

Good Practice Guidelines for the Conduct of Psychological Research within the NHS

This Report is published under the auspices of the British Psychological Society and the Professional Practice Board, Division of Clinical Psychology, Research Ethics Practice Working Party of the Training Strategy Group, The British Psychological Society, St Andrews House, 48 Princess Road East, Leicester LE1 7DR.

#### This report was written by:

Myra Cooper

Oxford Doctoral Course in Clinical Psychology, University of Oxford.

**Graham Turpin** 

Clinical Psychology Unit, University of Sheffield.

Romola Bucks

School of Psychology, University of Southampton.

**Gerry Kent** 

Clinical Psychology Unit, University of Sheffield.

Address for correspondence:

Dr Myra Cooper Isis Education Centre, University of Oxford, Warneford Hospital, Oxford OX3 7JX.

Tel: +44 (0)1865 226431 Fax: +44 (0)1865 226364

E-mail: myra.cooper@hmc.ox.ac.uk

The report will be submitted for publication to *Clinical Psychology* and made available separately as a DCP/PPB publication. The Executive Summary will be submitted to *The Psychologist* for publication. It is also proposed that it should be referred to within the revised ethics guidelines (BPS, 2004) and endorsed by the Society. We acknowledge Dr Angela Carter for contributing to the report from the perspective of occupational psychology.

## **Summary and Recommendations**

The new systems of NHS research and ethics governance pose particular issues for postgraduate education in applied psychology, which is frequently (and necessarily) conducted throughout the NHS, as well as for the conduct of psychological research *per se.* This may have serious consequences for the continued development of the knowledge base underpinning both psychological healthcare and patient care within the UK.

To begin to resolve some of these issues, a series of meetings has taken place within the British Psychological Society and also with Professor Terry Stacey, Chair of COREC. This *Good Practice Guide*, written for NHS managers, LREC members (including lay and service user representatives) and psychological researchers, is the result of these meetings.

The guide summarises for non-psychologists the nature of psychological research, types of research conducted by psychologists, and their contribution to the health care knowledge base. It also summarises the BPS guidance that exists to inform ethical practice and research in psychology. For psychologists, there is a summary of NHS Research Governance and LREC/MREC procedures, and advice on how best to engage with NHS services.

The guide deals with distinctions between research and audit activity. It also highlights the importance of service evaluation or improvement projects. The role and contribution that psychologists make in devising and conducting research and research-related activities is emphasised, together with the importance attached to these activities as evidenced by numerous DoH and NHS documents, policies and procedures. The role of service users within the conduct of psychological research is also addressed.

Research Ethics Committees and Research Governance procedures are reviewed from the perspective of psychological researchers and advice offered on the important distinction between research and clinical audit activities.

The various responsibilities of psychological researchers are discussed and include topics such as honorary contracts, indemnity, the time involved in setting up ethics and research governance approval, whether or not the research is student research, timely and full communication with RECs, the importance of preventing or undoing harm or distress, completion of paperwork, the importance of data protection and data storage, and risk management.

The following recommendations are made:

#### Recommendations for RECs and NHS Trust R&D (and clinical audit) Departments.

- 1. Many of the difficulties here would be resolved by a clear and transparent definition of audit and research that is agreed upon by RECs, and by Trust R&D and Clinical Audit departments. Ideally, it should be nationally disseminated and available to researchers, whose responsibility it would then be to make a decision about whether or not REC approval was required.
- 2. The role and status of service improvement projects must be addressed as a matter of urgency.
- 3. The length, method and storage of data and whether or not it should be destroyed needs to be agreed.
- 4. The role of clinical audit departments and staff in the planning and implementing of audit (small scale) studies conducted by students needs to be addressed and agreed. This presents additional and different challenges, and may require addressing in a separate document.
- 5. There should be agreement that a university's peer review procedures, if appropriate, may be used in place of R&D peer review, for R&D governance procedures.
- 6. Consideration should be given to how contracts issued by individual NHS Trusts to trainees might cover them both for clinical and research work undertaken in their employing Trust, and might also apply to other Trusts, thus removing the need for multiple honorary contracts.
- 7. Consideration should be given to clarifying the use of a single MREC approval for large-scale research projects that involve many NHS Trusts, and that does not require further local scrutiny and changes to be made.

#### Recommendations for psychologists (and students) conducting NHS research

- 1. Psychologists must be prepared to become members of R&D and REC Committees. This would facilitate communication, and understanding, of all the relevant issues that bodies involved in research governance developments are experiencing. However, until applied psychologists become members of the Health Professions Council and are subject to statutory regulation (Turpin & Stacey, 2004), recent REC regulations prohibit psychologists from being expert members of the committee although committees do maintain the option to recruit psychologists as lay members.
- 2. Training courses in applied psychology should ensure that students are exposed to teaching on all aspects of ethical practice including research, audit and clinical activities.
- 3. Research supervisors must do their utmost to ensure students have considered and are aware of all relevant recent developments in research governance and RECs.
- 4. Psychologists should ensure that all research and audit activities (including service evaluations, single case evaluations and service improvement projects) are subject to ethical consideration and, where appropriate, scrutinised by the *appropriate* body (e.g. LRECs, SPECs or local departmental ethics committees).
- 5. Psychologists should ensure that due attention is paid to issues of informed consent and capacity, and any changes in practice brought about by the proposed Mental Capacity Bill (*pers. comm.*. K. Ehlert, August, 2004).
- 6. Supervisors and students must ensure that their practice conforms to local NHS Trust and ethical approval procedures, as well as the Society's own ethical guidelines,

## Ethics, research governance, and psychological research within the NHS: A good practice guide

#### 1. Introduction

Within the last few years major policy and procedural developments have been introduced into the NHS with regard to 'research governance'. Many influences are at work here including a greater focus on peer-reviewed, high quality NHS research, greater accountability of clinical researchers following the Alder Hey Enquiry (HMSO, 2001), and the Clinical Trials Directive outlining ethical procedures for conducting therapeutic trails. Indeed, the Government laid The Medicines for Human Use (Clinical Trails) Regulations 2004 before both Houses of Parliament on 1 April 2004 and this Bill implements the European Clinical Trials Directive (Directive 2001/20/EC) in UK law. The Regulations came into force on 1 May 2004. This has implications for the conduct of all research, not just clinical trials involving new medicines, as the Government has decided to have one set of regulatory standards for all NHS research.

The current policy changes originate from the Department of Health's Research Governance Framework for Health and Social Care (2001) and the Governance Arrangements for NHS Ethics Committees (GAFREC, 2001). This working environment for NHS research potentially poses psychological researchers with new challenges. These include greater accountability, more intensive ethical scrutiny, open peer reviewing and NHS approval of research, greater clarity over the use of NHS resources, and the involvement of users within the research process, to name but a few.

Although many of these developments are to be welcomed and will protect NHS clients and resources from potential abuse, the implementations of some of these policies has the potential to make some important (and necessary) forms of psychological research difficult to carry out (Peck & Jones, 2004). This might include research that has even been given a high priority within DoH policy and publications, and which can be seen online in the Research and Development section of the DoH's website (http://www.dh.gov.uk/PolicyandGuidance/ ResearchandDevelopment/fs/en) or that which has been commissioned and funded by the DoH. Psychologists are not alone in being critical of the introduction of these new procedures, and articles, letters and guidance have recently been

published with regard to medicine (Norman, 2004; Greenhalgh, 2004), pharmacy (Jesson & Wilson, 2004) and nursing (RCN, 2004).

