ESRC Research Ethics Framework

Working paper – for discussion only

Not for quotation without permission of the authors

Discussion Paper 2

The international dimension to research ethics: the significance of international and other non-UK frameworks for UK social science

April 2004 (v2.0)

ESRC Research Ethics Framework Project
Science and Technology Studies Unit (SATSU), Department of Sociology
University of York and School of Social Studies and Law, Oxford Brookes University
ref@york.ac.uk www.york.ac.uk/res/ref

ESRC Research Ethics Framework: Discussion Paper 2

One of a series of four Discussion Papers that form part of the ESRC Research Ethics Framework project. All four Discussion Papers are available at http://www.york.ac.uk/res/ref/documents.htm

The international dimension to research ethics: the significance of international and other non-UK frameworks for UK social science

Graham Lewis, Mary Boulton, Nik Brown, and Andrew Webster [1]

1. Introduction: why the international context is important for UK social science research ethics.

1.1 There is general recognition that the ethics environment is changing, and international and other non-UK generated guidelines and standards, such as those developed by the European Union, are one of several influences on this process of change. The starting premise of this paper, the second of four commissioned as background material for the ESRC Research Ethics Framework project, is therefore that any UK framework for social science research ethics, such as the proposed ESRC Research Ethics Framework, must be informed by a clear understanding of global and other regional or national legal and regulatory frameworks.

1.2 As part of this process, such a Framework should be aware of steps that other national and international research funding agencies may be taking with regard to research ethics and research governance. Knowledge about such activities is particularly important where these may either impinge on UK research activities, such as through the imposition of obligations, or where the adoption of novel ideas or methodological approaches may usefully be incorporated into UK practice.

1.3 This 'international dimension' to ethics and UK social science research (SSR) is important for two additional reasons: research is increasingly international in scope in terms of topic, and is bringing together new international research networks as a result of the greater opportunity for collaborative research across borders provided by funding programmes such as those of the European Union (e.g. the FP6 programme), UK Research Councils themselves also increasingly encourage trans-national research (e.g. the ESRC UK-US exchange programmes). Such trends inevitably mean that non-UK regulatory frameworks will become increasingly significant for the conduct of research undertaken by UK researchers and institutions. Equally important, international guidelines and standards, such as those produced by the World Medical Association (WMA) and World Health Organisation (WHO) provide the generic framework upon which are based more localised national standards.

1.4 This paper seeks to explore the relevance of this 'international dimension' to UK SSR by describing existing global, regional and major national (such as the US) legal and regulatory frameworks and providing an outline of likely future directions of such frameworks; examining the challenges and opportunities such frameworks may present to UK funders and research organisations, such as universities and other research sites; and outline the activities of non-UK national and international research funders and related stakeholders in the area of research ethics and research governance.

[1] Authorship of REF Discussion Papers reflects lead pen

1.5 At the same time, it attempts to locate global and non-UK frameworks within those areas of most concern for SSR and which have, or are likely to have, an international dimension and hence engage in some way with non-UK or international regulatory frameworks, either currently or in the future. One of the most important of these areas has been identified as research conducted at what we have previously described as the "interface" between social science and biomedical research, and that related to, or involving ICTs (SATSU 2002).

1.6 The research areas of most interest in terms of international and other non-UK frameworks, and which are likely to influence and shape future UK ethics practice, are therefore:

- New medical technologies (as explored in the ESRC/MRC IHT programme 2001-2005)
- The construction and use of genetic databases and sample repositories, both public and corporate (Martin and Kaye 1999, Martin 2000, 2001, Department of Health 2003, Lewis 2004)
- Clinical trials and informed consent (as highlighted by the recent introduction of the EU Clinical Trials Directive (EU 2001) that came into force in the UK in December 2003).
- Challenges presented by what we may loosely call "virtual social research" – research methodologies based on use of internet technologies to some degree or another, and which allow research across geographical boundaries (and hence on different 'ethical territory' and outside UK oversight) to be undertaken more easily (see e.g. the ESRC Virtual Society? Programme)[2]

1.7 The SATSU 2002 Review (along with other commentators, such as Kent et al. (2002)) also identified concerns within the UK social science community that the imposition of practice developed in other disciplinary areas may unintentionally restrict the conduct of important, high quality, social science research. This concern is mirrored in analyses of SSR produced in other countries.[3] The same Review also identified two broad types of regulatory approach: one generally prescriptive in nature (exemplified by the Department of Health's Research Governance Framework (Department of Health 2003)); and a second that seeks to provide researchers and institutions with the necessary knowledge and capacity to deal with diverse ethical situations in an appropriate manner. The identification of these divergent approaches raises the question of whether there is a similar differentiation in approach in other countries or in international guidelines; and whether similar debates are taking place on their appropriateness or otherwise.

1.8 As Kent et al. (2002) note: 'The growth of information technologies, the development of new
health technologies and the increasing use of personal, including genetic, information for research shapes the context within which current researchers practice.' In practical terms, the growing 'internationalisation' of SSR is taking place in the context of a range of different ethics review structures. For example, in the UK and most of Europe, unlike the US, it is not routine practice for social scientists to seek ethics approval prior to commencing social research (although anecdotal evidence suggests a small number of UK institutions/university social science departments, do require such approval). The exceptions are cases where medical intervention is part of the research or where the research involves NHS personnel or patients, in which case formal ethics approval must be obtained as mandated by the RGF. There is therefore a clear separation in current approaches towards health research and social research in the UK, and in research governance regimes in different countries. These

[2] A further possible topic not covered in this discussion paper is the emerging interest in the possibilities of e-social science (such as the. ESRC E-Social Science Research Centre/Hub 2003).
[3] See, for example, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* from Canada, discussed below.

divergent regulatory structures relate to different professional and institutional perceptions of the risks attached to different forms of research and differing traditions within these areas of knowledge production.

The remainder of the paper describes global and regional regulatory frameworks, often orientated towards concerns about biomedical and health-related research, and significant national initiatives, such as those of Norway and Canada. It then looks at the specific areas of concern listed above.

2.0 Global regulatory frameworks

2.1 Global ethical principles for the conduct of medical research, as enshrined in the WMA's Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects[4] (WMA 2002) are widely recognised as the foundation upon which national frameworks are developed, and such principles which concern informed consent, confidentiality, anonymity and protection of research subjects from harm and exploitation, underpin the work of local ethics review committees and oversight processes.

2.2 The Helsinki Declaration is a set of general principles designed to protect the life, health, privacy, and dignity of the human subject. There are a number of similar international guidelines that seek to establish ethical and scientific standards for carrying out biomedical research on human subjects, including the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, WHO Guidelines, and ICH Guidelines for Good Clinical Practice (WMA 2000, CIOMS 2003, WHO 2000, ICH 1996).[5]

2.3 According to the WHO, for example: 'Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible'. All such international guidelines require the ethical and scientific review of biomedical research alongside informed consent and the appropriate protection of those unable to consent as essential measures to protect the individual person and the communities who participate in research. For the purposes of the WHO Guidelines, biomedical research includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records, and biological samples, as well as epidemiological, social, and psychological investigations, and therefore potentially relevant to a range of SSR areas.

