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Reassessing the Role of the Biomedical Research Ethics Committee

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Abstract The role of the Research Ethics Committee (REC) in the design, conduct and dissemination of scientific research is still evolving and many important questions remain unanswered. Hence, the aim of this paper is to address some of the uncertainty that exists around the role and responsibilities of RECs and to discuss some of the controversy that exists over the criteria that RECs should follow when evaluating a research proposal. The discussion is organised around five of the major roles currently performed by RECs when assessing proposals in the biomedical sciences. It will be shown that these five roles need to be critically evaluated and reassessed. The five roles addressed are: assessing the legitimacy and validity of the informed consent process, second, conducting a comprehensive risk/benefit analysis, third, assessing the validity of a research proposal, fourth, ensuring that researchers observe the social norms, values, customs, traditions and laws that prevail in the community or jurisdiction in which the research will be conducted and finally, monitoring the research project as it unfolds and providing an ongoing advisory and consultancy service to both new and experienced researchers. In reassessing the role of the REC, this paper concludes with a set of general recommendations for RECs. These provide some guidance on the minimum criteria that should be followed when RECs evaluate proposals. These guidelines will be beneficial for new and experienced members of REC, and will help to make the process a more objective, efficient and standardised process. The guidelines will also be beneficial for researchers in the biomedical sciences who are preparing proposals for ethical review.

Keywords Research ethics · Research ethics committee · Informed consent · Quality assurance · Social norms

Introduction

Research Ethics Committees (RECs) are an integral part of the wider quality assurance and quality enhancement processes that operate within all institutions that conduct research. The

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primary role of a REC is to review research proposals before any data collection begins and to ensure that the probability and the magnitude of any risks that either the researchers or the research participants may be exposed to has been minimised. A secondary, but equally important role, is protecting the integrity and reputation of science as a virtuous profession.

RECs were originally formed in the 1970s as a political response to public concerns over the treatment of human subjects in medical research (Montgomery and Oliver 2009). From these early beginnings, the number, size and influence of RECs has escalated and today, RECs exist in virtually all institutions and organisations that support pure and/or applied research. These institutions include universities, research centres, research or policy institutes, hospitals, government departments, community-based organisations and private companies. Some universities have a single central REC with responsibility for developing policies, offering training and guidance, and assessing research proposals. Others have a two-tier committee structure comprising a central research ethics committee, which has responsibility for setting standards and policies, and several faculty, department or school sub-committees, which assess the ethical acceptability of research proposals. The advantage of one central committee is consistency and uniformity in assessment criteria. The advantage of the two-tier structure is consistency in policies, but specialist expertise in the subject area in which the proposal is located (Tinker and Coomber 2004).

The membership of a REC will differ between institutions, but ideally will be an interdisciplinary committee with representatives from across several disciplines. Based on liberal democratic values, the idea is to facilitate an interdisciplinary exchange between committee members and thus to maximise the chance that any ethical concerns arising from the project under review will be identified. Most guidelines on establishing a REC recommend that the core membership should include members with expertise in ethics, law, sociology, theology, qualitative and quantitative research methodology and at least one layperson who represents the norms and values of the local community (UNESCO 2005). In addition, The Council for International Organisations of Medical Research recommends that members do not review proposals in which they have a direct interest, either as an investigator or an investor (CIOMS 1993). Finally, for research that is initiated or funded by a resource-rich nation, but conduced in a resource-poor nation, the REC should include at least one representative from the recruitment population because only a local representative will have the depth of knowledge of the local norms, customs and traditions to be able to assess the potential impact of the research on the individuals and the communities that constitute the study population (MacPherson 1999).

A number of analysts have suggested that although RECs originally formed to offer advice on ethics in research, their role has escalated to the point where RECs now function as the adjudicators, governors or 'gatekeepers' of research. Whittaker (2005) for example, has suggested that: "ethical review boards have become established as one of the most authoritative, if not authoritarian, gatekeepers in research history." Furthermore, the range of issues considered by RECs has gradually expanded into areas previously considered to be outside the boundaries of ethical review. Much of this expansion in the range of issues covered by RECs has come from within the committees themselves, as members (who are often active researchers themselves) feel obliged to adopt a holistic approach and assess all aspects of the proposal for clarity, consistency, feasibility and integrity. This expansion also mirrors the evolution, expansion and maturity of bioethics as the interdisciplinary study of the ethical, legal and social aspects of the biosciences. If bioethics is defined as the study of the ethical, legal and social aspects of the biosciences, then by extension, bioethics committees should be an interdisciplinary assessment of the ethical, legal and social issues arising from research in the biosciences.

Some critics have described modern RECs as a bureaucratic process of ensuring compliance with institutional guidelines and as a slow, costly and inefficient process of 'filling in forms,' which serves little to enhance the quality of the research process (Allen 2008; Loff and Black 2004; Shaul 2002). These critics have suggested that RECs need to be reassessed to rediscover their original intent, purpose and meaning, which is to facilitate and encourage creative, innovative and purposeful research, but at the same time, to ensure that this research is conducted within the parameters of what is considered ethically acceptable.

Another common critique of RECs is that the escalating power of RECs poses a threat to the autonomy and academic freedom of researchers and that RECs are unnecessary because researchers are vigilant and responsible professionals who can be trusted to follow their own moral conscience when conducting their research (Whittaker 2005). The lessons of history however, suggest that in their pursuit of knowledge and in their quest to find answers to scientific problems, not all researchers adhere to the fundamental ethical principles of beneficence, non-maleficence, autonomy and justice when conducting their research. Some infamous historical examples of unethical research involving human participants include: the Tuskegee syphilis trial on African Americans (Curran 1973); the American hepatitis B vaccine trials on mentally retarded children institutionalised in the Willowbrook State Hospital (Rothman and Rothman 1984) and the hypothermia studies, infectious disease studies, gunshot wound healing studies and sterilisation studies conducted on prisoners in Nazi concentration camps (Pence 2004).

