WAAHEC Western Australian Aboriginal Health Ethics Committee

Dear Researcher,

The Western Australian Aboriginal Health Ethics Committee (WAAHEC) recognises the important role that research can play in achieving evidence based improvement in Aboriginal health and health service delivery.

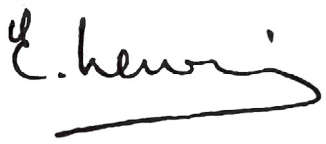
The WAAHEC was established to promote and support quality research reflective of the needs of the community. Therefore we have a role in effectively assessing and monitoring ethically sound and culturally appropriate proposed research.

All proposed research applications **MUST** provide the following information before the committee will review:

- Full completion of each question of the Application Form
- Letters of support from Aboriginal Community Controlled Health Organisations (ACCHOs) and / or communities involved
- If applicable, consent forms, information statements, copies of surveys, posters and other written statements to be given to participants
- If applicable, if conducting research in the Metropolitan region, make sure an application has been submitted to the Derbarl Yerrigan Health Service Aboriginal Corporation Research Sub–committee (DYHSACRC) for review and attach approval.
- If applicable, if conducting research in the Pilbara region, make sure an application has been submitted to the Pilbara Aboriginal Health Planning Forum (PAHPF) Research Sub–committee for review and attach approval.
- If applicable, if conducting research in the Kimberley region, make sure an application has been submitted to the Kimberley Aboriginal Health Planning Forum Research Sub–committee for review and attach approval – further information can be found at: **http://kams.org.au/research/kimberley-research-subcommittee/**

If you have not provided the following requirements when submitting your application to the WAAHEC, please be advised the committee will not review your application until all requirements have been met.

Kind Regards,



Erica Lewin

For, **Vicki O'Donnell**
Chairperson, WAAHEC

WAAHEC Western Australian Aboriginal Health Ethics Committee

Application Form

To undertake health research involving Aboriginal and Torres Strait Islander subjects
NB: Please answer all questions fully in terms which can be readily understood by an informed layperson.

1. Title Of Project (In Lay terms):

2. Chief Investigator:

Name:

Position:

Address:

Telephone:

Email:

3. Expected duration of project:

Please note that the research or recruitment of participants **must not** commence until a date after final approval has been obtained from the HREC.

From date of initial recruitment:

Date of expected completion:

4. Funding:

Is this protocol the subject of a grant application? ☐ Yes ☐ No

If '**Yes**', what is the funding agency?

Provide details of any affiliation or financial interest in funding source and/or commercialisation of research results

5. Other Ethical approvals:

Has the protocol previously been submitted to WAAHEC? ☐ Yes ☐ No

Has the protocol been submitted to another Institutional Ethics Committee? ☐ Yes ☐ No

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

What was the outcome of the submission?

6. Privacy Legislation:

Does this research project involve access to data held by a Commonwealth Department or agency? ☐ Yes ☐ No

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. Information and further documentation relating to these issues must be obtained from the Secretariat to the Committee.

Is the data to be collected, used or disclosed from an Organisation in the private sector? ☐ Yes ☐ No

Does the data include information that identifies the individual(s) concerned? ☐ Yes ☐ No

7. 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)*

8. Participant Group:

(a) Who will be the participants? Please include size of sample(s) and variable 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.

(b) From where and how will participants (including controls if applicable) be recruited?

How will the initial contact be made with the participants?

(c) Does recruitment involve the circulation/publication of an advertisement? ☐ Yes ☐ No

If 'Yes', please provide copies and details of publication

9. Details of procedures:

(a) Please describe briefly the project methodology. Describe all procedures to which participants will be subjected, highlighting anywhich may have adverse consequences.

(b) 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.

(c) Does the research involve use of drugs not marketed? ☐ Yes ☐ No

If 'Yes', Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) approval must be obtained before the project may proceed.

Investigation brochure enclosed. ☐ Yes ☐ No

CTN approval has been requested. ☐ Yes ☐ No

CTX approval has been requested ☐ Yes ☐ No

(d) 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.

