What research studies are eligible to be reviewed by AHREC?

AHREC will review all health and disability research studies that fulfil all of the following criteria:

- The study is not eligible for review for ethics approval by a Health and Disability Ethics Committee (HDEC)
- The study involves recruiting human participants from within the geographic region served by the Auckland DHB and/or from within non-Auckland DHB areas where the Auckland DHB is a clinical service provider in the area of practice for the research proposed
- The study involves health research conducted by any of the following: an Auckland DHB employee, a University of Auckland staff member, a University of Auckland student.

If a study involves recruiting human participants from multiple DHBs, including the Auckland DHB, applicants are to seek ethics approval either from AHREC or from another HRC-approved ethics committee to which they have access, such as the University of Auckland Human Participants Ethics Committee (UAHPEC).

Please note that the “University of Auckland staff member” includes academic staff, professional staff, honorary academics, and professoress emeriti.

How can I tell whether my study is eligible for review by an HDEC?

Researchers can refer to section 3 of the HDEC SOPs and summary flowchart, which detail the inclusion and exclusion criteria for review by an HDEC. Researchers can also contact an HDEC Ethics Advisor if they’re not sure whether or not their study requires HDEC review.
If I am a University of Auckland staff member or student and my study isn’t eligible for review by AHREC, do I still need to get ethics approval?

Yes. Any University of Auckland research involving human participants or their data requires approval from an HRC-approved ethics committee.

Where can I get more information about AHREC?

The AHREC [webpage](#) has comprehensive information about the Committee and its processes, including electronic copies of the AHREC [Manual](#) and all necessary forms.

When does AHREC meet and when are the deadlines for submitting an application to AHREC?

The Committee meets on the second Monday of each month. The deadline for submitting an application to a specific meeting of AHREC is three weeks prior to the meeting.

The 2017 and 2018 dates are below:

<table>
<thead>
<tr>
<th>2017 Deadlines</th>
<th>2017 AHREC meeting dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday, 23 October 2017</td>
<td>Monday, 13 November 2017</td>
</tr>
<tr>
<td>Monday, 20 November 2017</td>
<td>Monday, 11 December 2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2018 Deadlines</th>
<th>2018 AHREC meeting dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday, 22 January 2018</td>
<td>Monday, 12 February 2018</td>
</tr>
<tr>
<td>Monday, 19 February 2018</td>
<td>Monday, 12 March 2018</td>
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<tr>
<td>Monday, 19 March 2018</td>
<td>Monday, 9 April 2018</td>
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<tr>
<td>Monday, 23 April 2018</td>
<td>Monday, 14 May 2018</td>
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<tr>
<td>Monday, 21 May 2018</td>
<td>Monday, 11 June 2018</td>
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<tr>
<td>Monday, 18 June 2018</td>
<td>Monday, 9 July 2018</td>
</tr>
<tr>
<td>Monday, 23 July 2018</td>
<td>Monday, 13 August 2018</td>
</tr>
</tbody>
</table>
Can applicants attend AHREC meetings?

As the meetings are open, applicants can request to attend a meeting, specifically the discussion of their application. But the Committee reserves the right to close the meeting at any time in order to discuss the application without the applicant present. Please contact the University of Auckland Ethics Team to advise them that you wish to attend a meeting. The Committee may also request that an applicant attend. If so, the University of Auckland Research Office will contact the applicant to arrange their attendance.

Whom should I contact if I have any questions about AHREC?

For questions about AHREC, please contact Nick Reymond at the University of Auckland Research Office:

| Ethics Processes Team Leader | Nick Reymond | n.reymond@auckland.ac.nz | 9 923 4373 |

How do I submit my application to AHREC?

Only the PI can submit an application for ethics approval. For student (including Doctoral, Masters and Honours) research, applications should be submitted by the primary supervisor who will be named as the PI. All applications must be submitted via email to ahrec@auckland.ac.nz. The submission must include the most current version of the application form and all supporting documents.

How will my AHREC application be reviewed?

