



Equality Analysis

**Establishing the Health Research Authority as a
Non-Departmental Public Body**

1. Introduction

1.1 The Equality Act 2010

1. The general equality duty set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:
 - eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
 - advance equality of opportunity between people who share a protected characteristic and those who do not; and
 - foster good relations between people who share a protected characteristic and those who do not.
2. The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty. It is up to each organisation to choose the most effective approach for them. The Department of Health uses Equality Analyses as a way of demonstrating how it is giving due regard to the equality duty.

1.2 Scope of this equality analysis

3. This equality analysis assesses the equality implications of establishing the Health Research Authority as a Non -Departmental Public Body (NDPB).

2. The Health Research Authority

2.1 Policy background

1. The Health Research Authority (HRA) was established as a Special Health Authority (SpHA) on 1 December 2011 with the National Research Ethics Service (NRES) at its core. Its central purpose is to protect and promote the interests of patients and the public in health research. In meeting its overarching objective, the HRA is responsible for providing the NRES and working with other organisations to create a unified approval process for research studies and also to promote consistent and proportionate standards for compliance and inspection.

2.2 Objectives and aims

2. The aim of this draft legislation is to establish the HRA as a NDPB. This will mean that it is established as an independent regulator as part of a stable health and social care system, with an overarching objective to protect and promote the interests of patients and the public in health research.
3. The intended effects are to:
 - put the HRA at arm's-length from Ministers on a stable, independent footing assured by parliamentary scrutiny;
 - provide a stronger basis for the HRA to promote a consistent system of regulation of research across health and social care and across the UK;
 - strengthen public confidence in the protection that the regulation of research provides;
 - give the HRA independence so it can put the interests of research participants and the public first and be free from political interference; and
 - provide stability for researchers and funders, including industry.
4. Our intention is that, by protecting and promoting the interests of patients and the public in health and social care research, by providing a stronger basis for a consistent system of regulation across health and social care in the UK, and by providing stability, this will encourage long-term investment in the UK and contribute to the wealth and growth of the economy. The covering narrative and Impact Assessment that accompany the draft Bill provide further background on the establishment of the HRA.

2.3 Who will be affected by the policy?

5. Issues of equality can arise in relation to different aspects of health research and those involved in research. The representation of certain groups in clinical studies and the

composition of research ethics committees (RECs) are just two such questions that have been considered in the past.¹

6. Whilst the work of the HRA affects a range of stakeholder groups covered by the protected characteristics under the public sector equality duty, establishing it as a NDPB does not in itself involve reorganisation or substantive changes to the HRA's functions, and so the impact of the policy on these groups is expected to be limited. The draft legislation accompanying this equality analysis includes an amendment to the Equality Act 2010 to ensure that when the HRA is established as a NDPB, the public sector equality duty will continue to apply.
7. We have considered each of the stakeholder groups affected by the HRA's work including patients and the public, researchers and funders of research.

Staff in Bodies Affected

8. The main group that will be affected by the establishment of the HRA as a NDPB is staff that work for the HRA SpHA. This group will be impacted initially when the HRA NDPB is established and the HRA SpHA is abolished. It is expected that staff would transfer from the SpHA to the NDPB on their current terms and conditions. We do not, as the Impact Assessment for the establishment of the HRA as a NDPB sets out, envisage any change to the estate where staff are located as a result of the HRA's change in status. Should the HRA propose any changes in the future, proposals would be subject to a separate equality analysis. No differential impact across this group is therefore anticipated.
9. On its establishment as a SpHA, the HRA published an equality policy that sets out the culture and working practices the Authority intends to develop to address equality, as well as how it will take forward its public duty under the Equality Act 2010.² It is expected that this policy will evolve as the HRA's new role takes shape and is carried over into the NDPB.
10. The HRA requires equality training to be undertaken by its staff and by REC members, and is developing equality training for REC chairs and vice-chairs to address how they deal with researchers, staff and other members of the committee and to ensure equality issues are considered as part of ethical review. As the HRA develops the way in which it delivers its functions, the Department expects it to consider the impact of such functions on protected groups.
11. In the longer-term, as the intended effects of greater stability for researchers and funders, and greater public confidence in the protection that regulation of research provides are realised, the following groups will be affected.

¹ See for example: Clinical Research network Coordinating Centre, Equity in Clinical Research – inclusion of older participants, National Institute for Health Research, 2010.1. P1
http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/equity_in_clinical_research_22June2010.pdf
& Ethics? Whose Ethics? A Report on a Consultation Day, National Patient Safety Agency, 2007.1.P1-8

² <http://www.nres.nhs.uk/hra/hra-publications/?entryid85=138967>

Patients and the Public

12. Patients and the public stand to benefit from the production of new knowledge and findings arising from health research. At the same time, they must be assured that such research is effectively regulated and that research studies (in which they and others may participate) have been approved against relevant legislation and good practice guidance, and are both safe and ethical. It is anticipated that the increased independence of the NDPB will strengthen public confidence in the protection that the regulatory framework provides and encourage participation in research. The central purpose of the HRA reflects the need to both protect patients and the public and to promote their interests in research.

