**APPLICATION FOR ETHICS REVIEW**

**Checklist for Applicants**

**1 copy of the following (attached to the master file of the research proposal)**

[ ]  Cover letter

[ ]  Receipt of payment

**3 hard copies of the following**

[ ] *Part 1 & Part 11* of the application

[ ]  Research Proposal

[ ]  Academic supervisors’ letters (if relevant)

[ ]  Ethics approval from other institutions

[ ] Instruments (questionnaires/ interview guides/ checklists/ data extraction forms) to be used in the research in English with appropriate translated version (Sinhala, Tamil or both)

[ ] Participant information leaflet in English and with appropriate translated version (Sinhala, Tamil or both)

[ ]  Informed consent form leaflet in English and with appropriate translated version (Sinhala, Tamil or both) with the principal investigator’s contact information and contact number for any complaints

[ ]  CV of Principal investigator and the other relevant co-investigators (if the PI is not the subject specialist)

**20 copies of the,**

[ ]  Project summary **(refer section 1.10 of this application)** with principal investigators name and the project title.

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**Instructions to fill the ERC application**

**General Instructions**

General instructions on submissions and completion of the application form are under alphabetical listing below. The specific instructions on each item in the application are given under the same corresponding number. Sample participation information leaflet and consent form are available in the web site and use them as a guide when preparing your participant/patient information leaflet and consent form.

1. Ethical approval is required for all research involving human participants, biological samples or personal data. Personal data comprise information about living people who can be identified from the data or from combinations of the data and other information which the person in control of the data has, or is likely to have in future.
2. Application form should be filled in English. (Handwritten application forms will not be accepted). Applications can be obtained from the website and handed over to, ethics review committee, GWUIM.
3. Application forms should be submitted as Microsoft word documents with the font size 12, font type “Times New Roman” for text and line spacing at one point five. **Bold** should be used for headings rather than underlining. If and where there is a word limit please indicate the number of words. Instructions to the applicant are written in italics. Application forms with track changes will not be accepted.
4. The deadline for the submission is 15th of each month for it to be considered in the next Ethics Review Committee meeting. Proposals submitted after the deadline will be considered at the meeting of the following month.
5. Three full copies, each copy consisting of the application form with CVs of the principal and other relevant co-investigators (if the PI is not the subject specialist), research proposal, participant information leaflets, consent forms, questionnaires in English and the relevant languages and all supplementary documents should be submitted to the ERC. All three copies should be separately filed with no loose sheets hanging out. Filing and binding with a cord is sufficient. On top of each file cover print principal investigator’s (PI) name and the title of the project. One of the copies (Master file) should contain cover letter and receipt of the payment. Pages should be numbered.
6. Twenty copies of the project summary with PIs name and title of the research project also should be submitted.
7. If the proposal has undergone a scientific review, the review report should be attached to the application. Otherwise, ERC will conduct a scientific review prior to the consideration of ethical issues of the research.
8. Applicants will receive notification letter on the status of their proposal within seven working days of the relevant monthly ERC meeting.
9. The fee structure for reviewing and processing an application will be
10. For undergraduate students of GWUIM of Sri Lanka – No charges
11. If the principal investigator is a member or from the teaching staff of GWUIM, No charge
12. For all other principal investigators – Rs. 2000/=.
13. International applicants – US$ 100
14. Applicants from South Asian countries- US$ 50
15. For industry - Rs 5,000/= (non-pharmaceutical)
16. Pharmaceutical industry sponsored Rs 50,000/=
17. For resubmissions the above mentioned full amount has to be paid
18. For amendments: a new payment - Rs.1500/=

(However fee waiver can be considered on request for those who have financial constraints).

Payment should be made to the Shroff counter, GWUIM between 09.00- 15.00 hours of working days. Please note that all payments are non-refundable.

1. Any and all changes or additions to the proposal should be submitted in clear and concise English using the font styles and sizes mentioned above and triplicate copies should be handed over to the ERC secretariat.
2. The entire evaluation procedure could extend from a minimal of one to maximum of three months.
3. Submission of the copies of ethical approval from other ethics review committees and evidence of scientific review (grant approval, degree awarding institutions approval) with your application will expedite the review process.