There are two pathways for review of AHREC ethics applications: expedited review and full review.
Expedited Review A research project in which there is deemed to be a low risk of physical harm, psychological harm, exploitation or other potential adverse effect will be reviewed via an expedited review process. Expedited applications will be reviewed by one Committee member and the Chair outside of the Committee meetings. The turnaround time for applications is usually about three weeks from the time of submission of the application.

Full Review Any research not qualifying for an expedited review will be placed on the next AHREC agenda for review by the Committee. Each application will be reviewed by two Committee members prior to the meeting, and an outcome determined after Committee discussion of the application. After each AHREC meeting the ethics administrators will inform PIs of the Committee decision within five working days of the Committee meeting. The turnaround time for applications is usually about four weeks from the time of submission of the application.

How can I tell whether my AHREC application is low-risk and thus eligible for expedited review?
You can review the criteria for the Expedited Review Process here. Additional types of low-risk studies are those that:
- require access to health information only, where the person accessing the data is involved in the clinical service provision in that clinical area
- involve administration of low risk procedures (e.g., surveys, questionnaires, etc.) not as part of clinical care and not involving vulnerable participants
- observation only of clinical processes by members of the clinical team.

Applicants should be aware that during the expedited ethical review, reviewers may recommend that the application is referred to the committee for full review.

What documents do I need to include in with my application?
Different research projects will require different supporting documents, such as Participant Information Sheets, Consent Forms, Questionnaires, Interview Schedules, and Confidentiality Agreements. All such documents must be submitted in their final form.

In addition, all applications will need to include the following a Science Review and the PI’s Curriculum Vitae (CV). And most applications will need to include a Māori responsiveness review.

Will applications to AHREC be pre-screened?
All applications submitted to AHREC will be checked for completeness, but the content will not receive an administrative pre-screen prior to the Committee’s review. Incomplete applications will be returned to the applicant.
**How long is the AHREC approval for?**

Normally AHREC will approve an application for three years. But applicants can request a longer approval in their application. An extension of approval for a further three years can be requested. A researcher who wishes to request an extension of approval should submit an amendment request at least one month before its expiry. If ethics approval is still required for a project after a three-year extension, a new application is required.

**Can I make changes to my study after AHREC has approved it?**

If changes need to be made during the course of the research, permission needs to be sought from AHREC. This can usually be done by submitting (via email to ahrec@auckland.ac.nz) an Amendment Request Form explaining the nature of the change(s), and providing amended documents, such as the PIS and CF, if applicable. Minor changes (e.g., that do not increase the demands on participants or affect risk) are dealt with under delegation by the Chair. If the change(s) is substantial, a new application for ethics approval may be required or the requests for change will be put on the next agenda for the Committee to consider. Failure to notify significant changes to a research project risks jeopardising that project’s approval. Unapproved changes constitute unapproved research.

**What should I do about locality governance approvals for DHBs?**

For all applications, including those that are multi-site that include the Auckland DHB, it remains the responsibility of the applicant to obtain locality governance approvals for each DHB or other health providers from those organisations.

**Do I need to submit an annual or final report?**

AHREC does not normally require researchers to submit annual progress reports. But it does require researchers to submit (via email to ahrec@auckland.ac.nz) a Final Report Form once the study is complete.

**What format of CVs will be acceptable?**

Any format is acceptable, so long as it lists educational background, relevant experience and pertinent publications.
**What is the Māori responsiveness review?**

Researchers are encouraged to determine the level of consultation with Māori appropriate to their project in line with the criteria specified by Table 1 at the end of this document. The level of consultation will vary depending on whether there is no Māori involvement, if Māori participants are involved in non-Māori initiated research or whether it is Kaupapa Māori research. AHREC will assess each such review, following the standard DHB Māori locality assessment criteria, to ensure the appropriate level of planned consultation has been indicated by researchers.

