DECISION OF APPEAL PANEL

As a preliminary matter, it should be noted that, under the Regulations, the appeal panel is empowered to confirm the decision of the Committee, vary that decision or allow the appeal. The scope of these powers is such as to indicate that any appeal should be heard *de novo*, allowing all aspects of the application to be reviewed by the panel. That is the basis upon which the panel dealt with the appeal in the instant case and so we allowed the applicants to make submissions and adduce evidence going beyond those submissions and evidence that had been presented to the Committee. We also took into consideration material sent to us by the applicants after the hearing and relating to issues discussed at the hearing. In that context, we note that, as the applicants contended, there is no explicit obligation in the Regulations on applicants to submit substantive submissions to the panel within 30 working days of the provision of the Committee's written decision to an applicant (though it should be noted that the appellants were not, in fact, restricted in any way in relation to the submissions sent to the panel and that every request in relation to such matters was accommodated in the administration of the appeal).

In the absence of any power under the Regulations to remit a case to the Committee, the panel must itself determine the outcome of the application based on the material presented to it.

The issue before the panel is a net one of determining whether the terms of Reg.6(8)(b)(i) are satisfied, namely, does the public interest in continuing to carry out the health research significantly outweigh the public interest in requiring the explicit consent of the data subject? No issue was raised by the Committee in relation to the application satisfying the requirements of Reg. 6(6) and 6(7) and Reg.6(8)(b)(ii) does not appear to be applicable. In deciding this issue, the panel must operate in accordance with the Regulations as our jurisdiction is derived from the Regulations (though we must also perform our functions in a manner compatible with the State's obligations under the European Convention on Human Rights – s.3 of the European Convention on Human Rights Act 2003.) In this context, we do not consider that we have the jurisdiction to address the appellants' contention that the Regulations had restricted the lawful bases under Arts.6 and 9 of the GDPR for conducting health research on the basis of a data subject's explicit consent.

Burden of proof

In applying the test set out in Reg.6(8)(b)(i), we consider that the burden of proof rests on the applicant/appellant to adduce sufficient evidence to justify dispensing

with the requirement to obtain the consent of the data subjects. The requirement to obtain the consent of data subjects vindicates their constitutional and Convention rights to privacy and autonomy and therefore should not be set aside lightly. Moreover the evidence must be such as to show that the interest in pursuing the research "significantly outweighs" the public interest in obtaining the explicit consent of the data subjects.

Obtaining consent

The applicants complained that, in applying the test set out in Reg.6(8)(b)(ii), the Committee introduced an additional requirement, namely, that the applicants must establish that it was impossible or impracticable to obtain the consent of all living data subjects. The panel is of the view that the difficulty in obtaining consent is an appropriate factor to take into account in applying the test set out in Reg.6(8)(b)(ii). Where it is relatively easy to obtain the consent of the data subjects, it is difficult to envisage circumstances in which the public interest in obtaining such consent would be significantly outweighed by the public interest in pursuing the research. However it does not follow that the need for consent can only be dispensed with where it is impossible or impracticable to obtain that consent. There may be situations in which it may be difficult but not impossible to obtain consent but where risks attaching to attempts to obtain the consent mean that the public interest in obtaining such consent is significantly outweighed by the public interest in the continuance of the research. In this context, we note that Lowrance states that one factor, among others, taken into account in Australia, Canada, the UK and the US in deciding to permit the use of personally identifiable data without consent is that "It is undesirable to seek new consent because recontacting, or attempting to recontact such as by inquiring of relatives or neighbors, could induce emotional or social stress or resentment". (Lowrence, p.82.) In the instant case, we are satisfied that there are significant difficulties and risks attaching to attempts to obtain consent.

The Committee expressed the view that the involvement of a 'for-profit' organisation processing personal data introduces a higher risk that data subjects may have a deeper concern for their privacy rights. However, on the basis of Dr. Hilary's submissions at the hearing relating to the steps taken by GMI to protect the confidentiality of the patient, we are satisfied that those privacy rights are adequately protected.

In response to the Committee's statement that clinicians could be involved in obtaining consent, the applicants argued that it would seriously undermine the

doctor-patient relationship for a clinician to be asked to act as a proxy for a pathologist in obtaining consent. While involving GPs or oncologists to obtain consent might be disturbing for patients, the panel is of the view that this would not undermine the doctor-patient relationship. In any event, given the difficulties involved in obtaining consent from many of the data subjects or their relatives, the panel does not consider this to be a critical factor in coming to a conclusion on this appeal.

