RESEARCH RISK GUIDELINE & QUESTIONNAIRE

There are two parts to this guideline.

- the NZ Health and Disability Ethics Committee (HDEC) flowchart,
- and the Research Risk Questionnaire (RRQ).

Read HDEC flowchart

- If the outcome on the HDEC flowchart is '**yes'**, then your application requires approval **External** to REAC. Do not proceed to the RRQ.
- If the HDEC flowchart result is **'no'**, then proceed to the RRQ

Complete RRQ

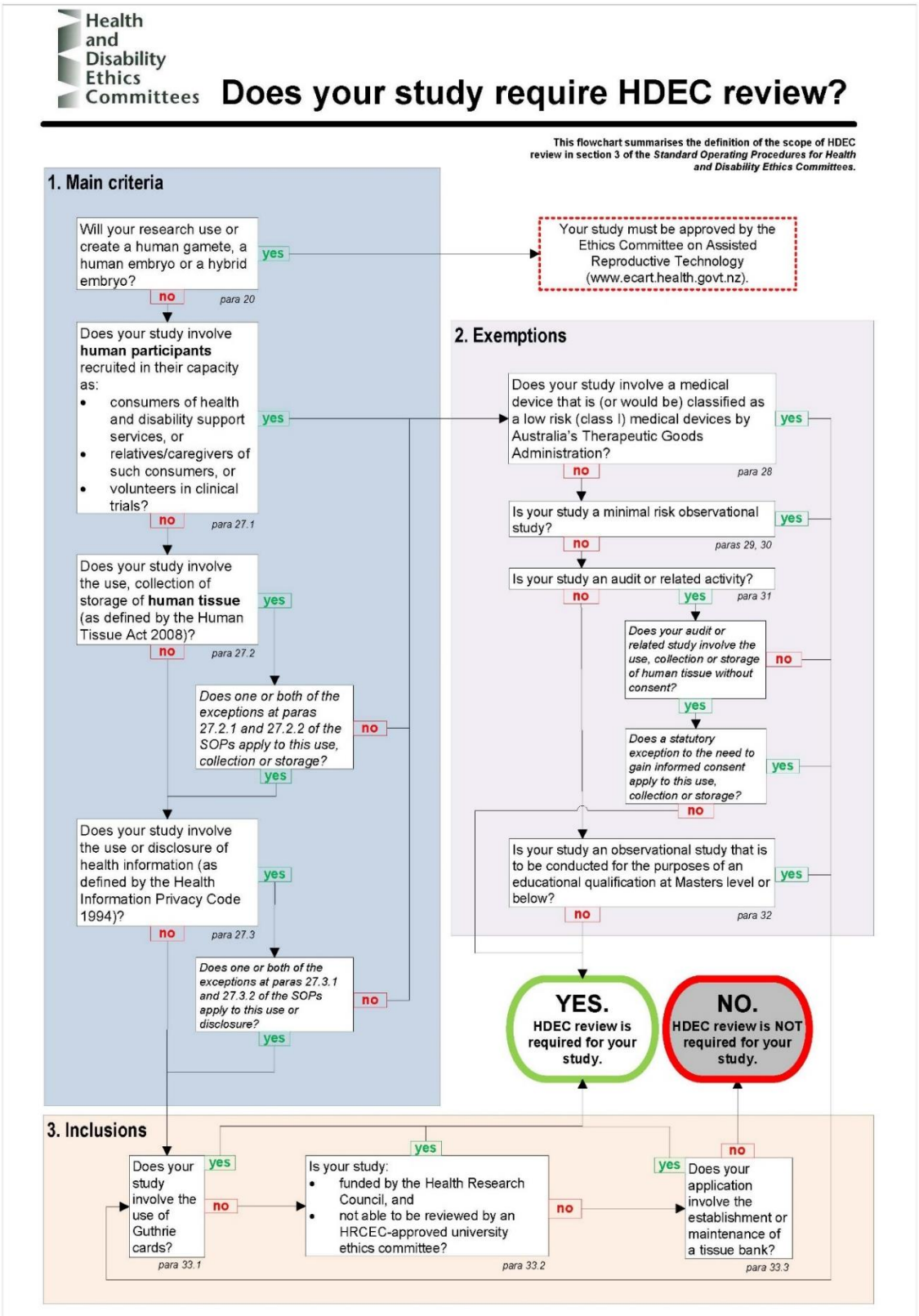
- If you answered '**yes**' to any of the questions in the RRQ, then use **AG210-21**.
- If you answered **'no**' to all of the questions in the RRQ, then use **AG210-20**.

