

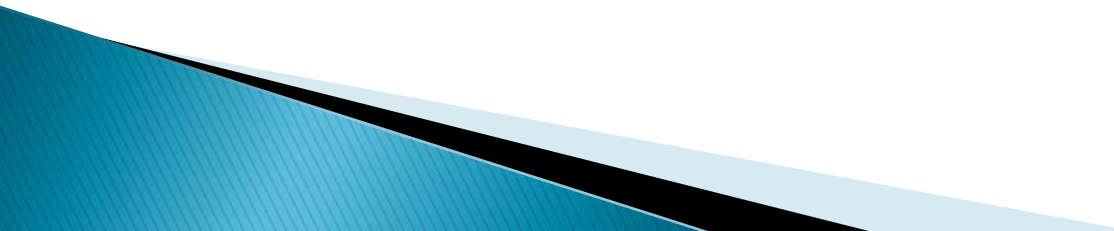
Statisticians on RECs

Chris Foy

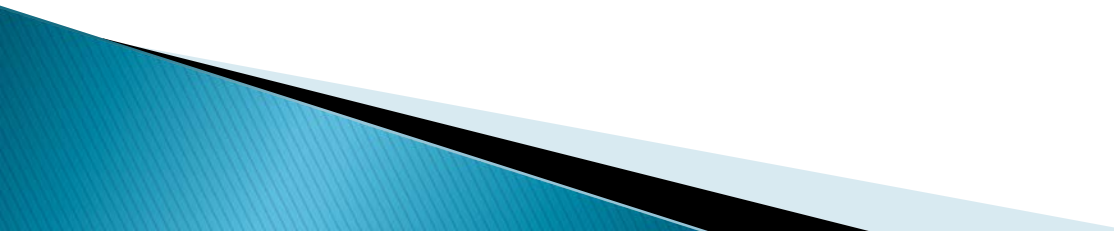
27 November 2014



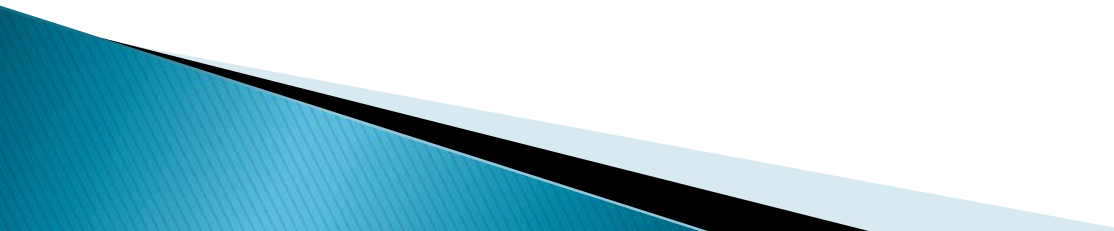
Background

- ▶ REC member for 19 years
 - ▶ Chair for 5 years
 - ▶ 7 RECs
 - ▶ c. 2000 studies
 - ▶ Other project work for NRES
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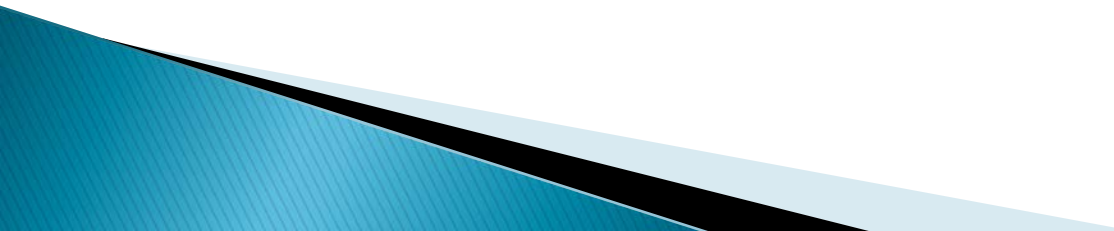
The REC's basic task

- ▶ Is this proposal fair to the participant?
 - ▶ How will participants be found?
 - ▶ Will participants be sufficiently informed, so that their consent is valid?
 - ▶ Are their data and bodily samples handled properly?
 - ▶ Unintended consequences? For example, scan shows unrelated disease
 - ▶ What happens to study results?
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The REC must weigh up...

