

## Chapter 27

# Research Ethics Committees and the Law in the UK

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### Introduction

This report discusses the Research Ethics Committee (REC) system in the UK, with special reference to the responsibilities that RECs have to attend to legal requirements generally, and data protection laws in particular, when they review research proposals. The UK has implemented Directive 2001/20/EC on Clinical Trials, through Statutory Instrument 2004 No. 1031, the Medicines for Human Use (Clinical Trials) Regulations. This entered into force on 1 May 2004. New standard operating procedures (SOP) for RECs were issued in March 2004, which apply to all National Health Service (NHS) RECs, not just clinical trials ethics committees.<sup>1</sup> There is much that is controversial in the new regulations. However, not all of this is directly relevant to the role of RECs in relation to protecting data protection rights specifically, and for the most part we have not commented on (or even drawn attention to) such aspects.<sup>2</sup>

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<sup>1</sup> COREC (2004) *Standard Operating Procedures for Research Ethics Committees in the UK* available on the COREC webpage: [www.corec.org.uk](http://www.corec.org.uk) (last accessed 18 May 2005). Version 2 were issued in October 2004, containing no fundamental changes to the operating system outlined in version 1, but clarification and guidance on certain points. Reference in this paper will be to version 2.

<sup>2</sup> Notable examples are the provisions lowering the age of consent for research in England and Wales from 18 to 16 (Part 1 para. 1), and those permitting the hospital to nominate anyone they choose (including a doctor not primarily responsible for the patient's treatment) to be the legal representative of a patient unable to give informed consent (Schedule 1, Part 1, paragraph 2(ii)).

## The Establishment and Regulation of Ethical Review of Medical Research in the UK

RECs have operated in the UK NHS since the mid-1960s.<sup>3</sup> Until 2004 there were two kinds of NHS RECs—local research ethics committees (LRECs) and multi-centre research ethics committees (MRECs). Where research was to be conducted in multiple locations, applications were made to an MREC. LRECs or MRECs could be responsible for single-site research conducted in their local area, and if a multi-centre trial was to take place within their jurisdiction, LRECs could review the MREC-approved application for ‘locality issues’.

The names ‘MREC’ or ‘LREC’ still exist, but a new system is now in place for grading RECs. All RECs in the UK are now either ‘recognized’, including those which can review clinical trials involving medicinal products for human use or any other research, or ‘authorized’, covering RECs which *cannot* review the aforementioned clinical trials, but can review other research. Recognized RECs are broken down into type I, II or III committees. Type I committees are recognized for review of phase I trials in healthy volunteers throughout the UK, typically including either NHS or private committees. Type II committees are recognized for the review of clinical trials of investigational medical products (not including phase I on healthy volunteers) taking place at sites within an area defined by the geographical remit of their own appointing authority, these only include LRECs. Type III committees are recognized to review the same trials as Type II, but they can be taking place at any site within the UK. This type includes all previous MRECs, and some LRECs—the difference between MRECs and LRECs thus being that *all* MRECs are now type III, which is not the case for LRECs.

Other agencies apart from the NHS, such as the Medical Research Council (MRC), may act as an ‘appointing authority’ and create independent RECs to review in-house projects. Similarly, UK universities<sup>4</sup> and the pharmaceutical industry have established RECs for their own purposes. These now all fall under the new REC grading system described above. However, NHS RECs review the majority of medical research conducted in the UK, and unless stated otherwise, the NHS REC system in general forms the basis for the remainder of this report.

Until recently, the REC system was voluntary. The LREC system in England and Wales was only formalized under Department of Health (DH) guidance in 1991, almost 30 years after RECs began to operate, while Scottish LRECs came under formal guidance in 1992. The MREC system was created in 1997. New guidance covering both LRECs and MRECs, Governance Arrangements for NHS

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<sup>3</sup> Royal College of Physicians of London *Committee on the Supervision of the Ethics of Clinical Investigations in Institutions Report* (London: Royal College of Physicians, July 1967).

<sup>4</sup> See the Nuffield Foundation *University Research Ethics Committees: Their role, remit and conduct* (London: Nuffield Foundation. 2004).



Research Ethics Committees (GAFREC), was published in 2001.<sup>5</sup> In addition, the Department of Health published its Research Governance Framework for Health and Social Care (RGF) in 2001.<sup>6</sup> The latter document also gives guidance to RECs, and there are similar framework documents for Scottish, Welsh and Northern Irish RECs.<sup>7</sup>

In 2002, the first legislation giving explicit statutory duties to RECs came into effect with the Health Service (Control of Patient Information) Regulations 2002 and the Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002. However, for RECs, the situation in the UK changed even further with the implementation of Directive 2001/20/EC. The Medicines for Human Use (Clinical Trials) Regulations 2004 (hereafter the 'CT regulations') include detailed rules for RECs, and have instigated changes in the REC system. But the regulations, like Directive 2001/20/EC, only cover trials involving medicinal products for human use. They do not cover, for example, trials using medical devices (unless used to deliver a medicine), or 'non-interventional trials' (even if these concern medicinal products for human use), although there remains some uncertainty as to what precisely is meant by a 'non-interventional trial'. Therefore RECs will only be governed by statutory law when they review studies that are covered by Directive 2001/20/EC. When reviewing research projects not under the CT regulations, RECs will continue to follow existing guidance, the SOP. However, according to the Department of Health, and as stated in the SOP, the conduct and performance of RECs under its control will be governed and assessed, in general, as if all research under their review fell under the CT regulations (SOP, Introduction).

