

Insights of an Ethics Committee

Heidi Chandler
Vice-Chair, Camden & Kings Cross REC,
R&I Manager, BHRUT
Co-Lead, NIHR GCP Programme, CRN: North Thames

Camden & Kings Cross REC

- ▶ Authorised REC
- ▶ Flagged for applications in the following:
 - Qualitative research
 - Research involving Adults Lacking Capacity
 - Research involving Children

Membership Constitution

Committee: up to a maximum of 18 members:

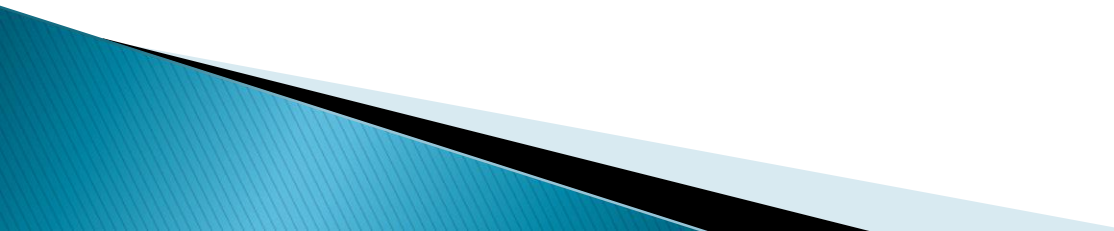
- ▶ Chair
- ▶ Vice-Chair
- ▶ Alternate Vice-Chair
- ▶ Expert Members
- ▶ Lay Members (at least 1/3 of Committee)

To be quorate, attendance needs to be a minimum of 7 members inc. Chair, at least one expert and one lay member

Appointments to REC is done via the HRA

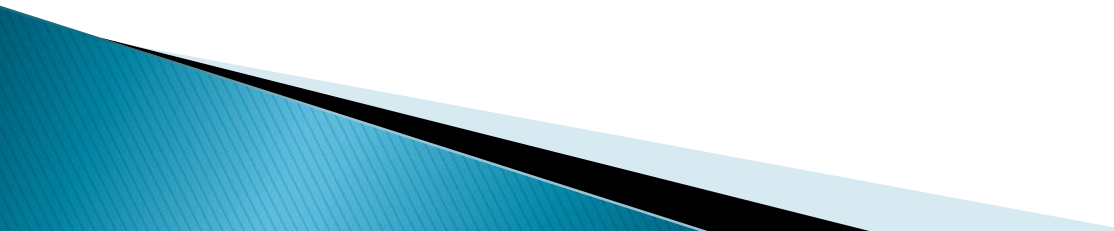
Can serve maximum of 2 terms (10 years) on same Committee.

Types of Meetings


- ▶ Face to Face ethics meeting; one afternoon per month for 10 months (up to 6 applications) for applications requiring a face-to face discussion.
 - ▶ Proportionate Review Committee; one per month via email (up to 4 applications) (3 members; Chair, 1 expert and 1 lay) for those applications with no material ethical issues
 - ▶ Sub-committee; every two weeks via email to review amendments & SSA forms (Chair and 1 other member)
- 

Decisions

- ▶ Favourable opinion
 - ▶ Favourable opinion with Conditions
 - ▶ Provisional opinion
 - ▶ Unfavourable opinion

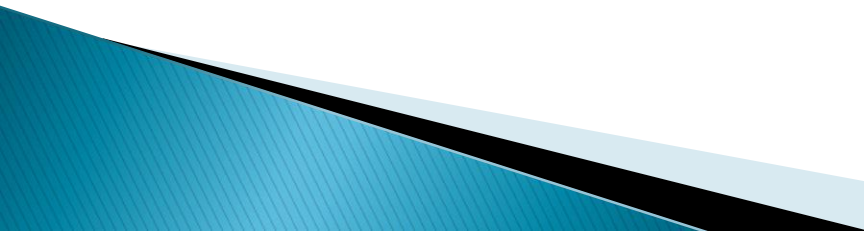
 - ▶ No opinion (PR; application would then be booked into a full REC meeting)
- 

