Mainly for Researchers:

A1 Does all ESRC-funded research need ethics review?
All ESRC-funded research that involves human participants will normally need to be reviewed by a Research Ethics Committee (REC). It is the responsibility of the researcher/research team to decide whether review is needed, and if the research is ethically sensitive requiring either expedited or full review by an REC (see REF 1.1.2; 1.1.3; 1.3.2.5/6).

A2 Do I need to submit my project for review before submitting a research grant proposal to the ESRC?
No. While a researcher may wish to do so, this is not a requirement. Proposals to the ESRC are not required to be reviewed by an REC before they are submitted to the ESRC (see REF 1.1.4). However, if a proposal is recommended for funding, and ethical review is required, the review must have taken place before funds are released. In a small number of cases, it may be agreed that it is more appropriate that ethical review takes place at a later stage in the project, and in these instances ESRC must have confirmation that this review has taken place, otherwise subsequent payments on the award could be delayed, or in extreme cases, refused.

A3 Are there any occasions when a speedier, expedited review can be regarded as appropriate?
Yes. Expedited review is most appropriate where there is minimal risk to human participants. It may be appropriate in cases where there is particular urgency. (see REF 1.2).

A4 What will happen if I secure an award in principle but fail to get ethics approval?
Most applications are likely to be given ‘conditional approval’ where ethical issues need further consideration, and are referred back for clarification or modification: it would be very unlikely that a project subject to prior peer review after submission to the ESRC would have major ethical problems remaining that would not be possible to be dealt with through consultation with an REC. Responses to the conditions set by the Committee might be reviewed either by the full committee or on its behalf by, for example, the Chair. If ethics approval is still not forthcoming, the grant award will not be made. (See REF 1.1.5).
When a university REC refers a proposal back to me for modification do I need to inform the ESRC?

No. The University or Research Organisation (RO) is authorised to deal with this. If, however, the RO's referral would mean that a major modification would need to be made to the project such that its objectives are jeopardised or the focus of the project would require significant revision, this will need to be relayed to the ESRC for further consideration (See 1.1.5).

Is ethical review ever needed for research that involves use of secondary data alone?

Review will not be required when data is not sensitive and where there is minimum risk of disclosure of the identity of individuals. Sometimes ethical review is needed for use of secondary data, and will always be required where use of such data with related data sets may produce results that generate new risks (through disclosure via birth dates for example) (See REF 1.3.2.6; 1.16)

If my research is jointly funded by two or more agencies, including the ESRC, will review by a single REC be sufficient?

Yes. The REC will be required to review the proposal according to the guidelines specified in the REF.

If my proposal involves collaboration with another partner organisation, or subcontracts some of the work to a third party, does ESRC expect that the proposal will be reviewed by these external bodies, too, and that third parties must, as organisations, conform to the REF guidelines?

In such situations, the ESRC would simply require that the principal investigator’s employing organisation would, through its own REC, ensure that the collaborating parties are aware of, and have endorsed, the review process. No duplication of review by external parties is required. It is the responsibility of the REC to ensure that the proposal has considered this question within its submission.

Will ESRC require research proposals that would normally go through an NHS REC (because they involve work that requires access to clinical data for example) also to be reviewed by a social science, university-based REC?

No: the ESRC does not want to duplicate the review process in this way. Council would expect review by one REC only (See REF 1.15)

Will ESRC funded research that involves NHS premises, staff or patients, but which is non-clinical, require review by an NHS REC?

It may be possible that an REC within an RO that meets the REF standards will have the jurisdiction to approve proposals, rather than they
are referred to an NHS REC. Further advice on this can be obtained from the ESRC.

A11 Does the REF apply to ESRC funded research undertaken in Business Schools which, traditionally, have not had to submit proposals to a REC?

As with all research submitted to ESRC after January 1 2006, proposals from within the fields of business and management will need to be subject to ethics review as specified in the REF Guidelines. Use of (primary or secondary) corporate data may well generate a range of risks (to individuals or organisations) that will need to be considered in advance of the work being undertaken.

A12 Is the REF endorsed by other social science funding agencies?

The REF has the broad support of a number of funding agencies that comprise the Strategic Forum for the Social Sciences, such as the Joseph Rowntree Foundation and the Nuffield Foundation. However, research proposals to such agencies will need to ensure that they meet any additional requirements that they may have, and it is in the interest of researchers to discuss these with the agencies in advance of a submission to them.

A13 When does the REF take effect?

All proposals submitted to ESRC after 1st January 2006 will be required to conform with the provisions of the Framework. It is hoped and expected that proposals submitted before then will also be consistent with the Framework.

A14 Where can I find the REF in full, and get more help if need be?

The REF is available in full and may be downloaded at: http://www.esrc.ac.uk/ref
There are also links to other web-based resources on research ethics from this page.

Enquiries may be made by email to: ethics@esrc.ac.uk

Mainly for Research Organisations (Universities etc) / Research Administrators

B1 Where in the RO should the review of social science proposals be properly undertaken?

Research Organisations (such as HEIs) may want to constitute a number of RECs by level (e.g. university-wide, faculty based) and discipline/department based: it is possible that a university-wide ethics committee is more likely to advise on broad strategy for ethics review and to monitor university performance overall rather than consider applications per se; most universities will, or already are adopting a mix of
the faculty-wide/dept-based RECs. Wherever they are located they should meet the requirements of the REF. (See REF: 1.3.1.1)

B2 Will an ethics review be required before an RO receives funding for a proposal from the ESRC?
Yes. Funds will not flow until the administering institution provides written confirmation that the required ethical approval has been received. However, if it is – as can be the case in some research proposals – more appropriate that ethical review is best located at a later stage in the project, ESRC should be informed of this, otherwise subsequent payments on the award could be delayed, or in extreme cases, refused.