(e) Will there be any invasive procedures other than blood or tissue sampling? ☐ Yes ☐ No

If '**Yes**', please provide details of these procedures.

(f) Will participants be exposed to ionising or non-ionising radiation? ☐ Yes ☐ No

(i) If '**Yes**', please provide details including the quantitative assessment of the absorbed dose, supported either by dosimetric calculation or other information.

(ii) If '**Yes**', has the radiation Protection Office been asked for approval?

If **'Yes'** *please attach a copy of approval notification*

10. NHMRC National Statement on Ethical Conduct In Human Research 2007(updated 2018)

(a) Please indicate whether the protocol conforms to these following guidelines:

- NHMRC Australian code for the responsible conduct of human research 2007
- NHMRC - Ethical conduct in research with Aboriginal and Torres Strait Islander people and communities
- NHMRC keeping research on track II

(b) Please indicate whether the protocol conforms to the National Statement on Ethical Conduct in Human Research with regard to the following areas of research:

Research involving children, young people, persons with intellectual or mental impairment, persons highly dependent on medical care or 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

(c) Please address the ethical considerations of the proposed research to satisfy the Committee that 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)

(d) 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)

11. Ethical Issues

Please indicate whether the project involves any of the following 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?	☐ Yes	☐ No

If the answer to any of the above questions is '**Yes**', please describe below.

12. Information Sheet and Informed Consent Form:

Each participant is given an information sheet and is required to sign a consent form.
(*It is strongly recommended that you gain advice on the development of these)*

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

(a) 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.

The required standard paragraph must be included at the bottom of all Consent Forms, or Information Sheets where appropriate.

(For example...

(b) If '**No**', please justify why.

13. Letters of support from the Communities invloved:

Being able to demonstrate consultation with the Aboriginal community/communities is essential in the review of applications submitted to WAAHEC. Normally this is obtained via the Aboriginal Community Controlled Health Services in the region

Have you obtained written support from the:

The local Aboriginal Community Controlled Health Service		Yes		No	N/A
The Kimberley Aboriginal Health Planning Forum / Kimberley research sub-committee (KAHPF) (for research in the Kimberley region)		Yes		No	N/A
Derbarl Yerrigan Health Service Inc. (DYHSAC)		Yes		No	N/A
Pilbara Aboriginal Health Planning Forum (PAHPF)		Yes		No	N/A

14. List of other investigators:

(a) Please indicate who are the other investigators involved in this research project.

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

15. Potential Benefits and Risks:

(a) What are the possible benefits of this research?

To the participant(s);

To the Aboriginal community;

To the broader Australian community;

(b) What in your view are the possible hazards of this research to the participants?

(c) Please describe your strategies to address these hazards if they occur?

(d) Please describe your result dissemination plan?

16. Renumeration:

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

If '**Yes**', please state how much will be offered and for what purpose, e.g. to cover travelling expenses, time spent etc. Volunteers may be compensated for inconvenience and time spent.

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 Guidlines 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	☐ Yes	☐ No
• Full scientific protocol	☐ Yes	☐ No
• Consent forms, information sheets and any other written statements to be given to the participants	☐ Yes	☐ No
• Application submitted to other Ethics Committee(s)	☐ Yes	☐ No
• Reply from any other Ethics Committee(s) to whom you have already submitted this application	☐ Yes	☐ No
• Letters of support from the ACCHSs and communities involved in the research	☐ Yes	☐ No
• If necessary, Application reviewed by Kimberley Aboriginal Health Planning Forum	☐ Yes	☐ No
• If necessary, Derbarl Yerrigan Health Service Inc. (DYHSAC)	☐ Yes	☐ No
• If necessary, Pilbara Aboriginal Health Planning Forum (PAHPF)	☐ Yes	☐ No

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.

Signed: _____ Dated:

Signature of Chief Investigator

Signed: _____ Dated:

Signature of head of organisation and community seal (if applicable)

END OF APPLICATION FORM