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| **SINGLE APPLICATION FORM FOR** **APPROVAL OF A RESEARCH PROJECT at Te Toka Tumai Auckland – Health New Zealand Auckland** |

This form replaces the Standard application form and Expedited application form for low-risk studies.

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| Study (A+) Number | (if known) | | | | Ethics Number | | |  | |
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| **Section A. General Summary** | | | | | | | | | |
| Full project title | |  | | | | | | | |
|  | | | | | | | | | |
| Short project title | |  | | | | | | | |
|  | | | | | | | | | |
| Principal (Co-ordinating) Investigator’s name and position | |  | | | | | | | |
| Physical address | |  | | | | | Work phone No. | |  |
| Emergency No. | |  |
| E-mail | |  |
|  | | | | | | | | | |
| Te Toka Tumai Co-investigator names /departments | | 1. | | | | | 2. | | |
| 3. | | | | | 4. | | |
| 5. | | | | | 6. | | |
| 7. | | | | | 8. | | |
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| Is the research project an interventional study/ clinical trial? | | | YES | NO | | If YES **all** investigators must be trained in ICH E6 GCP (Good Clinical Practice for investigators) within the last two years. Send evidence of training (e.g. training certificate) for all investigators to [researchoffice@adhb.govt.nz](mailto:researchoffice@adhb.govt.nz) **OR** ensure all investigators are on the Research Office ICH GCP training register. | | | |
|  | | | | | | | | | |
| Coordinator name | |  | | | | | | | |
| Contact details | |  | | | | | | | |
| **Contact details for communication if not via Principal Investigator or coordinator** | | | | | | | | | |
| Contact name | |  | | | | | | | |
| Contact details | |  | | | | | Work phone No. | |  |
| Emergency No. | |  |
| E-mail | |  |
|  | | | | | | | | | |
| Te Toka Tumai Auckland Contact name (*Required for non-staff researchers*) | |  | | | | | Signature | |  |
| Contact details | |  | | | | | Work phone No. | |  |
| E-mail | |  |

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| Scientific Review |  | Describe |  | |
| Scientific Review Documents Attached |  |  |
|  |
| Conflict of Interest |  | Describe |  | |
| **Section B: Document checklist** | | | | | |
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| **REQUIRED FOR ALL APPLICATIONS**   * Study protocol   **OTHER SUPPORTING DOCUMENTS** – remember to submit the following with this application form **if relevant**   * Signed budget * Ethics application form * Ethics approval letter * Participant Information Sheets and Informed Consent Forms * Central lab letter * Questionnaires / Surveys * Scientific peer review * Evidence of Māori consultation * Funding application (e.g. to Health Research Council) * Any other supporting documentation relevant to the application   **IMPORTANT** – submit supporting documents in **electronic** version by email to the Research Office study coordinator (if known) or to the generic Research Office email address ([researchoffice@adhb.govt.nz](mailto:researchoffice@adhb.govt.nz)). | | | |

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| **Section C: Research proposal** | | |
| C. 1. Research Proposal (use up to 4 pages)  This section will be reviewed by the Research Review Committee (RRC) for their scientific assessment of the study. Describe the proposed research project using the below headings. Be sure that it is clear how the research will involve Te Toka Tumai Auckland and what research activities will take place here.  Background/Justification  Aims/Hypotheses  If patients will be recruited where and how will this take place?  Research Design  Endpoints/Analyses   |  |  | | --- | --- | | Participant numbers – be as precise as you can. If it is not possible to estimate please say why. | | | Total number of participants worldwide |  | | Total number of participants in New Zealand |  | | Number of participants at Te Toka Tumai Auckland |  |   C.2. Clinical safety (use up to 1 page)  Does this proposal require study procedures provided by another Te Toka Tumai Auckland service or site?  YES NO  If YES:  1. How has your engagement with these service(s) ensured that those study procedures will be followed according to the protocol?  2. If the research involves a change to clinical practice, how will you ensure reliable implementation across all services that will participate?”  3. Ensure this application is authorised by all departments/services with significant involvement in the project in Section G. | | |
| **Section D: Responsiveness to Māori** |
| **Responsiveness to Māori is assessed using a separate form. Please download either the Māori review form for Interventional studies or the Māori review form for Observational studies**  [Research approval process | Te Whatu Ora Te Toka Tumai Auckland (adhb.health.nz)](https://www.adhb.health.nz/health-professionals/research/approval-process/) |
| D1. Will your study recruit Māori patients or their whanau, or will you access health information of Māori people? - please indicate (delete one):  YES – my study will recruit Māori or access the health information of Māori people  NO – my study will not recruit Māori and will not access the health information of Māori people |

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| **Section E: Financial** | | |
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| E1. Budget attached? | YES NO |  |
| E2. If NO please explain why your research will **not** incur any costs at Te Toka Tumai Auckland |  | |

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| E3. The below questions in italics are for studies that are budgeted as investigator initiated but funded by a commercial entity. You **DO NOT NEED** to answer these questions if your study does not fall in this category.  *Who initiated the study concept?*    *Who developed the study design?*    *Will any funder have the potential to influence the analysis or any resulting publication?*    *Who will retain the intellectual property rights to the study results?*    *Will any funder have access to the study data?*    *In what way is the business of the commercial funder(s) related to the questions to be addressed by the study?*    *Do any of the investigators have a financial interest related to the commercial funder(s)?* | |
|  | |
| E4. Clearly describe what patient care is standard and what is extra for Research  You **DO NOT NEED** to answer E4 if your study will not actively recruit patients | |
| Study Assessments / Visits: | Standard care |
|  | Non-standard care **extra** for this research project: |
| E5. Describe/justify Te Toka Tumai Auckland resource impact OR why there will be no impact | For all studies – including those without a budget. Resources will include any staff time and any usage of clinic space, facilities, equipment or consumables. |
| E6. Breakdown / Explanation of Budget (for studies with budgets ONLY) | |
| Working Expenses | Laboratories |
|  | Pharmacy |
|  | Radiology |
| Investigator time (if applicable) |  |
| Co-ordinator/Research Nurse time: | Study preparation and approval |
|  | Study visits and CRF completion |
|  | Monitoring |
|  | Other costs |
| Miscellaneous Costs: | Travel / taxi vouchers |
|  | Refreshments |
|  | Stationery |
|  | Archiving |
|  | Other miscellaneous costs |