Whilst most researchers agree on the value of ethical review, the need for RECs and the importance of reviewing research proposals for ethical competency, not all researchers agree on the procedural and substantive issues covered by RECs nor do they agree on where to set the boundaries of what should and should not be considered by members of a REC. The role of the modern REC therefore, is still evolving and many questions remain unanswered. Hence, the aim of this paper is to address some of the uncertainty that exists around the role and responsibilities of RECs and to discuss some of the controversy that exists over the criteria that RECs should follow when evaluating a research proposal. The discussion is organised around five of the key roles currently performed by university RECs and it will be shown that these five roles need to be critically evaluated and reassessed. These roles are: First, to assess the validity of the informed consent process. Second, to conduct a comprehensive risk/benefit analysis. Third, to assess the validity of a research proposal. Fourth, to ensure that researchers observe the social norms, values, customs, traditions and laws that prevail in the community or jurisdiction in which the research will be conducted and finally, to provide an ongoing advisory and consultancy service to researchers and to monitor the research as it unfolds.

Whilst the discussion is primarily focused on the role and responsibilities of University RECs in the United Kingdom (UK), most of the issues raised are relevant to all research that enrols human participants. Furthermore, whilst the focus is on research in the biomedical and clinical sciences, lessons can be learned that are transferable to research in the social sciences and humanities.

Reassessing the Process for Obtaining Informed Consent

Despite the general consensus within the research ethics community on the importance of providing a participant (or patient) information sheet (PIS), there remains considerable controversy over how much information to include in this sheet. Similarly, there is a general agreement on the need to obtain informed consent from all participants, but disagreements

arise over the processes used for obtaining and recording informed consent. This ongoing debate around informed consent has been recognised by the UNESCO as one of the key issues for ethics committees, leading to a conclusion that: "no aspect of human research has received closer scrutiny by RECs than informed consent" (UNESCO 2005: 41).

When analysts discuss the efficacy of participant information sheets and the validity of informed consent, some of the unanswered questions include: how much information should be included in the PIS? How much time should elapse between distributing the PIS to the prospective participants and asking them to sign the consent form? Does consent always need to be written or is oral consent sufficient for some projects? Should researchers seek narrow or broad consent? Does consent always need to be explicit, or are there special circumstances when a researcher can rely on implied consent? What is the best way to assess a person's capacity to consent and when is it necessary to seek proxy consent?

Based on the ethical principle of respect for autonomy (Beauchamp and Childress 2009), informed consent means that the participants have been provided with accurate information about the study and from this, have made a rational and autonomous decision about whether or not they wish to participate. This information is provided to prospective participants in a concise and accessible participant information sheet. The provision of a PIS therefore, is a prerequisite for obtaining informed consent. Consent may be given without the provision of information, but *informed* consent cannot be given without being *informed*. The provision of the PIS is uncontroversial, but what to include in, or exclude from the sheet is not always clear, and the requirements will differ for different projects depending on the characteristics of the recruitment population and the level of risk. Providing too much information in a highly esoteric language is unhelpful, especially for individuals who are illiterate or unfamiliar with research methodologies. As a minimum standard, the members of a REC should expect to see the following included within the PIS: an overview of the aims of the study; a short biography of the researcher and their institutional contact details; a statement on any sources of funding and any potential personal or institutional conflicts of interest; a description of the anticipated benefits arising from the study; an assessment of the nature, probability and magnitude of any physical or psychosocial risks associated with the study; a description of what the participant will be required to do and how much time they will need to commit to the project; an assurance that the privacy and confidentiality of all participants will be protected through secure data handling and data storage processes; a statement about the right to consent or dissent from the study and a statement assuring the participant that they may withdraw from participation at any stage, and can withdraw any unpublished data that has been provided by them up until a specified date.

In addition to confirming that this core information has been included, the members of a REC should ensure that the PIS has been written in a language that will be understood by the participants. For example, if the prospective participants are 12 year old children, then the PIS should be written in a style and language that the average 12 year old is likely to understand. If the prospective participants are illiterate or visually impaired, alternative forms such as audio, large print or Braille, should be made available.

If proxy consent is being sought for individuals from vulnerable or marginal groups, such as minors or people diagnosed with a severe mental illness, then the person acting as the proxy must also be fully informed and a separate PIS may be necessary for this purpose. The REC must ensure that the person acting as a proxy is not only informed, but is also authorised by law to give this consent. In the UK, the current laws and regulations on who can, and cannot, give proxy consent are specific, and the REC must ensure that the protocol is compliant with these laws. In the case of clinical trials involving minors for example, the *Medicines for Human Use (Clinical Trials) Regulations* (2004) states that

proxy consent may only be given by a person with parental responsibility, a personal legal representative or a professional legal representative. In the case of research involving incompetent adults, the researcher must comply with the *Mental Capacity Act* (2005) when obtaining informed consent, or if conducting a clinical trial involving incompetent adults, they must comply with the *Medicines for Human Use (Clinical Trials) Regulations* (2004).