- ▶ Risk and inconvenience to participants
 - ▶ Benefit to knowledge, and to participants
 - ▶ Need to strike a balance, but no fixed rule
 - ▶ Needs a committee, not an algorithm
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RECs do not assess the science

- ▶ It's not directly our problem if researchers want to waste their money
 - ▶ But it is our problem if participants' time and goodwill are misused
 - ▶ So we do need to assure ourselves that the science is sound
 - ▶ The research sponsor should give us this assurance
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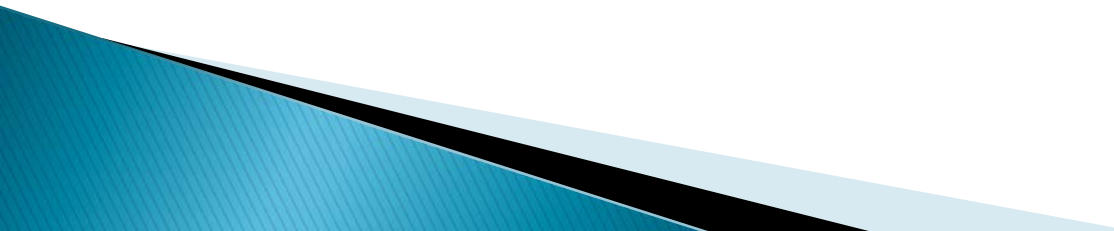
DH Research Governance Framework 2005

- ▶ 3.8.7 It is the sponsor's responsibility to be satisfied that:
 - ▶ • The research proposal respects the dignity, rights, safety and wellbeing of participants and the relationship with care professionals.
 - ▶ • An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money.
 - ▶ • An appropriate research ethics committee... has given a favourable opinion.

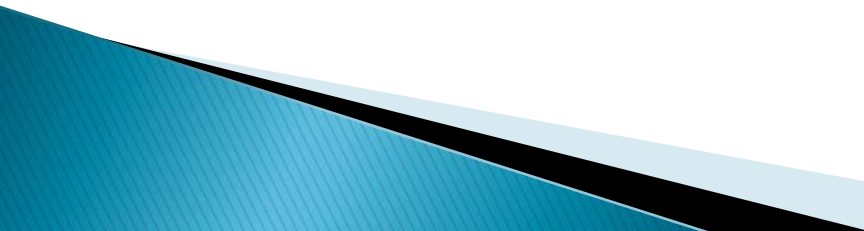
DH Research Governance Framework 2005

- ▶ **3.12.4** Research ethics committees are required to be independent when formulating advice on the ethics of the proposed research. Ethics review must be seen to be impartial. NHS RECs are not part of NHS Trust R&D management structures. While they operate within a framework of standards and NHS management, neither the Department of Health nor NHS bodies are entitled to interfere with NHS RECs' decisions.

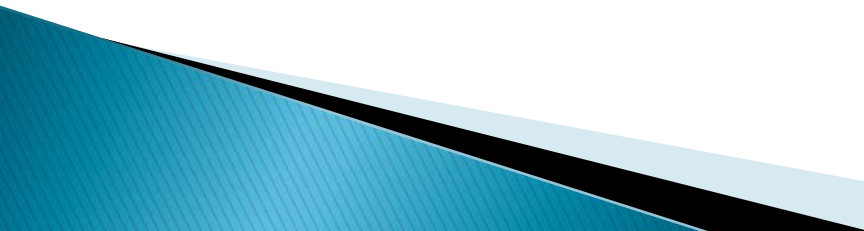
What does a REC statistician do?

- ▶ Provides assurance to REC members that the proposal is statistically sound
 - ▶ Quiz the applicant where necessary
 - ▶ Sample size (but not effect size?)
 - ▶ Randomisation
 - ▶ Blinding
 - ▶ Analysis
 - ▶ Publication plan
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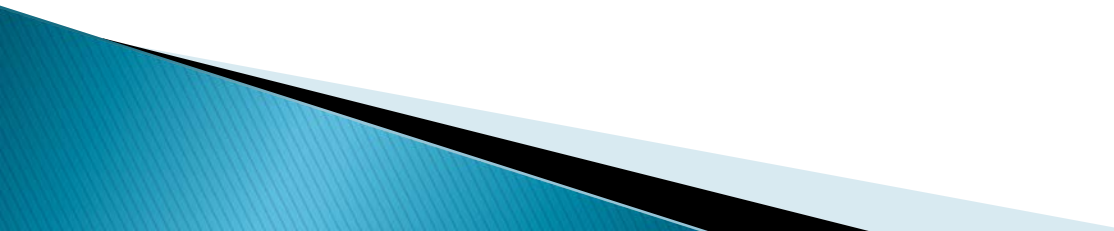
Who are the REC statisticians?