**Specific instructions for filling the application**

* 1. In addition to a descriptive title a short running title should be provided.
	2. Please submit full CVs of the principal investigator/s.
	3. Please submit full CVs of the co-investigators (if the PI is not the subject specialist).

1.10. SUMMARY OF THE PROJECT
Project summary of no more than 500 words (in nontechnical language) should be submitted to the ERC.  This initial summary would detail:

1. Introduction justification and existing knowledge in the relevant field
2. The objectives of the research and hypotheses
3. Expected outcomes of the research
4. The methodology used for the research
5. The sample size used for the research
6. The time frame of which the research will be conducted.

The summary should be written in clear, concise English and should be self-explanatory. This summary will be available to all the members of the ERC including lay members.

4.2. Use the given standard format (available in the web site) for the participation information leaflet (English). Take it as a guide and include only relevant sections. If you are using Sinhalese and Tamil speaking participants, submission of participation information leaflet in the relevant language/s along with the English participation information leaflet is mandatory.

4.3. Format for consent form in English is available in the web site. Take it as a guide and include only relevant sections. If you are using Sinhalese and Tamil speaking participants, submission of consent form/s in the relevant language/s along with the English consent form is mandatory.

4.9. In case of research involving children below the age of 12 years, informed consent should be obtained from the parents. If participants are between 12 to 18 years, assent (consent from children) and consent from their parents should be obtained.

**Application for Ethics Review - PART 1**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *for official use*  | No; ERC |  | Checked by |  |
| ERC Discussion | No Risk / Minimal Risk / Greater than Minimal Risk |
| ERC Recommendation | Exempt from Ethics Review / Expedited Review / Full Committee Review |
| Reviewer 1 |  | Reviewer 2 |  |
| Instrument, PIL and ICF reviewer | Sinhala |  | Tamil |  |
| Received date |  | Meeting Date |  |
| Decision | Approved/ Approved with corrections/Resubmission/Rejection | Date Informed |  |

* 1. Title of Research Project: descriptive and short *(please read Page 3 of the application before completing this)*

|  |
| --- |
| Descriptive title:  |
|  |
| Short title: |

* 1. Principal investigator/ applicant (*please attach CVs*)-if you have more than one PI please duplicate this form

|  |  |
| --- | --- |
| Title | Mr/Ms/Rev/Dr/Prof |
| Name  |  |
| Current designation |  |
| Institute where the applicant is attached |  |
| Highest educational qualification of the applicant |  |
| Telephone (office) |  |
| Telephone (home) |  |
| Telephone (mobile) |  |
| e mail (main method of communication) |  |
| Address for correspondence  |  |

* 1. Names, qualifications and affiliations of the co-investigators.

|  |  |  |
| --- | --- | --- |
| **Name**  | **affiliation** | **Qualifications** |
|       |       |       |
|       |       |       |
|       |       |       |

* 1. If this is a student project (undergraduate or post graduate) please give details of your academic supervisory arrangements.

|  |  |
| --- | --- |
| Course/Degree |  |
| Institution/ Faculty |  |
| Academic supervisor/s (*name, affiliation and qualifications*) |  |

* 1. Where will the study take place?

a. Is this a collaborative and multi-center trial?

[ ]  No

[ ]  Yes

If yes please describe the other centers and collaborating institutes or universities.

b. Please indicate what other research ethics committees have been approached and what the outcome of the proposal.

* 1. Has this research proposal undergone scientific review

[ ]  No

[ ]  Yes

*If yes please give details*

* 1. Please name the source of funding and the amount.
	2. Data collection period (*from the initial recruitment of participants to completion of data collection*)

 D D M M Y E A R

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Starting date |  |  |  |  |  |  |  |  |  |  |
| Finishing date |  |  |  |  |  |  |  |  |  |  |

* 1. Is this research in your opinion warrants expedited review?

[ ]  No

[ ]  Yes

*If yes please justify in a separate letter addressed to Chairperson ERC*

* 1. Project summary (*of no more than 500 words in non-technical language*) with PIs name, title of the research project on top and a word count in this form. Also submit twenty copies (20) of the project summary with PIs name, title of the project and word count in a separate file.