The review

- ▶ Lead reviewer; gives a summary of the study and then puts forward their concerns (or comments on areas happy with)
 - ▶ 2nd reviewer; puts forward their concerns
 - ▶ Rest of REC invited to contribute then have a discussion and questions to ask researcher identified
 - ▶ Researcher invited in and asked about their application; with particular reference to concerns raised
 - ▶ Researcher leaves the meeting and REC resume discussions and reach an opinion
- 

Ethical review: example of questions asked

Social/scientific value, design and conduct of the study:

- ▶ What is the research about?
 - ▶ Has the applicant identified/recognised potential ethical issues?
 - ▶ What is the justification for carrying out the research?
 - ▶ What is the methodology and design of the study?
 - ▶ Has there been any PPI and if yes, to what level of involvement?
 - ▶ What are the arrangements for ongoing safety reviews (if required)
 - ▶ Is the research relevant to the condition being looked at?
 - ▶ Is involving adults who lack capacity necessary for answering the research question(s)?
- 

Ethical review: example of questions asked

Participant selection, recruitment arrangements and access to health information:

- ▶ What are the inclusion & exclusion criteria's?
- ▶ How will participant's be identified and who will do this?
- ▶ Who will be making the first approach to the participant and when?
- ▶ Are participants being compensated for their time?
- ▶ What arrangements exist for the appointment of personal (and nominated) consultees for adults lacking capacity?
- ▶ Emergency research; is enrolment of the participant without prior consent justified?
- ▶ What procedures exist for obtaining consent once capacity regained/appointing an appropriate consultee?

Ethical review: example of questions asked

Risk benefit ratio; anticipate for research participants (present and future):

- ▶ What is the participant required to do in the study that is a) clinical and b) non-clinical?
- ▶ Would this exposure happen as part of current care? Any routine procedures being withheld? Is anything in the research different to standard care?
- ▶ How long is the participant involved in the study?
- ▶ Are there any risks and what is being done to prevent them?
- ▶ Any upset/distress expected?
- ▶ If using xrays/ionising radiation; is there any additional exposure risk?
- ▶ If tissue samples being collected are these anonymised/ pseudonymised?
- ▶ What are the plans for the tissue samples at the end of the study?
- ▶ Does the research have potential benefit to participants who lack capacity without imposing on them?
- ▶ If the research is intended to provide knowledge of the causes or the treatment or the care of the condition of adults lacking capacity is the risk to participants negligible? Will involvement significantly interfere with privacy or freedom of action? Is the research unduly invasive or restrictive?

Ethical review: example of questions asked

Care and protection of participants; respect for potential and enrolled participants welfare and dignity:

- ▶ Will the intervention (if any) be available to participants at the end of the study?
- ▶ If new findings during the course of the study, will participants be informed of these?
- ▶ Is the study being registered on publically accessible database? What are the plans for disseminating study findings?
- ▶ How is participant confidentiality being maintained during the course of the study?
- ▶ How and where is data be collected and stored? Who will have access to this?
- ▶ If access to medical records is required, has this been explained and why?
- ▶ Are there appropriate disclosure arrangements and are these transparent?
- ▶ If a participant withdraws from the study, what will happen with their data/tissue samples?
- ▶ Appropriate safeguarding for children/adults lacking capacity

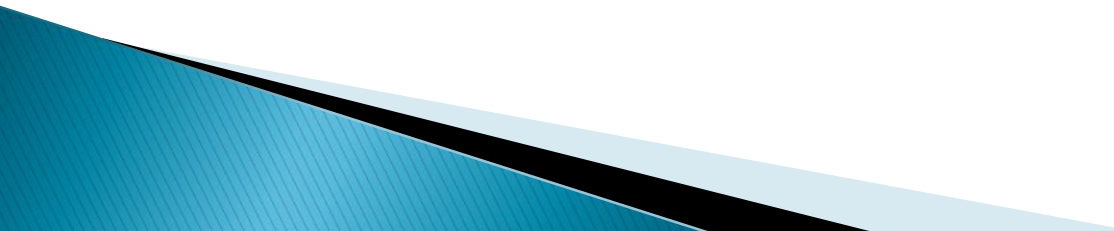
Ethical review: example of questions asked

Informed consent process and adequacy of participant information:

- ▶ What are the arrangements for receiving consent?
- ▶ Co-enrolment arrangements; are participants likely to be (or just finished) participating in other studies at time of approach?
- ▶ What arrangements exist for those who do not adequately understand verbal explanations or written instructions in English?
- ▶ If a participant loses the capacity to consent during the course of the research, what would the applicant do?
- ▶ Are participants/researchers to receive any incentives/payments for participation?
- ▶ Are the study team planning on informing the GP/other healthcare providers?
- ▶ What will happen with incidental findings/clinically significant findings? Are they to be reported back to the participant?