The Committee also expressed concern that there was no transparent public notice detailing GMI's subsequent use and provision of access of BTIS data to third parties. However the panel notes that GMI's privacy statement indicates, at para.2, that personal data will only be shared with third parties where this is necessary to enable GMI and the relevant third party to perform their respective duties. Para.9 of the same document states that investigating doctors, principal investigators and research collaborators are among the categories of third parties to which GMI discloses personal data while para.11 sets out the conditions under which GMI will transfer personal data to entities operating outside the EEA.

In light of these considerations relating to the obtaining of consent, we are of the view that we need to address the further point of whether the public interest in pursuing the research significantly outweighs the public interest in obtaining the explicit consent of the data subjects.

Public benefit

On the basis of the documentation we have reviewed and on the basis of the submissions made to us at the hearing, we are satisfied that this research is likely to result in significant new therapies, diagnostics, technologies and targeted drugs for patients with brain tumours and, therefore, that the public interest in pursuing the research significantly outweights the public interest in obtaining the consent of data subjects. We wish, however, to make the grant of the declaration subject to three conditions, the satisfaction of which will add further support to our conclusion. First, the public benefit in the research would be significantly enhanced if the anonymised genetic data from the GMI study was to be made available to other researchers. However a difficulty here is that public policy has yet to be formulated on when genomic data might be made available to qualified researchers and so we stipulate that the grant of the Declaration is conditional on GMI undertaking now to make the data collected during the research publicly available on a recognised genomic data repository once public policy in this area has been formulated by the relevant

authorities and in compliance with relevant legislation should such exist. Second, while we acknowledge the difficulties in obtaining the consent of all data subjects, we consider that a publicity campaign drawing attention to the proposed research and affording data subjects the possibility of withdrawing their samples from the research will improve somewhat the protection afforded to the privacy of the data subjects. The applicants indicated a willingness to undertake such a publicity campaign and so we stipulate that the grant of the Declaration is also conditional on the applicants conducting a publicity campaign in accordance with the conditions outlined in their email to the panel dated 5 September 2019. These conditions should be read subject to the additional conditions that BTI will be consulted in relation to the preparation of the public notices and that printed information about the research and, in particular, about the possibility of withdrawing samples, will be made available to both Beaumont Hospital and BTI for dissemination as each of those bodies deems appropriate. Finally, the grant of the Declaration is also conditional on the applicants agreeing to publish an annual report detailing the progress of the research.

The panel wish to address three further points in relation to applying the test in Reg.6(8)(b)(ii). In relation to the factors to be taken into account in applying the test, the applicants had argued that, in evaluating the public benefit of this research, certain factors taken into account by research ethics committees and listed in Reg.4(2) should not have been taken into account by the Committee. However the Regulations do not explicitly preclude the Committee from having regard to issues identified as ethical issues by Art.4(2). Moreover some of the issues identified by Art.4(2) as ethical issues cannot be beyond the purview of the Committee if it is to discharge its statutory function. In this context, for example, Reg.4(2)(a)(i) refers to whether the research is likely to substantially assist in the advancement or protection of human health, whether of the population as a whole or of any part of the population, Reg.4(2)(a)(iv) refers to whether the research is likely to substantially assist in the identification, prevention or treatment of illness, disease or other medical impairment and Reg.4(2)(e) refers to whether there are adequate safeguards in place to protect the privacy of individuals participating in the health research and the confidentiality of their personal data. Accordingly we consider that the Committee may have regard to factors listed in Reg.4(2) in the discharge of its function under the Regulations.

The applicants also contended that, as the Regulations did not require that a Declaration be limited in time, it was not appropriate for the Committee to consider the required duration of a Declaration in reaching its decision. However the panel cannot rule out the possibility that it might be appropriate in some cases to impose a

time limit as a condition on the granting of a Declaration and therefore we consider that asking the applicants to describe their exit strategy and to justify the continuation of the Declaration over a period of years was appropriate.

Finally, in its decision, the Committee indicated that the applicants should have provided evidence of efforts to engage relevant individuals around the specifics of the project to ensure robust patient and public involvement. However in the absence of an express provision in the Regulations requiring an applicant to demonstrate patient and public involvement with research, this factor can only be a relevant consideration to the extent to which it relates to the public benefit that may be derived from the research or the public interest in requiring the explicit consent of the data subjects. While robust patient and public involvement with research is unquestionably desirable, it is not clear to the panel that this factor is, in fact, relevant to either of these issues.

24 September 2019