



Unit 4D Leroy House
436 Essex Road
London
N1 3QP

Tel: 020 7704 3141

The Ethox Centre
Department of Public Health
University of Oxford
Old Road Campus
Oxford
OX3 7LF

Tel: 01865 226849

news release

For Immediate Release: 13th June 2005

Those questions that Research Ethics Committees need to know the answers to.

Today an exciting new booklet “Research and Rare Genetic Differences” has been published for members of Research Ethics Committees and medical researchers, by the Genetic Interest Group (GIG) the UK alliance for all people affected by genetic conditions, the Oxford Genetics Knowledge Park and the Ethox Centre at the University of Oxford. This booklet helps to highlight and answer some of the common questions and concerns that Research Ethics Committees (RECs) ask when looking at research proposals relating to genetic disorders. The booklet is available online at <http://www.gig.org.uk/gig/docs/GIG-OGKP.pdf> or in printed form from the addresses below.

Research Ethics Committee (REC) approval is a valuable safeguard for researchers and patients alike. Satisfying a research ethics committee helps to ensure that researchers have thought about the implications and the impact of what they are proposing to do, and so reduces the risk that potentially vulnerable patients will be disadvantaged by their participation in a research study. REC approval provides reassurance to patients and other volunteer participants that the proposed study is ethically sound, thereby maintaining confidence in the integrity of the researcher, and of the study, but also in the process of research itself. In addition to, and as part of, protecting patients, research ethics review facilitates good quality research.

In research into rare inherited disorders, the process of securing Ethics Committee approval for a proposed study can however sometimes prove disproportionately burdensome and this can, in some cases, undermine the viability of good-quality research.

This is particularly the case where such research is funded by patient groups. In the eyes of many such patient groups, who have had to work hard to raise funds to support research into “their” disorder, the bureaucracy of the REC process and, the questions asked by some RECs, can seem inappropriate, appearing to demonstrate either misperception by the REC about why what is proposed is proposed, or the application of an ethics framework more appropriate to a very different kind of research e.g. a large clinical trial, but inappropriate to smaller studies..

To help clarify this situation the Genetic Interest Group (GIG), the UK alliance of charities and support groups for all those with genetic disorders, convened a number of workshops to explore this issue. Resulting from these, a list of “frequently asked questions – FAQ’s” emerged that were indicative of the issues which RECs have seemed to find challenging when evaluating proposals.

This booklet has been written to help highlight some of these common questions and concerns that RECs ask when looking at research proposals relating to genetic disorders. The questions that follow reflect ways in which RECs can sometimes misunderstand this area of research and consequently turn down proposals. We hope that this document will help RECs to answer some of these questions.

Professor Mike Parker of ETHOX commented “It is important for the review of medical research to take seriously the full range of ethical implications of such research: these will include not only the protection of the interests of research participants but also the facilitation of high quality, ethical research. This means that the regulatory regime should be as light as possible concomitant with the requirement to ensure quality, appropriate methodology and the protection of research participants. For a variety of reasons research on very rare conditions currently faces disproportionate difficulties when submitted for review by ethics committees. The leaflet we have produced is intended to help to address that problem by informing members of ethics committees about the nature and benefits of such research.”



The Ethox
CENTRE

Unit 4D Leroy House
436 Essex Road
London
N1 3QP

Tel: 020 7704 3141

The Ethox Centre
Department of Public Health
University of Oxford
Old Road Campus
Oxford
OX3 7LF

Tel: 01865 226849

Alastair Kent, Director of the Genetic Interest Group added “When patient support groups have worked hard to raise funds into valuable research into their condition, the current process can be extremely frustrating, and we hope that this new guidance for ethics committees which is long over due will help give RECs insight into the real issues when dealing with rare genetic disorders”

Ends

For more information please contact

Alastair Kent, The Genetic Interest Group 020 7704 3141
Email address: alastair@gig.org.uk
Website: www.gig.org.uk

Or

Mike Parker, Oxford Genetics Knowledge Park 01865 226849
Email address: michael.parker@ethox.ox.ac.uk
Website: www.ethox.org.uk

Notes to Editors

- **The Genetic Interest Group (GIG)** is a national alliance of organisations with a membership of over 130 charities that support children, families and individuals affected by genetic disorders.
- Our primary goal is to promote awareness and understanding of genetic disorders so that high quality services for people affected by genetic conditions are developed and made available to all who need them.
- Individually, many genetic conditions are rare and as such it is difficult to raise their profile and the needs of those affected by them. GIG provides a common platform from which effective programmes to raise awareness, inform the media and influence government, industry and the NHS can be launched
- As an organisation focusing on issues of policy and practice GIG keeps an active watch on developments in the UK and Europe that will influence the effective transfer of knowledge and understanding into products and services for families that are supported by our member groups.

Genetic Interest Group (GIG) Working to Benefit All People Affected by Genetic Disorders. Registered Charity Number 803424

The Ethox Centre - Promoting high ethical standards in healthcare through research, education and support for practitioners



Unit 4D Leroy House
436 Essex Road
London
N1 3QP

Tel: 020 7704 3141

The Ethox Centre
Department of Public Health
University of Oxford
Old Road Campus
Oxford
OX3 7LF

Tel: 01865 226849

- In a potentially controversial field like genetics GIG provides a strong voice advocating the benefits of scientific progress in understanding the contribution being made now and that will be made in the years to come for improving health and combating many currently incurable diseases.

Registered Office:

The Genetic Interest Group
Unit 4D, Leroy House
London
N1 3QP

A Registered Charity (Number 803424)

The Oxford Genetics Knowledge Park

- The Oxford Genetics Knowledge Park (OxGKP) is one of six such Parks nationally, funded by the Departments of Health and Trade and Industry.
- The aim of the Genetics Knowledge Parks is to translate advances in genetics research into clinical practice.
- The OxGKP programme currently focuses on cardiovascular disease and cancer, two of the leading causes of death in the Western world. Our programme will evaluate whether genetic testing would help in the diagnosis or treatment of patients with these conditions.
- We also examine the ethical, legal, social and economic implications of conducting such tests. At the end of the programme we will make recommendations to government about whether genetic tests for these conditions are clinically worthwhile, technically feasible, and acceptable to the general public.

The Oxford Genetics Knowledge Park

C/O The Ethox Centre
Department of Public Health
University of Oxford
Old Road Campus
Oxford
OX3 7LF
Tel: 01865 226849