**Application form – ethics approval**

# Health research involving Aboriginal and Torres Strait islander people in Western Australia

All applications must comply with the following requirements:

* Full completion of all questions.
* If applicable, attach letters of support from Aboriginal Community Controlled Health Organisations and/or communities involved in the research.
* If applicable, attach consent forms, information statements, copies of surveys, posters and other written statements to be given to research participants.
* If conducting research in the Metropolitan region, provide evidence of support from the Derbarl Yerrigan Health Service Aboriginal Corporation Research Sub–committee.
* If conducting research in the Pilbara region, provide evidence of support from the Pilbara Aboriginal Health Research Advisory Panel. (https://paha.org.au/research/)
* If conducting research in the Kimberley region, provide evidence of support from the Kimberley Aboriginal Health Planning Forum Research Sub–committee.
* If conducting research in the Telethon Kids Institute (TKI) provide evidence of support from the Kulunga Unit
* Provide evidence of support from the Goldfields Aboriginal Health Planning Forum
* Provide evidence of support from the Greater Southern Aboriginal Health Planning Forum
* Provide evidence of support from the Southwest Aboriginal Health Planning Forum
* Provide evidence of support from the Wheatbelt Aboriginal Health Planning Forum
* Provide evidence of support from the Yamatji Aboriginal Health Planning Forum

Further details are available on the WAAHEC website. You may also email ethics@ahcwa.org with queries.

**Application Form**

Please answer all questions fully, using words that can be readily understood by an informed layperson.

# Title of Research Project (in lay terms):

# Chief Investigator:

|  |  |  |
| --- | --- | --- |
| Title and Name: |  | |
| Position: |  | |
| Address: |  | |
| Telephone: |  | |
| Email: |  | |
| Are you of Aboriginal and/or Torres Strait Islander origin? | |  |

# List of other Investigators:

Please include details of other Investigators involved in this research project.

|  |  |  |
| --- | --- | --- |
| Title and Name: |  | |
| Position: |  | |
| Address: |  | |
| Telephone: |  | |
| Email: |  | |
| Are you of Aboriginal and/or Torres Strait Islander origin? | |  |

|  |  |  |
| --- | --- | --- |
| Title and Name: |  | |
| Position: |  | |
| Address: |  | |
| Telephone: |  | |
| Email: |  | |
| Are you of Aboriginal and/or Torres Strait Islander origin? | |  |

|  |  |  |
| --- | --- | --- |
| Title and Name: |  | |
| Position: |  | |
| Address: |  | |
| Telephone: |  | |
| Email: |  | |
| Are you of Aboriginal and/or Torres Strait Islander origin? | |  |

|  |  |  |
| --- | --- | --- |
| Title and Name: |  | |
| Position: |  | |
| Address: |  | |
| Telephone: |  | |
| Email: |  | |
| Are you of Aboriginal and/or Torres Strait Islander origin? | |  |

|  |  |  |
| --- | --- | --- |
| Title and Name: |  | |
| Position: |  | |
| Address: |  | |
| Telephone: |  | |
| Email: |  | |
| Are you of Aboriginal and/or Torres Strait Islander origin? | |  |

# Expected duration of project:

Note: The research or recruitment of participants must not commence prior to final approval from the HREC.

|  |  |
| --- | --- |
| Date of initial recruitment: |  |
| Date of expected completion: |  |

# Location of research project implementation:

|  |  |  |
| --- | --- | --- |
|  | **Region** | **Specify the towns or communities in the Region** |
|  | Kimberley |  |
|  | Pilbara |  |
|  | Murchison Gascoyne/Midwest |  |
|  | Perth Metro |  |
|  | Central Desert |  |
|  | Goldfields |  |
|  | Great Southern |  |
|  | Wheatbelt |  |
|  | South West |  |
|  | Other – Please list (Provide name/s of town/s, city/cities, ACCHS, communities, region/s) |  |
|  | State Wide |  |
|  | National |  |
| Please list communities: | | |

# Funding:

Is this protocol the subject of a grant application?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |
| If ‘Yes’, what is the funding agency?  \*Provide the Funding application and Approval letter. | | | |
| Provide details of any affiliation or financial interest in funding source and/or commercialisation of research results. Any restrictions to publish. | | | |