## RECs and Clinical Ethics

RECs do not provide clinical ethics advice in the UK. Instead, over the last ten years, there has been a growth of separate clinical ethics committees (CECs) to provide this service. Currently, the UK Clinical Ethics Network consists of 63 CECs.<sup>8</sup> They are located in individual institutions and are usually formed on the initiative of interested parties. There are no formal guidelines dictating

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<sup>5</sup> DH (2001) *Governance Arrangements for NHS Research Ethics Committees*, available online at: <http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf> (last accessed 18 May 2005). There is also Governance for NHS Research Ethics Committees in Scotland.

<sup>6</sup> A second edition of the RGF was published in 2005. It incorporates changes related to the implementation of Directive 2001/20/EC. RGF references in this paper refer to the 2005 version.

<sup>7</sup> See the Research Governance Framework for Health and Social Care (Scotland), Research Governance Framework for Health and Social Care in Wales. The Northern Ireland Framework is currently under consultation.

<sup>8</sup> See the UK Clinical Ethics Network webpage which contains a list of all clinical ethics committees known to it, at: <http://www.ethics-network.org.uk/Committee/list.htm> (last accessed 18 May 2005). For more information on CECs, see D. Beyleveld, R. Brownsword and S. Wallace, 'Independent Ethics Committees in the United Kingdom' in G. Lebeer (ed.), *Ethical Function in Hospital Ethics Committees* (Amsterdam: IOS Press, 2002).



membership requirements or the activities in which CECs should engage; these vary from committee to committee.

### **The Criteria for REC Review**

According to the RGF, paragraph 2.2.2,

The Department of Health requires that all research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.

Specifically, research that must be reviewed by an REC is defined in GAFREC, paragraph 3.1, as:

any research proposal involving:

- a. patients and users of the NHS
- b. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS...
- c. access to data, organs or other bodily material of past and present NHS patients
- d. fetal material and IVF involving NHS patients
- e. the recently dead in NHS premises
- f. the use of, or potential access to, NHS premises or facilities
- g. NHS staff—recruited as research participants...

According to the SOPs, the types of research to be reviewed are the same as those stated in GAFREC (SOP 1.65–1.68). GAFREC (paragraph 9.7) states that RECs need to review projects

with special attention given to the nature of any intervention and its safety for participants, to the informed consent process, documentation, and to the suitability and feasibility of the protocol.

The research sponsor, on the other hand, ‘is responsible for ensuring the quality of the science’ (GAFREC 9.8). GAFREC also states that the purpose of REC review ‘is to protect the dignity, rights, safety and well-being of all actual and potential research participants’ (GAFREC 2.2), but ‘they should also take into account the interests, needs and safety of researchers’ (GAFREC 2.3). However, this should be of secondary importance to the concerns of the research participants.

This stated, the CT regulations do provide a list of matters the REC should consider, which includes weighing foreseeable risks against benefits (Schedule 1, part 2(2)). Schedule 1 also outlines the conditions and principles of good clinical practice, and states that these principles apply to all clinical trials. However, it is not stipulated that the REC take these into account, except for the weighing of risks against benefits. The SOPs do not mention the principles of good clinical practice,



and state that guidance on the matters to be considered within ethical review can be found in GAFREC (SOP 3.4).

## REC Membership Requirements

Membership requirements differ between the Scottish RECs and RECs from the rest of the United Kingdom. Non-Scottish RECs must not have more than 18 members, one third of which must be lay members with the remainder being expert members. Additionally,

at least half of these lay members must be persons who are not, and have never been either health or social care professionals, and who have never been involved in carrying out research involving human participants, their tissue or data (GAFREC 6.7).

Schedule 2, Section 3(5)b(iii) of the new CT regulations reflects this, and adds that the lay members should never have been a chairman, member or director of: aa) a health service body, or bb) any other body providing health care.

If necessary, RECs may obtain advice from outside experts on clinical and scientific matters where the REC is lacking expertise in that area. Such trials include those involving minors or incapacitated adults unable to give informed consent.<sup>9</sup>

Unlike the rest of the UK,<sup>10</sup> Scotland has in place the Adults with Incapacity (Scotland) Act 2000. The purpose of this Act 'is to provide for decisions to be made on behalf of adults who lack legal capacity to do so themselves because of mental disorder or inability to communicate'.<sup>11</sup> Therefore, additional requirements are needed for reviewing research proposals that might include adults covered under the Act. The Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002 also require Scottish RECs to have no more than 18 members; however, Section 3.3 requires,

The membership of the Committee shall, so far as practical, include at least—

- a. one person who has experience in relation to the treatment of adults who are incapable;
- b. one medical practitioner who provides personal, or general, medical services under sections 17C or 19 of the National Health Service (Scotland) Act 1978;
- c. one registered nurse or registered midwife;
- d. one registered medical practitioner having experience in clinical pharmacology;

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<sup>9</sup> See the CT regulations, 15.6 and 15.7.

<sup>10</sup> The Mental Capacity Act 2005, extending to England and Wales, has recently been enacted. The Act is in force, except for Sections 30 to 41 of the Act, which will come into force when the relevant orders are made. .

<sup>11</sup> See the Explanatory Notes for the Act.



- e. one registered pharmaceutical chemist as defined by Section 24(1) of the Pharmacy Act 1954 or a registered person as defined by Article 2(2) of the Pharmacy (Northern Ireland) Order 1976;
- f. one registered medical practitioner who holds the position of hospital consultant;
- g. one registered medical practitioner having experience in the field of public health medicine;
- h. one member who is registered as a member of a profession to which the Professions Supplementary to Medicine Act 1960 applies; and
- i. three lay members.