Moreover, many of these new arrangements have been introduced only very recently and the organisational structures to support the new governance arrangements are still in the process of being established (COREC, 2004) resulting, sometimes, in long delays or uncertain time scales for the completion of many NHS research projects. Indeed, further new proposals concerning the ethical scrutiny of student research projects in the NHS have only just been released for consultation (Doyal, 2004).

Following on from the introduction of these new procedures, many psychology researchers and students, university lecturers and research supervisors, as well as NHS clinicians and managers, have begun to familiarise themselves with and assimilate these important but complex new arrangements. We believe that the new systems of research and ethics governance pose particular issues for postgraduate education in applied psychology, which is frequently conducted within the NHS. By students, we refer mainly to postgraduate students either for a research degree (e.g. PhD, DClinPsy) or for a postgraduate professional qualification within a branch of applied psychology (e.g. MSc or DPsys in clinical, occupational, counselling, forensic or health psychology). MSc research project students typically have only a three- to fourmonth period in which to complete and write up the research. In some circumstances, the issue might have arisen in association with psychology undergraduates but the conduct of such projects within the NHS is relatively infrequent. Moreover, it is likely that the majority of undergraduate and possibly masters level research projects will in the future be subject to Student Project Ethical Committees established within higher education institutions but with close involvement of LRECs (see Doyal, 2004).

Many of the issues highlighted in these guidelines, however, have presented themselves over the past few years in the context of clinical psychology training. Indeed, it was the Training Strategy Group of the Division of Clinical Psychology of the British Psychological Society which first established a working party specifically to examine these concerns from both practising

NHS clinical psychologists and members of the training community. However, researchers in other areas of applied psychology, particularly those associated with occupational psychology, have voiced similar concerns, particularly in relation to research which is increasingly being commissioned by the DoH and NHS Trusts in order to make health services more effective. Not only is there concern about the impact of these procedures on the conduct of psychological research per se, but there was also a more general anxiety that if research were disrupted or delayed during the course of training applied psychologists, this would result in fewer staff with research qualifications, and fewer clinical psychologists in general, taking up posts in the NHS. This would have serious consequences for patient care since clinical psychology is already considered a shortage profession (DH/HO/BPS, 2005).

Before discussing the specific problems raised, it might be useful to provide some background to clinical and other applied psychology training. Clinical psychologists obtain their pre-registration qualification by completing a three-year doctoral training course, consisting of academic study within a university and supervised clinical practice whilst on placement within the NHS. There are around 6000 qualified clinical psychologists working within the NHS, and currently there are around 1500 trainee clinical psychologists employed by the NHS at anyone time (annual intakes of approx 550 within the UK) and studying at around 30 university courses. All entrants to clinical psychology training will have obtained a threeyear undergraduate degree in psychology (four years in Scotland) and, as such, have already received extensive training in research methodology. Unlike the majority of students within the NHS who are bursaried, clinical psychology trainees are all NHS employees and. as such, are also subject to enhanced Criminal Records Bureau clearance and relevant health checks. Given the doctoral level of qualification, it is an essential requirement for all clinical psychology trainees to conduct a research thesis that is original and that contributes to the discipline's knowledge base (Quality Assurance Agency, 2004). Usually this consists of the completion of a major clinical research project within the three years, together with the conduct of one or more small-scale research projects carried out during their clinical placements within an NHS Trust. During the course of their training they receive additional training in research methods and ethics.

Occupational psychology training is currently undertaken in two parts following a degree in psychology, the first being a one-year Masters degree (or a two-year part-time degree programme) followed by a minimum of three years' supervised practice that is externally assessed. An increasing number of occupational psychologists are being employed within the NHS either undertaking clinical work in areas such as rehabilitation or supporting service development in education, personnel services or organisational development. Many occupational psychologists provide research and intervention programmes for healthcare organisations. In addition, several universities support doctoral programmes where the NHS is the principal research area. All of these programmes contain rigorous training and assessment in research methodology, statistics and ethical practice. The situation for counselling, forensic and health psychology is similar to the above consisting of either three year doctorates or a masters degree at Stage 1 followed by a second stage of supervised practice and further study within the workplace.

Within clinical psychology training, the most frequently reported difficulties with LRECs and research governance have arisen with respect to the small-scale research projects. These projects are often (but not always) audit or small-scale service evaluations, of existing practice, rather than original research and, in the past, most LRECs have not wished to consider these. Sometimes these projects are also referred to as service improvement projects. These also include single case or experimental studies of routine clinical or novel treatments (Turpin, 2001, 2002). Increasingly, however, it appears that many LRECs are either asking to see these projects, or Trusts (either research and development (R&D) departments, or clinical audit departments) are insisting that they are seen by LRECs. The consequence is that these are frequently judged using research standards rather than audit or service evaluation criteria, and are often refused approval since they are not judged to be 'research' (i.e. because they lack originality or are statistically under powered) or because of the difficulties of obtaining consent for data that have been collected as part of routine practice. These sorts of problems are making it very difficult for clinical psychology trainees to meet their course requirements. Indeed, they have the potential seriously to compromise the completion rates of pre-registration clinical psychologists – it is now not uncommon for trainee clinical psychologists to have to extend their training

(with consequent financial and employment problems for the NHS) because of delays caused by these sorts of issues. Moreover, the NHS is in danger of losing many high quality audit and service evaluation projects that are often extremely well valued by clinical placement providers/supervisors and clinical services. These projects often play an important role in the development, review and planning of local services across all areas of the NHS from mental health to physical health and medicine.

Occupational psychologists are also commissioned to undertake large-scale research projects on behalf of the DoH. Many of these projects involve, for example, in excess of 30 NHS Trusts in different regions. This necessitates both MREC, and associated LREC submissions being made in each domain1 to each LREC within a domain. The workload is an immense burden on the research team and invariably detracts from the resources available for the research. These problems could easily be avoided if the local areas accepted the MREC approval (i.e. received and acknowledged it) but did not subject the proposal to further scrutiny, or request multiple copies of applications for additional LREC review, i.e. if no further alterations could be requested by LRECs after MREC approval has been granted. We are aware that the relationship between LRECs and MRECs has been subject to recent review by COREC (COREC, 2004).

In clinical psychology, and some occupational psychology training, other problems have occurred with regard to the major research thesis which is usually (almost always in clinical training) subject to scrutiny by an appropriate LREC or MREC. Frequently, there may well be delays because of the high number of comments and suggestions made by LREC members. While some of these may be invaluable in refining the project and ensuring that it is ethically acceptable, not infrequently the comments seem to reflect confusion and ignorance about the nature and value of psychological research to the NHS. Again, delays here are a frequent cause of extensions to training and research projects, which may delay qualification for up to 12 months. Delays may also be caused by the need to obtain approval from a range of different bodies, each with their own timetable. The 'peer review' procedures now required by R&D departments may add to these delays, even though most projects have been scrutinised carefully by

internal university research committees, sometimes including external examiners. The cumulative effect of these problems has not only delayed qualification but, importantly and worryingly, resulted in significant reduction in trainees' interest in and motivation for continuing to conduct research in the NHS, postqualification. This is not a good outcome, given that psychologists, unlike many other professionals working in the NHS are trained not only to consume and understand research, but also to conduct high quality research of their own. This skill is particularly important in view of DoH recommendations (NHS Priorities and Needs Research and Development Funding, 2002), also highlighted in a recent publication on NHS priorities (DoH, 2003).

