

EMERGING ETHICAL, LEGAL AND SOCIAL ISSUES OF IRB EVALUATION OF NEUROIMAGING RESEARCH PROTOCOLS

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Neuroscience research has been at the core of events that have led to modern research ethics. Third Reich racial hygiene policies to eliminate physically and mentally disabled children and adults were carried out in collaboration with neurologists and psychiatrists. Nazi experiments involved many neuroscientists (e.g., Schaltenbrand on multiple sclerosis; Hallervorden on neuropathology; Rascher on hypothermia) both in extreme situations such as death camps but also in prestigious neuroscience research centers. Investigation of these events and other Third Reich medical practices by the Austrian-born American neurophysiologist Leo Alexander led to the Medical Crimes Trial and finally to the Nuremberg Code. The later scrutiny of abuses of psychosurgery in the 1960s and 1970s contributed to the creation of Institutional Review Boards (IRB), the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and the resulting Belmont Report.

In the last two decades, neuroscience research has taken significant leaps forward. Institutional review board policies and procedures have followed the state of the art closely with specific attention emerging in neurogenetic research, brain banking procedures, and neuroclinical trials. Imaging technologies at the frontier of neuroscience today have brought advances in the understanding of brain morphology and brain function in the healthy and the diseased brain. Faster, higher resolution and noninvasive capabilities have expanded the scope of research and the range of suitable pools of volunteers, and stimulated private-sector relationships. The dynamic and ever-evolving nature of advanced neuroimaging creates challenges for institutional review boards (IRB). New targets of neuroscience research and improving technological capabilities in imaging are expanding the range of eligible volunteers for scanning, the scope of studies that probe the biology of the social and ethical brain, and academic-industry relationships. Accordingly, specific issues are surfacing :

1) Incidental findings. Neuroimaging research can reveal unexpected anomalies of potential clinical significance. Expanding neuroimaging community and technology create challenge for standardization of practice and shared approaches to informed consent forms.

2) Privacy, especially of thought. Expanding pool of neurosocial studies and scientific complexity may lead to applications that yield neuroprofiles of personal and private thought. Privacy challenges are amplified by growth of neuroimaging databases and consortia.

3) Confidentiality and recruitment practices. Neuroimaging research frequently relies on the recruitment of colleagues or students and challenges confidentiality and consent.

4) Decisional capacity; stigma and discrimination. Non-invasive neuroimaging procedures are expanding the pool of prospective volunteers. More vulnerable populations can now be imaged, challenging existing informed consent procedures and current approaches to mitigating stigma and discrimination.

5) Scientific and social value; conflict of interest; transfer of knowledge. Scientific evaluation of neuroimaging is complicated by the diversity of research methods. Social evaluation of research intermingles with emerging direct-to-consumer advertising of brain imaging products and academic/private sector relationships as well as current public understanding of neuroscience supporting expectations for early clinical applications.

We provide an overview of the new IRB landscape for neuroimaging, and discuss specific IRB triggers arising from it. We suggest approaches to tackle current issues, and identify areas for further collaboration between neuroimagers and IRBs.