A structured project summary should include the rationale/ background (2-3 sentences), objectives of the proposed study hypotheses to be tested and the methods. Study design, sample and sampling procedure, measurements and data collection, and data analysis with outcome measures should be included in the methods section of the summary.

*Title of the research*

*PI's name*

|  |  |  |  |
| --- | --- | --- | --- |
| Word count |  |  |  |

Project summary

**Application for Ethics Review - PART 11**

**SECTION A**

**RESEARCH PROJECT***-please attach a complete protocol of your research*

All proposals that has not undergone prior scientific review will undergo scientific review (Standards and operational guidance for ethics review of health-related research with human participants World Health Organization 2011)

2.1 **Please indicate study type**– *you may tick more than one box.*

|  |  |
| --- | --- |
|  | Laboratory study not using animals  |
|  | Laboratory study using animals |
|  | Laboratory study using stored human biological material  |
|  | Participant observation  |
|  | Interviews, focus group |
|  | Other type of qualitative study  |
|  | Social science research |
|  | Research on medical records or other personal information |
|  | Health system research |
|  | Implementation research |
|  | Cross-sectional study  |
|  | Case-control study  |
|  | Cohort study  |
|  | Randomized Controlled Trial not using experimental drug or device |
|  | Randomized Controlled Trial using experimental drug or device |
|  | Phase 1 or 2 of trial using a experimental drug or device |
|  | Other type of study (please describe) |

2.2 What are the Hypotheses and objectives of the research project?

2.3 How will the participants in the study be selected? What inclusion and exclusion criteria will be used?

2.4 Will any drugs or devices (in a clinical trial phases 1-4) used as part of the research that are additional to those which would be administered to these subjects as part of their routine clinical care?

[ ]  No

[ ]  Yes

*If yes, please complete Appendix A*

2.5 Will any ionizing radioactive substances or X-rays be administrated which are additional to those which would normally be administered to these subjects as part of their routine clinical care?

[ ]  No

[ ]  Yes

*If yes please complete Appendix B*

2.6 Does your study involve DNA analysis, storage, genetic modification, stem cell research?

[ ]  No

[ ]  Yes

*If yes, please complete Appendix C*

2.7 Does your study involves complementary and alternative medicine (CAM)

[ ]  No

[ ]  Yes

*If yes please complete appendix D*

2.8 Does your study involve animal research?

[ ]  No

[ ]  Yes

 *If yes please complete appendix E*

**SECTION B**

**PARTICIPANT RISK**

1. *Please fill the table below*

***Additional Procedure***

***Routine Procedures***

***Investigation***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | *Yes* | *No* | *Yes* | *No* |
| Self-completed questionnaires |  |  |  |  |
| Structured interviews/researcher completed questionnaires  |  |  |  |  |
| Venipuncture |  |  |  |  |
| Arterial puncture |  |  |  |  |
| Biopsy |  |  |  |  |
| Other tissue/ body sample |  |  |  |  |
| Ionizing radioactive substances/X-rays |  |  |  |  |
| Non-radioactive imaging investigations |  |  |  |  |
| Non-invasive tests (eg. ECG) |  |  |  |  |
| Anesthesia, sedation |  |  |  |  |
| Other medicinal products |  |  |  |  |
| Medical devices/ equipment |  |  |  |  |
| Hospitalization |  |  |  |  |
| Longer inpatient days |  |  |  |  |
| Additional outpatient attendances |  |  |  |  |
| Other investigations not part of routine care |  |  |  |  |

3.2 Description of the procedure to be carried out on these participants (administration of a questionnaire/drug/collection of blood/ samples/ investigation/surgery)

3.3 Safety measures employed during the procedure

3.4 Are there any potential hazards/ risks/discomfort / distress/ inconvenience to the participants, their relatives or the investigators? *Please describe*

3.5 How this will be minimized? *Please describe*

3.6 Potential benefits to the participants and the community and any steps taken to enhance these benefits. *Please describe*

