# Background on Research Ethics Function in the Health Information and Quality Authority

25 April 2012: Research is essential to the successful promotion and protection of health and wellbeing. Research ethics in Ireland are governed by legislation in the form of EU directives, existing policy, and national and professional guidelines.

One of the aims of Health Information Bill, which will be published by the Department of Health, is to provide a national approach to research ethics.

It is envisaged that this Bill, in conjunction with amendments to the existing regulation for clinical trials on medicinal products, will legislate for the Authority to become the supervisory body for recognising and monitoring research ethic committees (RECs)[1].

HIQA will also develop national standards for RECs which will include their remit, composition, function, management and accountability.

In anticipation of this new function, the Authority has conducted an *International Review of Research Ethics Structures* which looks at the operation and governance of research ethic committees (RECs) in five jurisdictions.

The background to this is that in 2004 the Member States of the European Union implemented the EU Clinical Trials Directive (2001/20/EC). In Ireland this was mandated by regulations, under which the Minister for Health is the supervisory body and is responsible for recognising and monitoring ethics committees.

The directive provides for the supervisory body to allow for a single ethical opinion to be obtained from any one of the committees recognised by them. So, for example, if one hospital committee gives ethical approval to a clinical trial then any other hospital taking part in the trial would have to recognise that. The other hospital would not be required to approve the trial if their patients are participating in it and they may not be permitted to re-examine it from an ethical perspective. This mechanism assumes, and indeed requires, that ethics committees are properly supervised.

The main motivation behind the clinical trial directive was to provide a mechanism to deliver a single ethical opinion. The nature of clinical trials today is that they are multiple-site, i.e. they involve participants from different hospitals typically and, increasingly these days, from different countries. Prior to the directive, researchers had to receive ethical approval from the ethics committee at each site which was clearly difficult and long drawn out.

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[1] A research ethics committee (REC) is a committee convened to provide the independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for research studies comply with recognised ethical standards.