

# **AMS review of UK medical research regulation and governance**

## **Submission from the Academy of Social Sciences in response to the second call for evidence**

### **Summary**

The Academy of Social Sciences (AcSS) welcomes the opportunity to provide further evidence to the AMS review of the regulation of medical research, with a particular focus on a possible single research regulator. This second submission expands on some of the points in the evidence submitted in June, discusses a number of issues relating to a single research regulator for medical research, and gives answers to the questions raised in the call for evidence. The key points are:

1. AcSS supports the view of the RCUK and others that regulation of research should always be proportionate and adopt a risk-based approach.
2. The current system of regulation and governance of medical research is dysfunctional and inappropriate for much of the social science research relating to health services and health and social care. Major difficulties arise because of the variable and multiple applications to, and requirements of, local NHS Trust's R & D procedures. The current structures create a problem of 'multiple jeopardies'. Radical change is needed to make the regulatory process more proportionate.
3. A single research regulator could not simply focus on 'medical' research, it would have to be responsible for all the research covered by the Department of Health's Research Governance Framework (RGF). This means the inclusion of work on health services, health care and adult social care - the Social Care REC (SCREC) is part of NRES - carried out by professionals from a wide range of disciplines, including the social sciences, employed by HEIs and other organisations.
4. It is important that a single research regulator is able to develop different levels of regulatory activity for research with different levels of risk.
5. While social science research is firmly embedded within the range of research being carried out within the RGF there are no social scientists on the AMS Review Committee. AcSS believe very strongly that a further Inquiry is needed to look at the appropriate inclusion of social science within a restructured regulatory system.
6. The benefits of a single research regulator will only be achieved if:
  - health-related and adult social care research are within its remit;
  - if it takes over most of the research governance within the NHS.
7. There needs to be one system for permissions to undertake research within the NHS in the same way that there is one system for ethics review (NRES).
8. A major disadvantage/challenge for a single research regulator is whether it is possible to incorporate a wide range of functions and responsibilities within

one organisation. In the short term the option suggested by the RCUK of creating a single 'facade' is logical.

9. The key functions of single research regulator, from the point of view of social scientists, are outlined.
10. The submission argues that even while maintaining the benefits of a single system of regulation certain tasks can be delegated to other bodies. AcSS contributors believe, as the RCUK has suggested, that much great use could be made of RECs in Higher Education Institutions to carry out ethics review, particularly of health and wellbeing-related topics.
11. It would be inappropriate for a single research regulator for medical and health-related research to have responsibility for creating an efficient and effective environment for public and private sector research generally.
12. Widening the remit of a single research regulator from the scope of the DoH RGF would not be recommended at the present time.
13. Considerable discussion, with all the relevant parties, from a wide range of academic disciplines and institutional backgrounds, would be needed before the optimal operation and governance arrangement for a single regulator could be identified. This could best be facilitated by the further review advocated at 5 above.
14. The most significant measures that are needed to improve the current regulation and governance framework are to ensure that the new arrangements encourage interdisciplinary work within the NHS, particularly between clinicians and social scientists and that the contribution that social scientists make to the broad field of medical and health research is recognised and appropriately supported.

## **Introduction**

1. The Academy of Social Sciences (AcSS) is glad to be able to provide a second submission to the Academy of Medical Sciences in relation to its review of the regulation of medical research. In addition to addressing some of the questions raised about a possible single research regulator, members of AcSS have given further thought to the issues raised in its first submission. Some of the points made here will therefore reinforce or amplify the comments in our earlier evidence. But we should also stress that, while there seems to be widespread agreement among social scientists about the problems that exist in the current regulatory system, and support for a simpler, more proportionate and risk-based system, it is not certain there is unanimity about possible solutions. In addition, due to the short time scale for responding, AcSS has only been able to carry out a limited consultation with its members. We hope there will be an opportunity for further discussion of more fully specified alternative solutions and structures and their likely effects on research

participants, on researcher training and careers and on the production of high quality social science research for public social and economic benefit.