# Disclosure of Interest

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |
| If ‘Yes’,  Explain the nature and extent of the interests and to which member of the team they apply.  Explain how you intend to manage these interests and any potential conflicts that may arise. | | | |
|  | | | |

# Other Ethical approvals:

Has the Research Project and Protocol previously been submitted to WAAHEC?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

Has the Research Project and Protocol been submitted to another Institutional Ethics Committee?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**Note**: This does not refer to support/approval from Aboriginal regional sub-committees or planning forums

If ‘**Yes**’, to which Committee(s) has it been submitted?

|  |  |  |
| --- | --- | --- |
| Name of Institutional Ethics Committee | | Date submitted/Outcome |
| 1. |  |  |
| 2. |  |  |

# Privacy Legislation

|  |  |  |
| --- | --- | --- |
| Does this research project involve the use or disclosure of information from a Commonwealth Department or agency?  If your proposed research project involves access to data held by a Commonwealth Department or agency, you will have to comply with the privacy principles established under Commonwealth Privacy Legislation. | Yes | No |
| Does this research project involve the use or disclosure of information from an organisation in the private sector? | Yes | No |
| Is all data/information securely de-identified?  ***Note:*** *‘De-identified’ information is information that has undergone a process of de-identification, and can no longer be applied to an identifiable individual, or an individual who is reasonably identifiable.* | Yes | No |

# Aims of the project:

Please give a concise and simple description of the aims of the project. This must be in lay terms (500 words maximum).

# Participant 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 |
|  | People in other countries |
|  | Aboriginal and Torres Strait Islander peoples |

1. Who are the participants? Please include size of sample(s) and variables such as age, sex and state of health. Please state clearly whether children, mentally ill individuals or persons in dependent relationships such as teacher/student, doctor/patient, staff etc. will be recruited.
2. From where and how will participants (including controls if applicable) be recruited?
3. How will the initial contact be made with the participants?
4. Does recruitment involve the circulation/publication of an advertisement?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If ‘Yes’, please provide copies and details of advertisement.

1. If this relates to Data Linkage, provide the Application for the Data Linkage as a supporting document. (Please include the Data Custodian information)

# Details of procedures:

1. Briefly describe the project methodology. Include all procedures to which participants will be subjected, highlighting any which may have adverse consequences
2. Will any chemical compound, drugs or biological agents be administered?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If ‘Yes’, describe names, dosages, routes of administration, frequency of administration, and any known or suspected adverse effects. All suspected adverse events should be listed on the Information Sheet/Consent Form.

1. Does the research involve use of drugs not marketed?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If ‘Yes’, Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) approval must be obtained before the project may proceed.

|  |  |  |
| --- | --- | --- |
| Investigation brochure enclosed. | Yes | No |
| CTN approval has been requested. |  |  |
| CTA approval has been requested. |  |  |

1. Will blood or other tissue samples (including genetic material) be taken?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |
| If ‘Yes’, please state site, frequency, volume of any blood or other tissue sampling and details of storage. | |  | |
| If ‘Yes’, please list all personnel who will be involved in this procedure. | |  | |

1. Will there be any invasive procedures other than blood or tissue sampling?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |
| If ‘Yes’, please provide details of these procedures | |  | |

1. Will participants be exposed to ionising or non-ionising radiation?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |
| If ‘Yes’, please provide details including the quantitative assessment of the absorbed dose, supported either by dosimetric calculation or other information | |  | |
| If ‘Yes’, has the radiation Protection Office been asked for approval? | |  | |
| If ‘Yes’ please attach a copy of approval notification. | |  | |

# National Statement on Ethical Conduct in Human Research 2007 (updated 2018) and other guidelines

1. Please ensure the protocol conforms to the following guidelines:
   * National Statement on Ethical Conduct in Human Research 2007 (updated 2018)
   * NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
   * NHMRC keeping research on track II
2. Please indicate whether the protocol conforms to the National Statement on Ethical Conduct in Human Research with regard to the following:

|  |  |  |  |
| --- | --- | --- | --- |
| Research involving children, young people, persons with intellectual or mental impairment, persons highly dependent on medical care or | Yes | No | N/A |
| Persons in a dependent or unequal relationships | Yes | No | N/A |
| Research involving collectivities | Yes | No | N/A |
| Research involving ionising radiation | Yes | No | N/A |
| Research involving assisted reproductive technology | Yes | No | N/A |
| Clinical trials | Yes | No | N/A |
| Innovative therapy or intervention | Yes | No | N/A |
| Epidemiological research (Department of Health or health service data) | Yes | No | N/A |
| Use of human tissue samples | Yes | No | N/A |
| Human genetic research | Yes | No | N/A |
| Research involving deception of participants, concealment or covert observation | Yes | No | N/A |

1. Please address the ethical considerations that ensure the research protocol gives adequate consideration to participants’ welfare, rights, beliefs, perceptions, customs and cultural heritage, both individual and collective.

