**­­­­­STUDY PROTOCOL**

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# Summary

To help eliminate inequity in health outcomes for Māori we need a more holistic and culturally responsive health system. The aim of this research is to determine the wider health needs of two priority groups: 1) Māori mothers and 2) Māori with chronic disease. We will use a co-design methodology to understand the health concerns of the two groups and to develop and test a culturally appropriate wellbeing assessment, care provision and service referral approach. We will trial the approach with Māori mothers and Māori patients with chronic diseases. This research will impact at many levels including DHB management, staff, community-based agencies as well as patients and whānau. It will also provide a service delivery model for the Ministry of Health, other DHBs and other agencies to make much needed radical and rapid progress toward achieving health equity.

# Rationale for Research

Eliminating health inequities for Māori is a key aim of the Waikato DHB Strategy [1]. This proposal also aligns to Te Korowai Waiora, the Waikato DHB Health System Plan. The co-PIs were instrumental in its development and are passionate about achieving its goals, including:

1. Partner with Māori in the planning and delivery of health services

2. Empower whānau to achieve wellbeing

3. Support community aspirations to address the determinants of health

4. Improve access to services.

We posit that a holistic approach to health care for Māori is urgently required if we are to achieve equity. As such, any equity-centred approach must adequately address not only physical and mental health needs but also the social determinants of health for individuals and their whānau and/or households.

The research group have demonstrated that we can embed a holistic Māori centred approach into the hospital system with our Health Research Council of New Zealand (HRC) funded Harti project (HRC/17/441) [2]. Indeed, with this study we have shown that we can substantially change the system and improve the hospital experience for patients and their whānau. However, it has taken seven years to get the Harti Hauora Tamariki programme/model to where it is. Expanding and implementing high quality holistic models into maternity and chronic care settings is urgently required and requires a solid research informed evidence base and an expert team. As such, this proposal will draw on the Harti Hauora Tamariki programme structure as described in the methods section.

This work requires a multi-agency approach, including a partnership with the Ministry of Social Development and Kāinga Ora (Housing New Zealand). We will be continuing to work in partnership with these and other relevant organisations. Developing health services by, with and for priority populations has shown to be effective in reducing inequities. We are particularly committed to working in partnership with Māori to improve health outcomes and achieve health equity. The way the health system operates means that some people do not gain the right type and level of support and information to enhance their health. We believe there is a need to change our approach to health care - to a more holistic and culturally responsive system. A holistic approach to health care addresses not only the individual physical health needs but will also address the social determinants of health.

Te Tiriti o Waitangi requires actions to be taken to achieve health equity for Māori who are tāngata whenua. The impact of health inequities on the potential of Māori individuals, whānau and communities is vast. Māori women have the highest preterm birth rates of any ethnic group in Aotearoa/New Zealand (NZ) and Māori pēpi are more likely to be small for gestational age at birth [3] and have an infant mortality rate of 4.9 per 1000 compared to the NZ European rate of 3.2 per 1000 [4]. There are also marked differences in life expectancy at birth for Māori. For Māori females’ and Māori males’, life expectancy at birth is estimated to be 77.1 years and 73.0 years, respectively, compared to 83.9 years for non-Māori females and 80.3 years for non-Māori males [5]. The root drivers of these differences are associated with ongoing colonisation and repeated breaches of Te Tiriti o Waitangi. These affect access to the determinants of health, including income, but also access to a health care system which, in turn, is not developed to meet Māori needs. Māori have inequitable access to healthy housing and home ownership [6], transport, economic resources, education, health care and receive poorer quality health care. Māori are disproportionately affected by racist and discriminatory attitudes and practices in the health system, known to impact health outcomes [7]. Māori also have lower access to healthy nutrition [8] and overexposure to tobacco, alcohol and recreational drugs [9]. In addition, Māori have lower access to preventative care such as vaccinations [10] and health screening [11]. The amenable mortality gap in NZ for deaths preventable by health care interventions is large and unacceptable. The amenable mortality rate for Waikato Māori in 2016 was 195.1 per 100,000 compared to 70.2 for non-Māori [12]. Much of the amenable mortality for Māori is due to differences in outcomes from chronic disease. This project aims to look at two important stages of life – the antenatal and immediate post-natal period and the adult age group when chronic disease become an important influence on life expectancy.

The study is informed by a Kaupapa Māori co-design process, following the He Pikinga Waiora (HPW) framework [13]. HPW helps progress implementation of initiatives that could, or have proven to be, effective for Māori and this proposed research offers the team an opportunity to continue to grow our translation and implementation skills. The study also draws on the following Harti Hauora Tamariki programme structure which comprises three important elements.

1. A safe, racism free, culturally aligned space (whānau in the current Harti trial report that they felt treated with value, dignity and respect and had a renewed sense of confidence for navigating additional services) [14].

2. A comprehensive wellbeing screening and support tool, called the Hauora assessment tool, with follow-up protocols for each question - administered by a trained Māori navigator who supports whānau to access a range of services, including providing help when possible. The Harti tool was developed through an iterative approach, informed by whānau, staff and data, and overseen by expert advisors including whānau.

3. Community engagement and systems level solutions - whānau, staff, providers and leaders co-design solutions with a focus on service integration and filling gaps (not replication), community engagement, sharing of resources and the provision of outreach and opportunistic care.

## Maternal Health

The first 1000 days of life (from conception to approximately age two years) are both critical and sensitive periods for targeted interventions to improve immediate and long-term health outcomes [15]. During this time, good nutrition and support for holistic wellbeing can have a lifelong positive impact [16]. Research shows that much of the inequity for Māori mothers are due to system failures. Māori women have poorer access to lead maternity carers (LMC) and are more likely to experience a delay before being registered with an LMC [17]. Young Māori women report systemic barriers from their first health contact. A lack of sufficient and appropriate information and support which impeded the process of gaining a midwife, has been described as a considerable barrier. [18]. Screening for diabetes during pregnancy is also half as likely to occur for Māori women as non-Māori despite a higher underlying risk [19]. Further, Māori mothers are at increased risk of adverse mental health outcomes. Maternal suicide is the leading cause of maternal mortality in NZ, seven times the rate in the United Kingdom [20]. Māori women are over-represented among maternal suicides. Between 2006 and 2016, 57 percent of the 28 women who died by suicide in pregnancy or within six weeks of pregnancy were Māori, more than seven times their population share [20]; In 2006, Maori women made up 7.58 per cent of population (319,300) and in 2016, Maori made up 8.29 per cent of population (395,700).

Currently, screening for mental health in pregnancy is ad hoc and there are notable gaps [21]. Maternal mental illness can not only lead to harm for the mother but also impacts, the offspring. While treatment in a mother and baby unit can help maternal mental health the wellbeing of the infants may still be of concern with lower birth weights and poorer health status. At discharge, 51% of infants were lagging behind developmentally, and 51% were exhibiting signs of infant mental health concerns [22]. Maternal experience of discrimination is also associated with lower birth weight and shorter gestation length among Māori women [23]. Poor maternal mental health, and experiences of racism and discrimination can provide the context for increased risk-taking behaviour, such as the use of alcohol and recreational substances.

