RHC HREC – Guidance for completing the HREA

Guidance to Completing the Human Research Ethics Application (HREA) in REGGS

This guide has been developed to assist researchers completing the HREA for applications to the Ramsay Health Care HREC.

The HREA and protocol are two distinct documents with different purposes

- The Protocol describes all aspects of your project - aims, hypotheses, background (justification) methodology, analysis
- The HREA allows you to demonstrate that the ethical issues raised by your research project have been considered
- As the protocol and HREA will be read together when assessing your application, do not cut and paste from the protocol when you complete the HREA.

The HREA is logic driven

- If the relevant checkboxes are not selected correctly at the initial questions, key sections of the HREA will not generate (For example questions pertaining to research methodology or participant cohort)
- Without all appropriate sections completed, the HREC cannot properly assess your application and you will receive questions

The more complete and succinct information you give the HREC in the project documents, the fewer questions you are likely to receive

- Where there is a reference to the National Statement embedded in a question, review that section prior to answering the question
- Use professional and appropriate language for the group you are describing
- People are described as “participants”, not “patients” or “subjects”
- Check your spelling and grammar before submitting

A member of the research team with relevant research experience and expertise should review the HREA before submission

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Section 1:	These questions are about your project and the sites where it will run
M:	These are about your study methods
P:	These are about your study participants
Section 2:	These are about Recruitment and Consent, including risks and benefits to participants
Section 3:	These are about Data and Privacy
Section 4:	This section is for attaching project documents including your protocol

If you still need assistance to complete your application, please contact the National Research Unit on (02) 9433 3854 or email the appropriate HREC:

RamsayHREC.NSW-VIC@ramsayhealth.com.au

RamsayHREC.QLD@ramsayhealth.com.au

RamsayHREC.WA-SA@ramsayhealth.com.au

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Aboriginal and Torres Strait Islander Participants

Additional ethical considerations apply when conducting research involving Aboriginal and Torres Strait Islander Peoples. Research that will include Aboriginal and Torres Strait Islander Peoples should be meaningful and culturally appropriate. The aim is to involve the people affected by the research in its design and implementation, and minimise harm and mitigate risks to those people and communities.

Where research will specifically include Aboriginal and Torres Strait Islander peoples, the HREC Secretariat will arrange for a review of the research to be undertaken by the Aboriginal Health & Medical Research Council in addition to local HREC review.

- The experience of Aboriginal people is an explicit focus of all or part of the research
- Data collection is explicitly directed at Aboriginal peoples
- Aboriginal peoples, as a group, are to be examined in the results
- The information has an impact on one or more Aboriginal communities

Aboriginal health funds are a source of funding

If your research project meets any of these criteria, refer to:
The NSW Aboriginal Health Ethics Guidelines, and
The NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities, and
submit to the AH&MRC Human Research Ethics Committee. You may submit to HNE HREC and AH&MRC HREC at the same time.

The six core values identified in the AH&MRC documents should be considered when answering questions in the HREC HREA. This applies to all questions, not only the targeted questions in Section P8 “Aboriginal and Torres Strait Islander People”.

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Culturally and Linguistically Diverse Participants

Additional ethical considerations apply when conducting research involving Culturally and Linguistically diverse people. Research participation should be made accessible to culturally and linguistically diverse people.

When designing your project, writing your protocol and completing the HREA, consider the following.

People should not be excluded from research based on their primary language of communication.
Information should be made available to people who do not speak, read or write English.
Consent may be expressed in many ways, and does not require a signature on a written document in the English language.
Consent may occur within a larger family and community structure and hierarchy – individual consent may not be suitable.
An interpreter service is available in the public health system for patients who communicate in languages other than English. Collection of cultural group level data (e.g. ethnicity) is only appropriate if the research data will be analysed at group level.

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Project Summary

PROJECT SUMMARY	
Q1.1 What is the Project Title	Recommend you use a short title followed by long title, so you can easily search in REGGS. e.g. TEST: **T**he **E**thical **ST**udy
Q1.2 Provide a Summary of the Research Project in Non-Technical Language	This should be a brief statement, in plain language. Avoid technical terms or acronyms. If you need to use technical terms or acronyms, define and explain them. A good guideline is to write like you are explaining your project to a year 12 student.
Q1.3 Which category/ies of research best describes the project	This will prepopulate from your project REGGStration. You do not need to change this.

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Location and Funding

LOCATION AND FUNDING	
Q1.4 In what environments will the research be conducted?	Please select every option that applies to give the HREC a full understanding of the scope of your project. Selecting these locations will not create more questions in the HREA.
Q1.5 What organisation has overall responsibility for this project?	The Sponsor Type and Sponsor Name will prepopulate from the Project REGGStration. Include all institutions, clinical, academic and granting bodies. For a project attached to a research degree, University Grant or Fellowship, include both the University where the student is enrolled and the site where clinical data will be collected.
Q1.6 Describe how this research currently, or will be funded?	If your project has funding, include the funding sources, the amount of funding, when they have been or will be awarded, and when they need to disbursed by. A project does not require funding to be approved. The HREC review will consider the potential impact on participants if an un-or-underfunded project is ceased prematurely.
Q1.7 When do you anticipate starting the research project?	Your start date will be when you will first perform any project specific tasks which include participants.
Q1.8 What is the anticipated duration of the research project?	Projects are given a maximum of 5 years HREC approval in REGGS, but the planned length of your project can be longer than this. If your project is expected to run longer, you may submit a renewal of approval when the initial approval expires. A project will end when all tasks are complete and it can be archived.

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Project Team

Complete for as many researchers are involved in this project. Anyone who will work on this project is considered a researcher.

PROJECT TEAM	
Q1.9	List Key personnel Use current details – do not cut and paste from previous applications as details may have changed
Q1.9.1 Title	
Q1.9.2 Name	
Q1.9.3 Surname	
Q1.9.4 Provide the preferred email address	This will prepopulate from the project REGGStration
Q1.9.5 Is this person the contact person for the application	Tick this box for the person who should receive automatic notifications from the research office
Q1.9.5.1 Contact Email Address	
Q1.9.5.2 Contact phone number	
Q1.9.5.3 Provide the address to which any hard copy materials should be sent	Provide a workplace mailing address.

