



Response to NCIN/onCoreUK/NCRI consultation on

Access to Samples and Data for Cancer Research

18 September 2008

Via email to access@ncri.org.uk

Dr Jane Cope, Administrative Director, NCRI
Mr Brian Clark, Chief Executive, onCoreUK
Mr Chris Carrigan, Head, NCIN Coordinating Unit
Dr William Lowrance, Independent Consultant

Dear Dr Cope, Mr Clark, Mr Carrigan and Dr Lowrance,

Re: Access to Samples and Data for Cancer Research

We refer to your invitation to comment on the consultation document "Elements of policies and agreements for access to samples and data for cancer research".

We are a consortium of brain tumour patient and caregiver support, advocacy and awareness-raising organisations which represent the interests of brain tumour patients in the United Kingdom and internationally.

We note at 1.2 that "the document considers matters relating to access to data and/or samples that have already been collected and held" and that "... it does take account of the interests of organisations and individuals who contributed to the forming of the collection, as well as interests of the patients who donated samples of data, and the wider public."

Free donor access to their own genetic information

We note that the document as presently drafted makes no reference to the subject of free donor access to their own genetic information, if donors request it.

With the development of targeted therapies, particularly in the area of brain tumour treatments, we believe that donors (patients) who provide their own tissue or blood primarily for research purposes should have the right, if they wish to exercise it, of freely (without cost to them) obtaining information about their own genetic material if they (the donors) believe it may assist them in choosing to access new therapies based on the genetic characteristics of their tumour, and if the recipients (the researchers) have identified such information.

We wish to emphasise that:

- donors (patients) should not be required to pay a fee to access this information
- this policy would apply to those *who request* such information and we are not advocating that researchers be obliged to automatically convey such information in the absence of an individual request.

Genetic profiling is gaining prominence in the hunt for more effective treatments

The importance of genetic profiling with regard to treating brain tumours is swiftly gaining prominence. An article by Patrick Y Wen and Santosh Kesari in the *New England Journal of Medicine* said:

“Recently, there has been important progress in the treatment of malignant gliomas and in our understanding of the molecular pathogenesis of these tumors and the critical role that stem cells play in their development and resistance to treatment. As our understanding of the molecular correlates of response improves, it may be possible to select the most appropriate therapies on the basis of the patient’s tumor genotype. These advances provide real opportunities for the development of effective therapies for malignant gliomas.” (*N Engl J Med* 359;5 www.nejm.org July 31, 2008)

Another recent article about glioma brain tumours in *Neurology* said:

"For nearly a century, glial neoplasms have been classified by microscopic features alone with treatment prescribed based on histology using a "one-size-fits-all" formula. However, recent advances in our understanding of the molecular events underlying gliomagenesis are beginning to change the way we think about the diagnostic classification of gliomas. Indeed several recurring molecular derangements are now being viewed as cornerstones of a new diagnostic framework because these alterations appear to be superior to traditional microscopic classification schemes as guideposts for treatment selection and prognosis. Moreover molecular analysis of tumor tissue is identifying aberrant growth signalling pathways in glioma which can now be blocked selectively by a new generation of targeted therapies, including small molecule inhibitors and monoclonal antibodies. Time will tell whether these new agents can be successfully introduced into the clinical arena. In the meantime, the molecular characteristics of gliomas are being used to select patients for both randomized trials and phase II studies." (*Warren P Mason, MD, FRCPC and J Gregory Cairncross, MD, FRCPC, The expanding impact of molecular biology on the diagnosis and treatment of gliomas, Neurology 2008;71:365-373*)

Additionally, very recent breaking news highlighted a massive cancer gene search, undertaken as part of the \$100 million Cancer Genome Atlas (TCGA) research programme which is funded by the US National Institutes of Health (NIH). An “array of broken, missing, and overactive genes – some implicated for the first time – have been identified in a genetic survey of glioblastoma...”

The discovery of these genetic changes may be targets for future therapies.

Dr William Shapiro, chief of neuro-oncology at Barrow Neurological Institute in Phoenix, Arizona, said: “It does give us new pieces of information. This new information will have an effect on what we do today and very likely will have more of an effect on what we do in the future.”

In another recent, but separate study from Johns Hopkins University in the United States, teams mapped the cascade of genetic aberrations that result in normal cells in the pancreas and brain turning into highly lethal cancers. Again, this type of discovery will lead to a more tailored, hopefully more effective treatment plan for patients suffering from these two devastating cancers.

An Australian precedent

Data confidentiality and protecting the identity of donors is, of course, of utmost importance. “There is a concern that the research use of genetic information could infringe upon an individual’s privacy and, if misused, could result in trauma or discrimination (e.g., paternity findings or diagnosis of incurable genetic disease). Researchers must be aware that patient concerns focus not only on privacy, but on questions of ownership...” (*J. Mark Waxman, Drug Discovery & Development magazine: Vol. 10, No. 12, December, 2007, pp. 30-31*)

But for those patients who wish to have information on the genetic characteristics of their tumour, we maintain that they should be able to obtain this.

It would be important that, in the transfer of any such information to the patient at the patient’s request, this information should be provided in a meaningful way.

An important precedent has now been set by the Australian Genomics and Clinical Outcomes of Glioma (AGOG) project. Following consultation with leading clinicians, researchers and the Chair of the International Brain Tumour Alliance (Mr Denis Strangman of Canberra, Australia), the patient questionnaire and information sheet for donor patients now incorporates the following wording:

“If participants would like to request their specific genetic results, then we will be happy to give these to them with the appropriate interpretation and guidance.”

Furthermore, AGOG noted that:

“...While this is contrary to usual genetic epidemiology study protocol, our patient advocate has strongly recommended that this opportunity be given to patients where knowledge of specific genetic markers might allow

participation in a relevant clinical trial that could potentially extend that patient's life...Given the relatively small number of patients to be recruited, and the very short survival time for most HGG patients, we feel that this is a reasonable request."

Summary

It is important to understand that for many of the rare and less common cancers, such as brain tumours, prevention, screening and lifestyle changes are irrelevant. Often, the only hope which a patient suffering from a rare or less common cancer has lies in access to promising, new therapies which, although they may not save life, can extend survival with a good quality of life.

With the emergence of promising new targeted therapies, it is becoming evident that the role genetic markers play is vital. For patients who desire to know their genetic profiles in order to make informed choices about their treatments, we feel it would be unacceptable and unethical to withhold this information from them.

As patient groups, we would also like to emphasise that in our opinion any informed consents dealing with a donor's tissue should be in simple, understandable language and should set out with absolute clarity and detail the nature of the donor's participation in any such research.

Thank you for considering our comments and we look forward to hearing from you in due course.

Yours sincerely,

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