- ▶ Some work for NHS (NIHR etc)
 - ▶ Some are academics
 - ▶ Some are from industry
 - ▶ Some are self-employed
 - ▶ Some are retired
 - ▶ “Expert” if involved in clinical trials (not just drug trials)
 - ▶ Otherwise “lay”
 - ▶ The expert/lay distinction is self-certified, and unique to statisticians
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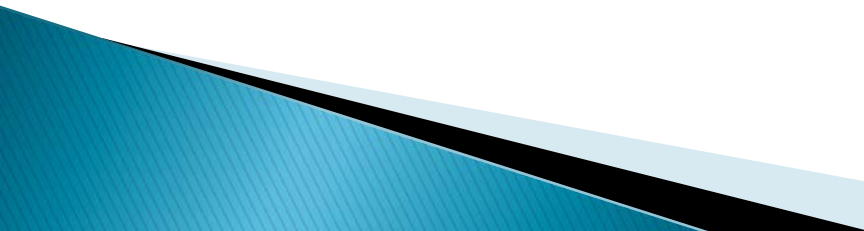
Statistical quality of the proposals?

- ▶ Industry (pharma) – will have had a lot of statistical input, but mostly in-house
 - ▶ Industry (SMEs) – more varied
 - ▶ Funded by major grant giver (e.g. MRC, NIHR) – already had substantial independent review
 - ▶ Funded by smaller grant giver – could need care and attention
 - ▶ Own account (NHS and students) – will need a careful look
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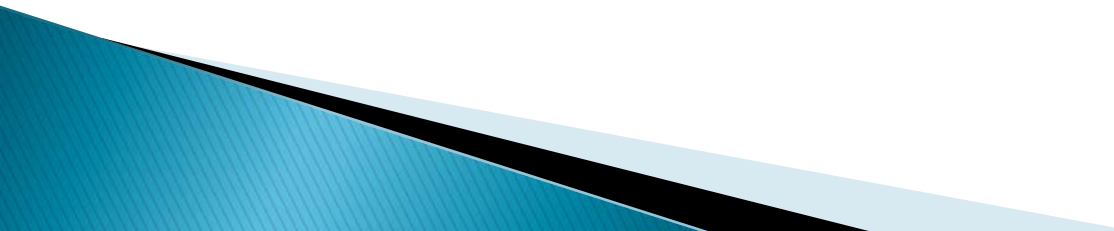
The application form and guidance

- ▶ Last substantial review of statistical section was 2005–6
 - ▶ Altering the application form is costly
 - ▶ Altering the question-specific guidance is easy
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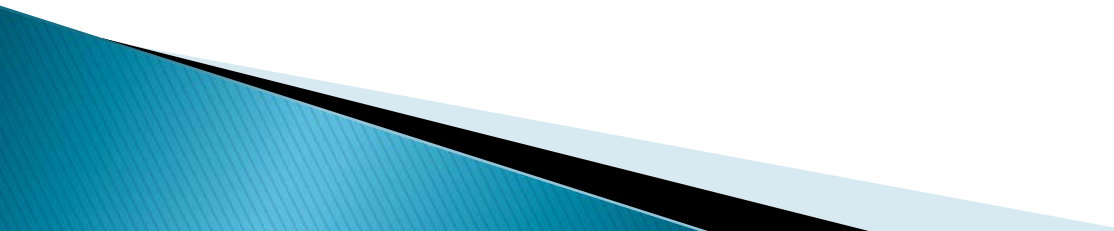
Question A56