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Student Researchers

STUDENT RESEARCHERS	
Q1.9.6 Is this researcher a student on the Project	Answer "Yes" if this research is contributing to an educational or clinical qualification. HNE HREC requires an academic or clinical supervisor to be the lead investigator. If the academic supervisor is not at the local university (University of Newcastle), list the clinical supervisor as the lead investigator.
Q1.9.6.1 Describe the Supervisory arrangements, support and training	Name all clinical and academic supervisors as members of the research team. Include the title and name of the main supervisor(s), their qualifications, and a statement of their expertise and previous student supervision. Include details of any training the supervisors will provide to the student.
Q1.9.6.2 Identify the student's educational program	
Q1.9.7 Institutional affiliation and position	Specify the degree and the institution of enrolment of the student. Include details of any workplace positions relevant to the research project. The HREC will review the suitability of the student to complete the research, *with consideration of the support and training provided to them by Senior Researchers*

Key Personnel

KEY PERSONNEL

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Q1.9.8 Staff ID	n/a.
Q1.9.9 ORCID ID	Provide ORCID ID for all staff who have one
Q1.9.10 What is the position of the person of the research Project	There is one Co-ordinating Principal Investigator (CPI) for a project. There is a Principal Investigator at each site. Other research team members are listed as Associate Investigators or Investigators
Q1.9.10.1 Other	You may add administrative staff who require REGGS access here
Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?	**The CPI is the only team member with authorisation to sign the REGGS application** Answer “yes” for “Co-ordinating Principal Investigator” and “No” for all other researchers

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Q1.9.12 Describe the research activities the person will be responsible for	List the research activities the person will undertake. These may be: Protocol development Recruitment; Consent Data collection; Sample collection; Data analysis; Sample Analysis; Regulatory management; Investigational agent management; Clinical care of participant. List activities for each role the researcher has in the project. e.g. A CPI who is also a site PI will undertake different activities in each role. Include if this person will directly supervise students.
Q1.9.13 Describe the person's expertise relevant to the research activity	Include a summary of this person's expertise relevant to their role in the project. This expertise may be shown by qualifications, training, experience, skills. List only the major tertiary qualification, the rest will be included in CV. If an aspect of a researcher's background is relevant to the research (for example if they identify as Aboriginal and the project will be recruiting Aboriginal people or focusing on issue relating to Aboriginal people) then it should be mentioned here.

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Conflict of Interest

CONFLICT OF INTEREST	
Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?	Conflicts of Interest will not preclude a researcher from being an investigator. A conflict of interest is any association with the project, including in an advisory capacity. Conflicts of interest which are affiliations with sponsors need to be declared.
Q1.10.1 Explain the nature and extent of the interests and to which member of the team they apply.	Conflicts of interest may include: A researcher's other interests and responsibilities affecting the research Or An institution's other interest or responsibility affecting the research These interests or responsibilities may be private, professional or institutional. Conflicts may be financial, contractual, or other. Include all potential conflicts of interest here. In hospital and outpatient clinical care, the most common conflicts will involve the clinical care of a patient overlapping with the research participation of that patient. Researchers who have affiliations with sponsors may have a conflict of interest. Please refer to the Medicines Australia advice https://www.medicinesaustralia.com.au/community/health-consumer-advocacy-and-support/workingtogether-guide/learn-about-medicines-companies/#Governance_and_compliance_of_pharmaceutical_companies

Q1.10.2 Explain how you intend to manage these interests and any potential conflicts that may arise.	The HREC will consider which specific tasks the researcher is conducting in the project with respect to their conflict of interest. Include detail on how the conflict will be managed for this project.

Project Affiliations

PROJECT AFFILIATIONS	
Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?	List any limitations on the publication of the research results due to contractual obligations or institutional policies, e.g. embargos, commercial in confidence. NDAs. Include who owns the data (more detail is provided in Section 3.) For sponsored trials, these restrictions can be briefly described, and refer to the Clinical Trials Research Agreement (which will be reviewed for research governance purposes).
Q1.11.1 Detail the restrictions or limits on publication of data arising from the research project and explain how these will be balanced with relevant accessibility expectations	The HREC will consider the restrictions on the publication of data and the public availability of research results.

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Prior Review

PRIOR REVIEW	
Q1.12 Has the scientific or academic merit of the research project been evaluated	Include the outcome of any formal, independent reviews. The HREC will consider the outcome of any prior reviews for research merit. Including this information saves a repeat review of an existing robust review.
Q1.12.1 What was the review process and what was the outcome?	State details of the reviewing process and panel, and if this was part of a grant application. Describe any changes made or planned to the project based on this review.
Q1.12.2 Attach evidence of the outcome of the scientific or academic review process	
Q1.13 Has this research project had prior ethics review?	Include any ethical reviews in overseas jurisdictions. The HREC will conduct its own review but may consider any prior approvals when reviewing the project.
Q1.13.1 Which ethics committee previously reviewed the application	Give the full title of the committee here. If you are planning a CTN submission, the HREC review must be by an NHMRC Registered committee.
Q1.13.2 What was the outcome of the prior ethics review	
Q1.13.2.1.1 Attach evidence of the outcome of the prior ethics review process	

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Q1.13.2.2.1 Provide the ethics committee's reason/s for not approving the research project	Include a summary of the ethics review conclusion – you do not need detail here, as the review outcome is been attached in 1.13.2.1.1
Q1.14 Will any further or additional specialised review of this application be sought?	List any other review bodies this project will be submitted to. Research Projects may have additional, concurrent or subsequent review by specialty ethics committees (e.g. Aboriginal Health Ethics Committee or Department of Education) or institutional scientific committees.
Q1.14.1 Name of entity conducting specialist review	
Q1.14.2 Date	
Q1.15 Will this research project be conducted at multiple sites	Each hospital is considered a different site. Similarly, each school would be considered a separate site even if in the same Local Government Area.
Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?	Separate Governance authorisation is required for every Ramsay Hospital location conducting this research, even if this is a single-site study Some private sites have Governance procedures.

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Research Methods and Participants (important)

RESEARCH METHODS	
Q1.17 From the list below, select all the research methods that will be used in the research project **This question is critical to answer correctly**	Select every kind of research methodology your project will use. Once you select your methods in this question, the HREA generates additional questions relating to those methodologies. These questions allow you to provide relevant information so the HREC can review your project properly. A description of each methodology is included on the REGGS page. Select all that apply to your project, there may be more than one methodology used in your research. Action Research Action research is carried out in the field. This involves testing ideas in practice, and proceeds in a spiral of steps consisting of planning, action, and evaluation. This method includes design and implementation research in a 'rapid appraisal' research. Biospecimen analysis Research Chapter 3.2 of the National Statement describes biospecimens as, "any biological material obtained from a person including tissue, blood, urine, sputum; it also includes any derivative of these such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person." Data Linkage "Secondary use of linked administrative data. This is typically data that has originally been collected for another purpose. Linkage may take place across data sets in a single domain (i.e. health) or across domains (i.e. health, education, environment, early childhood, etc.)" If data linkage involves statewide or commonwealth data collections, then separate or alternative ethics approval will be required. Please discuss with the Research office.

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	<u>Ethnographic research</u> Ethnographic research is a description of everyday life and practice and the interpretation of cultural meanings, patterns and systems emphasising an 'insider's point of view'. Ethnographic research is usually participant-observation and the research questions are developed in collaboration with research participants. The result is an account of the people, place or institution with whom or with which the researchers have interacted. <u>Epidemiological research</u> "the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. <u>Interventional / clinical trials research</u> Interventional research is the use of substances, devices, treatments, therapies, techniques or processes in participants to determine the impact or effect. Interventions can be physical, behavioural, psychological or informational and can be used in clinical, educational or other contexts. Interventional research may: Be comparative, Randomise the participants, Include an experimental arm, and/or Include a placebo arm. <u>Observational research</u> Observational research involves observing participant/s in their own environment, or in the environment being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment. Note: Observational research also includes reviews of data where the aim is to observe outcomes. <u>Survey/interview/focus group research</u> Interviews involve researchers talking to one or more participants, where the categories of response are focused but not necessarily pre-determined.

	Focus groups of participants discuss a set of research questions or topics. The researcher may act as a moderator for the discussion. This method includes research using oral history. <u>Textual analysis research</u> Textual analysis may involve evaluation of texts including film, television, photographs, magazines, advertisements, clothes, graffiti and other media. This method may include the study of content or specific language and its frequency (e.g. hermeneutics or linguistic analysis).