In order to begin to resolve some of these issues, a series of meetings has taken place within the British Psychological Society and also with Professor Terry Stacey who is the Chair of COREC. As a result, it was decided to produce a Good Practice Guide for NHS managers, LREC administrators and members (including lay and service user representatives), and psychological researchers. The Guide summarises for nonpsychologists the nature of psychological research, types of research conducted by psychologists and their contribution to the health care knowledge base (theoretically and empirically). It also contains a summary of the BPS guidance that already exists to inform ethical practice and research in Psychology. For psychologists, there is a summary of NHS Research Governance and LREC/MREC procedures and advice on how best to engage with NHS services. The guide also deals with distinctions between research and service evaluation and/or audit activity. The role of service users within the conduct of psychological research is also specifically addressed. Finally, there is some discussion of the key current difficulties which have already been identified, and some recommendations for their resolution are proposed. We have also included three appendices: the first helps to clarify definitions regarding research and audit activities, the second presents a flow chart to assist making decisions about distinguishing between research and clinical audit/ service evaluation projects, and whether LREC approval is required, and the third lists helpful references and websites associated with clinical research.

<sup>&</sup>lt;sup>1</sup> A domain is an area covered by a Strategic Health Authority (England), a Health Board (Scotland), a regional office of the NHS Wales Department or the whole of Northern Ireland.

#### 2. Psychological research

A popular definition of psychology is 'the systematic study of mind and behaviour' (BPS, 2003). Psychological research, therefore, is broad in nature and has contributions to make to education, health, the economy, work and social justice (BPS, 2003). The British Psychological Society (BPS) is the representative body for psychologists and psychology in the UK. Founded in 1901 (granted a Royal Charter in 1965), it has national responsibility for the development, promotion and application of psychology for the public good. It acts as a learned society but also maintains a voluntary register of Chartered Psychologists. From 2005, it is very likely that Applied Psychologists will be legally regulated through the Health Professions Council (Psychologist, 2004). Under these new arrangements it will be important to ensure that academic applied psychologists who are not registered under the HPC, since they do not offer direct psychological services to the public, retain their essential access to NHS research samples.

Many of the members of the BPS are applied psychologists; they apply psychological knowledge in specialist fields including education, health, work and the judicial system. Those who work in the NHS include (among others) clinical, counselling, health, occupational and neuropsychologists. Indeed, details of the applied psychology workforce in England, Wales and Scotland are available in a number of separate publications, although often subsumed within the broad Scientific, Therapeutic and Technical staff category (HMSO, 2003a, 2003b, 2004). The largest group within the NHS is clinical psychology (approximately 6,000 people). Many academic psychologists based within University departments of psychology are also active applied researchers within the NHS.

Psychologists conduct quantitative and qualitative research. Indeed, many clinical psychology doctorates have successfully adopted qualitative methods to study psychological clinical phenomena (Turpin et al., 1997). Research methods can involve interviews, self report questionnaires, observations and experiments. Issues that are typically addressed in psychological research include tests of theory, development of reliable and valid measures, and evaluation of the process and outcome of treatment, examination of working practices, change and staff well-being, along with organisational intervention studies. Studies may be large, conducted across multiple sites, with many hundreds of participants, and many NHS

Trusts, but more typically they involve a relatively small number of participants. Some studies focus specifically on small samples or even single case studies using either quantitative or qualitative methods to examine in detail processes underlying therapeutic change within an individual. In this they differ from some NHS research, for example, epidemiological studies that may have very large numbers of participants. It is important to recognise that there is also a distinction between psychological research and research conducted by psychologists. Psychologists may also be closely involved in research whose primary focus is nonpsychological, e.g. drug studies, epidemiological studies; to which they can bring valuable research design skills.

The importance of psychological research to the NHS is recognised, for example in the National Service Frameworks, where research and development are seen as key components in developing the knowledge base needed to implement these frameworks (e.g. NSF for Mental Health, DoH, 1999; NHS Priorities and Needs R&D Funding, DoH, 2002). Much of the knowledge gained about treatment evaluations highlighted in these publications is essentially psychological in nature. Indeed, psychological research has provided much of the evidence-base underlying recent clinical guidelines published by the National Institute for Clinical Effectiveness of schizophrenia, eating disorders, depression and the forthcoming guidance on post-traumatic stress disorder, to name just a few relevant conditions.

The majority of the occupational psychology research conducted in the NHS is by experienced researchers often working as part of a multidisciplinary research team. These projects are often large-scale (e.g. gathering data from all the A&E departments in England and Wales) and involve complex methodologies using quantitative and qualitative research methods. Experienced occupational psychologists may also support postgraduate research in NHS Trusts which, like much trainee clinical psychology work, provides input that is desperately needed to improve service delivery at very low cost to the NHS.

Within the NHS, much of the psychological research submitted to LRECs will be both from qualified clinicians and researchers based within universities and NHS, and also students undertaking postgraduate study in clinical, counselling and health psychology, as well as occupational psychology. It is important to emphasise that unlike most student research

conducted in the NHS which is considered unoriginal and should not qualify as original research (Doyal, 2004), the majority of these postgraduate student projects have to be examined to a publishable standard. Such research projects, therefore, make important contributions to the literature and are valued by both trainee and research supervisor. Student research of this type is often excellent value for money. All training courses should scrutinise the ethical (and scientific) aspects of trainee research projects before they are submitted to LRECs or MRECs. These procedures for scrutiny are rigorous and involve independent assessment by experienced researchers, and may even involve external examiners. Finally, it is worth emphasising that the scrutiny of the conduct of ethical psychological research is a major responsibility of the BPS. It produces extensive guidelines for psychological researchers, including advice on ethical issues (Code of Conduct, Ethical Principals and Guidelines, 2000; Professional Practice Guidelines, 1995), and maintains a strict complaints and disciplinary procedure for investigating and managing breaches of those guidelines. This guidance has currently been reviewed and a revised set of Guidance on Ethical research has been published (BPS, 2004).

#### 3. Research Governance

The NHS also has extensive guidance for both research governance and ethical scrutiny. The latter are also published in the documents Research Governance Framework for Health and Social Care (2001) and Governance for NHS Ethics Committees (2001). More up to date advice is available on both the DoH (http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment) and COREC websites (http://www.corec.gov.uk).

The Research Governance Framework for Health and Social Care (2001) is a set of guidelines for maintaining the scientific and ethical integrity of the studies conducted within NHS and Social Care settings. The Framework is designed to ensure that all types of research are carried out in a manner that the public can trust and support, and that the quality of such research allows it to contribute to improvements in health and provision of services. The Framework also sets out standards and describes the monitoring and assessment arrangements for ensuring that these are adhered to. Research and Development activity, including student projects, should not proceed without notification of the

staff member who is responsible for research and development within the organisation. All R&D activities must also have the approval of an appropriate ethics committee.

For the purposes of the Framework, R&D activity is defined as an attempt to discover generalisable and new knowledge by addressing clearly defined questions with systematic and rigorous methods, and/or involving experimental introduction into practice (for example, studies that examine two or more alternative methods of care and/or procedures). All studies and projects that meet this definition (see also Appendix 1) are subject to research governance. This includes most clinical psychology trainee large-scale research, but not the small-scale projects, which will typically fall under the remit of audit and/or service evaluation.

Full details about the DoH Research Governance Framework can be obtained from: http://www.dh.gov.uk/assetRoot/04/01/47/57/0 4014757.pdf.

