

## Consistency in REC Review

### Summary

1. **Consistency** is taken to mean that, for any specific application or other, similar, applications, Research Ethics Committees (RECs) give the **same decision** for at least roughly the **same reason**.
2. Consistency refers to both **consistency of procedure** (SOPs/Membership etc.) and **consistency of content** (decisions and their associated reasons).
3. **RECs should be procedurally consistent**. That is, they should
  - **be similarly constituted;**
  - **have access to the same information and expertise;** and
  - **consistently apply standard operating procedures;**
  - **consider the same range of ethical 'categories'** in the process of their review.
4. **Whilst consistency in terms of content** (i.e. REC opinions and their associated justifying reasons) **is desirable, different committees may legitimately come to different decisions about the same research proposal**.
5. However, **there are limits to the range of decisions that are acceptable**.
6. These limits (and so the values of RECs) should be **contextualised by taking into account relevant "real world" clinical and research practice**.
7. **Recommendations:**
  - **Contextualisation** requires **broader engagement with researchers, patients and the public** regarding the values, standards and practicalities of current clinical practice in specific parts of medicine.
  - **Past decisions/decisions of other committees** regarding similar research should be more formally taken into account as part of the review of new applications.
  - **Appropriate Opinion Type**. The decision regarding the appropriate opinion type (favourable, provisional, unfavourable etc.), consistent with the reasons and requirements underlying that opinion, is a matter of *procedure* amenable to SOPs and thus should be formally taken in consultation with the REC Manager and/or other HRA staff.



## Introduction

8. The overall objective of the National Research Ethics Advisors' Panel is to help Research Ethics Committees deliver robust, consistent and fair decisions. This paper aims to clarify what is meant by 'consistent decisions' and how we might better promote consistency amongst RECs.
9. RECs have occasionally been criticised for exhibiting an unjustifiable level of variation or inconsistency in their decisions. This is supported by academic papers that discuss variation in decision-making by RECs<sup>1</sup> as well as evidence provided by the National Research Ethics Service's own Shared Ethical Debate<sup>2</sup> exercises. Recent ShED reports have shown that presenting RECs with the same application results in a range of opinions being given, both in terms of opinion type (provisional, unfavourable, favourable (+/- additional conditions) etc.) and the reasons cited for their opinion.
10. This document sets out what is meant by "consistency", whether it can and should be achieved and finally, practical suggestions are made to improve the consistency of REC decision-making.

## What is "Consistency"?

11. For the purposes of this document consistency is taken to mean that **RECs give the same decision for at least roughly the same reason.**
12. It is important that REC decisions are not 'one-off' and consistency requires that two RECs would give the **same decision** (or the same decision for roughly the same reason) **in a series of similar cases.**
13. Consistency can refer to either **consistency of procedure** or **consistency of content.**

## Procedural Consistency

14. Procedural consistency means consistency of the **structure and process involved in the making of decisions** rather than the decisions themselves.
15. **RECs should be procedurally consistent.**
16. The argument for this assertion rests upon the **principle of justice** or fairness, i.e. all applicants for ethical review should be treated equally and subject to a fair process. A system in which REC decisions are inconsistent (one researcher's application is approved whilst another, similar, application is not) due to difference in procedures is unfair. Research participants should be able to expect that any research they have been involved in has been subjected to the same process as other, similar, research studies.
17. In practice, this means that RECs should be:
  - **similarly constituted** (number and type of members relevant to the type of applications reviewed);

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<sup>1</sup> Edwards et al.(2004), report 19 empirical studies on this or related issues whilst Abbot and Grady (2011), in their systematic review of empirical research evaluating ethics committees find 16 looking at variation in process and outcome.

<sup>2</sup> The Shared Ethical Debate (ShED) is a process of ethical review of a single application (previously reviewed by an NRES Research Ethics Committee (REC)) undertaken by a number of RECs with the purpose of reviewing consistency in decision making and issues raised at meetings.

- have **access to the same information and expertise**; and
- **follow consistent operating procedures**<sup>3</sup>.