Alcohol consumption during pregnancy places the foetus at risk of Foetal Alcohol Spectrum Disorders [24]. A survey of over 700 New Zealand mothers reported that 34% of women said that they drank alcohol at some time during pregnancy and 12% of pregnancies were at high risk of heavy alcohol exposure in early gestation [25]. In fully adjusted analysis, pregnancies most at risk were those of Māori women, Pacific women, smokers and drug users. Almost one-quarter (24%) of drinkers continued to drink following pregnancy recognition [25]. Smoking in pregnancy also has many adverse effects including leading to low birth weight [26]. In one study, 22.2% of women reported that they were smoking when they became pregnant though, 26.8% of these women then gave up smoking in the first trimester [27]. Factors significantly associated with stopping smoking in the first trimester were current employment (OR 2.37, 95% CI 1.16-4.85), first pregnancy (OR 2.18, 95% CI 1.11-4.28), and experiencing nausea during the pregnancy (OR 2.59, 95% CI 1.11-6.04) [27]. However, women who held a community services card (OR 0.41, 95% CI 0.19-0.86), Māori women (OR 0.38, 95% CI 0.15-0.98) and those whose partners smoked (OR 0.35, 95% CI 0.17-0.70) were significantly less likely to have stopped smoking [27]. Socioeconomically-deprived women were more likely to continue to smoke beyond the first trimester of pregnancy and this needs to be taken into account in the provision of smoking cessation support [27]. While this research has identified a number of health system factors that are associated with health inequities for Māori whānau at this critical and sensitive time, strengths-based factors are rarely identified in this specific population. Reorientation of the health sector for antenatal and perinatal support of whānau, that reflects Māori strengths, preferences and needs, is required if the most relevant health issues for Māori whānau are to be effectively addressed at the outset.

## Chronic diseases

In NZ, Māori, Pacific peoples, and those with lower socioeconomic status (SES) experience higher levels of chronic illness, which are the leading cause of mortality, morbidity and inequitable health outcomes in adults [28]. Māori are more likely to have a number of chronic diseases – the rate of hospital identified multimorbidity for Māori is estimated to be 13.4% compared to 7.6% in NZ Europeans [29]. However, the traditional approach to reducing amenable mortality focuses at individual health conditions - ischaemic heart disease (IHD), diabetes, stroke, chronic obstructive pulmonary disease (COPD) and cancer [11]. Other important causes of amenable mortality include suicide and accidents for which the Waikato DHB already has action programs in place. Renal failure disproportionately impacts Māori [30] and there is a 3.5-fold higher relative incidence of Māori and Pacific patients commencing renal replacement therapy. Patients with renal disease have an increased incidence of obesity, smoking and poverty relative to other members of the population [30].

Māori and Pacific people are less likely to access renal transplantation [30]. The interaction between diabetes, renal disease and cardiovascular disease means treating these conditions separately is counter intuitive. This project will look at providing co-ordinated and integrated care for Māori with cardiovascular disease (IHD and stroke), diabetes, COPD, and renal disease. We will include high quality coordinated medical care that also addresses the social, psychological and spiritual needs of patients and whānau. The Waikato DHB provides specialist services to manage specific conditions – cardiology, respiratory, renal, diabetes. The Harti Hauora Tamariki programme in paediatrics worked to change the way health care professionals see their role so that providing holistic care for patients and whānau became business as usual. We want to develop a similar evidence-based approach for providers in the chronic conditions space to use which is holistic, effective and responsive to Māori . The literature outlines factors that impact on Māori with a range of conditions – by looking at these separately it is apparent that there are common themes.

## Cardiovascular disease

Ischaemic Heart Disease (IHD) is a leading cause of death in NZ and disproportionately affects Māori [31]. Māori and Pacific people and those with low SES have disproportionately higher rates of IHD mortality [32,33]. Some of these inequities are related to differences in smoking, but other implications include poor housing, low income, and unemployment. These implications can lead to a poor diet and financial barriers to accessing primary care. Māori with health issues are less likely to consult a GP [34], and the much lower ratio of IHD hospitalisations to deaths among Māori and Pacific people compared to others suggests there are important barriers to preventive interventions and acute care. Māori are also more likely to experience significant barriers in calling an ambulance early after symptom onset of IHD and are more likely to suffer delays in treatment. For example, in ambulance-transported patients who received fibrinolysis, the median system delay is 86 minutes and delay is more likely for Māori patients compared to NZ European patients [35].

## Diabetes

It is well recognised that the prevalence of type 2 diabetes (T2D) is much greater in Māori [36]. T2D is complicated by both macrovascular and microvascular disease [37]. Thus, patients with diabetes are much more likely to have a cardiovascular event, stroke or peripheral vascular disease [38]. Compared with Europeans with diabetes, Māori have nearly double the mortality in diabetes, with standardised mortality rates for male-Europeans, female-Europeans, male-Māori and female-Māori aged 25+ being 1.16 (1.05-1.28), 1.10 (0.98-1.24), 2.49 (2.06-3.01), 3.12 (2.56-3.80), respectively [39]. The drivers of the mortality came from diabetes-related complications, such as cardiovascular disease, cancer and renal disease [Hazard-ratios 2.31 (95%CI 1.6-3.3), 1.83 (1.1-3.0), and 11.74 (4.8-29.0) respectively] [39]. In addition to morbidity and mortality, a diagnosis of diabetes impacts on an individual’s ability to thrive, including effects on a patient’s licence to drive, employment as well as the financial burden associated with a specialised diet and services, such as podiatry, optometry, and regular medical attendance. For many SES Māori, the addition of diabetes to this equation leads to further disparities that our health services need to address. We have been working with a range of stakeholders to co-design Māori-led solutions for diabetes. The Kimi Ora wellbeing programme is an example that could be enhanced through our proposal. Kimi Ora is a whānau exercise and nutrition programme, developed as part of the HPW research programme with a Māori provider. Initial findings suggest a wide range of positive effects. However, further funding is required to extend this programme to a greater number of clients/patients.

## Renal disease

Overall, the disparity in the incidence rates of end-stage kidney disease (ESKD) for Māori patients are markedly and persistently higher than those for non-Māori and non-Pacific patients [40]. Māori are more likely to develop diabetic nephropathy. For example, Māori account for 57% of new cases of ESKD across the Midland region, more than twice their regional population share [41]. Māori tend to be referred later to specialist nephrology services and receive a higher use of facility dialysis as the principal modality of care, in comparison to home-based modalities when compared with non-Māori and non-Pacific patients. Māori also continue to have markedly lower rates of pre-emptive kidney transplantation [40]. Factors which affect dialysis modality rates and transplant listing rates include not only later referral to renal services but are also influenced by the higher comorbidity burden and that there are fewer potential live donors who meet the criteria to be able to donate [40]. The impact for Māori of dialysis is accentuated by the higher number of Māori living rurally, in poorer housing or housing without services to allow home dialysis. In addition, there is an economic cost of having to attend dialysis, both in terms of transportation costs and loss of income [42].

Developing and sustaining trusting relationships among clinicians, whānau and the community has also been identified as central/significant to improving health gains for Māori and other indigenous groups. Poor communication between patients and clinicians is a barrier to Māori accessing quality and effective health care [34, 43]. In a previous study about Māori patient experiences of heart disease in NZ, patients considered that poor communication arose both from a lack of practitioner competency, together with discrimination against Māori during clinical care. Similarly, Māori recipients of chronic kidney disease care in NZ do not consider that existing health care services are meeting their need for adequate communication and engagement, with direct negative implications for their disease trajectory and dialysis preparation [44].

