Philippine Health Research Ethics Board

"Thriving in the New Normal"

3rd PHREB

NATIONAL CONFERENCE

Technical issues during ethics review

Carl Abelardo T. Antonio, MD, MPH, IPFPH, FRSPH, AFCHSM, MIHM
Associate Professor and University Scientist, University of the Philippines Manila

November 09, 2021

Preface

DISCLOSURES

- External referee for the PCHRD and Cochrane Public Health
- Ethics reviewer for UPMREB and SJREB
- Trainor for PHREB-CIDTA
- Contributor to the 2017 and 2022 national ethics guidelines

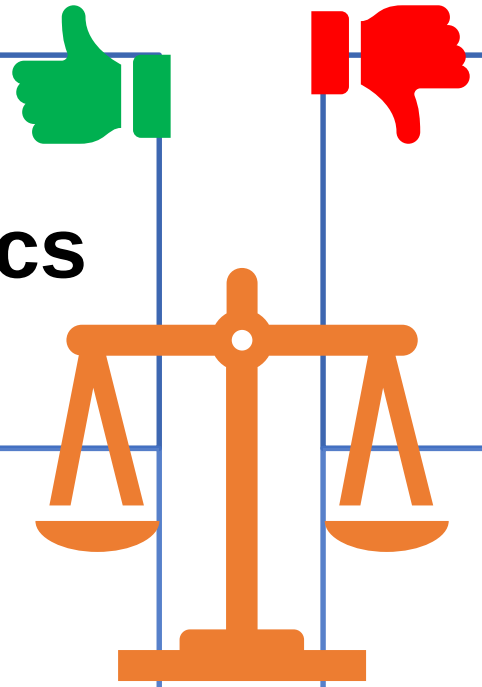
DISCLAIMER

- The views, information, or opinions expressed in this material are solely those of the presenter and do not necessarily represent those of the University of the Philippines or the other institutions or groups with which the presenter is affiliated.

Outline of presentation

1. Is technical review necessary at the REC level?
2. How frequently do RECs raise design-related queries?
3. What are the common design issues encountered by RECs?
4. Why are these technical issues still encountered at the REC level?
5. What can be done to address these concerns?

1. Is technical review necessary at the REC level?



Bad science = Bad ethics

Double jeopardy

QUALITY
i.e., part of peer review process

SOCIAL VALUE
i.e., trustworthiness of findings

NORM
i.e., prescribed by guidelines

INEFFICIENCY
i.e., duplicates prior peer review

SCOPE CREEP
i.e., undue focus on science vis-à-vis ethics

NO CLEAR BENEFIT
i.e., no evidence of improved research quality

Angell et al, 2007; Humphreys et al, 2015; Lutz et al, 2012; Mansbach et al, 2007; Newson & Lipworth, 2015

