MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

[redacted]

Response to your requests for official information

I refer to your requests under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) for:

> 20 July 2019 (H201906692):
> *"The attached protocol sys, "The Health and Disability Ethics Committees (a national-level committee) waived the need for ethics approval (17 January 2017)."*
> *Can I have copies of all correspondence relating to this please? This should include any proposal, emails, etc."*
>
> 4 August 2019 (H201907079)
> *"Are you able to provide me with a list of applications for research on any HPV/Gardasil/Cervarix vaccines between 2000 and 2006?*
>
> *At this stage I don't need the entire applications, but if I could have the following information that would be most helpful.*
>
> *Name of researcher/s*
> *Institution*
> *Vaccine*
> *Purpose of study*
> *Parent study if any (eg Merck V501-012)*
> *Age of subjects*
> *Gender of Subjects*
> *Number of subjects"*

The Ministry has identified two documents in scope of your 20 July 2019 request. These are itemised in Appendix one and copies are attached. Some information has been withheld pursuant to section 9(2)(a) of the Act to protect the privacy of natural persons.

The Ministry has identified two applications for research on human papillomavirus (HPV) vaccines that are in scope of your 4 August 2019 request. The details of these applications are attached as Appendix two. Please note that there were no Gardasil or Cervarix vaccine applications for research between 2000 and 2006.

I trust that this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request.

Please note that this response, with your personal details removed, may be published on the Ministry website.

Yours sincerely

PP Keriana Brooking
Deputy Director-General
Health System Improvement and Innovation

Appendix one: List of documents for release

#	Date	Title	Decision on release
1	n/a	HDEC – Scope of Review Form	Some information has been withheld pursuant to section 9(2)(a) of the Act, to protect the privacy of natural persons
2	17 January 2017	HDEC email submission letter	Released in full

Appendix two – Applications for Research on HPV Vaccine

Reference number: CTY/02/02/004
Name of researcher/s: Dr Sue Bagshaw, Dr Helen Roberts, and Dr David Peddie
Institution: Family Planning Association, Christchurch Women's Hospital
Vaccine: Quadrivalent HPV L1 Virus-like Particle
Purpose of study: To determine whether the vaccine, which includes four sub-types of human papillomavirus, reduces the incidence of external genital warts, vulvar intraepithelial neoplasia (VIN), cervical intraepithelial neoplasia (CIN), vaginal intraepithelial neoplasia (VaIN) and cervical/vaginal cancer related to vaccine HPV types in women
Parent study: N/A
Age of subjects: 16 to 23 year old
Gender of Subjects: Female
Number of subjects: 89 in New Zealand, intended to recruit 5700 globally.

Reference number: AKX/02/00/040
Name of researcher/s: Dr Helen Roberts, Dr Ronald Jones, and Dr David Peddie
Institution: Family Planning Association, National Women's Hospital, Christchurch Women's Hospital
Vaccine: Quadrivalent HPV L1 Virus-like Particle
Purpose of study: Taken from study title (same as for CTY/02/02/004):
A study to evaluate the efficacy of Quadrivalent HPV (types 6, 11, 16 & 18) L1 virus-like particle (VLP) vaccine in reducing the incidence of HPV 6/11-, 16- & 18-related CIN and VaIN and HPV 6/11-, 16-, & 18-related external genital warts and VIN in 16- to 23- year old women - the FUTURE study. Substudy: Immunogenicity and safety of quadrivalent HPV (types, 6, 11, 16, 18) L1 virus-like particle (VLP) vaccine in consistency lots for 16- to 23- year old women with an additional immunogenicity bridge to the monovalent HPV 16 vaccine pilot manufacturing lot study - the FUTURE study
Parent study: This appear to be the same as CTY/02/02/004, but approved by a different committee for different localities
Age of subjects: 16 to 23 years old
Gender of Subjects: Female
Number of subjects: N/A.

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

HDEC – Scope of Review Form

Introduction:

This form will help determine whether HDEC review is required, and if not, will result in an 'out of scope' letter from HDEC. This letter will not include an HDEC reference number but can be used as evidence of HDEC review not being required. This form is not considered a full HDEC application and can only determine whether a potential application should be submitted to HDEC for review. Please note this application form is oriented towards observational research.

Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.

Before you begin:

What is health and disability research?

Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes. Consider whether your study is health research, or some other kind of research. Only health research is reviewed by HDECs.

