**Interventional Research Required Document Checklist**

All items must be made available to Waikato Research Office prior to commencing any research involving patients, patient information, staff or sites of Waikato. Documents can be made available via EthicsRM application system (where appropriate) by authorising research@waikatodhb.health.nz to view your project.

**Waikato Registration#: RD**

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| **Documentation** | **Comments** | **Date** |
| Project Registration | Email [research@waikatodhb.health.nz](mailto:research@waikatodhb.health.nz) and request registration form. Waikato researchers can access form from [Research Hub](https://intranet.sharepoint.waikato.health.govt.nz/Pages/Quality%20and%20Patient%20Safety/Research%20hub.aspx) |  |
| Project Proposal/Protocol | Email to research@waikatodhb.health.nz |  |
| Waikato Approval of Research Form | Form will be emailed to researcher following registration and allocation of RD number. Researcher to seek sign-off of the form, as indicated (relevant Clinical Director, Operations Director and Executive Director/COO. |  |
| Waikato Clinical Support Services Sign-off (if any) e.g. Clinical Records, Pharmacy, Labs, Radiology, Chief Data Officer, etc. | Approval of Research form indicates which sign-offs required. Emails from approvers are acceptable as is electronic sign-off. Once signed, return signed form to research office to seek organisational approval  **Note:** any study that includes the administration of medicines to patients must adhere to the Waikato Clinical Trial Medicines Management protocol |  |
| Ethics Application Form & Approval letter  (HDEC or Institution) | Copy of the ethics application and ethics approval letter is required (electronic is fine).  For HDEC: Locality Authorisation must be requested in the online EthicsRM system: **Research@Waikatodhb.health.nz**. |  |
| Finance – complete the relevant item | * Clinical Trials – a memo from Finance regarding the viability/budget review * Research involving funding/grant: a memo from Finance regarding the viability/budget review * Other trials – registration indicates the cost to the DHB of undertaking the research (researcher time, extra clinic appointments, consumables….) |  |
| Procurement | For any study involving equipment or consumables not already approved by Waikato, log a portal request #521. Include copy of approval email with Approval of Research form. Guidance available from Research Office. |  |
| Privacy Impact Assessment and/or Cloud Assessment | If identifiable data is being collected and shared with other institutions, either within New Zealand or internationally, one or both of these documents may be required. Research Office can advise. |  |
| Participant Information Sheet and Consent form | Final **Waikato** version required. |  |
| Indemnity Agreement | For sponsored research, following internal legal review, the Chief Medical Officer (CMO) or authorised delegate must sign all research contracts on behalf of Waikato. Principal investigator to sign **before** CMO. |  |
| Clinical Trial Agreement or other funding contract | Following internal legal review, the CMO or authorised delegate must sign all research contracts on behalf of Waikato. Principal investigator to sign **before** CMO. |  |
| Insurance Certificate | For sponsored trial, please provide a valid insurance certificate from sponsor (Some are valid for the life of the trial whilst others are valid for a year) |  |
| Evidence of cultural consultation | Complete Māori Consultation Form (available from Research Office or Research Hub) plus the Tissue form (if applicable) and return to Research Office. Any queries, please contact Research Office ([research@waikatodhb.health.nz](mailto:research@waikatodhb.health.nz)) |  |
| Waikato Access to Information Declaration | Required for any non-Waikato staff accessing Waikato patients, patient information or premises. |  |

Any queries should be directed to Waikato Research Office by email **research@waikatodhb.health.nz**