Q1.18 Indicate with whom or with what the research will be conducted **<u>This question is critical to answer correctly</u>**	Select the appropriate box from the definitions included in REGGS. Once you choose an option, the HREA generates additional questions. These questions allow you to provide relevant information so the HREC can review your project properly. **"Human Beings (via active participation) including their associated biospecimens and or data"** Select this option for research where participants of individual human beings will occur – including by physical investigations, psychological investigations, interactive communication, being photographed, completing a questionnaire, or any research activity that requires the human mind or body to participate. Do not select if coronial material is the primary component of your research. If you are using biospecimens that <u>you will collect</u> from a participant in your study, select "Human beings by active participation". **NOTE:** Human Beings must also be ticked if you are seeking a waiver of consent so the relevant questions (2.8 and 2.8.1) will generate **"Human Biospecimens Only"**

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	Select this option if coronial material is the primary component of your research. Do not select this option if biospecimens are to be collected prospectively. Do not select this option if biospecimens are to be collected in conjunction with other active participation. **"Data Associated with human beings only"** Do not select this option if the data will be collected prospectively. If you are using data which will be collected after the commencement of the study, select "Human beings by active participation" and request a waiver of consent at question 2.8 If you choose "Human Biospecimens Only" or "Data Associated with human beings only", recruitment questions will not open. In this case, refer to these sections of the HREA: Consent, Data and Privacy.

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Q1.19 Will your research involve participation of any of the following. **This question is critical to answer correctly**	Select every kind of participant your project will recruit. Coincidental recruitment of people in any of these above categories does not require you to select this option. This question is critical to answer correctly. Once you choose an option, the HREA generates additional questions. These questions allow you to provide relevant information so the HREC can review your project properly. A description of each group is included in the National Statement, Chapter 4. Targeted recruitment of a group of people is considered to "involve participation", and you should select this group. Women who are pregnant and the human fetus Children and young people People highly dependent on medical care who may be unable to give consent People with a cognitive impairment, intellectual disability or mental illness People in dependent or unequal relationships People who may be involved in illegal activities (*Note, this group is only for projects which are designed to expose illegal activity. E.g. a drug and alcohol study may collect information on illicit drug use, which is an illegal activity*) People in other countries Aboriginal and Torres Strait Islander peoples Where the project is about a disease which is prevalant in a particular group, that group should be selected. For example, aboriginal children have higher rates of otitis media than non-aboriginal children. A study of otitis media should select "Aboriginal and Torres Strait Islanders" to reflect the greater proportion of Aboriginal or Torres Strait Islander participants who are likely to be offered this research than the general population. In locations where there is a higher proportion of Aboriginal and Torres Strait Islander people than the general population average, consider whether your project may recruit a higher proportion of Aboriginal and Torres Strait Islander people. If this is the case, contact the Research Office for advice.

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M1 Action Research

Action Research	
M 1.1 What is the challenge, need, phenomenon or question that the research will explore?	Clearly state the scope and focus of the research. Set boundaries on the research project and the focus of concern.
M 1.2 What process/es will be used to refine the objectives and design of the research, and how frequently will this be repeated during the project?	Set out the research plan including the methods, sequence and/or steps that will be undertaken to conduct the research. How will you manage the project data in a systematic, valid and reliable way? These methods should connect – observations, followed by focus group and then perhaps in-depth interviews – with each step providing the necessary data to form a clear picture of the situation to plan a response or "action".
M 1.3 What outputs do you anticipate will be generated by the research?	Describe how the outcomes of the research will be implemented. These may include implementing a new policy, training, procedural changes, adoption of different resources
Q2.1.M1.1 Describe the co-researchers for your project and how they will be identified, approached and added to the cohort.	Often action research will involve the development of a research team within the context of research. Describe how you predict the research team will evolve over the course of the project. Include your process for adding expert advisors as the project iterates.

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M2 Biospecimen Analysis Research

Biospecimen Analysis Research	
M 2.1 What type/s of human biospecimen/s will be collected and used?	List the specific specimens you will use
M 2.2 Will you be collecting biospecimens prospectively?	If you answer no here, no recruitment questions will open
If answer Yes Q 2.2.1 How, and from whom, will you be obtaining these biospecimens	Include if these specimens will be obtained during routine clinical care or if the participant will require an additional procedure or study visit.
M 2.3 Will you be using biospecimens from one or more existing archives or biobanks?	Specimens that are in the hospital laboratory meet this criteria
M 2.3.1 Name of archive or biobank	
M 2.3.2 Do you have confirmation you can use the specimens	
M 2.3.3 Is your use of the biospecimens consistent with the consent obtained at the time the biospecimens were collected?	Bio-specimens collected for routine health care would not usually have consent for use in research. If no, you will need to consider requesting a waiver of consent (see question 2.8.1)
M 2.3.3.1 Attach any available evidence of the consent obtained at the time the biospecimens were collected	You may have an example of previous consent document used. If the HNE HREC approved a previous research project to use these samples, we do not need to see this consent again as we have a copy on file. If this is the case, note the reference in M2.3.3.

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M 2.4 Will you be importing and/or exporting biospecimens internationally?	
<u>If imported</u> M 2.4.1.1 What is the source of the biospecimens?	
M 2.4.1.2 Do you have confirmation that you can access the biospecimens?	
If yes M2.4.1.2.1 Who provided the confirmation?	
M2.4.1.2.2 Attach evidence of the confirmation	
M2.4.1.3 How will you ensure that the research meets the guidance provided in National Statement 3.2.7 and, if applicable, National Statement 3.2.10 regarding the use of imported biospecimens?	Provide evidence the specimens were collected according to an ethical review of equal standing to an Australian HREC review.
<u>If exported</u> M2.4.2.1 Name of entity to whom the biospecimens are being exported.	
M2.4.2.2 Location of the entity to whom the biospecimens are being exported	

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M2.4.2.3 How will you ensure that the research meets the guidance provided in National Statement 3.2.9 regarding the exportation of biospecimens?	Provide evidence the specimens will be used according to the ethical review in Australia and the overseas jurisdiction will has ethical review. Address the exportation of bio-specimens in the Participant information sheet.

M2.5 Will you be obtaining post-mortem biospecimens?	If you answer yes, you are accessing coronial materials. Ensure this information is included in the PISCF.
M2.6 Will you be performing any genetic or genomic testing, investigation or analysis of the biospecimens?	Include information on genetic testing which may provide hereditary information and the considerations for distribution of this information to participant and family members Ensure the PISCF describes the following: The type of genetic/genomic testing Possible results generated from the genetic/genomic testing The potential for uncertain results The plan for giving results and possible implications of the results, both for the participant and their biological relatives The plan for genomic data protection/security Ensure the appropriate type of consent is used (e.g specific to this project? covering an extension of this project? covering further research studies on the same area of medicine as the original? Consent to store sample &/or data for future unspecified research? Dynamic consent?

