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ETHICS APPROVAL

Of all the regulations for clinical research in Australasia, Ethics Approval is often the most misunderstood. Why? Because this approval is required before any forward motion can happen. Unlike many other countries, Ethics is foundational here and the process is singular. After more than 20 years working with various Ethics Committees, PCRG have developed these fundamentals:

ETHICS approval in Australia and New Zealand are critical for clearance to undertake medical research in these countries. Ethics Approval is mandated before any medical study can be started in either/both regions. PCRG's 20+ year relationship with National Ethics often means we help Sponsors streamline to a single point ethics approval for use across all sites in Australia – with no need to apply for Ethics approval at the site level or even the State level.

In more than 20 years, PCRG have only ever been involved in two declined Ethics applications; that's less than 0.05% of all studies on our watch.

ETHICS Approval BEFORE Governance:

In Australasia, ETHICS precedes Governance – HREC approval must be obtained and submitted to the research governance officer (RGO) of each participating institution before institutional authorization is granted.

Ethics ensures that patient and participant rights, safety and welfare are respected. Elsewhere Ethics approvals are generally covered by an IRB (Institutional Review Board). Australian Ethics committees are made up of volunteer, specialist and independent reviewers who analyze the protocols, product, device or intervention to assure ethical compliance with human subjects in addition to ensuring the insurances and investigator eligibility to approve the study for conduct under Australian guidelines. These groups are known as HREC: Human Research Ethics Committee and there 200 of them across Australia alone.

Governance ensures the research study itself adheres to relevant institutional standards, including financial, legal, contractual and legislation requirements – according to the country in which the study takes place. The Governance committee is made up of in-house staff at each individual hospital site.

ETHICS oversees:

The HREC reviews the recruitment and consent processes as defined in your protocol. It weighs the benefits and risks of the research and considers its impact on the participants.

The HREC's role is to evaluate all ethical aspects of the protocol, spotlight possible risks and validate expected benefits to participants. Further it confirms the suitability of the researcher(s), facilities, and methods, and verifying the adequacy of privacy and confidentiality safeguards.

ETHICS ensures:

- The proposed research has scientific merit
- Its benefits outweigh the risks
- People working on your research (that's PCRG and sties) have the proper qualifications
- All participants are treated with respect
- Any potential ethical issues have been considered (ang any potential impact)

HRECs Comprise:

Broadly speaking, HRECs usually comprise at least eight members across the following disciplines:

- A chairperson
- Two lay persons:
- one man
- one woman
- (these two must no affiliation with the institution and must not be currently involved in medical, science, legal, or academic work)
- One person with knowledge of and current experience in the professional care, counseling, and/or treatment of people (physician, nurse, healthcare worker, etc.)
- One person who performs a pastoral care role in the community
- One lawyer
- Two people with current research experience relevant to the research proposals under consideration by the EC

Other members with additional areas of expertise may be added. HRECs may also obtain ad-hoc input from non-member experts whenever additional expertise is considered appropriate.

Applying for ETHICS Review

That's where PCRG come in. In Australia, all Ethics applications must be made by a "Local Sponsor" (PCRG) to facilitate the process and leverage local relationships and take responsibility for the study from a financial, regulatory, ethical and medico-legal standpoint For unapproved therapeutic goods or devices, application must fall under one of two regulatory schemes:

- the Clinical Trial Notification (CTN) scheme or
- the Clinical Trial Approval (CTA) scheme

Our role as Local Sponsor is to help determine which scheme best suits the protocol submitted for approval. Understanding this nuance is critical to speed approval.

Navigating HREC review in Australasia can be daunting. And securing Ethics approval on first submission is crucial to the successful (and timely) roll out of your trial. PCRG has successfully shepherded over 500 clinical trials across Australasia for more than 20 years. We can help you too.

Contact us to learn more: contact@pcrg.com.au