3.7 Justification of potential benefits over the risks. *Please discuss*

**SECTION C**

**RECRUITMENT AND CONSENT**

4

4.1 Who will approach the participants initially? *Please submit any letters / advertisements to employers/ schools etc. or newspaper advertisement that will be used. Please explain the training and educational qualification of the people who will obtain consent.*

4.2 Will there be a participant information sheet?

[ ]  Yes

[ ]  No

*If no please justify. If yes, please attach copies in English and in the language of the participant*

4.3 Will informed consent be sought?

[ ]  Yes

[ ]  No

*If Not please justify*

4.4 Will consent be written or oral? *Oral consent should be justified below. Please attach written consent form in English and in the language of the participant.*

4.5 Incentive or compensation if any offered to the participants

[ ]  No

[ ]  Yes

*Please justify if yes, or no and if yes describe the incentive*

4.6 Describe any steps to ensure whether participants have understood the information procedure

4.7 Please describe the procedure of obtaining consent (*describe the time interval between providing information to the participants and obtaining consent, the space given to discuss with their significant others about participating, any special considerations to vulnerable groups etc*)

4.8 Please describe the procedure if the participant wishes to withdraw from the study

4.9 Will there be proxy consent (in acutely ill patients, patients with cognitive impairment, and in children) please describe and justify

4.10 What data will be collected from the participants who refuse consent?

4.11Describe procedure for participants to ask questions and register complaints

**SECTION D**

**CONFLICTS OF INTEREST, INTELLECTUAL PROPERTY AND CONFIDENTIALITY**

5.1 Are there any financial or other incentives for the participants or recruiting physicians, mid wives or any other official?

[ ]  No

[ ]  Yes

*If yes, please give details*

5.2 Are there any interests for the investigators over and above those detailed in this form?

[ ]  No

[ ]  Yes

*If yes, please give details*

5.3 Are there any conflicts of interest or duality of interests such as that between providers of funding and the investigators?

5.4 Who besides the named investigators will have access to the participants’ medical/ personal records? Please describe the procedure to ensure confidentiality of data?

5.5 Is there any indemnity, Insurance or liability cover for the project? (This may not be necessary in majority of research projects) If No who would take responsibilities in the event of a claim?

5.6 Will the proposed research use technology, materials or other invention that, as far as you are aware, are subject to any patents or other form of intellectual property protection? Please give details (no more than 200 words).

5.7 Is the proposed research, (in whole or in part) subject to any agreements with commercial, academic or any other organizations? If yes Please give details (no more than 200 words).

5.8 Is the proposed research likely to lead to any results that could be patented or commercially exploited? Please give details (no more than 200 words).

5.9 Will any potentially commercially exploitable results be based upon tissues or samples derived from human participants?   Please confirm that there has been appropriate informed consent for such use.

**SECTION E**

**DISSEMINATION OF THE FINDING, PUBLIC ENGAGEMENT & COMMUNITY CONSIDERATIONS**

6. 1 Please describe if relevant the steps taken to consult with concerned community when designing the research and during the course of research (no more than 200 words).

6.2 Please describe briefly how you address or engage the community and the collaborations you have built with the community. (No more than 200 words).

6.3 Please outline your plans, for engaging non-academic public audiences. Particularly the way you intend to make the results of your research available to the participants and to the concerned community (no more than 200 words).

6.4 Please describe briefly the plan for dissemination of findings (no more than 200 words).

7.Declaration

I certify that the information given above is true and correct to the best of my knowledge. If there is change in the protocol or the research project is terminated before completion, I will inform the ethics review committee. I will also inform if there are any serious adverse events to the human participants during the research project.

 **Date:**       **Applicant’s signature:**

 **……………………………… ……..……………………………………**

**APPENDICES: A, B, C, D & E**

*(COMPLETE ONLY IF APPROPRIATE TO YOUR STUDY)*

**APPENDIX A**

**CLINICAL TRIALS**

A.1 Is the clinical trial registered with a clinical trial registry and if yes please provide details.

A.2.Please tells us if it is a phase 1,2,3 or 4 study.