2.4 Interestingly, WHO Guidelines are stated to be applicable to all countries, both developed and developing (see Discussion Paper 3); but specifically do not replace or supersede national laws and regulations. In other words, a form of subsidiarity is operating here. Thus WHO Guidelines are:

> 'intended to facilitate and support ethical review in all countries around the world. They are based on a close examination of the requirements for ethical review as established in international guidelines, as well as on an evaluation of existing practices of ethical review in countries around the world. They do not, however, purport to replace the need for national and local guidelines for the ethical review of biomedical research, nor do they intend to supersede national laws and regulations.'

2.5 According to the WHO, the establishment of international guidelines that assist in strengthening the capacity for the ethical review of biomedical research in all countries contributes to redressing the imbalance in the distribution of research between developed

[4] The Declaration of Helsinki was first adopted in 1964, and since amended several times, most recently in 2000, with Note of Clarification added in 2002.

[5] The tripartite harmonised ICH guideline - a consolidated document setting out a tripartite standard for the conduct of clinical trials, was finalised in May 1996, and subsequently adopted by the EU, USA and Japan.

and developing countries. The majority of biomedical research has been predominantly motivated by concern for the benefit of already privileged communities in the developed world. This is reflected by the fact that WHO estimates show that 90% of the resources devoted to research and development on medical problems are applied to diseases causing less than 10% of present global suffering (also see Discussion Paper 3).

2.6 Another leading body in the development of international ethics standards is the Council for International Organizations of Medical Sciences (CIOMS). CIOMS recently up-dated its International Ethical Guidelines for Biomedical Research Involving Human Subjects, which is of particular significance to medical research, clinical trials and good clinical practice. The CIOMS Guidelines relate to a range of issues: ethical justification and scientific validity of research; ethical review; informed consent; vulnerability - of individuals, groups, communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review; and obligations of sponsors to provide health-care services (CIOMS 2002).[6]

2.7 According to CIOMS, the scope of their latest guidelines reflects the changes, the advances and the controversies that have characterised biomedical research ethics in the last two decades. Like other global guidelines, the CIOMS Guidelines are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects, applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms. Mirroring the WHO Guidelines, a stated aim is to reflect the conditions and the needs of low-resource countries, and the implications for multinational or trans-national research in which they may be partners (CIOMS 2002).

2.8 UNESCO has also published a series of all-encompassing, globally-orientated reports on ethics, including the International Declaration on Human Genetic Data, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) and much more (UNESCO no date) According to UNESCO, confronted with the social and cultural effects of rapid technological change, COMEST has been given the task of recommending ethical principles 'to guide decision-makers who work in sensitive areas, setting out ethical criteria' (UNESCO n/d). This body has a wide-ranging remit: its most recent meeting in Brazil in December 2003 discussed issues as disparate as the teaching of ethics ('an increasingly pressing need at a time of rapid scientific change and when the influence of some "traditional" sources of ethics teaching is waning'); the ethics of freshwater, outer space, research on human beings in developing countries, sustainability, and nanotechnology.

2.9 These global guidelines are characterised by a set of over-arching principles based on protection of the individual research subject and informed consent. However, they say little about research governance and how such principles might be implemented in practice in different cultural, social, legal or political circumstances. In other words, they pay little attention to alternative concepts of informed consent, for example, or ethical issues around cultural diversity and dominant research paradigms (see Discussion Paper 3).

[6] The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organization in official relations with the World Health Organization (WHO). It was founded under the auspices of WHO and UNESCO in 1949 with among its mandates that of maintaining collaborative relations with the United Nations and its specialized agencies, particularly with UNESCO and WHO.

3. Research governance and the European Union

The following section examines two aspects of EU research ethics: ethics oversight within the European funding process, and EU sponsored ethics review initiatives.

3.1 Ethical oversight of EU funded research

As we argued above, one of the reasons for the significance of the 'international dimension' for SSR is the growth in EU funding. Considerable effort and information is required in order to obtain such funding, such as how it will be conducted, the researchers involved, when and where it will take place, and proposed dissemination activities. However, there are no formal ethics approval procedures and issues such as informed consent, confidentiality, and dissemination of information to research participants are not reviewed at the funding stage (Kent et al p7).

3.2 This state of affairs would appear to broadly mirror current procedures in the UK, where SSR is not automatically subject to ethics review but relies on a range of different and sometimes conflicting codes and procedures, often located in different institutions, and implemented in different ways and to varying degrees (SATSU 2002).

3.3 Since WW II, a great number of ethics standards have been adopted on a national basis in Europe. In recent years, there has been a tendency to replace the mainly autonomous handling of research ethics by professional bodies with legal acts (such as acts regulating embryo, stem cells and genetic research) and internationally recognised guidelines that are accorded semi-legal status. Nonetheless, wide variation remains in the status of such standards, between disciplines, countries and contexts. Whilst it is not the remit of this paper to analyse these many national standards, either in general terms or as they may apply to SSR, such variations are clearly of major significance when considering the possible emergence of a distinctive supranational European ethics framework.

3.4 Despite the many and varied cultural, political, and methodological problems inherent in any such enterprise, the European Commission's stated goal is the development of a more integrated European research ethics – the harmonisation of research ethics - with a view to promoting ethics in (social) science within the European Research Area (ERA). Of course, the extent to which this occurs, the form it might take, or what in practice such harmonisation might mean, all remain open questions.

3.5 An on-going project directed at constructing a European directory of codes of practice, based at Uppsala University, may be viewed as preparatory work towards this goal (European Codes of Practice 2002). The ultimate purpose is to provide a systematic information facility that would help promote awareness of, and consistency in the use of, existing codes of practice, and increase understanding of the problems they address. The aim is to assist future development of an integrated, coherent and effective European research ethics, by helping to overcome cultural differences and resolve conflicts. Allied to this effort is CODEX, a Swedish ethics archive (see below).

3.6 Two other European Commission initiatives must be noted: the European Information Network Ethics in Medicine and Biotechnology (EURETHNET), launched in January 2002, aims to develop an information network and knowledge base that integrates databases and other resources in these fields. Second, and arguably more relevant, is the European Group on Ethics (EGE), a body with an increasingly influential role in shaping EU thinking on ethics

3.7 The EGE is described as 'an independent, pluralist and multidisciplinary body that advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies' (EGE no/date). Set up by the Commission in 1997 to succeed the Group of Advisers on the

Ethical Implications of Biotechnologie (GAEIB), which operated from 1991[7], its task is to advise the Commission on all ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. During its first mandate, the EGE provided Opinions on subjects as diverse as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research.[8]

3.9 At the specific request of the Commission President, the Group also wrote the Report on the Charter on Fundamental Rights for European Citizens related to technological innovation. This was the first international instrument on Human Rights that refers to bioethics and 'infoethics'.[9] Recent changes have sought to strengthen the remit of the EGE. The EGE Secretariat is an integral part of the Commission's Group of Policy Advisers, a group that examine longer-term issues and concerns in the context of the EU. Subjects for analysis are decided in several ways: the EGE may consider to examine a topic itself; or either the European Parliament or the Council may draw the Commission's attention to questions that they consider of major ethical importance.