For a table of features of studies and their corresponding HDEC review level, see appendix 3.

Application Form

Study Title: Predictors of breakthrough pertussis in New Zealand infants and young children

Researcher Details:

Title i.e. Mr	Dr
First Name	Anna
Last Name	Howe
Address	The University of Auckland, Private Bag 92019, Auckland 1142
Organisation	University of Auckland
Email	s 9(2)(a) [redacted]
Phone	s 9(2)(a) [redacted]

Q1 Summary of study – briefly explain your study including your participants, aims, study question(s), benefits to individuals or others and any procedures and anticipated ethical risks

This project is an observational, retrospective cohort study. This project is interested in what the risk factors are for pertussis in vaccinated New Zealand infants and young children, and as such the aim is to identify risk factors for pertussis in vaccinated infant and young children populations.

Data linkage will determine the population of infants and young children who have received on time primary immunisation (3 doses by 6 months of age, with the first dose being administered no earlier than 4 days [inclusive] before 6 weeks of age and each dose being at least 4 weeks apart) for pertussis and their mothers between 2005 and 2015

We will use anonymised data from different governmental administrative sources, namely the immunisation registry, publicly funded hospitalisations, health index data (demographic variables), and disease notification data, that have been robustly linked and encrypted (to ensure privacy). These data are routinely and previously collected, managed and held by the Ministry of Health and Institute of Environmental and Science Research (ESR). No additional data collection is required. No time is required of participants.

Potential benefits of this study could include an understanding of factors that contribute to pertussis infection despite vaccination, and thus has the potential to reduce pertussis disease incidence and therefore also reduce pertussis circulation/transmission in the New Zealand population.

There are no anticipated ethical risks associated with this project. The study is observational in nature, no individuals are identifiable from the data and the results will be presented in aggregate form.

Health information:

Is there any identifiable health information involved in your study, at any point in time? (e.g. identifiable when the information is accessed, recorded, stored). No

If **Yes**, fill out Q1 – Q3. If **No**, go to Q4

Q2 Describe how you will identify your potential participants. If you are screening health information, has this been consented to, for instance by using a registry where potential participants have consented to being approached about research projects?

Q3 Explain who ordinarily has access to identifiable health information you are accessing or having disclosed to you, and who will have access to this information during the project.

Q4 Is your study an observational study or an audit and related activity? Please review Appendix 1 of this application, select a type of study and justify your answer.

Is the use of information primary or secondary use? Please see the Health Information Privacy Code for more information. The HDEC Secretariat notes that secondary use of health information requires review by an HDEC, if it is to be used in an identifiable form without consent.

This is an observational cohort study, which aims to use whole population, anonymised administrative data to examine the association between a vaccinated infant or young child getting pertussis disease and identified risk factors.

Human tissue:

Q5 Will your study use human tissue? No

If yes, please note that HDEC review is required for **most** health research studies that involve human tissue

HDEC review is not required if tissue is **both** anonymous and already consented for use. For example, when working with anonymous tissue taken from a tissue bank where consent for future research is already given.

HDEC review is not required for audit or related activities involving human tissue with consent.

Risks to participants:

Q6 If you have human participants they must be recruited in their capacity as consumers of health and disability services, relatives of consumers, or volunteers in early-phase clinical trials (for instance, health professionals or members of the general public)

According to Appendix 2, are any of your participants vulnerable? Please explain your answer below.

The population of interest are children born between 2005 and 2015. The data used will be previously and routinely collected, and anonymised. No individual will be identifiable to the researchers and results will be reported in aggregate form. Because the data are anonymised, contacting individuals whose data are used is not possible.

Supporting Documents:

1. Please list here any supporting documents that may assist in HDECs scope of review assessment.

    - **None**

Appendix 1 – Definitions of observational research

For more information please see http://ethics.health.govt.nz/ethical-standards-health-and-disability-research

Observational research:

The primary purpose or justification for observational research is to add to generalisable knowledge about a health or disability issue. The six main types of observational research are summarised below.

A note from the HDEC Secretariat: Generally speaking if health information is being accessed for research and the research is not directly related to the purpose for which the information was originally collected (e.g. quality audit) then it falls into the category of observational research.

Case control studies examine the relationship between an attribute and a disease by comparing those with and without the disease with respect to the presence of the attribute or level of exposure to it.