With this membership, the Scottish RECs will have the expertise needed if research involving incapacitated adults is considered.

As per Section 51(3)(c) of the Adults with Incapacity Act (Scotland) 2000, any research conducted in Scotland on adults with incapacities must be approved by an ethics committee approved by Scottish Ministers under Section 51(6) of the Act (which in essence means one of the Scottish RECs).

### Accountability of RECs

Prior to the latest reorganization, LRECs were responsible to the Strategic Health Authority<sup>12</sup> that established or inherited them, while MRECs were directly responsible to the Secretary of State for Health. However, from 1 March 2004, COREC assumed the responsibilities of these health authorities in relation to the operational procedures for all RECs. Under the CT regulations, relevant RECs come under the direct authority of the United Kingdom Ethics Committees Authority (UKECA). Only those recognized by UKECA (termed officially 'recognized RECs') will be able to review clinical trial research using medicines in humans.<sup>13</sup>

The Secretary of State for Health; the National Assembly of Wales; the Scottish Ministers; and the Department for Health, Social Services and Public Safety for Northern Ireland will be the ruling officials for UKECA. However, it is expected that they will devolve their responsibilities to other staff as necessary. For

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<sup>12</sup> GAFREC uses the term health authority; this was changed through the National Health Service Reform and Health Care Professions Act 2002 to Strategic Health Authority.

<sup>13</sup> It is important not to confuse UKECA with the 'Competent Authority' referred to in Directive 2001/20/EC. The latter body in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA), which licenses medicines and regulates medical devices. The role given to UKECA is strongly criticized by the editor of the *Bulletin of Medical Ethics* in his editorial to the April 2003 issue of the *Bulletin*, on the grounds that it threatens to politicize the decision-making of RECs. In our opinion the role given to COREC was also questionable as it was an arm of NHS R&D, creating an intrinsic conflict of interest, the role of R&D being to facilitate research, not to protect patients' rights. The recent (1 April 2005) move of COREC to the National Patient Safety Agency, following the DH's review of arm's length bodies, shows that the DH may have recognized this problem. However, whether this will be an improvement over NHS R&D remains to be seen. In our opinion, the REC system should be run by an independent commission answerable only to Parliament.



example, COREC is continuing to function after the establishment of UKECA. However, its exact role is yet to be determined. It currently monitors compliance with the SOP through the Offices of RECs (ORECs) and administers the Central Allocation System (the method used for booking in, allocating and distributing research proposals). COREC is also authorized by the DH to exercise UKECA's statutory function in relation to appeals (SOP 7.10). The situation may become clearer in the future following the implementation of the UK Government's review of 'arms length bodies'. Under this review, the National Patient Safety Agency will take the national lead in supporting the development of NHS RECs, and has already taken over responsibility for COREC from the Department of Health.<sup>14</sup> Similarly, the NHS Appointments Commission will take on functions necessary to guarantee the independent appointment of REC chairmen and members as required by Directive 2001/20/EC.

UKECA is responsible for establishing, recognizing and monitoring all RECs involved in the review of clinical trials in place at the time the CT regulations came into effect. In addition, UKECA can recognize as ethics committees even those bodies under other authorities, for the purposes stated in the CT regulations. UKECA may determine what research projects an REC will review or the area in which it will work, and can abolish a committee if necessary. UKECA may also monitor RECs and provide advice and assistance as necessary.

## General Powers of RECs

### *Approval*

RECs have the power to approve or reject applications within their remit; but, while REC approval is necessary for research to proceed, it is not sufficient for the research to go ahead. For example, under the RGF (paragraph 3.12.6) final approval from the host NHS institution is also needed. Additional regulatory approvals may also be needed for certain categories of research. For trials regulated under the CT regulations (regulation 12) no one is able to begin a clinical trial or recruit subjects for a trial without the approval of the REC. The regulation also requires that the principal investigator obtain appropriate authorization from the licensing authority.

### *Penalties for Non-Compliance*

According to RGF, paragraph 5.8, if an institution or staff member does not comply with the framework requirements, the situation will be dealt with 'through normal management channels'. This could include not submitting a proposal to an REC for review prior to beginning the research. The RGF does not specify penalties for offences.

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<sup>14</sup> Department of Health, *Reconfiguring the Department of Health's Arm's Length Bodies*, 2004, available on its webpage, [www.dh.gov.uk](http://www.dh.gov.uk) (last accessed 18 May 2005).

RECs themselves have no power to penalize those found committing an offence; however, they may file reports to the institutions or appropriate regulatory bodies detailing any relevant findings. Doctors and others may be disciplined under the rules of their own regulatory body. For example, in the case of Dr. Jyoti Argawala, the General Medical Council (GMC) found him guilty of 'serious professional misconduct'<sup>15</sup> when he was found to have forged REC approval for his research. As a result, the GMC struck him off the medical register.

Under the CT regulations, failure to follow some specific provisions will result in penalties. For example, any person who begins a trial without authority from the Medicines and Healthcare Products Regulatory Agency (MHRA—the licensing authority) or an REC will have committed an offence. Likewise, any person who provides false or misleading data to an REC or the MHRA in the course of the application or conduct of a clinical trial will have committed an offence. Other restrictions apply to those involved in the sale, manufacture or distribution of the investigational medicinal products used in the trials. Individuals committing an offence may face a fine or imprisonment depending on the severity of the crime. Penalties will be enforced through the licensing authority, not the REC.