#### 4. Audit vs Research

The distinction between audit and research is the source of considerable difficulty for clinical psychology training courses. Typically, but not always, audit unlike research, is considered by the relevant local Audit or Clinical Effectiveness Committee (under the direction of a Clinical Governance Committee) and does not need to be scrutinised by an MREC or LREC. Meeting local Audit Committee demands poses a different set of challenges, which can also cause difficulties for applied psychology projects, but these will not be considered here. The importance of a third type of project common in the NHS and in clinical psychology training has been highlighted more recently (Paxton, Whitty, Zaatar, Fairbairn & Lothian, unpublished). This has been termed 'service improvement or evaluation projects'. These do not fit, strictly speaking, most definitions of audit since they do not rely exclusively on service standards but neither are they 'research' as defined by the DoH. Hence, they do not fit neatly into any existing NHS category. A review of recent descriptions of clinical governance documents published by the DoH which detail the activities falling under the remit of Clinical Governance departments, suggests that they most clearly fall under their jurisdiction. However, their relationship to Audit Committees, designed specifically to scrutinise audit projects is unclear. Indeed, how they are to be assessed and 'approved' by the NHS does not appear to have been considered. This is a grey

area of considerable difficulty for clinical psychology training and often results in projects being passed back and forth between departments and committees, and considerable debate about who is responsible for them. This is unhelpful to everyone concerned. A similar problem arises around single case studies of routine clinical procedures in order to assess their effectiveness within a specific client. We judge that such studies ought to be the subject of clinical governance and not research governance. Clearly, however, where single case studies examine novel or innovative treatments, they should be subject to full LREC approval. A consensus, therefore, on the respective definitions and scope of audit and research, and how service improvement and single case projects fit within the current system of scrutiny and approval, is urgently needed. We discuss below their relative similarities and differences.

Audit determines whether existing clinical knowledge, skills and resources are being properly used. In contrast, research is concerned with generating new knowledge that will have general application, as for example in determining whether a new treatment is superior to an existing one or evaluating whether a particular theory provides an adequate explanation for a clinical phenomenon. The difference is between either adding to the body of knowledge (research) or ensuring that knowledge is being effectively used (audit) according to some predetermined criteria or standard of good practice or agreed protocol of care. Both collect data, but for audit findings are often relevant only to local circumstances. Audit is usually intended to influence the activities of an individual clinician, small team but also (sometimes) an entire service; while clinical research generally seeks to influence clinical practice as a whole. Thus, the primary aim of audit is to improve the local delivery of health care. Effecting change should be the intention of audit from an early stage (i.e. collection of data is not enough). Methods of dissemination will also differ between audit and research. Research is primarily disseminated through peer-reviewed journals, together with national initiatives to influence training and practice. Audit relies more on service evaluation reports and summaries written for local consumers, which may include staff and service users. However, it may also be published. Service improvement is similar to audit in many respects (e.g. it usually seeks local knowledge, and aims primarily to improve local services) but unlike audit it does not involve comparison against set standards. Paxton and

colleagues (Paxton *et al.*, submitted) provide the following useful definition: 'service improvement refers to projects that do not involve set standards, but which aim to identify issues and gather knowledge about local services in order to improve these services rather than to acquire generalisable knowledge' (p.7). They argue (in our view, correctly), that such projects should, like audit, be encompassed with the clinical governance framework, and reviewed and approved, in a way similar to that used for audit projects.

It would be very helpful if a decision tree were made available designed to help researchers and students determine if an NHS LREC (or MREC) application is required. Such a decision might then be usefully used as a marker of whether a project needs to go through research governance procedures or, as is currently true of audit, through the clinical governance procedures (i.e, both audit and service improvement projects). Nevertheless, it is stressed that both research and audit activities irrespective of which route is adopted should be subject to appropriate ethical scrutiny: ultimately the researcher is responsible to see that ethical standards of practice are upheld (Wade, 2005).

This decision tree should also address research conducted outwith NHS settings such as in social services and schools. Indeed, a recent consultation on ethical review in social care has been published (Pahl, 2004). Nevertheless, even when research is conducted outside of the NHS remit, if the researchers are located in the NHS, although they appear not to need LREC approval, in practice it is usually advisable to obtain NHS ethics approval for all research conducted by NHS employees, regardless of where it is done. Indeed Trusts are unlikely to be willing to provide indemnity for a project that has not had this approval and which they may not have been informed about. The impact of SPECs (Doyal, 2004) will also need to be factored into this decision tree once they have been approved. A suggested distinction between audit and research is outlined in Appendix 1. A possible decision tree for distinguishing between audit and research can be seen in Appendix 2.

All NHS research conducted by students or staff from University Departments of Psychology, is also likely to require ethics approval from an Institutional Ethics Committee, preferably before any NHS REC application is made (BPS, 2004). Again, this may be rolled into a single process for student projects undergoing SPEC as opposed to LREC approvals.

#### 5. Service user groups

Users have long been involved in research studies as research participants. In recent years there has been an increasing emphasis on involving users in the design and development of research. Two important websites relating to service user involvement are: CERES (Consumers for Ethics in Research), and INVOLVE: the NHS site which promotes public involvement in NHS research, public health and social care research.

INVOLVE lists important reasons for involving consumers in research, and suggests groups from which suitable people might be recruited. They also produce a number of very helpful publications and a checklist to help researchers identify the issues concerned with involving consumers (see http://www.invo.org.uk).

CERES is concerned that research be conducted ethically, and also publishes a number of documents, including a range for ethnic minority groups in different languages (see http://www.ceres.org.uk).

Psychologists should be encouraged to involve users at every stage of the research process from establishing research priorities through to the dissemination of relevant findings and clinical implications. Further discussion of these issues is covered by Telford and colleagues (http://www.sheff.ac.uk/scharr/sections/ph/research/public-involvement/completed-projects/successful-consumer.html). A more general discussion of user involvement in psychology and mental health services has recently been undertaken by Diamond and colleagues (Diamond *et al.*, 2003).

As researchers, psychologists must be sensitive to the impact of their research on participants (BPS, 2004). Strict confidentiality must be maintained at all stages of the research. The benefits and possible harm to those who take part must be carefully assessed. Researchers should have a procedure or policy in place in case any participant becomes upset or distressed. Generally, the risk of harm and distress is low in studies conducted by postgraduate psychology students. Indeed, many participants, including those who are severely affected by their problems, find the experience of a sympathetic researcher with whom they can discuss issues that are important to them, a helpful experience, even when ostensibly there is no clear benefit to them in taking part. Further discussion about minimising any risk to participants in psychological research is to be found in the new BPS (2004) guidance.

#### 6. Researcher responsibilities

Whether trainee or experienced researcher, the researcher is always responsible for his or her own actions. We have outlined below some of the major responsibilities and duties that the researcher should undertake. Further guidance around some of these topics is also to be found in Appendix 2. The list is by no means exhaustive but emphasises some key considerations for psychological researchers working into the NHS.

#### Honorary Contracts

Recommendations in the Follett Report, set up to examine University/NHS responsibilities following the Alder Hey tragedy, assume that honorary contracts are in place for university staff working in the NHS. The Follett implementation group has since recommended that NHS staff who teach or do research in universities should also have honorary contracts with the university. There is mutual advantage in this arrangement for university staff. The NHS body then accepts that researchers with honorary contracts (and thus university and other non-NHS employees) are covered, like NHS staff, by NHS indemnity, i.e. the NHS organisation must discharge its 'duty of care'. At the same time, by issuing university and other non-NHS staff with honorary contracts, the NHS organisation ensures that all researchers working on its premises with its staff, patients, and their data are contractually bound to take proper account of the NHS duty of care. Thus, honorary contracts afford protection to both parties.

