Date Received
……
HREC No:……

National Institute of Integrative Medicine

HUMAN RESEARCH ETHICS COMMITTEE

APPLICATION FOR ETHICS APPROVAL of a RESEARCH PROTOCOL

SECTION A: GENERAL INFORMATION

PROJECT FULL TITLE	
SHORT TITLE (If applicable)	
APPLICANT DETAILS	
RESPONSIBLE FIRST INVESTIGATOR / SUPERVISOR	**Name & Title/Position:** Tel No(s) Email Fax Address for correspondence:
	Email Tel No(s) Student ID Number Fax Degree Being Undertaken

List below the names of other Chief/Associate Investigators and Research Assistants (including those with access to identifiable data).

(Add (copy/paste) cells as required for additional investigators/assistants.

Name & Title: Institutional Address: Tel No(s)
Name & Title/Position: Institutional Address: Tel No(s)

Proposed Period During Which Human Research Activity Requiring Ethics Approval is Needed:	**From** dd mm 20…. yyyy **to** dd mm 20…. yyyy

[Double-click on ☐ YES/NO 'check box' to select box, then enter Default Value as Checked ☒ or leaving as Not Checked ☐]

TYPE OF ACTIVITY (Select as many boxes as applicable)	☐ Clinical Trial ☐ Survey	☐ Contract Research (Attach copy of contract)
	:	

Broad Category of Research

Select one category box which best fits the application:

☐ Social/Cultural/Humanities ☐ Business/Management ☐ Education/Training/Program Evaluation

☐ Psychological/Brain/Neuro-sciences ☐ Health/Safety ☐ Engineering/Science/Technology

☐ Other (please specify) ……

Official Use Only:
☐ **Higher Risk/Impact** ☐ **Minimal Risk/Low Impact Research Only**

Human Research Risk/Review Classification (Nb Checking to be consistent with published risk criteria.[#])

To enable a determination as to whether prima facie your research activity is Minimal Risk and/or Low Impact, please clarify by selecting [X] any one or more boxes below as to whether your research activity involves:

[Double-click on ☐ YES /NO 'check box' to select X by entering in Default Value as Checked ☒ or leaving as Not Checked ☐]

☐ Vulnerable participants, children or those dependent on care*	☐ Indigenous Peoples* or Special Cultural/Ethnic groups
☐ Externally funded research requiring HREC-level clearance*	☐ Multi-centre/Other sites requiring HREC-level approval*
☐ Research conducted overseas	☐ Conflicts of interest or dual researcher-professional roles
☐ Data access/use without an individual's prior consent*	☐ Data access/use subject to statutory guidelines &/or reporting*
☐ Identification of participant individuals/groups in research outcomes without full consent or there is unclear consent for this*	
☐ Sensitive information/issues vis-à-vis context/impact (legal*, regulatory compliance*, commercial, professional, cultural, etc)	
☐ Personally intrusive/confronting or quite inconvenient/embarrassing questioning or other activity	
☐ Physically confining/invasive techniques or significant physical contact/stimulation (TMS*, X-ray*, CT scan*, MRI*, clothing change, etc)	
☐ Working in hazardous environments (asbestos dust*, infectious disease*, war or civil strife*, etc)	
☐ Handling hazardous substances (eg, asbestos*, radioactive material* , explosives*, etc) or equipment	
☐ Administration of medical/herbal substances*/treatments*	☐ Administration of other (non-medical) substances/treatments
☐ Health/medical diagnosis*/therapy*	☐ Non-minimal impact therapeutic or other devices*/activity*
☐ Screening for healthy participant inclusion/exclusion	☐ Medical or psychiatric assessment/conditions*
☐ Serious psychological profiling, investigation or exploration	☐ Withdrawal of treatment/services or use of placebo
☐ Withdrawal/substitution of educational/professional/commercial/recreational/other programs or services	
☐ Deception or covert observation	☐ Limited or non-disclosure of research information/procedures
☐ Participant recruitment/selection via third party	☐ Human research activity commenced without clearance
☐ Participation incentives, prizes or significant payments	☐ Research placing researchers/assistants at risk

PLEASE NOTE: If you have selected any one or more of the above boxes, your project will ordinarily be put for NIIM HREC ethical review. Items above marked * **must** be put to NIIM HREC proper. But in other cases, you may wish to put a case for expedited review in the (expandable) box below.

