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

Gerwin Schalk, Wadsworth Center

1. Please briefly describe the neurotechnology or neurotechnologies you are working with and the nature of your research. Please also describe whether you do basic/translational/clinical research.

My laboratory is contributing to basic systems and cognitive neuroscience, as well as translational neuroengineering. Our neuroscience research investigates the neural basis of motor, language, and cognitive function. For these investigations, we primarily use recordings from the surface of the brain (electrocorticography (ECoG)) in humans. (For these studies, we use patients with epilepsy who have electrodes implanted on the surface of their brain for clinical reasons. We do not implant people for the purpose of our research.) As an example research topic, we study how brain signals in different cortical areas prepare for and execute spoken and imagined words or their components.

Our neuroengineering research combines the resulting neuroscientific understanding with efforts in electrical engineering, bioengineering, and computer science to work toward particular clinical problems. These clinical problems include the restoration of function in people with severe motor disabilities using brain-computer interfaces (BCIs). BCI systems translate neural activity from the brain into control signals that drive applications that allow people to communicate with or control their environment. As an example, we have built and validated a communication system that can decode one of two imagined phonemes directly using brain signals.

2. What, if any, are currently the main clinical applications of this technology?

This technology conceivably has numerous applications. In addition to our BCI systems described above, we have also been developing a system for the mapping of cortical function prior to epilepsy surgery. The necessary technology has been licensed is now being translated into a product.

3. What clinical applications of the technology do you envisage *in the future*? (Please try to specify a timeframe for these developments)

Real-time functional brain mapping: 1-2 years
Simple BCI systems for people with paralysis: ?
BCI systems for complex articulation of limb movements: ?
Direct and object neurological assessments using BCI technology: 10 years
Neurorehabilitation (e.g., stroke rehabilitation using BCI technologies): uncertain

4. What are, or were, the main barriers to overcome in translating your research into the clinical application(s)?

Simple BCI systems: the small market of people who can benefit from this technology strongly impedes translation
Complex BCI systems: market is dramatically larger, but need more research to provide appropriate system performance/robustness

5. How could the technology you work with help address unmet needs of neurologists and psychiatrists?

At present, neurological/psychiatric diagnoses are based on indirect and subjective assessments by experts. BCI technology has the potential to eventually support direct and objective assessments by an algorithm.

6. What do the technologies currently cost, and will it be possible to include them as part of regular service in the NHS? If not, what are the likely markets or funders?

7. Are there currently any non-medical applications of this technology? How far have these been researched and developed and commercialised? Are devices you work with available on the internet/direct-to-consumer?

There are some existing and many potential non-medical applications of BCI technology. These include gaming and neuromarketing. Gaming applications have been developed and in part commercialized, although, in my opinion, the future commercial success of gaming applications of BCI technology is uncertain. The field of neuromarketing attempts to derive information about a person's emotions (e.g., enjoyment, engagement, etc.) during presentation of marketing material (e.g., commercials) directly from brain signals. This field is rapidly expanding, and there are several successful companies in this space.

8. What non-medical applications of the technology do you envisage *in the future*? (Please try to specify a timeframe for these developments)

Cognitive testing batteries: 5 years
Cognitive training batteries: 5 years

9. Are there any unexpected or unintended effects of the technology, and if so, how frequent and serious are they? (Where applicable, please include clinical and non-medical applications)

10. Is there anything in your area of research and development that you find particularly problematic? Where do you feel you need more guidance? What is there in the way of guidance for these problems already?

Modern methods allow us to infer an increasing detail about people directly from brain signals. I do not find this particularly problematic at the moment, but further advances in this area may raise a number of ethical problems. At the same time, it is important to note that I cannot foresee technologies in the short and medium term that would make such assessments without the cooperation of the subject, e.g., to participate in a research project, etc.

There is not much guidance on these issues at the moment, although the young field of neuroethics is beginning to attract increasing attention by different scientists.

Questions if you work with patients

11. In your experience, what do patients and/or users expect from the technology?

I do not work with patients, at least not with patients that may benefit from our technology.

12. What risks are patients and/or users willing to take, and why?

13. How well-informed are patients and/or users about the technology, and how helpful is the notion of informed consent in your experience? What happens if patients lack the capacity to consent?

14. After an intervention: are expectations of patients and/or users regularly met?

Broader questions about the field of novel neurotechnologies

15. If you consider the whole field of novel neurotechnology development, what advances do you believe are possible over the next ten years? What aspects (e.g. material technologies, theories of underlying mechanisms and pathways, treatment targets) of today's novel neurotechnologies will be with us in ten years' time?

In ten years, we will have sensor technologies that will allow for sensing of brain function at unprecedented detail. We will also have advanced interpretation techniques that will be able to infer substantial details of cognitive, language, and motor function from brain signals. This includes details on imagined, instead of actual, actions, speech, etc. It is important to note that these sensors will most likely remain invasive.

16. Looking at the whole field, what are the main challenges/barriers in the innovation trajectory from idea to bedside/ market for novel neurotechnologies, and how could these be tackled?

There are currently few, if any, “killer-apps” of neurotechnologies
Thus, markets for such technologies have often not yet been identified, or are small
Regulatory hurdles
Technological hurdles
Multidisciplinary nature of the field of neurotechnology. I.e., research requires groups with extensive and varied expertise, which is expensive and difficult to come by.

17. Recently concerns have been raised about the regulatory regime for medical devices both in the US and in Europe. What are your views on the current regulatory regime for novel neurotechnologies in your region, and in what ways, if at all, do you think it needs to be improved?

18. Could there be a need for more regulation of novel neurotechnologies *in the future*; and if so, what should this permit, prevent, and inspire?

19. Advances in neurotechnologies raise a lot of interest and many hopes. Do you believe that there is ‘hype’ surrounding these technologies? If so, how can we distinguish between the ‘hype’ and the reality? And who is responsible for creating the hope and for managing the hype?

There is definitely a lot of hype surrounding neurotechnologies, in particular around BCI devices that allow people to control devices/limbs with their brain. There are currently only very few experts world-wide that have the necessary multidisciplinary understanding (ranging from science, technology, to clinical and regulatory needs and processes) to make comprehensive and informed assessments that can dissociate the hype from reality. For example, while it may be scientifically conceivable to produce particular devices, they may likely never come to existence due to issues that are completely non-scientific. For the same reason, there is currently no effective system that manages the hype. Even funding agencies are influenced by popular media, etc., and there is great incentive to scientists to cater to this hype, and little incentive to propose “less-exciting” research.

20. What do you think are the main social and ethical concerns raised by novel neurotechnologies and their applications?

I do not see too many social/ethical concerns at the moment, but they will certainly increase, perhaps

substantially, with time. Also see the “Brain-Computer Symbiosis” article that is attached. It has a section on ethical issues.

21. Who do you think should be the target audience for a report on the ethics of novel neurotechnologies that intervene in the brain? If the Working Party developed direct recommendations to any particular groups or institutions, who should they be in your view? What would you like the Working Party to recommend?