Before considering the legitimacy of the consent given by any individual from a vulnerable group, and the legality or legitimacy of the consent given by their proxy, the REC should ask whether it is indeed necessary to enrol such individuals. If the study can be conducted equally well with competent adults, then it would be unethical to recruit individuals from a vulnerable group. If competent adults cannot be used to generate valid results, then the use of minors or incompetent adults may be justified and approved. If the study seeks to evaluate a new treatment for a childhood illness for example, then the researchers would need to test the treatment on children living with the condition. Similarly, a clinical trial to test the efficacy of a new anti-psychotic medication can only be tested on people living with the condition. The researchers cannot evaluate whether the clinical symptoms have been alleviated by the new medication if there are no initial symptoms.

Another issue for RECs to consider is whether the researcher is seeking narrow or broad consent. Narrow consent means that consent is limited to the current study, whereas broad consent allows the researcher to use the data in any subsequent or related projects that may emerge or evolve from the current study. With narrow consent, there is a need to obtain consent again if the data is used for any different projects or purposes, or if it is transferred to another research team, and this should be explicit in the PIS. As Beauchamp (2011) explains, it is both illegal and immoral to use data that has been collected for one specific purpose for another purpose unless broad consent or secondary consent has been obtained.

Whilst there is a general agreement on the need to obtain voluntary and informed consent, there is some variation in the type of consent given and the processes used for obtaining and recording consent. A signed paper consent form is the most usual mode, but this explicit, formal, written consent may not always be necessary. When researchers are using an anonymous postal survey for example, a written consent form is unnecessary since the act of completing and returning the survey implies that consent has been given (Andanda 2005). Similarly, if an epidemiologist is proposing to conduct an analysis of data stored in a large population data base, or central disease registry, then consent from the people whose information is stored within the database may not be necessary (See The International Guidelines for Ethical Review of Epidemiological Studies (CIOMS 1991)). Sutrop (2011) has suggested that this relaxation of individual consent for public health research maybe justified by appealing to the utilitarian or communitarian ethos of research for the common good (Sutrop 2011).

Where a written PIS is necessary, questions arise over how much information to include, how to measure understanding and how to avoid the therapeutic misconception. The latter has been defined by Appelbaum as a false belief that the research will confer a therapeutic benefit for the participant (Appelbaum 2002). Providing too much detailed information can lead to confusion rather than understanding. Wendler and Grady (2008) question how much information is needed for a person to give informed consent and how to ensure that participants understand that they are participating in research, rather than receiving treatment (Wendler and Grady 2008). In some instances, the REC will approve an alternative to the written PIS, for example, it may be more appropriate to conduct a community consultation forum where prospective participants have the opportunity to listen to the researcher explain the project and then, to raise concerns or ask questions.

An important part of the consent process is informing participants of their unconditional right to withdraw from the project, and to withdraw any unpublished data. The participants should understand that they are not signing a legal contract when they sign a consent form, but rather they are entering into a voluntary and reversible relationship. As stated by the UNESCO *Declaration on the Human Genome and Human Rights* (1997): "consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice" (UNESCO 1997).

The researcher's promise to withdraw any data can be problematic when the data is fully anonymised. For example, if a person returns a questionnaire by post and there is no code or identifier on the questionnaire, then the researcher would be unable to withdraw that questionnaire if the person so requests. The members of the REC need to assess whether any claims such as this, that have been included in the PIS, are indeed practical and possible and not misleading. To inform participants that they may withdraw any unpublished data, when the data is fully anonymised, would be to provide misleading information and this should be assessed as by the REC as unethical. Furthermore, it is often recommended that participants are given a "final date" for withdrawing data, and should be informed that after this critical date, it may not be possible to delete their data.

An assurance of protecting the privacy and confidentiality of all participants should be included in the PIS. The participant should be assured that any information they provide during the study will be stored in a secure data storage facility and will not be disclosed or transferred to any third party without their knowledge and explicit consent. The participant should also be assured that they will not be identified in any reporting or presentation of the results. This assurance of protecting privacy and confidentiality is based on the assumption that most people do not want to be identified. Yet surprisingly, a number ethnographic, narrative and biographical studies conducted by medical anthropologists have shown that this strict requirement for confidentiality can be a source of disappointment for individuals who want their personal experiences told (Whittaker 2005). For these individuals, their participation in the research is an opportunity to tell their own unique life story.

Whilst all the national and international guidelines on research ethics rightly emphasise the importance of maintaining privacy and confidentiality, it remains contested whether this is an absolute rule, or whether there may be some exceptional cases where it may be acceptable, or even desirable, to breach confidentiality. Consider the following scenarios: First, a research proposal involves testing all participants for antibodies to HIV and one of the participants returns a positive test result. Should the researcher inform the individual's spouse or partner? Second, a researcher is studying child abuse and one of the participants reveals that they are abusing their 2 year old daughter. Should the researcher take action and notify the police or child protection agency? Finally, a research proposal involves the identification of a severe disease causing gene mutation and one of the participants returns a positive result for the mutation. Should the researcher contact the participant, or indeed, other family members and warn them that they may be at risk? If situations like these are likely to arise, then the REC should ensure that the investigator is aware of their rights and obligations, and has a contingency plan for addressing the situation.

The usual solution to this type of dilemma is to require that the participant information sheet contains a statement that in the event of the disclosure of any information about unlawful actions, or any threat to the health and safety of another person, the researcher may

disclose this information to a relevant authority. The researcher may also state that in exceptional cases, the researcher may be issued with a subpoena to release the data.[1] This is part of the overall risk management process, which is now integral to the research process. In essence, ethical review is a form of risk assessment and ethics committees are responsible for identifying any physical, psychological or legal risks and for ensuring that where there is a risk, there is an accompanying risk management strategy.