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M2.7 Will the biospecimens be destroyed at the conclusion of the project or will they be retained for future use?	Include information regarding the identification of the samples that will be held and if they are reidentifiable. Describe the sharing of any samples or sequences with other researchers, and confirm that any sharing plans are described in the Information Sheet and Consent Form. Describe any planned re-analysis of the samples.
<u>If destroyed</u> M2.7.1.1 How will the biospecimens be destroyed?	
<u>If retained</u> M2.7.2.1 Describe which biospecimens will be retained, any intended future use/s and any arrangements for future access to the biospecimens?	Describe any planned and unplanned future use of the samples and what approvals will be required. Describes if the samples are to be stored in a biobank. If a biobank or other sample collection/repositories are used, what approvals and governance are in place (ie is there a process for other researchers accessing the samples

M2.8 Having regard to the answers to the above questions, describe any ethical considerations related to your collection, use and analysis of biospecimens.	Genetic and genomic testing can offer many results. In answering this question, please list the results you are proposing to generate from your testing. Describe your ethically defensible plan for your choice to return results to participants or not. **If results are to be returned to participants**: Describe how you will seek consent from participants to receive their results. Describe the health significance of any known pathogenic variants you anticipate generating, for the research condition you are studying, and other diseases that may become available through your testing. Describe the clinical actionably of the results you anticipate generating. Confirm the NATA accreditation of the laboratory. Include if your testing will reveal genetic pre-dispositions to the disease you are studying Include if your testing will reveal variants of unknown significance, and if so, how you will manage this data Describe your plan for managing results that indicate misattributed paternity or maternity.

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	Ensure your PISCF includes adequate information regarding: The possible implications for other biological relatives. The possible implications for personal insurance products (e.g life insurance). The participant's choice to receive results, and the option to change this preference. Detail your plan for returning results to participants: Include the qualifications of the person giving the results. Describe the process to refer participants to a genetic service. Outline the psychological support available if the results cause the participant distress. **If results are not being returned to participants** Describe the de-identification of samples and associated data to protect privacy **If your research involves specific ethic groups** Describe your engagement with appropriate community representatives. If participants do not speak English, provide translation of research findings. **If your research includes children** Describe what will occur when those participants reach the age of majority (18 years of age in Australia)

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M3 Data Linkage Research

Data Linkage Research	
M 3.1 How will your research/findings account for any limitations arising from your choice of data sets/databases or from missing data?	State the plan to address these limitations in your analysis.
M3.2 How will you control for confounding factors or other vulnerabilities toward bias in your research?	Address any biases that may occur due to incomplete datasets.
M3.3 How will you manage any risk that linking databases of non-identifiable data could subsequently result in the individuals being identified?	Describe contingency for research of rare diseases, where the amalgamation of many data sets (including location data) may create a situation where an individual with a rare disease can be identified

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M4 Ethnographic Research

Ethnographic Research	
M4.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction?	Provide information on how you will include and exclude observed persons from your research so only the intended persons will be included as participants. Include information on how participants will be advised they may be observed, and how they can request that such observations do not proceed or cease. Include any documentation or scripts used

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M5 Epidemiological Research

Epidemiological Research	
M5.1 What population/s will be studied?	Describe the population in detail Advise whether or not consent will be obtained. Note a request for a waiver of consent will be need to be made at question 2.8.1 if consent is not to be sought. Justify the collection of any diversity data (e.g. aboriginality, marital status) which is not directly related to your primary outcomes.

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M6 Interventional Clinical Trials Research

Interventional Clinical Trials Research	
M6.1 Briefly describe the intervention/s that you will be using	Keep this as short as you can – this information will also appear in Q1.2.
M6.2 Is your intervention related to the prevention, diagnosis, treatment or management of a health condition?	
M6.2.1 Do you consider that you are conducting a clinical trial?	Use the definition provided in REGGS. The World Health Organisation defines a clinical trial as: "Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes".

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M6.2.1.1 What does the clinical trial involve the use of?	<u>If drug</u> Provide information on the current use (including dose) and the current jurisdictions where the drug is approved. Any approvals for groups of countries (e.g. EMA) do not require a listing of individuals countries Include IND number (or equivalent), for any prior regulatory review and approval <u>If device</u> Any approvals for groups of countries (e.g. EMA) do not require a listing of individuals countries Include regulators identification number (or equivalent), for any prior regulatory review and approval <u>If Xenotransplantation</u>, Xenotransplantation ha unique risks and ethical concerns. Contact the research office for detailed advice for this research

Drug Details	
M6.2.1.1.1.1 – M6.2.1.1.1.17	Include details that are currently known about the drug Enter as many drugs as are to be used in the trial
Device Details	
M6.2.1.1.2.1 – M6.2.1.1.2.14	Include details that are currently known about the device Enter as many devices as are to be used in the trial
Xenotransplantation	

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Describe the ethical considerations related to your xenotransplantation research and your strategies for addressing and managing these issues?	Xenotransplantation has potential for very high risk to the participant. Refer to NS chapter 3.4 and address each part in detail. Contact the research office for detailed advice due to the unique nature of the risks in this research Refer to the following legislation and regulations: The Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition, 2013, Gene Technology Act 2000, Research Involving Human Embryos Act 2002, Prohibition of Human Cloning for Reproduction Act 2002
Attach an ethically defensible plan for the management of risks related to xenotransplantation research	Include consideration of the list in Section 3.4.5 of the National Statement, parts a) to i)

General Questions	
M6.2.1.2 Does the clinical trial differ from standard care?	
M6.2.1.3 Will trial participants be exposed to ionising radiation to which they would not have been exposed to if they did not participate in the trial?	If yes, submit an application for review by the radiation safety committee. This committee will submit a report to you and copy the research ethics office. The report will state how much additional radiation the participant is exposed to by their participation in the research study, and will give a suggested wording to include in the PICF. Note: there will need to be a radiation safety review for each study site. If the reviews from different sites stipulate different risks, these wordings must be included on the PICF, and listed as as alternate wording on the MASTER PICFs

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M6.2.1.2.4 Will your clinical trial be conducted under either the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?	The CTN / CTX notification will be managed by the trial sponsor. If HNE Local Health District is the Sponsor of the trial, the TGA submission will be prepared by the clinical trial coordinator and submitted through the HNE Research Office. Contact HNE Research Office for drafter status in the TGA business portal if you don't already have this
M6.2.1.2.5 Who is the sponsor of the clinical trial?	For commercial trials, the Sponsor will usually be a pharmaceutical company or its nominated Clinical Research Organisation (CRO) For Investigator Initiated trials, the LHD may be the sponsor
M6.2.1.2.6 Provide the following details for each site where the clinical trial will be conducted.	List all known sites where the trial will be open in Australia If the trial will operate in other countries, list the names of the countries, the number of sites within that country and the International PI in the "Person Responsible" box e.g. "France 17 sites" and "Title First Name Surname"
M6.2.1.2.7 Select the phase or class of your clinical trial.	
M6.2.1.2.8 Has this clinical trial been Registered on a Primary Registry in the World Health Organization Registry Network?	
M 6.2.1.2.8.1 Do you want to Register your trial with the Australian New Zealand Clinical Trials Registry (ANZCTR) now?	

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M6.2.1.2.9 Do you intend to make the trial intervention available to participants after the completion of the trial?	
M6.2.1.2.10 Explain how and when participants will be informed about post-trial access to the trial intervention	Note: it is not mandatory that participants can access the therapy/device/drug after the trial, just that they are aware of what will happen after the project completes. Include confirmation if this information is included in the Participant Information Sheet
M6.3 With regard to your answers above, describe any ethical considerations related to your use of the intervention/s in this research project and your plans for addressing these issues.	Justify the access or lack of access to the trial intervention after the end of the trial here. Also include any mitigation strategies if the participants are disadvantaged if they cannot access the intervention, particularly if they have benefitted from it.

