This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Novel neurotechnologies: intervening in the brain* between 1 March 2012 and 23 April 2012. The views expressed are solely those of the respondent(s) and not those of the Council.

Mim Schwartz

Response to Nuffield Consultation
Re: Neurostimulation

April 2012

1. Have you ever used a technology that intervenes in the brain, and with what consequences?
I have studied invasive somatic procedures from a very personal advantage. My spouse had gamma knife neurosurgery capsulotomy for OCD in January 2006. In attempting to make a decision for this procedure I found a paucity of resources for informing advocacy of this treatment. As a Board Member of NAMI SWPA – national alliance on mental illness of southwest Pennsylvania, I have collaborated with the doctors involved in these procedures to form a Policy statement on the neuroethics of these procedures in direct response to my experience.

Also, as a community member of the IRB at University of Pittsburgh I am aware of Risks and benefits presented during a research trial, vs longterm therapy with these Devices.

Mainly: 1. what happens when equipment is implanted and the research trial ends, Who pays for 'upkeep' of equipment/device? If these are extremely ill pts, which is the qualifying event, most likely they will be part of a public health system, or experience many changes in insurance and payment availability. Lacking insurance may be and automatic disqualifier, at which this would violate a justice question For ethics, and equitable access.

2. DBS is billed as potentially reversible procedure, again, this would depend on 'who pays' for explantation as when the study ends or the treatment proves to be not Efficacious.. Another consideration as stated in the Cleveland Clinic experience as up to 12% hemorrhage rate on explantation. But of utmost importance, what precautions are Taken to protect from 'lost to followup' cases? Trials/therapy must insist on family Or close other consented to help reduce this possibility since if devices fail, symptoms return suddenly and the pts/subjects maybe unable to request assistance.. Also unknown is the long term effect of implanted devices in the brain. As in Parkinsons, where these procedures Are common, most pts are over age 60, when DBS is offered for Serious Mental Illness They are recruiting as young as 18. It has been stated, long term is not a problem, They have looked at 10 years experience. This is not a very long time, in terms of Our younger subjects.

3. A registry has been called for previously, as in the National Commission in 1977 to safeguard from renegade procedures. This has never happened, and these procedures are increasingly available at an alarming rate, obsesity, addiction, aggression, depression, bipolar, schizophrenia, and performed at over 300 centers. Outcomes should be evaluated, and tracked.

4. In a recent presentation, i heard a presentation on Consents, in which the 'subjects' enrolled for a DBS study, did not feel brain surgery (as in dbs) was risky. Granted if they thought it was risky they may not have enrolled....I think because it is 'offered by doctors' there is an incorrect assumption that it is 'safe'. The entire audience of 'docs' chuckled... this proves, the onus is on the providers

to accurately relate experiences anticipated. Another very public portrayal, last week they had on CNN Dr Sanjay Gupta reporting on DBS where the pt, during the programming phase reported instant relief. this is not entirely accurate, as it does not act "like a switch" .

Thank you for the opportunity to respond, and i do hope i am not too late.