## COPD

People with severe chronic obstructive pulmonary disease (COPD) experience multilevel barriers to accessing health care in the NZ health system [45]. Māori patients with COPD have highlighted the importance of communication and relationships and the role of whānau (extended family) for support [46]. Patients' accounts showed variable ability to access services through having a limited understanding of COPD, a limited knowledge of services they could access, being unable to attend pulmonary rehabilitation (due to comorbidities) and direct (medication and co-payment charges) and indirect (transport) costs [46]. Pulmonary rehabilitation is one of the cornerstones of treatment for patients with COPD. Patients are less likely to be offered pulmonary rehabilitation if they live more than 20km away from the hospital where it takes place [47]. Lack of attention to cultural factors in the delivery of pulmonary rehabilitation is believed to be a barrier to its uptake by Māori [48]. Indigenous-led or culturally responsive health care interventions for COPD have been suggested as a solution to this issue [48].

## Multimorbidity

Multimorbidity (the co-existence of two or more chronic conditions in an individual) is a growing health care burden internationally [49]. A NZ study suggested that the eight most prevalent chronic conditions in both Māori and Pacific patients were obesity, anxiety or depression, hypertension, asthma or chronic obstructive pulmonary disease, gout, diabetes, cardiovascular disease and osteoarthritis [50]. Many of these conditions co-exist. For instance, of the Māori renal patients in the Waikato region, 54% also have coronary artery disease, 57% have COPD and 25% have peripheral vascular disease [Unpublished]. Health care delivery focuses largely on single diseases [51] and many people with multimorbidity are managed with multiple single-disease guidelines. However, single-disease care may not be appropriate for people with multimorbidity. Rehabilitation is integral to chronic disease management, but is frequently structured in single-disease siloes, such as cardiac and pulmonary rehabilitation [52,53]. Multimorbidity is associated with poor quality of life, high health care costs and contributes to ethnic health inequity in NZ. The main barriers to effective care for patients with multimorbidity have been identified as availability and affordability of primary and secondary health care. These findings support the value of patient-centred care to address access and care coordination [54]. In a cross-sectional survey study, 70% of workers who live with multimorbidity reported reduced workplace productivity, and 20% found it difficult to meet the costs of health needs and[55].

These findings suggest a need for holistic care and that issues, such as income, employment and other social determinants, be tackled.

We can see that while the Waikato DHB provides individual specialist services, there is evidence common themes exist that can cause inequity or Māori. These include systemic factors, financial barriers, and cultural barriers, all of which must be addressed if we are to be able to eliminate inequity. While we do not have a systematic way of identifying the factors that are contributing to inequity, the Harti Hauora Tamariki programme has provided a pathway to researching these health care needs. This and other research suggest it is important that health care professionals ask questions and exchange information about stress and lifestyle with a patient, if the quality of care is to be improved [56].

## Research impact

The likelihood for findings from this proposed research to be translated into Māori health gains is high with impact at many levels including Waikato DHB management, staff, community agencies and for patients, whānau, hapū and iwi. Through the HRC funded Harti project, we have shown that we can change hospital systems and improve experiences for patients and whānau. There is a growing sense of urgency within Waikato DHB on the need to dramatically increase efforts to achieve equity for the 85,000 Māori living within the region. We believe this research will provide immediate benefit for Māori in the Waikato as well as providing a powerful framework for the Ministry of Health, and other DHBs and agencies in addressing health equity. It will also provide a platform for future research to measure the impact of our approach on maternal, and ante and postnatal care.

# Aims

The aim is to explore the wellbeing needs of pregnant Māori women and adults with chronic disease through the co-design and testing of a hauora assessment tool and solutions [57] to improve wellbeing.

## Research question

This project addresses one primary research question.

Does a co-designed hauora assessment tool identify wellbeing needs of pregnant Māori women and adults with chronic disease and what solutions could be developed to improve wellbeing?

# Methods

As stated earlier the study will be informed by a Kaupapa Māori co-design process, following the HPW framework [13]. It will draw on the Harti Hauora Tamariki programme structure which has three parts.

1. A safe, racism free, culturally aligned space
2. Comprehensive wellbeing screening and support using a screening tool with protocols for each question
3. Community engagement and systems level solutions.

We plan to partner with a range of stakeholders (as shown in the Figure below) to develop a hauora (wellbeing) assessment tool to assess and meet needs for wāhine hapū, and Māori adults with chronic disease. We will assess the prevalence and significance of unmet need for patients and their whānau in a sample of patients from these two priority groups, and pilot our hauora assessment tool. This will inform the refinement of the hauora assessment tool to support individuals and whānau which will then be implemented by Waikato DHB. Further methods for measuring impact of implementation will be co-designed. The proposed project is outlined below:

 **Study 1** **Study 2**



## Study 1: Improving wellbeing for pregnant Māori Women

1. **Key objectives**
2. **Co-design a hauora assessment tool with wāhine Māori who are pregnant** (or have new pēpi) **and their whānau**  which includes:
3. A culturally safe, mana enhancing approach;
4. A screening tool that health services staff can use to identify wellbeing and clinical services that wāhine and their whānau may benefit from and safe and effective follow-up protocols to address those needs either on the spot, or by referral;
5. A systems level approach to ensure all aspects of the hauora programme assessment tool are high quality, clinically safe, continuously improved and to advocate for change at multiple levels when required.
6. **Trial the newly developed hauora assessment tool with wāhine Māori and their whānau**;
	1. Identify the needs of pregnant Māori women and their whānau regarding wellbeing needs;
	2. Determine the effectiveness and usability of the hauora assessment tool; and
	3. Determine the required infrastructure to enable the hauora assessment tool to address unmet need.
7. **Use integrated knowledge translation methods to enhance the hauora** assessment tool **for implementation.**

Guided by the He Pikinga Waiora framework, we will engage with a wide range of influencers and potential users to develop:

1. An implementation toolkit in consultation with potential users;
2. A local proposal for implementation.
3. **Population**

Waikato DHB hospitals have around 3500 babies born each year, of whom 1400 are to Māori mothers. We aim to develop a tool that will help assess wellbeing needs early in a pregnancy and facilitate access to appropriate health care and interventions. We will involve Māori women and their whānau who have recently experienced maternity services with aims to have a diverse cohort of women in age, parity, employment, financial deprivation, locale, and other points of difference.

1. **Steps**
2. **Establishment**
3. Establish the **co-design group**. We will establish a co-design group that includes consumer, whānau, provider, and research team membership. At least 50% of the co-design group will be consumers or whānau. The research team will partner with the co-design group to lead all phases of the research project.
4. **Stocktake**. We will look at what knowledge is already available around unmet need for pregnant Māori women and their whānau. Our original proposal suggested that we would start with a blank slate and ask whānau and communities what their unmet needs are and what services would meet those needs. However, upon reflection, we realise that recently this information has been collected from whānau and providers in the Waikato and nationally. As a team we have agreed that it is unethical to keep asking and not deliver, and that it is time for action. Hence, we will conduct a stocktake of information from the last five years both locally and nationally to inform the development of the hauora assessment tool. We will sense check the stocktake findings with our co-design group.
5. **Co-development and iterative testing of a draft hauora assessment tool for wāhine Māori who are pregnant and their whānau**
6. We will weave the stocktake findings, through the lens of the co-design group, into the development of a draft hauora assessment tool. To do this, we will work with our co-design group and also a wider group of consumers and whānau.
7. This early draft will be tested with 10 women and their whānau and the feedback and results used to feed into quality improvement for the next iteration.
8. We will engage with stakeholders in the community involved in the provision of services for wāhine hapū and run at least four focus groups to understand issues around meeting wellbeing needs for Māori mothers and their whānau.
9. We will then take a draft hauora assessment tool into wider testing and consultation to further refine the hauora assessment tool for different scenarios and settings. This will include consulting with subject matter experts and providing the hauora assessment tool to another 10 wāhine and their whānau.

