

ADSS Guidance Note

Research Governance Framework for Health & Social Care: Implementation Plan for Social Care, May 2004

Purpose

This Guidance is directed primarily to Social Services Departments in England and Wales – referred to as CSSR¹s. It draws on and refers to “*The Research Governance Framework for Health and Social Care: Implementation Plan for Social Care*”, published by the Department of Health (DH) in May 2004. It is intended to provide a more detailed interpretation of the DH guidance and the actions needed by CSSRs, especially over the months May to December 2004. It therefore supplements and does not replace reference to the full Implementation Plan. This can be found at www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment. The topic is Research Governance Social Care and the document Gateway ref. No.3402

Structure

The structure of this Guidance incorporates Section 7 of the DH guidance referred to above, adding three additional columns:

- “*What it means*”(especially for CSSRs),
- “*What needs to happen*” (more generally),
- *Comments*.

The DH text quoted from is accurate as at 24 May 2004. References to “Sections” are to that text.

Definitions

The full Implementation Plan proposes extensive and important definitions of “research”, “Research Funder”, “Research Sponsor” and so on. They are therefore not repeated here.

Issues and Questions

ADSS welcomes and invites responses about this phase of implementation of the Research Governance Framework. They will be included in the ongoing consultation mentioned in the Implementation Plan. In particular we would welcome reports of experience of use of the risk assessment framework referred to below.

¹ Acronyms

These are drawn from the fuller text. Commonly occurring are

- CSSR Council with Social Services Responsibilities
- DH Department of Health
- F/HEI Further/Higher Education Institution
- LGA Local Government Association
- RGF Research Governance Framework
- SC Social Care

Timetabled Action and Implications (as at 24 May 2004)

Date	Action	What it means	What needs to happen	Comment
Action 1: From May, 2004	All bodies willing to act as research sponsors inform DH of their intention to do so.	For the present, only those CSSRs who wish to be 'sponsors' of external research – i.e. research conducted by another organisation, not the CSSR itself - are required to state their intention.	The sponsor registration process and standards for acceptance by DH need to be set out. Being named on the list does not imply an "open-ended commitment"	The 'Sponsor' has significant responsibilities to secure scientific and independent ethical review of projects. See Section 4.
Action 2: May-December, 2004	DH works with care organisations and other stakeholders to clarify roles under RGF and develop Guidance where necessary	Any problems of interpretation of roles defined within the RGF need to be resolved. ADSS Research Group is happy to act as a conduit for issues in discussion with DH	CSSRs will need to identify current or anticipated issues, having studied the full Implementation Plan, to assess their preparedness to implement the RGF (see action 3 below)	Early experience by CSSRs of how sponsors perform their roles, including handling potential conflicts of interest, will be important.
Action 3: July-December 2004	DH publishes consultative proposals for ethics review in social care.	Options for the independent ethical review of ethical aspects of research proposals are currently being explored by the DH. ADSS will be the contact point for responses from CSSRs, linking with LGA.	During the period CSSRs may need to discuss with potential local partners possible choices and costs. Central govt. resources to set up and maintain ethics review systems have not been promised by the DH	From July 2004 independent ethics review applies to any external research, involving CSSRs: but CSSRs could also consider adapting systems for (later) application to internal research. A risk assessment framework tool is currently being tested, and is therefore available on this basis. Resources will need to be appropriate to commitments: i.e. proportionate to the number and complexity of predicted projects

Date	Action	What it means	What needs to happen	Comment
Action 4: From beginning July, 2004	Funders indicate for each study whether willing to take on sponsorship role	Funder role defined in Implementation Plan, Section 3 Sponsorship responsibilities summarised in Section 4.	CSSRs that have in-house research capacity and, in effect, fund projects will, de facto, assume the role of research sponsor. They need not indicate an intention to sponsor their in-house research, but must if they take on the sponsor role for other organisations.	
Action 5: From beginning July, 2004	No new research should begin without an identified sponsor.	CSSRs can support <i>external</i> research as long as the sponsor is registered with DH, including possibly the CSSR itself as sponsor. Otherwise the CSSR will need to make a specific check for each project that it has a specific (registered) sponsor.	CSSRs will need to have a doorway to check the sponsor status for all external research involving access to staff, users, & data – See Section 5	In-house research undertaken by a CSSR will necessarily have sponsor duties undertaken by the CSSR, provided it has the systems to do so, alone or with partners. (see Section 4) For student projects, the role of F/HEIs as sponsor will need to be addressed within F/HEIs. Usually the student's academic supervisor will be the sponsor.
Action 6: From beginning July, 2004	No new external research should begin without independent ethics approval	There is a reasonable expectation that full results of the review of each project will be supplied to CSSRs as part of procedure.	CSSRS will need enough documentation to confirm that ethical issues for the project have been effectively addressed before and/or in response to the ethics review process	The position of students is equivocal, depending on their employment status (i.e. are they on secondment from the CSSR in which they may be seeking to conduct research; or are they not employees of the CSSR?) In either case potential risks to research participants may be high and benefits from research relatively low.
Action 7: By end December, 2004	All CSSRs achieve 'first stage' RGF implementation.	CSSRs will need to have established a clear system of registering details: including sponsor, funder, and whether ethics review completed.	Model documentation will be valuable	A review of the scientific quality of the research is separate, but should be assured by the sponsor. There may be compliance issues in voluntary sector and user managed surveys

Date	Action	What it means	What needs to happen	Comment
Action 8: January 2005	DH undertakes follow-up national survey of CSSRs' progress on implementation.	CSSRs will be tested on whether they are prepared for the challenges of "second-stage" implementation.(see Section 5)	CSSRs need to maintain the high response rate achieved in the first survey, 2002.	This survey will cover both external and in-house activity, as before.
Action 9: June 2005	DH publishes Implementation Plan for national system of social care ethics review.	ADSS will respond, based on information supplied by CSSRs, on activity so far. Timing is half way through period assumed for second stage (internal) implementation.	Thorough assessment of potential issues and how they have been tackled. ADSS will gather case experience supplied by CSSRs	Likely to be low volume external activity to refer to, with the exception of student projects. However, handling of ethics issues in internal research will be on the agenda.
Action 10: June- December, 2005	DH works with stakeholders to develop governance arrangements for social care ethics system.	ADSS offers to be the contact point for responses from CSSRs, linking with LGA.	Further guidance to be prepared. Needs to take account of child care organisational changes.	Objective is to achieve status comparable to Health Research Ethics Committee system, and be recognised as such, especially where research crosses social/health care boundaries.
Action 11: By end December, 2005	All CSSRs achieve full RGF implementation.			
Action 12: January 2006	DH undertakes final national survey of CSSRs			
Action 13: By June 2006	National system for social care ethics review established.			