18. In addition, RECs should consider the **same range of ethical ‘categories’** in the process of reviewing each proposal<sup>4</sup>. For NHS RECs these will be the categories used in the latest HRA ‘Ethical Review Form’ as published (and Ethical Review Form for MCA Studies’) i.e.:

- **Social or scientific value; scientific design and conduct of the study** (including involvement of patients, service users and the public, in the design, management, and undertaking of the research)
- **Recruitment arrangements and access to health information, and fair research participant selection**
- **Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future)**
- **Care and protection of research participants; respect for potential and enrolled research participants’ welfare & dignity**
- **Informed consent process and the adequacy and completeness of research participant information**
- **Suitability of the applicant and supporting staff**
- **Independent review**
- **Suitability of supporting information**

19. It is reasonable for all stakeholders, including researchers and potential participants, to expect that RECs will consider the same set of issues for each research proposal. Given this, RECs should have a common understanding of what each category involves and explicitly consider each of them. The minutes should be produced in a consistent format using the above categories in order to clearly demonstrate the REC has taken into account each of these issues as part of the review process.

### **Content Consistency**

20. Content consistency means consistency of **opinions** given by the REC as well as the **reasons** that justify those opinions.

21. Such consistency would require that **RECs should reach the same decision about a particular research study, for broadly the same reasons. However, unlike procedural consistency it is less obvious that we should expect consistency in terms of content from RECs.**

<sup>3</sup> The current [NRES Standard Operating Procedures for Research Ethics Committees](http://www.hra.nhs.uk/resources/after-you-apply/knowledgebase-nhs-rec-review-outcomes/nres_sops_v5-1_2012-03-14-2) (Version 5.1, March 2012) are available at: [http://www.hra.nhs.uk/resources/after-you-apply/knowledgebase-nhs-rec-review-outcomes/nres\\_sops\\_v5-1\\_2012-03-14-2](http://www.hra.nhs.uk/resources/after-you-apply/knowledgebase-nhs-rec-review-outcomes/nres_sops_v5-1_2012-03-14-2)

<sup>4</sup> Similarly, Emanuel et al. have proposed 7 requirements that they argue systematically elucidate a coherent framework for evaluating the ethics of clinical research studies: (1) value (2) scientific validity (3) fair subject selection (4) favourable risk-benefit ratio (5) independent review (6) informed consent (7) respect for enrolled subjects. [What Makes Clinical Research Ethical?](https://doi.org/10.1001/jama.283.20.2701) Emanuel et al. JAMA. 2000;283(20):2701-2711. doi:10.1001/jama.283.20.2701.

22. Individuals, and by extension, individual committees, will value (weigh or judge) different ethical elements differently and can do so in a way that would be considered reasonable<sup>5</sup>. **Reasonable disagreement between the members of the committees will translate into reasonable disagreement between committees.**
23. The direct consequence of this is that two RECs (that are procedurally consistent) **may legitimately reach different opinions about the same research proposal.**
24. **However, there are limits to the range of valuing or weightings, and thus decisions, that may be considered acceptable.** We would not accept *all possible* combinations of weightings of the ethical considerations in research<sup>6</sup>. Whilst the decisions that RECs make can vary (so long as they are procedurally consistent) they **should do so only *within certain limits*.**
25. **These limits (and so the values of RECs) should be calibrated against the limits of accepted, relevant “real world” clinical and research practice.**
26. It is reasonable for all stakeholders to expect that once all of the ethical categories have been considered and taken into account by the REC that the REC will apply the **same opinion type**<sup>7</sup> for broadly the **same reasons**. The choosing of the applicable opinion type, as opposed to the exposition of the complex reasons behind that opinion, is essentially a question of appropriate *procedure* and thus may be determined by reference to standard operating procedures.
27. **It is important that RECs always provide clear reasons for their decisions** (explicitly linked to the ethical categories) within the minutes and subsequent opinion letters. RECs should reference any published guidance used to inform their decision.

## Limiting the Range of Acceptable REC Decisions

28. Limits on the range of acceptable REC decisions can arise in two ways by:
  - i. **Considerations of fair process;** and
  - ii. **Appropriate contextualisation of the research as it would apply in the clinical setting.**

### Considerations of Fair Process

29. **The limits imposed by considerations of fair process** may be addressed by the following **general rule** which is derived from the argument that people can reasonably disagree about the relative priority of the ethical categories in particular cases:

<sup>5</sup> Edwards et al. point out that “*If we were to reject the legitimacy of some differences in substantive decisions from person to person, from culture to culture, we should also have to reject the very need for independent review by RECs.*” Edwards, S. J. L., R. Ashcroft, R., and S. Kirchin, S. 2004. Research Ethics Committees: Differences and moral judgement. *Bioethics* 18(5): 408 - 427.