3.10 On-going EGE activities include preparation of an Opinion on ethical aspects of umbilical cord blood private banking, and ethical aspects linked to nanotechnology. Another area examined is the use of person identifiable personal health data. This data includes, as specified in Directive 95/46/EEC, any data which either directly or indirectly identifies an individual by reference to her/his name, identification number or to one or more factors specific to her/his physical, physiological, mental, economic, cultural or social identity.

3.11 Personal health data encompass a wide range of information about an individual, which all touch upon an individual's private life. According to the EGE, a health biography could include, not only basic medical data: such as a history of all medical diagnoses, diseases and medical interventions, medications prescribed, test results, including imaging etc., but also sensitive data on mental health relevant to family history, behavioural patterns, sexual life, social and economic factors, and healthcare administrative data (admissions and discharge data, routine operational data, insurance and financial transactional data, etc). As the EGE notes, almost all such data can be recorded in digital form and processed electronically, and remain sensitive even after the death of an individual.

3.12 The range of data uses covered by the EGE Opinion on personal data covers all aspects of personal health data management: collection, processing, recording, storage, access, uses, management, responsibility, follow up, evaluation, systems and network design. According to EGE,

> 'it is important to recognize that personal health data are used not only in the practitioner-patient interaction but also by the numerous spatially distributed third parties. Such third parties may include medical practitioners who are given access to a patient's medical data in the context of shared medical care, administrative bodies charged with the management of healthcare services, as well as other third parties such as insurers, and employers.'

Issues not considered include the use of non-identifiable personal health data. Importantly, the Opinion does not cover aggregated data concerning the professional activities of

[7] See http://europa.eu.int/comm/european_group_ethics/gaieb/en/index.htm
[8] For details of these EGE Opinions, see http://europa.eu.int/comm/european_group_ethics/index_en.htm
[9] For details see http://europa.eu.int/comm/european_group_ethics/docs/rap_en.pdf

healthcare professionals even if these data raise specific ethical questions, such as genetic data and aggregated information contained in repositories like biobanks.[10]

3.13 The RESPECT project (Professional and Ethical Codes for Technology-related Socio-Economic Research), funded under the European Commission IST programme, involves several European partners.[11] The aims of the project are to: develop a voluntary code of practice for the conduct of socio-economic research in the Information Society; contribute to the development of common European standards and benchmarks for socio-economic research; contribute to the development of high standards in cross national and inter-disciplinary socio-economic research contribute to the broader ethical and professional debates within the socio-economic research community; help reduce the barriers to the mobility of socio-economic researchers with the EU and Accession states; provide succinct information on good practice in socio-economic research for research users both inside and outside the IST community.[12]

3.14 The first stage of RESPECT involved the development of guidelines or codes in a number of separate areas: data protection, intellectual property rights, research ethics, professional issues and professional competencies. The next stage will be to develop an overall code of practice covering all these areas, which will be accompanied by a user's guide to socio-economic research, designed for those who commission research, evaluate research proposals and review the results. This document is therefore is potentially of value in the context of the present work in that the goal is to provide practical guidance for funding agencies.

3.15 Currently, the project has released a set of ethical guidelines or a 'code' of standards to inform the conduct of socio-economic research in the European Union. These guidelines are aimed at all those involved in socio-economic research, whether commissioning, bidding for or managing projects, or working as part of a research team on a project.

3.16 As the project website notes:

> 'Guidelines or 'codes of practice' offer a framework in which researchers can work. They do not, however, offer all the answers. Making ethical decisions involves addressing a series of dilemmas and, ultimately, decisions have to be made by the researchers involved. Ethical guidelines enable these decisions to be made from an informed position. They also offer protection to researchers, providing them with a source to quote if pressured by others to adopt unethical practices. These guidelines aim to offer minimum acceptable standards for the conduct of ethical research in Europe. However, guidelines on their own are not enough, they only offer a starting point. What is needed is an 'ethical conscience' so that making ethical decisions becomes an automatic part of the research process. Guidelines can be used as part of the educational process leading to this.'
>
> 'The draft guidelines have been constructed at four levels. The first three provide a summary of the main principles and possible dilemmas, and these are included as in this summary. The report is the fourth level, providing a more detailed discussion of the issues underlying the main principles, the nature of dilemmas which may be faced

[10] In the UK context, the Medical Research Council have also issued a thorough and comprehensive guidance document, 'Personal Information in Medical Research' which offers advice of use to all researchers working with personal data of any kind (MRC no date).
[11] The UK participants in the RESPECT project are the Institute for Employment Studies and the social Research Association (SRA).
[12] More details at http://www.respectproject.org/

in ethical decision making and how some of these ethical issues may be addressed in practice.'

3.17 In this sense, the RESPECT approach appears to be similar to the Framework project in terms of substantive outputs and adoption of a supportive, as opposed to prescriptive, model. The objective is to provide a set of basic codes to guide practice and encourage the development of appropriate behaviour by institutions and individual researchers – in other words, to encourage an appropriate culture rather than be overly prescriptive.

3.18 The status of the RESPECT project and the degree to which it will influence Commission thinking on ethics structures and EU research, and hence impact on UK research governance, remains unclear. However, in the context of this Paper, it is important to recognize that RESPECT intervenes at the level of principles and does not attempt to provide practical guidance on ethics oversight procedures. The project seeks, in other words, to raise awareness, spread good practice, and develop a common set of basic standards through a synthesis of existing materials.

3.19 The final EU initiative highlighted is specifically directed at biomedicine: the Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research,[13] as approved by the Steering Committee on Bioethics (CDBI) on 20 June 2003.[14]

4. European States

4.1 Sweden – CODEX project

CODEX is a Swedish ethics archive based at Uppsala University, and funded by the Swedish Research Council. The goal of CODEX is to facilitate access to and knowledge about legislative documents and guidelines regarding research ethics (http://www.codex.uu.se/). Completed in 2001, it consists largely of Swedish material but there are links to international documents, and it will link to the European Directory discussed above. The site is currently in Swedish only, although it has recently received funding to update material and provide it in English translation.

4.2 Norway

One (non-EU) example in Europe that should be highlighted is that of Norway, where a National Committee for Research Ethics in the Social Sciences and the Humanities (NESH) was established in 1990. NESH provides an example of one possible model: establishment of a national body to provide guidance on specific concerns related to SSR, and is one of several such committees in Norway. The Norwegian approach is discussed further in Discussion Paper 4 with regard to the proposed ESRC Research Ethics Framework.

4.3 The Norwegian model of organizing national research committees is unique in that a system for disciplinary areas that have traditionally been subordinate has developed alongside that for medical ethics and bioethics (see http://www.etikkom.no/Engelsk/about). The three independent but coordinated national committees cover all scientific disciplines. It is a characteristic feature of the Norwegian model that the committees do not only deal with issues within the more narrowly defined field of research ethics, but include the broader field of the ethics of science. This includes issues of scientific responsibility for larger social concerns.