Feedback will be sought on:

1. how to measure and improve the experience of the hauora assessment tool for wāhine and their whānau;
2. how best to deliver the tool in different scenarios, locales and settings, including;
	1. consulting on iterations of the tool and approach for the different stages of pregnancy and for women and whānau with different requirements. For example, we would need to develop a tailored approach for women with diabetes in pregnancy and for women in gangs;
3. how best to deliver the programme within existing services and planned new services; and
4. identifying needed services that are not currently available and adequately address ongoing systems issues.
5. **Large scale trial of the hauora assessment tool with 400 wāhine hapū and their whānau**
	1. We will recruit wāhine hapū from across the Waikato who present to their local hospital for any reason including birthing, antenatal programmes, or by referral. Up to 400 wāhine and their whānau will be offered an assessment and be taken through the hauora assessment tool. The tool will identify the needs of these women and their whānau regarding wellbeing needs, including health, access to health services, appropriateness of those services, and access to the socioeconomic determinants of health.
	2. Two analyses will be undertaken to determine the effectiveness and usability of the hauora assessment tool. First, findings from the tool will be analysed to compare the difference across first-time mothers and multiparous mothers, younger and older mothers, urban and rural mothers, as well as other birth data. As with the Harti Hauora Tamariki programme, we will analyse documentation of issues, provision and referral to wellbeing services included in the tool (e.g. enrolment with primary care, immunisation, housing and income support, community agencies etc.). Unpublished results from the Harti study show poor documentation of most issues of need before use of the hauora assessment tool.
	3. determine the required infrastructure to enable the hauora assessment tool to be developed into a programme to address unmet need, including service, leadership, clinical safety and service integration structures.
6. **Use integrated knowledge translation methods to enhance the hauora assessment tool for implementation.**

Using guidance from the He Pikinga Waiora framework, we will engage with a wide range of influencers and potential users to develop**;**

1. An implementation toolkit in consultation with potential users including Midwives, Whānau Ora providers, the Ministry of Health, District Health Boards and other primary, secondary and tertiary care providers.
2. A Waikato DHB proposal for implementation in consultation with Waikato DHB potential users, funders and related services.

## Study 2: Improving wellbeing for Māori adults with chronic diseases

1. **Key objectives**

There are four key objectives

* Identify the key concerns of Māori patients with CVD, diabetes, COPD, and renal disease.
* Develop a screening tool for health services staff to identify Māori patients with chronic disease who may benefit from both a health and/or social service intervention, and mechanisms for identified needs to be met.
* Trial the newly developed supportive care needs tools on Māori patients presenting with chronic disease (CVD, diabetes, renal, COPD) and determine the frequency of relevant health needs.
* Develop strategies and interventions for the key health needs of these patients with chronic disease.

While most patients with chronic diseases are managed in primary care, those with the most complex and/or acute cases are managed through Waikato Hospital services. Thus, patients who have a myocardial infarction or receive a stent for acute coronary syndrome will be admitted to hospital, and following treatment they will be offered cardiac rehabilitation. Currently, Waikato Hospital sees over 1100 patients per year following a myocardial infarction, of whom 11% are Māori. The Waikato Regional Diabetes Service has a current retinal screening register of over 20,000 patients, but the specialist service only manages 2,000 of these patients per year – predominantly those with type 1 diabetes, and those who have severe T2D or complications. Māori are over-represented in the patients being seen by the Regional Diabetes Service. The respiratory department also provides rehabilitation services to patients who attend with COPD and this group of patients will include 20% Māori. The renal service provides care to 140 new end stage patients with kidney disease and 57% of these patients are Māori. The service provides ongoing care to over 1,000 Waikato patients with end stage kidney disease. The common thread for all of these patients is that they have a chronic condition which requires constant monitoring, reduced life expectancy and, as shown above, are predominantly Māori .

**Recruitment for the second part of the study is thus in two parts:**

1. Community consultation.

As described above, this study will adopt a kaupapa Māori approach, undertaken by Māori researchers with Māori providers and community groups and Māori patients. Using the principles of a kaupapa Māori co-design process, we will work with a group of Māori providers and community groups to try and focus on the health needs of Māori with chronic disease. We have established links with key Māori community and primary care groups, such as Te Kōhao Health, Raukura Health Services, Raukawa Health Services, Maniapoto Health Trust and Rauawaawa Kaumātua Trust. All of these groups have been engaged in health delivery and research activity with the project investigators and the Waikato DHB. They all have a keen interest and understanding of the needs of their communities and the impact of chronic diseases. They are equally aware of the barriers and facilitators which help and hinder improved outcomes for their patients. Thus, a consultation process with these groups will provide important insights into the needs of the patient groups currently accessing Waikato DHB hospitals.

1. Focus groups with patients.

Having identified the needs of patients from consulting community providers, we will then test these findings through a consultation process with groups of patients with the four key conditions: cardiovascular disease, diabetes, COPD, and renal disease. Four focus groups will be undertaken with patients, one for each of four aforementioned chronic conditions. Focus groups with patients will cover four main themes.

The first theme will draw on the Te Whare Tapa Whā model of care, to explore five aspects of wellbeing; taha tinana (physical wellbeing), taha hinengaro (mental wellbeing), taha wairua (spiritual wellbeing), taha whānau (family wellbeing) and whenua (connection to ancestral roots and land) [58].

The second theme will explore the broader social determinants of health which are external to but influence the experience of the health system but, include housing, income, employment and other aspects of everyday life.

The third theme will examine the issues relating to health care delivery. This will look at past experiences, attitudes and expectations, access issues, and programme experiences. Further it will explore treatment and the wider effects of these, such as weight, substance use, income, employment, health literacy support, family support, mental health housing other effects.

The hauora assessment tool will explore issues as to the management of comorbidities and how each service addresses the needs of patients who have more than one condition. It is important that we also ask what health services are also contributing to the management of their condition and how these work for patients, such as general practice, pharmacists and other health practitioners, and identify what other services patients are accessing.

1. Feedback to focus groups.

Once the findings from the four focus groups are collated and analysed, they will be shared with the Māori community groups and the patients to validate those findings. The findings will be shared anonymously between the groups so that similarities and differences can be explored and discussed. Following these meetings, we will have a list of prioritised health related issues to incorporate into the hauora assessment tool which embodies the principles of inclusion and holistic, supportive care.

1. Pilot hauora assessment tool.

Based on previous experience developing screening tools, the hauora assessment tool will list the holistic health related issues and concerns as identified in the focus groups.

Like the screening tool used in Harti Hauora Tamariki, the hauora assessment tool will comprise a set of questions about a patient’s medical (enrolment with primary care, immunisation etc) and non-medical needs (housing, income etc.), as identified in the focus groups.

Both barriers and service satisfaction will be identified for each health issue/level. The hauora assessment tool is intended to be used by a Māori health navigator. Having identified the gaps, then used to provide information and facilitate access to a wide range of service to meet their needs. We intend to determine through the focus groups, when and how often the assessment tool should be applied.

Once the assessment tool has been developed, it will be trialled with Māori patients in CVD rehabilitation, diabetes care, COPD rehabilitation, and renal services at Waikato DHB hospitals. The hauora assessment tool will also ask about comorbidities. Patients will be recruited by our Māori researchers in a safe environment. It is expected that at least 200 patients with chronic disease will be piloted with the hauora assessment tool. Once the hauora assessment tool has been completed, then as with the Hapū Māmā project, we will go back to key stakeholder groups for input as to the development of a study intervention.