Although the CT regulations make no mention of this, it is arguable that it is also possible for REC members to commit offences. For example, presumably because of workload issues, the SOP states that applications may be given to a 'lead reviewer' who then may present a summary of the application to the Committee (SOP 2.20–2.23). Hypothetically, if that member wilfully provided incorrect or incomplete information to the other committee members in the process of that review, perhaps to mislead them into believing the trial is safer than it is, then that member might be held to be guilty of an offence.

Under Regulation 8 of the Health Service (Control of Patient Information) Regulations 2002, if the investigator does not process the medical information in the manner approved, or acts without approval of the REC or the Secretary of State for Health, he or she may face a fine of up to £5 000. Once more this is not determined by the REC but the Secretary of State.

### *Legal Consequences of REC Decisions*

Section 60 of the Health and Social Care Act 2000 empowers the Secretary of State to pass regulations to render lawful the processing of confidential personal health data without the consent of the subject, where certain conditions are fulfilled: namely the regulations are in the interests of improving patient care or in the public interest (s.60(1)); it is not reasonably practicable to achieve the purposes of the regulations by obtaining consent (s.60(3)); and the purpose of the regulations is not solely or principally to determine the care or treatment of particular individuals (s.60(5)). The specific effect of the regulations is to render the processing of personal health data lawful despite any obligation of confidence owed (see s.60(2)(c)). According to Section 60(6), the regulations must be consistent with the

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<sup>15</sup> D. Carnall, 'Doctor struck off for medical fraud' (1996) 312 *British Medical Journal* 399–400.



Data Protection Act 1998; but this does not affect the effect of Section 60(2)(c). It should be noted that Section 60(2)(c) is ambiguous. On one interpretation it states that the regulations will render the processing of confidential information lawful. On another interpretation, it states only that the regulations will render the processing of personal data not unlawful on account of the processing breaching an obligation of confidentiality. The latter interpretation is surely correct, for, on the former interpretation, Section 60(6) states that the regulations could render the processing of some personal data lawful despite being in breach of the Data Protection Act 1998. This cannot be right, because the Data Protection Act 1998 stands in lieu of the Data Protection Directive in UK law, satisfying the conditions sufficient for the regulations is not sufficient to guarantee conformity with the data protection law, and, according to the doctrine of the supremacy of EC law, the UK Parliament cannot legislate in contravention of an EC Directive while the UK remains part of the EU.

Using these powers, the Health Service (Control of Patient Information) Regulations 2002 have been passed. Two of the regulations provide for the involvement of RECs. Regulation 2 permits confidential information on patients referred for diagnosis or treatment of neoplasia (which includes cancer) to be used, disclosed or obtained for medical purposes. This includes medical research approved by an REC by persons approved as individuals or a class by the Secretary of State (in practice the Patient Information Advisory Group 'PIAG' set up by Section 61 of the Health and Social Care Act 2001), and the person lawfully in possession of the information. This is provided (see regulation 7) that the person is a health professional or a person acting under an equivalent duty of confidentiality in the terms of the Data Protection Act 1998, and certain security measures are satisfied.

Regulation 5(a) permits confidential patient information to be processed in circumstances laid out in the Schedule to the regulations, on the condition that this is approved by an REC and the Secretary of State (again, in practice PIAG), the procedure being that an REC must first approve the activities involved in research, and then the proposal must be submitted to PIAG. In view of the position taken on the legal responsibilities of RECs by the DH (see below), the idea behind this arrangement is quite possibly that the REC acts solely as ethics filter, while PIAG considers the legality and public policy aspects of the proposed processing.

Apart from these cases, decisions made by RECs do not have any formal role in rendering lawful activities that would otherwise be unlawful. However, it is not beyond the bounds of possibility that the Courts would treat REC approval as a mitigating factor of an action the Court rules to be unlawful when it considers what penalties to impose on researchers or what damages to award against them. This raises the question of the responsibilities of RECs themselves to attend to the law in their decisions. For it is arguable that the more likely it is that Courts will treat REC approval as a mitigating factor in actions brought against researchers, the more important it becomes that the RECs themselves be accountable for their decisions in relation to the law, if the rights of research subjects are to be adequately protected.



## General Legal Responsibility of RECs

The RGF, at 3.12.7, states,

It is not the role or responsibility of NHS research ethics committees to give legal advice, nor are they liable for any of their decisions in this respect. Irrespective of the decision of a research ethics committee on a particular application, it is up to the researcher and the NHS or social care organisation who have the responsibility not to break the law.

If RECs have concerns 'that implementation of a research proposal might contravene the law' (RGF 3.12.7), they may inform the researcher submitting the application and the appropriate authority of their concerns. The researcher and the authority should then seek legal advice.

Under GAFREC,<sup>16</sup> at paragraph 2.6, it is made clear that RECs are 'required to have due regard to the requirements of relevant regulatory agencies and of applicable law', and this has been reiterated by the DH and COREC in a joint publication.<sup>17</sup> This is reinforced by the fact that the Annex to the RGF lists relevant laws (including the Data Protection Act 1998) as ethical principles that RECs should apply. However, the DH/COREC document states in its Annex B(7) that 'the governance arrangements make it clear that it is not for RECs to interpret regulations or laws', which faces RECs with the conundrum of having to give due regard to regulations and laws they are not permitted to interpret. What might be intended is that RECs are not to interpret *unclear* laws and regulations, the DH taking the view that some laws are clear and do not require interpretation. If this is so, then the statement is still unhelpful because it is notoriously the case that the import of a law or regulation can seem perfectly clear to one person, yet receive a different interpretation from another person who also regards the provision as transparent.