[13] Details at: http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/Activities/Biomedical_research/CDBI-INF(2003)6eREV.pdf

[14] The draft Protocol has been submitted to the Committee of Ministers. It is foreseen that they will consult the Parliamentary Assembly for an opinion, prior to proceeding to examination of the draft Protocol in view of its adoption.

4.4 NESH's charter states, among other things, that the Committee shall draw up guidelines for research ethics in the social sciences, law, the humanities and theology.[15] According to the Committee, it uses the guidelines actively when giving its opinion on specific research projects. Since its formation NESH has given its opinion in more than 50 individual cases. In 2002 six such cases were submitted to NESH. Two of these came about because foreign authorities required an ethical evaluation before allowing a research project to start. Individual researchers and research institutes occasionally ask NESH to evaluate the ethical aspects of a specific research project. When the Norwegian Data Inspectorate is processing applications for permission to process personal data, it sometimes asks NESH for advice. It also happens that researchers, wanting to safeguard ethical considerations in their research projects, ask NESH for an evaluation. Typical questions that NESH is asked to evaluate include how best to ensure that consent is freely given and whether children can consent by themselves to take part in research projects. The Committee has also been asked to evaluate a number of other aspects, such as the limits for the protection of sources and researchers' duty of confidentiality and duty to inform about planned criminal acts.[16]

4.5 NESH's main priority in 2003 was to develop and offer a course in research ethics for researchers from all over Norway.[17] Although clearly there are major differences in scale, this does suggest one possible route to UK ethics training through the adoption and promotion of an agreed national training programme for SSR ethics. Recent publications include guidelines for internet research (NESH 2003), the inclusion of women in medical research (NESH 2001); and research ethics in the social sciences, law and the humanities (NESH 2001).

4.6 The guidelines for research ethics in the social sciences, law and the humanities 'are intended to help researchers and the research community to think about their ethical views and attitudes, become aware of conflicting norms, and become better able to reach well-founded decisions [...] and not limited to norms which apply to individual scholars and the heads of research institutions, but also contain norms for other bodies which influence research and its consequences.' In this respect, the Norwegian approach to ethics and SSR encourages the creation of an ethics culture capable of handling a diverse set of situations, rather than the prescriptive model.

4.7 The Norwegian approach notes that guidelines for research ethics do not have the same functions as laws: 'Guidelines are an aid for researchers themselves. They point to relevant factors which he or she should take into account, but which in certain cases should be weighed against other important considerations' such as when they overlap with legal requirements that take precedence.

5. Ethics review in the US

5.1 United States

The review of research involving human participants in the US is characterised by a complex network of codes and regulations. Only a brief overview of agencies and sources that may be relevant to the UK context is provided here. The Department of Health and Human Services (DHHS) is the United States government's principal agency for protecting the health of Americans and providing essential human services, especially for those who are least able to help themselves, and hence has overall responsibility for ethics standards.[18]

[15] The first version of the NESH guidelines was published in 1993, and revised in 1999. A new 2004 edition will contain updated references to relevant legislation. The inclusion of guidelines for Internet research in addition to the existing guidelines has also been proposed.
[16] http://www.etikkom.no/Engelsk/NESH
[17] The course started in the autumn of 2003 and the project is implemented in collaboration with the University of Oslo.
[18] For more details, go to: http://www.os.dhhs.gov/

5.2 The DHHS's remit is overseen by the Secretary's Advisory Committee on Human Research Protections (formerly known as the National Research Protections Advisory Committee) which provides 'expert advice and recommendations to the Secretary of HHS and the Assistant Secretary for Health (ASH) on issues and topics pertaining to or associated with the protection of human research subjects.' More specifically, the committee will 'provide advice relating to the responsible conduct of research involving human subjects with particular emphasis on:

• special populations, such as neonates and children, prisoners, and the decisionally impaired;
• pregnant women, embryos, and fetuses;
• individuals and populations in international studies;
• populations in which there are individually identifiable samples, data, or information;
• investigator conflicts of interest.'

The DHHS Secretary's Committee is also responsible for the ongoing monitoring and oversight of IRBs and the institutions that sponsor research.

5.3 An important body within the US bioethics world, and which impinges on social science research, is the President's Council on Bioethics, which advises on ethical issues related to advances in biomedical science and technology, with recent pronouncements on cloning, stem cells, potential uses of biotechnology for purposes "beyond therapy", exploring the scientific, ethical, and social implications; patenting human life; biotechnology and public policy; and sex selection.[19]

5.4 The Council on Bioethics effectively replaced the National Bioethics Advisory Commission (NBAC), when the Commission's charter expired in October 2001, but the latter archived information on its meetings, subcommittees, and reports, including reports on: Ethical Issues in Human Stem Cell Research, Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity, and Cloning Human Beings.

5.5 For our purposes, a key feature of US ethics review is the mandatory scrutiny of proposed research by an institutional review boards (IRB) (roughly equivalent to a UK research ethics committee (REC)) prior to commencement, and for federally funded research, the requirement for Federalwide Assistance (FWA).

5.6 An important source of information on US regulations for protecting human subjects in social science research involving funding by the US Federal government is the National Science Foundation.[20] Seventeen federal agencies have adopted what is termed the "Common Rule" for regulations governing human subjects of research. Some agencies have adopted additional regulations ("subparts") dealing with special populations. (The Common Rule is also referred to as "Subpart A" of the DHHS regulations of human research 45 CFR 46). Institutions, such as universities, assure that they will comply with the regulations regarding human subjects research. This assurance is normally filed with the appropriate federal agency that sponsors their research. Most universities have assurances from DHHS. Under the Common Rule, each agency (e.g., NSF) agrees to accept an assurance issued by DHHS as a commitment that the institution will follow the regulations – with enforcement through a requirement for a FWA. When no FWA exists, each department or agency issues its own assurance.

5.7 The Division on Behavioral and Social Sciences and Education, one of the major divisions of the National Research Council (NRC), the principal operating agency of the US

[19] President's Council on Bioethics at http://bioethics.gov/
[20] A useful resource on US regulations is at: http://www.nsf.gov/bfa/dga/policy/hsfaqs.htm

National Academies, has recently published two studies on ethics review and the protection of research participants (Federman et al. 2003, Citro et al 2003)

5.8 The US Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the U.S. Department of Health and Human Services (HHS) to publicise standards for the electronic exchange, privacy and security of health information. The HHS *Standards for Privacy of Individually Identifiable Health Information* ("Privacy Rule") establishes, for the first time, a set of national standards for the protection of certain health information. The standards address the use and disclosure of individuals' health information — called "protected health information" by organizations subject to the Privacy Rule — called "covered entities," as well as standards for individuals' privacy rights to understand and control how their health information is used.

A stated goal of the Privacy Rule is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being. According to the US HHS, it:

> 'strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing. Given that the health care marketplace is diverse, the Rule is designed to be flexible and comprehensive to cover the variety of uses and disclosures that need to be addressed' (HHS http://www.hhs.gov/ocr/privacysummary.pdf).

