

SECURING ETHICS APPROVAL: THE ROUTE MAP FOR SOCIAL CARE RESEARCHERS

Key Principles:

- (i) *Reciprocity* – mutual respect between different sources of ethics review is a central principle; this principle should obtain within as well as between ethics review systems that operate to the same standards¹.
- (ii) *Avoidance of 'double-handling'*. No study should normally be required to go to more than one REC and no REC should review a study that has been formally approved by another appropriate body².
- (iii) *Proportionality*: to avoid unnecessary bureaucracy and not untowardly hinder the progress of good research, the level or intensity of review must be appropriate to the risks involved. Procedures for expediting low-risk research should be established.
- (iv) *Independence*: properly to avoid any potential conflict of interest, reviewing committees should be independent of the institutions or individuals that are funding and/or undertaking the research³.
- (v) *Researcher-led*: the responsibility for identifying and securing appropriate review lies with the lead researcher, but funders may reserve the right to recommend a particular source of review to their research contractors.

Definitions and Coverage:

- (vi) The proposed definition of '*research*' for university ethics committees is provided by the ESRC in its Research Ethics Framework (REF) document: '*...any form of disciplined enquiry that aims to contribute to a body of knowledge or theory*' (2005:5)⁴. The definition used by research ethics committees within the National Research Ethics Service (NRES) is provided in the DH Research Governance Framework for Health and Social Care. Neither definition excludes, apriori, particular designs or approaches (i.e. surveys or service evaluations) which are designed, managed and presented as research. The Social Care REC is concerned with studies presented as research that raise ethical issues, and is therefore sympathetic to a broad definition.
- (vii) The Mental Capacity Act (MCA -2005) covers '*intrusive research*'. This is defined very broadly as any research that would require consent if undertaken with people who have capacity. This covers all kinds of primary research, including observation or the collection of data about an individual indirectly from another source. This is not the same as the (more restricted) definition of '*intrusive research*' contained in the ESRC's REF.

¹ ADASS has indicated concern about the variation in standards across URECs, especially in respect of the documentation required.

² Exceptionally, a study may need to be submitted elsewhere if a Committee discovers during the review that it is not the appropriate Committee for that type of study.

³ Independence is a legal requirement for Committees recognised to review clinical trials of investigational medicinal products

⁴ ADASS has noted, and prefers, the slightly different definition of '*research*' provided on the ESRC web site: <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/research/ResearchMethods/>

- (viii) The proposed definition of ‘*social care*’ is that contained within the DH *RGF Social Care Implementation Plan* (DH, 2004). i.e.: research undertaken ‘in or with’ bodies (independent or statutory) providing personal social services – the PSS sector. The key to this definition is thus whether access to research populations is being sought via PSS agencies, or the provider organisations contracted by them.
- (ix) Currently, only *adult social care* is formally covered by the DH RGF, although some Councils have chosen to implement corporately and the DCSF is currently recommending the RGF as good practice. The RGF issued by the Department of Health covers research that falls within the responsibility of the Secretary of State for Health in England. Other UK nations have issued compatible Frameworks.

Sources of Social Care Ethics Review:

- (x) The main sources of independent ethics review considered in this paper are:
- committees operating within the national research ethics system (*NRES Committees*), including the new Social Care Research Ethics Committee (Social Care REC);
 - *University-based committees* (URECs), of which many (but not all) are operating under the ESRC’s REF. The Association of Research Ethics Committees (AREC) is working to consider ways to encourage greater consistency of UREC operation, incl. accreditation.
 - *other systems*:
 - some research funders, including many government Departments, do not obtain independent ethical review, but ensure good ethical practice via their research procurement processes. For government Depts., this process is guided by the new GSR ‘*Ethical Checklist*’⁵.
 - some non-university research institutes (e.g. National Centre for Social Research) have established their own ethics committees, with independent members;
 - some local councils (CASSRs, councils with adult Social Services responsibilities) have established *local governance committees* that undertake review (science and ethics) of in-house or ‘own account’ research and provide local governance clearance for externally-funded studies⁶.

Reciprocity Between and Within Review Systems:

- (xi) *Between URECs and NRES Cttees*

⁵ http://www.gsr.gov.uk/downloads/professional_guidance/ethical_assurance/ethics_guidance.pdf

⁶ A minority of CASSRs reserve the right to undertake ethics review of externally-funded studies if they are concerned about the quality, or evidence, of the review undertaken.