We are not aware of any legal reason why RECs may not reject proposals that are *lawful* on the grounds that they consider the proposals to be nonetheless unethical (unless specific laws provide to the contrary, though currently there are none such that we are aware of). However, the DH guidance does not positively rule out, and may even be taken to positively suggest, that RECs may approve proposals that they believe are *unlawful* if they consider the proposals to be nonetheless ethical. This is because it neither requires (as against permits or at most recommends) RECs to draw actions they have legal concerns about to the attention of researchers or their employers, nor makes the provision of positive legal advice by the researchers or their employers a condition of REC approval.

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<sup>16</sup> The SOP direct one back to GAFREC for guidance on the matters to be considered in ethical review (SOP 3.4).

<sup>17</sup> Department of Health/COREC *The use of human organs and tissue: An interim statement. Annex B(2)* (London: DH Clinical Ethics and Human Tissue Branch, April 2003).



This is highly controversial because there are a number of legal considerations that indicate that RECs must make lawfulness a condition of ethical approval.<sup>18</sup>

As far as the law is concerned, it is arguable that RECs are public authorities under UK statutory and common law. This is for several reasons. Their source of power comes from a statutory body; they perform public functions and they have responsibilities under statutory law, these being the standard criteria used by the Courts to determine which bodies are public. In the first instance, public authorities are liable to judicial review of their decisions under the common public law. Judicial review is the protection granted individuals from the potential abuse of the power given to public authorities. An individual can request from the Courts leave to apply for judicial review of a decision made by a public authority. If granted, the Court will then review the circumstances of the case to see if there are grounds for judicial review of the decision. If the decision is reviewed, the Courts will prescribe actions to be taken by the public authority to redress the mistakes made in the original decision.

RECs are also, arguably, public authorities or 'emanations of the state' under EC law, in which case they must obey EC law over any contradictory domestic law. The European Court of Justice in *Foster v British Gas plc*<sup>19</sup> (at 3348), gave this description of emanations of the state:

A body, whatever its legal form, which has been made responsible pursuant to a measure adopted by the State, for providing a public service under the control of the State and has for that purpose special powers beyond those which result from the normal rules applicable in relations between individuals is included in any event among the bodies against which the provisions of a directive capable of having direct effect may be relied upon.

RECs are under the control of the State, through the Department of Health, and they have special powers to act in the public good. These powers are laid out in statute and supervised by the State. In consequence, if, for example, the UK Data Protection Act 1998 does not properly implement Directive 95/46/EC on Data Protection, RECs must obey the Directive over the domestic law. If they do not, they may be open to judicial review procedures.

Bearing in mind that the RGF (2.2) specifies the role of RECs as, *inter alia*, to protect the rights of research subjects,<sup>20</sup> it is significant that RECs (assuming them to be public authorities) must also act in accordance with the UK Human Rights Act 1998 (HRA), which extensively, if not completely, implements into UK law the European Convention on Human Rights (ECHR) (specifically Articles 2–12 and 14, Articles 1–3 of Protocol 1 to the ECHR, and Articles 1 and 2 of Protocol 6

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<sup>18</sup> It should be noted that, in its now superseded Notes for Guidance to researchers making application to an MREC, COREC stated that MREC approval is conditional upon researchers observing all legal requirements. This statement did not fully square with the statements in the RGF, and the 'New Operational Procedures for NHS Research Ethics Committees: Guidance for Applicants to RECs' (COREC, April 2004) do not mention this.

<sup>19</sup> *Foster v. British Gas plc* [1990] ECR I-3313.

<sup>20</sup> The CT regulations and the SOP are silent on the role of research ethics committees.



to the ECHR, which are to be read with Articles 16–18 ECHR, subject to any derogations or reservations per Sections 14 and 15 of the HRA (see Section 1)). Specifically, the HRA forbids public authorities from acting incompatibly with the ‘Convention rights’ unless primary legislation makes it impossible for them to comply with the Convention rights (see Section 6(1) and (2)), and to act incompatibly with the Convention rights includes failure to act compatibly with the Convention rights (see Section 6(6)). Section 6(3) of the Act defines public authorities as:

- a. a Court or tribunal; and
- b. any person certain of whose functions are functions of a public nature.

During the passage of the Act, the Home Secretary declared that public authorities fell into three groups: standard public authorities, functional public authorities, and Courts and tribunals.<sup>21</sup> Standard public authorities are those governmental in nature, including ‘bodies which are self-evidently of a public nature, such as the police, government departments, the Probation Service, local authorities’.<sup>22</sup> Functional public authorities, on the other hand, are those that have both private and public functions. The Courts have used many tests to determine whether a body is a public authority: for example, function, authority, public funding, statutory basis, public interest and the jurisprudence of the European Court of Justice (ECJ).<sup>23</sup> RECs have a public function; their authority is a Government body; their funding comes from the NHS; they have statutory duties; they exist to act in the public interest and they are surely emanations of the State under EC law. On this basis, RECs appear to be standard public authorities and, if so, they must protect the rights of individuals accorded by the HRA when performing their functions.

As is pointed out in the ‘Overview of International Materials Regarding the Role of RECs’ in an accompanying volume,<sup>24</sup> Directive 2001/20/EC also appears to require EC Member States to give a specific role to RECs in interpreting data protection law. Specifically, reading Article 3(2)(c) with Article 6(3)(g) and 6(4) of the Directive 2001/20/EC implies that RECs have a responsibility to safeguard subjects’ data protection rights under Directive 95/46/EC that may not be devolved elsewhere (including to the researcher, the researcher’s employer, or even to PIAG—whose role under the Health and Social Care Act 2001 is, in any event, intrinsically in relation to confidentiality not data protection law as such, though it

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<sup>21</sup> See, for example, the House of Commons debate on the Human Rights Bill, 17 February 1997, col. 773.

