## Locality Authorisation Checklist

All health research conducted in Te Whatu Ora - Southern and Dunedin School of Medicine (DSM) is required to be registered with Health Research South and have Locality Authorisation (LA).

Health research can range from fully costed commercial trials with complex protocols for pharmaceutical companies to relatively compact and straightforward studies for beginner researchers.

Because of the variation in complexity of health research, it is not possible to take a “one size fits all” approach to Locality Authorisation and Health Research South takes an approach which customises LA to each study. However, there are always six key areas that must be considered: peer reviewed protocol, ethical review, Māori consultation, research costs and funding, contracts, consultation with Te Whatu Ora - Southern and DSM staff.

The following is a checklist of the full set of requirements but please work with the Health Research South team at [hrs@otago.ac.nz](mailto:hrs@otago.ac.nz) to determine which requirements are appropriate for your particular study.

|  |  |  |
| --- | --- | --- |
| **Requirement** | **Note** | **Check** |
| Locality Authorisation (LA) form - fully completed |  |  |
| Protocol |  |  |
| Abstract/summary of study/who does what |  |  |
| Clinical Trials Research Agreement (CTRA) - completed and signed | Commercial trials |  |
| Other evidence of funding if no CTRA e.g. Letter of Award |  |  |
| Indemnity - completed and signed | Commercial trials |  |
| Certificate of insurance | Commercial trials |  |
| Any other legal notifications e.g. letters of delegation (if required) | Commercial trials |  |
| Budget - NZACRes Clinical Research Costing Tool | Commercial trials |  |
| Budget - other approved format if not commercial e.g. UoO CCW |  |  |
| Quotes for resources - procedures, tests, rooms etc. |  |  |
| Other costs itemised (including evidence) e.g. personnel time |  |  |
| Request to open a Te Whatu Ora Southern account (if required) |  |  |
| Ethics letter of approval |  |  |
| Ethics application |  |  |
| Ethics - patient information and consent |  |  |
| Peer Review letter |  |  |
| Medsafe Certificate (if required) | Commercial trials |  |
| Māori consultation |  |  |
| Alert sheet (if required) |  |  |
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