Some university researchers work in many NHS organisations. This is particularly the case for those working in primary care. Only individual NHS Trusts can issue contracts - there is no such thing as an 'NHS wide honorary contract'. This also creates problems for clinical trainees who are usually employed by one NHS trust but who will have clinical placements in several Trusts and may conduct research across several trusts. Drawing up an honorary contract is often a lengthy process, and many Trusts insist on new criminal records clearance each time, increasing the time taken to set up arrangements to work in Trusts that are not the employing Trust. Fortunately, at least one 'host' Trust has successfully managed to modify trainee contracts to allow for cross-NHS Trust working without the need for further honorary contracts. With the new employment arrangements being introduced within the NHS as a consequence of Agenda for Change (DoH, 2004), discussions are taking place about a nationally agreed trainee contract which might seek to clarify indemnity arrangements for both

clinical and research activity of trainees employed by one NHS trust but working either on placement or doing research within another trust.

#### Indemnity

An Honorary Contract with an NHS trust means that, like NHS staff, researchers are covered by NHS indemnity. The situation with regard to student research, however, is less clear than it first appears. The supervisor (who usually applies as a co-investigator) takes responsibility under Research Governance for the student's study. The supervisor is not always an NHS employee, honorary or otherwise. In these circumstances, it may be advisable for the supervisor to arrange an honorary NHS contract. In the case of research conducted across many sites and Trusts this may be a lengthy process. The situation will also be dependent upon the student's status and whether they themselves are NHS employees, as is the case for clinical psychology trainees. Additionally, most universities will also have their own research governance procedures in place and will have arrangements for indemnifying their students and staff. Researchers and students should ensure that they have discussed these issues with their local R&D Department and that there is agreement as to who the Principal Investigator should be and which organisation should act as the research sponsor. Our experience, in practise, is that these arrangements vary across NHS Trust to NHS Trust.

#### Time

Although, under the new legislation, LRECs will be required to turn around applications in 60 days, the overall process of obtaining REC approval in practice usually takes a minimum of two months and can take as long as six months, if multiple localities or honorary contracts are involved. The 60-day clock will also stop if a request for further information or clarification is required from the application, and start only when a response is received. The researcher is advised to begin this process as early as possible, and to make use of all available sources of support, especially LREC administrators (for contact details in England see: http://www.corec.org.uk/applicants/contacts/ contacts.htm) and R&D co-ordinators (contact the NHS Trust which will be the main or only source of participants for your study).

#### Research governance approval

In addition to REC approval, investigators must also seek permission to conduct their study from the R&D Directorate of the Trusts where they wish to recruit and also from the relevant Data Protection/Caldicott Guardians. These bodies are responsible for ensuring that the standards set out in the Research Governance Framework are met. All NHS Trusts now require R&D approval before they will accept a submission to an REC. Many trusts are implementing a 'passport' system. This requires the researcher to obtain signatures or codes on a checklist, which allows the NHS trust to be certain that all safeguards are in place before research commences. Your REC Administrator and/or R&D Co-ordinator should be able to advise you on local procedures.

R&D approval may take an additional two months to arrange; although most R&D Departments are developing more streamlined approaches alongside the REC process, which should increase their efficiency.

#### Student research

The student research agenda is of particular interest to RECs, who have discussed it at meetings of the Association for Research Ethics Committees (AREC). The AREC website gives details of past and future meetings and can be found at http://www.arec.org.uk. A system of Student Project Ethics Committees (SPECs) is currently in development, to which student projects will be sent for ethical scrutiny. The Society generally welcomes their establishment, and has suggested that these may be a suitable place to review undergraduate projects, some MSc dissertations, and clinical psychology smallscale projects, but that large scale doctoral projects, because of their potential contribution to knowledge, should continue to be treated as original research and to be scrutinised by RECs.

#### Communication

Timely and full communication with RECs is one of the researcher's key responsibilities. Most RECs and R&D Directorates now have forms for protocol amendments, annual reports and final reports. In the absence of specific forms, RECs should be written to on the headed paper of the institution regarding any amendments to the protocol, annual and final reports of the study and with copies of any publications arising from the study. It is generally advisable to obtain advice in writing; and e-mail is usually sufficient. Postgraduate students are recommended to keep copies of all documentation and any correspondence with the RECs and Trust R&D or Audit offices. This documentation should be kept in a file and copies made available to the supervisor. Some NHS Trusts stipulate that such

'site files' need to be stored confidentially for up to 15 years. Many clinical psychology courses require a copy of the REC approval letter to be bound into the thesis in an appendix.

Preventing or undoing harm and distress

It is important to specify what steps have been taken to prevent or alleviate the potential for harm caused by a study. It is useful to divide this into actions to take before, during and after the study. Before the study, researchers may wish to consider carefully the nature of the tasks they are asking participants to complete. During the study it is important to consider what the researcher will do in the event that an individual becomes distressed. Taking a break, if possible trying a different task, or stopping altogether are the usual options. If appropriate, a short debriefing session is advisable afterwards, to explain any results, answer questions, etc.

Unfortunately, many RECs take the view that it is always unethical to ask participants questions that might upset them regarding this as an unacceptable level of distress. We would argue that with sensitive handling and full debriefing, the risk that a participant may feel anger or sadness, for example, should not necessarily be an impediment to psychological research. Firstly, many participants find such research experiences are a safe and anonymous opportunity to explore thoughts and feelings that they do not feel that they can share with family or friends. Secondly, to take such an approach prevents important research into areas such as bereavement, terminal care or following a disaster (e.g. Collogan et al., 2004), to name just a few. Thirdly, applied psychologists (by virtue of their training) are very appropriate researchers to conduct such sensitive, but essential work.

#### Paperwork

It is important to complete all forms accurately, on time and as fully as possible. No question should be omitted. If questions are clearly irrelevant then a note explaining the reason should be made, rather than leaving the space for a response blank. Guidelines on word length and style should be followed. It is very important that supplementary information such as consent forms and information sheets are compiled as directed by the guidance notes and as faithfully as possible. These can be found on the COREC website (http://www.corec.org.uk), together with the standard electronic application form.

Data Protection

The Data Protection Act (1998)

(http://www.dataprotection.gov.uk/) provides security to individuals about the uses to which their personal data can be put. Personal details include all information from which an individual may be identified. For example, the age, gender and street name of an individual's address would be considered personal information as it may be sufficient to identify them. Perhaps the biggest Data Protection issue is about access to clients' records. The Act considers reading records a form of processing. This can be particularly confusing for trainee clinical psychologists and their supervisors due to the mixture of Universitybased and NHS-based training. If a trainee is working on a clinical placement with their supervisor and he, or she, would normally have access to the patient's records then there is no breach of the Act to look at them. If a trainee is carrying out research only, and needs to process the records to select participants, then most RECs insist that the local clinician first identifies and contacts potential participants, if the researcher has no clinical role there.

#### Data storage

Researchers should take all reasonable steps to anonymise their data, or to pseudo-anonymise in circumstances where there will be a need to revisit the identity of the individual participants, say for longitudinal studies. Following the recent passage of European legislation (Directive 2001/20/EC) in relation to clinical trials, the Medicines for Human Use (Clinical Trials) Regulations (2004) came into force on 1 May 2004. This means that standards of Good Clinical Practice for Clinical Trials in relation to the archiving of original data are now being applied across all research being conducted in the NHS. The law requires storage for up to 15 years. Clarity on the degree to which this legislation will be applied to student research in the NHS is needed. Further complications arise because some LRECs have asked students to destroy original data (for example, videos of participants) as soon as the study is finished. This may be because they view the transcripts of these videos as data that is not so easily rendered anonymous. However, most scientific journals require original data (which would apply to videos as well as transcripts) to be stored for five years postpublication. Most universities, on the other hand, do not ask supervisors or students to keep student data for more than one year, unless the data are published, in which case the five-year

rule usually applies. This is clearly an area requiring clarification, in particular as it presents applied psychology programmes with significant logistical and storage difficulties. In the case of destroyed data, it prevents checks on the data itself, including its existence, and the validity of its use and interpretation by the student. This is a particular problem for work that is to be examined.