As noted at the start of this section, it is not possible within the space available to review all the many facets of US legislation on ethics scrutiny procedures or to draw out all the relevant points that may usefully influence the development of the REF. The most salient feature of US procedures is that, unlike the current position in the UK, all research must be submitted to a properly constituted IRB for approval prior to commencement. And any UK Research Organisation that has US research partners will confront the need for ethics scrutiny based on US standards and procedures.

6. Ethics review in Canada

6.1 Tri-Council Policy Statement (TPS)

Canada has devoted considerable effort to the development of ethics guidelines, with adoption of the first Tri-Council Policy Statement (TPS) in 1998 (with minor updates in 2003) and creation of the Interagency Advisory Panel on Research Ethics in 2001, committing the three agencies responsible for research funding (the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council) 'to promote the ethical conduct of research involving humans' (PRE 2004). The outcome has been the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). (Ref: http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm).

6.2 The Canadian Statement is one of the most interesting and valuable documents produced to date. It is not possible to cover all the points contained within it, but two of the most important are highlighted here. The first is that the agencies will consider funding (or continued funding) only to individuals and institutions that certify compliance with the policy statement. However, whilst this might suggest otherwise, there is no national accreditation or compliance, surveillance or oversight system in place for the TCPS.[21]

[21] The section on the Canadian TCPS draws on correspondence with the Secretariat for Research Ethics, whose help is gratefully acknowledged.

In 1998, as a condition for continued funding, the three funding agencies requested institutions receiving federal funding from them for research undertaken under the institutions' auspices to adapt their ethics policy or develop one when they did not have one. This type of approach appears to mirror that adopted by some UK funders, such as the Wellcome Trust, for example.

6.3 The ethics policy applies to all disciplines and fields of research and applies to all research undertaken in such institutions, even research that is not funded by the agencies. The agencies have also requested institutions to submit their revised written policies to the agencies, who review them and provide the institutions with the status of their policies and how they meet the spirit of the TCPS requirements. This is an iterative process between the institutions and the finding agencies, with the technical assistance of the Secretariat on Research Ethics.

6.4 In 2002, the agencies also released a Memorandum of Understanding: Roles and Responsibilities in the Management of federal Grants and Awards (MOU). Institutions are being asked to sign this memorandum that describes the basic requirements for obtaining and maintaining institutional eligibility to administer agency funds. The MOU complements the Agencies' program guides, which define the roles and responsibilities of grant and award holders. It includes a schedule on Ethics, Integrity in Research and Investigations and Resolution of Breaches of Agency Policies, and a list of good practices.[22]

6.5 According to the Secretariat, discussion and debate on governance, accreditation or other oversight systems is taking place in Canada. The three granting agencies do not however see a role for themselves in accreditation as such, and they do not have regulatory powers. Preference would be given to a body at arm's length from the agencies.

6.7 The Canadian approach is interesting conceptually because it recognises that:

> 'The key is sensitive and thoughtful implementation of the spirit and requirements of the document' [and] …'that considerations around the ethical conduct of research involving human subjects are complex and continually evolving…' Therefore, they 'welcome comment and discussion, and commit themselves to regular updates [of the document]'.

This suggests an acceptance that different circumstances and research paradigms may warrant adoption of different approaches to ethical oversight – a point made in SATSU's 2002 Review and elsewhere.

7. Commentary on specific areas of interest and concern

The final part of this Discussion Paper concentrates on specific research areas that are generating concern, or may do so in the future, in the international or regional context. Most of these relate to areas that are traditionally related to bioscience but which now attract increasing interest from a (critical) social science community. Discussion of these areas can only be touched upon due to space limitations and what follows is not comprehensive but merely highlights some key points and areas for discussion and debate.

7.1 Genetic testing

7.1.1 Like a number of other groups, the European Group on Ethics in Science and New Technologies (EGE) have called for a careful assessment of advertising genetic tests via the Internet. In a 2003 statement, the EGE said that policy makers and society at large should

[22] See http://www.nserc.ca/institution/mou_e.htm and http://www.nserc.ca/institution/good_practices_e.htm respectively.

examine more closely the ethical, social and legal issues surrounding the increasing use of the Internet to market, in particular, genetic tests that establish paternity or detect heart disease and diabetes. The statement also highlighted the aggressive nature of such marketing and the unlikely locations where it can be found: high street shops, petrol stations, and motorway restaurants.

The concern is that marketing genetic tests in such a way can lead to inaccurate and insufficient information about genetics and potential ramifications. There are also concerns that when such tests are carried out, rules relating to the participant's consent are not being followed during the collection of genetic data, particularly for paternity related tests.

7.1.2 Another fear is that databases containing genetic test results could be misused in order to endorse a deterministic relationship between genes and diseases or reinforce associations between ethnic groups and diseases, thus violating equality and confidentiality rights. Finally, appropriate advice and counselling must be provided before and after genetic tests are carried out to ensure all ethical, social and legal aspects are respected, according to the EGE. (http://www.eubusiness.com/imported/2003/02/104196). The concerns of the EGE broadly mirror those of the UK Human Genetics Commission (HGC 2003). [23]

7.2. Genomics - pharmacogenetics and pharmacogenomics (PGx)

7.2.1 In one of the earliest interventions, a Wellcome Trust workshop in 1999 highlighted four themes relevant to social perspectives on PGx:[24] that the social world is more complex than biological reality; issues around use of personal information (also see above); 'lay' public participation in decision-making; and implications for oversight and regulation (Spallone and Wilkie 1999). There is now an enormous literature on PGx, including that specifically directed at ethical, social and legal issues (see e.g. Rothstein and Epps 2000). The usual focus on individual rights common to western ethics frameworks is complemented in the case of PGx by debate over collective rights - such as (it is argued) arises when 'communities' are the subject of genetics research precisely because of their unique characteristics.[25] (see e.g. Weijer and Miller 2004).

7.2.2 The Nuffield Council on Bioethics has an international reputation in bioethics and is perhaps the main UK body that other countries and international bodies look to for guidance on bioethics. The Council established a 'Working Party on Pharmacogenetics: ethical issues' in 2002, and its report was published in September 2003 (Nuffield 2003). The terms of reference were to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern; to encourage and promote public understanding of such issues, and where needed to formulate new guidelines.

7.3 Clinical trials

7.3.1 A central area where robust research ethics are required is the domain of biomedical research and clinical trials procedures in particular. Clinical trials (CTs) using both healthy volunteers and patients undergoing treatment are a necessary part of the development of new medicines. However, oversight of clinical trials is generally less developed than drug approval procedures, with a variety of protocols and demands in different countries and regions. In some countries there is a fair degree of regulatory overview prior to commencement, whereas in other locations there is only perfunctory review. These

[23] On genetic testing and ethical and policy concerns in the UK, see also: Martin and Frost (2003).
[24] PGx can be defined here as the relationship of drug response to individuals' genetic variation. It has been understood for more than 50 years, but recent advances in knowledge and renewed scientific and commercial interest follow the Human Genome Project.
[25] Examples of such communities would be populations such as are found in Estonia, Iceland, Newfoundland and several other locations, Native Americans, Mexican-Americans etc. – although the validity and importance of such groups, genetically speaking, is contested.

variations are set against a background of increasing interest on the part of academic researchers and pharmaceutical companies in conducting CTs in Eastern Europe and developing countries, where recruitment and trial costs are lower.

