Guidelines for completing the Application Form for Approval of a Low Risk Study at ADHB (form for the Expedited Approval Pathway)

All research at the ADHB requires Institutional Approval. The expedited approval pathway for low risk studies is undertaken by the Research Office (RO) and / or the Clinical Advisor for Research on behalf of the ADHB Research Review Committee (RRC). The Māori Advisor for Research will also review low risk studies if the research involves ADHB patients as participants.

The expedited pathway is appropriate for cost-neutral research projects that a) can be defined as audit or related activity (e.g. outcome analysis, benchmarking), or b) are minimal or low risk observational studies either not requiring HDEC review or reviewed by the HDEC expedited pathway, or c) low risk observational research reviewed by an institutional ethics committee.

The expedited pathway is not appropriate for research requiring a budget at ADHB, research requiring the approval of the Health and Disability Ethics Committee (HDEC) full review pathway, or research not requiring HDEC approval, but where the research affects the normal care of patients. If your research project has any of these features it will need to be approved via the standard pathway (i.e. by the RRC at a full meeting) and you should use the Application Form for Approval of a Research Project at ADHB (v August 2014).

The above descriptions of research appropriate and inappropriate for the expedited pathway are intended as guides only. Some features of observational research will need more scrutiny than others and the RO retains the discretion to decide whether a study will need to be reviewed via the standard pathway.

Use below link for more information.
http://www.adhb.govt.nz/ResearchOffice/Research-Approval/Expedited/expedited.htm

When an ethical approval is required for a low risk study, the ADHB expedited pathway should ideally be sought in tandem with the ethics approval.

1. The review process

Use the ADHB application form for research approval of a low risk study v2. The form must have signatures indicating approval at a minimum from the departmental Clinical Director, but also any other appropriate person i.e. Nursing or Allied Leader if nursing or allied research. The completed application and any associated documents are forwarded to the RO. The RO reviews and / or submits to the Clinical or Māori Advisor for Research as necessary. The Clinical and / or Māori Advisor for Research will review the application and convey the response to the RO. The RO will communicate with the principal investigator / designate conveying the decision.

Decisions to support applications via the expedited pathway need, at a minimum, to demonstrate the following characteristics:

- Application form is fully completed and authorised (signed off)
- Research is cost-neutral
- Research is feasible
- Research is consistent with ADHB policies, goals and objectives
- Complies with all current regulations, standards, guidelines and ethical approval processes

The RO will submit the application form and related documents to the Māori Advisor for Research where required. The purpose of the Māori locality assessment is to increase Māori participation in research occurring at ADHB with the end goal of improving health outcomes for Māori and other populations.

The focus of the Māori locality assessment is to ensure that research projects meet the requirements of the Treaty of Waitangi and Tikanga Best Practice.

2. Application Form Guide

Section A: General Summary

Please complete the general information requested.

- Project title should be the same as the title of the ethics application if there is one.

- Provide the name, role, address and contact details for the Principal Investigator/Co-ordinating Investigator[1]. If an ethics application has been made this person should either be the Principal Investigator/Co-ordinating Investigator according to the ethics application, or the lead named investigator at the ADHB site.

- For non –ADHB researchers an ADHB Contact is necessary when the research study does not include an ADHB investigator directly. The contact person agrees to be the link for the project within the ADHB and must sign on the application form to confirm this agreement. They are responsible for ensuring that the external researchers are aware of any relevant ADHB processes and policies. They need to ensure that confidentiality agreements (where required) are signed and that, if appropriate, ID badges are obtained. This person will assist the study team with access, as required, to patients or records. Note that it is the investigators' responsibility to identify and recruit an ADHB contact person.

[1] Note that the use of the terminology of Co-ordinating Investigator (as per New Zealand Health and Disability Ethics Committee's SoPs) and Principal Investigator are used interchangeably in this document.

- Student projects require an ADHB clinical supervisor, who will need to sign the application for to confirm their agreement. It is the Clinical Supervisor's responsibility to ensure the student is appropriately advised on clinical safety and correct processes in the interests of the patients involved in the research, and in the interests of ADHB.

- Registered with Awhina Research and Knowledge Centre, Waitemata DHB? This question is asked to coordinate Māori review where required.

Section B: Type of study

Indicate what type of study this application is for. Definitions of the various types of study can be found in the National Ethics Advisory Committee's (NEAC) "Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities".
http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research

All applicants should have read and be familiar with the NEAC guidelines.

Section C: Responsiveness to Māori

This section of the application form is read by the Māori Advisor for Research as part of the Māori locality assessment. The relevant information is now required in the application form whereas previously it was obtained from the application for ethical approval and related documents. This change has been made for the sake of consistency of process, as since 2012 institutional ethics committees as well as HDECs review health and disability research, and the different committees have different requirements for Maori responsiveness. Some of the questions have been taken directly from sections p.4 and f.1 of the HDEC Main (application) Form and applicants can cut and paste from this form if appropriate.

