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Improvements to the Ethical Review Process are Good News for Psychologists and Health Researchers in Europe, especially in the UK

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Amid the doom and gloom surrounding the European Union's (EU) economic situation, one stream of activity gives cause for optimism: health research. Not only have recent changes made life much easier for health psychologists, but also the UK government wants to streamline all health research in the UK to make it more cost effective, if not profitable (Secretary of State for Business, Innovation and Skills, 2011). These improvements have been applauded by the research community. Indeed these improvements might even make the UK the country of choice for health-related research in the EU, something that would have been unthinkable six or seven years ago. Some of the changes I outline below are specific to the UK, and I would be interested to hear from psychologists in other parts of Europe regarding any recent changes to the ethical review process there.

The benefits of taking the time to conduct good research should be obvious to anybody interested in the wellbeing of human kind. Indeed patients should feel reassured if their doctor is actively involved in cutting-edge research aimed at improving their condition. Equally obvious is the degree to which psychologists appreciate the importance of ethics in research – the lessons learned from famous studies by Milgram and Zimbardo et al. are drummed into the mind of every psychologist from the earliest stages of education in psychology. All psychologists in the EU are now obliged to follow a code of ethics based on the guidelines described in the Declaration of Helsinki (World Medical Association, 2008), itself based on the Nuremberg Code (1949). In the UK this code of ethics is described by the British Psychological Society (BPS, 2009) and broadly similar guidelines (respect for participants, competence of the psychologist, responsibilities of the psychologist, and integrity) apply across the EU, for example, the European Federation of

Psychologists' Associations (2005) *Meta-Code of Ethics.* The psychologist is at all times bound by ethical guidelines. These codes not only protect the research participant, but also protect the researcher and their institution by helping them to conduct work that is ethically sound and thus not inviting disrepute or legal liability issues. Because of heterogeneity of interpretation of guidelines the researcher is well advised to seek the opinion of their local research ethics committee (REC). The BPS also offer guidance on ethics and ethical approval on their website (BPS, 2011).

For psychologists in general, ethical review is best handled by institutional (departmental or university-wide) (RECs, but for health psychologists working with hospital patients there has been an additional step in the research process - the hospital REC. (Allmark and Tod (2009) provide a good outline of the hospital REC process in the UK). Permission to do psychological research in a hospital context requires approval from the hospital REC and the university REC. Although the REC system is based upon principles (Nuremberg Code, 1949) designed to prevent the recurrence of travesties of the kind seen in concentration camps in World War II, hospital RECs – especially in the UK - have earned a reputation for causing long and unreasonable delays to everyday research studies, and for treating psychology studies with a mix of scepticism and confusion.

Six years ago I wrote an editorial for the EJOP outlining the history of problems with health research in the UK (Barry, 2006). My own experiences up until that point with hospital RECs had been typically abysmal; unnecessary delays caused by a National Health Service (NHS) research ethics committee had very nearly prevented the completion of my MSc Health Psychology dissertation and the same thing looked like happening to my PhD. I was by no means alone in my problems with the RECs; the discontent of years of dissatisfaction from health professionals of all kinds was coming to a head at this time, and shortly before my editorial was published, a report came out (Department of Health, 2005) that outlined new guidelines that would soon come into force, altering the face of health research in the UK and across the EU. In my previous editorial on this subject I could only hope that the Department of Health guidelines would have a positive impact, and I am delighted to say that the present editorial is largely a fortunate story of improvements to the REC system in the UK.

As far as changes across the EU are concerned, one major improvement for health psychologists was removing the problem of the REC making judgements regarding the scientific merit and statistical credibility of a study. Previous to this an REC might, for example, review an interview-based study and delays of several months might ensue while the REC – not used to dealing with psychological studies - struggled with

the idea that a low-risk qualitative study need not be treated in the same way as, say, a randomized controlled trial (RCT) of a new type of medication. The university RECs – who will probably understand the methodology of the study much better than the hospital REC – have generally made their approval entirely contingent on the hospital REC's approval, a bit like a dentist waiting for the opinion of a chiropodist before a tooth can be pulled. Researchers of all kinds have argued that the ethics committee should stick to making judgements on ethics not science, but the standard response has always been that it is unethical to ask patients to participate in a study that is scientifically flawed. Today however researchers seek experts in relevant fields to review their study prior to REC review, and pass on these external reviews to the REC. In some cases an REC may commission an external scientific or statistical review of its own, as long as this does not cause delay to the review process.

Another bonus for researchers in the EU has been the adoption of a 60-day time limit in which the REC must come to a decision on a study. This '60-day clock' starts and stops at various points until the review is complete. The limit is measured in calendar days i.e. includes weekends, holidays etc. It starts at the time the REC receives the application, stops when the REC sends further correspondence to the researcher, restarts when the researchers reply, and so on. Even if the REC commissions its own external review or seek other advice, the clock will continue to run. At present the vast majority of studies are not approved on first application and need to submit amendments of various kinds (e.g. changes to the wording of the patient information sheet) before research can begin. As an additional measure to keep the process timely, RECs are required to give at least a provisional opinion to the researchers within ten days of the REC meeting. Although National Research Ethics Service (NRES) have a complaints procedure, in practice there are no very strong incentives for an REC to keep to time limits because there are no penalties as such for exceeding time limits.

