THE LAW SOCIETY OF SINGAPORE

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Our Ref: LS/10/RLR/Council/CON(8)/2013/BAC(1)/MWC/JF/sr
Your Ref: To be advised

12 March 2013

Bioethics Advisory Committee Secretariat
11 Biopolis Way, #10-12
Helios
Singapore 138667

BY EMAIL & POST
Email address:
contactus@bioethicssingapore.org

Dear Sir

CONSULTATION PAPER ON ETHICAL, LEGAL AND SOCIAL ISSUES IN NEUROSCIENCE RESEARCH

1. We refer to your email dated 15 January 2013 inviting the Law Society to provide feedback on the Consultation on Ethical, Legal and Social Issues in Neuroscience Research ("BAC Neuroscience Paper").

2. The consultation was referred to an ad-hoc Committee appointed by the Law Society (the "Committee"). Their views are enclosed in Annex A.

3. The Council of the Law Society has considered the Committee's feedback and shares their views in this regard.

4. Thank you for giving the Law Society the opportunity to present our views on this matter. We would be grateful for an update after the Bioethics Advisory Committee ("BAC") has considered the feedback provided.

Yours faithfully

Michelle Woodworth Cordeiro
Director, Representation and Law Reform Department

Encl.

Cc: 1. Council
2. Committee

ANNEX A

VIEWS OF THE AD-HOC COMMITTEE APPOINTED BY THE LAW SOCIETY

BAC Consultation Paper on Ethical, Legal and Social Issues in Neuroscience Research dated 9 January 2013

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1. The BAC Neuroscience Paper has raised some very important and pertinent questions in relation to Neuroscience Research. The members of this ad hoc committee are involved in advising and representing individuals and organizations within the healthcare industry, as part of their legal practice. Some of the members also sit as members of Institutional Review Boards (IRBs) that review clinical research proposals. The questions discussed in the BAC Neuroscience Paper are issues that members of this Ad Hoc Committee would face from time to time.

2. We intend to deal with the questions raised and provide the Ad Hoc Committee's views on the issues raised.

3. We set out below our comments on the following specific issues highlighted in the BAC Neuroscience Paper:-

Should persons lacking mental capacity be included in research other than clinical trials? If so, under what conditions?

4. Paragraphs 47 to 51 the BAC Neuroscience Paper deals with the concerns relating to persons lacking mental capacity. Most of the members take the position that such persons belonging to a vulnerable class of individuals should only be included in clinical trials only if their interest and welfare are not compromised. The BAC Neuroscience Paper has made specific reference to the Mental Capacity Act and the fact that donees who are expressly authorized to give or refuse consent to the carrying out or continuation of medical treatment by a healthcare providers, or a deputy appointed by the Court under the Act and given the same authority, may make decisions regarding participation in clinical trials. However no reference has been made to Regulation 11(3) of the Medicines (Clinical Trials) Regulations ("Regulation"). In reality, we believe that many investigators in clinical trials continue to follow Regulation 11(3) and seek consent from parents, spouses or guardians (as the case may be) where the subjects themselves lack capacity to give consent, and the Regulation legitimizes this practice so long as there is reasonable prospect that the clinical trial will directly benefit the subject in question. If the subject has previously given authority under a Lasting Power of Attorney to consent to the carrying out or continuation of medical treatment, then the Attorney's consent should be sought but again this should be done only if the Principal Investigator ("PI") and the subject's attending physician certify that there is reasonable prospect the clinical trial will directly benefit the subject and risk of injury is at an acceptable level.

5. We are of the view that the BAC should take this opportunity to address the fact that in the vast majority of cases where the research subjects lack capacity to consent, the research is more likely to proceed on the basis of consent obtained as provided for by Regulation 11(3) rather than on any authority given to a donee or deputy under the Mental Capacity Act. Deputies acting under the Mental Capacity Act remain accountable to the Court that appoints them. If donees or deputies fail to carry out their duties and responsibilities with full regard to the subjects' best interests they have to answer to the Court and the Office of the Public Guardian may also be notified and can investigate into cases of abuse of authority. However, where consent

is obtained as provided for in Regulation 11(3), there is arguably less oversight and hence less protection for the subjects.

6. Hence we would like the BAC to consider evaluating the consistency in the approaches adopted by the Medicines (Clinical Trial) Regulations and the Mental Capacity Act and in particular, whether there is a need for Regulation 11(3) to be reviewed with a view to providing additional safeguards to protect the interests of this vulnerable group.

7. In the case of invasive neurotechnologies, we are of the view that a requirement that the PI and the attending physician certify that either there is no available proven alternative treatment or such alternative treatment is unproven or unsatisfactory for the subject in question, would be prudent.

Should researchers have a duty to return incidental findings? If so, under what conditions?

8. In paragraph 52 and 53, the question is raised as to whether there is a real need to insist that all brain scans taken for research purposes be reviewed by a suitably qualified expert. Two sub-issues arise in this question. First, the subject's "right-not-to-know" having regard to the possible psychological harm that may result if the finding turns out to be a false positive. Secondly, whether suitably qualified experts should be appointed to review these findings particularly for brain imaging which requires special expertise to interpret.