Finally, the PIS should provide information about any incentives or payments that may be offered to participants. Incentives may include financial payments, gift vouchers, access to healthcare services that would not otherwise be accessible, access to new medicines that would not otherwise be available, or for prisoners, the incentive may be a reduced prison sentence. Without some prospect of payment, reward or benefit, either extrinsic or intrinsic, most individuals are unlikely to participate in research.

For therapeutic research, the prospective participants are usually people living with the condition being studied and the incentive is gaining access to new medicines or treatments. For non-therapeutic research, the incentive may be financial gain, or it may simply be an altruistic desire to contribute to the advance of scientific knowledge and thus, to benefit the health and wellbeing of future generations.

As a general rule, the higher the risk involved, the greater the incentive needed to recruit participants. Prospective participants will conduct their own risk/benefit analysis based on the information provided in the PIS and their own subjective perception or evaluation of the risks involved. If the participants perceive the risks to be high, then they will need a correspondingly higher incentive to compensate for this risk. Researchers need to be aware that an individual's subjective perception of the risk may be very different from the actual or objective measure of the risk.

The Nuffield Council on Bioethics recommends that when RECs are assessing whether an incentive is appropriate, they should consider the proportionality, that is whether the incentive being offered is in proportion to the actual and perceived risks and the physical and emotional costs to the participant. Consideration should also be given to the autonomy, capacity and vulnerability of the participants (NCB 2002: 80).

Whatever the form or amount of incentive, the principle of justice demands that the same incentive, reward or payment is offered to all participants (Edwards 2005). It would be unjust, and therefore unethical, to offer a different incentive for different individuals who contribute the same time and effort to the same research study.

It is generally agreed that participants should be reimbursed for any expenses incurred in attending the research, such as travel costs, meals, lost wages or child care. These are not considered as payments, but simply reimbursement for reasonable expenses. Above this, the voluntariness of participation maybe compromised. Another concern raised by the use of payments is that it may compromise the participant's propensity to exercise their right to withdraw. When a participant has received a payment, they may perceive the relationship between themselves and the researcher as more akin to a business agreement, rather than a voluntary, altruistic relationship, and having entered into this business agreement, they may feel more obliged to fulfil their commitment.

Bentley and Thacker (2004) suggest that one of the advantages of using financial incentives is that they generally increase the number of willing participants (Bentley and Thacker 2004). However, because payments increase the cost of conducting the research, the sample size may be constrained by the project budget. The researcher can only recruit as

[1] For an interesting case study that challenged the principle of absolute confidentiality see Lowman and Palys 2000.

many participants as the budget allows. Another disadvantage of payments is that for private sector pharmaceutical companies, payment for participants adds significantly to the cost of conducting clinical trials. In turn, this adds to the unit cost of the medicines purchased by the consumer, when the medicine enters the consumer market.

The central dilemma here is that without some payment or reward, the research may be perceived as exploitation, but when a payment or reward is offered, the research may be perceived as coercive. One solution to this dilemma is to give the gift or payment after the data collection is complete. At the end of a focus group session for example, the participants could be presented with a gift. This would serve as a token of appreciation to the participants, but because it was unexpected, it has not influenced their initial decision to participate. This avoids exploitation and coercion at the same time.

Conducting a Comprehensive Risk/Benefit Analysis

Ethical review has become synonymous with risk assessment and risk management and thus, the second essential role for a REC is to conduct a risk/benefit analysis. Since there is an element of uncertainty in all research projects, and since there is always a level of risk associated with uncertainty, there is an element of risk in all research. The role of the REC is to judge what is an acceptable level of risk for the participants, for the researcher, for the host institution and for wider society.

There is a general consensus within all national and international guidelines that protecting research participants against any physical or psychosocial risk is the principal concern for the REC. The Declaration of Helsinki (2000) states that in assessing the risks and benefits of any research, the interests of the subject must always prevail over the interests of science, industry or society. Similarly, the UNSCO Declaration on Bioethics and Human Rights (2005) states that "The interests and welfare of the individual should have priority over the sole interests of science and society." And finally, the Department of Health in the UK states that: "The dignity, rights, safety and well-being of participants must be the primary consideration in any research study" (DH 2005: 7).

Whilst this goal of protecting participants from unreasonable risk is to be applauded, questions are raised about whether RECs are being overly paternalistic when they prohibit competent adults from participating in risky research. Informed by the principle of respect for autonomy, it is the competent individual, not the ethics committee, who should make this ultimate decision about participation (Edwards et al. 2004b). Furthermore, Sutrop (2011) suggests that the recent emphasis on respecting autonomy and protecting the individual participant maybe at the expense of encouraging research for the common good (Sutrop 2011).

Whilst protecting participants against any unreasonable physical or emotional risks is the primary concern of a REC, it is not their only concern. A REC is also concerned with identifying, assessing and evaluating any risks to the researchers. For example, an ethnographic study observing the operation of an overcrowded military hospital during a period of intense military conflict may not be approved by a REC because the safety of the researcher would be placed at an unacceptably high level of risk. Similarly, if a researcher was proposing to infect themselves with the human immunodeficiency virus and then test the efficacy of a new anti-retroviral drug, the REC is unlikely to approve the project because of the unacceptably high risk to the health and safety of the researcher. Even with informed consent, the project is unlikely to be approved if the physical, psychological or legal risk is above a threshold level. Informed consent is a necessary, but not sufficient condition for ethical approval.

