**National Institute of Integrative Medicine**

Date Received

………………..…

HREC No:………

**HUMAN RESEARCH ETHICS COMMITTEE**

**APPLICATION FOR ETHICS APPROVAL
of a
RESEARCH PROTOCOL**

## SECTION A: GENERAL INFORMATION

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| --- | --- |
| **PROJECT FULL TITLE** |  |
| **SHORT TITLE** **(If applicable)** |  |
| **APPLICANT DETAILS** |  |
| **RESPONSIBLE CHIEF INVESTIGATOR** | **Name & Title/Position:**  |
| Tel No(s):  |
| Email:  |
| Address for correspondence:  |

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

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

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

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| **Proposed Period During Which Human Research Activity Requiring Ethics Approval is Needed:** | **From** |  |  | .. | **to** |  |  |  |
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*[Double-click on* [ ]  *YES/NO 'check box' to select box, then enter Default Value as Checked* [x]  *or leaving as Not Checked* [ ]  *]*

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| --- | --- | --- |
| TYPE OF ACTIVITY(Select as many boxes as applicable) | [ ]  Clinical Trial | [ ]  Contract Research (Attach copy of contract) |
| [ ]  Survey | [ ]  Observational Study |
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| *Official Use Only:*  **[ ]  Higher Risk/Impact [ ]  Minimal Risk/Low Impact Research Only** |

Have you previously submitted this study to another human research ethics committee for approval?

[ ]  Yes [ ]  No

**If you answer ‘yes’ above, please indicate the reason(s) for rejection**

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### A1 *WHY* IS THE PROJECT TO BE UNDERTAKEN

**What is the research question**, and how does this emerge from gaps in the knowledge base? Summarise these in one paragraph each here and refer to the Research Protocol for the more extended discussion.

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| **Gaps in the current knowledge:****Research Question:** |

### A2 *WHAT* OUTCOMES WILL BE MEASURED?

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| **Primary Outcomes**:**Secondary Outcomes:** |

### A3 *HOW* WILL THE RESEARCH BE CONDUCTED?

**Summarise the research process**

Please attach the Research Protocol (which should include all attached screening instruments, questionnaires, interview protocols etc) and where relevant, the Investigator Brochure (detailing the investigational product(s)).

In the case of a clinical trial, detail whether observational or controlled (and how)

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**How will the research outcomes be measured?**

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### A4 DESCRIBE ANY RISKS THAT MAY ARISE TO THE PARTICIPANT

Please describe any risks you perceive and the protective measures to be taken.

Including, regret, embarrassment, civil or criminal liability, disease, physical harm, loss of employment or professional standing, etc. Please consider such possibilities carefully

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| **Potential adverse events/reactions:****Potential serious adverse events/adverse reactions:****Any other risks:** |

### A5 DESCRIBE ANY RISKS THAT MAY ARISE TO THE RESEARCHERS / ADMINISTRATORS?

Some research activities may put the researcher at risk through what is being done or simply through their participation.

Please describe the risks you perceive and the protective measures to be taken.

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### 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

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

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### A7 CONTINGENCY PLANS FOR POTENTIAL PROBLEMS

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.

*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.*

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### A8 PROFESSIONAL QUALIFICATIONS AND EXPERIENCE IN RESEARCH

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) Detail what each investigator/assistant will do in this project and their individual experience/expertise/competence to do so.

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

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### A9 FUTURE USE OF DATA

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

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| The data collected will be used to |

### 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

**If you answer ‘yes’ above, please detail the nature of the other body’s involvement. Are they a sponsor?**

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### A11 RESEARCHER / SPONSOR RELATIONSHIP

Is there any relationship or association between a sponsor and any of the researchers listed in Section A of this form, for example are any of the researcher’s 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.)

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### A12 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.

Is external approval necessary?

[ ]  Yes

If so 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)

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[ ]  No

## SECTION B: ETHICAL ISSUES OVERVIEW

### ETHICAL ISSUES

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

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| --- | --- | --- | --- |
|  |  | **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.)

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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)*

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| --- | --- | --- | --- | --- | --- | --- |
| Males: |  | Females: |  |  | Total participants |  |

Over what range of ages?

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| From (youngest): |  | To (Oldest): |  |

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

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How did you determine the sample size needed (e.g. did you undertake a power calculation and if not, why not)?

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Inclusion criteria

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Exclusion criteria

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### C2 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)?

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### C3 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, poster, email or other notices please attach proposed copies or text.*

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### C4 DISCLOSURE AND INFORMED CONSENT

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

[ ] Participant Information Statement and Informed Consent Form(s) will be used

OR

[ ] Consent implied by return of anonymous questionnaire (Please explain how and why)

OR

[ ]  Other (Please explain how and why)

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**Copies of appropriate consent instruments must be attached to your application**.Please consult the [Guide to Human Research Informed Consent Instruments](http://www.research.swinburne.edu.au/researchers/documents/Oct09_Guide_Consent.doc) 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

1. Provide details of any financial or other reward or inducement which is being offered to subjects for participation (including provision of product). Indicate the source of the funds.

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1. If products are being offered without charge, will subjects in the placebo arm be offered the same quantity of verum products at the end of the project as those in the placebo arm?

[ ]  Yes [ ]  No

1. Detail any payments the subjects will be required to make (e.g. for products or consultations)

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### 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.

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### 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; groups with special circumstances - eg. persons with an intellectual or mental impairment.
Please identify and describe the nature of the groups and procedures used to obtain permission.

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### C8 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.*

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## SECTION D: DATA & PUBLICATION ARRANGEMENTS

(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*)

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1. 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* [x]  *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 identity 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:

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[ ]  **The project is based on pre-existing unidentifiable data and we apply for the waiver of the requirement to present a Participant Information Statement and Informed Consent Form**

### D2 DATA SECURITY

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) is 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? **and**
* **for how long**? (if not consistent with the NHMRC guidelines, please justify)

In your explanation, you will need to make clear **how due confidentiality and/or anonymity will be maintained**.

(a) During the study

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(b) Following completion of study

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### D3 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 involve 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.

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### D4 PUBLICATION/OUTPUT

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.

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Please detail any possible restrictions on publication in any sponsor contract, and reference to the paragraph or item number in the contract (and attach the contract)

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### D5 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.

If applicable, what consultation has taken place and what arrangements have been made.

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### D6 OTHER ISSUES

Are there any other issues 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.)

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## SECTION E: SUBSTANCES & CLINICAL ISSUES

[ ]  ***No***matters in this section are applicable to the study *or complete the following:*

### E1 ADMINISTRATION OF SUBSTANCES/AGENTS

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

Anticipated effects:

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***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?

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Frequency and volume

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How are samples to be stored?

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How will samples be disposed of?

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Who will take the samples?

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What are their qualifications for doing so?

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

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

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## 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.**

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| **NAME: (block letters)** | **SIGNATURE:** | **DATE:** |
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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**

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| **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: ……………………………………………………………………………….… |

**Attachments**

[ ]  Research Protocol

[ ]  Attachments (screening instruments, questionnaires, interview protocols etc)

[ ]  Participant Information Statement and Informed Consent Form(s)

[ ]  Permission of owner / occupier of premises at which the research will be conducted (if not at NIIM)

[ ]  Contract with sponsor

[ ]  Administration of foreign substances or invasive procedures - statement accepting responsibility for those procedures by a medical or paramedical practitioner with Indemnity insurance

[ ]  Ethical Issues attachments (Part B)

[ ]  Investigator (Product) Brochure

[ ]  Research Agreement (Contact) (where relevant)

[ ]  Advertising material (emails texts, posters etc)