2. How frequently are design-related queries raised?

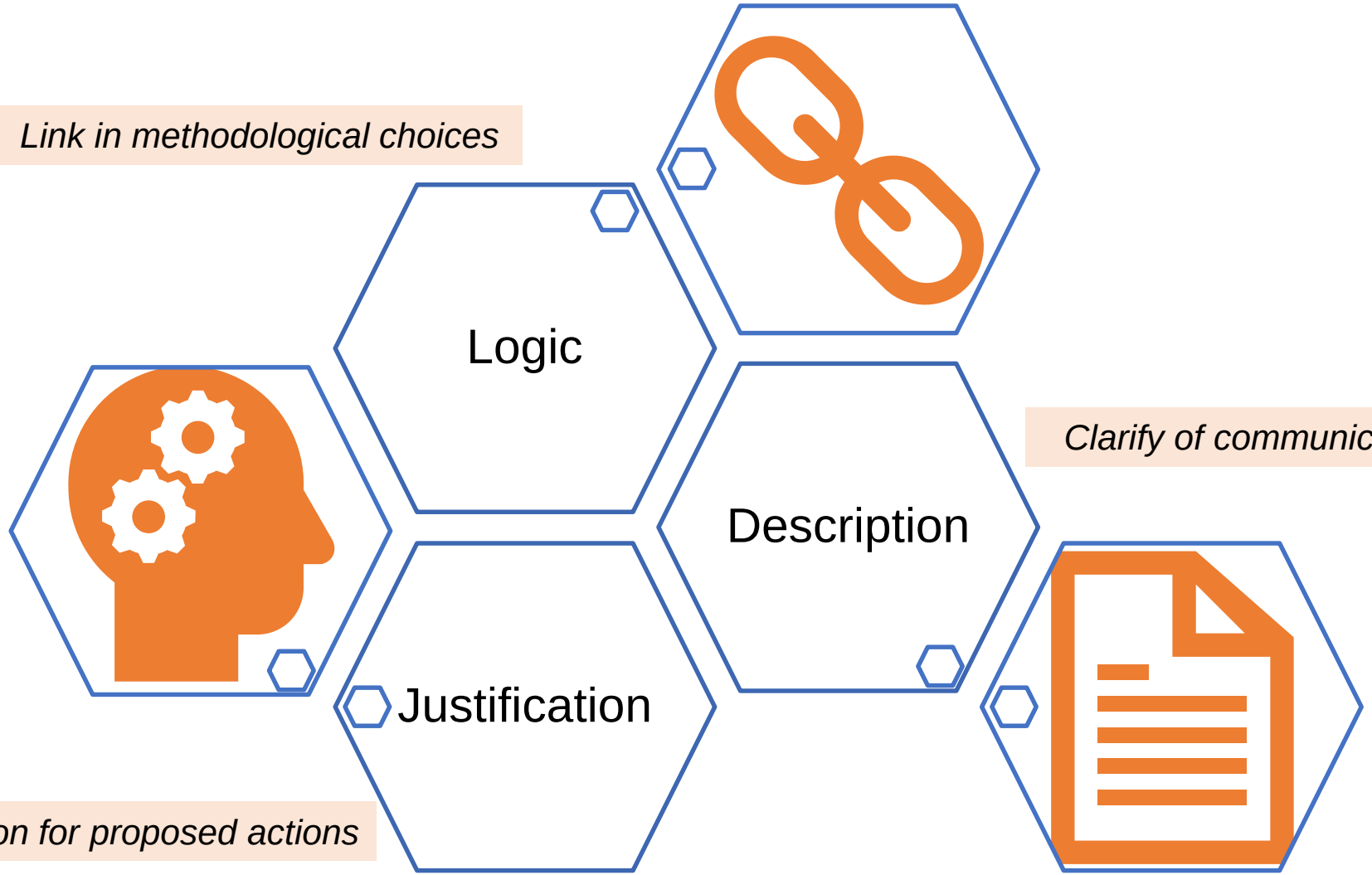
Source	Country	Inclusive period	Technical issues raised		
			n	%	unit
Dal-re et al, 1999	Spain	1995	–	**52%**	queries/comments
Bueno et al., 2009	Brazil	2007	205 / 800	**26%**	queries/comments
Tsoka-Gwegweni et al, 2014	South Africa	2008–2012	222 / 1,040	**21%**	queries/comments
Silaigwana et al, 2019	South Africa	2009–2014	–	**17%**	queries/comments
Kent, 1999	United Kingdom	1996	–	**22%**	decision letters
Angell et al, 2007	United Kingdom	2005–2006	104 / 141	**74%**	decision letters
Boyce, 2002	United Kingdom	1997–2000	171 / 339	**50%**	protocols
Adams et al, 2013	Thailand	2009–2012	235 / 291	**81%**	protocols
van Lent et al, 2014	The Netherlands	2010–2011	160 / 226	**71%**	protocols
Hemminki et al, 2015	Finland	2002–2007	106 / 336	**32%**	protocols
Happo et al, 2017	Finland	2009–2013	181 / 349	**52%**	protocols

3a. What are the design issues encountered by RECs?