### **Problems with the current system**

2. One issue that has become clearer since June is that the current regulation and governance system for medical research is dysfunctional and inappropriate for much of the social science research studying health issues and health and social care services. The procedures in relation to ethics review, managed by NRES, have become simpler over time. The main difficulties arise over the variable and multiple applications to, and requirements of, local NHS Trusts' R&D departments. Some of these problems were included in the example in our first submission from CIRCLE. Further examples, in summary, which were given at a recent conference, are attached at Annex 1.

3. As the evidence from the MRC, on behalf of the Research Councils UK (RCUK) has reiterated, regulation of research should always be proportionate and adopt a risk-based approach. In recent years there has also been an emphasis on principle-based approaches. A number of the systems in current operation have adopted, or are moving to, this approach including NRES and the ESRC's Framework for Research Ethics. But there remains considerable diversity in local NHS Trust R&D bodies.

4. It is perhaps inherent in the current structures that there is a problem of 'multiple jeopardies'. RECs cannot resist getting involved in consideration of methodology, even where research has been funded by reputable bodies, following high quality peer review. NHS R&D governance committees have a duty of care and corporate responsibility which requires them to assess research quality and ethics where this affects methods. While the functions of research ethics review and research governance are different and need to be seen as separate, a system is needed that allows decisions on particular aspects to be taken once and which then obliges other bodies to accept them. This requires some radical change from the current arrangements to ensure that regulation does become more proportionate. More central decision-making about both ethics and governance making would facilitate large scale multisite research and would ensure more consistent approaches are to review being taken.

### **Boundary questions in relation to a 'single research regulator'**

5. A number of questions emerge when thinking about a single research regulator for medical research. The first is the definition of 'medical research' itself. While the original rationale for the current NHS regulatory framework was concerned with clinical research, as echoed in the terms of reference of this Review, the scope of the Department of Health's Research Governance Framework (RGF) is much broader so that it encompasses a much wider range of medical and health research including a considerable amount of social science research.

6. In theory, it would be possible for a single regulator, if one was created, to return to a narrow definition of 'medical research' covering clinical trials, experimental medicine and epidemiological studies, perhaps with the addition of the responsibilities covered by Human Tissue Authority and the Human Fertilisation and

Embryology Authority. But this is not realistic in practice. Nor has the idea found favour with members of AcSS who have contributed to the development of this submission. Medical and health research has become a broad and inclusive church with much valuable work being done by professionals from a range of disciplines, increasingly including interdisciplinary work, even within the context of clinical trials. It would be very important that a single research regulator did not put this range of work in jeopardy.

7. Social science research is an important component of the work within this broad church. The Social Care Research Ethics Committee (SCREC) is part of NRES and works within the DoH RGF in relation to adult social care. This is to be welcomed in the context of the increasing overlap between health and social care issues and reinforces the point that medical, health and social care research are heavily intertwined and cannot easily be separated.

8. At the same time, the DoH's RGF is not felt to be appropriate for all social care. AcSS has been given access to the summary of a report to be published in October which examined Research Governance in Children's Services – a study commissioned by DCSF (now DfE). The study found a lack of fit between the RGF – designed for health and adult social care – and research carried out in the context of children's services, which include, for example, education and early years provision, as well as social care. The definition of 'health' or 'medical' research in children's services is also becoming increasingly blurred, particularly with regard to the integration of services within children's trusts, and growing interest in the interaction between biological and social factors in children's health and development. In terms of the Review currently being carried out, consideration of the scope and responsibilities of the single research regulator would have to encompass some aspects of health and social care research as well as 'medical'. But further work will be needed before an appropriate boundary could be defined.

9. Within whatever boundary is created it would be important that it was possible to have different levels of regulatory activity for research with different levels of risk. The risks in a RCT are completely different from those inherent in an anonymised postal survey asking about a non-controversial aspect of health care. The inclusion of SCREC within NRES demonstrates that it is possible to operate in different ways within the same set of principles. The aim of the Social Care REC is to complement, not replace, other RECs. It addresses gaps in provision and operates on the basis that no investigator should have to seek ethics review from more than one REC. This approach could beneficially be extended to other health and health care research.