<sup>6</sup> For example, a committee that systematically rated a high risk of substantial harm as a relatively minor consideration in the face of largely speculative research would be considered to be acting inappropriately. Similarly, a committee that treated any risk of harm or inconvenience to participants as of over-riding importance, no matter what the potential gains from the research would also be deemed to be equally inappropriate.

<sup>7</sup> I.e. ‘favourable opinion with standard conditions’, ‘favourable opinion with standard and additional conditions’, ‘unfavourable opinion’, ‘provisional opinion’ with request for further information, clarification or revision, ‘provisional opinion’ pending consultation with a referee, ‘no opinion’ refer to full meeting for further review of significant ethical issues (proportionate review only).

**Committees should consider each of the ethical categories as though it was the overriding ethical category for the given piece of research.**

#### **Appropriate contextualisation of the research as it would apply in the clinical setting**

30. **The limits imposed as a result of the need for appropriate contextualisation of the research as it would apply in the clinical setting**, taking into account the values of participants and wider society, are related to how similar the research is to actual clinical or other practice and can be expressed as a concern that:

**Without appropriate contextualisation RECs can become isolated and removed from the practical context in which research is conducted, medicine is practiced and patients are treated.**

31. Contextualisation is designed to guard against weightings and biases that are the product of a lack of familiarity, knowledge or understanding of the way in which values are weighted by both patients and healthcare professionals in the actual context of clinical practice.
32. The relative weights given to the ethical considerations need to be adjusted so that they apply to the different clinical (or other) contexts in which the results of the research will be applied. For example, in the emergency care setting drastic measures must often be taken in the face of great risks, great uncertainties and with an incapacitated patient. In considering the ethical acceptability of research in this context the more usual trade-offs between compromised consent and risk of harm must be seriously revisited if the value of novel or existing interventions in acute, life threatening contexts are to be appropriately investigated.

#### **Previous REC Decisions**

33. A researcher who was conducting a similar piece of research to one approved earlier by either the same REC or another one in the same system would be justified in questioning an unfavourable or provisional opinion. In such a case the **researcher would be entitled to an explanation for why the decision on their project differed from the earlier one.**
34. **Previous REC decisions (by the same or other RECs) should be considered as an indication (where appropriate) of what might count as a reasonable decision regarding the application currently under consideration.** Past judgements should not necessarily determine the current one, but it is important that the REC engage with them and, where the current decision diverges, an account given of the ways in which the current application is relevantly distinct from the previous one.

## Practicalities and Recommendations

35. There are a number of practical consequences for both procedural and content consistency that follow from the arguments provided above. Some of these have already been addressed or are being addressed by the HRA, whilst others are novel.
36. There is a need to assess the effectiveness of current and future initiatives with regards their ability to promote greater consistency. It is suggested that the HRA should identify appropriate 'key performance indicators' (KPIs) and/or other methods to measure and monitor consistency of REC decision making. The current Shared Ethical Debate (ShED) exercises, involving the review of the same application by several RECs, may provide a useful means to assess levels of REC consistency over time.

