**Research Title:**

**A+ number:**

**Auckland DHB lead investigator:**

**Reason RRC approval of amendment is required**

1. There will be a significant change to study objectives
2. The amendment could impact the safety or convenience of participants
3. Additional use of Auckland DHB resources will be required
4. There will be a change to the study budget

|  |
| --- |
| Answer the below questions so that a non-expert can easily understand the requested changes and how these will impact the conduct of the study at Auckland DHB. Answer all that are relevant to your amendment request. |
| 1a. Describe any significant changes to the research objectives |  |
| 1b. How will the changes impact the conduct of the study? |  |
| 1c. Why should these changes be approved? |  |
| 2a. Describe why the amendment might impact the safety or convenience of study participants? |  |
| 2b. Why should the changes be approved? |  |
| 3a. Describe what additional use of Auckland DHB resource will be required.  |  |
| 3b. Why should the changes be approved? |  |
| 4a. Explain why there will be a change to the study budget. |  |
| 4b. Provide a detailed breakdown of the new budget. |  |
| 4c. Why should the changes be approved? |  |
| For changed budget requests ensure both original and revised budgets are attached and readable |
| 5. Which study documents were updated for this amendment? |  |
| 6. Will the proposed amendment potentially impact upon access to Auckland DHB services for patients NOT in the study? |  |
| 7. Will the proposed amendment involve Auckland DHB services that did not sign off the original proposal? |  |

|  |
| --- |
| **Section G: ADHB Departmental sign-off (if research is to be undertaken by more than one ADHB department, obtain extra signatures as appropriate)** |
| **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? |  |

|  |
| --- |
| **Principal (Co-ordinating) Investigator or ADHB site lead investigator:** * *I assert that all the known uses of ADHB 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 ADHB 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: ADHB 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 ADHB policy compatible 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-ADHB 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? |  |