B3 Does the ESRC specify the composition of research ethics committees that are located within research organisations such as HEIs?
The Guidelines offer advice about the composition of an REC. Most importantly, it should be multi-disciplinary and include lay members and if possible members independent of the University (See REF 1.4; 1.5)

B4 Does the ESRC require that all REC members are trained in ethical review, and if so, that all must be by January 1 2006?
Training for all REC members is not a formal requirement. Rather, research organisations will be expected to build ethics competences over time through both informal and formal training of existing and prospective members. (See 1.10.3). Informal training might involve observation of REC sessions, while more formal training via workshops and training modules can complement this. Indeed, both models are in place in many UK universities already, and ESRC is keen to see these approaches deployed throughout the sector. Institutions will be expected to report on training provision as part of the ‘dipstick testing’ process (see question B8, below).

B5 Will my university be able to secure any resource to meet any additional costs it might have with respect to the scrutiny of research proposals using the REF guidelines?
Universities will be able to include provision for ethics scrutiny as part of their FEC calculations when costing research proposals. There is no set figure for this provided by the ESRC, but one that will be determined locally by the university concerned, and be set at a reasonable and justifiable level. If research is designed in such a way that return, iterative advice may be sought from an ethics committee – such as is the case with many ‘action research’ projects – this should be factored in to the initial FEC costing where possible. ESRC will not make any extra funding available for ethical review once the initial award has been made.

B6 Will all undergraduate and postgraduate proposals need to be reviewed by an REC?
The fact that a proposal is made by a student (rather than a staff member) does not determine whether it should be reviewed or not: this will, as in all cases, depend on the likely risks that the research might create (the level and form of review proportionate to the risk). However, where minimal risk is involved, projects could be given expedited ethical approval either by a student Supervisor or the Chair of the REC. It should be noted, however, that ESRC does not itself fund undergraduate research and the REF, therefore, has no formal role to play at this level. This issue is more appropriately a matter for the wider University governance and review procedures relating to student work. Some universities have adopted a policy of giving generic approval to undergraduate projects that form part of a group of similar or identical project-based work.

Postgraduate research might well be dealt with in the same way, through a form of expedited review. However, where such research is in receipt of ESRC funding (through a doctoral studentship for example) this will be likely to require full REC review if the proposal raises more than minimal risk.

In the case of a studentship being awarded and then requiring ethical review, this could be undertaken during the early period of the award, so providing a useful opportunity for the new student to gain experience and understanding of ethics and the review process itself. (see REF 1.13)

B7 Where the ESRC is supporting research that needs to be subject to the Department of Health Research Governance Framework, who is to act as the ‘sponsor’ of the research?

The ‘sponsor’ for the research with respect to RGF requirements is the researcher’s employing organisation, not the ESRC. Research Organisations will normally arrange for sponsorship to be signed off through their research or external liaison office.

B8 Will ESRC be monitoring universities to determine the degree to which the REF Guidelines have been introduced, and if so how will this be undertaken?

Yes, through occasional review via ‘dipstick testing’ of a Research Organisation’s processes and procedures. ESRC does not want to impose a single model on universities: the REF Guidelines are more about standards and how they can be secured than about the imposition of uniform protocols.

The ‘dipstick testing’ is expected to be undertaken as part of existing ESRC financial reviews of universities rather than be a separate ‘event’. ESRC will provide more detailed guidance on the information sought, which will primarily be made up of documentation and reports that the institution would already be producing as part of its local oversight of ethics provisions and procedures. (See 1.11)
B9 Are there any sanctions that ESRC would invoke in cases where the REF guidelines were seen to have been infringed or not followed?
Yes. The question of sanction in regard to ethical/academic misconduct in research is discussed in the initial Framework document of the REF (see page 2) and could result in immediate suspension of the project and other projects at the same University/Research Organisation: in extreme cases this may require the ESRC to seek to recoup its funding, but this would be highly exceptional.

B10 What should a research organisation regard as compulsory elements of the REF with respect to actual practices and provisions that must be adopted, rather than guidelines that are to be followed?
The REF specifies minimum requirements on pages 3 and 4 of the REF. These establish the basic components of the REF. With respect to the adoption therein of specific requirements, the following are compulsory:

- At least one lay member of the REC should be in place: lay membership is primarily defined in terms of non-affiliated status; this would not thereby rule out an academic from a neighbouring institution. The lay member should be trained in ethics review (see question B4 above)
- An REC must have at least one academic member from outside the Department conducting the research and at least one appropriately trained lay member
- That REC review should be undertaken prior to research being undertaken, unless there is agreement with the ESRC that research design indicates that review best occurs after an initial period of work (for example to scope out a novel area of inquiry)
- For proposals submitted after 1st January 2006 and which have been awarded funding, research managers must conform to ESRC that ethics scrutiny has been undertaken and any approval secured. This is likely to be by the ‘Start Certificate’ return made to the Council
- Training for postgraduate research students in regard to fostering ethical literacy is a requirement and falls within the Council’s Postgraduate Training recognition provisions.
- Universities and other research organisations should establish appropriate procedures to monitor the conduct of research which has received ethical approval until it is completed, and to ensure appropriate continuing review where the research design anticipates possible changes over time that may need to be addressed.
- Research organisations must have mechanisms for receiving and addressing complaints or expressions of concern about the conduct of research carried out under their auspices
- Research organizations must comply with legislative requirements and with the requirements of data providers.

version 3 (Dec 05)