

Ethics is not a dirty word: Recognising value in ethics and governance processes in health services research

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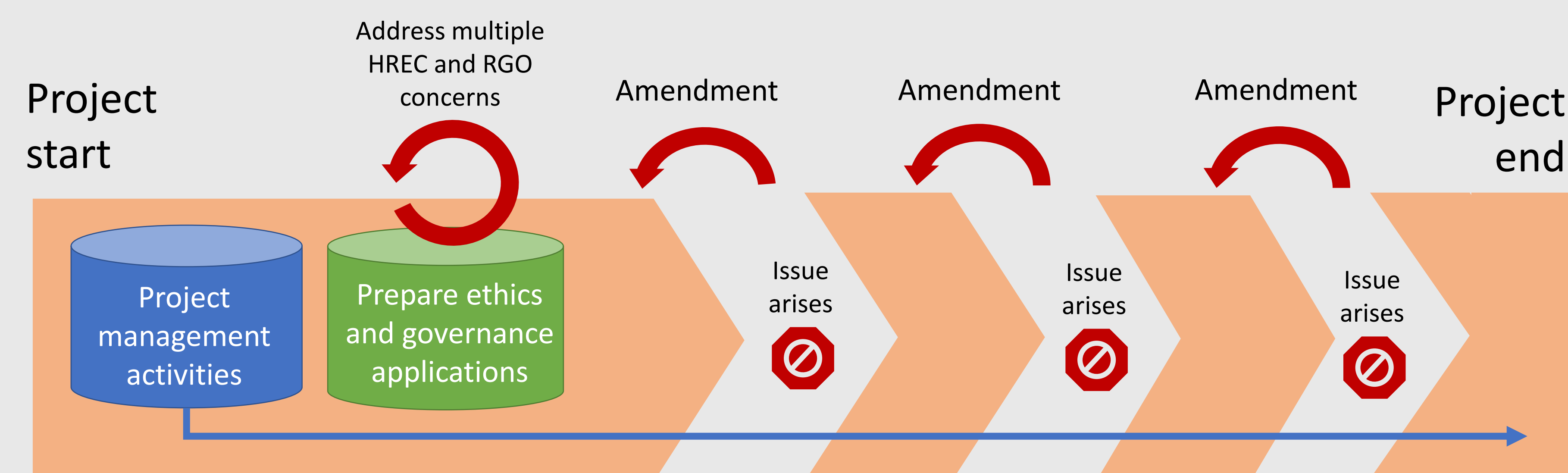
Background

Ethics and governance processes for health research in Australia are often considered onerous, unnecessarily time consuming and separate to core project activities.

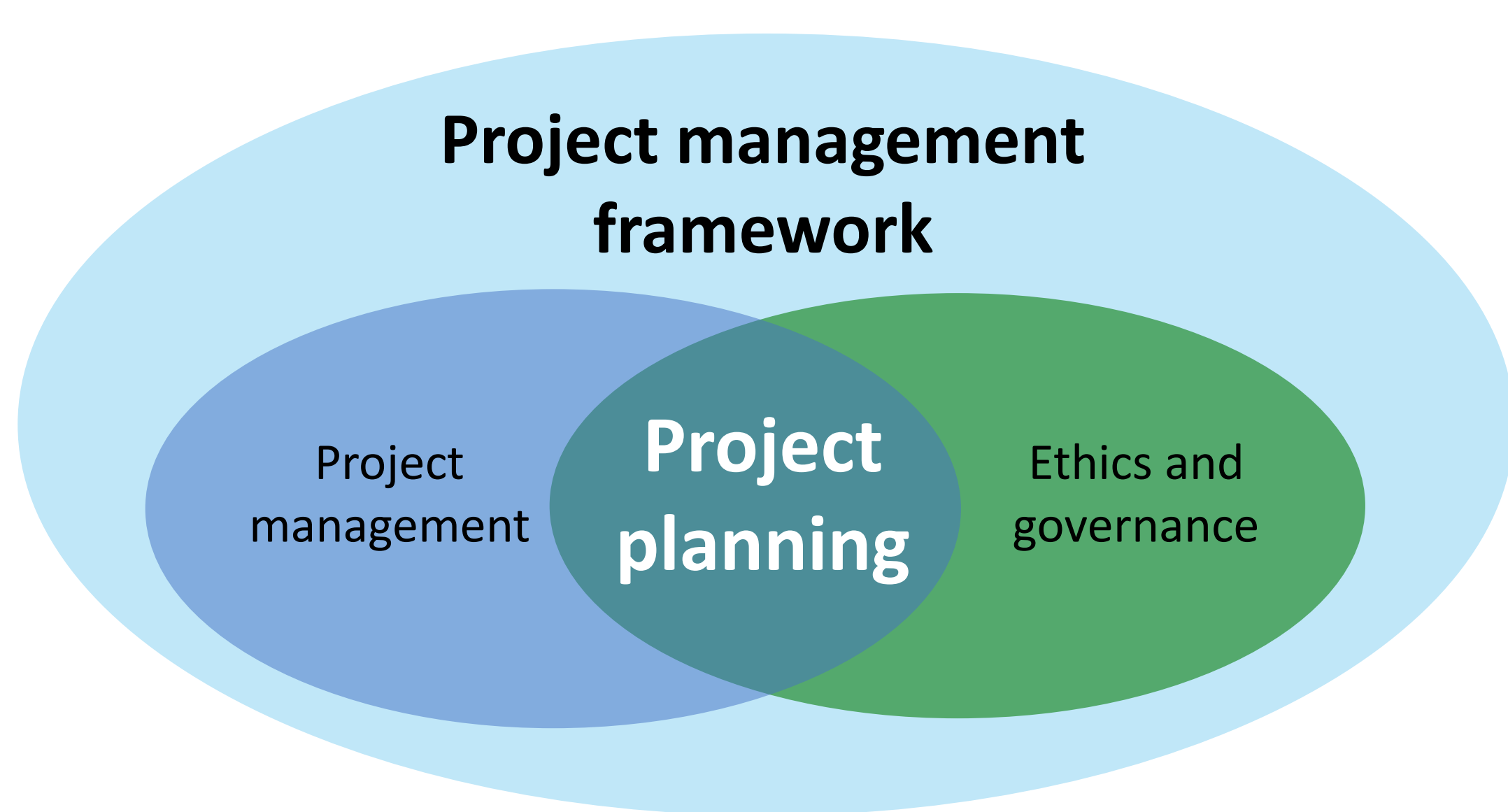
Decisions made during the preparation of ethics and governance documentation and processes have direct implications for the longer term management of the project. However, documentation for ethics and governance is often approached as a distinct activity from overall project planning.