- All research undertaken 'in or with' the NHS⁷ needs to be reviewed by an appropriate NRES Cttee using the Integrated Research Application System (IRAS). URECs must be informed, and may require copies of IRAS applications, but should not undertake additional review.
 - All social care research that is funded by the DH will be reviewed by the new Social Care REC. This will ensure a single approval system for all DH-funded research.
 - Non DH-funded social care research may be reviewed by the Social Care REC or by the relevant UREC. The decision will be made by the lead researcher, in the context of the HEI's internal requirements and any made by funding bodies.
 - All 'intrusive' research involving people who lack capacity to consent, however funded and of whatever type (i.e. no definition of 'social care' is needed here), must **by law** be approved by a body recognised under the MCA. Currently only some Committees operating under the NRES, are so recognised. The Social Care REC is approved for this purpose..
- (xii) *Within UREC and NRES systems.*
- As required under the ESRC REF, HEIs should make appropriate arrangements to identify a lead UREC to review studies being carried out by a *consortium of HEIs*. This would normally be the UREC in the HEI of the principal investigator of the study. Copies of the study proposal and approval documents should be sent to UREC chairs in all collaborating HEIs.
 - NRES should establish clear procedures for the allocation of *research that involves both NHS and social care sectors*. It is recommended that **multi-site studies** involving both sectors, but without any clinical dimension (e.g. service or system evaluation, especially if only involving staff) should normally be dealt with by the Social Care REC. This recommendation may be revised in the light of impending changes to the Dept. Health document governing research ethics committees (GAfREC).
 - Access to the Social Care REC will be via *SCIE* (Social Care Institute for Excellence *or NRES routes*, using the IRAS application system (accessed via www.myresearchproject.org.uk). NRES/SCIE coordinators need to agree common standards and definitions in the handling of social care research and IRAS forms should provide a distinctive information route, and guidance, for social care applicants.

⁷ A more detailed definition of this condition will be provided in the revised GAfREC document (due shortly).

- (xiii) *Between Local Governance and NRES/UREC systems*
- CASSRs are responsible for ensuring appropriate review of in-house or own-account research. For studies they identify as 'high-risk' they may wish to secure approval by the Social Care REC, or local UREC (if available). Approval of a recognised committee however is required for any study covered by the MCA.
 - for all externally funded research, the CASSR is required to check that prior approval of ethics has been undertaken by an appropriate body (NRES Committee, UREC or 'other system', see vii above). Where this is the case, they should not then subject the study to further ethics review. However they will still need to assess, and ultimately decide, whether the work is appropriate for local circumstances/populations⁸. Councils may indicate changes necessary to enable access but should avoid requiring any changes to the proposed study that would invalidate the approval already secured.
 - where prior approvals have not been obtained the lead researcher will be required to seek ethics approval from an appropriate body. For DH-funded NHS and social care research, proposals will need to be submitted to the appropriate NRES Committee; for all other *single studies*, review will be provided by the lead researcher's UREC or local UREC/CASSR collaborations, or referred to the Social Care REC if review cannot be accessed elsewhere.
 - for *multi-site studies* the Social Care REC should be used, unless a single lead UREC arrangement (see x above) has/can be established.

(xiv) *Within CASSR Local Governance Systems*

- In the case of multi-site studies, participating CASSRs should avoid requiring researchers to submit different documentation. Ideally, a single Council should agree to undertake the necessary checks on behalf of the other partners.

Other Issues:

(xv) *Remit of the Social Care REC*

- The Social Care REC coordinator will be able to provide advice for researchers seeking ethics review, but is not currently resourced to provide advice on other aspects of research governance. It is not considered appropriate for the Social Care REC to produce ethical guidelines for social care researchers. These are already adequately provided by professional societies (e.g. British Sociological Assoc., British Psychology Society, Market Research

⁸ CASSRs will require sight of REC application forms and decisions and may also require relevant documents (e.g. participant invitation letters, questionnaires), especially if these have not been submitted to the REC. Councils are also required to check whether independent review of the science of the study has taken place and that the approval of the Association of Directors of Adult Social Services has been secured for multi-site (4+) studies.

Society, Government Social Research, Social Research Association) and by the ESRC.

- (xvi) *Risk Assessment*
- The Social Care REC will work towards developing a risk assessment approach appropriate to the social care context. This will enable the 'fast-tracking' of proposals judged to be of low risk. The 'Risk Assessment Tool' produced by the DH SC RGF Working Group or the ESRC's criteria for identifying low risk research (ESRC, 2005: s.1.2.2.) may be useful in this respect⁹.
- (xvii) *MCA Training*
- MCA Training provided by the NRES is designed to cover all types of research. The Social Care REC will monitor, as far as is feasible given the lack of baseline figures, the application and effect of the MCA on social care research. Both the British Psychological Society¹⁰ and the Government Social Research Unit are publishing guidance for researchers working under the MCA.
- (xviii) *Student Research*
- The Social Care REC will not expect to deal with student research; this will be the responsibility of the relevant UREC or UREC/CASSR collaboration, unless it is covered by the MCA. For practitioner-research, where there is no HEI involvement, ethical review should normally be provided by the CASSR's Local Governance Committee/Lead.

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⁹ ADASS has marked up however the need to develop a clear and comprehensive typology to guide the initial identification of 'low risk' studies.

¹⁰ *Conducting Research with People not having the Capacity to Consent to their Participation*, due November, 2008.