#### Risk Management

The general sources of risk to participants have been addressed earlier. Risk to investigators also needs careful consideration. The most significant sources of risk arise through the potential for harm to the investigator by a participant (e.g. home visits) and it is essential that risk assessments and appropriate researcher safety protocols are agreed with the supervisor. Consideration also needs to be given to the potential for risk to both participant and investigator from equipment. A clear and full risk procedure needs to be in place for the risks of every study. It is usual for both universities and NHS Trusts to have Risk Assessment protocols. Students and supervisors should be aware of these and implement them.

#### 7. Recommendations

Whilst we would not wish to advocate a lessening of ethical or scientific standards for research, more time efficient and user-friendly systems that facilitate rather than impede the process of obtaining approval for student and organisational studies are likely to be beneficial in the long run, both to students and to the NHS. We believe the procedures recently instituted by COREC and the proposals to institute SPECs will go a long way towards increasing the level of ethical scrutiny and public protection within the NHS, and also in co-ordinating and hopefully streamlining the processes undertaken by researchers and the students for whom they act as supervisors. Nevertheless, in writing this Good Practice Guide, we believe that there are still some outstanding issues which require further attention and resolution. Our recommendations fall into two major categories and we have identified these below:

#### Recommendations for RECs and NHS Trust R&D (and clinical audit) Departments

- 1. Many of the difficulties here would be resolved by a clear, and transparent, definition of audit and research that is agreed upon by RECs, and by Trust R&D and Clinical Audit departments. Ideally, it should be nationally disseminated and available to researchers, whose responsibility it would then be to make a decision about whether or not REC approval was required.
- 2. The role and status of service improvement projects must be addressed as a matter of urgency.
- 3. The length, method and storage of data and whether or not it should be destroyed needs to be agreed.
- 4. The role of clinical audit departments and staff in the planning and implementing of audit (small scale) studies conducted by students needs to be addressed and agreed. This presents additional and different challenges, and may require addressing in a separate document.
- 5. There should be agreement that a University's peer review procedures, if appropriate, may be used in place of R&D peer review, for R&D governance procedures.
- 6. Consideration should be given to how contracts issued by individual NHS Trusts to trainees might cover them both for clinical and research work undertaken in their employing Trust, and might also apply to other Trusts, thus removing the need for multiple honorary contracts.
- 7. Consideration should be given to clarifying the use of a single MREC approval for large-scale research projects that involve many NHS Trusts, and that does not require further local scrutiny and changes to be made.

#### Recommendations for psychologists (and students) conducting NHS research

- 1. Psychologists must be prepared to become members of R&D and REC Committees. This would facilitate mutual communication, and understanding, of all the relevant issues that bodies involved in research governance developments are experiencing. However, until applied psychologists become members of the Health Professions Council and are subject to statutory regulation (Turpin & Stacey, 2004), recent REC regulations prohibit psychologists from being expert members of the committee although committees do maintain the option to recruit psychologists as lay members.
- 2. Training courses in applied psychology should ensure that students are exposed to teaching on all aspects of ethical practice including research, audit and clinical activities.
- 3. Research supervisors must do their utmost to ensure students have considered and are aware of all relevant recent developments in research governance and RECs.
- 4. Psychologists should ensure that all research and audit activities (including service evaluations, single case evaluations and service improvement projects) are subject to ethical consideration and, where appropriate, scrutinised by the *appropriate* body (e.g. LRECs, SPECs or local departmental ethics committees).
- 5. Psychologists should ensure that due attention is paid to issues of informed consent and capacity, and any changes in practice brought about by the proposed Mental Capacity Bill (*personal communication*. K. Ehlert, August, 2004).
- 6. Supervisors and students must ensure that their practice conforms to local NHS Trust and ethical approval procedures, as well as the Society's own ethical guidelines.

#### 8. Conclusion

In this Guide we have raised concerns about the various ways in which new developments might hinder the research training of psychology students. Many of these also apply to research conducted by qualified psychologists. Our intention in producing this Guide was not to criticise the new developments – all of them have

important and desirable goals – but to suggest a way forward that will enable psychology educators and the NHS to maximise the contribution that psychological researchers, including psychologists in training, can make to the NHS agenda. We hope that it is received in the spirit of collaboration and desire for progress with which it was conceived.

#### 9. References

- BPS (1995). *Professional Practice Guidelines*. Division of Clinical Psychology, BPS: Leicester.
- BPS (2000). Code of Conduct, Ethical principles and Guidelines. BPS: Leicester.
- BPS (2003). About the British Psychological Society. See: http://www.bps.org.uk/about/welcome.cfm
- BPS (2004). Draft Guidelines for Minimum Standards of Ethical Approval in Psychological Research. BPS: Leicester
- COREC (2004). New Operational Procedures for NHS RECs: Guidance for applicants to Research Ethics Committees. Queries@corec.org.uk
- Collogan, L.K., Tuma, F., Dolan-Sewell, R., Borjas, S. & Fleischman, A.R. (2004). Ethical issues pertaining to research in the aftermath of disaster. *Journal of Traumatic Stress*, 17, 363–372.
- Diamond, B., Parkin, G., Morris, K., Bettinis, J. & Bettesworth, C. (2003). User involvement: Substance or spin. *Journal of Mental Health*, *12*, 613–626.
- DoH (1999). National Service Framework for Mental Health. London, Department of Health.
- DoH (2001). Research Governance Framework for Health and Social Care. London, Department of Health.
- DoH (2002). NHS priorities and needs research and development funding. London, Department of Health.
- DoH (2003). Report on the NHS priorities from 2001/2. London, Department of Health.
- DoH (2004). Agenda for Change Proposed Agreement: Final Draft. London, Department of Health.
- DoH/HO/BPS (2005). English survey of the applied psychology workforce. Leicester, BPS.
- Doyal, L. (2004). The ethical governance and regulation of student projects: a draft proposal. COREC.
- EC20/20 Clinical Trials directive, UK implementation of the European Clinical Trials Directive: the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Greenhalgh, T. (2004) The new ethics. *British Medical Journal*, 328 (15 March), 651.
- HMSO (2001). Redfern Report: Report of the Royal Liverpool Children's Inquiry. London: Her Majesty's Stationery Office.
- HMSO (2003a). The NHS Workforce in England 2003. London: Her Majesty's Stationery Office.
- HMSO (2003b). Staff directly employed by the NHS (Wales), 30 September, 2002. London: Her Majesty's Stationery Office.