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M7 Observational Research

Observational Research	
M7.1 What type of observation will you be conducting?	Describe the observations you will use. noting: If the researcher will interact with the participants, The proposed length of time of the observations, The setting of the observations, The technology used to conduct and record the observations, whether there may be other people present at any stage of the observation period, and how this will be managed, including informing bystanders of the observation and allowing for them to request that the observations cease
M7.2 What sampling strategy will you use?	Describe how you will ensure those you observe are representative of the population you are studying
M7.3 How will you match and follow up participants?	Describe how you will identify participants if your research has temporal observations or occurs in more than one location.
M7.4 How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias?	There are many biases, but you may consider Selection, Measurement, Confounding, Recall, Misclassification and Reporting bias

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M8 Survey / Interview / Focus Group Research

Survey/Interview/Focus Group Research	
M8.1 What process/es will your research project use?	Select each type of research you will conduct: Survey, focus group, interview or any combination of these methods
M8.2 How will you engage with your participants?	Include list of questions or interview prompts to be used as attachments - described the focus of the question and list standard instruments to be used Include details of any electronic recording of participants Specify who will be interacting with participants, and recording their responses
M8.3 How will personal identifiers be retained or removed over the course of your project?	Specify how you will store the data and if you will de-identify it. Define when your participant identifiers will change. Specify which research members will have access to the identified data, and who will have access to deidentified data.
M8.4 Will participants have the opportunity to review or edit their responses or contributions prior to data analysis or publication?	If review and edit of responses will not be offered, explain why it cannot be, and why it is important to retain the survey, interview or focus group responses as they were originally provided.
M8.5 Is it foreseeable that your project will explore topics that may cause distress for participants?	Identify the risks and include mitigation strategies and include information regarding how you will offer support to participants. This may be by research team members if they are trained to offer this support, or may be referral to external support services or a combination of both.

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M9 Textual Analysis Research

Textual Analysis Research	
M9.1 In what way do you consider your research to be human research?	Include information on how the text will be associated with a specific human being. Include the source of the text, how the text will be obtained and how the text will be stored so it is not changed by the process of analysis.

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P1 Pregnant Women and the Human Fetus

Pregnant Women and the Human Fetus	
P 1.1 Who will the research involve?	Clarify if fetal tissue includes the placenta in your project
P1.1.1 Explain why there are no suitable alternatives by which the aims of the research can be achieved, as required by National Statement 4.1.12.	The separated Human fetus or fetal tissue – describe how your project can only meet its outcomes by researching the human fetus, and not another type of participant. Women who are pregnant and the human fetus in utero – describe how your project can only meet its outcomes by researching women who are pregnant and the human fetus in utero.
P1.2 Is there a foreseeable impact on the fetus in utero?	Address this in the risks section of HREA. If there is any risk to the fetus, outline your mitigation strategies to reduce this risk.
P1.3 How will the wellbeing of the pregnant woman and fetus be managed?	Include both clinical and emotional wellbeing.

P1.4 Describe any arrangements for counselling that will be provided or made available to the women	Include details of counselling by adequately trained members of the research team, and any external services that will be offered (by self referral or formal referral)

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P1.5 How will you ensure that the research meets the guidance provided in National Statement 4.1.20 regarding the information that should be provided to female participants?	Describe the consenting process in detail. Show that the information provided to the participant includes information listed in 4.1.20 a) to f) regarding Whether she may seek the consent of any other person The storage of tissue Withdrawal of consent before or after the fetus leaves the body Whether there is planned development of cell lines That there will be no profit sharing for any commercial applications Whether tissue or stem cells will be exported to another country
P1.6 Will the research involve the removal of organs or tissues from fetuses that have been delivered dead?	
P1.6.1 How will you ensure that the research meets the guidance provided in National Statement 4.1.22 regarding the removal of organs or tissue from a fetus?	Provide information specifically regarding the process of research for a fetus that has been delivered dead
P1.7 Will fetal cells be derived from fetal tissue and stored or propagated, or will the tissue or cells be used for human transplantation?	
P1.7.1 How will you ensure that the research meets the guidance provided in National Statement 4.1.23 regarding obtaining consent for this derivation or use?	If your project will derive cell lines or tissue or cells will be used in human transplantation, describe this process. The HREC will seek specialised advice to review this research project.

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P2 Children and Young People

Children and Young People	
P2.1 How will the children or young people participate in this research?	List all the ways children will be involved. Describe whether their parent(s)/guardian will be present during the research activities and if not, justify this.
P2.2 Explain how the research is likely to advance knowledge about the health or welfare or other matters relevant to children or young people	Describe how this research will provide results relevant to children and young people.
P2.3 Explain how the children's or young people's participation is indispensable to the conduct of the research.	The HREC will review your project with respect to whether this research could be achieved in participants who are not children. If this is the case, the project should not include child participants. *Some circumstances the research may need to include children are* This project is researching a disease that occurs in children Testing whether a drug regimen may be appropriate for a paediatric population Assessing the health service experience of children For clinical trial, include if this project is part of a Paediatric Implementation Program
P2.4 How will you ensure that the children's and/or young people's safety, emotional and psychological security and wellbeing are protected?	Address how you will risk mitigate for the safety of children and young people as they participate. Include information for participants of all ages, with regard to the evolving capacity of a participant to understand and consent as they progress through childhood and adolescence. Include information for participants in long term studies whose needs will change over the course of the project, and who may attain Age of Majority during the research project timeframe.

P2.5 How will you establish that participation in the research is not contrary to the best interests of the children or young people?	Your response should demonstrate that the research has been designed to minimise the risk to the child participants and that involvement in the research will not be to the childs' short term or long term detriment

P3 People Highly Dependent on Medical Care

People highly Dependent on medical care	
P3.1 Who will the research involve?	People receiving neonatal intensive care People receiving intensive care People receiving emergency care People receiving end-of-life care People who are unconscious
P3.2 Describe how the research will be minimally invasive or provide a therapeutic benefit that is related to the participants' condition	Refer to the primary outcomes of the study and demonstrate that the person's clinical care will not be compromised by their involvement in the research
P3.3 Describe how the research will lead to increased understanding about, or improvements in, the care of people receiving this type of medical care or who are in this condition	State the outcomes you hope to achieve in your project and the information this may provide for future clinical care.

P4 People with a Cognitive Impairment, an Intellectual Disability or a Mental Illness

People with a cognitive impairment, an intellectual disability, or a mental illness

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P4.1 Who will the research involve?	People with a cognitive impairment People with an intellectual disability People with a mental illness
P4.2 How will the research project accommodate people with a cognitive impairment, an intellectual disability or a mental illness?	Include information on specific support provided through the consenting process. Note this does not have to be person to person support, but it could be simplified recruitment documentation or alternative information via video etc)
P4.3 How will the participants' degree of cognitive impairment, intellectual disability or mental illness be assessed?	Name members of the research team who will assess participants. Refer to their training, experience and education which makes them suitable for this task(including expertise in using screening assessments).
P4.4 How will you assess whether participants' cognitive impairment, intellectual disability or mental illness increases their susceptibility to discomfort or distress?	Name the members of the research team who will assess participants. Refer to their training, experience and education which makes them suitable for this task (including expertise in using screening assessments).