Researchers, Research Sponsors and Hosts

13. Researchers, along with research sponsors and host organisations, similarly benefit from the assurance that the research conducted by themselves and their peers is safe and ethical. The regulation of health research has clear implications for their work, for example affecting the time it may take them to commence a study. It will also mean that the HRA's role in promoting a consistent system of research regulation across health and social care and the UK will be enshrined in primary legislation. This is in contrast to a SpHA where functions are conferred by the Secretary of State, and whose role, remit or even existence can be changed at any point.

Funders of Research

14. The HRA's work has an impact on organisations that invest in and, in some cases, employ those doing health research. This group includes charities (eg the Wellcome Trust and Cancer Research UK), private companies and industry (eg Johnson & Johnson and Glaxo SmithKline) and public funders of health research (eg the Medical Research Council and the National Institute for Health Research). The way in which health research is regulated has implications for the cost effectiveness of research. The stability achieved by establishing the HRA as a NDPB will provide assurance to this group that the HRA will continue to make it easier to undertake research in the UK through proportionate regulation, encouraging long-term investment in the UK.

3. Evidence

1. As a more stable and independent body, with enhanced credibility, the HRA will be better placed to protect and promote the interests of patients and the public (including those in the protected groups) in research. Very little evidence has been found showing what effect the change in status of the HRA would have on individuals in the protected groups.
2. In conducting its analysis, the Department has sought evidence from the HRA SpHA, the public participation group INVOLVE, and has also conducted literature searches using databases such as Swetswise and NHS Evidence. However, as acknowledged in the equality analysis prepared for the Health and Social Care Act 2012 (in particular the part addressing changes resulting from the ALB review) there is limited evidence available about the impact of organisational change on health inequalities or the promotion of equality.

3.1 Sources reviewed for evidence

3. Below we set out the sources we have reviewed for evidence.

The Academy of Medical Sciences' review of regulation and governance in health research

4. Following the Government's announcement proposing a research regulator, the Department asked the Academy of Medical Sciences (AMS) to consider the scope and functions of a research regulator as part of an independent review of the regulation and governance of health research the Department had commissioned. The AMS's report, *A new pathway for the regulation and governance of health research*, was published in January 2011.³ There is no evidence in the report on equality impacts associated with the establishment of a research regulator.

Information from the HRA SpHA

5. Because the HRA SpHA is a relatively new organisation, it is not yet practicable to conduct a rounded assessment of the impact of its establishment on issues of equality, but a better picture should emerge as the HRA takes steps to meet its public sector equality duty. In developing its plans to deliver a unified approval process for research and to promote consistent and proportionate standards for compliance and inspection, the HRA has worked with a team including the Human Tissue Authority, Medicines and Healthcare products Regulatory Agency, the National Institute of Health Research and NRES. These plans were published as an update to the HRA's 2012/13 business plan⁴. The Department has considered the HRA SpHA's equality policy, which takes into account the impact of its functions upon each of the protected groups and sets out the culture and working practices the Authority intends to develop to address equality, as well as how it will take forward its public duty under

³A new pathway for the regulation and governance of health research, Academy of Medical Sciences, 2011.1.P1-128 <http://www.acmedsci.ac.uk/index.php?pid=99&puid=209>

⁴HRA updated business plan addition, Health Research Authority, 2012.1.P1-12 <http://www.hra.nhs.uk/hra/hra-publications/?p=2>

the Equality Act 2010.⁵ The policy addresses the behaviour of HRA staff and research ethics committee members, the HRA working environment and the delivery of HRA services to its users. It is expected that this policy will evolve as the HRA's new roles take shape.

6. The Department has also considered equality data and proposed objectives for the HRA⁶. This data relates to HRA SpHA staff and volunteer REC members and is based on returns to their former employing organisations. The HRA has committed to collect more comprehensive data in the future. It has also invited interested groups to participate in shaping proposed equality objectives, as well as to suggest any further objectives that they feel appropriate.
7. Neither the equality policy, nor the equality data and objectives, address the impact on equality as a result of the Authority's proposed change in status to that of a NDPB.

Research Governance Framework

8. The Department currently publishes the Research Governance Framework for Health and Social Care which requires that researchers take account of issues of diversity in formulating their work. It states that: "Research, and those pursuing it, should respect the diversity of human society and conditions and the multicultural nature of society. Whenever relevant, it should take account of age, disability, gender, sexual orientation, race, culture and religion in its design, undertaking, and reporting."⁷ The draft legislation to establish the HRA as a NDPB gives responsibility for publishing guidance about principles of good practice in health and social care research to the HRA. The HRA itself may therefore have an impact on protected groups through this guidance.