- HMSO (2004). NHS Scotland Workforce Statistics. London: Her Majesty's Stationery Office.
- Jesson, J. & Wilson, K.A. (2004). The New UK Research Governance: its impact on pharmacy undergraduate research projects. *Pharmacy Education*, 14, 41–48.
- Norman, J. (2004). New system for ethics approval is unacceptable. *British Medical Journal*, 328 (24 April), 1018
- Pahl, J. (2004). Ethics in Social care Research: Option Appraisal and Guidelines. London: Department of Health.
- Paxton, R., Whitty, P., Zaatar, A., Fairbairn, A. & Lothian, J. (unpublished). Research, audit and service improvement.
- Peck, D. & Jones, A. (2004). Bureaucratic barriers to research training in the NHS. *Clinical Psychology*, 36, 7–10.
- Quality Assurance Agency for Higher Education (2004). Subject benchmarks for clinical psychology. http://www.qaa.ac.uk
- RCN (2004). Research guidance for nurses. London: The Royal College of Nursing Research Society. http://www.man.ac.uk/rcn/rs/publ/researchethic.pdf
- Turpin. G. & Stacey, T. (2004). NHS ethics committees. *The Psychologist*, 17, 433–434.
- Turpin, G., Barley, V., Beail, N., Scaife, J. Slade, P., Smith, J. & Walsh, S. (1997). Standards for research projects and theses involving qualitative methods: Suggested guidelines for trainees and courses. *Clinical Psychology Forum*, 108, 3–7.
- Turpin, G. (2001). Single case methodology and psychotherapy evaluation: from research topractice.
  In C. Mace, S. Moorey & B. Roberts, (Eds.), Evidence in the balance: A critical guide for practioners.
  (pp.91–113). London: Routledge.
- Turpin, G. (2002). Single case methods and evaluation within psychotherapy. In M. Hersen & W. Sledge (Eds.), Encyclopaedia of Psychotherapy, Vol. 2 (pp.659–668). Academic Press.
- Wade, D.T. (2005). Ethics, audit and research: All shades of grey. *British Medical Journal*, *330*, 468–471.
- Wainwright, T. (2004). Surveying the health of the profession. *The Psychologist*, *17*, 246–245. See also BPS website; tinyurl.com/yrg7e.

### Appendix 1

## GUIDELINES ON THE DISTINCTION BETWEEN RESEARCH AND AUDIT

It is sometimes hard to find the dividing line between research and audit. The following is designed to make the distinction clearer.

How is audit different from research? Audit determines whether existing clinical knowledge skills and resources are being properly used. In contrast, research is concerned with generating new knowledge which will have general application, as for example in determining whether a new treatment is superior to an existing one. The difference is between adding to the body of knowledge (research) and ensuring that knowledge is effectively used (audit). Both collect data, but for audit the findings are often relevant only to local circumstances.

Audit is intended to influence the activities of an individual or a small team; clinical research seeks to influence clinical practice as a whole.

#### Research

Features of research include:

- 1. May involve experiments on human subjects, whether patients, patients as volunteers, or healthy volunteers.
- 2. Is a systematic investigation which aims to increase the sum of knowledge
- 3. May involve allocating patients randomly to different treatment groups
- 4. May involve a completely new treatment
- May involve work or input for patients and staff beyond that required for normal clinical management
- 6. Usually involves an attempt to test an hypothesis
- May involve the application of strict selection criteria to patients with the same problem before they are entered into the research study
- 8. Usually will be sufficiently statistically powered.

#### References

Crombie, I.K., Davies, H.T.O., Abraham, S.C.S. & du Florey, C. (1993). *The Audit Handbook: Improving Heathcare through Clinical Audit*. John Wiley & Sons: Chichester, UK.

DoH (1993). Clinical Audit: meeting and improving standards in healthcare. London: Department of Health.

Audit

Clinical audit or service evaluation is a systemic approach to the peer review of clinical care in order to identify opportunities for improvement and to provide a mechanism for bringing them about.

'Clinical audit involves systematically looking at the procedures used for diagnosis, care and treatment, examining how associated resources are used and investigating the effect care has on the outcome and quality of life for the patient' (DoH, 1993).

'The systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient' (DoH, 1989).

'Audit is the process of reviewing the delivery of health care to identify deficiencies so that they may be remedied' (Crombie *et al.*, 1993)

The primary aim of audit is to improve the delivery of health care. Effecting change should be the intention of audit from an early stage (i.e. collection of data is not enough). Audit should also compare current practice with standards of care.

Features of Audit/service evaluation include the following:

- 1. Never involves experiments, whether on healthy volunteers, or patients as volunteers.
- 2. Never involves allocating patients randomly to different treatment groups
- 3. Never involves a completely new treatment
- 4. Places demands on patients and staff that do not significantly exceed those required for normal clinical management
- 5. May involve patients with the same problem being given different treatments, but only after full discussion of the known advantages and disadvantages of each treatment. The patients are allowed to choose freely which treatment they get.

DoH (1994). The Evolution of Clinical Audit. London: Department of Health.

DoH ( $\overline{1989}$ ). Working for Patients. London: Department of Health.

## Appendix 2

# DECISION TREE TO DECIDE WHETHER OR NOT A PROJECT IS AUDIT OR RESEARCH (and requires REC approval or not)

Eth	ics decision tree	Answer	Outcome Continue to 2 Continue to 3
1.	Does the study require access to any of: a) NHS patients b) NHS staff c) Relatives of NHS patients	No Yes	
2.	Does the study require access to any of: a) Social services patients b) Social services staff c) Relatives of social services patients	No Yes	REC application not required  REC application may be required  Continue to 3
3.	Does the study require access to children or their parents sourced through schools?	Yes or No	REC application not required Continue to 4
4.	Does the study involve any activity which is not part of routine clinical care? (Such as extra visits to hospital or home visits by researcher, extra assessments, new or extra interventions or therapy not normally offered)	Yes No	REC application required  REC application may not be required  Continue to 5
5.	To determine if the study is research or audit answer the following:  a) Is the study a systematic investigation which aims to increase the sum of knowledge? b) Does the study involve allocating patients randomly to different treatment groups? c) Does the study involve an attempt to test an hypothesis? d) Does the study involve the application of strict selection criteria to patients with the same problem before they are entered into the research study?	If any answer: Yes No	REC application required REC application may not be required Continue to 6
6.	Does the study involve patients with the same problem being given different treatments, but only after full discussion of the known advantages and disadvantages of each treatment, and the patients are allowed to choose freely which treatment they get? (If only one treatment, this is not relevant).	Yes No	REC application may not be required Continue to 7  If patients cannot choose, REC approval required
7.	Is the study an evaluation of routine services/ clinical care?	No Yes	REC application required REC application may not be required Continue to 8
8.	Has this routine clinical care previously been offered by this NHS service?	Yes No	REC application not required REC application may not be required Continue to 9
9.	Although new, is this service/clinical practice based on services/clinical practice for which there are established standards in the scientific literature?	Yes No	REC application not required REC application required

Although research guidance is designed to cover Health and Social Care, presently it is only set up for NHS settings. This means that technically LREC approval for Social Services-based research is currently not required but that it will be at some stage in the future. However, most RECs will be happy to consider an application for Social Services-based research should you feel that scrutiny of the ethics of your study would be beneficial.

### Appendix 3

### REFERENCES AND WEBSITES

#### **AUDIT**

Madden, A. (2003). Research or audit? In S. Eckstein (Ed.). Manual for Research Ethics Committees.