A.3 Please tell us the centers that are participating in the study or whether it is a single center study

A.4 Do you have trial steering committee, management group and data and safety monitoring board? If yes please provide brief description about it and the personnel

(*Please attach CVs of all committee members*)

A.5 Is this product registered in CDDRA if yes please provide evidence and if not please justify

A.6 Is this clinical trial related to new pharmaceutical product or device or a new indication of already registered pharmaceutical product or a device; if it is please providing details of it (approved name, purity, stability, dosage, frequency of administration, storage, dispensing, accountability, placebos, etc).

A.7 Details of animal studies, human toxicological data, adverse events, serious adverse events.

A.8 Details of indemnity and insurance coverage for participants, investigators and ethics committees.

**APPENDIX B**

**RADIATION EXPOSURE**

B.1 If you are intending to use non-ionizing radiation, i.e. lasers, microwave, ultra-violet or other type of electro-magnetic energy, please provide details of exposure:

B.2 Details of radioactive substances (isotopes) to be administered or radiographic procedures.

B.3 Who will administer the radio-pharmaceuticals? Please provide name and list their qualifications.

B.4 Quantity of radioactivity to be given (MBq). Give source of reference or submit calculation.

B.5 What is the dose constraint expressed as the effective dose (mSv) for the research-related exposure for the participant? Give source of reference or submit calculation.

B.6 Have pregnant patients/volunteers (except in specified exceptional circumstances) been excluded?

B.7 Have breast-feeding volunteers (for radionuclide studies only) been excluded? If not justify why not.

B.8 For patients, are there any radiation exposures specific for the project over and above those required for normal clinical management.

B.9 Does the information to patients/volunteers make clear that some additional exposure to ionizing radiation is involved and the consequent risk.

B.10 Could the clinical information be obtained by an alternative method involving a smaller dose? If YES, attach details describing the reasons for choosing the proposed examination.

I have delegated authority to administer the radioactive substance(s) in this project to Prof/Dr/ Mr./Ms…………….…………………………………and I approve the arrangements that have been made.

………………………………………………………… ...……………….

Signature of Consultant/ Head Radiology or Nuclear Medicine Date

Name of the Institute ………………………………………………………………..

**APPENDIX C**

**RESEARCH INVOLVING Human Biological material including DNA / RNA**

**This section will be developed further**

C.1 Are you using any part of the human body for research into DNA or RNA (biopsy, tissue, buccal smears, tumor, blood, hair, nail cadaveric tissues are human biological material). If yes please describe

C.2. Will the biological material have stored after research? If yes please describe the storage and whether the human biological material is anonymised or unlinked.

General instructions

Genotyping results should not be given to individual participants unless there is a high risk of a disease occurring because of the genetic variant carried.

When obtaining consent to take a sample of biological material for research it is important that donors have sufficient understanding not only of the process involved in taking the samples and any associated physical risks, but also of what the sample is to be used for and how the results of the research might impact on their interests.

The use of anonymised, unlinked samples is recommended wherever possible. Anonymised means that individual samples are not identifiable while ‘unlinked’ means that it is not possible to trace samples back to the individual, for example through the use of a key-code.

Where there is the potential for the sample being used for further research outside the remit of the study for which consent is being sought, a two part consent process should be used. The first should request consent for the planned research and the second should ask for consent for the storage and future use of the sample for further research. Only where a sample is irreversibly anonymised is it acceptable to seek blanket consent for the future use of tissue samples in all biomedical research (as opposed to seeking consent for use in specific projects or types of research e.g. projects looking at genetic variants associated with depression).

There are certain types of genetic research which gives rise to particular concern, for instance, that relating to personality, behavioral characteristics, sexual orientation or intelligence. It is particularly important that specific consent is obtained to use samples in these or other areas of research that are likely to cause special concern to the donors, even if the samples are to be irreversibly anonymised.

When samples are not anonymised or may be linked to individuals, possible future research should be explained in terms of the types of studies that may be done, the types of disease that could be investigated, and the possible impact of the research on them personally.

Participants must be assured that all secondary uses will require approval by an ethics committee. Participants should be informed of when and how any surplus material will be disposed of.

“The human body and its parts shall not, as such, give rise to financial gain”. Therefore, while reasonable travel expenses may be reimbursed, research participants should never be offered any financial or material inducement to donate biological samples for research. There should be no inducements to donate but participants may be reasonably compensated for time, inconvenience and discomfort.