In addition to assessing any potential harm to participants and any possible risk to the researcher, RECs should assess whether the proposal presents any possible harm to the public image of science. As suggested by Hirtle et al.: "One of the goals of the review system is to establish public trust in how research is being reviewed and conducted" (Hirtle et al. 2000). Similarly, the Department of Health states that the "proper governance of research is essential to ensure that the public have confidence in, and benefit from, quality research in health and social care" (DH 2005: 2).

Studies in the governance of science and the public understanding of science suggest that that there has been an erosion of public trust in science, and a general loss of confidence in the regulatory authorities that govern science (Jones and Slater 2003). RECs are one solution to regaining and rebuilding this public trust in science, scientists and the policy networks that govern science. Indeed, RECs originally evolved as a response to the unethical medical research that has been performed in the past and their primary role is to prevent any future episodes of unethical research.

Essentially, the role of a REC is to balance the conflict between the need to protect participants from harm and the need to facilitate the advance of scientific knowledge. As Cave and Nichols suggest: "ethical review systems must strike an appropriate balance between the duty to protect participants and the duty to facilitate research and promote continued improvements in healthcare for the benefit of the wider public" (Cave and Nichols 2007: 197). Thus, while it may be considered unethical not to engage in biomedical research because of the opportunities foregone, at the same time, it is unethical to conduct research that causes harm to individuals. The challenge for a REC is to balance these conflicting tensions between benefit and harm, between the individual and society and between present and future generations.

Assessing the Scientific Integrity of the Proposal

It is generally agreed that RECs should assess the scientific validity of a research proposal and should reject (or request amendments to) a proposal that lacks scientific rigor. This is based on a belief that it is unethical to expose participants to risk and to ask individuals to commit their time to a project that is poorly designed and inconsistent with the expectations of good scientific methodology. Research that is poorly designed will not produce valid results and is therefore, an irresponsible use of scarce resources. In essence, it is irresponsible, and thus, unethical to invest human and financial resources in a project that will not produce any beneficial outcomes. As stated by the Nuffield Council on Bioethics: "Research which is not appropriately designed will fail to provide answers to the questions posed by the research, and thus will have limited benefit or no benefit either to the participants, or to the wider community" (NCB 2002: 102).

The Nuffield Council on Bioethics (2002) describes the duty to conduct scientifically sound and reliable research as one of the fundamental ethical principles in research ethics. The Council states that there is a "need for research to be based on sound scientific principles, on knowledge derived from laboratory and animal experiments if appropriate, and on a sound understanding of the scientific literature" (NCB 2002: 57). The Council further states that: "rigorous scientific evaluation of each research proposal is essential" (NCB 2002: 102).

If the REC does not have the subject expertise to evaluate the scientific merit of the proposal, then it should be referred to an external expert for peer review. Ideally, ethics committees should adopt the same rigorous and independent peer-review process that is used

by funding bodies, philanthropic trusts, research councils and journal editors. Whilst this may add extra time to the process, (and therefore may be a source of frustration for researchers) ultimately, it will save time because projects that are unlikely to generate a publishable result, will be screened out at the initial phase of ethical review, rather than the end phase of peer review for publication. Furthermore, the comments received from the REC will often enhance the design, and hence, success of the project. It is worth emphasising that the ultimate role of a REC is not to obstruct or delay research, but rather, to facilitate, support and encourage good research practice. RECs are simply a quality assurance and quality enhancement mechanism for ensuring that the highest quality of research is maintained.

In some cases, a research proposal has already undergone scientific peer review if it has been submitted for competitive external funding and has been successful in receiving this funding. When this occurs, ethical review by a REC is still necessary because the research council or funding body will not scrutinise the ethical details. For example, the sponsors will not examine the practical elements such as the participant information sheet and consent forms, they will not explore how the data will be stored and destroyed, and they will not assess the researcher's plans for protecting the dignity, privacy and confidentiality of every participant. Hence, scientific review is a necessary, but not sufficient criteria for ethical research. Good quality research requires both scientific *and* ethical review.

When reviewing the scientific merit of a project, the members of a REC (or the experts on an independent review panel) should generally reject proposals that investigate topics that are trivial, frivolous or futile on the basis that committing resources, and exposing participants to risk, for a frivolous or futile project is unethical. This stems from a belief that the responsible conduct of research includes the responsible use of scarce resources. Researchers have a duty to demonstrate that the anticipated benefits arising from their work are sufficient to warrant the investment of time and resources and the exposure of participants to risk. If the proposed research is devoid of intellectual substance (i.e. frivolous) and devoid of any prospect of a useful outcome (i.e. futile), then it is difficult to justify committing financial and intellectual resources to the project.

One of the problems with this criterion for ethical assessment is the definition of trivial. For example, a research project that is designed to develop a better technique for cosmetic surgery may be perceived as trivial to some, yet to others, the results may make a significant contribution to the branch of reconstructive medicine that makes a significant difference to a patient's psychological health, mental well-being and quality of life. In essence, the line between cosmetic and reconstructive surgery can be difficult to draw.

It is noteworthy that under the UK's Human Fertilisation and Embryology Act (1990, 2008), the use of human embryos is only permitted for a restricted number of specified research purposes. These include: "promoting advances in the treatment of infertility; increasing knowledge about the causes of congenital disease; increasing knowledge about the causes of miscarriages; developing more effective techniques of contraception, or developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation" (HFEA 1990). The use of human embryos for trivial research is prohibited and a licence will not be granted by the Human Fertilisation and Embryology Authority for researchers to use human embryos for trivial purposes.