Section D: Ethical considerations

Not required when a completed HDEC Main Form is submitted along with the application. Otherwise, complete this section.

Benefits of the study. Explain why the research will provide benefit, particularly in the context of benefit to ADHB if relevant. It should be clear to the reader why the proposed study has been developed.

Risks of the study. Almost all research involves risk however minor. You should acknowledge all risks of the study. Acknowledging risks won't mean that you will not receive permission to start the study, but it will convince the reviewers that you understand the risks, which means you will be better able to manage these effectively.

Low risk studies often involve some secondary use of health information or observations of patients without consent, and so carry some risk of loss of privacy (loss of control of access others have to individuals and their personal information) and loss of confidentiality (identifiable information is accessible only to those authorized to have access). You should acknowledge the risks of secondary use of data without consent even if you intend to recruit patients by informed consent but have to first have access private information to identify potential participants. Involving vulnerable persons in research is another potential risk and should be acknowledged. Vulnerable persons include (but are not limited to), children, psychologically or intellectually impaired persons, refugees and prisoners.

Minimising expected risk. Explain what steps you will take to minimise the risks acknowledged in your answer to the previous question. When the study involves secondary use of patient information without consent you can explain how you intend to limit the amount of access you have to individuals and their information so that only that required to undertake the specific study procedures will be accessed. You can describe how you will minimise the risks of loss of confidentiality by explaining how you will safely manage study information so that unauthorised persons cannot obtain access to it. You can mitigate risks to privacy and confidentiality by removing personal identifiers from your data set so that the identity of persons and their information cannot be linked.

Collecting information directly from individuals? If "Yes" you should describe how you will identify persons to approach to recruit for your research project and why the methods you will use to approach and consent are safe and appropriate. You should consider the context and timeframe in which these activities will take place and whether potential participants will be able to give free and fully informed consent in that setting. Where possible you should ensure that the study team member doing the consenting process is not someone who normally would be providing healthcare to these patients. If this is not possible then the investigator should be especially careful to ensure that the patient-clinician relationship does not affect the patient's autonomy to choose whether or not to participate.
If you need to pre- identify specific individuals to approach (e.g. persons who have had a certain medical condition treated in last five years) consider the most sensitive way to undertake this, as some people may prefer to not be contacted "out of the blue". If you would not normally have access to information about the patients in your study (e.g. you are not employed at ADHB or supervised by an ADHB staff member) you should not contact identified patients directly, but have your ADHB contact person telephone the patients or send a letter to the patients on your behalf.

Collecting information from a third party. If you intend to collect information about individuals from a third party explain why it will be safe and appropriate. The NEAC guidelines have information about collecting health information from third parties.

Accessing health information. Indicate from which repositories you will be collecting health information (where relevant). It is important that you acknowledge if you are collecting **identifiable** health information, that is, where the identity of the person could be obtained from the record being accessed. Health information is identifiable if it contains names, NHIs or any other unique identifier that could enable linkage of the record to other databases. You should acknowledge if the information being accessed is identifiable even if you do not intend to collect the identifier (name, NHI etc.) for your dataset.

Consent for access to identifiable records? Will ADHB patients be asked to provide informed consent for access to their health information for secondary purposes (i.e. not directly related to their healthcare)? Informed consent is recommended when the persons wanting to access the information are not employees or contractors of ADHB and as such do not have the same obligations to keep health information confidential. The same may apply to ADHB employees wanting to access identifiable health information from other organisations, especially if the unique identifiers will be retained in the dataset. If informed consent will not be obtained in these circumstances an ethics committee approval is generally required.

For research that will involve patient information being entered into study databases or patient registries, informed consent and / or an ethical approval should be obtained if identifiable health information will be shared with researchers from other organisations. If the identifiable patient information will remain secure and available only to the ADHB, or available to other researchers only in a deidentified form, it is still recommended you allow patients the option to opt out of having their information entered into database or registry. Describe the steps you will take to provide reasonable information to patients on how their information will be used and stored and how you will ascertain if patients wish to opt out of any involvement.

It is not acceptable to include patient information in a database or registry if doing so is known to be contrary to the patient's wishes.

Justification for not obtaining informed consent. If you are not seeking informed consent for use of patient identifiable information you must justify why you are not. It is generally considered appropriate for employees of the organisation holding the health information to access this for secondary purposes without consent if undertaken for the purpose of audit or related activity. There may also be scientific reasons why it is necessary to use all known or available "cases" of a health condition in order to obtain the true clinical picture and / or to not exclude any groups of participants for which gaining informed consent might be challenging.

Confidentiality of participant information. All applicants should have read and be familiar with ADHB Policies "Clinical Record Management" and "Privacy of Patient Information".

Describe how you will manage the safe handling of the study data. Any identifiable participant information must be confidential to named member of the study team only. It must be stored securely, as a minimum in a locked cabinet if in paper form or disc form, or as a password protected file if electronic. If patient unique identifiers will be collected in the dataset to avoid duplications, you should explain how these will be stripped from the dataset when the data collection is complete.
You should have a plan for where and for how long you will retain your study data that is consistent with any information you have given to participants, and that demonstrates your understanding of all relevant ADHB policies and the requirements of any other bodies (journals, tertiary institutes, colleges, meetings) to which the research finding might be disseminated.

