Health Research Authority

Guidance on conducting consultations in the HRA –

Internal HRA guidance only

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Contents

Introduction

The government is committed to more open policy making and consultation with stakeholders forms part of that process of opening up policy making. Traditionally new policy is formally consulted on once the final draft of the policy has been developed. Increasingly however policy makers are being encouraged to consult with stakeholders at an earlier stage in the process. Consultation can take place at many different stages in the process of policy development.

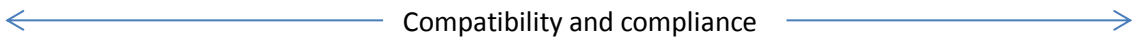
This document

This document is an internal Health Research Authority (HRA) policy document on the conduct of consultations. It outlines the process that the HRA should follow and draws on the Cabinet Office guidance on consultation principles. For the sake of simplicity, all types of consultation are referred to as a 'consultation' in this document even if they take the form of a simple 'call for comments'. Various templates to help with the consultation process are attached as an appendices.

Background

As a Special Health Authority, the Health Research Authority had no direct responsibilities for health research policy that required formal consultation. The HRA (and predecessor organisations) have through custom and practice adopted development and implementation of operating procedures, advice and guidance through periods of comment and / issue for a period of use and comment. In developing operating procedures, advice and guidance, the HRA (and predecessor organisations) must ensure compliance and compatibility for EU, UK, country specific Directives, Regulation, Legislation and Policy.

	EU Directives	**EU / UK Regulation**	**UK / Country specific Legislation**	**Health Research Policy**	**HRA Operating procedures/ standards and templates**	**HRA Advice and guidance**
Input/ remit	HRA input	HRA input	HRA input	HRA input – as Special Health Authority HRA remit – as NDPB*	HRA remit	HRA remit
Consultation		Consultation in partnership with the Devolved Authorities	Consultation in partnership with the Devolved Authorities	Formal consultation	Consultation/ comment as best practice	Consultation / comment as best practice



The HRA Special Health Authority Directions give responsibility for the HRA to develop and manage Standard Operating Procedures (SOPs) for Research Ethics Committees (RECs). The Research Governance Framework (RGF) references the need for sponsors and investigators to comply with conditions of REC approval and makes consistent reference to the application of 'good practice'. The HRA (and predecessor organisations) has through periods of comment or in use and comment ensured the required compliance with legislation and appropriate application within the context of good practice. There has been increased visibility of the role of the HRA with respect to setting standards for good practice and issuing guidance and advice, and increasingly the HRA has received responses beyond those of its immediate stakeholders that can be managed through established meeting s and networking. The HRA developed guidance in September 2014 for its management of calls for comments, and how it would provide feedback to those submitting responses and more widely.

As the HRA became a Non-Departmental Public Body* (NDPB) on 1st January 2015, it took direct responsibility for research policy in England, and duties to collaborate with the Devolved Administrations to provide a UK wide setting for health research. It is important that in taking these responsibilities and to manage its greater visibility as a leader in the field of health research policy, operating standards, guidance and advice that the HRA sets out clearly how it will manage consultations and calls for comments. The HRA should be able to demonstrate as a public body that we are cognisant with the Cabinet Office Guidance on Consultation Principles published in October 2013.[1]

Why consult?

To paraphrase the Cabinet Office Consultation Principles, there can be many reasons to consult stakeholders; to inform developing policy and guidance, to understand different views and preferences, to get views on implementation and more importantly to understand any unintended consequences of a policy or guidance.

A consultation or call for comment should only take place if there is a genuine question to be addressed and if there is scope for the answers to that question to be taken into account. Issues which have already been decided upon should not be consulted on.

What form can a consultation take?

Consultations can take many forms including:

- simply asking for open responses to a series of questions
- surveys (online and paper) using a mixture of closed and open questions
- stakeholder meetings, focus groups and workshops to deliberate and debate the issues.

Where a large response is anticipated, it is helpful to try and quantify opinion with an online survey. It should be noted that the HRA has access to Surveymonkey for online surveys.

Formal consultations should be as open and transparent as possible and it may be helpful to use multiple methods to increase accessibility. For example, a formal consultation might include an

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255180/Consultation-Principles-Oct-2013.pdf

online survey, availability of hard copy questionnaires for those that want them, regional workshops and focus groups with specific target groups that might be affected by the policy.

A proportionate approach to undertaking consultations

Seeking the views of others can take place at different stages in the process of developing policy or guidance; it may simply be identifying existing problems and collecting new ideas for improvement as opposed to testing different policy options.

Formal lengthy consultations are not always necessary but would be expected when the policy or guidance is likely to have a significant impact. Topics which are likely to have a high impact on some or all stakeholders or are likely to be contentious should be regarded as a formal consultation. At the other end of the spectrum we have simple 'calls for comment' on a particular issue or set of issues. In some cases, a 'call for comment' refers interested parties to a particular website or document where such parties can find more information about the consultation process. 'Calls for comment' may also include some background information or analysis concerning the issue or issues raised for consideration and usually run for a much shorter time than a formal consultation. Alternatively an informal consultation might simply be a call for evidence to understand the impact of existing guidance or policy.

