HUMAN RESEARCH ETHICS APPLICATION CHECKLIST

**PART A. Mandatory components for all submissions to a Human Research Ethics Committee.**

Options for each component are: YES, NO, N/A

**Also add a functionality to add a document for AI review (**if any component contains a documentation e.g. Option to add a cover letter or list of any supporting documents or Master Participant Information Sheet etc or any completed forms etc.**)**

1. **Cover letter signed by the Principal Investigator**.

• A brief description of the project including the Phase of the study if it is a clinical trial.

• A list of all sites applicable to the HREC application for the research study.

• A list of supporting documentation submitted including version dates/numbers.

• For commercially sponsored research studies; the name and address of the sponsor

organisation/CRO/CRA for the (Human Research Ethics Application Checklist) HREC review. (must have an Australian address).

• Principal Investigator should not be a student. If the project is student research, then the student’s main supervisor should be listed as Principal Investigator.

2. **Human Research Ethics Committee Application Form (completed)**

3. **Study Protocol Document (completed)**

The protocol contains some of the information such as the formal design or specific plan for the research, in the research ethics application, but the protocol is certainly required because it is the working document for the study. If revisions occur during the course of the research, a revised protocol must be submitted to the reviewing HREC as an amendment. The protocol must include a version date/number, which is changed as the document is updated.

4. **CV of the Principal Investigator. CVs are not required for other researchers.**

**5.** Summary **of expertise relevant to this research (National Statement on Ethical Conduct in Human Research 2007, Chapter 4.8.7 and 4.8.15).**

**PART B. Other components that may be required depending on the research project. Options for each component are: YES NO N/A**

6. Master Participant Information Sheet required (completed)

7. Letters of Approval from other Human Research Ethics Committees.

**•** Full letterhead with contact details.

• Mandatory statement underneath research title “This Is For You To Keep”.

• Written in plain English.

• Local researcher’s name and contact details included. (Site specific).

• Contains relevant information (i.e. description of research, aim of research, what is required of participants, storage of data, risks and benefits).

• A paragraph on assurance of confidentiality.

• A paragraph on concerns and complaints with contact (if any)

**8. Master Participant Consent Form**

**•** Full letterhead with contact details.

• Mandatory statement underneath research title “NO is not applicable”.

• Must be written in plain English.

• Local researcher’s name and contact details included. (Site specific)

• Consent for all procedures (e.g. access to medical records, audio/video recording).

• A space for study participant’s printed name and signature, and date time of consent.

• A space for witness / interpreter’s printed name and signature.

• A space for the researcher’s printed name and signature.

9. CTN (Clinical Trial Form(s)) – include original CTN forms with details for each site. (for clinical trials only)

10. CTX Form (Clinical trials only)

11. Questionnaires/surveys/other instruments – (include templates of all)

12. Data collection tool(s) e.g. Data Collection Form, Case Report Form.

13. Certificate of Insurance (for Clinical trials)

14. Clinical Trial Registration Number and public register details (for Clinical trials)

15. Form of Indemnity (Medicines Australia HREC Review Only Form) for each participating site.

16. Copy of the Form of Indemnity (Standard Form) for each participating site. (Clinical trials)

17. Advertising materials (including transcript for advertisement, e-mail, website, letter, telephone calls etc).

18. Letter of invitation / Letter to GP etc.

19. Participant diaries

20. Participant wallet card.

21. **Other correspondence** e.g. FDA reviews, correspondence with other HRECs, expert independent reviews, peer review etc.

22. **Working with Children Clearance**

• Photocopies of Ochre cards as required by the NT *Working with Children Act 2007.*

23. **Part D, Question 31 Aboriginal and Torres Strait Islander Research**

• Please note that applications will not be accepted without completion of this section if it is applicable in the research study.

24. **Community Support**

• Attach letters of support from selected participating communities.

25. **Remote Health Services**

• Letter of Support.

• Funding.

• Support staff available.

• Agreement of other resources providers involved. (i.e. Pathology Department).

• Letters of support from Community Authorities/relevant organisations.

26. **Original Signatures**

• All investigators.

• Department head and organisational head printed name, signatures and roles in the

Organisation/Institution.

• Please note that applications will not be accepted without complete original signatures.

• If it is impossible to ascertain original signatures and only electronic signatures can be provided.

• Please attach a letter or email from the researcher involved as evidence of consent for the use of their electronic signature and acknowledgement of support to the research study.

**PART C. Research using gene technology. Options for each component are: YES NO N/A**

27. **Ionising Radiation Certificate**

28. **Institutional Biosafety Committee (IBC) approval letter**.

29. **Licence for dealings with Genetically Modified Organism (GMO)**

**PART D. Research using radiological procedures that are performed for research YES NO N/A**

31. If Yes for each site attach either of the following:

• A letter from the Principal Investigator stating that radiation exposure is part of normal clinical management/care.

• If radiation exposure is **additional** to that received as part of normal clinical management/care, an independent assessment report by a Medical Physicist of the total effective dose and relevant organ doses including risk assessment.

**Part E Aboriginal and Torres Strait Islander Health Research YES NO N/A**

33. Does the research involve Aboriginal and Torres Strait Islander people? If Yes ensure:

* Section 4.7 of the National Statement on Ethical Conduct in Human Research is adhered
* Each of the six core values is addressed under separate headings, even if your project is not specifically targeting Aboriginal and Torres Strait Islander people

34. Are permits to undertake research and enter remote communities taken?

* Please ensure that a permit to enter lands and undertake research has been sought from the appropriate land council and community and attach the approval with this application. Please note that letters of support from communities and other health service providers may be necessary to support your application.