Section E: Proposal
Required for all applications.

What is the study question? Your research should be designed to answer a question or set of questions. Describe the question/s your research project is designed to answer, providing a background or rationale as to why you are interested in this question (e.g. relevance to current or future clinical practice), and hypotheses if relevant.

What is involved for participants in this study? If the study will involve participants, describe what taking part in the study will entail. You should provide detail about where, when, by whom and for how long the research procedures will take. If participation will involve the disclosure of health information by individuals you should describe how this will be undertaken in a location and manner that respects individual's privacy.

New knowledge and health outcomes. Your project should be an original piece of research that will contribute new knowledge, ideally with the potential to influence health outcomes. Explain why you project meets these expectations.

Methods. One page is recommended but not strictly enforced. Include the following information where relevant:

- Research Design – what type of study design will you use to address the study question (e.g. retrospective/prospective, interventional/observational, between groups/repeated measures etc.)?; describe the study population including inclusion and exclusion factors; what is the sample size and how has this been determined (e.g. with a power analysis); what data will you collect or what instruments will be used?; describe any risks and moderators for minimizing risks including a stopping plan where relevant.

- Endpoints/Analyses – how will you evaluate the data/information collected for the research to answer the study questions? What is the statistical analysis plan?

How will the outcomes be represented? How will the outcomes be translated to inform practice?

Impact on ADHB resources. Describe the required involvement of ADHB staff, equipment and premises. The conduct of the study should not disrupt the normal activity of the clinical setting or the care of patients. External researchers recruiting patients from ADHB should be clear about how patients will be identified and approached, in what setting, and how/whether ADHB staff will assist in this process.

Section F: Departmental sign-off

Please obtain the appropriate signatures illustrating support of your project. At a minimum the department Clinical Director (or similar position) and, where relevant, the Allied or Nursing leader are required. If your project crosses two services i.e. Paediatric and Adult Neurology then both sets of Clinical Directors and leaders are required to sign. If an Investigator in the study is also the departmental Clinical Director then the form should be signed by the Clinical Director of the ADHB healthcare Directorate instead. You are not able to authorise your own studies.

Section G: Administration and Declarations

Applicants need to sign the application form to confirm intended start and end dates, that they will inform the RO when the study is complete, and if approved by an HDEC, will ensure annual reports are submitted for the study by the due date annually, and evidence of reapproval (HDEC approved progress report letter) provided to the RO at least annually.

This section also describes other documentation required for the ADHB review of the application, in addition to the fully signed application form.

- All applications must be accompanied by a protocol or study plan, as detailed as possible.

- An application for ethical approval (if required).

- The research will not be required to have prior ethical approval for ADHB to review, but if you have received approval (full or provisional) from an ethics committee, submit the letter with your application.

- All Participant Information Sheets (PIS) and Informed Consent forms (ICF) to be used in the research must be provided. Provide age-appropriate and culturally-appropriate versions if children, young adults or specific populations are being targeted for the study. When participants will be recruited from Auckland or Waitemata DHBs you must include the below Māori cultural and research support contact details in the PIS or ICF.

(If you require Māori cultural support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324
If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext 3204)

- Questionnaires are vital if the research involves evaluation (e.g. validity, reliability) of a questionnaire or when a questionnaire has been specifically developed or updated to collect the study data. You do not need to submit questionnaires with your application if they are standardised instruments.

- Provide evidence of any consultation with Māori that has been undertaken for the research. This is required for research that is Māori – focussed or using Kaupapa Māori methodology. For other research consultation is recommended but not required. You can also provide evidence of Māori Tikanga/cultural best practice and safety training that the investigators and research staff have undertaken. Māori research review is undertaken by the Māori Advisor for Research (or designate), but coordinated by the Research Office. It will be organised automatically when the documents for review are submitted.

3. Administration

The Research Office (RO) acts as the conduit to the Clinical and Māori Advisors for Research. The RO will create a file with all your documents, and once complete, will determine whether a) RO can review and approve on delegated authority, or b) the study will require approval from the Clinical and / or Māori Advisor for Research. If the approval of the Advisors is required RO will submit the project to the Clinical Advisor for Research and the next Māori review list.

RO retains the discretion to decide whether a study will need to be reviewed by the RRC via the standard pathway.

The RO may be able to offer advice and suggestions and as such the earlier they are aware of the project the more they can assist.

Documents required for review

See 2, Section G of this document. It is recommended that you send the documents as you complete or receive them. A file will be created in the RO with a unique identifier (i.e. your project registration "A+" number (see RO web site). Once all documents are received the study can be reviewed as per above.

If your study requires ethical approval please submit a copy of your ethics approval letter as soon as you receive it as final ADHB approval is dependent on the RO receiving and confirming you have ethics approval.