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| Income source for study (tick all that apply) | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | A+ Trust |  | Other NZ govt agency |  | Foreign govt agency |  | | Other Trust or charities |  | NZ tertiary education sector |  | Commercial sponsor |  | | Ministry of Health |  | NZ private sector |  | Collaborative trials group |  | | | | | | | |
| Funding letter attached? |  | Date funding result expected | | |  | | |
| Trust funding support Requested |  | Trust funding support application attached | | | |  |  |
| Savings identified in budget? |  | Describe |  | | | | |
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| Capex Required |  |  | |  | |  | |
| Capex approval attached |  | If not why not? |  | | | | |

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| **Section F: Contracts and Legal** | | | | |
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| Contract required |  | Legally reviewed and approved |  |  |
| Final contracts attached |  | Date Contract anticipated to be finalised by |  | |
|  | | | | |
| ACC study |  | Non-ACC study |  |  |
|  | | | | |
| Indemnity & Compensation signed |  | Date |  | |
|  | | | | |
| Current Insurance Certificate |  | Expiry date |  | |

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| **Section G: Departmental sign-off (if research is to be undertaken by more than one Te Toka Tumai Auckland department, obtain extra signatures as appropriate)**  ***National Women’s Health and Newborn Services studies*** *- NOTE TO RESEARCHERS: After this form is signed the application will be considered for the next steps of approval by the Research Review Committee AND by the Women’s Health and Neonatal Research Governance Group (WNRGG). The WNRGG meeting dates can be found on the National Women’s Health research webpage:* [*https://nationalwomenshealth.adhb.govt.nz/healthprofessionals/programmes-and-research/research/*](https://nationalwomenshealth.adhb.govt.nz/healthprofessionals/programmes-and-research/research/)  *Applications must be submitted to WNRGG by the dates on the webpage to be considered for the next meeting. Applications not received by the deadline will be considered at the following meeting.* | | | | | | | |
| **Service Clinical Director :**   * *I agree that the study aligns with department/service area interests and access to patients/staff/health information is justified YES / NO/ N/A* * *I agree that access to care for non-study patients will not be adversely affected YES / NO / N/A* * *I agree that the study is feasible and clinically appropriate YES / NO / N/A* * *I agree that staff workload is acceptable and PI and team are suitably qualified and experienced YES / NO / N/A* * *I agree that the potential group of patients/clients is not over researched already YES / NO / N/A* * *I agree that the recruitment target is achievable YES / NO / N/A* * *I agree that the department/service area can manage the research in the time frame suggested YES / NO / N/A* * *I agree that there are no conflict of interest issues that need declaring/addressing YES / NO / N/A* | | | | | | | |
| Name | |  | | Do not sign if any of above are *NO*, if you are an investigator or supervisor, or you are not authorised to do so | | | |
| Dept / Service Area | |  | | Signature | | |  |
| Job title | |  | | Date | |  | |
| Comments or qualification about the study? |  | | | | | | |
| Name |  | | Do not sign if any of above are *NO*, if you are an investigator or supervisor, or you are not authorised to do so | | | | |
| Dept/ Service Area |  | | Signature | |  | | |
| Job title |  | | Date | |  | | |
| Comments or qualification about the study? |  | | | | | | |

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| **Principal (Co-ordinating) Investigator or Te Toka Tumai Auckland site lead investigator:**   * *I assert that all the known uses of resources related to operationalising of the research have been considered and any potential costs identified have been discussed with a research accountant.* * *I confirm I will inform the Te Toka Tumai Auckland Research Office when the study is complete.* * *(where applicable) I confirm I will submit a progress report to the Health and Disability Ethics Committee annually, and a final report when the study has been completed.* | | | |
| Name & |  | Signature |  |
| Service Area |  |  |  |
|  |  | Date |  |
| Comments or qualification about the study? |  | | |
| **Section H: Finance (for studies with budgets only)** | | | |
| **H1: Financial sign-off (to be signed by a) RC manager if total income will be $10,000 or less, b) Service Clinical Director if total income will be between $10,000 and $50,000 or, c) by Level 2 manager if total income will be more than $50,000)** | | | |
| * *I agree the research project is compatible with Te Toka Tumai Auckland policies YES / NO / N/A;* * *I agree that any usage of existing and future resource has been fully identified and is acceptable YES / NO / N/A* * *I agree the research project has HR requirements identified for non-staff personnel i.e. screening, ID & confidentiality YES / NO / N/A* * *I agree the research project is financially viable and payment schedules (where applicable) have been noted and are appropriate YES / NO / N/A* * *I agree the research project has all resources/costs identified and accounted for YES / NO / N/A* * *I agree if savings are identified for use or transfer YES / NO / N/A* | | | |
| Name & |  | Signature |  |
| Service Area |  |  |  |
|  |  | Date |  |
| Comments or qualification about the study? |  | | |
| Name & |  | Signature |  |
| Service Area |  |  |  |
|  |  | Date |  |
| Comments or qualification about the study? |  | | |
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| **Section I: Clinical trial registration** | | | |
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| Clinical Trial Number |  | |  |
| Trial Website |  | |  |
| Comment |  | | |