

CHALLENGES IN RECEIVING RESEARCH ETHICS COMMITTEE APPROVAL FOR STUDIES INVOLVING CHILDREN AND YOUNG PEOPLE WITH LIFE-LIMITING CONDITIONS AND LIFE-THREATENING ILLNESSES: AN ANALYSIS OF RESEARCH ETHICS COMMITTEE MINUTES AND CORRESPONDENCE WITH PRINCIPAL INVESTIGATORS



Ashleigh E Butler ¹, Katherine Vincent ¹ and Myra Bluebond-Langner ¹

¹ Louis Dundas Centre for Children's Palliative Care, UCL Great Ormond Street Institute of Child Health



BACKGROUND

- Children and young people with life-limiting conditions and life-threatening illnesses (CYP with LLC/LTI) and their families are a vulnerable, complicated and difficult to treat population.
- Research of all types is needed to drive improvements in the care and treatment of these patients and their families ².
- Research ethics committees (RECs) are commonly identified as one of the largest barriers to conducting research with CYP with LLC/LTI ¹⁻³.
- However, little is known about RECs primary concerns about research with CYP with LLC/LTI or their correspondence with researchers when studies are reviewed.

AIMS

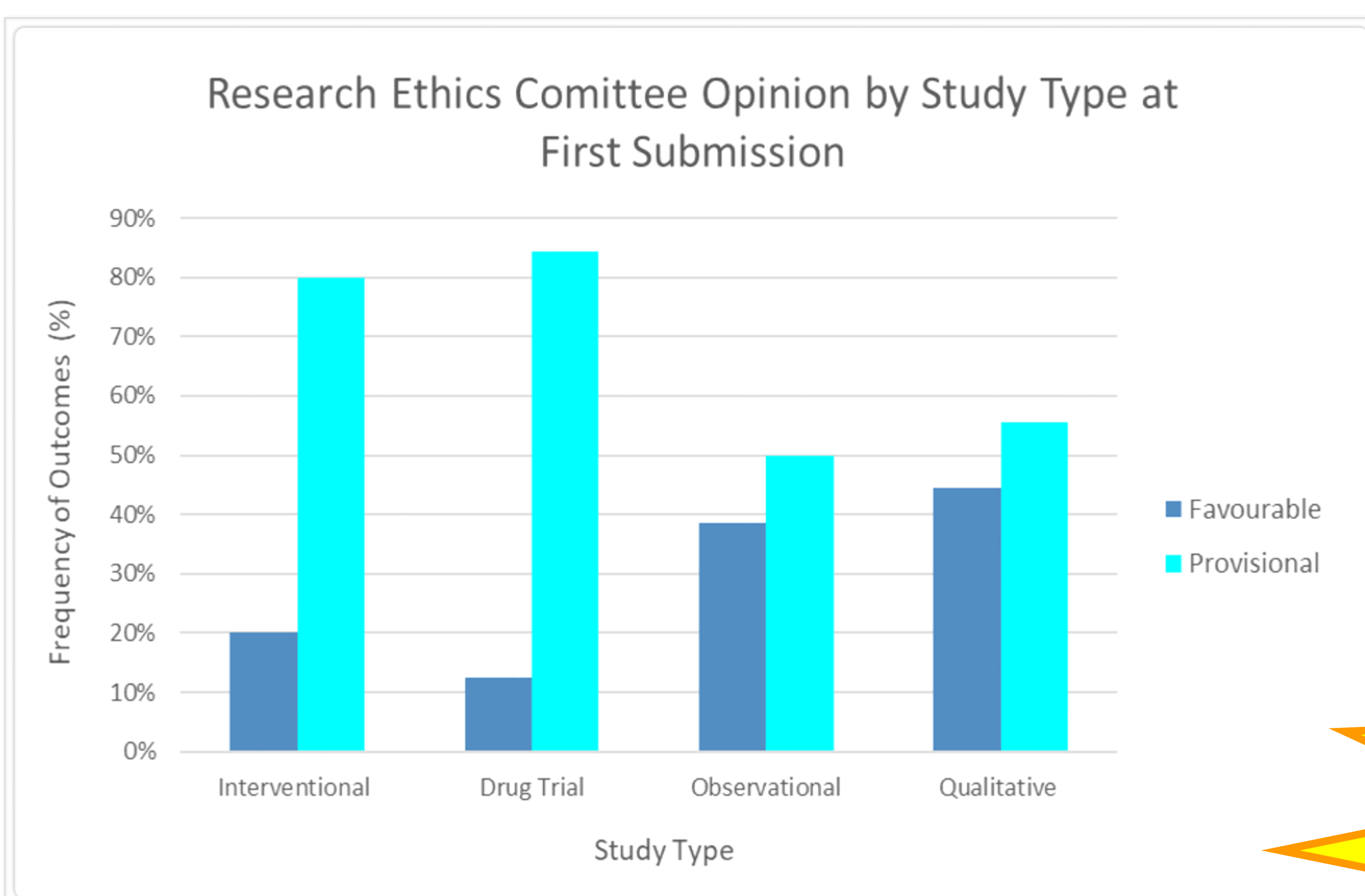
- To explore REC decisions based on study type.
- To identify the key concerns of RECs in studies involving CYP with LLC/LTI.
- To explore the researchers' responses to REC requests.
- To analyse the impact of researcher presence at REC meetings on decisions made.