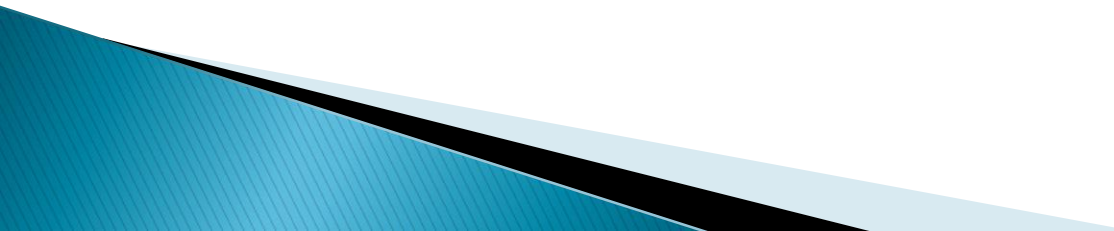
Ethical review: example of questions asked

Suitability of applicant and supporting staff:

- ▶ Are the study team qualified and experienced for carrying out the study?
 - ▶ If carrying out interviews that have potential for upset/distress, how experienced is the team member doing this?
 - ▶ How experienced are the study team with doing research with adults who lack capacity/children
- 

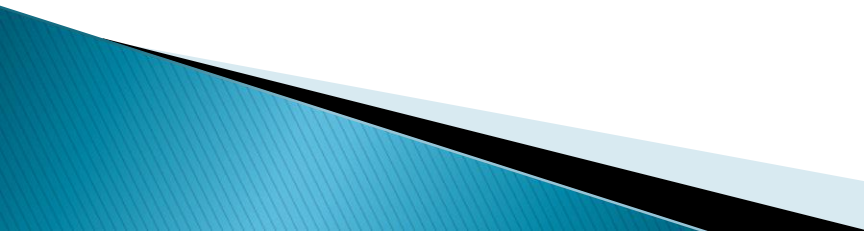
Ethical review: example of questions asked

Independent review:

- ▶ If a peer review has been submitted, this will be looked at as part of the submitted document pack. REC will read through to see what comments were made and if application has taken these comments on board
 - ▶ If not submitted and study funded by one of the big funders, will take assurance this has been done but will be requested if no funding and uncertainty around study design
- 

Ethical review: example of questions asked

Suitability of supporting information:

- ▶ Has relevant topic guides/interview schedules been submitted?
 - ▶ Are all QoL questionnaires submitted?
 - ▶ Provision of summary sheets if PIS too long?
 - ▶ If using advertisements; is the wording of these appropriate?
 - ▶ REC will comment on language in A6 (Summary of Research) as this published on HRA website
- 

What makes a good application?

- ▶ IRAS form written in language understandable to a lay audience that is free from spelling mistakes, acronyms etc
 - ▶ Not copying and pasting from the Protocol into the IRAS form
 - ▶ Clearly labelling what the different PIS/ICFs/Declarations are for
 - ▶ If a tricky study design, enclosing a flow chart to summarise what will happen
 - ▶ Understanding the study; obvious when somebody else designed the research
 - ▶ Attend the REC meeting; and come prepared
 - ▶ Demonstrating that ethical issues been identified and addressed
 - ▶ Not completing IRAS form with loads of references
 - ▶ Not recycling previous PIS/ICF templates – mistakes more likely to be made
 - ▶ Correct study type selected in filter questions
 - ▶ If study involves a number of work packages; clearly identifying what work package the REC is being asked to approve
 - ▶ Ensuring all documents are provided
- 