A1 *WHY* IS THE PROJECT TO BE UNDERTAKEN

Summarise in sufficient detail why the project is being undertaken. If references are quoted, full citations should be given. Include the educational and/or scientific aims of the project. *(boxes will expand for your text)*

A2 *WHAT* - BRIEF DESCRIPTION OF PROJECT

In plain English

A3 *HOW* - PROCEDURES

Please detail clearly and sufficiently the proposed research/statistical method(s), procedures and instruments to be used in the project, including all screening and research 'procedures' to which the participants will be subjected, and asterisk those which may have adverse consequences.
Please include as appendices all screening instruments, questionnaires, interview protocols etc (at least in draft form if not finalised).
If you feel that it is necessary to include further material, please append.

A4 DESCRIBE ANY RISK THAT MAY ARISE TO THE PARTICIPANT / DONOR?

Risk to participants (and to researchers) can be real but does not need to be physical. Risk includes such as self esteem, regret, embarrassment, civil or criminal liability, disease, physical harm, loss of employment or professional standing, etc. Please consider such possibilities carefully
Some research activities may put the participant *at risk through what is being done or simply through their participation.*
Please describe the risk you perceive and the protective measures to be taken.

A5 DESCRIBE ANY RISK THAT MAY ARISE TO THE RESEARCHER / ADMINISTRATOR?

Some research activities may put the researcher *at risk through what is being done or simply through their participation.*
Please describe the risk you perceive and the protective measures to be taken.

A6 WHAT BENEFITS ARE ANTICIPATED FROM THE PROJECT

Ethical principles would require that benefits flowed from the activities - but please avoid grandiose claims.
(a) To the Participant (what and how so)

(b) More generally (to society, profession, knowledge, understanding, etc, and how so.)

A7 POTENTIAL PROBLEMS

From time to time in the course of a research project important information, such as an individual found to be at risk, or entirely unforseen events may come to pass.
What procedures are in place to handle unexpected or particularly significant personal or other information that may come to light through the project, eg, unknown medical/psychiatric condition, a particularly distressed participant, civil or criminal liability, etc.

A8 PROFESSIONAL/ETHICAL ABILITY & TRAINING (Researchers/Students/Assistants)

NS 1.15 Research must be conducted or supervised only by persons or teams with experience, qualifications and competence appropriate to the research … using (appropriate) facilities … (and with appropriate skills and resources for dealing with any contingencies…

(a) Sufficiently detail what investigators/assistants will do in this project and their expertise/competence to do so.

(b) Sufficiently detail any further training/qualifications required for investigators/assistants to carry out the project.

A9 FUTURE USE OF DATA

Will any of these data be used by yourself, your students or others for any purpose other than for this project as described in the protocol? If so please describe.

A10 EXTERNAL INVOLVEMENT

Is a body external to NIIM involved in initiation or support of the project?

☐ Yes Name of body/organisation. .....

If an external body is associated with the project you **must** provide the HREC with detail of the arrangements, *including details of any funding or other resources being provided*. A copy of relevant pages from the contractual arrangements should be attached.

☐ No

A11 EXTERNAL APPROVALS

Projects involving other organisations or entities may require approval from other institutions or their ethics committees, etc. for such things as access to prospective participants, contact lists, data, facilities, etc. A copy of such approvals may be required to be provided to the HREC at the time of application or be made available as soon as possible. In which case, the project may not commence, until such evidence is provided.

Please indicate, as appropriate, if formal clearance/permission has been obtained or sought:

Institutional	Yes	☐	Documentation Attached	☐	or to follow ☐	(estimate when likely to be obtained)
Next of Kin (for special groups)	Yes	☐	Documentation Attached	☐	or to follow ☐	(estimate when likely to be obtained)

☐ No (please explain)

A12 RESEARCHER / SPONSOR RELATIONSHIP

Is there any relationship or association between the sponsor and any of the researchers listed in Section A of this form, for example are any of the researchers directors, officers, employees, shareholders or promoters of the sponsor or do they receive any personal benefits from the sponsor under any other contracts or arrangements?