One size does not fit all, and the HRA is expected to take a proportionate approach when deciding on the scale and duration of a consultation based on the potential impact of the policy or decision. Where adequate consultation has already taken place at an earlier stage, a large scale formal consultation might not be necessary. Minor or technical amendments to existing guidance or frameworks may not require a formal consultation.

It is important to bear in mind any impact on small groups of stakeholders who may be disproportionately affected by a change in policy or guidance. Where this might be the case, a longer and more detailed consultation should be considered.

Whatever type of consultation is embarked on, staff need to be able to justify the chosen approach.

Timing and duration

Consultation with stakeholders should take place as early as possible in the policy development process. It may be appropriate to engage with different groups at different stages of the process or use different methods of consultation at different stages of policy development. So, for example, one might hold small workshops with stakeholder groups in the very early stages of the process and finish the final stage of the process with a formal large scale national consultation which would be open to anybody to take part in. Early consultation allows for the early detection of unintended consequences without to having to back track later.

It is good practice to explain the rationale for proposed changes as early as possible to allow challenge to take place.

Consultations can run from a minimum of two weeks up to 12 weeks but a large scale, formal consultation is expected to run for 12 weeks. Certain times of year are to be avoided and formal consultations should avoid taking place over key holiday periods, for example, Easter, summer

holidays, Christmas. Where formal consultations do take place over the holiday periods, the duration of the consultation should be extended to take this into account. Certain stakeholder groups may be more affected by timing than others, for examples, academics might be more likely to be unavailable in August than some other groups and the capacity of different stakeholder groups to respond within the given timeframe should be taken into account.

Making information accessible and useful

Consultations should be made accessible to their target audience. Early consultation may be restricted to a small number of targeted groups but a formal consultation would be expected to be accessible to anyone that wanted to comment.

Consideration needs to be given as to whether patients or public would be interested in commenting on particular policies, in which case the consultation document needs to be worded in an accessible format. If patients and public are the target audience of a consultation, it will be important to ensure that it is accessible. This might mean not restricting responses to online surveys and running workshops and meetings for face to face consultation. Depending on the subject matter, it might be important to seek the views of the general public rather than just experienced patients. Where patients and the public are a key stakeholder group in a consultation, it is important to ensure that a simple plain English version of the consultation is made available.

Where face to face consultation is used as a method, it is also important to ensure that meetings for the general public and patients are not just held in London.

Potential stakeholders should be given enough background information to enable them to form opinions or at least be directed to where this information might be found.

Transparency and feedback

The purpose of the consultation process should be made clear including how the feedback will be used. It is helpful to make clear upfront what issues are not up for debate and which ones are open to change.

Stakeholder groups

The HRA has a number of different stakeholder groups, not all of which will necessarily need to be consulted every time. Some consultations will need to take a targeted approach and a decision as to who should be consulted and on what scale will need to be made on a case by case basis. A template for a consultation plan for stakeholder groups is included in the appendices. Possible stakeholder groups include:

- REC members
- the research community
- NHS R&D management
- HRA staff
- NIHR
- Academia
- Industry
- Third sector
- Other regulatory bodies

- Patients
- General public.

Process on commencing a consultation

Each consultation must have a nominated lead at a senior level (not necessarily a Director). This will person will be responsible for ensuring compliance with this guidance and for acquiring formal sign off for the project.

The vast majority of projects will benefit from some early internal consultation in the development of the consultation document. Key internal stakeholders who might be asked to contribute to this process depending on the subject matter are:

- National Research Ethics Advisor Panel (NREAP)
- Confidentiality Advisory Group (CAG) or (CAG membership)
- REC Chairs and members
- HRA staff
- Patients and public acting in an advisory role to the HRA.

The lead person will be responsible for establishing a steering group to advise on formal consultations.

Some consultations may attract a large response and where this is anticipated, the lead person should flag the project with the Project Management Office as requiring additional administrative resource.

Each consultation should have its own dedicated email address to avoid individuals using their own email addresses and a nominated individual should be given access to the email account. Email addresses for consultation purposes should all adhere to the following format: 'HRA.xxx@nhs.net'. It is good practice to set up an automatic response on the email account for the duration of the consultation to acknowledge receipt of comments.

UK wide consultations

There will be times when the HRA wishes to consult on issues outside of England. Before embarking on a UK wide consultation, the exact nature of what will be consulted on, the methodology to be used and the duration will need to be agreed with each of the Devolved Authorities (DAs). It is likely that each DA will manage their own consultation locally although the HRA may develop online consultation material to be accessed across the UK with the agreement of the DAs concerned. The nominated lead with be expected to have liaised with the DAs either through the Four Nations Group or via a specially convened group including the DAs. UK wide consultations may need to allow for variations across the UK depending on local policy and legislation. Occasionally issues which we treat as an informal call for comment maybe regarded differently by an individual DA and the questions asked in the consultation may also be required to vary in order to take into account local differences.