### **A more fundamental review of the regulation of social science research**

10. The RCUK has argued for the adoption of an approach that begins with first principles. This would involve examining the basis for regulation of medical research, including why research needs statutory regulation and what particular areas of research society deems needs this level of oversight. AcSS supports this approach as the necessary basis for being able to create a framework for the regulation of research which is fit for purpose for the foreseeable future but considers that it can only succeed if there is a further and separate Review, in parallel to the present AMS Review, focussed on the distinct issues represented by social science

within health-related research. The current AMS Review's remit is medical research and there are no social scientists among its membership. Yet, as this submission and the earlier evidence from AcSS have shown, a large amount of social science research is firmly embedded within the health and social care research being carried out within the remit of the DoH Research Governance Framework. The present review was not designed, staffed or organised for that purpose. It would repeat earlier mistakes to assume that its conclusions could simply be read across into the social sciences, with social science research being shoe-horned into systems designed for the governance of medical research as an afterthought. .

11. Such an additional Review need not compromise the timetable for the creation of any new single regulator. The Department of Health's paper on the future of arms-length bodies suggests that the introduction of a single research regulator is seen as a potential issue for the later years of the present Parliament rather than one for immediate action, leaving ample time for a parallel Review, informed by the work already done by the present AMS Review. Assuming that such an inquiry was set up on a similar model to the current AMS Review, it could be expected to deliver within an appropriate timescale. This need not, of course, delay a preliminary consolidation of currently separate functions behind a single façade as envisaged by RCUK. Such consolidation may itself create the infrastructure capable of sustaining the proposed social science-oriented Review.

12. Such an Inquiry would also be in a position to examine one of the current social science concerns about NRES RECs. There is simply inadequate representation of social science on many such RECs. Many social scientists experience the domination of the medical science paradigm within NRES RECs and a failure to understand other perspectives or see their relevance, which is not a helpful basis for sound decision-making. It is also the experience of a number of social scientists working within health based organisations that a clinical mentality and a RCT mindset is the 'default thinking' which governs procedures and informs regulatory decisions. If health and social care research is to continue to be reviewed by NRES RECs then a change of culture and a broadening of perspectives are needed.

13. It may be of interest to the Review to know that the UK has a lot of experience and knowledge of what constitutes effective regulation as a result of investment by the ESRC in social science research carried out by groups like the Centre for Analysis of Risk and Regulation (CARR) at LSE. Advice and information could perhaps be sought from such centres.

## **Questions**

**What are the possible advantages and challenges of 'placing the responsibilities for different aspects of medical research regulation within one arm's length body'?**

14. Simplification of the system, reduced duplication and speedier processing of applications would be widely welcomed in the social science community. However, the full benefits of a single research regulator in relation to medical research would only be achieved if two things were to happen:

1. that *non-medical research* in the health field was included and given equal status and consideration to medical research (the scope could be any research covered by the DoH RGF);
2. in addition to having one system for ethics review (NRES) for the whole of the NHS, as at present, the single regulator also handled all aspects of permissions to undertake research with NHS patients and staff – both medical and non-medical.

Local Trusts and similar bodies could retain discretion about participation in research in relation to local issues such as experiencing overwhelming pressures, or being over-researched, rather than on the basis of views of the quality of the research or the bona fides and characteristics of researchers. These can be established centrally as could the assumption that, as public bodies, Trusts should be expected to take part in research, unless they can make a good case for not doing so.

