Seventeenth Thing: Human Research and Ethical Considerations

Research with human participants can have huge benefits but also comes with risks. Reviews and approvals help to mitigate risks, although navigating these processes can feel onerous, it doesn't have to be. Shift your point of view – viewing your research through the experience of your participants can shift the focus to the information relevant to these approvals and highlight the benefits for your research, as Helena Clements outlines in this Thing.

The integrity of your research

When you publish your research, how do you make sure people know it can be trusted? One critical way is to show that you have all the appropriate approvals in place. Review and approvals show other researchers that your research stands up to scrutiny. They're also important for maintaining community trust; approvals demonstrate that you, and your research have integrity. When you're doing research with people, approvals provide reassurance of respect for your participants – a stamp of quality and of trust.

Human research ethics review

Why do I need approval?

When people agree to put themselves in your hands and give you access to information about themselves, they do so because of trust. Researchers bear a great responsibility for respecting the rights of individual participants just as much as the potential outcomes for society, weighing up the risks and the benefits.

What does 'approval' mean?

The National Statement on Ethical Conduct in Human Research was created to guide research approvals. In Australia, research conducted with people, their data or their biospecimens must meet its requirements. Review involves a committee of people reading through your application, considering your participants' experience of the research, weighing up the benefits versus the risks and determining whether the requirements of the *National Statement* have been met.

What will help my review go smoothly?

If the committee is missing a piece of the puzzle – perhaps something isn't explicit enough in your application, or the application focuses more on the benefits to society and less on the experience of the participants – then they will need to elicit that information. This adds time and effort to the application process. What can you do to help?

From the beginning of your planning, put yourself in the place of your participants and review your research through their eyes.

Ask (and keep asking):

- Who are they?
- How will you approach them and make sure they understand what they'll need to do?
- Can they opt in rather than out?
- Could they experience inconvenience, discomfort or more than discomfort?
- How does your research design minimise risks?

The more aware you are of these questions during your planning, the clearer your application will be, and it will be easier for the committee to quickly provide approval.

You don't need to be an expert on things like data management or privacy, but you do need to be conscious of how you manage these.

The information we hold about people can be sensitive. Depending on who they are and what the research is about, it can be even more so. If personal health data is involved, there is legislation to be aware of. It can be hard to know what 'the right' thing is let alone how you should go about it. Where can you find more information?

- The online application form contains links to information that will help you.
- If you're still not sure, contact the University's Office of Research Ethics and Integrity for advice.

What else do I need to know if I'm doing a clinical trial?

When undertaking research that will inform clinical decisions, the potential benefits – and risks – are heightened. It's even more important to demonstrate that your research considers the participants. A sponsor is required for all clinical trials in Australia, their role being to ensure that appropriate governance measures are in place, including insurance both for trial participants and your research team. If the University is to be the sponsor, contact the Office of Research Ethics and Integrity. They will help you submit a sponsorship request and concierge you through all the many moving parts. Get in contact early so they can help you, right from the start.

What happens if something goes wrong?

Sometimes, no matter how careful you are, research with human participants doesn't go exactly to plan. They may experience adverse effects, or the integrity of your research may be questioned. Contact the Office of Research Ethics and Integrity. They can help guide you through our National framework, the Australian Code for the Responsible Conduct of Research and how that applies at the University of Melbourne.

By viewing your research through the eyes of your participants and being explicit about how you meet best-practice research and community expectations, you can enhance the integrity of your research outputs and make the approvals processes a lot easier.

About the Author

Helena Clements is Manager, Human Research Ethics within the Office of Research Ethics and Integrity and has a long history of supporting researchers through governance and publication processes.

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