Sign off at HRA

Before going live each consultation must be signed off by the HRA. The level of sign off will vary with the type of consultation:

- Simple calls for comment and informal consultations - to be signed off by lead person (working with any specific project group) with Director or CE approval. EMT should be given the opportunity to comment on all simple calls.
- Formal consultations to be signed off by both EMT and the Board. Versions seen by EMT and the Board do not necessarily need to be the final drafts, but must be considered at that level with a final signoff delegated to the CE, Director or EMT.

Recommended process on closure of consultation

Where responses are submitted by email, each submission including email texts and their attachments should be numbered, logged and uploaded to a file on the shared drive. A template for logging responses is attached. Responses submitted as hard copies should be logged, scanned and uploaded.

After each consultation, a summary of responses should be produced. This summary should state how many responses have been received, how many are from individuals and how many are from organisations. The responses should be summarised, ideally with an explanation of the next steps for the HRA. It is good practice to state how this feedback will be used and the HRA response to key points. It is important to differentiate between recommendations made by respondents and the final recommendations made by the HRA following consideration of the responses.

A summary of responses should be produced ideally 12 weeks after a formal consultation has closed. Where it is not possible to produce a summary of responses within 12 weeks, then it is necessary to make a statement as to why a longer period is required.

The nominated lead for the consultation might want to consider the effectiveness of their consultation including the methods used. As well as volume and range of responses, this might also include use of google analytics to assess use of webpages.

Confidentiality and sharing of responses

In the interest of transparency, all comments made on behalf of an organisation will normally be published and attributed unless an explanation is given as to why the information should not be made available. Individual comments will be summarised in a way that does not identify individual respondents unless they have specifically given permission for their information to be shared. However information received may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). Under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. Consequently it may become necessary to disclose information.

Any consultation response received without an accompanying form will be assumed to be attributable if they belong to an organisation and will be treated as anonymous if it is an individual responses.

An agreed form of wording explaining the HRA position on how responses will be treated together with questions which should be asked of all respondents is included in the appendix. This must be included in **all** consultation documents.

Impact assessments

All formal consultations of policy should be accompanied by an impact assessment. This might include an equality and diversity assessment where this is applicable. Where it is felt that a policy might disproportionately impact on a particular stakeholder group, then it might be sensible to target this group in the consultation process in order to inform any impact assessment. HRA templates for equality and diversity assessments can be found on the HRA intranet.

Appendix

Template for consultation plan for stakeholder groups

Consultation Plan

This is/is not a formal consultation asking the public to comment on guidance.

Duration:

The consultation/ call for comments will go live on (insert start date)with a deadline of (insert end date) for comments.

Action following close of response period

For example:

Following comments we will revise the paper and issue as formal policy/ guidance by (insert date)

Potential Stakeholder Groups

We plan to cover a wide range of stakeholders (potential groups to be decided in each case in liaison with Communications team) using the template below:

Stakeholder Category	Stakeholder Group	Email address…	Named contact

Template for logging responses

	Type of response	**Organisation**	**Respondent**	**Email only**	**Attachment**
1	Org/Individual	Name of organisation	Name of respondent	Yes/No	Yes/no
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
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22					

Suggested wording to be included in all consultations

(NB. In a formal consultation additional demographic data may also be sought).

About you

What will we do with your response?

The HRA has a commitment to transparency. We will analyse the comments we receive, and publish a report on our website explaining how we will address the themes raised. The published report will compare the views of different organisations and groups of individuals.

Organisational responses: In the interest of transparency, all comments made on behalf of an organisation will normally be published and attributed unless an explanation is provided with your response as to why you consider the information should not be. (Please note the Confidentiality of Information section below.).

Individual responses: We will aim to summarise individual responses in such a way that does not not identify individual respondents unless we have your permission to identify you.

If we receive a consultation response without an accompanying form we will adopt the position that organisational responses are attributed and individual responses anonymised.

Are you responding in an organisational or personal capacity?

○ **Organisational**

○ **Individual**

If you are replying in an organisational capacity, please note that your response may be published and quoted in the final report.

○ If you do not wish your organisational response, and any quotes used from it, to be identified in any consultation report and any future HRA publications, or published once the consultation has ended please explain why below:

Individual responses

I am responding primarily as a: ○ Researcher/ research team ◉ Research support ○ Member of the public ◉ Patient ○ REC member ○ HRA staff ○ R&D community ○ NHS staff ○ Industry ○ Phase 1 company ○ Regulatory body ○ Academic ○ Other Please write in below:
○ I am willing for my response, and any quotes used from it, to be made identifiable in any consultation report and any future HRA publications
◉ I do not wish my response, or any quotes used from it, to be identified in any consultation report, future HRA publications, or published once the consultation has ended.

All responses

○ I am willing to be contacted by the HRA for further information in relation to this consultation or future consultations.
If you have checked the box above please provide your contact details below. By providing these contact details, you are giving your consent for a member of HRA staff to contact you about your submission. The HRA takes data protection very seriously. We promise we will not pass your details on to any other organisations or use them for any other purposes.
Contact name:

Email:

Confidentiality of information

The HRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties without your permission or unless required by law.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the HRA.