(Refer section 4 of the National Statement on Ethical Conduct in Human Research)

1. Please address how the values and their components outlined in the NHMRC – Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities document will be applied in this proposed research.

(Refer section 4.7 of the National Statement on Ethical Conduct in Human Research)

# Ethical Issues

|  |  |  |
| --- | --- | --- |
| (a) Does data collection require access to confidential data without the prior consent of participants? | Yes | No |
| (b) Will visual recordings be made, eg: photo, video, etc? | Yes | No |
| (c) Will audio recordings be made, eg: tape or digital, etc? | Yes | No |
| (d) Will participants be asked to commit any act which might diminish self-respect or cause them to experience shame, embarrassment or regret? | Yes | No |
| (e) Will any procedure be used which may have an unpleasant or harmful side effect? | Yes | No |
| (f) Does the research use any stimuli, tasks, or procedures, which may be experienced by Participants as stressful, noxious, or unpleasant? | Yes | No |
| (g) Will the research use no-treatment or placebo control conditions? | Yes | No |
| (h) Will any samples of body fluid or body tissue be required specifically for the research, which would not be required in the case of the ordinary treatment? | Yes | No |
| (i) Does the research involve a fertilised human ovum? | Yes | No |
| (j) Does the project use embryos beyond a period of fourteen days after fertilisation? | Yes | No |
| (k) Does the project involve the implantation of embryos, which have been the subjects of prior experimentation? | Yes | No |
| (l) Are there in your opinion any other ethical issues involved in the research? |  |  |

If the answer to any of the above questions is ‘Yes’, please describe.

# Information Sheet and Informed Consent Form:

When required, research participants are given an information sheet and are required to sign a consent form.

|  |  |  |
| --- | --- | --- |
| Do you undertake to obtain written consent for each participant? | Yes | No |

1. If ‘Yes’, please attach a copy of the Information Sheet and the Consent Form to be given to and signed by all participants and/or their responsible signatory.

The Information Sheet should describe all the procedures proposed in clear, simple terms. It should list any potential short - or long-term side effects and any hazards. All relevant contact details should be included in Consent Forms or Information Sheets, so that research participants can report complaints or ask questions about the research project. This includes WAAHEC contact details.

1. If ‘No’, please justify why

# Letters of support from the Communities involved:

1. Demonstrate evidence of the engagement with Aboriginal and Torres Strait Islander Peoples.
2. Evidence of consultation with Aboriginal community/communities is an essential component of applications. Usually this is obtained via the Aboriginal Community Controlled Health Services in the relevant region.

Have you obtained written support from the:

|  |  |  |  |
| --- | --- | --- | --- |
| The local Aboriginal Community Controlled Health Service | Yes | No | N/A |
| Kimberley Aboriginal Health Planning Forum Research Subcommittee | Yes | No | N/A |
| Derbarl Yerrigan Health Service Inc. (for research in the metropolitan region) | Yes | No | N/A |
| Pilbara Aboriginal Health Research Advisory (for research in the Pilbara region) | Yes | No | N/A |
| Kulunga Unit (for conducting research in the Telethon Kids Institute) | Yes | No | N/A |
| Goldfields Aboriginal Health Planning Forum | Yes | No | N/A |
| Greater Southern Aboriginal Health Planning Forum | Yes | No | N/A |
| Southwest Aboriginal Health Planning Forum | Yes | No | N/A |
| Wheatbelt Aboriginal Health Planning Forum | Yes | No | N/A |
| Yamatji Aboriginal Health Planning Forum | Yes | No | N/A |

# Building capacity of Aboriginal people:

How will this research project build the capacity of Aboriginal people to undertake research in the future?