7.3.2 There have been attempts to codify and improve existing standards for medical research, which includes clinical trials protocols, such as recent guidelines published by CIOMS (CIOMS 2002), and UNESCO (UNESCO 2003) – see above. In the European context, the most recent development is introduction of the EU Clinical Trials Directive (EU 2001), implementation of which in the UK is the responsibility of the Medicines and Healthcare Products Regulatory Agency (MHRA). The Directive provides the framework for implementing various aspects of good management, including those conventionally called "good clinical practice" (GCP), consistent with the aims of the Declaration of Helsinki, and aims to make such procedures more transparent.[26] The Directive was to be transposed into local law in each EU country during 2003, with compliance a legal obligation by 1 May 2004.

7.3.3 The EMEA is responsible for approving the sale of medical products on the European market and the standards for safety and efficacy are set out in various Regulations, Directives and Guidelines (Abraham & Lewis 2000). Such proof is normally demonstrated by means of (usually randomised) controlled clinical trials, comparing the new drug with a placebo control.

7.3.4 There are a number of ethical issues regarding appropriate treatment of patients and clinical trials methodology. Perhaps the most important is that a strict interpretation of the Helsinki Declaration appears to rule out use of a placebo control arm where authorised therapeutic methods exist (EMEA/CPMP 2001). This is contrary to the widely held view amongst regulators that placebo-controlled trials are necessary to satisfy public health needs (such as when similar efficacy but a better safety profile to an existing drug can be demonstrated). It is the view of the EMEA and CPMP that ‘ although the efficacy of some new medicinal products can be satisfactorily demonstrated without the use of a placebo, for others the judicious use of placebo remains essential to demonstrate their value’. However, whilst active controlled trials are permitted, they are inherently less reliable than placebo-controlled trails. (EMEA 2001) - EMEA/17424/01 28 June 2001)

7.3.5 The two principle EU directives that form the basis of marketing authorisation are 65/65/EEC (EU 1965) and 75/318/EEC (EU 1978). The latter, for example, states that:

> ‘in general clinical trials shall be done as ‘controlled clinical trials’ and if possible, randomised; any other design shall be justified. The control treatment of the trials will vary from case to case and will also depend on ethical considerations; thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with that of an established product of proven therapeutic value rather than with the effect of a placebo.’

Directive 75/318/EEC also specifies that:

> ‘all clinical trials shall be carried out in accordance with the ethical principles laid down in the current revision of the Declaration of Helsinki.’

7.3.6 Guidance on the design of CTs is provided in CPMP guidelines, either harmonised globally through the International Conference on Harmonisation (ICH) or in the EU (through

[26] The Directive’s scope is very broad and only "non-interventional trials" are excluded. It does not distinguish between commercial (industry sponsored) and publicly funded (research council, charity and NHS funded) studies. For the MRC response, see: http://www.uclh.org/services/research/documents/EU_regulation_clinical_trials_jul03.pdf

the Committee on Proprietary Medicinal Products).[27] Both of these bodies are key players in the global 'regulatory state' that has evolved over the past several decades (Abraham and Lewis 2000). The ICH, which comprises the respective pharmaceutical industry associations and regulatory agencies in the US, EU and Japan (the so-called "six-pack") have been instrumental in harmonising international drug approval and clinical trial procedures.[28]. However, ultimately, ethical oversight of CTs is the responsibility of local ethics review committees, not EU or national agencies.

7.5 Sample repositories and biobank formation

7.5.1 Another area of potential concern is the development of both public and private biobanks, such as UK Biobank and clinical trials sample collections and related genetic databases (see e.g. Tutton and Corrigan 2004). While less visible, corporate repositories are important sites of tissue collection and the construction of genetic databases, and hence for ethical overview and governance (Lewis 2004). As regards the importance or otherwise of such concerns for SSR, they are likely to impinge where research is conducted on individuals and communities, and is done on an international basis, who contribute to such repositories and databases, and in practical terms, where such research is required to be approved by a local research ethics committee (LREC).

7.5.2 UK Human Tissue Bill

The present UK law on removal, retention, and use of human tissue contains many uncertainties, as was made very apparent during the Bristol, Alder Hey and Isaacs inquiries. The UK Government's response has been to draft a new Human Tissue Bill (HOC (2003). The aim is for 'light touch' legislation that provides a single comprehensive framework, with emphasis on practice guidelines. The Bill seeks to establish a Human Tissue Authority to license regulated activities.[29]

7.5.3 The UK Medical Research Council (MRC) issued its own guidance on human tissue in 2001 (MRC 2001). This document emphasised the need for patient confidentiality, consent and information. According to the MRC, since the use of human tissue is critical for medical research, the public and research participants must be confident that such tissue has been obtained lawfully and with appropriate consent, and will be handled and used sensitively and responsibly by researchers.

UNESCO recently published the International Declaration on Human Genetic Data. Accordingly 'in laying down the ethical principles that should govern the collection, processing, storage and use of human genetic data, the Declaration's stated aim is to ensure the respect of human dignity and the protection of human rights.' The document also gives 'due consideration to freedom of thought and expression, including the freedom of research' (UNESCO 2003).

7.5.4 COGENE is described officially as 'a strategic accompanying measure aimed at promoting the development of synergies between national genome research programmes related to human health in Europe' and acts on behalf of the Forum of Genomes Programme Managers with representatives from 25 European countries. (COGENE no date).It seeks to co-ordinate the activities of the increasing number of biobanks in Europe.

7.5.5.1 Corporate biobanks

The corporate sector is an important stakeholder in biobank formation, with pharmaceutical and genomics companies increasingly active in the areas of sample collection and genetic

[27] The CPMP is the scientific advisory committee of the European Medicines Evaluation Agency (EMEA http://www.emea.eu.int/), which in turn is an agency of the European Commission.
[28] The ICH has met on six occasions from 1990 – 2003. For more information, go to: http://www.ich.org/
[29] The MRC has published its views on the Human Tissue Bill. See MRC (2004).

database formation (Lewis 2004). They are also actively developing what they consider appropriate means to protect individual rights and ensure public trust in the methods adopted.

7.5.6 The Roche Charter on Genetics, which sets out company's principles regarding use of genetics and genetic information, is an example – and one that is made publicly available. The charter emphasises the right of every individuals to self-determination, privacy, and confidentiality regarding procurement and use of genetic information. The company undertakes to prevent any misuse of genetic information acquired during course of its research activities, and the key that links clinical identifiers to individuals in the Roche Sample Repository is deleted. This anonymisation process is strengthened by only analysing data held in aggregate (Roche 2002).