	Technical issue	Source							Level of intensity	Rank
		Angell et al, 2007	Bueno et al., 2009	Adams et al, 2013	Tsoka-Gwegweni et al, 2014	van Lent et al, 2014	Hemminki et al, 2015	Happo et al, 2017		
★	1. Justification for study	■	■		■		■		**4 / 7**	3
	2. Research question	■							**1 / 7**	5
★	3. Study design		■	■	■	■	■	■	**6 / 7**	2
★	4. Sample and sampling design	■		■		■		■	**4 / 7**	3
★	5. Data collection procedures	■	■	■	■	■	■	■	**7 / 7**	1
	6. Instrumentation	■							**1 / 7**	5
★	7. Data analysis	■	■			■		■	**4 / 7**	3
	8. Feasibility of the study	■			■				**2 / 7**	4

3b. What are the design issues encountered by RECs?

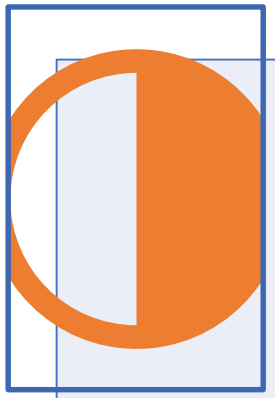
Link in methodological choices



Clarify of communication

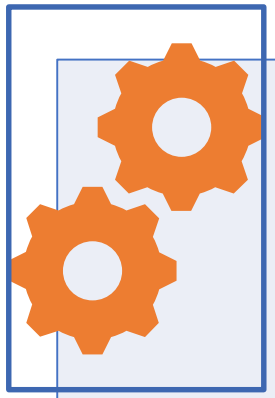
Explanation for proposed actions

4. Why are these technical issues still encountered?



Philosophical differences

i.e., predominance of positivist perspective



Methodological expertise

i.e., limited range and breadth

Trust in prior review

i.e., quality of technical review

Scientific writing

i.e., quality of written proposal

Dolan, 1999; Stevenson et al, 2015; Tod et al, 2002

5. What can be done to address these concerns?

Researcher

- Adhere to research best practices in the discipline
- Clearly communicate design choices in the proposal (i.e., why and how)

Technical review panel

- Undertake a review of the technical merits of a research proposal that upholds fairness, integrity and objectivity (Coveney et al, 2017)

REC

- Ensure broad representation of methodological expertise
- Practice “epistemic humility” (Churchill, 2020)
- Focus on good-for-context, not best-in-the-world, design

Key messages

- Technical review at the REC level is important to ensure scientific and ethical soundness of the protocol
- Detection of design issues at the REC level point to issues concerning the researcher, the technical panel, and the REC
- RECs should recognize methodologic plurality, practice epistemic humility, and remember that scientific soundness is about both validity and feasibility

Questions or comments? You may email me at ctantonio@up.edu.ph

Thank you for listening!

