## Application Form

Date: *Click here to enter a date.*

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| Study title:type or paste text here | Documentation provided with this application:[ ]  all patient information and consent forms[ ]  study protocol[ ]  ethics application form[ ]  data management plan [ ]  other documentation, please describe: *type or paste text here* |
| Principal investigator: Organisation:Indigenous status:Country of residence:Co-investigator 1: Organisation:Indigenous status:Country of residence:Co-investigator 2: Organisation:Indigenous status:Country of residence:Co-investigator 3: Organisation:Indigenous status:Country of residence:Co-investigator 4: Organisation:Indigenous status:Country of residence: |
| Contact person: Contact details:  |
| Phone:  | email:  |

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| 1. Details of Research |
| 1a) In layman terms please provide a brief outline of your research project  |
| 1c) Is your study registered with: [ ]  Te Whatu Ora Waitematā Research and [Knowledge Centre](http://staffnet/kc/default.asp) [ ]  Te Whatu Ora Te Toka Tumai [Research Office](http://www.adhb.health.nz/health-professionals/research/) [ ]  Other |

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| 2. WHAKAPAPA. Research should involve the development and maintenance of respectful relationships, engage Māori in decision making, and include clear, appropriate communication |
| 2a) Consultation and Engagement: In what ways have you engaged with Māori organisations or communities in the planning stages of the research? ☐ some consultation or engagement [please provide details]:  ☐ Māori reviewer ☐ Peers/colleagues  ☐ attended Māori responsiveness training in last two years [(please provide evidence ie certificate of  attendance] ☐ attended Treaty of Waitangi training in last two years [please provide evidence ie certificate of  attendance]  ☐ Other [please provide details]  ☐ significant consultation or engagement [please provide proof and/or details]: ☐ Whānau  ☐ Hapū  ☐ Iwi  ☐ Mana whenua  ☐ Other [please provide details]  |
| 2b) Please explain how participants and their whānau will be informed about the study progress and its completion:  ☐ pānui /progress reports sent to participants and or whānau ☐ summary of results provided to participants and or whānau ☐ hui held with participants and whānau  ☐ On-going discussions with participants and whānau  ☐ Other [please explain] 2c) Please detail how study results will be disseminated to key Māori stakeholders ☐ pānui /progress reports sent to Te Whatu Ora research committees  ☐ pānui /progress reports sent to other Māori organisations  ☐ journal article published - accessible to Māori  ☐ meetings/hui with Māori communities ☐conferences  ☐ other [please explain] ☐ not applicable Many Māori consider their blood and genetic and genomic material to be tapu. Participation in studies that involve the collection of tissue samples requires careful cultural consideration. The collection of tissue samples for study purposes is recognised as a significant cultural issue.2d) Does this study involve the collection of tissue samples? ☐ No. (go to section 3)  ☐ Yes. 2e) Please confirm that you have included a statement about Māori cultural thinking regarding tissue usage. ☐ Yes. ☐ No. 2f) Please confirm that you have included a statement about protection of tissue from misuse  ☐ Yes. ☐ No. 2g) Please confirm that separate consent forms are supplied for storage of samples for future unspecified use ☐ Yes ☐ Not applicable (not part of this study)2h) Please confirm whether separate consent forms are supplied for use of samples for genetic and or genomic analysis (e.g. biomarker sub-studies) ☐ Yes ☐ Not applicable (not part of this study) |

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| WHAKAPAPA continued |
| Māori view data derived from the tissue as the ‘shadow’ of the tissue.2i) Please confirm you have a data management plan  ☐ Yes. ☐ No. 2j) Please confirm the data management plan includes responses to the Māori data sovereignty principles  ☐ Yes. ☐ No. 2j) Has the study been registered with the Auckland Regional Tissue Bank. Send email to biobank@auckland.ac.nz . In the subject line put Atten: to the Manager  ☐ Yes. ☐ No.  |
| 3. TIKA. Researchers should have the appropriate skills and experience required to design research that contributes to equity and to Māori health development |
| 3a) What is the expected level of involvement for Māori in your research project? ☐ Māori governance group ☐ expert advisors (tikanga, research)  ☐ lead investigators ☐ co-investigators  ☐ research assistants ☐ co-ordinators  ☐ as participants ☐ other [please explain]3b) The proportion of Māori participants in the study should reflect the proportion of Māori in the community with the health condition of interest. * Please detail how participants are recruited for this study, and strategies to ensure appropriate recruitment of Māori:
* Please detail the following:
* Total number of study participants in this locality:
* Total number of Māori participants expected:
* Proportion of Māori participants expected:

3c) Please explain your calculations for 3b above, and provide the source of any data used:  |