1. **No expected involvement:** Although Māori have been excluded by the research design in the first level, this type of study is still of interest to tangata whenua as it is conducted in Aotearoa, and also represents research that has been funded at the expense of a project that could have addressed Māori issues. The challenge here therefore is to identify opportunities within the project for Māori health development, such as health literacy improvement, resource sharing, or Māori researcher capacity development.

2. **Possible involvement:** The second level of research includes the possible involvement of Māori as study participants (although minor), and/or junior research positions. A further consideration of the protection of Māori study participants comes into perspective here and more so with the third level of research.

3. **Probable involvement:** Although the third level of research has been initiated by non-Māori, the expected Māori participation is considerable. It is likely to be an area of interest to Māori either where Māori may have high representation, or a health topic that has been prioritised by the DHB, mana whenua, or other Māori community groups. Depending on the design of the study it may be appropriate to use some Kaupapa Māori Research methods, and data should be analysed by ethnicity.

4. **Definite involvement:** Māori-centred research (level 4) is that which is initiated by Māori and has a high involvement of Māori as participants and as senior researchers and advisors.

5. **Significant involvement, possibly exclusive:** In Kaupapa Māori research (level 5) there is significant, and possibly exclusive, involvement of Māori, who have a governance role in the project. These two categories have clear aims on the contribution of the research to hauora Māori, and typically use Kaupapa Māori research methods and methodology.

**What is the Scientific Review?**

Applicants to AHREC are responsible for including proof of independent peer review in their application prior to its submission. This peer review will be advisory only and AHREC will not be required to follow the reviewers' assessment. AHREC can request another peer review, and can specify that the reviewer must have particular expertise, if it deems another review to be desirable.

Where research had been funded by a peer-reviewed competitive funding source (internal Auckland DHB / University of Auckland or external), proof of funding award will be sufficient to confirm peer review has been undertaken. For unfunded projects, applicants will be required to provide an independent scientific peer review with their application as detailed below. The following is based on NEAC processes in order to ensure all research studies approved are of appropriate research merit:
i. An independent senior active researcher, or research-active clinician, with subject matter expertise and familiarity of the research area, must provide the peer review. This reviewer is permitted to be, but is not required to be, employed by the same employer as the Principal Investigator. ‘Independent… reviewer’ means a reviewer that has no role in the project being reviewed.

ii. For applications concerning student projects at or below masters level, the main supervisor may instead provide an explicit assessment of the research merit of the project, paying attention to the issues indicated below, but recognising that benefits for student learning may be part of the justification for a project and properly balanced against such things as scope and significance of health outcomes of the proposed research.

iii. For University staff and students, the Head of Department or LSRI Director will be signatory to the peer review, confirming that (a) the reviewer is independent and (b) the study can be done in their Academic Unit. Where the HoD or Director is conducting the research or is part of the research team, the Head of School or UARC representative will be the required sign-off.

Scientific review will address the three issues listed in the guidelines for peer review in the NEAC Ethical Guidelines for Interventional and Observational Studies (2012):

NEAC: Areas of focus during peer review
Peer review can be tailored to deliver opinions on a variety of matters relating to a health and disability research proposal. In order to determine scientific validity, the following factors should specifically be determined and the person providing the scientific review must provide brief comments on each:

- **The relative merit of the research**: A key consideration is whether the proposed work is important, worthwhile and justifiable. The research should address a health issue that is important for health and/or society. The aims, research questions and hypotheses will build on and address gaps in existing knowledge.

- **The design and methods**: The quality of study design and methods should be reviewed to assess its robustness. This might include study methodology, a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) and proposed methods of data analysis. Indication of timelines for the research should be included.

- **The feasibility of the research**: This includes assessing:
  - whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project
  - whether the research has the likelihood, on balance, of improving scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions.
  - whether the research will be achievable within the specified timeframe and the research team has the appropriate experience and expertise to undertake the research.
Why was this Committee created?

In 2012 the Auckland Academic Health Alliance (AAHA) formalised a research, teaching and clinical delivery relationship spanning more than four decades between the Auckland DHB and the University of Auckland. A key goal of the Alliance is ‘improving research, education and clinical outcomes through making better use of existing resources’. One area where there is potential to achieve this goal is the process for securing human research ethics approval.

