

Human Tissue and Biological Supplies for Use in Research.
Interim Operational and Ethical Guidelines issued by the MRC (Nov 1999)

The Response of the Genetic Interest Group

- 1 The Genetic Interest Group (GIG) is the UK Alliance of Charities and Support Groups for families and individuals affected by genetic disorders. With over 130 independent organisations in membership its interest spans the spectrum of genetic disease ranging from those caused by mutations in a single gene to those where a genetic predisposition may be one factor amongst many. GIG's purpose inter alia is to promote research into the causes of and cures for the disorders which affect the families which comprise our membership. However, it must be emphasised that research in itself is not enough. That research must be translated into safe, effective intervention and treatments that are available and affordable for the benefit of those affected. It is our experience that patients are not concerned **who** does this, so long as it is done as quickly and efficiently as possible.
- 2 GIG welcomes this consultation exercise by the MRC. Maintenance of public confidence in the probity of research and of effective protection of the interest of those who take part in it as subjects, or through the provision of samples, is essential for the success of the research endeavour now and in the future. Without research, people will continue to experience the effects of potentially treatable disease. The knowledge that guidelines exist, that they are applied rigorously, and policed effectively, will do much to reassure people that their interests will not be compromised as a result of their participation in the MRC's research programme.
- 3 The general framework proposed for controlling the use of human tissue and other biological samples in the consultation document is realistic and workable and we would support the introduction of the procedures and safeguards proposed. There are, however, a number of specific comments that we would wish to make in respect of particular aspects of the documents.
- 4 In paragraph 1.3 attention is drawn to the potential for maximising the value of collections for (ethical) uses not envisaged at the time the sample was collected. We are keen to see this potential exploited and would not wish to see unreasonable constraints on them. In particular, reference is made to the anxieties that people have about the possible implications for insurance or employment. In practice this fear is likely to prove groundless. The use of research derived data by insurance companies is expressly disallowed in the code of practice of the Association of British Insurers. This **only** permits the results of a defined services of tests in use as a mainstream service by the NHS to be incorporated into the underwriting decision. The DoH Genetics and Insurance Committee (GAIC) is likely to ensure continued control and restraint in this respect. Research results are unlikely ever to be allowable and this should be made clear in order to reassure donors. As far as we are aware there is no systematic use of pre-symptomatic genetic data by employers in the UK. Again, regulation is likely to require that any such proposed use excludes data from research because of the difficulties associated with assigning validity and

reliability to the results. The MRC should issue briefing on this issue to researchers in order that they can ensure that accurate information can be given to sample donors. In addition under MRC and General Medical Council guidelines, personal data is anonymised unless strong ethical or scientific reasons (as quoted in 2.4 in the consultation document). Therefore many participants would not receive results of research on their own sample donation.

- 5 Clearly the issue of ownership of the donated sample is important (para 2.1.). Clarity and the limits on future use are important if the altruistic nature of the gift relationship is to survive and this should be explicit. In particular direct financial gain from the purchase or sale of samples per se should remain prohibited. In order to ensure that research outcomes are translated into useful outcomes for patients appropriate use of intellectual property rights, licensing, orphan medicinal products regulations etc should be exploited to the full.
- 6 GIG supports the vesting of gifts with institutions rather than with individuals. Institutions which collect and retain samples must agree to abide by the code of practice as finalised (para 2.2).
- 7 The nature of the partnership between public and private sectors in ensuring the application of research findings to the development of useful products is well established in society. We endorse the restriction in para 2.3 on the granting of exclusive rights as we do not believe this to be in the best interests of patients who stand to benefit from the new knowledge acquired as a result of the donation of samples by themselves and others similarly affected. We note that the consultative document recognises the need for limited exclusivity to date in order to secure patent protection. There should be a level playing field for all potential competitors who might wish to develop products using **existing** sample collections. No one venture capital company (or any other commercial developer) should have preferential access. The organisation best positioned to achieve a successful outcome for the benefits of patients should be the one given the first opportunity in each case.