7.6 Stem cell research

7.6.1 The potential for human stem cells to give rise to different types of bodily cells raises the possibility of major advances in healthcare, including transplant therapies for treating many disease and conditions, changes in methods of drug testing and improved understanding of normal human development. Much current research is controversial because it involves deriving stem cells from human embryos and cadaveric fetal tissues (Nuffield 2001). As the Nuffield Report notes, the ethical issues that arise are primarily concerned with the origin of the cells and the way in which they are derived. The origin of these cells means that careful examination of the ethical issues is necessary prior to the progress of research in this field. There has been a long running and serious debate in the UK and elsewhere about the morality of research on human embryos and elective abortion. Although both are permissible in the UK under certain conditions, there are widely differing views about the ethical issues raised by such research. There is a parallel and more contentious debate underway in the US, and in a number of other countries.[30]

7.6.2 In September 2002 the Medical Research Council and the Biotechnology and Biological Sciences Research Council announced funding to establish a UK Stem Cell Bank. The Bank has been charged with providing ethically-sourced, quality-controlled adult, fetal and embryonic stem cell lines for research and for the development of therapies by the national and international research and industrial communities. The Bank is hosted by the National Institute for Biological Standards and Control (NIBSC).

7.6.3 The Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines has produced two Codes of Practice. The first is an Interim Version of a Code of Practice for the UK Stem Cell Bank.[31] This specifies the good practice standards that the UK Stem Cell Bank must adopt in terms of validating, screening, processing, storing, providing and delivering stem cell lines to users. It also specifies the criteria against which the UK Stem Cell Bank will be audited by the Steering Committee and the funding agencies. The Code covers banking of all forms of stem cell lines derived from human tissues. A draft of this Code was first published for consultation during September/October 2003. (MRC 2003) [32]

7.6.4 The second draft Code of Practice is for the Use of Human Stem Cell Lines. This specifies the practical, regulatory, quality, risk management, safety, legal and other relevant issues that should be considered and complied with in order to meet national and

[30] See e.g. President's Council on Bioethics 2004 Ref: Monitoring Stem Cell Research, The President's Council on Bioethics, Washington, D.C., January 2004, Pre-Publication Version. Available at: http://bioethics.gov/reports/stemcell/index.html; National Bioethics Advisory Commission (1999) Ethical Issues in Human Stem Cell Research: Volume I, National Bioethics Advisory Commission, Maryland, USA.

[31] According to the MRC, this interim version 'may need to be revised further in light of the responses to the consultation on the draft Code of Practice for the Use of Human Stem Cell Lines' (MRC 2004b).

[32] For more information, go to: http://www.ukstemcellbank.org.uk/

international legislation, increase scientific understanding and benefit human health. It also addresses the key issues of deriving, authenticating and characterising stem cell lines, donor selection, information, consent, confidentiality and feedback, ethical and intellectual property issues, and the licences, accreditations and authorisations that researchers must secure to work with human stem cell lines. It covers all classes of stem cells derived from human tissues. Revision is also likely to this second Code following piloting.

7.7 Nanotechnology.

Social science research is increasingly characterised by expansion into new areas of study. Such developments are, in turn, often reflected by the emergence of new areas of ethical concern. One area that is likely to encompass both global reach and innovative technologies, and which may require ethical overview, is nanotechnology. Several publications on nanotechnology and ethics have already appeared (see the ESRC's own report on the field, Wood et al, 2003), and a number of areas of general concern have been identified, such as environmental worries, equity and human health, potential criminal and terrorist uses, privacy and surveillance, the human/machine boundary, intellectual property disputes, and concerns about democracy, government and public participation (see e.g. EthicsWeb n/d)

However, the extent to which nanotechnology is likely to present specifically new ethical concerns is unclear, as is the degree to which such developments may impinge on social research that examines these developments. It is important to remember that the term encompasses a wide range of both existing and potential technologies, some of which may require additional oversight. But this does not automatically translate to a requirement for new approaches or procedures for ethics review.

7.8 Internet-based research and ICT

Finally, recent years have seen a rapid growth in Internet technologies, which offer new possibilities of reaching hard to reach groups and conducting anonymous research. SSR conducted via the Internet is not, of course, intrinsically international in orientation, but ICTs do, however, allow SSR to be carried out across borders more easily that would otherwise be the case. These technologies therefore raise a number to ethical issues that will need to be addressed in the UK context. However, guidelines for such research are not well developed. According to Brownlow and O'Dell (2002), the principle questions are those of informed consent, privacy of participants, and new power relations that may arise through online interaction.

8. Implications for ESRC Research Ethics Framework

Our discussion of the international guidance and protocols on ethics principles and ethics has, we hope, provided a useful mapping of the prevailing global discourse and guidance in this area. It also raises a number of implications for the ESRC's REF, and thereby for consideration by UK researchers working in social science, whether funded by the ESRC or not. We suggest that when developing research proposals there are some basic steps that might be taken by research teams and/or ethics review panels, especially in regard to work that is international, linked to health-related or bioscience areas, or that involves the sharing of international data sources.

- The review should consider first, how far a proposal meets the spirit of the broad principles set down by agencies such as the WHO, and second, where relevant, endeavour to ensure that these principles are shared by collaborating partners (a point we have developed more fully in Discussion Paper 1).

- At the same time, it is important to note that these principles do not provide us with clear guidance on the process of ethics review, so here we suggest some more specific points that inform the REF. Social science researchers should recognise the

saliency and relevance of the major international guidelines such as those of the WHO and WMA that are applicable to all countries, both developed and developing (see Discussion Paper 3), while interpreting them in the UK national context and with regard to other countries where collaboration is to be agreed.

- As discussed at more length in Discussion Paper 3, a number of different but important issues are likely to arise when research involves participants and/or researchers located in developing countries.

- There is an attempt to establish a degree of basic consistency across Europe with regard to data protection, but local versions of the Data Protection Act (DPA) prevail at a national level. Attention to this variation is important when drafting research involving the deposition and/or secondary use of data.

- Be aware of the developments within the European Commission to harmonise, as well as to identify specific principles for discrete areas of work, all of which are becoming of central interest to some fields within social science, viz., the areas of human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research.

- Attend to the ongoing guidance provided by the EGE with respect to work on what is clearly a much more broadly defined conception of 'personal health' related data and consider the guidance relating therein to the exchange of international data and results.

- Consult the basic guidance provided by the RESPECT project, especially in regard to joint European research proposals, and determine whether partners are aware of the guidance provided therein.

- Ensure that any international projects involving collaboration with those countries discussed in section 4 and 5 above consider national guidelines in relation to ethics review to ensure compliance to provisions where appropriate.

- Build effective ethics provisions into future research partnerships in SSR when building new
networks of excellence, where responsibility for ethics review is to be located within a management committee of the Network itself. This is a requirement for all such collaborations but reference to international guidelines will be especially important in providing a gold standard for ethics scrutiny to which all partners can be expected to conform.

References

Abraham, J and Lewis, G (2000) *Regulating Medicines in Europe.* London: Routledge.

Brownlow, C and O'Dell L (2002) Ethical Issues for Qualitative Research in On-line Communities, *Disability and Society* 17(6): 685-694.

CIOMS (2002) Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). *International ethical guidelines for biomedical research involving human subjects*. Geneva: WHO.