Not only should RECs reject proposals that are trivial, and thus offer no clear benefit to science or society, they should also reject proposals that merely replicate or duplicate previous studies. Originality is an important element of scientific work, and should be an integral part of assessing the scientific merit of a proposal. In the *Research Governance Framework,* the Department of Health (2005) states that: "Research which duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical" (DH 2005: 13).

An exception to this may be in the case of undergraduate student projects, which are primarily designed to teach students how to conduct research and how to use different research techniques. Another exception may be in the case of studies that replicate a previous study to verify the results. Reproducibility is an important part of scientific work, and means that the results of one research team can be verified through repetition. If the results cannot be reproduced, then the validity and reliability of the original study is called into question.

An important question for the REC is how original does the project need to be to be considered 'original?' Is it sufficient to ask the same question, but perform the study at a different time, or in a different place, or using a different sample? For example, a study conducted in 1912 may be repeated in 2012 and the originality lies in the temporal difference and the comparative analysis that this may generate. Another example may be the repetition of a study conducted in one country with a large heterogeneous population in a second country with a small homogeneous population. The originality here lies in the cultural, political, socioeconomic or geographical difference and the comparative analysis that this may generate. A third example may be the replication of a study protocol that involved the participation of young males in a new study that recruited young females. In this case, the originality lies in the different sample and the capacity to explain any differences that may arise from this gender difference.

RECs should also assess the dissemination strategy of a research proposal and should reject, (or request amendments), to proposals that have no plans for publishing or communicating the results. This dissemination strategy should include making the results available to the participants, the general public and the scientific community. Dissemination may be in the form of a short article in a newsletter, a conference paper or a research article in a peer-reviewed scholarly journal. RECs must accept that some research cannot be published immediately due to intellectual property agreements.

As discussed above, it is unethical to conduct a project that does not generate an original, substantive and beneficial result. It is equally unethical to conduct a project that generates a result that is never communicated. Whilst knowledge does have intrinsic value, the greater value comes when knowledge is transferred into practical applications. It is the cumulative and incremental nature of scientific work that knowledge builds upon prior knowledge. This requires that researchers have access to the data and results of previous studies. According to the Department of Health: "There should be free access to information both on the research being conducted and on the findings of the research—positive or negative—once these have been subjected to appropriate scientific review" (DH 2005: 14).

Researchers in receipt of public funds, (i.e. taxpayers' money), have an obligation to disseminate the results back to the taxpayers. In essence, taxpayers have a right to a return on their investment. In this case, the information should be presented in a language and format that is informative and engaging for the general public. Communicating the results to a journalist, who then writes an article for a newspaper, may fulfil this requirement. The funding bodies, research councils, private organisations and charities that support biomedical research likewise want a return on their investment and will usually require an executive summary of the findings along with copies of the full article and report.

Increasingly, gaining ethical approval for a project is a pre-requisite for gaining access to patients, being awarded grant money and for getting research published in scholarly journals. The International Committee of Medical Journal Editors now advise that editors should seek evidence of ethical review and approval before publishing (ICMJE 2010). Thus, as Cave and Nichols suggest "increasingly, journal editors are seen as a final barrier to unethical research" (Cave and Nichols 2007: 187). This reiterates the idea that ethics is a continuous process and does not stop after receiving a letter from the ethics committee.

As part of their comprehensive assessment of research integrity, RECs should assess the competence of the researcher and should reject a proposal if the researcher cannot demonstrate the necessary competence to conduct the research. The REC may not carry out the competency assessment, but they should request that the researcher submits a letter, licence or certificate showing that they have the necessary qualifications and experience. This stems from the common sense principle that research conducted by incompetent researchers increases the risk to participants. It is therefore unethical and should not be approved by a REC whose overarching goal is to minimise exposure to risk. This principle is articulated in the Department of Health's *Research Governance Framework* which states that: "Quality in research depends on those responsible being appropriately qualified, with the skills and experience to use their professional judgement effectively in the delivery of dependable research" (DH 2005: 6).

In clinical research, it is essential that the researcher has the necessary qualifications and clinical experience, or alternatively, is working in collaboration with someone who has the appropriate skills and qualifications. In the case of laboratory work, the researcher needs to provide evidence to the committee that they are familiar with current laboratory health and safety rules and that they are experienced in using the relevant laboratory equipment and techniques. Working with biohazardous materials, toxic chemicals or radioisotopes presents a risk to the researcher and to others working in the laboratory and therefore, guided by the bioethical principle of nonmaleficence, the REC have a duty to minimise the risk of individuals being exposed to harm.

Competency is not limited to clinical and laboratory research. In qualitative research, a researcher can cause emotional harm to participants if they are offensive or insensitive in the way they conduct their interviews, or if they fail to protect the interviewee's confidentiality. Good interviewing and communication skills are therefore an important part of the competency skills required for qualitative researchers. Good interviewing skills are not only necessary for collecting quality data, they are essential for ensuring the ethical validity of the data.

Ensuring Compliance with Current Legislation and Prevailing Social Values

In addition to assessing the process for obtaining informed consent, the risk/benefit ratio, the scientific integrity of the proposal and the competency of the researcher, the REC should also ensure that the research proposal is compliant with all the relevant laws and regulations of the country in which the research is to be performed. At the same time, the committee should ensure that the proposal is consistent with the norms, values, beliefs, customs and traditions of the society in which the research is being conducted.