### Initiatives Already In Place / In Progress:

37. **Standard Operating Procedures (SOPs)** have been in use since 2004 and detail the review process and the mechanisms by which decisions are made by RECs.
38. **Health care professionals and active researchers are members of RECs<sup>8</sup>** and thus provide a level of **contextualisation** where the application concerns research within their clinical and/or research experience.
39. **Attendance of researchers at REC meetings** is strongly encouraged by NRES and helps to ensure that the REC is made aware of the context in which the research is taking place.
40. The **Shared Ethical Debate (ShED)** exercise was first introduced in 2007 and enables greater dialogue and reflection about both the process and the substantive judgements made across the NHS REC system. The ShED process now includes individual feedback to each REC regarding their performance, comparing this to the results from all RECs taking part, which promotes self-reflection and greater consistency.
41. New **Ethical Review Forms** have recently been made mandatory for use by RECs in order to standardise the review process. The minute templates will reflect the headings in the review template so that the minutes of the meeting are produced in a consistent format and will document that all ethical categories have been addressed.
42. **Transparency.** The publication of the decisions made by RECs and the reasons for those decisions alongside summaries of the research will present a resource available to researchers and RECs to explore previous REC decisions. This will also serve to promote public understanding of research as well as helping to ensure transparency and accountability.
43. **Pre-application Advice Service.** The HRA recently piloted the use of "HRA Ethics Officers" to investigate whether experienced representative of the NRES, will increase the proportionate of favourable opinions at first review, improve the timelines of review and reduce the administrative burden on RECs, through the provision of advice and support to the researcher and committee. Following completion of this pilot the possibility of rolling out this function throughout NRES as a 'pre-application advice service' is currently being explored.

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<sup>8</sup> The Governance Arrangements for NHS Research Ethics Committees ([GafREC](#)) Harmonised edition (September 2011) states that "4.2.6 Each REC should have expert members to ensure methodological and ethical expertise about research in care settings and in relevant fields of care, as well as professional expertise as care practitioners. This expertise should be appropriate to the types of research proposal the REC reviews."

44. **Engagement with Researchers.** The HRA are currently setting up a workshop with REC members so that a group of researchers can present their proposed research along with guidance, evidence and results of previous discussion groups with other bodies to RECs in order to discuss the ethical issues involved and collate their views and opinions.

#### **Novel Recommendations:**

45. **Contextualisation** requires **broader engagement with researchers, patients and the public** regarding the values, standards and practicalities of current clinical practice in specific parts of medicine. Such contextualisation might be achieved through:
- Extended discussions about broad programmes of research and the ethical issues that might arise in particular contexts between groups of researchers, patients and committee members including workshops on specific topics<sup>9</sup>; and
  - Greater involvement of REC members in the provision of early advice to researchers (from RECs who would not subsequently review any submitted application).
46. **Past decisions/decisions of other committees** regarding similar research should be taken into account as part of the ethical review of new applications. The ‘institutional memory’ of committee held within its members and associated HRA staff can serve this role to a certain extent as do initiatives such as the shared ethical debate and the NREAP/Chairs Regional Network Meetings. However, a more formal method for capturing and searching past decisions would facilitate the explicit consideration of previous decisions. The HRA have published research summaries since 2008, and will soon expand these to include the ethical opinion of the REC and details on how the opinion was reached. RECs should engage with these previous decisions and, where the current decision differs from these, an account given of the ways in which the current case is relevantly distinct from the previous one.
47. **Appropriate Opinion Type.** The decisions made by RECs and any associated issues identified that should be addressed by the applicant are primarily within the realm of *content* consistency (and thus the responsibility of the REC members). However, the application of the appropriate *opinion type*, consistent with the reasons and requirements underlying that opinion, is a matter of *procedure* amenable to SOPs and thus should be formally taken in consultation with the REC Manager and/or other HRA staff in order to improve consistency in the application of the opinions available to RECs. The current SOPs should be amended to clarify the involvement of HRA staff in this decision along with more detailed guidance on the specific criteria for each opinion type and the circumstances in which a REC’s final opinion (but not the substantive *reasons* for that opinion) might be revised where an incorrect opinion type has been applied<sup>10</sup>.

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<sup>9</sup> For example, the HRA organised an “Emergency Research Workshop” on the 21 June 2012 in order to bring together researchers, members of RECs and other stakeholders together to discuss the ethical issues involved in this type of research.

<sup>10</sup> Currently, in line with para.3.60 of NRES SOPs v5.1, a REC may only vary its opinion where information is subsequently received suggesting that the opinion was based on a “factual error or misunderstanding”. However, it is suggested here that the final opinion might be also varied where it is deemed that the incorrect *opinion type* has been applied (and this is not related to a factual error or misunderstanding) and that a change would not alter or otherwise interfere with the substantive underlying reasons for that opinion. E.g. a ‘provisional opinion’ might be inappropriately applied in a case where the changes required are limited and can be easily specified and thus a ‘favourable opinion with standard and additional conditions’ would be the appropriate decision category in line with SOPs.

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