1. Co-design intervention.

This will comprise three parts:

* Consultation with the community providers and stakeholders as to what interventions are needed;
* Consultation with patient groups to identify what needs they would like the DHB to address;
* Consultation with DHB key staff.

These consultations will cover what interventions are already in place to address the identified needs, which of these need to be improved and what new initiatives may be needed to meet the health-related concerns that have been identified. We expect that while some services may already be in place, there will be demand for more services, available through general and Māori providers. We also expect demand for more cross-sectoral initiatives. However, after these two main studies have been completed, the Waikato DHB should have the evidence necessary to begin to explore the appropriate funding and propose interventions which are aimed at reducing disparities for Māori mothers and Māori with chronic diseases.

## Patient Information and Informed Consent

For both arms of the study, participants will be approached and explained the study. The patient will be told what the study involves for participants (including matching NHI number against other databases and access/use of other health services), and ask for consent. The patient will be provided with a copy of the Patient Information Sheet ([Appendix 2](#_Appendix_2)) and offered ample time to ask questions and discuss participation with their whānau. For those agreeing to take part, the patient consent form ([Appendix 2](#_Appendix_2)) will be signed by the patient. Patients will have the opportunity to withdraw from the study at any time. If they agree, information collected up until withdrawal from the study will continue to be used and included in the study. Participants may ask for it to be deleted when they withdraw, unless analyses have been undertaken. Those patients who develop a medical condition during their involvement in our study will be referred to the relevant provider to ensure that this is appropriately addressed.

Participants in the Hapū māmā arm of the study, will be recontacted after the birth of their pēpi/baby to gain consent to collect data on their baby’s, birth weight, immunisation and health checks.

## Subject Selection

### Hapū Māmā

Inclusion Criteria

* Waikato DHB residents
* Adults aged 16 years of age and above
* Māori wāhine hapū attending antenatal clinics in the Waikato (Hapū Wānanga and Plunket WHIRIHIA) AND/OR those presenting to Waikato hospital maternity services, or in the community (e.g. self referrals)

Exclusion Criteria

* Patients who are not a current resident in Waikato DHB at the time of recruitment
* Patient aged under 16 years
* Patients who have already entered the study
* Patients who are not eligible for publicly funded health care in New Zealand

### Māori with chronic conditions

Inclusion Criteria

* Waikato DHB residents
* Adults aged 16 years of age and above
* Māori attending CVD rehabilitation, diabetes care, COPD rehabilitation, and renal services at Waikato DHB hospitals

Exclusion Criteria

* Patients who are not a current resident in Waikato DHB at the time of recruitment
* Patient aged under 16 years
* Patients who have already entered the study
* Patients who are not eligible for publicly funded health care in New Zealand
* Patients with severe illness deemed by their medical team likely to die within six months.

## Recruitment Procedure

For those who agree, they will be referred to the research officer to make contact, by either coming to the clinic or over the phone. A free, prior, informed consent process will be followed in accordance with Kaupapa Māori principles and practices of whakawhanaungatanga, tino rangatiratanga, koha, manaakitanga, and kanohi ki te kanohi. Key to this is treating all participants with dignity and respect.

**Hapū Māmā**

Research staff will work with antenatal clinics in the Waikato (e.g. Hapū Wānanga and Plunket WHIRIHIA) and Waikato hospital maternity services to recruit participants. Research staff will outline to those attending antenatal classes, or those identified through the hospital system (e.g. on the antenatal wards), the aims of the project and ask if anyone would be interested in receiving more information. Those interested will be given the study PISCF with time to read, review and ask questions. Informed consent processes will be followed at this point with participants free to choose to sign consent and conduct the hauora assessment tool (if somewhere suitable is available). An alternative time and place can also be negotiated.

We will work with our colleagues in the outpatient clinics to identify eligible participants to have their information passed on to the researchers. A researcher will then contact eligible participants for recruitment, and following a free, prior, informed consent process.

We will also recruit via local LMCs and self-referrals. Posters advertising the study will be co-designed and placed in appropriate locations throughout the Waikato region (e.g. at Māori Health providers). The poster will give an overview of the study, what’s involved and how to contact the research team if anyone is interested in participating.

**Māori with chronic conditions**

Case finding will be conducted by outpatient clinic staff who know the patient and their health status and circumstances. Thus, they are best placed to advise the researcher on those who are able to participate in the research safely and without undue stress. We will not approach or involve people whose health issues are acute. Participation will not be sought if participants are so ill that they are deemed (by their medical team) likely to die within 6 months.

Outpatient clinic staff will identify eligible participants and make contact over the phone, in person on the ward or clinic apt. Māori attending CVD rehabilitation, diabetes care, COPD rehabilitation, and renal services at Waikato DHB hospitals, relevant clinics or inpatient services are potential participants. Outpatient clinic staff will ask prospective participants if they are happy to have their information passed to the research team.

**Focus groups**

For chronic conditions, recruitment will be carried out within the relevant in-patient clinics by either the research fellow or the clinical nurse specialists within these areas. In each area we will focus on the key health needs of these patients.

For Hapū Mama, we will engage with stakeholders in the community involved in the provision of services for wāhine hapū and run at least four focus groups/hui to understand issues around meeting wellbeing needs for Māori mothers and their whānau. Three of these will be conducted in rural locations in the Waikato region and one urban hui (Hamilton). We will also invite wāhine hapū who have been through the testing of the tool if they would like to join the focus groups.

Invited focus group participants (that are not part of the research team) will be asked to sign a consent form ([Appendix 3](#_Appendix_3)) before any research activities commence. For all focus groups the appropriate tikanga will be observed guided by our kaumātua, beginning with karakia and whakawhanaungatanga. Kai and koha ($100 supermarket voucher) will be provided to participants. They will be held at an appropriate location for a group setting at a time and location that suits the invited members and they will be audio recorded and transcribed afterwards. It is expected the focus groups will take up to two hours to complete. We understand that sometimes talking about health conditions can have an emotional impact. So if any participants feel upset or distressed at any point during the focus group they can leave the group. We will also ask them if they require support and if they agree we would refer them to appropriate support services.

## Data and follow-up

Demographic and any/all participant data will be collected at the point of consent, including self-identified ethnicity using the Census NZ question, iwi, and NZiDep.

For Hapū Māmā, we will collect information from participants, hospital data, midwives (LMC), birth centres and other relevant health databases (e.g. Pathlab). This includes:

* gestational age at time of recruitment
* name of relevant care providers such as the GP and midwife
* pēpi health (birth weight, location, immunisation and health checks)
* relevant antenatal health information (e.g. HBa1C scores)

This is so that we can look at the characteristics of the sample group of 400 to compare to regional population datasets available through Waikato DHB.

For those with chronic conditions, we will categorise them into one of the four condition groups (cardiovascular disease, diabetes, COPD, and renal disease). Other data collected includes:

* date of diagnosis
* time since diagnosis
* number of previous inpatient stays and outpatient visits (in the past year)
* number of previous outpatient visits (in the past year)

We will collect all responses to the hauora assessment tool questions for both arms of the study, yet to be determined. We will also collect follow-up data from external resources to compare to National datasets. The information will be collected from the time period from consent up to 6 months after consent and sources include:

* GP enrolment from Primary Health Networks (PHO)
* Smoking cessation enrolment and quit attempts with the local provider ‘Once and for all’ (Midlands Health Network)
* immunisation status from the National Immunisation Register (NIR)

# Ethics and Safety

## Ethics application

A full application to the Health and Disability Ethics Committee (HDEC) has been made. No patient will be recruited to the study until HDEC approval is received.