Cambridge: Cambridge University Press.

weblink: N/A

The Audit Commission

weblink: www.audit-commission.gov.uk

Clinical Research and Audit Group weblink: www.show.scot.nhs.uk.crag

The Commission for Health Improvement

weblink: www.chi.gov.uk

The National Audit Office weblink: www.nao.gov.uk

#### **PATIENT & PUBLIC INFORMATION**

Duman, M, (2003). Producing patient information – How to research, develop and produce effective information resources. London: Kings Fund. ISBN: 1-857-17470-4.

weblink: www.kingsfund.org.uk/pdf/poppisummaryinfo.pdf

Secker, J. & Pollard, R, (1995). Writing leaflets for patients – Guidelines for producing written information. Edinburgh: Health Education Board for Scotland. ISBN: 1-873-45271-3.

weblink: www.show.scot.nhs.uk/nhsfy/clineff/documents/patient%20information%20guidelines.pdf

Shepperd, S., Charnock, D. & Gann, B. (1999). Helping patients access high quality health information. *British Medical Journal*, *319*, 764–766.

weblink: bmj.bmjjournals.com

#### RESEARCH GOVERNANCE

Research Governance Framework for Health and Social Care (2001). This document outlines the responsibilities of students, clinicians and researchers both in the NHS and in Universities undertaking research on patients, their families or the staff who care for them.

weblink: www.dh.gov.uk/assetRoot/04/01/47/57/04014757.pdf

Guidance notes on Research Governance and Honorary Contracts

weblink:

www.dh.gov.uk/PolicyandGuidance/ResearchandDevelopment/ResearchandDevelopmentA2/ResearchGovernance/fs/en#5036858

Governance Arrangements for NHS Research Ethics Committees weblink: www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf

Association for Research Ethics Committees

weblink: www.arec.org.uk

#### ETHICS AND CONSENT

Social Research Association (SRA). The SRA is an organisation open to social research practitioners and trainees from all sectors, as well as others with an interest in social research. The SRA website contains useful codes of practice on ethical issues in social research and safety for lone researchers.

weblink: the-sra.org.uk

Central office for research ethics committees (COREC). Lists all the Local Research Ethics Committees and gives e-mail contact details for the UK.

weblink: www.corec.org.uk

COREC, Guidelines for researchers: Patient information sheet and consent form.

weblink: corec.org.uk/appliants/help/docs/Guidance\_on\_Patient\_Information\_pdf

Guidelines on seeking patients consent (1998) - General Medical Council.

weblink: www.gmc-uk.org/standards

Draft Protocol on Biomedical Research. The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (Strasbourg 251 2005) is intended to build on the principles embodied in the Convention, with a view to protecting human rights and dignity in the specific field of biomedical research. Its purpose is to define and safeguard fundamental rights in biomedical research,

in particular of those participating in research.

weblink: www.coe.int/t/e/legal\_affairs/legal\_co-operation/bioethics/activities/biomedical\_research/195%20Protocol%20recherche%20biomedicale%20e.pdf

The Ethical Conduct of Research on the Mentally Incapacitated. Working Party on Research on the Mentally Incapacitated (1993).

weblink: www.mrc.ac.uk/pdf-ethics-mental.pdf

#### ETHICS AND BEST PRACTICE

The Medical Research Council issues guidance and advice on the conduct of research in key areas. Some guidance concentrates on ethical, legal and practical aspects of ensuring the interests and safety of people participating in research is protected. Other guides cover principles for the conduct and organisation of high quality, reliable, and safe research.

weblink: www.mrc.ac.uk/index/publications/publications-ethics\_and\_best\_practice.htm

Declaration of Helsinki, World Medical Association (1964). Ethical Principles for Medical Research Involving Human Subjects.

weblink:www.wma.net/e/policy/b3.htm

Informed consent - BMJ.

Collected resources on informed consent from the online *British Medical Journal*. eBMJ collections list the most recent BMJ articles (usually with links to the full-text) in a subject area or speciality, and also links to relevant books and journals from the BMJ Publishing Group.

weblink: www.bmj.org/cgi/collection/informed\_consent

#### DATA PROTECTION

Data Protection Act (1998).

weblink: www.hmso.gov.uk/acts/acts1998/19980029.htm

NHS Confidentiality Code of Practice.

This is a guide to required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to use their health records. It replaces previous guidance. HSG(96) 18/LASSL (96)(5) – The Protection and Use of Patient Information, and is a key component of emerging information governance arrangements for the NHS.

weblink: www.dh.gov.uk/assetRoot/04/06/92/54/04068254.pdf

#### RISK MANAGEMENT

Working Alone in Safety: Controlling the risks of solitary work. Health and Safety Executive. **weblink: www.gov.uk/pubns/indg73.pdf** 

A Code of Practice for the Safety of Social Researchers.

This is the Social Research Association's Code of Practice for the safety of social researchers, particularly those conducting research in the field on their own. The code focuses on safety in interviewing or observation in private settings but is of relevance to working in unfamiliar environments in general.

weblink: www.the-sra.org.uk/stay%20safe.htm

Guidelines on Good Research Practice. Medical Research Council.

weblink: www.mrc.ac.uk/index/publications/publications-ethics\_and\_best\_practice.htm

Guidelines on Personal Information in Medical Research. Medical Research Council.

weblink: www.mrc.ac.uk/pdf-pimr.pdf

Research: The Role and Responsibilities of Doctors. General Medical Council.

weblink: www.gmc-uk.org/standards

Code of Conduct, Ethical Principles & Guidelines. British Psychological Society.

weblink: www.bps.org.uk/documents/code.pdf

Avoiding plagiarism in psychological writing.

This site provides a handout on how to avoid plagiarism.

It is provided by Monmouth University, New Jersey, US.

weblink: bluehawk.monmouth.edu/~psych/conducting-research/plagiarism.pdf

#### WELLCOME TRUST'S BIOMEDICAL ETHICS PROGRAMME

Wellcome Ethics Bulletin: the newsletter of the Wellcome Trust's Biomedical Ethics Programme.

weblink: www.wellcome.ac.uk/doc%5FwtX023241.html

The British Psychological Society was founded in 1901 and incorporated by Royal Charter in 1965. Its principle object is to promote the advancement and diffusion of a knowledge of psychology pure and applied and especially to promote the efficiency and usefulness of Members of the Society by setting up a high standard of professional education and knowledge.

## The Society has more than 42,000 members and:

- has branches in England, Northern Ireland, Scotland and Wales;
- accredits around 800 undergraduate degrees;
- accredits over 150 postgraduate professional training courses;
- confers Fellowships for distinguished achievements;
- confers Chartered status for professionally qualified psychologists;
- awards grants to support research and scholarship;
- publishes 10 scientific journals and also jointly publishes *Evidence Based Mental Health* with the British Medical Association and the Royal College of Psychiatrists;
- publishes books in partnership with Blackwells;
- publishes The Psychologist each month;
- supports the recruitment of psychologists through the *Appointments Memorandum* and *www.appmemo.co.uk*;
- provides a free 'Research Digest' by e-mail;
- publishes newsletters for its constituent groups;
- maintains a website (www.bps.org.uk);
- has international links with psychological societies and associations throughout the world;

- provides a service for the news media and the public;
- has an Ethics Committee and provides service to the Professional Conduct Board;
- maintains a Register of more than 12,000 Chartered Psychologists;
- prepares policy statements and responses to government consultations;
- holds conferences, workshops, continuing professional development and training events;
- recognises distinguished contributions to psychological science and practice through individual awards and honours.
- maintains a Register of Psychologists Specialising in Psychotherapy.

#### The Society continues to work to enhance:

- recruitment the target is 50,000 members by 2006;
- services the Society has offices in England, Northern Ireland, Scotland and Wales;
- public understanding of psychology addressed by regular media activity and outreach events;
- influence on public policy through the work of its Boards and Parliamentary Officer;
- membership activities to fully utilise the strengths and diversity of the Society membership.

#### The British Psychological Society

St Andrews House, 48 Princess Road East, Leicester LE1 7DR, UK
Tel: 0116 252 9530 Fax: 0116 247 0787 E-mail: enquiry@psychtesting.org.uk Website: www.psychtesting.org.uk