

## **Implementing the recommendations of the *Ad Hoc Advisory Group***

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### **Introduction**

The Genetic Interest Group (GIG) welcomes the decision to undertake a review of the operation of research ethics committees, and is pleased to be able to offer a response to the consultation paper, "Implementing the recommendations of the *Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*."

As the UK alliance of over 140 charities and support groups for individuals and families affected by all types of genetic disorder, GIG speaks from the perspective of those who have a keen interest in the undertaking of high quality, ethically sound biomedical research into the links between genetics and human health and disease. Uniquely amongst the many stakeholders in the research enterprise, GIG's members and the families they support are involuntary partners. They did not choose to be affected by an intractable genetic disease, and they depend on research, and its application in the form of new products and services to eliminate or alleviate the impact of diseases which currently cause chronic ill health, frequently progressive disability and sometimes premature death.

GIG's members are an important constituent in the understanding of biomedical research for other reasons too. In addition to providing samples and specimens and volunteering to take part in trials they are frequently a major source of funds – raised through voluntary activity – enabling fundamental research to be undertaken into causes and cures for genetic disease.

For these reasons, we feel that their views should carry particular weight in determining the appropriate framework for the ethical oversight of research in the area of serious genetic diseases.

### **The role of regulation**

GIG is a strong advocate of a clear and robust regulatory framework, based on sound ethical principles, to underpin biomedical research. A clear framework gives confidence to patients, families and researchers alike that what is proposed is reasonable and rational. As such it will sustain public and professional confidence in the legitimacy, necessity and desirability of high quality investigations across the spectrum from fundamental biology to health services research in practice. Proper ethical oversight will benefit patients and families by contributing to the development of safe, effective interventions and therapies delivered in a timely and appropriate manner.

### **Patient experiences**

As has been documented in our booklet "*Research and Rare Genetic Differences*" it has been the experience of many patients that the work of RECs, whilst well meaning and ostensibly in patient's best interests, has all too often placed unnecessary hurdles in the way of undertaking projects which are seen to be important and useful (and for which in many cases the money to fund the work has been raised) by the patients and families with the disease or condition under investigation. Whilst a protection must be afforded to patients potentially at risk from the activities of over-eager or under-qualified researchers, patients and families are themselves active partners in the research process and their views as to what is / is not appropriate must carry weight.

## **Responses to topics for consultation**

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### **4.1 The research ethics service and proportionality of review**

Central to the maintenance of stakeholder confidence in any regulatory framework is the notion of proportionality between the risk to which participants may be exposed and the steps taken to reduce this and/or protect participants. If too high a barrier is put in place then research that is necessary and desirable will not take place.

In order to reach a balanced decision, any review of a proposal by a REC should consider not only the risks and costs associated with the research intended, but also the potential losses to patients' health arising from not doing the work or delaying the work substantially.

We welcome the review's proposals to simplify and streamline the process of granting ethical approval to scientifically sound, relevant applications. In reaching their decisions RECs need to include inputs from patients and families as to the impact of the condition, and the salience of the research proposed to those affected.

All research contains an element of uncertainty and some may pose an element of risk to those participating. In reaching a decision as to the acceptability of the risk entailed, current understanding of the disease and its impact should be included in decision making processes. The fact that, without research and development potentially treatable life limiting conditions will remain untreated is an important consideration in our view.

When proposals involving rare conditions are considered, some of the normal requirements for research may be impossible to apply without effectively preventing, or making disproportionately expensive, the work proposed. Anonymity, for example, may be effectively compromised by the fact that patients, families, and the clinicians and researchers interested in the specific condition are known to one another. Patients in this situation are realistic about data protection issues, and will have a view on the relative sensitivity of information to be revealed in comparison with the desirability of furthering understanding and raising awareness of their condition.

The remarkable level of awareness of, and involvement in, research amongst many patient groups should be respected. Their knowledge of conditions, particularly rare, poorly understood conditions, should be considered in the review process. GIG has experience of patient groups raising money themselves to fund research into their own medical condition – the wishes of empowered patients such as these should be considered carefully.

#### **4.1.1-5 Restructuring of the review process**

GIG applauds this approach to increase efficiency in the system, and is pleased to see that these major changes will be introduced carefully and gradually. Consistency and clarity of review should be a priority during this period of change.

