HREC Standard Operating Procedure

5.18 Collaborative Research Groups

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling the NHMRC Collaborative research: A guide supporting the Australian Code for the Responsible Conduct of Research (2020) read alongside the Australian Code for the Responsible Conduct of Research (2018) by ensuring collaborative research projects with other organisations have formalised agreements, to ensure specific issues such as sharing intellectual property, managing research findings, managing conflicts of interest, and commercialising research outcomes are formally agreed upon to minimise risk.

Definitions

Collaboration is defined as the recursive process where two or more people and/or organizations work together in an intersection of common research goals. The capacity in which one contributes to a collaborative venture is broad, and may include assistance with research methodology, data collection, analysis and/or publication.

Established Collaborative Research Group is defined as a formally appointed entity, which exists for the conduction of collaborative research. This may be at a local, national or international level. Status is independent of funding.

Collaborative Research Group is defined as an informal group who form a collegiate to facilitate collaborative research between organisations. This may be at a local, national or international level. Status is independent of funding.

Procedures

Research may involve a wide range of collaborations both within institutions and between institutions. This may also occur at a local, national or international level.

Organisations involved in a joint research project should ensure that an agreement is reached with the partners on the management of the research, based on the principles of the Australian Code for the Responsible Conduct of Research (2018) including integrity, honesty and a commitment to excellence.

The agreement should be in writing where possible, and must include information pertaining to financial management, intellectual property, confidentiality and copyright issues, managing research findings, commercialisation and the sharing of commercial returns, authorship and publication, consultancy and secondments, responsibility for ethics, safety and regulatory clearances, and ongoing reporting to appropriate agencies. It should also address the protocols to be followed by all parties involved when disseminating the research outcomes, and the management of primary research materials and/or data.

To facilitate the operation of the agreement, each of the collaborating parties should identify a person to manage the research data, primary materials and other items to be retained at the end of the project (usually the site Principal Investigator).

Before entering an agreement, each party must ensure that they are aware of, and understand, the policy and agreements governing the joint research collaboration.

An agreement may take various forms, including a legal contract signed by the Director of Research or Deputy Director of Research (as a delegate of the Chief Executive Officer on behalf of the institution), or a research management plan signed by appropriate representatives from all parties (in the form of a letter, or Memorandum of Understanding).

At SVHM all established Collaborative Research Groups must ensure that a formal agreement is in place the form of a Medicines Australia Collaborative Research Group Clinical Trial Agreement. The Research Governance Unit and internal Corporate Counsel may however use discretion if an acceptable alternative template is required.

The Medicines Australia Collaborative Research Group Clinical Trial Agreement must be executed prior to the commencement of work, and must be signed by an authorised member of both the Collaborative Research Group and the Institution.

All other Collaborative Research Groups must also submit an agreement. It is encouraged that such agreements be written using the Medicines Australia Collaborative Research Group Clinical Trial Agreement, however, where this is not applicable, a research management plan signed by appropriate representatives from all parties (in the form of a letter, or Memorandum of Understanding) is required. Advice should be sought from Corporate Counsel when devising such documents. External legal advice may also be required, for which applicants will be charged a fee.

Agreements must be submitted with the ethics submission to ensure a comprehensive governance review can occur. This will ensure the appropriateness of the contract, and minimise the risks to all parties involved in the research.

Once executed, a copy of the agreement must be provided to all parties. A copy will also be held by the Research Governance Unit.

Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Australian Code for the Responsible Conduct of Research (2018)
- Collaborative research: A guide supporting the Australian Code for the Responsible Conduct of Research (2020)

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5.18 Collaborative Research Groups

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