**Ethics committee reference number: 21/CEN/148**

We have also obtained approval from the Māori Research Review Committee at Waikato DHB.

## Data Management

The information collected will be treated with respect, privacy, protection and care. It will be only available to members of the research team. The study files and all other information that provided will remain strictly confidential, unless there is an immediate risk of serious harm to someone. When the study ends, records will be securely stored for at least 10 years at Waikato DHB. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

The information provided will help us to produce a report and an assessment tool. The study findings will be published, but there will be no identifying information included, so there is no way that anybody could identify participants from what is reported.

A data management plan (using HRC template) has been completed and the PI, Ross Lawrenson, and the project manager will be responsible for ensuring the policies and ethical standards are met and adhered to.

## Consultation with Māori/Māori health advancement

The main goal of the study is to improve health care delivery and outcomes for two groups of Māori patients. Through the kaupapa Māori co-design process detailed above, two tailored health screening tools will be developed which can be delivered within an established hospital system. This tool represents a different/Māori focussed approach/solution, one which effects change at the system and health care provider level rather than the patient level. Other learnings about how health services can engage better with their Māori patients in a culturally responsive approach will be shared with relevant personnel and parts of the health system. In these ways, we hope health equity for Māori will be improved.

The research team has an established track record in building and delivering on relationships with Māori communities and community providers. Development of a strong relationship between Māori communities and the Waikato DHB will have an equally transformative role. This project builds and develops Māori health researcher development at many levels. Dr Nina Scott has a track record of DHB-led research working within the Te Puna Oranga (Māori Health Service) and will co-lead the project. She is the principal investigator for the Harti Hauora Tamariki project and will advise on the structure of the development of the Harti tool. Dr Jade Tamatea is an emerging Māori health researcher. She is a practicing endocrinologist who has researched the health inequity for Māori with diabetes and thyroid disease. Mr Hemi Curtis will support the project as our kaumātua and he will ensure our adherence to culturally appropriate research practices, as has been done with our other research projects. These expert leaders will ensure our research centres on Māori health needs.

Our group is committed to the development of our current and future workforce. Our Māori researchers within the team and our kaumātua will continue to upskill all of our research team in tikanga and in our engagement with Māori. Our group is always looking at opportunities to support and develop Māori researchers and are pleased to be involving Nikki Barrett who is an emerging researcher undertaking her PhD. We will endeavour to recruit prospective students or junior Māori researchers to work with our team as the opportunity arises. This proposal has a strong emphasis on developing Māori led research. The DHB has an increasing number of Māori staff with research training and thus this project will utilise their research skills while at the same time provide excellent opportunities for research leadership.

# Translation of Research into Health Delivery

Our HPW framework helps progress translation and implementation of initiatives that could, or have proven to be effective for Māori. This proposed research offers the team an opportunity to continue to sharpen our translation and implementation skills. Two principal investigators are embedded within the Waikato DHB Strategy and Funding Division. They are well placed to ensure that the translation of these findings into the equity strategy for the Board and to ensure that the study findings are enacted in our highest priority localities. This year the Harti Hauora Tamariki programme was implemented into business as usual with the Waikato DHB contracting two Harti navigators (our research assistants), to work in paediatrics. The Waikato DHB’s Harti based COVID response with Māori providers has also had a business case accepted for implementation. The team are confident that our results will be translated at the Waikato DHB level and will work with our national networks to translate at the national level. For example, the chronic disease hauora assessment tool has potential to be added to the cancer screening pathway. Discussion on the need for such an approach has been ongoing for some years – especially for bowel screening. Further, Nina Scott will link the Hapū Māmā hauora assessment tool into the National Well Child Tamariki Ora Review discussions.

# Advisory groups

The following people will act as clinical advisors for this project:

* Veronique Gibbons – Waikato DHB research manager / patient quality and safety

***Hapū Māmā project***

* Dr Narena Dudley –Clinical Unit Leader for Women’s Health
* Dr Isabel Camano – Clinical Director Obstetrics
* Sarah Power - Associate Clinical Midwife Director
* April Irwin - Associate Charge Midwife Manager Maternity Wards
* Ruth Galvin – Maternity Quality Improvement Co-ordinator

***Chronic Disease Project***

* Dr Andrew Henderson – FRACP, Clinical Director Renal Services
* Dr TV Liew – FRACP Specialist Cardiologist
* Tracy Butler-Holdaway - Clinical Nurse Manager for Community Cardiology
* Dr Cat Chang – MD, FRACP. Specialist Respiratory Physician, Senior Lecturer, University of Auckland
* To be named – Clinical Nurse Specialist, Respiratory Care
* Justina Wu – PhD, MD, FRACP, AFRACMA. Clinical Director, Diabetes Service

# Funding

The study is principally funded by the Health Research Council of New Zealand under Contract number: 20/1178

# Reporting and Dissemination

The likelihood for findings from this proposed research to be translated into Māori health gains is high. We believe the findings from the study will impact at many levels including Waikato DHB management, clinical staff, community agencies as well as for patients and their whānau. We engage with a wide range of stakeholders through our work and there is a growing sense of urgency within the Waikato DHB to dramatically increase efforts to achieve equity for the 85,000 Māori living within the region. We have shown with the HRC Harti project that we can substantially change the system and make the hospital experience much better for patients and whānau. In the Harti trial whānau reported that they felt treated with value, dignity and respect and had a renewed sense of confidence for navigating additional services. The provision of comprehensive wellbeing screening identifies health related issues that are important to Māori and currently may not be addressed. The study will allow the Waikato DHB to provide targeted support to where it is most needed. We also believe that due to our community engagement we will be able to influence activity across the whole system. We will focus on service integration and filling gaps (not replication), community engagement, sharing of resources and the provision of outreach and/or opportunistic care. We believe this proposed research will provide immediate benefit at Waikato DHB and also provide a powerful framework for the Ministry of Health, other DHBs and other agencies in addressing health equity.

# Study acknowledgement

By signing below, I confirm that I have received, read andunderstood the protocol, dated 27-Aug-21, for the Determinants of Health for Māori Mothers and Adults with Chronic Diseases study.

I agree to follow the protocol and attachments and provide the necessary assurance that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality and according to local legal and regulatory requirements and to the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice.

If other personnel at my practice are involved in the study I will provide and discuss the protocol with them to ensure that they are fully informed about the treatment and the study.

I understand that the protocol may be revised at any time and I undertake to ensure the most current version is adhered to at all times.

I understand that the study may be terminated or enrolment suspended at any time if it becomes necessary to protect the best interests of the study participants.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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# Appendix 1

## Projected Time-Line

This study‘s duration will take 36 months to complete.

###### Year 1

* Recruit Māori research fellows and arrange academic and clinical advisory board meetings
* Presentation of foundation work to Iwi Māori Council
* Co-design meetings with community stakeholders for health of Māori mothers (study 1) and Māori with Chronic disease (Study 2)
* Co-design hui / focus groups with Māori mothers (study 1) X4 communities and Māori with chronic disease (Study 2) in 4 groups of patients
* Develop supportive care needs tools for both Māori mothers
* Develop supportive care needs tool for Māori with chronic disease

###### Year 2

* Screen 400 Māori mothers with the supportive care needs tool
* Screen 200 Māori patients with chronic disease using the supportive care needs tool
* Identify the frequency of co-morbidities/multi-morbidity in patients with chronic disease
* Report back to key stakeholders, academic and clinical advisors

###### Year 3

* Evaluate data from the supportive care needs tool for use in intervention development
* Co-design interventions / strategies to improve health outcomes and reduce equity for Māori
* Report back to key stakeholder, academic and clinical advisors
* Dissemination of research findings

#

# Appendix 2

## Patient information sheet and consent form (pilot) – Version 2 (30/7/21)

|  |  |
| --- | --- |
| **Participant Information Sheet** |  |
| Study title: | **The determinants of health for Māori mothers and adults with chronic diseases** |
| Locality: | **Waikato District Health Board** | Ethics committee ref.: | **21/CEN/148**  |
| Lead investigator: | **Prof Ross Lawrenson** | Contact phone number: | **+64 7 8379484** |

An invitation

[Summary of study in Te Reo Māori to be inserted]

We are inviting you to be part of our study. You are invited to take part because you are either pregnant, or you have a chronic (long-term) health condition (e.g. diabetes, kidney, heart or lung disease).