15. As mentioned earlier there would be considerable advantages to a single research regulator having the capacity to consider what level and kind of regulation is appropriate for research involving different levels of risk. AcSS members would like to see a system where low-risk research, carried out by professional researchers, could be: registered rather than vetted; that review decisions should be taken once in a consistent fashion; that public bodies (or organisations in receipt of public funds) should be expected to co-operate with legitimate professional research as a dimension of their democratic accountability to taxpayers and users; and that refusal of co-operation by such a body should be permissible only on clear evidence of research overload. The present system does not deliver this because of the diffusion of responsibilities between different actors like NRES, NHS RECs, R&D and HEI RECs. This leads to duplication, inconsistency and waste of resources. A single regulator would be in a good position to rationalise structures and functions.

16. One possible way of overcoming some of the difficulties of competing responsibilities would be to embed the review process within overarching principles such as Rigour, Respect and Responsibility from the Universal Code for Scientists proposed by David King as Chief Scientific Adviser. These were based on the outcome of consultations with natural and social scientists. Core issues for Rigour would ordinarily be determined against the methodological position of the proposed research rather than seeking to impose particular methodologies or engage in disputes between methodologies (<http://www.berr.gov.uk/files/file41318.pdf>). One of the advantages of these three principles is that they direct both reviewers and researchers to the critical main issues and help to avoid diversions on the basis of secondary matters.

17. A major disadvantage, or challenge, of one regulatory body for medical research is whether it is possible to incorporate a wide range of functions and responsibilities in one organisation effectively. One body would not, in itself, remove the different interests of different organisations and, in some ways, they could be intensified. This could lead to interminable wrangles. In some cases too, it would not be possible for all the necessary expertise to reside in that one body. As the MRC has argued, merging functions into a single regulator is unlikely to provide a step-change in the regulatory burden. For a single body to work its creation would need to lead to a much simpler regulatory regime than at present especially for research which is low risk.

18. Within a simplified system it would also be possible to address what some social scientists see as anomalies in the current NRES system - the current blanket exclusion of service evaluation, service user consultation, and audit. Inclusion needs to be based on the potential risk represented by a particular study, and its methodology, rather than the purposes for which the study was commissioned. For example, the evaluation of a learning disability service could generate serious harm, if not carried out with due respect for confidentiality or if evaluators were not checked in exactly the same way that a health service researcher would be. While the risks in such research may be low or minimal, nevertheless some research falling into these categories does raise significant ethics and governance issues, for example around coerced consent or data protection. Discretion would always be required in making decisions about what kinds of study were included, but the definition of research in the RGF may be helpful in deciding which studies come under the purview of the single regulator:

**What should be the future of the NRES and research regulatory activities of the HFEA and HTA?**

19. In the short term the option suggested by the RCUK of creating a single 'facade' to enable relevant parts of various regulators to be put together within a single organisation is logical. The three organisations identified should be part of this. But there would then need to be a proper review of the functions of regulation, and how best they could be achieved, to be able to determine responsibilities in the long run. This should include looking at the existing responsibilities of each organisation in terms of proportionality in relation to the degree of risk. It should also be based on a sound appreciation of the full range of bodies that commission health research (and perhaps social care research) and the array of clinical and non-clinical disciplines that are already involved in this field.

**Which approvals or 'permissions' should be within the remit of a 'single research regulator' to maximise its effectiveness and impact?**

20. It would be particularly helpful if, as has already been argued, a single research regulator for medical research were to take responsibility for the majority of the governance functions currently held by local NHS Trust's R & D bodies. Care would need to be taken to ensure that the system created by the single regulator properly recognised the difference between a governance function (focussed on local risk management) and an independent ethical review function (risk-aware but intended to facilitate research) and kept them as separate activities within the one organisation. The current system of NRES and NHS R & D, as well as bodies outside the health service such as local authorities, does maintain this distinction so that governance review focuses on the potential for damage to the institution while ethics review maintains a concern for the rights, welfare and wellbeing of research participants and researchers. They are separate functions but this does not mean that governance decisions cannot be taken centrally or through a centralised arrangement. Both kinds of review should be within the remit of a single research regulator.