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| **TIKA (cont.)** |
| 3d) Please confirm that ethnicity data is collected, stored and handled using the standard ethnicity question as recommended by the Ministry of Health [ ]  Yes  [ ]  No [please explain]3e) Might there be opportunities in future research projects to undertake an analysis of results by ethnicity? [ ]  Yes [please explain] [ ]  No3f) Please describe how measures to ensure privacy and confidentiality are provided for participants and whānau:  |
| 4. MANAAKITANGA. Research should be conducted with respect for all persons involved and respect for their culture |
| Please confirm the following:4a) [ ]  Yes, contact details for cultural support are provided in the participant information and consent form. [ ]  No, please explain: 4b) [ ]  Yes, provision has been made for the participant’s whānau to be involved in the study.  [ ]  No, please explain: 4c) [ ]  Yes, provision has been made for participants to undertake the study in te reo Māori if desired. [ ]  No, please explain: 4d) [ ]  Yes, provision has been made for appropriate tikanga Māori protocols to be carried out when required. [ ]  No, please explain: *type or paste text here*  |

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| **MANAAKITANGA (cont.)** |
| 4e) Please describe how measures to ensure privacy and confidentiality are provided for participants and whānau: .4f) Describe any other provisions you have made in your study to ensure the cultural preferences of Māori have been considered:*Please include copies of any support agreements with this application.* |
| 5. MANA. Equity and distributive justice is at the core of mana. It relates to the potential or realised risks, benefits and outcomes of the research.  |
| 5a) Describe the process for obtaining consent from participants (and whānau): 5b) Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study? ☐ Yes ☐ No ☐ Not applicable (not part of this study)5c) Have the cultural risks of the study been fully explained  ☐ Yes ☐ No ☐ Not applicable (not part of this study)5d) Please explain who will own the study results and why. 5e) Might your study contribute to improving health gains for Māori? Yes/No (f1.1 HDEC form)Explain why yes or no (f. 1.2 HDEC form)5f) Describe how this research project can contribute to improving health literacy for Māori participants and whānau: For example: What steps have you taken to ensure your patient information and consent forms are appropriate for Māori?   |

**Resources you may find useful:**

**Te Ara Tika**: <https://www.hrc.govt.nz/resources/te-ara-tika-guidelines-maori-research-ethics-0>

**Hei Tangata Kei Tua**: <https://www.waikato.ac.nz/__data/assets/pdf_file/0019/321535/He-Tangata-Kei-Tua-Biobanking-Guidelines.pdf>

**Te Mata Ira**: <https://www.waikato.ac.nz/__data/assets/pdf_file/0018/321534/Te-Mata-Ira-Genome-Research-Guidelines.pdf>

**Te Mana Raraunga Charter:** <https://www.temanararaunga.maori.nz/tutohinga>

**Ngā Tikanga Paihere:** <https://data.govt.nz/toolkit/data-ethics/nga-tikanga-paihere/>

**Māori responsiveness statement (sponsored international clinical trials only)**

Internationally sponsored clinical trials are unlikely to benefit Māori as a population group as Māori tissue is counted as ‘other’ by the sponsors. However, there may be benefits for you as an individual from participating in this study. If there are benefits for you as an individual there may also be benefits for the Māori population in the future if a drug is produced.

Te Whatu Ora Waitematā and Te Toka Tumai have a memorandum of understanding with Ngāti Whātua and Te Whatu Ora Te Toka Tumai has a memorandum of understanding with Waipareira Whānau Trust. The memorandums acknowledge the importance of these trials as part of health services moving forward. Te Whatu Ora Waitematā and Te Toka Tumai also have a Tikanga Best Practice Policy that we comply with in our practice.

With these in mind, if you decide to participate in this study and tissue is gathered we acknowledge we have kaitiaki responsibilities to protect your tissue and data originating from the tissue. Unless a contract exists that explicitly requests the tissue and data remains or is returned to Aotearoa it is unlikely that we will be able to maintain this kaitiakitanga once your tissue and or data leaves the country. Because we cannot maintain this kaitiakitanga we have a whakawatea (karakia/blessing) process that takes place as the tissue leaves Aotearoa. As per our usual practice we will keep you informed about the study and your involvement in it when you come in for treatment. We may also let you know how the study is going nationally and internationally. A kawe taonga process will take place when the study is completed. The kawe toanga process represents the returning of the spirit of your tissue and data usually in the form of summary results.

Any issues associated with participating in this study, sending your tissue samples and data overseas and/or storing your tissue and data can be discussed with your whānau as appropriate. If you need cultural support this can be provided. Please let us know and we will arrange this for you or you can ring the number at the bottom of the participant information and consent form. Cultural support is different to knowing more about the study treatments. In these cases we can arrange a primary investigator to come and talk to you and your whānau.