Appropriate expert ethics review of research proposals by a Health Research Council (HRC) approved ethics committee not only safeguards institutional reputation through ensuring research conforms to the highest ethical standards, but is also a prerequisite for most funded research and journal publication. Changes to the Health and Disability Ethics Committees (HDECs) in July 2012 divided the scope of HDEC review into ‘main criteria’, ‘exemptions’ and ‘inclusions’, and this means that they no longer accept minimal risk studies, or studies carried out wholly or principally for the purposes of an educational qualification (with some exceptions). Therefore, a significant tranche of health research falls between this ‘higher risk’ threshold and low risk audits identified by the National Ethics Advisory Committee (NEAC) as not requiring ethical review. Review of this “intermediate risk” research by an accredited ethics committee currently is not required of or available to Auckland DHB researchers who are only required to obtain Auckland DHB research governance approval, but is a requirement for University of Auckland researchers, who seek review through the University of Auckland Human Participants Ethics Committee (UAHPEC).

While Auckland DHB investigators do not currently have access to an HRC approved institutional research ethics committee, their research proposals are considered by the Auckland DHB Research Review Committee for review of appropriate locality governance. Currently there is duplication of activities between UAHPEC and the Auckland DHB Research Review Committee, for example in review of scientific merit and Māori review. Projects which involve both University and Auckland DHB investigators, and projects involving University investigators studying Auckland DHB data and/or patients, must currently be submitted to both bodies for review.

What are the intended benefits of this new ethics Committee?

- Auckland DHB researchers will have access to an HRC-approved institutional ethics committee for research that does not meet criteria for HDEC assessment, thus minimising risk to the researchers and the institution, and better meeting requirements of funding bodies and publishers.
- Inclusion of an expedited process for low risk projects will simplify and speed up the review process for researchers.
- Both Auckland DHB and the University of Auckland researchers will have their applications reviewed by a committee with the appropriate health research and clinical expertise to assess the ethical aspects.
- Shared processes will provide significant potential for rationalisation of locality assessment and Māori review, to avoid duplication of effort for both institutions.
- A forum for discussion between the University of Auckland and Auckland DHB researchers is likely to identify opportunities for research collaboration.

**Who will govern and administer AHREC?**

While AHREC is a joint initiative of Auckland DHB and the University of Auckland, for administrative convenience it will report through the Deputy Vice-Chancellor Research (DVCR) to the University Council. An Advisory Board will advise the DVCR regarding all matters relating to the conduct and membership of AHREC. This Board will have four members, two appointed by the Auckland DHB CEO and two by the Dean of the Faculty of Medical and Health Sciences (FMHS) of the University. Usually the nominees would be the Auckland DHB Chief Medical Officer, the Auckland DHB Director of Research, the Deputy Dean FMHS, and the Associate Dean Research FMHS. The Chair will provide an annual report of AHREC’s activities to the Advisory Board and DVCR.

The University of Auckland Research Office will administer the Committee, with input from the Auckland DHB Research Office, the Manager of which will attend meetings to provide guidance on DHB matters.

**Do I need to be aware of any relevant policies or guidelines?**

The AHREC’s ethical principles and procedures are consistent with the Health Research Council’s ethics framework, the Health Research Council Guidelines for Approval of Ethics Committees, and with those of the National Ethics Advisory Committee.

**Māori responsiveness:**

You may wish to consult the standard ethnicity data protocols for the Health and Disability Sector, and the HRC Guidelines for Researchers on Health Research involving Māori.

**Science Review:**

The scientific review will address the three issues listed in the guidelines for peer review in the NEAC Ethical Guidelines for Interventional and Observational Studies (2012).
Use of human tissue:
The use of human tissue in New Zealand is regulated by the Human Tissue Act 2008 and the Code of Health and Disability Services Consumers' Rights 1996. Furthermore, the use of all human tissue must be in accordance with the informed consent (including consent to future unspecified research) that has been obtained from participants, donors of existing stored human tissue, or other persons entitled to give informed consent under the Human Tissue Act 2008.