Recent years have seen an increase in the number of laws that directly or indirectly relate to the conduct of biomedical research. Examples from the UK include: The Data Protection Act 1998; The Human Rights Act 1998; the Human Fertilisation and Embryology Act 1990, The Health and Social Care Act 2003, The Human Tissue Act 2004, The Mental Capacity Act 2005, the Safeguarding Vulnerable Groups Act 2006; The Medicines for Human Use (Clinical Trials) Regulations 2004 and The Equalities Act 2010.

In order to assess whether a proposal is compliant with current legislation, the members of a REC need initial and continuing training in both research ethics and any relevant legislation (European Forum of Good Clinical Practice 2001). It is unrealistic to expect committee members to comment on the legality of a proposal, if they are unfamiliar with the terms of the relevant laws. This training requirement has been recognised by the Nuffield

Council on Bioethics, which states that: "for research ethics committees to function effectively, committee members must receive adequate training" (NCB 2002, 108).

Cummins (2002) suggests that as the laws and regulations governing biomedical research increase in volume and complexity, RECs will need to become more professionalized, and will need to undergo a more formal process of accreditation, quality assurance monitoring and independent audit (Cummins 2002). This places a high demand on the members of a REC, who must assess the ethics, the law, the scientific merit and social acceptability of a proposal. Many foresee the growth of private RECs, which will operate on a for-profit basis and which will offer specialist ethical advice and review (Petryna 2007). According to Cummins, it is likely that bioethics consultation will gradually become an autonomous and specialist profession, a move away from the current system of bringing together individuals within an institution who volunteer to represent their different disciplines (Cummins 2002). Whilst this may offer a number of advantages such as promoting independence of the REC from institutional conflicts of interest, and making the application process a more objective, uniform and standardised process, it will inevitably raise the cost of conducting research.

RECs should not only assess whether the research is compliant with all relevant legislation, but also whether it is consistent with the local values, norms, customs and traditions of the region in which the research will take place. Conducting research that is offensive to local values and traditions is unethical and should not be approved by a REC even if it complies with all the relevant legislation and even if the scientific value of the research is judged to be of great significance.

To assess the possible impact of the research on social norms and values, a REC should include members from the lay community and for research that will be conducted in a developing country, the REC should include a representative from the developing country. This lay representative will help to ensure that the research is socially and culturally sensitive and non-exploitative. The Nuffield Council recommend that: "in some countries, it is considered an advantage to have a majority of members in a research ethics committee who are not professionals in the various fields covered by research (sometimes referred to as lay members). Their primary role is to reflect the values of the local communities and the local and national culture" (NCB 2002, 105).

In some cultures, especially those characterised by a collectivist rather than individualistic value system, it is expected that the researcher will obtain consent from both the individual participants and from the wider community in which the individual is located (NCB 2002). Some studies present a risk to the entire group and therefore group consent should be sought, or where this is impractical, the researchers should engage in a community consultation exercise. For example, research in population genetics may give rise to data that suggests that a particular ethnic group have a higher than average incidence of a disease-causing mutation. In turn, this may result in the stigmatisation or discrimination of the whole group. The group may therefore decide to dissent from the study. Likewise, a study may reveal a higher than average incidence of mental illness or sexually transmitted infections, which could stigmatise the group as a whole or harm the reputation of the group. To illustrate this social risk, Beauchamp (2011) has discussed a case study on the collection of genetic data from members of the Havasupai tribe. This data was initially collected for diabetes research, but was then used in a secondary study to show a higher incidence of schizophrenia (Beauchamp 2011). These social risks, (the risk of stigmatisation, prejudice, defamation or discrimination), should be considered by the REC alongside any physical or health risks to individual participants.

Being sensitive to the possible effect of a research project on social values, customs and traditions suggests that REC should develop flexible, local policies and procedures rather

than adhere to rigid universal standards. Universal documents and international standards should inform the policies adopted by a local REC, but local variation should guide the ultimate decisions (Edwards et al. 2004a). Ethical imperialism should be avoided, and more ethical relativism should be encouraged (Petryna 2007).

Some examples of international documents that inform local ethics guidelines include: *The Nuremberg Code* (1947), *The Belmont Report* (1979); the *Universal Declaration of Human Rights* (1948); The *Declaration of Helsinki* (WMA 1964, 1975, 1983, 1989, 1996, 2000); The *International Guidelines for Ethical Review of Epidemiological Studies* (CIOMS 1991); and The *International Ethical Guidelines for Biomedical Research involving Human Subjects* (CIOMS/WHO 1993).

The advantage of following international guidelines is the standardisation of procedures and the consistency of decisions. This is especially true for large clinical trials that often involve international, multinational or multisite collaborative research teams (Hirtle et al. 2000). The disadvantage of following international guidelines is that they can be too rigid and do not allow for local variation in values, beliefs, customs, norms and traditions.

The Nuffield Council on Bioethics (1999) states that the various international guidelines were never intended to deal with the more detailed aspects of clinical protocols, which are sometimes controversial and are therefore open to different interpretations. Guidelines are only intended to provide general guidance. For example, a clinical trial to test a more effective contraceptive may be approved in a largely secular country, but strongly opposed in another country, which has a high Catholic representation. Similarly, different countries vary in their attitudes towards the use of human embryos in stem cell research and this difference can be largely explained by the different religious beliefs and normative structures of the society (Salter and Salter 2007).

Providing a Monitoring and Consultancy Service

Recognising that research can take on new directions as data is collected and as the process of analysis begins, RECs should monitor the progress of research at regular intervals. Any significant changes to a protocol should go before the REC for re-approval. A new participant information sheet, or revised consent form may be needed if the participants are being asked to do something extra, or different from what they originally consented to. The committee should retain the right to suspend or revoke approval if the project changes direction and becomes unethical (Hirtle et al. 2000).

