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Title: Have centralised ethics and governance applications improved the time-variable, and approval process to conduct research in Victorian hospitals.

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COMPETING INTERESTS

The authors have no conflict of interest to declare. The study referred to in this letter was funded by the Department of Health and Human Services, Victoria.

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EXCERPT

Dear Editor-in-Chief

Recent articles by White et al. [1] and Sansom-Daly et al. [2] detail the heterogeneity and difficulties in timely review and approval of Human Research Ethics Committees (HREC) and site specific assessment (SSA) multi-site research applications in Australia. In 2014-15, Victoria introduced a centralised HREC/SSA process for multi-site research projects to reduce multiplication of applications, and time variations to commencing research [3]. We recently completed a medical records review of oesophageal cancer treatment in 18 Victorian hospitals (5 private), and experienced considerable delays in SSA approval [median 61.5 working days (range: 26-98)], and time to commence data collection after SSA approval [median 18 working days (range: 12-56)]. Similar to previous experiences, we found an inflexible approach regarding governance requirements, which appear ideally suited to clinical trials [4, 5], but not low risk research projects [1, 2], a barrier to conducting timely multi-site research projects.

We found substantial differences in SSA requirements between public hospitals (n=13). One hospital did not accept the multi-site HREC approval, requiring hospital-specific HREC approval. The number of documents (median 12.5; range 6-17) required for each SSA varied, including submission of: Victorian Specific Module (11/13), professional indemnity

(7/13), confidentiality agreements (7/13), and legal requirements in research agreements. Despite the project involving a review of medical records, 2/13 hospitals required, and several hospitals requested, the local investigator to obtain a clinical practice certificate, which is primarily a requirement for clinical trials. Honorary appointments for research assistants (RA) were necessary at 7/13 hospitals, with variations seen in hospitals requiring immunisation checks (4/13) and police checks (7/13). Two hospitals required position descriptions to advertise the role to our RA's, and one hospital processed referee checks, and required remuneration details, certified proof of identification and qualifications, for their unpaid honorary position. Demands on research and hospital staff to comply with these regulations appear out of proportion to the time research assistants spent onsite (median 3 days) with no patient contact.

We agree with Sansom-Daly et al. [2], the 'time-cost trade off' needs to be considered for large multi-site research studies. Inflexibility in research governance offices (RGO), and in some cases human resource offices, resulted in a considerable time spent organising busy local investigators to sign documents, and considerable duplication of processes (e.g. police checks). Considering the time interval to start data collection (~60 working days), delays have implications for staff retention and time/costs associated with training new personnel. Unlike Queensland and New South Wales, many RGOs in Victoria charged fees for SSA submission (range $150-500) adding additional costs for multi-site projects.

Whilst we support and endorse the importance of appropriate ethical/governance oversight of all research projects, greater harmonisation in RGO procedures and differentiation between clinical trials and low risk research is needed to suit a centralised

system. For cancers with a low 1-year survival rate, such as oesophageal cancer (48%)[6], the delays in SSA approvals may hinder research-practice translation, where it is imperative every effort is made to improve the health status and quality of life of these patients.

REFERENCES

1. White, V.M., et al., *Inconsistencies and time delays in site-specific research approvals hinder collaborative clinical research in Australia.* Intern Med J, 2016. **46**(9): p. 1023-9.
2. Sansom-Daly, U.M., et al., *Something's got to give: time-cost trade-offs in site-specific research approval can negatively impact patient recruitment in multi-institutional studies.* Intern Med J, 2017. **47**(9): p. 1088-1089.
3. Department of Health & Human Services., *Research Governance and Site Specific Assessment Process and Practice*. 2015, Victorian Government: Port Melbourne.
4. Vaughan, G., et al., *Ethical issues: the multi-centre low-risk ethics/governance review process and AMOSS.* Aust N Z J Obstet Gynaecol, 2012. **52**(2): p. 195-203.
5. Barnett, A.G., et al., *The high costs of getting ethical and site-specific approvals for multi-centre research.* Res Integr Peer Rev, 2016. **1**: p. 16.
6. Australian Institute of Health and Welfare., *Cancer in Australia 2017. Cancer series no. 101.* 2017, AIHW: Canberra.

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