The purpose of this study is to improve access to holistic health and social services for hapū māmā (pregnant women) and those with long-term conditions. We plan to design an assessment tool that could be used to improve outcomes for these groups. We are interested in services and care provided on top of the care you are already receiving. This could include welfare support, or support for healthy homes or smoking cessation. This study will help us look at the best ways to keep whānau well and healthy.

It is your choice to take part or not. If you don’t want to take part you don’t have to give a reason. You will still receive the same care from the hospital, your doctor and other health services. If you do want to take part you can pull out of this study at any time. If you do take part, you can change your mind at any time. If you choose to withdraw from the study, we will use the information that has already been collected but we will not collect any more from you or your whānau. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

If you would like, we can arrange to have someone else explain the study to you in Te Reo Māori. They can go over this consent form and explain what is involved in taking part. Please let us know if you would like this.

You can also answer the hauora assessment questions in English or Te Reo Māori. Please tell us if you would like to request this.

This Information Sheet will help you decide if you would like to take part.

It tells you:

* who can take part
* what taking part would involve
* the benefits and risks to taking part in the study
* who to contact for more information

You do not have to decide today whether you want to take part or not. Before you decide, you may want to talk about the study with other people, such as whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of this Information Sheet and Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages. We can answer any questions you may have.

WHO CAN TAKE PART IN THE STUDY?

We aim to include 400 Māori women who are pregnant and 200 Māori with long-term conditions. Those patients must live in the Waikato DHB area with access to publicly funded health care in Aotearoa NZ.

What will my participation in the study involve?

A researcher will explain the study to you and ask for your consent to take part.

**Hauora assessment**

The researcher will take you through a hauora assessment which includes questions about wellbeing. You will be asked about your access to and use of a range of health and wellbeing services.

The hauora assessment should take 20-40 minutes, but it could take longer. An iPad will be used to collect your answers. Where possible, these questions will be asked somewhere private or virtually using a computer or phone. We will try to make sure that the questions are asked at a time, and in a place, that works for you. You can stop at any time. You do not have to answer any questions that you do not want to.

If any needs are identified during the hauora assessment, we have pathways in place to support your needs. This could include providing you with information, resources (e.g. pamphlets) or a referral to relevant services.

**Information from records**

With your consent, information will be collected from your hospital records. This information will be from your past, dating back to one year before consent. We also want to collect information from outside of your hospital records, such as from your lead maternity carer (LMC), birth centre or other health databases (e.g. Pathlab). Information that is not about this study will not be looked at.

For hapū māmā we want to collect information about:

* HbA1c (diabetes test)
* Your pēpi (birth data, immunisation and health checks) – separate consent for this data will be asked from you at a later date

For those with long-term conditions we want to collect past information about:

* Your diagnosis
* Inpatient hospital stays
* Outpatient visits

For everyone, we want to collect current and future (within the next 6 months) information about:

* GP enrolment
* Immunisation status
* Smoking cessation

What are the possible benefits and risks of this study?

Taking part in this study will take time. You may not directly benefit from the study. However, we hope that this study will help the people who fund, provide and deliver health services improve support for patients and their whānau. This study may be of benefit to the larger population and perhaps the future generations to come.

The information that you share with us will be treated with respect, privacy, protection and care. It will be only available to members of the research team. The study files and all other information that you provide will remain strictly confidential, unless there is an immediate risk of serious harm to yourself or others.

When the study ends, your records will be securely stored for at least 10 years at Waikato District Health Board. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

The information you provide will help us to produce a report and an assessment tool. The tool could be used to improve outcomes for hapū māmā and those with long-term health conditions. The study findings will be published, but there will be no identifying information included, so there is no way that anybody could identify you from what is reported.

Who pays for the study?

This study is funded by a research grant provided by the Health Research Council (HRC) of New Zealand.

There should be no direct costs to you in taking part in this study.

You will receive a koha ($50 supermarket voucher) to acknowledge your contribution to this study.

Who has approved the study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee. They check that studies meet ethical standards. The Northern B Health and Disability Ethics Committee has approved this study.

What if something goes wrong?

We understand that sometimes talking about health conditions can have an emotional impact. If you ever feel upset or distressed at any point during the study you can stop at any time. We would be happy to refer you to your GP or other relevant services for further support (e.g. social workers for renal or diabetes).

What are my rights?

You have the right to access any information about you or your whānau that is collected as part of this study. You also have the right to ask that any information you disagree with is corrected. If you have any questions about the collection and use of information about you, you should ask the researcher, Lead Investigator or Project Manager.

Who do I contact for more information or if I have concerns?

If you take part in this study, you can choose not to answer any of the questions. You can also change your mind and stop at any time. If you want to completely pull out of the study, you can do so at any time by contacting us.

If you have any questions or concerns about your rights as a participant in this study, you may wish to contact an independent **Health and Disability Advocate**. This is a free service provided under the Health and Disability Commissioner Act:

Free phone: 0800 555 050

Free fax: 0800 2787 7678 (0800 2 SUPPORT)

Email: advocacy@hdc.org.nz

Website: <https://www.advocacy.org.nz/>

For Māori health support, please contact:

**Te Puna Oranga** (Waikato DHB Māori Health Unit), Hockin Building, Level 1, Pembroke St, P.O. Box 934, Hamilton. Ph: (07) 834 3628 Fax: (07) 834 3619.

You can also contact the **Health and Disability Ethics Committee** (HDEC) that approved this study:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

If you have any questions, concerns or complaints about the study at any stage, you can contact the **Lead Investigator** or Project Manager for this study:

*Prof Ross Lawrenson, Lead Investigator*

*Pembroke Street*

*Waikato District Health Board*

*Hamilton, 3204*

*Email: ross.lawrenson@waikatodhb.health.nz*

*Phone: 07 8379484*

*Dr Amy Jones, Project Manager*

*Te Puna Oranga, Hockin L1*

*Pembroke Street*

*Waikato District Health Board*

*Hamilton, 3204*

*Email: amy.jones2@waikatodhb.health.nz*

*Phone: 839 8899 ext. 975*

***Please keep this brochure for your information.***

***Thank you for reading about this study.***

|  |  |
| --- | --- |
| **Consent Form** |  |

**Please indicate you consent to the following**

|  |
| --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  |
| I have been given enough time to consider whether or not to participate in this study. |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |
| I consent to the research staff collecting information about my health from hospital medical records from Waikato District Health Board.  |
| I consent to the research staff collecting health data about my health (GP enrolment, immunisation, smoking cessation (‘Once and for all’ – Midlands Health Network)), from my LMC, birth centre or from health databases (e.g. Pathlab). |
| I consent to research staff accessing records from my GP, LMC or other healthcare provider, including information relating to referrals and visits. |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. I know I can ask for it to be deleted when I withdraw, unless this is after the study analyses have been undertaken. |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. |
| I understand that my involvement in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |
| I know who to contact if I have any questions about the study in general. |
| I understand my responsibilities as a study participant. |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher name: |
| Signature: | Date: |