If samples are to be used by the commercial sector this should be detailed and the researcher must ensure that participants are made aware of this in the study information and that they know they will not be entitled to a share in the profits.

**High risk genetic research**

Tests done on samples of human material in the course of research may reveal information that has implications for the donors’ future health or healthcare, or otherwise impacts on their interests. It is important to decide before the start of a research project what will be done if this arises. Researchers should be cautious about assuming that they, rather than the individuals concerned, are best placed to judge what information is of interest to donors on a case-by-case basis. For instance, some researchers may take the view that information should only be fed back if there is a treatment or preventive intervention available. However, research participants might wish to know predictive information about their future health, even if there is no treatment available, for example to take it into account when making important life decisions, such as whether to have children. Researchers should assume that participants have a right to know information that may affect their interests, but that they might choose not to exercise that right. When participants are asked to make a decision on whether or not they want results to be fed back to them they must be given sufficient information to allow them to decide what their interests are and to make any refusal meaningful.

Researchers must decide at the outset what their strategy is with regard to feeding back information on individual results to participants - noting that this should only be done when it is essential. If feedback is to be provided then the most appropriate method of keeping data is for researchers to retain a linking code between anonymized data and participant identities (meaning the anonymisation is reversible). In all other cases data should separated from identifiable information and rendered truly, irreversibly anonymous.

This must be set out in their submission to the ethics committee, and the policy adopted must be explained clearly to research participants before they consent to take part in the research. If you decide that individual results will not be provided then the rest of the section will not be relevant to you – however, you should ensure that a clear justification for this decision is given within the application form.

Where a result that can be linked to an individual has immediate clinical relevance (for example, if it reveals a serious condition for which treatment is required), the researcher involved has a clear duty of care to inform the research participant, either directly or via the clinician responsible for his or her care (in which case the participant must give permission for the researcher to share this information). A research result should not be relied on as the sole basis for diagnosis, since quality control standards in research laboratories generally differ from those used for clinical testing. Research participants or their clinicians should be advised to seek a repeat or confirmatory test by a clinical diagnostic laboratory where possible. Where a confirmatory test is not available the diagnosis might need to be verified by the research laboratory using a new sample.

Genetic tests of known clinical or predictive value should not be done on samples that can be linked to an individual without their specific consent, and appropriate counseling should be available if consent for such a test is sought. Participants should be advised of the possible implications of genetic information for other family members and the potential impact on family relationships, and also of the implications of genetic risk information for employment or their ability to obtain insurance, before they decide whether to give consent to the test or whether they want to know the result. The feeding back of other genetic information, the significance of which is currently unknown could also have a similar implication in the future which is why this is not recommended.

**Changes that may need to be incorporated into the consent form**

• I give my consent for my blood to be genotyped for this study.

• I understand that I will not receive any results about my own genotype.

• I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data and samples up to the point of publication or up until the point stated on the Information Sheet.

• I understand that I will only have the option of receiving information about my particular genotype if I am found to carry a variant associated with the disease.

• I would/would not like to be informed if it is suspected that I am a carrier of a gene variant associated with the disease.

**Changes that may need to be incorporated into the information leaflet**

• Inherited risk and implications for wider family including brothers, sisters, and children e.g. future reproductive decisions.

• Insurance status, for example, at some point in the future, this result, if known to the individual, may result in rejection for a policy or loading of a premium.

• Knowing this result may mean that individual ought to receive treatment to reduce possible consequences.

• That knowing this result may now or in the future need to be declared during the course of a medical examination for employment, or applications for life assurance or sickness insurance, and that failure to declare this may be contrary to the terms of the policy of employment or contract.

• What counseling support would be available?

• It may be necessary to refer the participant for re-testing by genetic services outside the study.

**APPENDIX D**

**COMPLIMENTARY AND ALTERNATIVE MEDICINES (CAM)**

This ethics review committee will accept to review research proposals in fields of complementary and alternative medicine. When reviewing such research it will look for the presence of accepted standards of research norms, ethical considerations, and research methodologies in the proposals. But it will also accept some important concepts and realities unique to CAM.