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P5 People in Dependent or Unequal Relationships

People in dependent or unequal relationships	
P5.1 Describe any potentially detrimental effects on people in dependent or unequal relationships who may participate in your research, and how will you manage them.	Many people accessing health care are in dependent or unequal relationships. In many cases, the Researcher/Participant relationship may be unequal, particularly if there are extensive study activities incorporated in clinical care. There needs to be clear information about all aspects of the research and sharing of knowledge and decision making between the research team to mitigate this. Describe these expected relationships and provide a plan for managing them to protect the participant from harm.

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P6 People Who May be Involved in Illegal Activities

People who may be involved in illegal activities	
P6.1 Is the research designed to discover or expose illegal activity?	
P6.1.2.1 Does the illegal activity bear on the discharge of a public responsibility or the fitness to hold public office?	
P6.2 Will you or your institution have a legal duty to disclose information about illegal activity that is discovered?	Refer to the Crimes Act 1900, Section 316 Include reference to research staff who may be mandatory reporters and how this will affect their duty to disclose illegal activities.
P6.3 Will you have contact, in a professional role, other than as a researcher, with people who may be involved in illegal activities?	
P6.3.1 How will you ensure that the research is not compromised by contact in that professional role and that obligations to participants related to that role will not be compromised by the research?	Declare as COI and describe plan to protect participants and researchers. Name the research team members who will complete each task to minimise the risk.
P6.4 Will the research involve participants who are subject to criminal justice processes?	

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P7 People in Other Countries

People in other countries	
P7.1 How will local cultural values be acknowledged and reflected in both the design of the research and the conduct of researchers?	Name the researchers in other countries who will act as co-researchers, and describe their involvement in planning the research protocol to suit their country
P7.2 How will the design of the research take into account local power relations, inequalities and divisions?	Name the researchers in other countries who will act as co-researchers, and describe their involvement in planning the research protocol to suit their country
P 7.3 Ethics Review Process	List the Committees and the National ethics guidance of that country
P7.4 Describe any factors that may make it problematic to conform to ethical standards expressed in the National Statement and what steps will be taken to address these matters.	Refer to how the safety of participants will be considered where the NS is not in effect
P7.5 Do you plan to engage individuals from any country in which the research will be conducted to help conduct the research?	
P7.5.1 Who do you intend to engage and how will you employ them?	
P7.5.2 How will the capacity and expertise of these individuals to conduct the research be assessed?	Include proof of education, training and experience.

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P7.5.3 How will you ensure that these individuals conduct the research in a manner that accords participants no less respect and protection than the National Statement requires?	Describe the relevant human rights instruments in these jurisdictions.
P7.6 To whom will participants direct any questions, concerns or complaints about the research?	Provide local contracts for each country where this research will be conducted
P7.7 How will you engage with participants and their communities with respect to their expectations of the research project?	Refer especially to first nations peoples
P7.8 How will you manage these expectations in light of any resource limitations of the research project?	Declare how you will advise participants of any resource limitations.

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P8 Aboriginal and Torres Strait Islander Peoples

Aboriginal and Torres Strait Islander Peoples	
P8.1 How have you considered and addressed local Aboriginal and Torres Strait Islander cultural values in the design and conduct of this research?	Refer to any consultation with local Aboriginal and Torres Strait Islander groups, and any liaison with the Aboriginal Health Unit. Determine whether the NSW Aboriginal Health Impact Statement is required Indicate what cultural safety measures will be in place.
P8.2 Describe the process that will be used to satisfy the requirements for community consultation, engagement and governance that apply to your research?	Please follow the relevant guidance at: https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-straitislander-peoples Ensure you consult with the local communities that will be participating in your research and an requested agreements are in place
P8.3 List any relevant ethics guidelines that you have consulted during the development of your research project	Include which NHMRC policies you have used Please see: https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-andtorres-strait-islander-peoples)

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Section 2: Recruitment

RECRUITMENT	
2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant sections of your Project Description/Protocol as appropriate.	Different groups of participants may be recruited in different ways. Include information for each different group separately. Include details for: How the potential participant will be identified, and by whom. How the potential participant will be approached, and by whom. What documents will be used How and when these documents will be provided to the potential participant How much time the potential participant will likely have to review the documents. Who they may ask questions. How and when those documents will be signed Who will conduct each of these parts of recruitment Specify any existing relationships between the potential participant and the researcher and if so, how you will reduce the potential for coercion. Justify excluding groups of potential participants. e.g. if you have an age criteria to participate, justify this exclusion in terms of access to research and generalisability of results. If you exclude people who communicate in languages other than English, justify this exclusion in terms of access to research for CALD people, people with disabilities. State if you plan to include a certified translation of the PICF for CALD participants. Note if you are requested a waiver of questions this should be indicated in the responses from 2.1-2/2/7 as the justification is given at 2.2.8

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If you are conducting Action or Ethnographic research, extra questions will open here	
Q2.1.M1.1 Describe the co-researchers for your project and how they will be identified, approached and added to the cohort.	Name the group from whom the researchers will be accessed.
Q2.1 M1.2 Will there be any participants or stakeholders involved in your research who will not be researchers?	
Q2.1.M7.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction?	Include how people will be aware the research is occurring and how they can decline being involved. Can non-participants ask for any research activities to cease and how will that be done.
Q2.1.M7.2 How will you determine whether it is appropriate to obtain consent from the people whom you are observing?	Consent is necessary if a person's presence or activities are contributing to research activities If you record or analyse the presence or activities of a person, they have become participants in your research.

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2.1.2 How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?	The response at this section should be detailed. Ensure you address sections 3.1.12 to 3.1.22 of the National Statement Describe the exclusion of any groups of participants and justify this exclusion Include any potential coercion of people and how you will address this. <u>Refer to specific groups of people you are recruiting</u>: Women who are pregnant and the human fetus Children and young people People highly dependent on medical care who may be unable to give consent People with a cognitive impairment, intellectual disability or mental illness People in dependent or unequal relationships People who may be involved in illegal activities People in other countries Aboriginal and Torres Strait Islander peoples <u>Other groups not specified in the National Statement include</u>: Culturally and Linguistically Diverse people – address access to interpreters and culturally appropriate consenting practices. People with physical disabilities - accessibility issues and consideration of time to complete assessments People with communication disabilities – including deaf persons and those with speech and language disorders.