- ▶ “How have the statistical aspects of the research been reviewed?”
 - ▶ Appears in all cases except qualitative
 - ▶ Answer categories are something of a hierarchy of quality
 - ▶ Last one “No review necessary... statistical input not required” a bit of an escape clause
 - ▶ ...especially if the statistical reviewer is also the applicant
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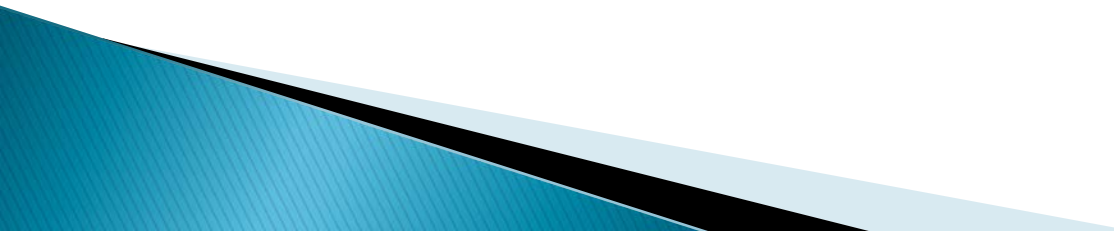
Questions A59 and A60

- ▶ What is the sample size, and why is it that?
 - ▶ Doesn't require a calculation in all cases
 - ▶ But if there was one, we want to see that we can reproduce it
 - ▶ Sometimes it is clear that the writer didn't take advice, or didn't understand it
 - ▶ Guidance has to cover comparative and non-comparative designs
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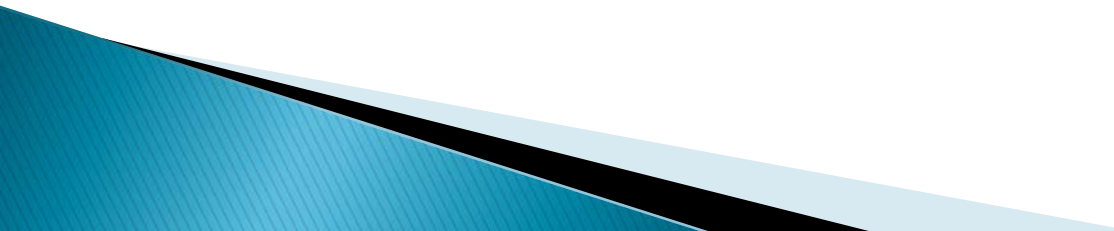
Question A61

- ▶ If there is random allocation, how is it done?
 - ▶ Are opportunities for bias reduced as far as possible?
 - ▶ ICH-GCP doesn't think much of envelopes
 - ▶ Interactive phone or web is the norm
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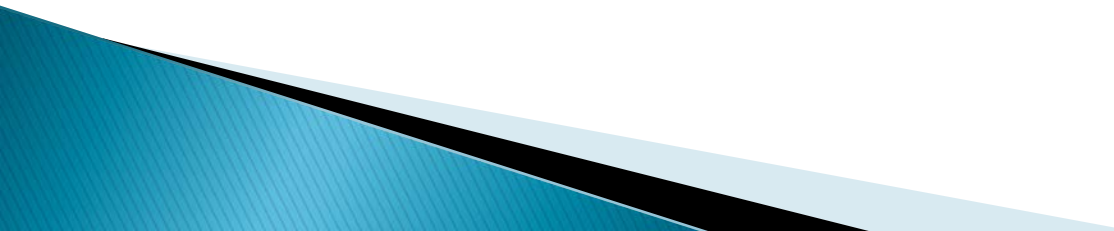
Question A62

- ▶ Describe the methods of analysis...
 - ▶ Has to cover all study designs including qualitative
 - ▶ Hence there are no sub-headings
 - ▶ Not looking for a big extract from the protocol, but it happens
 - ▶ Guidance recognises that a Statistical Analysis Plan may not be ready at time of application
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Question-specific guidance

- ▶ Fairly general
 - ▶ No idea how many applicants look at it
 - ▶ Does it need revision?
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Conclusion – REC members

- ▶ Being a statistician on a REC is a satisfying role
 - ▶ We need more
 - ▶ But is it seen as a good career move?
 - ▶ And maybe not everyone wants to stay for ever
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Conclusion – applications

- ▶ Should we specify who is qualified to answer the statistical review question?
 - ▶ Would that vary by study type?
 - ▶ What about independence?
 - ▶ And should the statistical reviewer “sign” the form?
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