<sup>22</sup> H. Fenwick, *Civil Liberties and Human Rights* (3<sup>rd</sup> edn., London: Cavendish Publishing, 2002).

<sup>23</sup> D. Oliver, ‘The Frontiers of the State: Public Authorities and Public Functions Under the Human Rights Act’ (2000) *Autumn Public Law* 476–493.

<sup>24</sup> See D. Beyleveld, D. Townend and J. Wright (eds.), *Research Ethics Committees, Data Protection and Medical Research in Europe – Key Issues* (Aldershot: Ashgate Publishing Ltd. 2005).



must be borne in mind that *unlawful* breaches of confidentiality in processing personal data are breaches of the first data protection principle of the Data Protection Act 1998). However, the CT regulations make no mention of this.<sup>25</sup> The CT regulations do state that the condition that 'the rights of each subject to physical and mental integrity, to privacy, and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded' applies to all clinical trials, but does not mention who will ensure this (CT regulations, Schedule 1, Part 2, Section 15).

An interesting point in relation to whether or not the REC takes into account the law when reviewing a protocol also arises when considering research using human tissue. The Human Tissue Act 2004 includes stipulations that research using human tissue from a living person can go ahead without consent, on the condition that it is both ethically approved and the researcher cannot identify, or possibly identify, the person the tissue originates from. The requirements are the same for the use of the results of DNA analysis for research. The RECs will surely have to take these provisions into consideration in the future when reviewing relevant protocols, as it mentions ethical approval explicitly.

Finally, it should be noted that RECs are also not responsible for any ongoing monitoring of research; again it is the responsibility of the sponsor and the principal investigator to ensure 'that a study follows the agreed protocol' (RGF 3.12.8). The CT regulations state that a

... trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored (Schedule 1, part 2, section 14).

It does not mention who should monitor this. The SOP outlines that the main REC has no responsibility for the 'proactive monitoring' of research studies, the accountability for which lies with sponsors and employing organizations (SOP 9.3). However, the main REC should receive progress reports on the research at least annually, which they should use to keep their ethical opinion under review. The ethics committee may request a meeting to discuss ethical concerns, and it may review its favourable opinion at any time (SOP 9.4, 9.52).

## Practice of RECs

In view of the DH's advice, it should not be surprising that RECs will pay different amounts of attention to an applicable law, such as the Data Protection Act 1998, according to the awareness, insight, and expertise available within the membership and the administrative officer(s) of the individual REC.

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<sup>25</sup> The ambivalence of the Department of Health to legal responsibilities of RECs in the period leading up to the RGF is discussed in D. Beyleveld, 'Law, Ethics, and Research Ethics Committees' (2002) 21 *Medicine and Law* 1, 57–75.



A PRIVIREAL questionnaire was sent<sup>26</sup> to RECs in the UK to determine what their actions may be when confronted with a) a protocol which is unlawful but *otherwise* ethical, and b) a protocol which is unethical but *otherwise* lawful. This brief survey also asked if the respondents believed that RECs should give advice on purely ethical considerations, independent of legal ones.

Two MRECs responded, both with the view that they believe they would approve a proposal which is unlawful, if it is otherwise ethical, reflecting the opinion that they should give advice on purely ethical grounds. One MREC stated its members sometimes regard the law as unethical and judge on ethical grounds alone, and when a proposal could be illegal but is otherwise ethical, they would approve it and comment on this possible illegality. The same MREC mentioned that interpretation of the Data Protection Act can itself cause problems, for example when considering what is and is not a matter of national interest, a decision which could cause some aspects of data protection to be sidestepped.

The other MREC outlines that the committee is not able or expected to give legal opinions, including whether or not a proposal infringes the law, and judges a protocol only on whether it is ethical or not. This committee also mentions that on some occasions, a proposal could be illegal but ethical, and gives the example of the cannabis study, a collaboration with the Home Office where, as information was required for governmental purposes, the subjects were guaranteed that prosecution would not follow. In the spirit of helpfulness, this committee would point out any action it believes to be against the law to the investigators, who would be responsible for taking any action to avoid breaking the law, and who would be responsible for the consequences. This committee in general believes that it is not the responsibility of the committee to interpret the law.

A local REC responded to these questions and stated that the committee would reject proposals which are either unlawful and otherwise ethical, or unethical and otherwise lawful, perhaps reflecting the opinion that proposals should be both ethical and legal. The divergent views between the MRECs and LREC show that within the UK, what matters are taken into consideration during ethical review are far from standardized.

### **Liability of RECs Under Common Law<sup>27</sup>**

As we have opined, RECs have public law responsibilities under Statute and common law. As yet there is no UK case where an REC has been brought to Court under private law proceedings because of a decision it has made. However, if it does happen in the future, there is Canadian case law that may be taken into

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<sup>26</sup> This survey was completed in mid-2003, before the CT regulations came into effect, therefore the respondents are termed MREC and LREC, within the meaning of the old system.

<sup>27</sup> We wish to thank our colleague Dr. Shaun Pattinson for his comments and advice on this section. We, however, remain solely responsible for its contents.



account. In *Weiss c. Solomon*<sup>28</sup> a man, W, agreed to enter a research study on the use of ophthalmic drops. The procedure consisted of the participant being administered the drops, then undergoing a fluorescein angiography to judge the results of the treatment. After being injected with the fluorescein, W suffered cardiac failure and died. It was known at the time of the procedure that W suffered from a heart condition, but this information did not lead to him being excluded from the trial. In addition, the room in which the procedure was carried out was not equipped with resuscitation equipment, which might have been used to save his life. The plaintiffs claimed that the physicians and the hospital were negligent in their duty because they did not properly inform W of the possible risks involved with the procedure, they did not exclude patients with heart conditions from the study, and they did not provide resuscitation equipment. The defendants were found liable. Specifically, the hospital, through its research committee, was found negligent for not ensuring that the information given to the prospective trial participants adequately explained the possible risks of the research procedure.