The committee will accept the following issues in CAM research when reviewing the proposals and will approve such proposals while making sure the basic ethical and methodological standards are met.

Some of the Issues that are recognized by the ERC, GWUIM would be as follows:

1. Need to allow research with CAM drugs without undergoing the same rigorous procedures as when researching with a new drug when the drug/s under study;

1. had been mentioned in the original classical texts of their relevant fields,

and/or

1. Had been in use over a long period of time without reports of concern

and

1. Are already in wide use in CAM sector,

2. Need to accept the “Patient individualized treatment model” of some CAM systems like Ayurveda in clinical research.

3. Accepting the properties of single herbs will not be manifested when they are in combination with many others in complex drugs which are used in CAM systems and that these drugs may possess entirely different properties than if each ingredient is studied in isolation.

4. Please address these concerns and issues in your protocol.

* Disclosure of the formula of traditional drugs involved in the research.
* Potential toxic effects in the traditional medicine
* Importance of having western medical personnel in the research team.

**APPENDIX E**

**ANIMAL RESEARCH**

Please read this guidance carefully.

**Animals - reduction, replacement and refinement (the 3Rs)**

In all animal experiments the principles of reduction, replacement and refinement will apply. In all experimental studies, it is the responsibility of the Principal Applicant to actively consider:

* The complete replacement of live animals with tissues derived from either animals or humans;
* The possibilities of reducing the numbers of animals that need to be used;
* Refining the experimental design in order to obtain the maximum amount of information from the minimum number of animals.

Refined methods in animal research are those which alleviate or minimize any adverse effects for the animals involved, and/or enhance animal welfare. Refinements may be applied at any stage in the life of an animal. Thus, refinement encompasses all aspects of a procedure, including:

* the source, transport, husbandry and environment of the animals involved;
* the experimental design (e.g. the choice of species and the group size employed);
* the techniques applied;
* the end points of the procedures; and
* Care of the animals before, during and after a procedure.

**Monoclonal antibodies**

The use of ascetic animals for monoclonal antibodies (mAb) production *in vivo* should only be proposed when *in vitro* attempts at mAb production have failed or the use of animals is considered justified for specific diagnostic or therapeutic products. If *in vitro* production methods are not considered to be suitable, a full explanation must be given.

E. 1. Do your proposals involve the use of animal tissue?

E. 2. What would be the severity of the procedures used?

E. 3. Details of any procedures of substantial or moderate severity (no more than 250 words).

E. 4. Why animal use is necessary: are there any other possible approaches? (no more than 250 words).

E. 5. Animal species to be used

1. Primate
2. Cat
3. Dog
4. Equidae
5. Genetically altered animals
6. Other animals

E. 6. From where will the animals be sourced? (no more than 250 words).

E. 7. Will it be necessary to transport the non-human primates (i.e. from breeding facility and within the host institution environment)?

E. 8. Indicate approximate journey times and the measures that will be taken to minimize the potential stress during transport (no more than 250 words).

E. 9. Will single housing of the non-human primates be necessary at any time?

E. 10. Please provide details in terms of the justification for single housing, its duration, and what additional resources will be provided to the animals to minimize the impact on animal welfare (no more than 250 words).

E. 11. Describe the experimental procedures involved and how any pain, suffering, distress and/or lasting harm will be minimized.

E. 12. Will any of the experimental procedures involve food and/or water restriction? Justify why this is necessary and outline what alternatives have been considered (no more than 250 words).

E. 13. Will any of the experimental procedures involve restraint? What alternatives have been considered? Describe the nature of the restraint, its duration and frequency, and what will be done to avoid distress. (no more than 250 words).

E. 14. What prior experience and training in non-human primate use, care and welfare has the staff named in the application had? What provision is made for continuing professional development in these areas? (no more than 250 words).

E. 15. What prior experience and training in non-human primate use, care and welfare has the staff named in the application had? What provision is made for continuing professional development in these areas? (no more than 250 words).

E. 16. Will any of the staff involved require specific training for any of the procedures concerned?

E. 17. Please provide details of the training needed and where it will be undertaken (no more than 250 words).