Studies in the history, philosophy and sociology of science have shown that research is a fluid, dynamic elastic, creative and opportunistic process with much uncertainty and contingency (Feyerabend 1975). Research is never a perfect linear process that unfolds in accordance with the precise details given in the initial research protocol. As Hoonaard suggests: “much research grows out of serendipity” (van den Hoonaard 2006: 267). Acknowledging the contingency, fluidity and serendipity of the research process, ethics should also be seen as a dynamic and continuous process, rather than a single event that ends as soon as the project has been reviewed and approved by the committee. Submitting a proposal to a REC is just the first step in the ongoing process of conducting research responsibly and ethically. A second step is monitoring the research and to formalise this monitoring process, researchers should ideally submit an annual or interim progress report to the REC outlining what has been done and highlighting any changes that have occurred, or any difficulties that

may have been encountered. Any adverse conditions should immediately be reported to the committee.

Some analysts have suggested that a potential weakness in the current REC system is that committee members do not follow up on the progress of the data collection or the dissemination of the final results. One explanation for this is that the dissemination of the findings is generally many months, or years away from the time of granting initial ethical approval. The process of ethical review could be enhanced if RECs added this long term monitoring to their current remit. Periodic inspections and continuous monitoring by the REC should become an integral part of the research process and a copy of the final article, report or thesis (in the case of graduate students) should be submitted back to the REC for record keeping. In an article calling for more evidence based human participant protection, McDonald and Cox (2009) argue that "there is a need for monitoring of research in progress that is proportional to the amount of predicted risk and longer term follow up on the effects on research participants after research (McDonald and Cox 2009: 3). Similarly, an empirical study by Karunaratne et al. (2006) found that the current systems of monitoring by RECs are either inadequate or non-existent. To remedy this deficiency, Karunaratne et al. suggest a number of corrective strategies. The first is that an annual compliance report should be completed by the researchers and submitted to the REC, the second is that random visits by members of the REC should be made and the third is that feedback forms should be collected directly from the participants after the study is complete (Karunaratne et al. 2006).

In addition to reviewing proposals, granting ethical approval for data collection to commence and monitoring the progress of a research project, the members of a REC should be available to offer specialist advice to investigators on any ethical issues that may arise in preparing their proposal or conducting their research. This is especially true for university based RECs, where committee members should perform an advisory role and should assist in teaching their research students how to conduct research ethically, professionally and responsibly. Thus, the university-based REC performs an important role in socialising, informing and cultivating the next generation of responsible scientists.

This consultative role has been recognised by the Nuffield Council on Bioethics in their statement that: "the activities of RECs need not be confined to approving or rejecting proposals for research. They may also play an educational or advisory role by suggesting modifications to proposals that are consistent with ethical requirements" (NCB 2002: 107). Similarly, the Department of Health defines a REC as a "committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards" (DH 2001: 19).

Conclusions and Recommendations

Research ethics committees were originally established to protect the health, safety and well-being of researchers and research participants. Over time, the role of the REC has expanded and diversified. Part of this diversification can be explained by the emergence of new technologies, part from the growing public awareness of the impact of science on society, part from the growth in international and multinational research collaborations and part from the emergence of a "Risk Society" which is more sensitive to the high-consequence risks manufactured by modern science and technology (See Beck 1992). Whatever the cause, this expansion has brought forth a need to reassess the fundamental roles and responsibilities of the REC. The aim of this paper was to make a contribution to this important debate.

In reassessing the role of RECs, this paper concludes with a set of recommendations for researchers preparing proposals for ethical review and for the members of RECs who assess proposals. The following is summary and outline of these recommendations.

- RECs should ensure that the researcher will provide an accurate and accessible participant information sheet and will obtain and document informed consent from all participants.
- RECs should ensure that the researcher will protect the privacy and confidentiality of participants and will comply with data protection legislation.
- RECs should ensure that any incentives offered to participants are non-coercive, and that they do not compromise the voluntary nature of consent.
- RECs should conduct a risk/benefit analysis taking into consideration any physical or psychosocial risks to the participants or the researchers.
- RECs should ensure that the participants will not be subjected to any harm, abuse, manipulation, coercion, undue influence, intimidation, or exploitation.
- RECs should assess the scientific validity of a research proposal and should either reject, or recommend amendments, when a proposal lacks scientific rigor.
- RECs should reject proposals that investigate topics that are trivial, frivolous or futile on the basis that committing resources, and exposing participants to risk, for a frivolous or futile project is unethical.
- RECs should assess the originality of a proposal and should normally reject proposals that lack originality on the basis that committing resources, and exposing participants to risk, for a project that lacks originality is unethical.
- RECs should assess the dissemination strategy of a research proposal and should recommend amendments when proposals have no plans for publishing or communicating the results to others who may benefit from the findings.
- RECs should assess the competence of the researcher and should reject a proposal if the researcher cannot demonstrate the necessary skills, competence and qualifications to conduct the research.
- RECs should ensure that the research proposal is compliant with all current legislation.
- RECs should ensure that the research is consistent with the social norms, values, beliefs, customs and traditions of the location in which it will be conducted.
- RECs should monitor the progress of research at regular intervals to ensure continual compliance with ethical standards.
- RECs should perform an advisory or consultative role and members of RECs should offer specialist advice to investigators on any ethical issues that may arise in preparing their proposal or conducting their research.

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