

**RSS/HRA co-sponsored workshop for statistician members of
Research Ethics Committees**

Thursday, 17th December 2015

10:30am-4:30pm; Registration from 10:00am.

at the Royal Statistical Society, 12 Errol Street, London EC1Y 8LX

Workshop outline:

This workshop was co-sponsored by the Royal Statistical Society (RSS) and the Health Research Authority (HRA) and is for statisticians who are members of Research Ethics Committees (RECs). The agenda included the following general topics:

- (i) Discussion of statistical experiences and issues arising from REC submissions and their assessment – both process and technical aspects,
- (ii) Training and support for statistician members of RECs – what works well and what could be improved/added,
- (iii) How to encourage greater participation of statisticians in the work of RECs.

Workshop output summary

(Prepared by Chris Foy, John Kirkpatrick, Trevor Lewis)

Statistical experiences and issues arising from REC submissions and their assessment – both process and technical aspects (including a review of actions following the November 2014 workshop)

- a) In the opening presentation, Sheila Oliver had pointed out that IRAS was now “owned” by the HRA. However, HRA’s direct remit is for England only, whereas IRAS is a UK-wide resource. Any change to the form needed the agreement of all four nations.
- b) There was general agreement that the plan to remove the last option in IRAS A56 (“no review necessary...”) was the right way to go.
- c) Most were in favour of obtaining the e-signature of the person reviewing an application from a statistical point of view.
- d) There were mixed views on whether a CV should be required from the statistical reviewer. Some favoured a CV, but others thought a brief statement of the reviewer’s background would suffice.

- e) There was discussion of whether the signature would relate only to the quality of the application as submitted, or would also imply responsibility for the statistical aspects of study delivery. Most did not think the latter would be seen as practicable.
- f) In cases where the REC considered the statistical review to be inadequate, there was a suggestion that HRA should commission a review of the application documents from the statistical viewpoint, maybe at the sponsor's expense.
- g) Qualitative studies do not need a strictly statistical review (A56 is not displayed), but the number of participants nevertheless needs reasoning behind it. There was a view that all studies, including qualitative ones, should specify a primary (A57) and secondary (A58) outcome measure – these questions are currently omitted when the “qualitative only” option on the filter is selected. However, it was recognised that one school of qualitative research has strong views on this matter, so it could not be decided by statisticians alone.
- h) Some regret was expressed that the primary and secondary objectives (A10 and A11) are a long way from the outcome measures (A57 and A58) on the IRAS form. On occasions, the distinction between objectives and outcome measures was blurred.
- i) There was some concern that lower statistical standards might be inappropriately applied to smaller studies.
- j) Data security and retention were also discussed. It was noted that IRAS A38, A40 and A43 referred to “personal data”. Applicants were not always clear whether this meant identifiable data (the Data Protection Act 1998 uses the term “personal data” in this sense) or individual but de-identified data. More clarity would help here. For de-identified data on case record forms (or equivalent), there was a strong case for long retention periods, and/or deposit in a data archive. Currently, there is no IRAS question on archiving.

Training and support for statistician members of RECs – what works well and what could be improved/added

- k) Why increase communication between REC statisticians?
 - To access complementary expertise
 - To identify emerging (statistical) issues
 - To provide support and advice on current applications
 - To identify sources of statistical expertise
 - To share resources (e.g. publications) to help deal with technical problems
 - Mentoring those new to REC work
- l) How to do it?
 - Avoid complexity in communication approach.
 - It is useful to have annual workshop (possibly with a different kind of agenda)

- To consider a webinar (type of meeting)
 - Improve mentoring process for statisticians (both from members of same committee (other disciplines) and from statisticians (likely to be on other committees))
- m) The following specific suggestions were made:
- John Kirkpatrick to work with 2 other volunteers to explore the potential of a mailing list of REC statisticians in order to establish communication across REC statisticians. The proposal needs to address concerns about retaining confidentiality of research applications.
 - To investigate why the current mentoring system within RECs for new members is not uniformly working well.
 - To establish a mentoring scheme for support from other REC statisticians, particularly for those new to REC work and/or early in their careers.
- n) The feedback forms at the end of the workshop had a consistent message advocating annual meetings/workshops of REC statisticians with a number of ideas for the content of such sessions:
- Some advocated closed meetings (REC statisticians only) others advocated inviting other interested people.
 - There was a desire to supplement sharing experiences/ideas with presentations on relevant technical statistical topics (by experts) or (anonymised) case studies (by REC statisticians) or presentations on ethical issues.
- o) Generally the training provided to REC members (including statisticians) was felt to be good. However, there was a suggestion that a course on influencing skills in committee work would be helpful.
- p) The suggestion was also made that the highly regarded Gordon Taylor course given to non-statistician members of RECs, might be supplemented by a follow-on course of more 'advanced' statistical concepts and considerations.

How to encourage greater participation of statisticians in the work of RECs.

- q) The approach adopted over the past year was summarised as follows:
- Actions over the past year
 - HRA advert: Vacancies for Statistician members
 - Article in StatsLife (March 2015)
 - RSS-PSF webinar (CF, JK) (April 2015)
 - Webcast (May 2015)
 - Article in PSI e-Newsletter SPIN (June 2015)
 - It was acknowledged that although these were good initiatives they had not been as effective in encouraging participation as anticipated.
- r) Some new ideas were presented:
- Advocate participation through Committee of Professors of Statistics (COPS)
 - Lobby HEFCE to support participation
 - Contact heads of statistics groups (eg in Pharma, CTUs, MRC Biostats)

These were generally supported as good ideas by the workshop participants.

- s) The workshop participants came up with the following additional ideas:
- Raise awareness of the REC process with (medical) statisticians; and of the role of statisticians in that process.
 - Identify the benefits to statisticians and employers. Excellent CPD opportunity, good research is ethical research, broadens expertise, selling point to attract staff.
 - Contact heads of statistics in a variety of organisations (e.g. medical schools, MRC, RDS units, British Psychological Society stats section, Royal Society of Biology stats section, CTUs, CSO (Scotland), NHS)
 - Advertise on ALLStat, MedStat.
 - Regularly advertise.
 - Develop partnering models (2 statisticians on the same REC – mentoring opportunity, sharing the workload).
 - Look to fund statistician involvement. Contact Wellcome Trust, ABPI, Big Pharma, NIHR, MRC, ESRC.
 - Develop a model for statistical review commissioned by HRA/REC, paid for by proposer of research project.