This siloed approach can result in ongoing problems, causing projects to repeatedly stop and start as potentially preventable issues arise.

Project timeline with siloed ethics and governance



Methods








Professional research support staff - including research managers and coordinators - in our large health services research centre coordinate multiple projects. Staff are responsible for managing ethics and governance processes, as well as overall research project management.

Research coordinators are using a strong project management framework when developing key project documents to address issues that commonly cause delays in research projects and promote an integrated approach to overall project planning.


Documentation from previous and current ethics and governance submissions and subsequent project progression and delivery was reviewed. Key factors that affect both the ethical and practical considerations of project planning were identified.

Results

The following key factors are relevant to the practical operationalisation of a health services research project and for addressing the ethics and governance implications of the research.

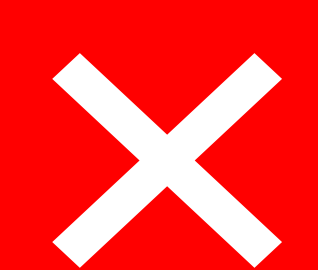
 <h3>People</h3> <ul style="list-style-type: none"> Who are the project team members? What are their roles and responsibilities? Is there sufficient capacity to complete the project? Who are the site investigators? Do they have sufficient understanding of the project and their role? Who are the key stakeholders? What influence do they have on the project's success? 	 <h3>Participants</h3> <ul style="list-style-type: none"> Who are the research participants? How will they be accessed and identified? Who will be making initial contact with the participants and how? What type of consent is required? Who will be collecting this, and how? 	 <h3>Data</h3> <ul style="list-style-type: none"> What type of data is being collected? Who is collecting this, and how? Is the data available and sufficient to address the research question? Are data custodian approvals required? Have data custodians been consulted and engaged? How will data be extracted? Are there specific transfer requirements? Have all requirements for data management and privacy been considered and addressed? 	 <h3>Finance</h3> <ul style="list-style-type: none"> Have all research activities been considered in the budget? Are participants being reimbursed? Is in-kind support required from partners or sites? Has this been calculated and confirmed? 	 <h3>Dissemination</h3> <ul style="list-style-type: none"> What are the ongoing and final reporting requirements? How will results be shared with participants, consumers, and the wider public? How will results be disseminated to key stakeholders and policy makers? What publications are planned? Are all project team members aware of the authorship guidelines? Are there open-access limitations or requirements?
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Conclusion



Projects **with** a combined project management/ethics and governance preparation approach:

- address more of these key factors prior to commencing the research,
- demonstrate faster approval turnarounds, and
- increase clarity of processes and outcomes for both the study team and external stakeholders.



Projects **without** a combined project management/ethics and governance preparation approach:

- may miss addressing key requirements early in the project,
- often require multiple amendments,
- risk scope creep, and
- can experience delays to project progress caused by multiple 'start/stop' points.

Maximising value...

- ★ Apply project management principles when planning research activities
- ★ Consider and address each of the key factors
- ★ Integrate ethics and governance preparation with project management planning activities