November 09, 2021

References

1. Adams P, Wongwit W, Pengsaa K, Khusmith S, Fungladda W, Chaiyaphan W, Limphattharacharoen C, Prakobtham S, Kaewkungwal J. Ethical issues in research involving minority populations: the process and outcomes of protocol review by the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Thailand. BMC Med Ethics. 2013 Sep 11;14:33. doi: 10.1186/1472-6939-14-33.
2. Angell EL, Bryman A, Ashcroft RE, Dixon-Woods M. An analysis of decision letters by research ethics committees: the ethics/scientific quality boundary examined. Qual Saf Health Care. 2008 Apr;17(2):131-6. doi: 10.1136/qshc.2007.022756.
3. Boyce M; London multicentre research ethics committee 1997-2000. Observational study of 353 applications to London multicentre research ethics committee 1997-2000. BMJ. 2002 Nov 9;325(7372):1081. doi: 10.1136/bmj.325.7372.1081.
4. Bueno M, Brevidelli MM, Cocarelli T, Santos GM, Ferraz MA, Mion D Jr. Reasons for resubmission of research projects to the research ethics committee of a university hospital in São Paulo, Brazil. Clinics (Sao Paulo). 2009;64(9):831-6. doi: 10.1590/S1807-59322009000900002.
5. Coveney J, Herbert DL, Hill K, Mow KE, Graves N, Barnett A. 'Are you siding with a personality or the grant proposal?': observations on how peer review panels function. Res Integr Peer Rev. 2017 Dec 4;2:19. doi: 10.1186/s41073-017-0043-x.
6. Churchill LR. Three Kinds of Humility in Bioethics Certification. Perspect Biol Med. 2020;63(3):420-428. doi: 10.1353/pbm.2020.0030.
7. Dal-Ré R, Espada J, Ortega R. Performance of research ethics committees in Spain. A prospective study of 100 applications for clinical trial protocols on medicines. J Med Ethics. 1999 Jun;25(3):268-73. doi: 10.1136/jme.25.3.268.
8. Dolan B. The impact of local research ethics committees on the development of nursing knowledge. J Adv Nurs. 1999 Nov;30(5):1009-10. doi: 10.1046/j.1365-2648.1999.01221.x.
9. Happo SM, Halkoaho A, Lehto SM, Keränen T. The effect of study type on research ethics committees' queries in medical studies. Res Ethics. 2017;13(3-4):115-127. doi: 10.1177/1747016116656912.
10. Hemminki E, Virtanen JI, Regushevskaya E. Decisions by Finnish Medical Research Ethics Committees: A Nationwide Study of Process and Outcomes. J Empir Res Hum Res Ethics. 2015 Oct;10(4):404-13. doi: 10.1177/1556264615599685.
11. Humphreys S, Thomas H, Martin R. Science review in research ethics committees: Double jeopardy? Res Ethics. 2014;10(4):227-237. doi: 10.1177/1747016114552340.
12. Kent G. Responses by four Local Research Ethics Committees to submitted proposals. J Med Ethics. 1999 Jun;25(3):274-7. doi: 10.1136/jme.25.3.274.
13. Lutz K, Wilton K, Zytaruk N, Julien L, Hall R, Harvey J, Skrobik Y, Vlahakis N, Meade L, Matte A, Meade M, Burns K, Albert M, Cash BB, Vallance S, Klinger J, Heels-Ansdell D, Cook D; PROTECT Investigators in collaboration with the CCCTG and ANZICS-CTG. Research ethics board approval for an international thromboprophylaxis trial. J Crit Care. 2012 Jun;27(3):225-31. doi: 10.1016/j.jcrc.2011.12.012.
14. Mansbach J, Acholonu U, Clark S, Camargo CA Jr. Variation in institutional review board responses to a standard, observational, pediatric research protocol. Acad Emerg Med. 2007 Apr;14(4):377-80. doi: 10.1197/j.aem.2006.11.031.
15. Newson AJ, Lipworth W. Why should ethics approval be required prior to publication of health promotion research? Health Promot J Austr. 2015 Dec;26(3):170-175. doi: 10.1071/HE15034.
16. Silaigwana B, Wassenaar D. Research Ethics Committees' Oversight of Biomedical Research in South Africa: A Thematic Analysis of Ethical Issues Raised During Ethics Review of Non-Expedited Protocols. J Empir Res Hum Res Ethics. 2019 Apr;14(2):107-116. doi: 10.1177/1556264618824921.
17. Stevenson FA, Gibson W, Pelletier C, Chrysikou V, Park S. Reconsidering 'ethics' and 'quality' in healthcare research: the case for an iterative ethical paradigm. BMC Med Ethics. 2015 May 8;16:21. doi: 10.1186/s12910-015-0004-1.
18. Tod AM, Nicolson P, Allmark P. Ethical review of health service research in the UK: implications for nursing. J Adv Nurs. 2002 Nov;40(4):379-86. doi: 10.1046/j.1365-2648.2002.02385.x.
19. Tsoka-Gwegweni JM, Wassenaar DR. Using the Emanuel et al. framework to assess ethical issues raised by a biomedical research ethics committee in South Africa. J Empir Res Hum Res Ethics. 2014 Dec;9(5):36-45. doi: 10.1177/1556264614553172.
20. van Lent M, Rongen GA, Out HJ. Shortcomings of protocols of drug trials in relation to sponsorship as identified by Research Ethics Committees: analysis of comments raised during ethical review. BMC Med Ethics. 2014 Dec 10;15:83. doi: 10.1186/1472-6939-15-83.