## Appendix 1: Data Sovereignty Principles

### Data Sovereignty guiding principles

Within Aotearoa Māori data is protected by the same legislation as everyone else’s data; the Privacy Act and within this the Health Information Privacy Code 2020. Māori data is also considered a taonga and therefore protected by Te Tiriti o Waitangi. The data sovereignty principles give effect to Te Tiriti in the genomic domain. These principles are referenced in the National Ethical Standards (National Ethics Advisory Committee, 2019, pg. 161) and the Health and Disability Ethic Committee data management plan (Health and Disability Ethic Committee, 2020). Investigators are expected to address the data sovereignty principles in their data management plans (National Ethics Committee, 2019; Health and Disability Ethic Committee, 2020; Te Mana Raraunga, 2015). The Mana Raraunga Charter proposes a mana (governance)/mahi (operational) framework.

### Mana (governance)

At a **mana** level the mana-mahi framework proposes three tikanga; whānaungatanga, rangatiratanga and kotahitanga. **Whānaungatanga** refers to the non-kin, non-whakapapa based relationships. **Rangatiratanga** refers to the hapū, iwi/Māori aspirations to be in control of their own affairs and to influence those taking place within iwi boundaries. **Kotahitanga** relates to the collective vision and unity of purpose while balancing the mana of rangatira from hapū and iwi (see Table 1) (Hudson, et. al., 2017)

Table 1: Mana: description

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| Tikanga  | Description |
| WhānaungatangaObligations | *Balancing rights*. Individuals’ rights (including privacy rights), risks and benefits in relation to data need to be balanced with those of the groups of which they are a part.  |
| *Accountabilities*. Those responsible for the creation, collection, analysis, management, security or dissemination of Māori data are accountable to the individuals and groups from whom the data derive. |
| Rangatiratanga Authority | *Control*. Māori have an inherent right to exercise control over Māori data and Māori data ecosystems. This includes but is not limited to data creation, development, stewardship, analysis, dissemination and infrastructure. |
| *Jurisdiction*. Decisions about the physical and virtual storage of Māori data should enhance control for current and future generations. Whenever possible, Māori data should be stored in Aotearoa NZ.  |
| *Self-determination*. Māori have the right to data that is relevant and empowers sustainable self-determination and effective self-governance. |
| KotahitangaCollective benefits | *Benefit.* Data ecosystems should be designed and function in ways that realise collective benefit for Māori and avoid harm and stigma. |
| *Build capacity.* Māori Data Sovereignty requires the development of a Māori workforce to enable the creation, collection, management, security, governance and application of data. |
| *Connect.* Connections between Māori and other indigenous peoples shall be supported to enable the sharing of strategies, resources and ideas in relation to data and the attainment of common goals. |

### Mahi (operational)

At a **mahi** level it proposes the tikanga of whakapapa, manaakitanga and kaitiakitanga. **Whakapapa** establishes the linkages between man, te ao turoa and te taha wairua and identifies the nature of the relationships, a whakapapa relationship based on Māori concepts of genealogical association. **Manaakitanga** is about the responsibility investigators have to provide hospitality and protection to whānau, hapū, iwi, the community and the environment. **Kaitiakitanga** refers to the responsibilities hapū and iwi have to be effective stewards or guardians and is related to actions that ensure a sustainable future for all people (see Table 2) (Hudson, et. al., 2017).

Table 2: Mahi: description

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| Tikanga  | Description |
| WhakapapaRelationships  | *Context*. All data have a whakapapa (genealogy). Accurate metadata should at minimum capture and maintain the provenance of the data, the purpose(s) for its collection, the context of its collection, and the parties involved. |
| *Data disaggregation.* The ability to disaggregate Māori data increases its relevance for communities and iwi. Māori data should be collected and coded using categories that are relevant to Māori and that prioritise our needs |
| *Future use.* Current decision-making over data can have long-term consequences, good and bad, for future generations of Māori. The governance of Māori data should be enduring and minimise future harm. |
| Manaakitanga Reciprocity | *Respect.* The collection, use and interpretation of data should uphold the intrinsic dignity of Māori individual, groups and communities.  |
| *Consent.* Free, full and informed consent should underpin the collection and use of all data from or about Māori. Less defined types of consent should be balanced by stronger governance arrangements. |

| **Kaitiakitanga****Guardianship** | *Ethics.* Tikanga, kawa (protocols) and mātauranga (knowledge) should underpin the protection, access and use of Māori data |
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| *Stewardship.* Māori data needs to be stored and transferred in such a way that it enables and reinforces the capacity of Māori to exercise kaitiakitanga over Māori data.  |
| *Restrictions.* Māori should decide which Māori data sets should be tapu (controlled) or noa (open). |