Exemptions from ethics reviews – comparing Australia to the UK, USA and the Netherlands

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BACKGROUND

Inefficient regulation and management of research contributes to research waste, costing $200B/annum. Streamlining of regulations and guidelines governing research – by aligning them with the level of risks associated with research – is one way to mitigate this waste.

OBJECTIVES

To identify examples of health/medical research exempt from ethics review, ultimately aiming to offer rationale for bringing Australian standards into alignment with similar jurisdictions.

METHODS

We analysed 4 national-level ethics guidance documents to identify health/medical research exempt from ethics review: NHS's National Research Ethics Service (UK); Department of Health & Human Services, Office for Human Research Protections (USA); Netherlands Central Committee on Research Involving Human Subjects; and NHMRC's National Statement.

RESULTS

All four countries exempt from ethics review studies of existing specimens or data. The broadest set of exemptions is evident in the Netherlands, which exempts: surveys or questionnaires, post-marketing studies, population screening programmes, and some RCTs. UK exempts post-marketing studies and research involving staff acting in their professional roles. USA exempts research evaluating public service programmes, studies in educational settings, and survey/questionnaires and interviews. Australia has fewest exemptions – beyond the existing specimen exemption, only studies lacking foreseeable risk of harm (i.e. no more than inconvenience) are exempt.

CONCLUSIONS

Australian guidance lists the fewest circumstances where research is exempt from ethics reviews. We will use these findings to generate a set of exempt research scenarios, and survey Australian researchers and ethicists' views on exempting these different types of research from ethics review in Australia.