21. The single regulator should also be the body with responsibility for the governance functions across the NHS as a whole in the reorganised structure that will be created following the abolition of Primary Health Care Trusts.

22. There are differences in governance between health and social care research in that the governance of social care is the responsibility of local authorities and other service providers, rather than the local NHS Trust. The SCREC was established after careful negotiations between social care organisations such as the Social Services Research Group (SSRG) and the Association of Directors of Adult Social Services (ADASS) and representatives from NRES. Having a single research regulator with responsibility for both ethics and governance for all research within the DoH's RGF would therefore require sensitive development and consultation with these disparate bodies to establish appropriate roles and responsibilities.

### **What should be the key functions of a 'single research regulator'?**

23. The key functions of a single research regulator for medical, health-related and social care research should include:

- Being the first port of call for the regulation, in terms of both ethics review and governance, of all medical, health and social care research currently within the remit of the DoH Research Governance Framework.
- Having oversight of the current regulatory system including examining, and instituting appropriate inquiries, of structures and processes within that system that could be improved.
- Ensuring that the regulatory system is proportionate, risk-based and efficient in the ways sought by Government: increase the speed of decision-making; reduce complexity; and eliminate unnecessary bureaucracy and costs. This should involve identifying the activities that need to be carried out by the regulator itself and those which could be delegated, with appropriate safeguards, to other organisations.
- A single regulator would be a suitable body to have the responsibility to explore the accreditation of RECs in the Higher Education Sector, and similar bodies, so that they can carry out ethics reviews for certain categories of health and social care research. If this is considered feasible by all the parties involved, a single regulator could also be the body that ensures an accreditation system is implemented.

### **How would a 'single research regulator' best fit into the wider regulatory and governance framework?**

24. The Rawlins Review may not be aware that the regulation of standards and ethical practice in research outside the medical field has developed significantly in the last 10 years. The Social Research Association led the field in updating ethical guidelines for social science research in 2001. A number of other disciplinary associations and learned societies in the social sciences have also had codes and guidelines for research ethics for many years which are updated and augmented as

required. The RESPECT project for the European Commission established pan-European standards for socioeconomic research in 2003 which subsequently informed the ethical regulation of all EC scientific research. The ESRC's Framework for Research Ethics produced in 2004, and recently updated, led to the majority of universities and other Higher Education Institutions, and certainly those carrying out research with human participants, setting up their own subject-specialist and generic HEI RECs.

25. We have argued that a single regulator, operating a single system, needs to have the capacity to apply different criteria, within the regulatory process, to research having different levels of risk. Equally, a single system does not have to be administered by one organisation. Certain tasks can be delegated to other bodies, constituted in different ways, provided these are set up and accredited appropriately. A number of AcSS contributors have suggested, as the RCUK have done, that much greater use could be made of HEI RECs for certain types of social science research on health and wellbeing-related topics. These bodies are, to a large extent, offering a parallel system to the one that exists in the NHS and they satisfy the ESRC's requirements for independence of scrutiny. They are also audited periodically by the ESRC. They are therefore bodies to whom ethics review of some projects could be devolved. Organisations outside the NHS use HEI RECs in this way, apparently successfully. For example, SCREC staff recommend that researchers go to their University's REC wherever possible. The study of research governance in children's services for the DfE also recommended a system of passporting of ethics review, to allow for a wide range of ethics review bodies, including those in HEIs.

26. A way forward could be for the Secretary of State's 'recognition' to be extended to HEI RECs for social science research in health-related topics, with clear criteria being required for such recognition. A single research regulator would need to work closely with HEI RECs, and other bodies carrying out ethics review, to identify clear lines of responsibility. Guidelines for the accreditation of such bodies could be jointly developed with the ESRC, AREC and other relevant organisations. What would be important is that the potential for duplication, which currently exists and occasionally occurs, should be avoided.