Cohort studies examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease (or other outcome) by observing large numbers of people over a period of time and comparing incidence rates of the disease (or outcome) in relation to exposure levels. A cohort study may be a clinical cohort study (for example, where a group of patients with a given disease is followed to examine the prognosis).

Cross-sectional studies examine the relationship between diseases (or other health-related characteristics) and other variables of interest in a defined population at one particular point in time, by collecting health and other information concerning members of the population. These include questionnaires or surveys done for research purposes.

Case reports are reports of cases from health or disability services or research settings.

Case series describe a set of cases of a disease (or similar problem). For example, a clinician may assemble a case series on a topic of interest, such as an unexpected adverse effect experienced by patients taking a particular medication.

Descriptive studies examine the existing distribution of variables in populations, for example, analyses of cancer registry data or emergency department data by person, place or time.

Audit or related activity:

The primary purpose or justification for an audit or related activity is to improve delivery of the particular health or disability support service being studied or to control a threat to public health. (The results of audits and related activities should be disseminated at least to those able to take necessary action. Wider dissemination, including through publication in scientific journals, may sometimes be appropriate.) The 10 main types of audit and related activities are summarised below.

A note from the HDEC Secretariat: For the sake of clarity, the purpose of accessing identifiable health information for audit or related activity must be **closely connected** to the purpose for which the information was originally connected and can reasonably be assumed to be within the expectations of the person from whom it was collected.

Audits involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.

Programme evaluation is a type of audit where a whole programme is evaluated, rather than specific interventions.

Evaluation studies aim to determine the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity.

Quality assurance activities aim to improve health and disability support services by assessing the adequacy of existing practice against a standard.

Outcome analyses involve the assessment of health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness.

Benchmarking aims to improve practice through the comparison of two or more health and disability support services

Public health investigations explore possible risks to public health, are often of an immediate or urgent nature and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.

Public health surveillance involves the monitoring of risks to health by methods that include the systematic collection, analysis and dissemination of information about disease rates.

Pharmacovigilance (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).

Resource utilisation reviews evaluate the use of resources in a particular health or disability service activity, for example, by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.

Appendix 2 – Vulnerable populations

For more information please see http://ethics.health.govt.nz/ethical-standards-health-and-disability-research

A study poses more than minimal risk where one or more participants are potentially vulnerable.

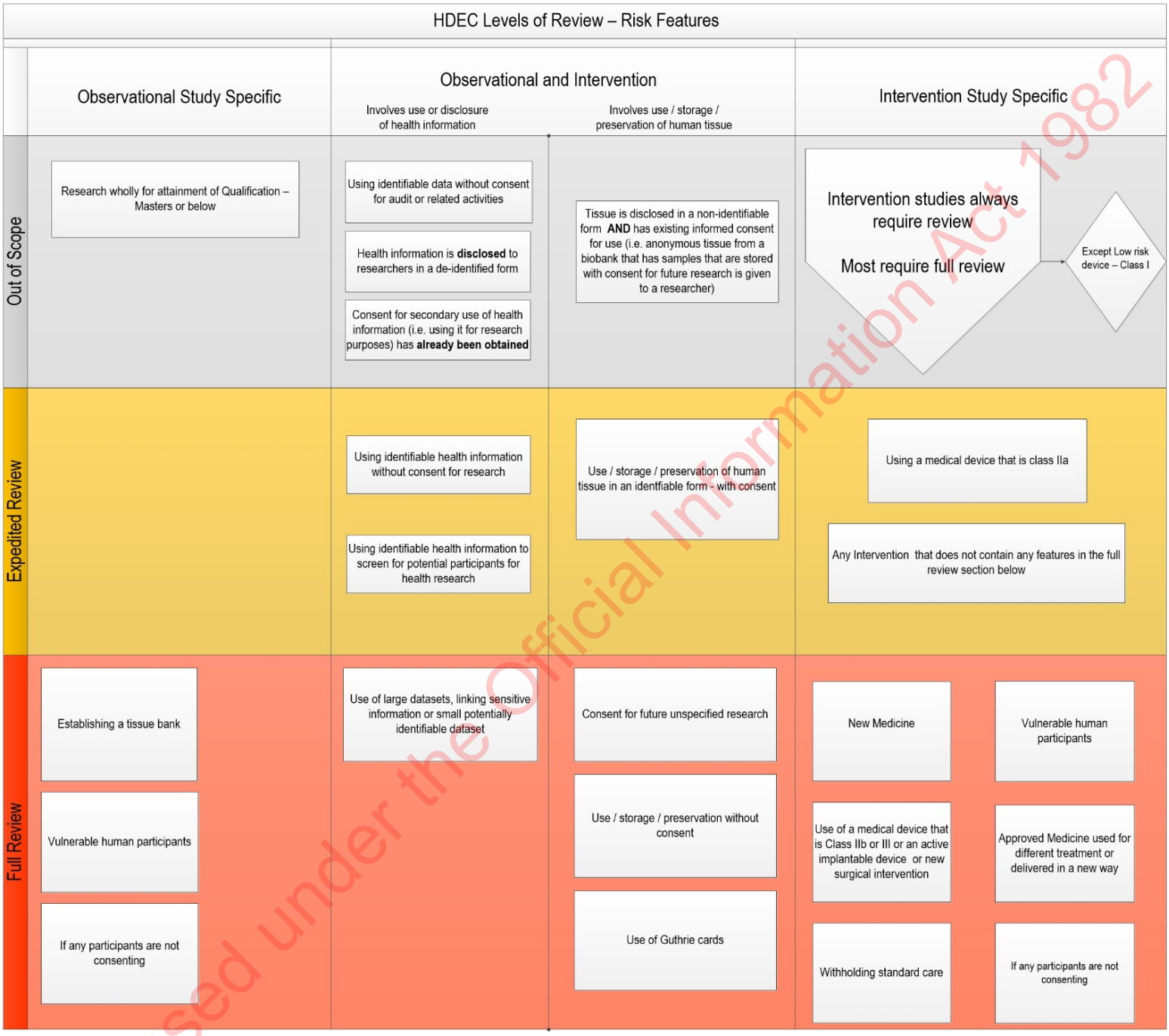
Vulnerability is a broad category. It includes people who have restricted capability to make independent decisions about their participation in the study (ie, who might traditionally be regarded as lacking the capacity to consent to participate). It also encompasses people who may lack the ability to consent freely or may be particularly susceptible to harm either because of their health status, physical or mental capacity or employment status, or as a result of imprisonment. Non-exhaustive examples of potentially vulnerable people include:

- children and young people
- people with mental illness
- people with serious intellectual disability
- people with English as a second language and/or a different cultural background to the investigators (for studies whose details are primarily, or only, stated in English)
- people whose freedom to make independent choices is restricted (eg, prisoners, employees or students of a researcher or sponsoring company).

It is important to remember that even if a group is identified as being likely to be vulnerable, the label may not apply to all individuals in such groups, and even where it does apply, it may do so only intermittently.

A note from the HDEC Secretariat: This may include the context of recruitment.

Appendix 3 – Features of Health Research



Health and Disability Ethics Committees
20 Aitken Street
Freyberg Building
PO Box 5013
Wellington

0800 4 ETHICS
hdecs@moh.govt.nz

Tuesday, 17 January 2017

Dr Anna Howe
The University of Auckland,
Private Bag 92019,
Auckland 1142

Dear Dr Howe,

Study title:	Predictors of breakthrough pertussis in New Zealand infants and young children

Thank you for emailing HDEC a completed scope of review form on 17 January 2017. The Secretariat has assessed the information provided in your form and supporting documents against the Standard Operating Procedures.

Your study will not require submission to HDEC, as on the basis of the information you have submitted, it does not appear to be within the scope of HDEC review. This scope is described in section three of the Standard Operating Procedures for Health and Disability Ethics Committees.

An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).

For the avoidance of doubt, an observational study is classed as more than minimal risk if it involves one or more of the following:

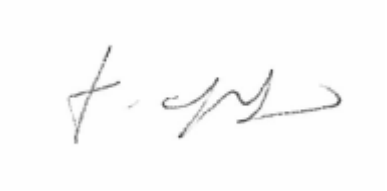
- one or more participants who will not have given informed consent to participate, or
- one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study),
- standard treatment being withheld from one or more participants, or
- the storage, preservation or use of human tissue without consent, or
- the disclosure of health information without authorisation.

If you consider that our advice on your project being out of scope is in incorrect please contact us as soon as possible giving reasons for this.

This letter does not constitute ethical approval or endorsement for the activity described in your application, but may be used as evidence that HDEC review is not required for it. Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.

Please don’t hesitate to contact us for further information.

Yours sincerely,



Tom Kent
Advisor
Health and Disability Ethics Committees
hdecs@moh.govt.nz