☐ No

☐ Yes (please explain the relationship(s), including how a vested or a conflict of interest situation does not arise.)

SECTION B: ETHICAL ISSUES OVERVIEW

B ETHICAL ISSUES

[Double-click on ☐ YES/NO 'check box' to select box, then enter Default Value as Checked ☒ or leaving as Not Checked ☐]

		YES	NO
(a)	Non-/Limited Disclosure or Deception: Is any detail in relation to research purposes, methods or questions being withheld from participants? Or will deception of any kind be involved? Or any covert/undeclared observation? (Refer *National Statement* Chap 2.3)	☐	☐
(b)	Does the data collection process involve access to confidential personal data (including access to data provided for a purpose other that this particular research project) without the prior consent of subjects?	☐	☐
(c)	Will participants have pictures taken of them, e.g., photographs, video recordings?	☐	☐
	If "YES", please explain how you intend to retain confidentiality and ultimately dispose of the material.		
(d)	If interviews are to be conducted, will they be record by electronic device?	☐	☐
	If "Yes", please explain how you intend to retain confidentiality and ultimately dispose of the material.		
(e)	Will participants be asked to perform any acts or make statements which might compromise them, diminish self esteem or cause them embarrassment or regret (minimal, moderate or significant)?	☐	☐
(f)	Might any aspect of your study reasonably be expected to place the participant at risk of criminal or civil liability (not just immediately or directly)?	☐	☐
(g)	Might any aspect of your study reasonably be expected to place the participant at risk of damage to their professional/social/cultural/financial standing or employability?	☐	☐
(h)	Will the research involve access to data banks subject to privacy legislation?* *(NOTE: Annual reporting to Government may be required on this item. For info: please contact the Research Ethics Officer.)*	☐	☐
(i)	Will participants come into contact with any equipment which uses an electrical supply in any form e.g., audiometer, biofeedback, electrical stimulation, magnetic stimulation, etc.? If "YES", please outline below what safety precautions will be followed.	☐	☐
(j)	Will any treatment be used with potentially unpleasant or harmful side effects?	☐	☐
(k)	Does the research involve any stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, noxious, aversive or unpleasant during or after the research procedures?	☐	☐
(l)	Will the research involve the use of placebo control conditions or the withholding/substitution of treatment, programs or services (health, educational , commercial, other)?	☐	☐
(m)	Will any samples of body fluid or body tissue be required specifically for the research which would not be required in the case of ordinary treatment?	☐	☐
(n)	Will participants be fingerprinted or DNA "fingerprinted"?	☐	☐
(o)	Are there in your opinion any other ethical issues involved in the research?	☐	☐

NOTE: If the answer to any of the above questions is "yes", please **explain** and **justify** below in sufficient clear detail. (The box below will expand to fit your response.)

Attach further documents if appropriate

SECTION C: PARTICIPANT DETAILS

C1 PARTICIPANT DETAILS

The composition of the participant group may, in some circumstances, distort and invalidate an outcome, and risks may arise through the composition of the participant group.

How many individual participants will be involved? *(Number/number ranges for which approval is sought)*

Males: ☐ Females: ☐ Total participants ☐

Over what range of ages?

From (youngest): ☐ To (Oldest): ☐

If there is a gender or age imbalance in the number of participants please explain why.

C2 RECRUITMENT

How will participants be recruited/selected?

Please outline the process in sufficient detail how this is to occur.

***Note**: Where participants are obtained from or through schools, hospitals, prisons or other institutions, appropriate institutional or other authority will probably be needed. If soliciting for participants by advertisement or poster please attach proposed copies or text.*

(See also Project Information Consent Statements and Signed Consent Forms info at the end of this application form.)

C3 PRE-EXISTING CONDITIONS

In some situations an underlying medical or other significant condition of a participant may result in an otherwise relatively innocuous situation causing excessive stress and exacerbate the condition. Researchers must, therefore, be alert to *such situations and be able to address the resulting issues.*

Do participants have any medical or other significant condition of which you are aware, eg. diabetes, asthma, depression, epilepsy? What steps are in place to handle any resulting problems (you may need to correlate with A3, A4 and A7 of this form)?