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Section 2: Consent

CONSENT	
2.2.1 Indicate by reference the relevant section/s of your Project Description/Protocol that address/es consent.	Include a summary of the recruitment and consent process, addressing Sections 2.2. and 3.1.23 to 3.1.39 of the National Statement Information the committee will be looking for includes: Who is being consented: participants, parent/guardians, children, incapacitated persons. How potential participants with additional cultural or accessibility needs will be supported. Those who identify as Aboriginal or Torres Strait Islander, cultural and linguistically diverse backgrounds, people with communication disadvantage. The first approach to a potential participant is someone they would usually interact with in (for example receptionist or treating clinician at a clinic). The person who answers questions about the research and obtains consent has no clinical or other power relationship with the potential participant.
Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research?	
Q2.2.2.1 What is the scope of consent that you will be seeking?	**Specific - for this project only** Specific consent is limited to this project only **Extended** Extended consent refers to consent for this current study and future research that is closely related to this project **Unspecified** Unspecified consent is given to the use of data or tissue for any future purpose
Q2.2.2.2 How will consent be obtained?	Consent does not have to be written to be valid

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Q2.2.2.3 Are you proposing to obtain consent using limited disclosure?	This is only allowed if a case has been made in the application that the research cannot proceed without limited closure (see section 2.3.1-2.3.4 of the National statement). These issues need to be address in the protocol as well as the HREA.
Q2.2.2.3.1.2.1 How will you ensure that the research meets the guidance provided in National Statement 2.3.2 regarding the use of limited disclosure with active concealment or planned deception?	Address each point in the National Statement 2.3.2.
Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?	Some groups with specific considerations: *Women who are pregnant and the human fetus* These participants may have additional persons who have an interest in the protection of the fetus *Children and young people* Education research may include the community or school *People with cognitive impairment* A guardian or person authorised by law to act on this persons behalf *People in dependent and unequal relationships* Ensure especially vulnerable or powerless participants are supported and offered patient advocates if necessary Of additional importance are participants who experience more than one vulnerability. Address all additional protections for these people, including reference to the additional risk.

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Q2.2.3.1 Outline the family members, authorised representatives or others that will be involved in the decision to participate in the research and the extent of their involvement.	Include how you will invite these people to the consenting process.

Q2.2.P1.P3.1 Will the process of providing information and obtaining consent from the participants be separate from obtaining consent for nonresearch purposes (such as for a clinical procedure)?	It is preferred these processes are separate.
Q2.2.P1.P3.1.1.1 How will you ensure that these processes are separate?	There may be some clinical research where it is impossible to separate these processes – address how you will ensure the consenting processes are differentiated and make clear what are solely research activities and which are necessary for clinical care This is particularly important for projects where a person may regain capacity to consent for themselves during the course of a project (for example in ICU or emergency care research where consent may have originally been obtained from someone other than the participant).
Q2.2.4 Will there be an opportunity to confirm or renegotiate consent during the research project?	
Q2.2.5 Has consent been obtained from participants for the use of their data in the proposed research?	

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Q2.2.5.1.1 How has consent for use (or secondary use) of the data been obtained?	Consent may exist as a legacy from another research project or via a biobank or Registry. Consent may also have been obtained at the time of the non-research use of the data.
Q.2.2.5.2.1 Explain why consent for use (or secondary use) of the data has not been obtained?	Possible scenarios include institutional policy or legal avenues to access data. You may be submitting approval for an opt our approach or waiver of consent.
Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.	Refer to the specific groups of people you are recruiting: *Women who are pregnant and the human fetus* Explain the issues of consent to removal and storage of tissue from the fetus. Explain the issues related to consent for propagation of cell lines. *Children and young people* Explain the process to include the child or young person in the consent to their research involvement. Specify the role of any authorized representative who may give consent. Explain the process you will follow if the child/young person and the authorized representative have differing views and how you will determine this. *People with a cognitive impairment, intellectual disability or mental illness* Explain the process you will use to ensure the participation of the person is not against their will. *People in dependent or unequal relationships* Explain how you will determine any existing relationships between researchers and participants. Explain how you will mitigate against these relationships during consenting process. *People who may be involved in illegal activities*

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	Explain how you will address full disclosure to potential participants regarding any requirements to report this activity if uncovered. *People in other countries* Explain how your consenting process will account for local practices including power dynamics. Explain the local factors that may affect the influence on the participants. Address any issues related to the understanding of the participants specifically due to language and cultural differences.

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Section 2: Alternatives to Consent

ALTERNATIVES TO CONSENT	
Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all participants?	
Q2.2.7.1 How will you ensure that the research meets the guidance for approving an opt-out approach, as listed in National Statement 2.3.6?	Detailed response Include how you will adhere to the requirements of the National Statement, and address each point in turn – section 2.3.6, parts a to i
Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants?	
Q2.2.8.1 How will you ensure that the research satisfies the guidance for waiving consent as listed in National Statement 2.3.10?	Detailed response Include how you will adhere to the requirements in the context of the project Address each point in turn – section 2.3.10, parts a to j
Q2.2.8.P6.1 How will you ensure that the research meets the guidance provided in National Statement 2.3.11 regarding waiving consent for research aiming to expose illegal activity?	Explain how you will protect the participant's privacy and protect the confidentiality of their data. Explain how exposing illegal activity justifies any risks to the participant.

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Section 2: Consent for Specific Groups of Participants

Ethnographic Research Consent

ETHNOGRAPHIC RESEARCH CONSENT	
Q2.2.M5.1 Describe how you will determine whether it is appropriate to obtain consent from people whom you encounter and intend to write about.	Have made comments about Action research above - do they also apply here
Q2.2.M5.2 Describe how and when you will obtain consent.	

Children and Young People Consent

CHILDREN AND YOUNG PEOPLE CONSENT	
Q2.2.P2.1 From whom are you obtaining consent?	
Q2.2.P2.2 Will the research involve the participation of any children who are not of sufficient maturity to consent?	
Q2.2.P2.3 Explain how the children or young people's capacity to consent will be judged.	Name members of the research team who will assess participants, and refer to their training, experience and education which makes them suitable for this task
Q2.2.P2.4 Describe how you plan to discuss the research project with children at their level of comprehension.	Name members of the research team who will assess participants, and refer to their training, experience and education which makes them suitable for this task

Q2.2.P2.5 Are you proposing to obtain consent using standing parental consent for the participation of the children or young people?	The answer to this will usually be No as this is usually relevant for education research Usually only used in education research - parent can consent for all school based research for the year This option is for education research only and will not be applicable for applications to HNE HREC

People Highly Dependent on Medical Care Consent

PEOPLE HIGHLY DEPENDENT ON MEDICAL CARE	
Q2.2.P3.1 Will some or all of the participants have impaired capacity to provide consent for participation in the research?	
Q2.2.P3.1.1 Are you intending to commence the research without prior consent from the participants or authorised representatives as per National Statement 4.4.13?	If this is the case then a strong justification is required: Explain how the research would be compromised if this did not occur Explain that the research poses minimal risk to the participants Explain that consent will be obtained at the first opportunity Explain that the participant or their person responsible can decline consent and research activity can cease at no detriment to the participant and the data collected about them will be destroyed
Q2.2.P3.1.2 How will you communicate with and obtain consent from the participants' carers, their families, their guardians and/or other responsible persons?	Name members of the research team who will assess participants, and refer to their training, experience and education which makes them suitable for this task
Q2.2.P3.2 Describe how the process of obtaining consent (or not obtaining consent) is consistent with the processes outlined in National Statement 4.4.9-14.	Name members of the research team who will take this consent, and refer to their training, experience and education which makes them suitable for this task

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People with Cognitive Impairment Consent

PEOPLE WITH A COGNITIVE IMPAIRMENT	
Q2.2.P4.1 Describe the process that you will use to determine a person's capacity to provide consent to participate in the research if that person has a cognitive impairment, intellectual disability or mental illness.	Name members of the research team who will assess participants, and refer to their training, experience and education which makes them suitable for this task
Q2.2.P4.2 Describe how the process of obtaining consent is consistent with the requirements outlined in National Statement 4.5.5-11 regarding having respect for participants with a cognitive impairment, an intellectual disability, or a mental illness.	Refer directly to the sections in the National statement

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Section 2: Risks

RISKS	
People Involved in Illegal Activities	
Q2.2.P6.1 How will you ensure that participants are aware of the likelihood that illegal activity may be discovered and any duty that you may have to disclose information about illegal activity that is discovered?	Declare any researchers who are mandatory reporters
2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.	This questions can be answered generally or specifically If risks are included in the research protocol and information sheets, you do not need to repeat this information here – include the sections of the protocol and PIS where this information is.
Q 2.3.2 Describe how these risks will be mitigated and managed.	This should specifically address all the risks identified at question 2.3.1.
People in Dependent or Unequal Relationships	
Q2.3.P5.1 How will you ensure that a person declining to participate in, or deciding to withdraw from, research will not suffer any negative consequences?	