METHODS

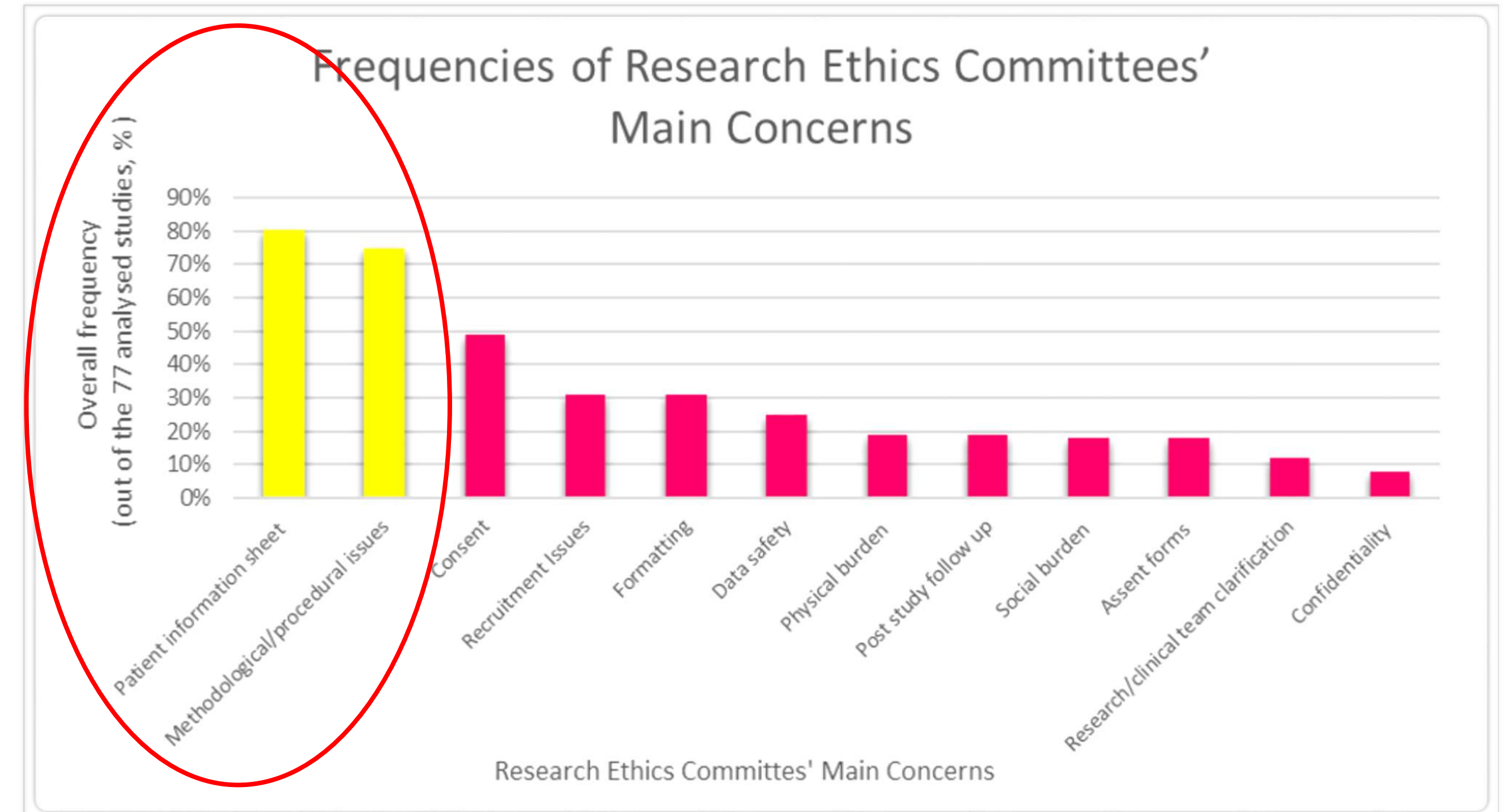
- Content analysis, including inductive and deductive codes, was used.
- Coded meeting minutes, decision letters and researcher response letters were for type of issue being raised and the type of response that was given to each issue.
- Frequencies of each of the codes/categories were then calculated.