Should MRC wish to establish exclusive rights over **new** collections this should be made explicit from the outcome and acknowledgement of this incorporated in the consent signed by the donor.

We do not think it appropriate that sample donors should benefit from commercial development which may result from their participation. This is inevitably arbitrary and divisive, as it is a matter of chance who samples are taken from. However, we believe that profits derived from the development of research outcomes that are returned to the MRC as a consequence of licences granted to commercial partners should **normally** be applied to generating further understanding of the condition which produced the commercial gain.

- 8 The importance of informed consent is clearly central to maintaining public confidence in the probity of the research process (para 2.4). Clearly it is desirable that unforeseen future uses should not be ruled out by poorly drawn up consent forms. We note that the document would permit the use of personal identifiers if there were "strong scientific justification". Taken at face value this could give a degree of latitude that might permit donors' confidentiality to be compromised. Whilst we do not disagree with the principle, we feel that examples of when this might be appropriate and necessary should be worked out. The MRC should develop examples of good practice for use in a variety of situations, taking input from all those with a genuine interest in ensuring research progress and its beneficial application to patients.

With regard to research involving children, and those unable to give informed consent by virtue of mental incapacity, special care must be taken to avoid exploitation. However, work by groups such as "People First" "Change" and others has demonstrated that people with severe learning difficulties are capable of sophisticated decision making if materials are presented in an appropriate manner. Given this and given the fact that there is no reason to suppose that people with learning difficulties are either more or less altruistic than any other section of society, we suggest that such advocacy groups be specifically consulted about the development of consent procedures in research involving those unable to make use of more widely understandable and applicable systems.

- 9 We recognise the desirability of adding to the value of sample collections by incorporating data generated by new users, but are concerned that, in practice an over rigid insistence on this will act as a deterrent to new research and to the commercialisation of research outcomes. This would delay patient access to new treatments as those unwilling to divulge all data might feel obliged to duplicate research in order to create their own collection, which would be wasteful. There is also question as to how such a requirement could be policed in practice.

Given the number and variety of sample collections currently held in hospitals and universities we recommend that a comprehensive directory be compiled and maintained to ensure that unnecessary duplication is avoided and the most efficient and effective use of resources is made.

- 10 The point about possible insurance implications of genetic research is reviewed again in 2.7.1. This should be clarified and authoritative guidance issued as pointed out in paragraph 4 above so that perceived anxieties are not allowed to create unnecessary barriers that might limit the willingness of subjects to participate in research programmes.

- 11 Although the feedback of results on an individual basis may not be appropriate or feasible, many people appreciate information in an accessible form about that which has resulted from programmes in which they have played a part (para 2.7.3). Researchers should be encouraged to produce newsletters and the like which could then be made available to sample donors whether directly, or through the clinician responsible for obtaining the original sample, as appropriate. Clearly this could not continue in the event of subsequent uses of samples once the original programme is complete

- 12 Genetic tests of known predictive value (para 3.3) may on occasions be needed using samples from donors who have subsequently died. In such situations there will possibly be implications for surviving relatives, some of whom may be known to the researcher or to the clinician responsible for obtaining the original sample. In such situations the centrality of the samples to the research should be determined and if possible alternatives sought. However, if the original consent included the option of future use then this should be seen as an expression of the donor's wishes. If clinically significant information relevant to surviving relatives results, they should have the option of deciding whether or not they want it in the same way as would have applied to the original subject. However whilst this is a simple principle to articulate, in practice caution should be exercised because the surviving relatives may not be aware of the deceased's participation in the research programme. The information revealed may have a devastating impact if the person to whom it is revealed may not suspect that there is the possibility of a risk .

- 13 Given the above, which we intended as clarification of the points in the consultation document to which they refer, the Genetic Interest Group welcomes the proposals contained in the document and would wish to see them adopted and put into operation as quickly as possible.

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26.3.00