For these developments to work in practice a great responsibility will be placed on the shoulders of the Local Research Ethics Advisors in trusts and institutions; these individuals will need to be adequately trained, and operate in a robust and transparent context if they are to carry the confidence of both the research and the patient committees.

A common request from our member groups is for COREC to publish details of previous applications where possible, particularly failed applications. This would allow applicants to learn from the deficiencies of past applications, and potentially streamline the service further.

### **4.2 Payment for service (pertains to 4.5 Membership Data)**

The membership of RECs should be inclusive and as far as possible comprise a representative cross-section of society. Compromise will always be necessary in order to secure a proper balance between practicality and true representation, but in GIG's view there must be adequate

input of patient perspectives to REC deliberations. The memberships of RECs should always include those with this insight.

To make this possible, participation in the work of RECs should not result in financial loss. Arrangements should be made for participants to receive:

- Reimbursement of travel costs (including any special arrangements for disabled participants)
- Reasonable out of pocket expenses
- Respite care or childcare cost where incurred
- Loss of earnings

Bearing in mind that the attendance of professional members of RECs will often be considered a part of their role, and not subject to financial penalty, the operation of the principles of natural justice would require that patients and other lay involvement central to the effective operation of the system is not unduly reliant on good will.

We are aware that some members of the medical professions already feel negative pressure to sit on RECs from their employers, and are concerned that the withdrawal of backfill payments may increase this pressure.

GIG understands from the Change Forum for Consumers meeting on the 6<sup>th</sup> of March, that £305 will be the maximum allowance for loss of earnings, and that £160 will be the rate given to unemployed members. We would like to see further clarification on these issues:

- The relationship between benefits and unemployed member's payments. Will acceptance of payments render claimants ineligible for some of their benefits? Will unemployed members be able to refuse payments if this is the case?
- The relationship between expenses and unemployed member's payments. We would expect respite care and childcare costs to be considered separately.
- A clear definition of a lay member. There is some confusion on this issue.

To progress further towards COREC's target of a fully representative lay component to each committee, innovative methods need to be employed, both to engage the lay community and to raise awareness.

#### **4.3 Frequency, timing and location of REC meetings**

Whilst RECs should meet sufficiently frequently to allow their membership to generate trust and mutual respect, and develop expertise and consistency, the frequency of meetings should not impose such demands as to restrict membership to a privileged elite able to commit the time and energy required.

GIG believes that the new proposals for standardising requirements and for providing expert ethical advice to would-be applicants prior to the submission of formal applications will streamline the process. Making REC centres broadly coterminous with SHAs (Topic for consultation **4.6.2**) will reduce numbers and be a vehicle for greater consistency in decision making.

GIG recommends that a system of formal moderation of advice given be put in place to monitor standards and increase consistency. GIG further recommends that a system for challenging apparently unreasonable decisions made by advisors or by RECs, should be instigated and should be open to all stakeholders affected by such decisions. Such a system should be simple and quick to operate, but should guard against frivolous or disgruntled challenges – perhaps by requiring such approaches to be explicit, in writing, and open to independent scrutiny.

## **5 COREC's standard NHS REC application form**

Whilst GIG welcomes the promotion of ethical issues on the form, and supports the continual evolution of the application form; our members and their research associates report continued difficulties with describing rare disorders on the form.

GIG understands that a full review of the application forms used by NHS R&D units is outside of the scope of this consultation; however, responses from our member groups indicate that it is now this phase of the application process that causes the most frustration and repetition for applicants. This stage in the application process would benefit from the same streamlining and standardisation strategies that have been employed to improve COREC's standard NHS REC application form.


## **Conclusion**

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GIG broadly welcomes the decision to review the role and operation of RECs. Subject to the caveats outlined above; we endorse the proposals contained in the consultation document. Properly implemented and adequately resourced we feel that they will improve the procedures for ethical approval of high quality biomedical research in this country.

These comments have been circulated to our member groups for their endorsement, and have been formally approved for adoption by GIG's trustee board at a meeting held on the 14<sup>th</sup> of March 2006.

We would be happy to expand on any of the above in writing or face to face if this would be helpful.



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