RESULTS: REC DECISIONS BY STUDY TYPE

- Although there was some variability in REC decisions at first review depending on study type, this was not statistically significant (probability 0.231)
- For all study types, provisional opinions were offered more frequently than favourable opinions at first submission.



RESULTS: MAIN REC CONCERNS



REC CONCERNS SPECIFIC TO STUDIES INVOLVING CYP WITH LLC/LTI

- RECs commonly requested that researchers gain assent from children prior to participation.
- RECs often suggested that researchers involve the child's senior treating clinicians in the recruitment process.

REC CONCERNS NOT PERTAINING TO ETHICS OR GOOD PRACTICE

- Whilst 62% of REC concerns were coded as being related to ethics/good practice, over one third (38%) of all comments were coded as administrative or relating to formatting.

RESULTS: RESEARCHERS' RESPONSES TO REC CONCERNS

- Most commonly, researchers' agreed to REC comments and made the requested changes.
- However, 15 out of the 27 research teams who provided a response letter disagreed with one or more of the RECs comments.

Research ethics committees' comments	Agree and comply	Justify, changes made	Disagree, changes made	Disagree, changes not made	Justify, no changes required
Participant information sheet	107	14	1	12	3
Consent	21	2	2	6	1
Formatting	14	0	0	3	0
Other	8	3	0	2	7
Physical burden	2	0	0	0	5
Data safety	2	3	0	0	4
Methodology	2	11	0	1	21
Recruitment	2	2	0	2	7
Post-study follow-up	2	0	0	0	2
Social burden	1	0	0	0	1
Confidentiality	1	0	0	0	1
Research/clinical team	0	0	0	0	1
Totals (279)	162	35	3	26	53

TAKE HOME MESSAGE: GO TO THE REC MEETING WHEN YOUR PROPOSAL IS BEING EVALUATED

- The likelihood of receiving a favourable opinion after first REC meeting was significantly increased by a researcher being present.
- Favourable review was never given at first meeting if the research team was absent.

CONCLUSIONS

- Research protocols involving CYP with LLC/LTI submitted to RECs usually require changes before approval is given.
- Understanding the main concerns needed to be addressed by researchers before approval can be granted may help researchers consider key issues before submission, minimising perceptions of RECs as a barrier to research and improving research quality overall.

IMPLICATIONS FOR RESEARCH

- Many REC concerns, such as formatting issues or insufficient detail, can be easily resolved with increased attention to detail or peer review prior to submission.
- Researchers should endeavour to attend committee meetings wherever possible to clarify issues raised by the REC.

References:

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2. Liben, S., Langner, R., & Bluebond-Langner, M. (2014). Pediatric Palliative Care in 2014: Much accomplished, much yet to be done. Journal of Palliative Care, 30(4), 311-316
3. Peake JN, Beecham E, Oostendorp LJ, Hudson BF, Stone P, Jones L, Lakhanpaul M, Bluebond-Langner M. Research barriers in children and young people with life-limiting conditions: a survey. BMJ supportive & palliative care. 2018 Jul 31;bmj.spcare-2018.

Hi, my name is Katherine Vincent. If you have any further feedback or questions, you can contact me on:

katherine.vincent.14@ucl.ac.uk

Follow us on Twitter: @LDCentre1

Website: www.ucl.ac.uk/ich/gpp/louis-dundas-centre