Privacy
Researchers should consult the Privacy Act for information about how privacy relates to research, in particular Principles 10 and 11 which state the following:
“An agency that holds personal information that was obtained in connection with one purpose shall not use the information for any other purpose unless the agency believes, on reasonable grounds...that the information—
(i) is used in a form in which the individual concerned is not identified; or
(ii) is used for statistical or research purposes and will not be published in a form that could reasonably be expected to identify the individual concerned”.

Further information is available in the Health Information Privacy Code 1994, especially Rule 10 on the “Limits on the use of Health Information”.

Use of health information
The Health (Retention of Health Information) Regulations 1996 require that some health information be retained for a period of ten years.

Institution-specific requirements
Staff and students from the University of Auckland must adhere to the Code of Conduct for Research (2012). In particular, the University’s general requirements for the storage, retention and destruction of research data are set out in section 5.4.

Information about the handling of potentially hazardous materials can be found on the University of Auckland Biological Safety Committee webpages.

Definitions
The AHREC uses the following NEAC definitions:
**Intervention study** - “An intervention study is a study in which the investigator controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term ‘intervention study’ is often used interchangeably with ‘experimental study’. Many intervention studies are clinical trials.”

**Observation study** - The NEAC Ethical guidelines for observational studies (2012) identify 10 main types of audit and associated activities in the area of health and disability services.

**Vulnerable participants** - “Vulnerability is a broad category. It describes 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 of a sponsoring company)
- people with serious illness for which the study treatment offers potential benefits that substantially exceed those of any other available treatment.”
### Table 1: Criteria to help researchers determine the level of consultation with Māori appropriate to their project

<table>
<thead>
<tr>
<th>Level of Māori involvement:</th>
<th>Non-Māori initiated research</th>
<th>Māori-centred research</th>
<th>Kaupapa Māori Research</th>
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</thead>
<tbody>
<tr>
<td>• as participants</td>
<td>(1) no expected involvement</td>
<td>(4) definite involvement</td>
<td>(5) significant involvement, possibly exclusively</td>
</tr>
<tr>
<td>• on research team</td>
<td>No expected involvement</td>
<td>Possible involvement as junior researcher positions</td>
<td>Definite involvement as researchers, senior researchers and advisors</td>
</tr>
<tr>
<td>Type of consultation recommended</td>
<td>DHB Māori review</td>
<td>DHB Māori review</td>
<td>DHB Māori review and possible engagement with DHB Māori reviewers (face to face meeting)</td>
</tr>
<tr>
<td>Description of research</td>
<td>• Māori have not been included in the design of the project</td>
<td>• The research topic is not designed to be analysed by ethnicity</td>
<td>• Clear aims for the contribution of the research to Māori Health and equity</td>
</tr>
<tr>
<td></td>
<td>• There are still possibilities to contribute to Māori development</td>
<td>• Not a topic of particular relevance for Māori.</td>
<td>• Māori knowledge produced, but non-Māori methods may be used</td>
</tr>
<tr>
<td></td>
<td>• There are still possibilities to contribute to Māori development</td>
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<tr>
<td>Control Analysis</td>
<td>Non-Māori</td>
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<td>Non-Māori and/or Māori</td>
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<td>Non-Māori</td>
<td>Non-Māori and/or Māori</td>
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<td></td>
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<td></td>
<td>• Ethnicity analysis</td>
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<td></td>
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<td></td>
<td>• Equity analysis</td>
</tr>
</tbody>
</table>

- DHB: District Health Board
| Tools          | Non-Māori | Non-Māori | Non-Māori Possibly some Kaupapa Māori Research methods | Non-Māori or Kaupapa Māori Research methods and Kaupapa Māori Epidemiology | Kaupapa Māori Research methods and Kaupapa Māori Epidemiology |