In addition to the changes that are common across the EU, hospital ethical review in the UK has undergone other improvements. One major improvement for psychologists is that since Sept 2011, NHS REC approval for low risk, uncontroversial questionnaire studies is now quicker and requires much less paperwork than before. The review process has been streamlined for questionnaire studies recruiting NHS patients or staff provided that (a) the topic is not considered highly sensitive and (b) disclosure (accidental or otherwise) would not have serious consequences (NRES, 2012a). Questionnaire research of this kind will be 'fast tracked' via the proportionate review service (PRS; NRES, 2012b). Proportionate review has already

been successfully adopted by US and Canadian RECs. Because NRES now recognises that many psychological studies carry minimal risk, PRS has become a major benefit to health psychologists. The PRS route requires less paperwork that a full review, and NRES is planning to reduce the paperwork burden even further. PRS is much faster than the traditional full review time, taking an average of 13.2 calendar days for a decision to be given, roughly three times faster than the time usually taken (~35 days). On the down side, it should be noted that the REC's decision may be the recommendation of a full review of the study, or even outright rejection of the study. A study might be rejected because it does not meet the criteria for review by PRS, and it is important that researchers check the qualifying criteria before submission (see NRES, 2012b).

The new policy regarding questionnaire studies suggests that NRES have begun to recognise a fact that many people will consider common sense; just because for every study there is inevitably a risk of causing distress to a participant, it should not mean that theoretical potential for distress ought to be an obstacle to the study taking place. Research evidence supports the common sense view; a systematic review found that even in psychiatric patients – by definition a vulnerable group – less than 10% experienced distress (e.g. anxiety, depression, embarrassment, regret) due to interview or questionnaire assessments of their mental state (Jorm, Kelly, & Morgan, 2007). In most cases the distress was of short duration, and more often the participants felt positively about having taken part in research.

More good news for UK researchers - further improvements are coming. One persistent problem facing RECs has been the heterogeneity of decision making across the 81 RECs in the UK. To take a real example, one UK REC has a policy of forbidding chief investigators from recruiting participants, while another has a policy of insisting that chief investigators must recruit participants. Two steps being taken should reduce this type of inconsistency. Firstly, predefined 'template approval' of elements of a study that are common across studies will ensure that certain aspects of research should always be viewed in the same way by all RECs. Secondly, 'shared ethical debate' is a new process by which RECs discuss and reflect on examples of each other's decision making. Another planned improvement is the promotion of 'programme approval' which will give general approval for a set of studies within a defined research programme. The template approval and programme approval routes are being trialled by NRES under the guidance of the Health Research Agency (HRA) and the results of this will be published in April 2012.

The setting up of the HRA is very good news for anyone interested in health research in the UK. However the HRA is part of the NHS and, unlike the 2005 EU Directive, will

not have a Europe-wide effect. My advice is that health psychologists and other health professionals press for the implementation of the HRA's spirit of change in all countries in Europe. This is important because what happens in medical ethics usually 'trickles down' into how ethical review is implemented in the social sciences.

Health psychologists need to be aware that research involving NHS patients, staff, premises or equipment requires approval from another body – the Research and Development (R&D) Department. This is a unit that is entirely separate from the RECs, and their approval for NHS-related research is needed even in cases where REC approval is not. Although the R&Ds are generally only concerned about the financial costs that a study might incur to the hospital, occasionally R&D departments can cause delays, even where a study incurs no cost to the hospital. Although the REC system has been improved in the past few years, any changes to R&D are generally more relevant to medical research than psychological research. A review by the Academy of Medical Sciences (AMS, 2011) of the state of health research regulation in the UK concluded that there was lots of ways research approval could be streamlined in both RECs and R&D. Since Dec. 2011 the improvements suggested by the AMS have been overseen by the HRA.

It is interesting to note that the improvements in recent years mostly involve reducing the degree of influence of RECs on research activities. Prior to 2005/06 the UK had become an unattractive place to do health-related research largely because of the over-zealous application of ethical principles, and the research industry often took its business elsewhere. Today, the main obstacles to conducting health psychology research in the NHS have been fixed. However RECs – whether hospital or university – still may vary enormously in how facilitatory or obstructive they are towards research. This heterogeneity can be the result of idiosyncrasies of the REC members in the decision making process. In the same way that the police should not use the law to settle personal grudges, REC members should not use ethical guidelines – or rather the over-interpretation of ethical guidelines - as a way to create obstacles to legitimate research projects. In other words, all RECs should be very much guided by the second part of the NRES mission statement - "to facilitate and promote ethical research that is of potential benefit to participants, science and society" (NRES, 2012c). To borrow from a comment by a well-respected psychologist: it's generally acceptable to ask someone 'How are you feeling today?', but if this question is asked as part of a psychological research study then it might take many hours of paperwork, protracted meetings, and many weeks of waiting before a university ethics committee will allow the question to be asked. In the busy world of university life researchers simply don't have time to struggle with unreasonable delays, and if a

massive organisation like the NHS can change for the better then maybe it's time for university RECs to change too, for example, by initiating shared ethical debate and other strategies to reduce heterogeneity in decision making.

NRES costs UK taxpayers £10 million per year, and if this money is spent on facilitating research that will benefit patients, add to scientific knowledge, and make the UK a place that welcomes top quality research programs, then this is money well spent. I hope that universities in the UK and Europe take note of the significance of the improvements to the NHS REC system and make similar sensible changes.

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