UK judges may consider this case when determining a judgment against an REC. However, it is possible that the reasoning used in this case would not be persuasive. The judges might instead rely on the *Bolam*<sup>29</sup> test as used in *Sidaway*,<sup>30</sup> in relation to which it could be argued that a reasonable REC would have provided the same information as was provided to W. If this argument failed, as Brazier notes, '[h]ow would a court decide whether a reasonable ethics committee would/should have noted the potential illegality in the trial?'<sup>31</sup> The Department of Health states in GAFREC at 9.11,<sup>32</sup> that 'RECs need to take into account the potential relevance of applicable laws and regulations'. However, as we have seen, in the RGF, at 3.12.7,<sup>33</sup> it states that '[i]t is not the responsibility of NHS research ethics committees to give legal advice, nor are they liable for any of their decisions in this respect'.

The REC is responsible for contacting the researcher or sponsor if there are potential legal concerns regarding the study, but this is the end of their responsibility. The researcher and/or sponsor are responsible for seeking legal advice.<sup>34</sup> RECs are not provided with legal assistance in order to make their decisions; therefore they might not know if a trial might result in injury to a patient. However, as noted, as public authorities, RECs are required to implement EC law as well as UK statutory law and the DH states that they must be aware of

<sup>28</sup> *Weiss c. Solomon* [1988] RJQ 731.

<sup>29</sup> *Bolam v. Friern Hospital Management Committee* [1997] 1 WLR 582.

<sup>30</sup> *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1985] AC 871.

<sup>31</sup> M. Brazier, 'Liability of ethics committees and their members' (1990) 6 *Professional Negligence* 188.

<sup>32</sup> DH *Governance Arrangements for NHS Research Ethics Committees* (2001). Available to download from the DH website [www.dh.gov.uk](http://www.dh.gov.uk) (last accessed 18 May 2005).

<sup>33</sup> DH *Research Governance Framework for Health and Social Care* (2<sup>nd</sup> edn., London: Department of Health, 2005).

<sup>34</sup> *Ibid.* at 3.12.9.



the law and potential illegalities. However, if they used their best knowledge to come to a decision, this might prove sufficient to avoid private law claims.

The UK Courts have historically proven reluctant to hold public authorities liable in negligence for their actions,<sup>35</sup> although current case law shows that this is beginning to change. For example, in the case of *Hill v. Chief Constable of West Yorkshire*,<sup>36</sup> the plaintiff sought to appeal a lower Court judgment dismissing the claim that the police had been negligent in their duty to protect her daughter from being murdered. As other murders had been occurring in the area that the daughter frequented, the crime should have been foreseeable and the police under a duty of care to prevent it. Their Lordships based their judgment, amongst other reasoning, on whether there was a special relationship between the defendant and the deceased that would create a duty of care that would hold the police responsible for preventing the attack on the deceased. The appeal was dismissed as Their Lordships found that there was not a special relationship, that the police had a general duty to protect the public but not to protect specific individuals. In addition, they agreed that if a precedent was set by finding the police negligent, other cases would be brought and time and manpower would be spent dealing with litigation, rather than on crime detection and prevention.

This second 'public policy' reasoning can be applied directly to RECs. Many RECs review a large number of proposals for research studies every month.<sup>37,38</sup> If cases were brought against RECs for even a fraction of these projects, RECs would be forced to spend more time and money defending their actions than on reviewing protocols. Therefore, a case can be argued for not finding RECs liable in negligence.

However, while this public policy defence is still in place, there has been a retreat from giving public authorities blanket immunity for their actions. As noted, in *Hill*, one question was whether or not there was a duty of care placed on the public authority. In order to prove a duty of care, the Courts look for three features, as stated in *Caparo plc v. Dickman*<sup>39</sup> at 617:

... [I]n addition to the foreseeability of damage, necessary ingredients in any situation giving rise to a duty of care are that there should exist between the party owing the duty and the party to whom it is owed a relationship characterised by the law as one of 'proximity' or 'neighbourhood' and that the situation should be one in which the court considers it fair, just and reasonable that the law should impose a duty of a given scope upon the one party for the benefit of the other.

<sup>35</sup> Palmer Company Law Challenging the FSA's decisions. *UK Palmer 11.008*, 2001.

<sup>36</sup> *Hill v. Chief Constable of West Yorkshire* [1988] QB 60.

<sup>37</sup> R. Nicholson, 'A study of local research ethics committee annual reports' (June/July 1997) *Bulletin of Medical Ethics* 13–24.

<sup>38</sup> J. Blunt, J. Savulescu and A. Watson, 'Meeting the challenges facing research ethics committees: some practical suggestions' (1998) 316 *British Medical Journal* 58–61.

<sup>39</sup> *Caparo plc v. Dickman* [1990] 2 AC 605.



In *Kent v. Griffiths and Others*,<sup>40</sup> the issue of proximity was questioned. In this case, K, a woman, was suffering from an asthma attack. An ambulance was called. However, it was delayed in its arrival. Before arriving at the hospital, K suffered a respiratory arrest resulting in brain damage. The claimant brought an action against the ambulance company alleging negligence for failing to arrive promptly. The appeal brought by the defendant was dismissed as the judges agreed that a duty of care existed in this case. Proximity was established when the call was accepted by the ambulance service. In addition, it was foreseeable that K would suffer if the ambulance did not arrive promptly and there were no circumstances to preclude a duty of care from existing.

