcome judgment. Those vignettes that contained a description of the forensic MRI procedure generated significantly more guilty verdicts that the other two conditions, thus showing that the use of fMRI in this context is very influential and should only be used with reservation. Notwithstanding this it should be noted that patents have been filed in the US Patent Office for brain imaging procedures that claim to detect deception (Faro et al., 2013).

However it is worth bearing in mind that there has been a number of other techniques used within a forensic setting as well. Take for example, event-related potentials (ERPs) which 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. Like most advocates of any specific idea Farwell is enthusiastic in his support and offers a bounty of $100,000 to anyone who can verifiably beat a brain fingerprinting paradigm with countermeasures (to date no one has been able to achieve this). He also quotes an impressive litany of results in support of the efficacy of this approach in a forensic setting with ‘... field tests at the FBI, CIA, US Navy and elsewhere have resulted in
0 per cent errors, no false positives and no false negatives. 100 per cent of determinations made were correct...’ (Farwell, 2012, p.115). However, even with such glowing support for his own technique it still engendered criticisms in the pages of the same journal with the direct statement that ‘...Farwell is misleading and misrepresents the scientific status of brain fingerprinting technology’ (Miejer et al., 2013, p.155).

While both forensic fMRI and applications of EEG have generated much interest in the media they both suffer from a significant oversimplification of the cortical response to 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’⁴. Yet a lie is rarely so simple 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; Farah 2012 for further discussion of this emerging field).

However when research collaboration may lead to the incarceration of an individual special consideration should be given to the proposed research. Such consideration should focus on (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). In light of the fact that the neuroscience community now receives ‘hundreds of millions of Department of Defense dollars’ (Tennison & Moreno, 2012, p.1) in the US there is an obvious need for a renewed discussion as to ethical practice within national security settings.

⁴ http://news.bbc.co.uk/1/hi/sci/tech/3495433.stm
Social responsibility

Given that most cognitive neuroscience techniques require access to a relatively large laboratory setting at some point, the issue of the social responsibility of Society members 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 envision the physical entity of complex cognitive processes. 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).

Taking this into account, it is clear that more needs to be known of the effects of such imagery in driving decision-making. In light of this, the use of brain scan imagery to illustrate and support 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 and Farah et al., 2014 for discussions here). For the sake of this paper only neuropharmacological enhancements will be discussed (see Farah, 2002). Such enhancements are surprisingly common, with a commentary in *Nature* even highlighting their use by 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 by healthy people to increase concentration and memory. But some of these drugs clearly have potentially harmful side effects. 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).

Modafinal and Ritalin (and any other type of cognitive enhancement) cost money and are therefore only available to people who have money to spend on them. Accordingly any drug that brings benefit to someone’s work life would also bring an unfair disadvantage to those who do not have access to it, who may then start to address the unfair distribution of these resources. At the societal level this might lead to a rise in crime in sections of society to gain access to such medications. However, at the level of the individual, participation in experimental procedures where the effects of these drugs are being examined would be one such way in which distributed justice could be evoked. 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.

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5 But see Luber & Lisanby (2014) for application of transcranial magnetic stimulation for cognitive enhancement.
In some experimental procedures healthy individuals are recruited as control participants and in such cases researchers need to be aware of the fact that recruitment to their procedures may be biased in certain instances towards 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 to ensure that the healthy participants have a 50 per cent chance of receiving either the active drug or placebo. By reducing the chance that participants will be given the active drug the involvement of people who repeatedly attempt to participate in such paradigms is likely to be reduced.

It is hoped that this discussion paper will initiate consideration of the various ethics factors that should be considered in contemporary cognitive neuroscience research.

If you have any comments on this paper, please e-mail them to The Ethics Committe c/o: lisa.morrisoncoulthard@bps.org.uk.
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