C4 DISCLOSURE AND INFORMED CONSENT

How will participants be informed about the project in order to give valid consent:

- ☐ Consent Information Statement(s)/Letter(s) and Signed Consent Form(s) will be used.
  A copy must be attached to your application. A guide to consent instruments is given at the end of this form.
- ☐ Consent Information Statement(s)/Letter(s) and consent implied by return of anonymous questionnaire
- ☐ Verbal advice (Please explain how and why)
- ☐ Other (Please explain how and why)

Copies of appropriate consent instruments must be attached to your application. Please consult the Guide to Human Research Informed Consent Instruments in carefully preparing informed consent instruments.

C5 COMPENSATION

Consent to participate must be freely given and not induced through the level of reward, perceived reward, or power relationships

Provide details of any financial or other reward or inducement is being offered to subjects for participation. Indicate the source of the funds.

C6 RELATIONSHIP TO INVESTIGATOR(S)

Free consent may be difficult to ensure if the participant is dependent upon the investigator for employment, assessments etc

Some relationships cause special ethical issues to arise

Are participants linked with the investigator through some particular relationship - eg. employees ultimately responsible to or superiors of the investigator, students of investigator, family members, friends etc.

C7 INVOLVEMENT OF SPECIAL GROUPS

Particular issues of consent may arise where special groups of participants are to be involved. There may be, for example, a need to obtain informed consent from persons other than the direct participant. Examples of such special groups include
special cultural groups - eg. indigenous Australians; children and young persons (Guidelines section 4.2); groups with special circumstances - eg. persons with an intellectual or mental impairment (Guidelines s. 5)
Please identify and describe the nature of the groups and procedures used to obtain permission.

Note. Persons proposing research projects involving Indigenous Australians should consult with the relevant University manager of indigenous programs prior to finalising definition of the project.

C8 PRIVACY

NIIM is subject to the Victorian Information Privacy and Health Records Acts as well as the Commonwealth Privacy Act and, in particular, the Information/Health/National Privacy principles (IPPs/HPPs/NPPs) set out therein and is required to report annually on projects which relate to or utilise particular records.

Does the research involves access to data which was collected by an organisation for its own purposes (ie. not specifically collected for *this* project) such as student records, other data banks, human pathology or diagnostic specimens provided by an institution/s?
If yes, please indicate source/s.

C9 LOCATION OF STUDY

Please indicate where the research will be carried out. If the research will not be on NIIM premises permission of owner / occupier may be required. If so, please indicate what authority or permission may be required and how it will be obtained. ***NB**: Where required, please attach to this application evidence of authority obtained or provide the Secretary, HREC as soon as practicable.*

SECTION D: DATA & PUBLICATION ARRANGEMENTS (Nb Section D Revised Aug 2007)

PLEASE CONSIDER CAREFULLY YOUR RESPONSES TO THIS SECTION. YOU NEED TO BE CLEAR AS TO WHAT IS OCCURING WITH RESPECT TO DATA COLLECTION, RETENTION and DISPOSAL.
(In your responses, you should demonstrate familiarity with National Statement requirements for confidentiality and relevant Privacy Principles

D1 DATA COLLECTION/RECORDING

Please note that, with any information or data collected/retained, if any individual can reasonably be identified, the information can be deemed "personal information" or "health information" under National/Health/Information Privacy Principles (NPPs/HPPs/IPPs).

(a) How or in what form will **data** be collected/recorded?

(*eg, notes; verbatim, audio and/or video recordings; transcriptions of recordings; recorded or signed consents; etc*)

(b)

As regards **any individual**, in relation to any data collection or retention, you need to acknowledge either or both of the following:

[*Double-click on ☐ 'check box' to select X by entering in Default Value as Checked ☒ or leaving as Not Checked ☐*]

☐ **An Individual can be identified OR is Potentially Identifiable / Re-Identifiable**

(*An individual can be identified at some point or by the very nature of the data collected/retained: at time of an interview, by signed consent form, identified or labelled voice or image recording, pen-and-paper questionnaire, on-line survey instruments, etc.*

Whilst data may not have (explicit) identifiers, an individual's identify can still reasonably be worked out.