**Additional consent to collect my pēpi / baby’s data –** *this will be gained at a later date after the birth of your pēpi.*

**Please indicate you consent to the following for your pēpi / baby**

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| --- |
| I consent to the research staff collecting health data about my pēpi / baby’s health (GP enrolment, immunisation or health checks), from my GP, LMC, birth centre or from health databases. |

**Declaration by participant:**

I hereby consent to take part in this study on behalf of my pēpi / baby.

|  |
| --- |
| Participant’s / parent’s name:Baby / pēpi name:Baby / pēpi date of birth:Baby / pēpi NHI number (if known): |
| Signature: | Date: |

#

# Appendix 3

## Participant information sheet and consent form for focus groups Version 2 (30/7/21)

|  |
| --- |
| **Participant Information Sheet – Focus Groups** |
| Study title: | **The determinants of health for Māori mothers and adults with chronic diseases** |
| Locality: | **Waikato District Health Board** | Ethics committee ref.: | **21/CEN/148**  |
| Lead investigator: | **Dr Ross Lawrenson** | Contact phone number: | **+64 7 8379484** |

An invitation

[Summary of study in Te Reo Māori to be inserted]

We are inviting you to be part of our study. If you agree to take part you will be part of a focus group hui. You are invited to share your knowledge of or experience with being hapū or having a long-term condition (e.g. diabetes, kidney, heart or lung disease). The aim of our study is to improve outcomes for hapū Māmā (pregnant women) and those with long-term conditions.

It is your choice to take part or not. If you don’t want to take part you don’t have to give a reason. You will still get the same care. If you do want to take part you can pull out of this study at any time. You can fully withdraw from the focus group at any time before the focus group begins. You can also choose to leave while the focus group is in progress. However, it will not be possible to withdraw the information you have provided up to that point as it will be part of a discussion with other participants.

This Information Sheet will help you decide if you would like to take part.

It tells you:

* why we are doing the study
* what taking part would involve
* what the benefits and risks to taking part in the study might be for you
* what will happen after the study ends

You do not have to decide today whether you want to take part or not. Before you decide, you may want to talk about the study with other people, such as whānau, or friends. Feel free to do this.

If you agree to take part, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of this Information Sheet and Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages. We can answer any questions you may have.

WHO CAN TAKE PART IN THE STUDY?

We aim to include wāhine māmā (who have birthed in the Waikato region) and Māori with knowledge or experience with long-term conditions.

What is the purpose of the study?

The purpose of this study is to improve access to holistic health and social services for Māori and their whānau. We plan to design an assessment tool that could be used to improve outcomes for hapū māmā and those with long-term conditions. We are interested in your feedback and opinion on current services and care for these groups of people. This study will help us look at the best ways to keep whānau well and healthy.

For both groups we want to understand:

* issues in meeting their wellbeing needs
* ways to improve their experiences
* how we can best deliver the tool in different settings
* what services are needed to support them

What will my participation in the study involve?

We will invite people to participate in a group hui. There will be up to 10 members invited to join the group hui. There will be a researcher present who will facilitate the group discussions. The researcher will explain the study to you and ask for your consent to take part.

The hui should take 1.5-2 hours. The hui will be audio recorded with an electronic device. This is for research purposes only.

You do not have to talk about anything that you do not want to. The information shared during the focus group is confidential. You may choose to be identified in the research findings. Otherwise, your identity will not be shared with anyone other than the research team. If you choose to remain anonymous however, we are unable to guarantee complete confidentiality within the hui due to the number of people involved. We ask you to keep the content of the hui confidential.

What are the possible benefits and risks of this study?

You may not directly benefit from the study. However, we hope that this study will help the people who fund, provide and deliver health services improve support for patients and their whānau. This study may be of benefit to the greater population, and perhaps the future generations to come.

The information that you share with us will be treated with respect, privacy, protection and care.

Who pays for the study?

This study is funded by a research grant provided by the Health Research Council (HRC) of New Zealand. There should be no direct costs to you in taking part in this study.

You will receive a koha ($100 supermarket voucher) to acknowledge your contribution to this study.

Who has approved the study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee. They check that studies meet ethical standards. The Northern B Health and Disability Ethics Committee has approved this study.

What if something goes wrong?

We understand that sometimes talking about health conditions can have an emotional impact. If you ever feel upset or distressed at any point during the focus group feel free to leave. If this happens, we would be happy to refer you to appropriate support services to help.

Confidentiality

The information you provide will be only available to members of the research team. The recording, hui notes and any other information that you provide will remain strictly confidential, unless there is an immediate risk of serious harm to yourself or others. All computer records will be password protected. All use of the information collected will be strictly controlled in accordance with the Privacy Act.

The study findings will be published, but there will be no identifying information included. However, we are unable to guarantee complete confidentiality, due to people being involved in the hui, but we will try our best to do so. The audio recording will be transcribed. However, we will delete any details in the transcription that might potentially identify any participants, e.g. names of patients or clinicians.

What are my rights?

If you have any questions or concerns about your rights as a participant in this study, you may wish to contact an **independent Health and Disability Advocate**.

This is a free service provided under the Health and Disability Commissioner Act:

Free phone: 0800 555 050

Free fax: 0800 2787 7678 (0800 2 SUPPORT)

Email: advocacy@hdc.org.nz

Website: <https://www.advocacy.org.nz/>

For Māori health support, please contact:

**Te Puna Oranga** (Waikato DHB Māori Health Unit), Hockin Building, Level 1, Pembroke St, P.O. Box 934, Hamilton. Ph: (07) 834 3628 Fax: (07) 834 3619.

You can also contact the **Health and Disability Ethics Committee** (HDEC) that approved this study:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

What happens after the study or if I change my mind?

If you take part in this study, you can choose not to answer any of the questions, and you can also change your mind and stop at any time. If you want to pull out of the study, you can do so at any time by contacting us. However, it will not be possible to withdraw the information you have provided in the hui as it will be part of a discussion with other participants.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact the **Lead Investigator** or Project Manager for this study:

*Prof Ross Lawrenson, Lead Investigator*

*Pembroke Street*

*Waikato District Health Board*

*Hamilton, 3204*

*Email: ross.lawrenson@waikatodhb.health.nz*

*Phone: 07 8379484*

*Dr Amy Jones, Project Manager*

*Te Puna Oranga, Hockin L1*

*Pembroke Street*

*Waikato District Health Board*

*Hamilton, 3204*

*Email: amy.jones2@waikatodhb.health.nz*

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***Thank you for reading about this study.***

|  |  |
| --- | --- |
| **Consent Form** |  |

**Please indicate you consent to the following**

|  |
| --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  |
| I have been given enough time to consider whether or not to participate in this study. |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |
| I understand that taking part in this study is voluntary (my choice) and I can withdraw from the focus group while it is in progress. However, it will not be possible to withdraw the information I have provided up to that point as it will be part of a discussion with other participants. |
| I acknowledge that I am agreeing to keep the information shared during the focus group confidential.  |
| I understand that my involvement in this study is confidential if I so choose, however, we are unable to guarantee complete confidentiality within the hui due to the number of people involved. |
| I know who to contact if I have any questions about the study in general. |
| I understand my responsibilities as a study participant. |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher name: |
| Signature: | Date: |