Could this issue of proximity relate to RECs? If an REC approved a research study, and subsequently a patient was harmed, could the REC be held liable in negligence? The answer would perforce depend on the circumstances. If the individual harmed was known to the committee because he or she was, for example, identified in the protocol for the study, then proximity might be proved and there might be a case to argue. However, it is extremely unlikely that the individual persons recruited into a study will be known to an REC (at least in its capacity as an REC), making proximity establishing a duty of care difficult to prove.

Another consideration is whether UKECA, as a third-party responsible for RECs, could be held liable for their supposed negligent actions. Again, based on prior cases, such an action is unlikely to succeed. In *Yuen Kun Yeu and Others v. Attorney-General of Hong Kong*,<sup>41</sup> the plaintiffs sought to appeal a lower Court decision dismissing their claim that the Commissioner of Deposit-taking Companies should be held negligent for not ensuring that the companies under his responsibility properly safeguarded the assets of depositors. The plaintiffs had deposited funds into such a company, which went into liquidation resulting in the loss of the plaintiffs' money. The Court, as in *Hill*, considered whether there was a special relationship such that the Commissioner owed a duty of care to members of the public. The Court dismissed the appeal, finding that there was not such a duty of care owed. As Lord Keith of Kinkel stated, at 195 of the judgment,

The commissioner did not have any power to control the day-to-day management of any company, and such a task would require immense resources. His power was limited to putting it out of business or allowing it to continue. No doubt recognition by the company that the commissioner had power to put it out of business would be a powerful incentive impelling the company to carry on its affairs in a reasonable manner, but if those in charge were determined upon fraud it is doubtful if any supervision could be close enough to prevent it in time to forestall loss to depositors.

This reasoning can be used regarding RECs under UKECA. While UKECA is the umbrella body over RECs, it does not have day-to-day responsibilities for REC activities. UKECA does not have the power to overrule REC decisions. Therefore,

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<sup>40</sup> *Kent v. Griffiths and Others* [2000] QB 36.

<sup>41</sup> *Yuen Kun Yeu and Others v. Attorney-General of Hong Kong* [1988] AC 175.



the relationship will not be close enough to impose a duty of care on the participants in research projects approved by the REC. However, interesting questions would arise if UKECA were to require RECs to follow regulations that in turn caused the REC to act in such a way that research participants were harmed in some way. Unfortunately, space precludes us from pursuing this thought here.

Next is the question of whether individual REC members can be held liable for their decisions. Because most RECs discuss proposals in confidence<sup>42</sup> it would be difficult to place blame on individuals. If, for instance, a researcher claimed that an REC member was biased against them and deliberately led the committee to refuse their application, unless 'inside information' was obtained, it would be very difficult for an outsider to know what was said and by whom. If an individual can be named, the CT regulations, as noted earlier, can impose penalties in specified cases on those who wilfully mislead an REC in their decision-making regarding trial falling under the regulations. In other situations, if the individual at blame is an NHS staff member, the person complaining would most likely be instructed to follow 'normal [DH] management channels and disciplinary procedures' as indicated in the RGF at 5.8.

Liability coverage is provided for NHS staff. The National Health Service (Liabilities to Third Parties Scheme) Regulations 1999 and the National Health Service (Liabilities to Third Parties Scheme) Amendment Regulations 2000 provide liability coverage for third-party loss, damage or injury for NHS trusts, health authorities, primary care trusts and special health authorities. These would cover the expert members. As for lay members, GAFREC states, at 4.14, that

[t]he appointing Authority will take full responsibility for all the actions of a member in the course of their performance of his or her duties as a member of the REC other than those involving bad faith, wilful default or gross negligence.

In addition, at 5.9, GAFREC states that, '[t]he appointing Authority shall provide each appointed member with a personal statement regarding the indemnity provided, and its conditions'. Therefore, members are provided with information as to the coverage provided for them.<sup>43</sup>

## Concluding Remarks

In this report, we have argued that RECs have specific legal responsibilities to protect data protection rights of research participants, in the main public law responsibilities, responsibilities under the UK Human Rights Act 1998 and Directive 2001/20/EC. DH guidance and the way in which the UK has implemented Directive 2001/20/EC at best plays down (and often obscures these

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<sup>42</sup> R. Ashcroft and N. Pfeffer, 'Ethics behind closed doors: Do research ethics committees need secrecy?' (2001) 322 *British Medical Journal* 1294–1296.

<sup>43</sup> This sits rather oddly with the guidance that RECs bear no responsibility for their decisions in relation to the law.



responsibilities), and may even be held to deny them. Legislation on confidentiality might also be interpreted to be in breach of the Data Protection Directive insofar as it suggests that the conditions to render actions that are in breach of confidentiality not unlawful on this count are to be considered lawful even if they breach the UK Data Protection Act 1998. Apart from issues of legality that all this gives rise to, it is also questionable from an ethical point of view. This is because of the particularly vulnerable position of research subjects in relation to protection of their data protection rights. Unless RECs play an active role in protecting these rights, they are unlikely to be protected effectively, but the DH guidance (in large part because of the conflicting and unclear way in which it is couched) and the new regulations at best do nothing to positively encourage RECs to take data protection seriously, and it is clear that at least some RECs interpret the DH guidance to mean that the protection of legal rights to data protection is none of their business.