If you have already received HDEC approval or approval from another external agency please complete the External Ethics Approval Notification Form, AG210-22, and submit that to RIC for forwarding to REAC

External	Full Application	Low-Risk Application
If the outcome on the HDEC flowchart is '**yes'**, then: **Download the HDEC User Manual,** which outlines the process for submitting an online application For further information, see the **HDEC website**.	If the HDEC flowchart result is '**no**' and you answered **'yes'** to any of the questions in the RRQ, then Complete the **Full Application** Form Submit • Your RRQ, • **Full Application** • **Participant Information Sheet,** and • **Participant Consent Form** to the RIC for forwarding to REAC, 2 weeks before the monthly RERAC meeting **You may be asked to present at the monthly REAC meeting**	If the HDEC flowchart result is '**no**' and you answered '**no**' to all the questions in the RRQ, then Complete the **Low Risk Application** Form**.** Submit • Your RRQ, • **Low Risk Application** • **Participant Information Sheet,** and • **Participant Consent Form** to the RIC for forwarding to REAC.

HDEC Flowchart

Use the flowchart below to determine whether your project requires ethical approval by the NZ Health and Disability Ethics Committee.



The Research Risk Questionnaire

Whakapapa

Project Details

Project Title	
Project Start Date	
Project Duration	

Mana

Applicant details

Name of Applicant(s)	
Applicant's email address	
Applicant enrolled qualification *(if applicable)*	
Supervisor(s) *(if applicable)*	
Supervisor(s) email address(es)	
Advisor (s) (if applicable)	
Advisor (s) email address(es)	

The following statements are being used to determine the risk of your project causing physical or psychological harm to participants and whether the nature of the harm is minimal and no more than is normally encountered in daily life. The degree of risk will then be used to determine the appropriate approval procedure.

If you answer '**yes**' to any question, you should complete the EIT Full Ethics Application Form

Tika & Manaakitanga

Process and participant care details

Does your Project involve any of the following?
(Please answer all questions. Please indicate either YES or NO for each question)

		YES	NO
Risk of harm			
1	Places the researcher in a situation in which they may be at risk of harm		
2	Māori people or Māori knowledge (Mātauranga Māori) as the primary focus and/or uses Māori archaeological material		
3	Pacific people or Pacific cultural knowledge as the primary focus and/or uses Pacific archaeological material		
4	Uses biological samples		
5	A distinct and disadvantaged social group as the primary focus of the research		
6	Uses a questionnaire, interview format or other tool which might reasonably be expected to cause discomfort, embarrassment, or psychological or spiritual harm to participants		
7	Processes or results that are potentially disadvantageous to a person or group, such as the collection of information which may expose the person/group to discrimination		
8	The collection of information concerning illegal behaviour(s) which could place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or professional or personal relationships		
9	Administering any form of exercise regime, physical examination, deprivation (e.g. sleep, dietary), or the administration of any form of drug, medicine or placebo		
10	May cause physical pain, beyond mild discomfort		
Informed and voluntary consent			
11	Includes participants who will give oral consent rather than written consent		
12	Includes participants who are unable to give informed consent		
13	Is undertaken by Te Pūkenga staff and involves Te Pūkenga students that they teach as participants		
14	Involves the participation of children aged seven years or younger		
15	Involves the participation of children aged under sixteen years old where parental consent is not being sought		
16	Includes participants who are in a dependent situation, such as people with a disability, or residents of a hospital, nursing home or prison, or patients highly dependent on medical care		
17	Includes participants who are vulnerable in any way not stated above[1]		
18	Requires the use of previously collected data or biological samples for which there was NO explicit consent for this research		

[1] Vulnerable participants are people who have a restricted ability to make independent decisions about their participation in a study. These can include children & young people (<16 yrs), people with a mental illness, people with a serious intellectual disability, or people with restricted ability to make independent choices. For more information see: Potentially vulnerable study participants (HDEC)

Anonymity and confidentiality			
19	Makes a best endeavour effort to maintain the confidentiality of participants but is unable to guarantee this[2]		
Deception			
20	Involves deception of the participants, including concealment, covert observation		
Compensation of participants			
21	Offers payments or other financial inducements (other than reasonable reimbursement of travel expenses or time) to participants		
Procedural			
22	Requires human ethics approval to meet the requirements of an outside organisation, e.g. a funding organisation or a research publication		
Conflict of interest			
23	Uses researcher(s) who are in a position of power in relation to the participants, e.g. by virtue of: roles of authority; distinctions of class, ethnicity, gender, educational level, intellectual ability, developmental stage or any other cause of power imbalance		
24	Is funded by an agency that could have a financial or reputational interest in the research findings		
25	Involves researchers who have no cultural connection or cultural advisor associated with the participant group		

[2] There are some types of research in which anonymity or confidentiality are not necessary and acknowledgement of the participants is more appropriate. If you feel this applies to your project, please provide a brief explanation of the reasons on a separate sheet.

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