**How might a 'single research regulator' interface with other bodies or approvals to create an efficient and effective environment for public and private sector research?**

27. Other than HEI RECs which have already been discussed, AcSS is not aware of any organisation that has an overarching regulatory responsibility of the kind operated under the auspices of the DoH RGF. Funding organisations and learned societies have frameworks and guidelines in relation to research ethics which are widely followed. For example, within social science a substantial proportion of private sector research is carried out by members of the Market Research Society who abide by that organisation's code of conduct. This seems to work in an efficient and effective manner which indicates that there are alternatives to a bureaucratic, regulatory system for research which is low risk. It would be inappropriate for a single research regulator for medical and health-related research to have responsibility for creating an efficient and effective environment for public and private sector research generally.

28. At a more specific level, contributors to the AcSS submission have reiterated the value of a separately constituted Social Care Research Ethics Committee. It is hoped that this will continue to be run under the auspices of the single regulator (as it is now part of NRES) and fully recognised to approve research involving NHS patients and staff. In the increasing likelihood of jointly commissioned services there will be more social care research that needs to access NHS staff and users of Health run services, making it even more important to have a separate Social Care REC that can approve research to be undertaken in the NHS. Furthermore, social care research, often involves both local authorities and NHS Trusts. Different approaches are required to change regulation in the two bodies as local authorities have more autonomy. Consequently, early involvement of representatives from local authorities would be necessary, in order to ensure a coordinated system.

**Should the scope of the `single research regulator' encompass health-related research permissions currently outside the remit of the Department of Health or other areas of research affecting health outcomes and public health?**

29. It may be that there are special considerations relating to medical and health-related research which could justify a distinctive regulatory approach being applied to projects outside the remit of the Department of Health. But the recent DfE study, the report and recommendations of which will be published shortly, found that an RGF-derived research governance system was problematic for some forms of research in children's services. It seems likely that widening the remit of a single research regulator would not be recommended at the present time. A careful review and full debate with those outside the health field, including social scientists, would be necessary before any extension of the remit was considered.

**What would be the optimal operational and governance arrangements for a `single research regulator'?**

30. There would need to be considerable discussion, with all the relevant parties, before the optimal operational and governance arrangements could be identified. However, it would be extremely important that the structures, cultures and personnel of the new body were fully representative of, and conversant with, the diversity of the disciplines, fields and methods of those being regulated and with the implications for research into integrated service frameworks that may include health.

**Should a new `single research regulator' have a UK-wide remit and how would this fit with current structures in the devolved nations?**

31. There are arguments both for and against a UK wide remit. It may be that a different approach has to be adopted for some medical research in that clinical trials are often UK-wide. But research on health and social care is often specific to the organisational context. There is increasing divergence between the health and social care systems of the different nations within the UK. A single research regulator may not therefore be the best solution. Whatever system is adopted would need to be sensitive to these divergences and to have separate relations with the devolved governments.

**What other significant measures are needed to improve the regulation and governance framework for medical research?**

32. The single most urgent action, in the view of the AcSS, is to give much fuller consideration to ensuring that arrangements for regulation and governance facilitate the current flourishing of interdisciplinary research between clinicians and social scientists and promote the contributions that social scientists are making to the broad field of research in health and social care.

14.9.2010

## Appendix 1

Examples of problems with NHS R&D mentioned at the 2010 Medical Sociology Conference.

1. A researcher who had to have two full Occupational Health Examinations by the same contractor for two different Trusts because one asked for a blood test that covered rubella and another did not.
2. A researcher in his 60s who had not had chicken pox was required to have a vaccination which led to him contracting the disease and being unable to carry out the fieldwork anyway.
3. A project on retail optometrists in 10 PCT areas where the first PCT R&D declared that they had no jurisdiction over optical contractors and did not want an application and the other 9 each demanded their own set of forms be completed.
4. A 12 month DoH project which was about to be abandoned because there was no longer time to carry out any fieldwork given R&D delays over the summer.
5. A national survey that had been abandoned because of the workload involved in getting R&D approvals for professional staff to fill out mailed questionnaires. (This echoes the experience with an online survey reported previously).