Or data may have (explicit) identifiers removed and replaced by codes that permit matching of an individual with the data collected/retained, in which case it is possible to identify or re-identify the person to whom the data relates.)

☐ **An Individual is Non- or Un-identifiable**

(Data collected/retained anonymously and with no reasonable possibility of being identified.)

Your acknowledgement may require further explanation or clarification; if so, please include in the following box.

D2 DATA SECURITY (Nb Section D2 Revised Aug 2007)

Please note that "data must be held for sufficient time to allow reference. For data that is published this may be for as long as interest and discussion persists following publication. It is recommended that the minimum period for retention is at least 5 years from the date of publication but for specific types of research, such as clinical research, 15 years (or more) may be more appropriate."

Please indicate **how data** (all types of data, including, eg, signed consent forms) **will be securely retained** (eg, electronic form in password-protected disk drive, locked filing cabinet, etc) **and where**? With more than one type of data, will the types be separately stored?
In your explanation, you will need to make clear **how due confidentiality and/or anonymity will be maintained**.

(a) During the study

(b) Following completion of study

D3 PUBLICATION/OUTPUT (Nb Section D3 Revised Aug 2007)

Please explain in sufficient detail:

(a) What, if any, publication (conference, news media, academic journal, other journal, etc) is envisaged following on or in relation to this project, both in terms of data proper and/or analysis of data?

(b) Will participants be informed about any envisaged research publication/outcome? (This information is normally to be included in the information given prior to obtaining informed consent.)

(c) Would any participants be able to be identified through the publication of data proper or research findings? If so, explain why this is necessary.

a)
b)
c)

D4 INDIGENOUS ISSUES

Storage arrangements for data relating to research into Indigenous matters must be determined in compliance with the Policy on the Conduct of Research after consultation with the communities involved.

What consultation has taken place and what arrangements have been made.

D5 OTHER ISSUES (Nb Section D5 Revised Aug 2007)

Are there any other issue relating to data collection, retention, use or disclosure which the ethics committee should be made aware of and, if so, please explain how you are to deal with this.

(Eg, Research outcomes unduly impacting on any individual or group not directly participating, etc.)

SECTION E: SUBSTANCES & CLINICAL ISSUES

☐ ***No*** matters in this section are applicable to the study *or*

E1 ADMINISTRATION OF SUBSTANCES/AGENTS

Name of substance(s)		
Dosage per administration		
Frequency of administration		
Total amounts to be administered		

Anticipated effects:

NOTE: *If the research involves administration of foreign substances or invasive procedures, please attach a statement accepting responsibility for those procedures by a medical or paramedical practitioner with Indemnity insurance.*

☐ STATEMENT ATTACHED

E2 BODY FLUIDS OR TISSUE

What fluids or tissue? How will be samples be obtained?

Frequency and volume

How are samples to be stored?

How will samples be disposed of?

Who will take the samples?

What are their qualifications for doing so?

Do participants carry, as far as you know, the Hepatitis B or HIV virus? If so how will the risks be handled

Do participants carry, as far as you know, any other contagious diseases or viruses? If so how will the risks be handled

SECTION F Declarations for Signature [1 2 3]

1. With respect to this project**, I / We, the undersigned Investigator(s)/Assistant(s) agree**:

- **To undertake human research activity or handle data confidentially in accordance with NIIM requirements, including any standard or special ethics clearance conditions, under the proper oversight of the NIIM Director of Research.**

NAME: (block letters)	SIGNATURE:	DATE:

All listed applicants must sign. The Chief Investigator/Supervisor is also responsible for personnel subsequently joining the project. Expand this table or duplicate this page as required.

****** Please note that ******
PROJECTS MUST NOT COMMENCE WITHOUT PRIOR WRITTEN APPROVAL from the NIIM Human Research Ethics Committee

2. Declaration of Compliance by Chief Investigator(s).

I declare that the above project has been developed and will be conducted in accordance with relevant NIIM standards, policies and codes of practice, including any standard or special conditions for on-going ethics clearance. I further declare that all listed and subsequently appointed researchers or assistants involved in this project will be made aware of the conditions of ethics approval as communicated to me, including approved documentation and procedures.

Signature & Date: ……..…

Name of Signatory & Position: ……..……