3.2 Impact on each of the protected groups

9. We have considered the impact that the policy proposal to establish the HRA as a NDPB may have on each of the protected groups:
 - disability;
 - sex;
 - race;
 - age;
 - gender reassignment (including transgender);
 - sexual orientation;
 - religion or belief;
 - pregnancy, and maternity; and
 - carers.

⁵Equality policy, Health Research Authority, 2011.1.P1-9 <http://www.hra.nhs.uk/hra/hra-publications/?entryid85=138967>

⁶Equality data and objectives, Health Research Authority, 2012.1.P1-8 <http://www.nres.nhs.uk/hra/hra-publications/?entryid85=140512>

⁷Research and Development Directorate, Research Governance Framework, Department of Health, 2011.2.P1-44 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474

10. Given that this draft legislation is amending the status of an existing body, and because it does not in itself involve any reorganisation and the functions that the HRA as a NDPB will have will not differ from those of the SpHA, the Department does not anticipate that there will be a material impact on any of the protected groups as a result of the policy.
11. The HRA SpHA is a relatively new body and a clearer picture of the impact of its establishment on issues of equality should emerge as it takes further steps to meet its public equality duty. It has set out how it intends to do so through its equality policy.

3.3 Impact on elimination of discrimination, harassment and victimisation, advancement of the equality of opportunity, and promotion of good relations between groups

12. We have considered how the proposal to establish the HRA as a NDPB impacts on elimination of discrimination, harassment and victimisation, advances equality of opportunity and promotes good relations between protected groups.
13. Given that this draft legislation is amending the status of an existing body, and because it does not in itself involve any reorganisation and the functions that the HRA as a NDPB will have will not differ substantially from those of the SpHA, the Department does not anticipate that there will be a material impact on any of the protected groups as a result of the policy.

3.4 Engagement and involvement

14. Neither the establishment of the HRA as a SpHA nor as a NDPB have been subject to a formal Government consultation. The Code of Practice on consultation recognises that, at times, a formal, written, public consultation will not be the most effective or proportionate way of seeking input from interested parties. The Government asked the AMS to conduct an independent review of the regulation and governance of health research which included looking at the possible scope and functions of a research regulator. Some 280 written submissions were received in response to the AMS's calls for evidence, including from academia, industry, the NHS, regulators and medical research charities. A full list of the organisations and individuals that responded to the AMS's call for evidence can be found at Annex IV of the AMS report. Consultations with unions and staff took place in the usual way where staff have, or are, transferring to the SpHA.
15. Proposals for a research regulator were made in both the Department's review of arm's-length bodies and the AMS report, which gained input from a wide group of stakeholders. In establishing the HRA as a SpHA, the Department has met with a range of stakeholders, including health research charities, patient and public groups, industry and other regulators with whom the HRA works. These meetings have provided opportunities for engagement and the exchange of views about the SpHA's role and objectives as well as those of the proposed NDPB.
16. The passage of the Health and Social Care Act 2012 included a number of debates on establishing the HRA as a NDPB. In response to these debates, the Government announced

its intention to publish clauses in draft covering the establishment of the HRA as an executive NDPB for pre-legislative scrutiny in the second session of this Parliament. There will be on-going stakeholder engagement throughout the pre-legislative scrutiny process with both the HRA and other interested stakeholders, and the Department will consider any further relevant recommendations.

4. Summary of Analysis

17. Given that this draft legislation is amending the status of an existing body; that the functions the HRA will have as a NDPB will not differ substantially from those of the SpHA; and that no evidence has been found of any impact on equalities as a result of the HRA's proposed change in status, the Department does not anticipate that there will be a material impact on any of the protected groups as a result of this change. Because the HRA SpHA is a relatively new organisation, it is not yet practicable to conduct a rounded assessment of the impact of its establishment on issues of equality, but a better picture should emerge as the HRA takes steps to meet its public sector equality duty. It has established how it will do so through its published equality policy⁸.

4.1 Overall impact

18. Overall the Department has found no evidence that the establishment of the HRA as a NDPB will impact on inequalities.

4.2 Action planning for improvement

19. Whilst no equality issues have been identified, the Department recognises that there is little evidence about the impact that the policy may have on equality. The Department will continue to engage a range of stakeholders in developing and implementing the policy, working closely with the HRA itself. The Department will consider evidence provided as part of the pre-legislative scrutiny process and, if this identifies equality issues, will consider what appropriate action is required.
20. There will be on-going stakeholder engagement throughout the pre-legislative scrutiny process and an opportunity to comment on the Equality Analyses. Any further comments and evidence will be considered as part of this process and the Analyses will be updated when legislation is introduced to Parliament.

⁸ Equality policy, Health Research Authority, 2011.1.P1-9 <http://www.hra.nhs.uk/hra/hra-publications/?entryid85=138967>

For the record

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