# Potential Benefits and Risks:

1. What are the possible benefits of this research?

|  |  |
| --- | --- |
| To the participant(s) | (500 words maximum). |
| To the Aboriginal community | (500 words maximum). |
| To the broader Australian community | (500 words maximum). |

1. What in your view are the possible hazards of this research to the participants?
2. Please describe your strategies to address these hazards if they occur?

# Dissemination of research results:

Please describe the dissemination plan for the results of the research project.

# Translation Plan:

Please provide a clear Translation Plan, ensuring benefits and outcomes.

# Closing the Gap

(a) Does your research align to any of the four Priority Reforms outlined in the National Agreement on Closing the Gap? If so, how?

(b) Does your research contribute to the progress of the socio-economic targets outlined in the National Agreement on Closing the Gap?

# Remuneration:

|  |  |  |
| --- | --- | --- |
| Is any financial remuneration or other reward being offered to participants in the study? | Yes | No |

If ‘Yes’, please indicate the specific amount and purpose of the payment, e.g. to cover travelling expenses, time spent etc.

# Data Sovereignty:

1. How will Data Sovereignty principles apply and guide the project?
2. Detail how Aboriginal and Torres Strait Islander peoples exercise control of the data ecosystem including creation, development, stewardship, analysis, dissemination and infrastructure.
3. Explain how data structures are accountable to Indigenous peoples and First Nations.
4. Clealy explain how Data analysis represents interests/priorities and respects Aboriginal and Torres Strait Islander peoples individual and collective interests.
5. Detail the governance of Aboriginal and Torres Strait Islander peoples data.

# Project Narrative:

|  |
| --- |
| Please provide the project Narrative (Guidelines below) |
|  |

|  |
| --- |
| **Project Narrative Guidelines** |
| Communicates the public health relevance of the project to the public |
| No more than 2-3 sentences |
| Use plain language understandable by a general audience |
| Describe how, in the short or long term, the research would contribute to: the fundamental knowledge about the nature and behaviour of living systems, and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. |
| If the application is approved, the narrative will be available on the Ethics website |

# Declaration and Checklist

**To assist with processing this application I have read:**

|  |  |  |
| --- | --- | --- |
| NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018) | Yes | No |
| NHMRC National Statement on Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities | Yes | No |
| NHMRC Guidelines under Section 95 of the Privacy Act 1988 | Yes | No |
| NHMRC Keeping Research on Track II: A companion document to the ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities. | Yes | No |

**Checklist of documents to be included:**

|  |  |  |
| --- | --- | --- |
| Application form | Yes | No |
| Statement addressing Values and Ethics if not addressed within the application | Yes | No |
| Full scientific protocol or Research Proposal | Yes | No |
| Consent forms, information sheets and any other written statements to be given to the participants | Yes | No |
| Grant Funding Application and Approval letter | Yes | No |
|  |  |  |
| Reply from any other Ethics Committee(s) to whom you have already submitted this | Yes | No |
| Letters of support from the Aboriginal Community Controlled Health Services and communities involved in the research | Yes | No |
| If necessary, evidence of support from Kimberley Aboriginal Health Planning Forum Research Subcommittee | Yes | No |
| If necessary, evidence of support from Derbarl Yerrigan Health Service Inc. | Yes | No |
| If necessary, evidence of support from Pilbara Aboriginal Health Research Advisory Panel | Yes | No |
| If necessary, evidence of support from Goldfields Aboriginal Health Planning Forum | Yes | No |
| If necessary, evidence of support from Greater Southern Aboriginal Health Planning Forum | Yes | No |
| If necessary, evidence of support from Southwest Aboriginal Health Planning Forum | Yes | No |
| If necessary, evidence of support from Wheatbelt Aboriginal Health Planning Forum | Yes | No |
| If necessary, evidence of support from Yamatji Aboriginal Health Planning Forum | Yes | No |

# Documents for the Project

It is important to accurately name the attachments as you want them to appear in the approval letter.

Do not include special characters in file names.

Ensure version control

|  |  |
| --- | --- |
| Attachment Type | Attachment Name (include version) |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

Email your application, any attachments and this signed declaration form to: ethics@ahcwa.org

DECLARATION: I certify that the information given above is correct to the best of my knowledge. I acknowledge that I must notify the Western Australian Aboriginal Health Ethics Committee if there are any ethically relevant variations.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature of Chief Investigator |  | Dated |  |
| Signature of head of organisation and community seal (if applicable) |  | Dated |  |