9. We are of the view that ideally subjects should be notified of clinically significant findings (incidental or otherwise) that would impact on the subjects' health or well-being. This is because such findings may have a concomitant impact and consequence for the subjects. Alternatively, the subjects may be asked if they wish to be apprised of such incidental findings and this option should be included in the Patient Informed Consent. It can be provided in the Patient Informed Consent that unless the subject informs the PI in writing that they do not wish to be notified of clinically significant incidental findings, the PI will notify the subject of such findings. In other words, all subjects will be told of clinically significant incidental findings unless they inform the PI in writing that they do not wish to receive such information on such findings.

10. The Committee is of the view that where there is a possibility for the incidental findings to be provided to the subjects, it would be necessary for a suitably qualified expert to review the brain scans. We do not think this would necessarily add to the cost of the research given the nature of the research in question involving brain imaging, the research team is likely to have a suitably qualified expert in brain imaging already on the research team.

Should sham surgery be allowed to test for the efficacy of invasive neurotechnologies, such as stem cell transplantation into the brain or DBS? If so, under what conditions?

11. Most of the members of the Committee take the position that invasive sham surgeries should be avoided as it impinges on the principle of non-maleficence. It is accepted that sham surgeries offer no direct benefit to the subject. Given the significant risks of neurosurgery, it will be difficult to draw the line as to when such invasive procedures are justified when considered against the possible benefits to society (and possibly the subjects)

12. One member takes the view that this should only be allowed under very exceptional circumstances where:-

(a) There is no other less invasive and dangerous alternative experimental design which can adequately cover the control arm;
(b) Risks of the sham surgery are set out in detail in the Patient Informed Consent and accepted by the subject;
(c) Risks of the sham surgery are verbally articulated to the subject in the presence of the PI and his team, his attending physician and an independent neurologist familiar with the procedure.

What factors should be considered when assessing research with neurotechnologies, in particular research where one's sense of identity may be affected?

13. The Committee is of the view that healthy individuals should not be recruited for research using neurotechnology. This is because such technology when used on subjects can lead to change in personality and physical injury. There is no good reason to subject healthy individuals to such invasive and risky procedures.

14. As for subjects that may benefit from such research, this should still be allowed only in cases where there is strong justification that the subjects are likely to benefit from the procedure and sufficient and satisfactory safeguards are put in place such as:-

(a) The subject and family have been thoroughly advised by the research team in the presence of an independent neurologist and the subject's attending physician of the risks of such procedures including risk of personality changes, and consent is given;
(b) The subject and family have been thoroughly advised by the research team in the presence of an independent neurologist and the subject's attending physician of the potential benefit(s) of such a procedure. If there is a possibility that there may be no benefit to the subject, the subject and family should be informed.
(c) Satisfactory data and records have been obtained confirming that such personality changes and other associated risks may be controlled; and
(d) Close monitoring will be carried out by the PI and his team.

Should healthy individuals be included in research involving the use of neurotechnologies for non-medical purposes, particularly cognitive enhancement? If so, under what conditions?

15. The Committee is of the view that healthy individuals should not be involved in research using neurotechnologies for non-medical purposes. Such technologies should be focused on helping those who have medical needs. As stated in paragraph 46 of the BAC Neuroscience Paper, there are serious concerns regarding how neurotechnology may have long term effects on the development of the brain.

16. The Committee is not prepared to suggest conditions under which such research may be carried out on healthy individuals.

Should children be included in research involving the use of neurotechnologies? If so, under what circumstances?

17. Unless there are exceptional circumstances, the Committee takes the view that children should not be included in research involving use of neurotechnologies. In such cases consent is likely to be given not by the subjects themselves, but by parents or legal guardians, but it will be the children who will suffer any adverse effects of the research.

18. Some members are of the view that unless the following conditions are strictly complied with, children should not be included in such research unless all of the following conditions are satisfied:-

    (a) The child's parents or legal guardian have consented in writing to the child's participation in the research and the Patient Informed Consent has fully dealt with the issue of risks of the procedure etc;
    (b) Additionally, such consent is only sought in cases where the child is in a life threatening situation because there are no other viable treatment options available to the child;
    (c) There is a reasonable prospect that clinical trial using neurotechnology will directly benefit the child; and

    (d) An independent physician has certified (b) and (c) above.

Is neuroscience research exceptional? What particular safeguards should there be in the ethics governance of such research, in additional to what is already in place for other types of human biomedical research?

19. Given the increased risks associated with neurotechnologies, greater emphasis and focus must be paid to the prospect of benefit to the subjects. The Committee takes the view that it is not enough merely to say that the subjects may or may not benefit from the procedure. The expectation is for the research team to satisfy itself that there is a reasonable prospect for the subjects to gain direct benefit. The research team must be prepared to defend its assessment that there is a reasonable prospect of direct benefit. If there is a possibility that the subject may not benefit from the procedure, the subject should be informed.

20. Secondly, such research involving invasive neurotechnology would necessarily mean increased medical costs and extended hospital stay for the subjects. There must be a separate set of more definite criteria put in place as to how such costs are to be borne as well as costs of any complications or side effects

21. Thirdly, there may be a need to put in place a requirement that before any subject is recruited for research involving neurotechnology, an independent neurologist with adequate experience in treating patients using neurotechnology should be asked to review the subject's case notes to provide a second opinion as to the subject's suitability to participate in the research as well as to evaluate if the subject does in fact have a reasonable prospect of obtaining direct benefit from participating in the research.