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Section 2: Benefit

BENEFIT	
Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.	Usually a research participant will not benefit in any way from participating in research Benefits should never be overstated and preferably be circumspect
Q2.4.2 Explain how the benefits of this research justify any risks or burdens associated with the research.	In this contexts the focus is on the wider Benefits of the research (not just to the individual participants)
Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?	This should refer to both written information and verbal discussions

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Section 3 Data and Privacy

DATA AND PRIVACY	
Q3.1 Indicate the type of information/data you will be collecting for this project.	The collection of data may be from a participant or from other sources, including publically available databases and websites, and information gained through surveillance technology. *Health information is a subset of sensitive information* *Sensitive information is a subset of personal information* Select the information that is the most accurate i.e. if you select sensitive information, this automatically includes personal information Definitions can be found in the Privacy Act 1988
Q3.2 Indicate the type of information/data you will be using in this project.	As above
Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.	These levels of identifiability may change depending on the group you are researching. In particular, smaller groups of participants (e.g. small populations of people, or participants with rare diseases), are more easily identifiable in context. Different people may also be able to infer the identity of a participant. For example, other participants may know the identity of a participant, where researchers cannot.
Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.	As above

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Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.*	Describe how the data will be accessed if it has been collected for another purpose. Describe who will access data with identifiers. Describe how the identifiers will be removed. Describe who will have access to non-identifiable data and how that will be controlled. Address the contingencies to prevent data breaches. Address the ramifications of a data breach on the participants – refer to psychological, physical, economic and reputational
Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.	Tick boxes
Q3.6.1 Has the data custodian/s, if any, agreed to provide access to the data for use in the proposed research?	A data custodian is the person who currently owns the data you wish to use. Unit level data in HNE has a separate approval process, and will be covered in governance review. If this approval is pending the HREC review, select “Data custodian has not provided approval”
Q3.6.2 Provide any supporting letter or material. Optional	Attach any relevant supporting document from data custodian/s
Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question	List the manner in which you will seek consent for the use of the data. Consider consent from both the participant and from the data custodian.

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Q3.8 Was the information/data that you are using previously collected for a purpose other than research?	Most health data has been collected for the purposes of health care.
Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.	Health workers with access to the HNE medical record do not have approval to access health data for other purposes. If your project will use health data for a research purpose, describe the reasons here.
Q3.9 Do you plan to disclose any personal information/data in this project to a third party?	
Q3.9.1 To whom do you plan to disclose the personal information/data?	
Q3.9.2 Describe how you will protect the privacy of the participants and the security of the personal information/data that you will be disclosing?	
Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?	
Q3.11 Are there any restrictions on your ability to assure the confidentiality of the participants?	Yes / No This may not apply if you do not have a duty of care. If this is case, select no

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Q3.11.1 Describe how you will explain to participants the restriction of on your ability to give them an assurance of confidentiality	Refer to the PIS where you advise the participants Explain the process by which you will explain this, including who will give this information and the location and timing of this conversation. Specify the scenario in regards to ensuring no coercion is applied

Q3.12 Do you plan to share any individual research results obtained during this research to the participants	Yes / No
Q3.12.1 Describe any ethical considerations relating to the sharing of individual research results with the participants	Consider results which form part of the medical record Consider results which may have any impact on clinical care Consider results which may impact on blinding in clinical trials Consider results which may jeopardise a placebo controlled trial
Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information / data	Consider findings of clinical relevance
Q3.14 Describe how the information/data will be stored, accessed, archived and /or destroyed	Note how long information / data will be held Note how information / data will be destroyed State who will have custody of the data if it is stored Note the location and governance of the archive Include reference to internal policies / procedures governing data access Research data may be sent to other jurisdictions outside Australia. If you research data will be sent outside Australia, address the security and governance processes for the data transfer and storage.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information / data in this project	Research data may be sent to other jurisdictions outside Australia. If you research data will be sent outside Australia, address the security and governance processes for the data transfer and storage.

Q3.16 Will the outcomes of this project be disseminated to the participants?	
Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants.	
Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.	
Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.	

Section 4 Document Uploads

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Document Uploading	
Q4.1 Attach the Project Description/Protocol to your HREA.	
Q4.2 Are there any other relevant documents associated with conducting your research project?	
Attach any other relevant documents associated with conducting your research project.	Choose from the categories available. If you have separate documents for separate groups of participants, load these separately.
Version Control	All documents except the HREA require version control. List this information in the footer of the document and include the following as a minimum: Project Name | Document Name | Version Number | Date e.g. TEST PGISCF Master V1 15SEP2021 TEST PGISCF Site V1.1 15SEP2021 TEST Protocol V3 15SEP2021 TEST Budget 2021 TEST Exercise Diary V3 15SEP2021

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Naming Conventions	Name your documents in a consistent manner. The file name, document name and information in the footer should all match. Use the following suggested shortened phrases for participant documents: PIS – Participant Information Sheet PCF – Participant Consent Form PISCF – Participant Information Sheet & Consent Form PGIS – Parent Guardian Information Sheet PGCF – Parent Guardian Consent Form PGISCF –Parent Guardian Information Sheet and Consent Form Adolescent IS – Adolescent Information Sheet Child IS – Child Information Sheet Version control should be incorporated into the document name, including version number and date e.g. TEST PGISCF V1 15SEP2021 Name documents without version numbers in reverse order so they fall sequentially when filed. e.g. "TEST CoC 2021", "TEST CoC 2022", TEST CoC 2023"
Category to Choose	Select from the drop down list. If you have a combined Information Sheet and Consent Form, use either category. Note – you should almost never need to use the "Other" category
Q4.3 Attached Project Registration form	

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Section 4 HREC

HREC	
Q 4.3 Select the organization that hosts the HREC or other review body	Choose from drop down
Q4.4 Select the HREC or other body to which you are applying from the list below.	Choose from drop down
Q4.4 Select the HREC or other body to which you are applying from the list below.	The Low and negligible risk pathway is used when the risks of the project are not more than discomfort or inconvenience. Low risk projects are when discomfort is the most risk possible. Negligible risk is when there is no chance of discomfort, and the only risk is inconvenience. The Greater than low risk review pathway is used for all other research
Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme?	The national mutual acceptance scheme is a nationwide agreement where sites accept an HREC review (by an NHMRC Registered committee) as equivalent to one done locally, and accept and adopt the decisions of that other HREC.