

The ethical neuroscientist

The increase in research carried out by private companies raises concerns about ethical standards for human subjects.

A recent paper¹ and an accompanying commentary² illustrate how seriously the academic community takes the ethical decisions involved in research on human subjects. However, neuroscience research is increasingly being done in the private sector, which is not obligated to follow the same guidelines as academic institutions. To avoid concerns similar to those raised about private-sector medical research, commercial neuroscience should follow standard ethical guidelines.

The new study¹ compared abandoned children reared in Romanian orphanages to similar children who were moved to foster care. Unsurprisingly, cognitive development in children who remained institutionalized was markedly lower than that of never-institutionalized children or of children who were removed from institutions and placed into foster care. The authors conclude that early institutionalization has serious negative consequences on child development and that family placement should be preferred.

The study raised several ethical concerns, discussed in both the article and the commentary². Many of these issues go back to the Belmont report, first formulated in the 1970s, which provides guidelines for ethical conduct of research on human subjects. The report (along with the Helsinki declaration of 1964) guides academic research in many countries.

The Belmont report emphasizes that subjects must provide informed consent, which obligates researchers to ensure that the subjects understand the risks and benefits of the protocol and that they can choose what does or does not happen to them. Children are unable to provide informed consent, so their legal guardians usually provide consent on their behalf. In this case, however, there was no clear guardian acting in the children's best interests, and so there was little possibility that any selected children could decline to take part in the study. Being unable to give informed consent and being institutionalized, the subjects were doubly vulnerable.

Such populations may be studied ethically only under certain conditions. The authors state that these conditions were met: the children were no worse off than if they had not taken part in the study, as the researchers stipulated that no child placed in foster care would ever be moved back to an institution. The authors also communicated their results to the Romanian government, which has since prohibited institutionalization of children less than two years old unless they are severely handicapped.

This in-depth consideration of ethical issues contrasts sharply with some private-sector research, particularly the drug-testing business, where reported problems include undocumented immigrants participating in drug trials and subjects lacking adequate care and treatment. In some parts of the United States, there is a community of 'professional' subjects for drug testing, which has its own magazine that rates the protocols offered by different companies in terms of pay scales and comfort. Obviously, this community includes more than its fair share of the economically disadvantaged, a clear violation of the Belmont report's stipulation not to favor or select only 'undesirable' persons for risky research.

Although the situation in neuroscience research is not so dire, many bioethicists believe that the root of the problem in drug testing is that the

interaction between subjects and experimenters is purely a commercial transaction, as subjects are increasingly recruited by businesses. A similar problem concerns researchers seeking to apply neuroscience techniques to the commercial sector. Companies have applied functional magnetic resonance imaging (fMRI) to evaluate attitudes toward marketing stimuli, determine political orientation of swing voters and detect lies.

The public discussion of this research³ has emphasized widely held doubts about the validity of findings from this emerging field, but ethical concerns are at least as important. Judy Illes, a neuroethicist at the University of British Columbia, says, "Private sector research has no generally required ethical guidelines and is not obligated to follow the Belmont report, in contrast with academic research. There is also less oversight of such private research compared with most taxpayer-funded research." Although little potential harm may result from misstating people's preferences for soda or even candidates, falsely concluding that someone is lying or telling the truth could have very serious consequences for individuals and society.

Not all companies follow the Belmont report guidelines. For example, two suspects accused of colluding with Al Qaeda in terrorism against the United States were released without charge from Guantanamo Bay. They were recruited to participate in an fMRI lie-detection study, despite serious ethical concerns. Bioethicists worry that if this technology becomes commonly used in fighting terrorism, refusing to take part in such an experiment could be seen as being suspicious. In contrast to the Romanian orphans, the study left the terrorism suspects significantly worse off because British television reported the fMRI results, which indicated that they were indeed lying in some parts of their account. Whether these findings would stand up to scientific scrutiny is an open question, but it is likely that their participation caused the subjects to be regarded with greater suspicion in their communities.

Stanford law professor and civil liberties advocate Hank Greely has called for regulation of fMRI lie detection by an impartial agency, but companies are currently responsible for their own ethical oversight. Thus, little is known about the occurrence of ethical lapses, although such data are sorely needed to determine the appropriate course of action. Many neuroscientists do both academic and commercial research, and there is no justification for applying different ethical standards, particularly for subject selection and informed consent, in the two areas. To avoid the need for such regulation, we urge all neuroscience research companies to commit to following the Belmont report guidelines and to publicly disclose how they evaluate ethical concerns.

1. Nelson, C.A. *et al. Science* **318**, 1937–1940 (2007).
2. Millum, J. & Emanuel, E.J. *Science* **318**, 1874–1875 (2007).
3. *Nature* **450**, 457 (2007).

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