Citro, C F, Ilgen, D R, and Marrett, C B (eds) (2003) Protecting Participants and Facilitating Social and Behavioral Sciences. Research Panel on Institutional Review Boards, Surveys, and Social Science Research, [US] National Research Council.

COGENE (no date) Coordination of Genomes Research Across Europe. Available online at: http://forum.europa.eu.int/irc/rtd/cogene/info/data/pub/home.htm (accessed 15 January 2003).

Department of Health (2003), Research Governance: Department of Health Research Governance Framework for Health and Social Care, Second Draft.

EGE (no date) European Group on Ethics in Science and Technologies. http://europa.eu.int/comm/european_group_ethics/index_en.htm.

EMEA/CPMP (2001) EMEA/CPMP Position statement on the use of placebo in CTs with regard to the revised Declaration of Helsinki (28 June 2001 EMEA/17424/01).

EthicsWeb (no date) http://www.ethicsweb.ca/nanotechnology/index.html

EU (2001) Clinical Trials Directive (2001/20/EC).

European Codes of Practice (2002) *Provision of Study on Codes of Practice for Ethics in Research* (No. SAS5-CT-2002-30051).

Federman, D. D., Kathi E. Hanna, and Laura Lyman Rodriguez (eds) (2003) *Responsible Research: A Systems Approach to Protecting Research Participants*. Committee on Assessing the System for Protecting Human Research Participants, [US] National Research Council.

HGC (2003) *Genes Direct. Ensuring the effective oversight of genetic tests supplied directly to the public*, London: Human Genome Commission. http://www.hgc.gov.uk/genesdirect/#report (accessed 21/01/04).

HOC (2003) Human Tissue Bill (introduced 3 December) http://www.parliament.the-stationery-office.co.uk/pa/cm200304/cmbills/009/2004009.pdf

ICH (1996) International Conference on Harmonisation. *E6: Good Clinical Practice consolidated Guideline* Available online at: http://www.ich.org/

Kent, J. et al. (2002) Social Science Gets the Ethics Treatment: Research governance and ethical review, *Sociological Research Online* 7(4) at: http://www.socresonline.org.uk/7/4/williamson.html

Lewis G (2004) Tissue collection and the pharmaceutical industry: Investigating corporate biobanks. In: R Tutton and O Corrigan (eds) *Genetic Databases: Socio-ethical issues in the Collection and Use of DNA*. London: Routledge.

Martin, P. (2000). 'The Industrial Development of Human Genetic Databases'. Written evidence to House of Lords Select Committee on Science and Technology. http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/115/115we52.htm (accessed 13 February 2003).

Martin, P. (2001) 'Genetic governance: the risks, oversight and regulation of genetic databases in the UK', *New Genetics and Society* 20(2): 157-183.

Martin, P. and Kaye, J. (1999). The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research. London: The Wellcome Trust.

Martin P and Frost R (2003) Regulating the commercial development of genetic testing in the UK: problems, possibilities and policy. *Critical Social Policy* 23(2): 186-207

MRC (no date) *Personal Information in Medical Research*. Available online at: http://www.mrc.ac.uk/ethics_a.html

MRC (2001) *Human Tissue and biological Samples for Use in Research: operational and ethical guidelines*. London: Medical Research Council. Available online at: http://www.mrc.ac.uk/index/public-interest/public-consultation/pdf-tissue_guide_fin.pdf

MRC (2004a) Human Tissue Bill Views of the Medical Research Council (26 January 2004). Available online at: http://www.mrc.ac.uk/index/public-interest/public-consultation/public-human_tissue_consultation.htm

MRC (2004b) Stem Cell Codes of Practice. Available at: http://www.mrc.ac.uk/index/public-interest/public-consultation/public-stem-cell-consultation.htm

NESH (2003) *Research ethics guidelines for internet research*. National Committee for Research Ethics in the Social Sciences and the Humanities, Norway. Available at: http://www.etikkom.no/Engelsk/Publications/internet03

NESH (2001) *Guidelines for the inclusion of women in medical research: gender as a variable in all medical research.* National Committee for Research Ethics in the Social Sciences and the Humanities, Norway. Available at: http://www.etikkom.no/Engelsk/Publications/women

NESH (2001) *Guidelines for research ethics in the social sciences, law and the humanities*. National Committee for Research Ethics in the Social Sciences and the Humanities, Norway. Available at: http://www.etikkom.no/NESH/guidelines.htm

Nuffield (2001) Discussion Paper: Stem cell therapy: the ethical issues. Nuffield Council on Bioethics. Available at: http://www.nuffieldbioethics.org/publications/pp_0000000007.asp

Roche (2002) The role of ethics in clinical trials, Roche Facets 18. http://www.roche.com/pages/facets/18/ethicstriale (15 November 2002).

Rothstein, M., & Epps, P., (2000). Ethical and Legal Implications of Pharmacogenetics. *Nature Reviews Genetics* 2, 228-231.

SATSU (2002) *A Review of Ethics and Social Science Research*. Commissioned by the ESRC on behalf of the Strategic Forum for the Social Sciences. Unpublished paper by G.

Lewis, N. Brown, S. Holland and A. Webster. (Summary available at: http://www.york.ac.uk/res/ref/documents.htm)

Spallone, P. & Wilkie, T., (1999). Social, ethical and public policy implications of advances in the biomedical sciences. Paper presented to the European Workshop on Legal, Regulatory and Ethical Aspects in Pharmacogenetics, November 12, Berlin.

Tutton R and Corrigan, O. (eds) *Genetic Databases: Socio-ethical issues in the collection and use of DNA.* London: Routledge.

UNESCO (no date) Available online at: http://www.unesco.org/

UNESCO (2003) International declaration on human genetic data. Available online at: http://www.unesco.org/confgen/2003/genetic

Weijer C and Millar P (2004) Protecting communities in pharmacogenetic and pharmacogenomic research. *The Pharmacogenomics Journal* 4: 9–16.

WHO (2000) Ethical standards and procedures for research with human beings. Available at http://www.who.int/ethics/research/en/

WMA (2002) World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Available online at: http://www.wma.net/e/policy/b3.htm

Wood S, Jones R and Geldart, A (2003) The Social and Economic Challenges of Nanotechnology. ESRC Report. Available online at: http://www.esrc.ac.uk/esrccontent/DownloadDocs/Nanotechnology.pdf

Acknowledements
The authors acknowledge the assistance of the following external commentators, who read earlier drafts of one or more of the four Research Ethics Framework Discussion Papers: Priscilla Alderson (Institute of Education, University of London), Richard Ashcroft (Imperial College London), Jose Cordoba (Hull University Business School), Robert Dingwall (University of Nottingham), Ann Jacoby (University of Liverpool), Julie Kent (University of West of England), Jan Pahl (University of Kent), Naomi Pfeffer (London Metropolitan University). The content of all four Discussion Papers remains entirely the responsibility of the authors.

Contact details:

ESRC Research Ethics Framework Project
Email: ref@york.ac.uk
Project website: http://www.york.ac.uk/res/ref/