



## RESEARCH ETHICS COMMITTEE APPLICATION FORM

**For Applicant to complete:**

Applicants' Name:

Title of Project:

**For Ethics Committee use only:**

Reference Number:

Date received: \_\_\_\_/\_\_\_\_/\_\_\_\_

Review Date:

Outcome:

☐

Approval

☐

Provisional Approval

☐

Deferral

☐

Approval Declined

Applicant informed (Date): \_\_\_\_/\_\_\_\_/\_\_\_\_

***Please complete form and select YES/NO options as appropriate. An electronic version of this form is also available on the AIT website.***

An application will only be accepted for review by the AIT Research Ethics Committee (REC) if it is completed fully and the relevant enclosures are received. Refer to the accompanying Guidance Notes when completing the form and complete the checklist on the next page before submitting the form. Where you have received permission to do this, or similar research in another institution, please provide evidence of permission with this application.

**Please ensure that all copies of the same document are collated together in sets: application form, proposal, participant consent form(s), patient information sheet(s) and Questionnaire(s).**

**Address to send application:**

**The Secretary  
AIT Research Ethics Committee  
Office of the Vice-President for Research  
AIT  
ethics@ait.ie**

## SUBMISSION CHECKLIST

Please indicate if the following have been enclosed by selecting YES/NO/Not applicable options below. Please forward copies of the form and relevant enclosures required as outlined below.

Qty		YES	NO	Not applicable
1	Electronic Copy of complete application. Filename: <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Copy of application form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Qty		Electronic Copy YES	Hard Copy YES	NO	Not applicable
1	Research Proposal Summary ( <u>No more than 4 A4 pages</u> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Participant consent form(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Participant information sheet(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Questionnaire(s)* <input type="checkbox"/> Final version <input type="checkbox"/> Draft Version	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Sample letters (GP, Recruitment etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Copy of Risk Assessment Form**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Copy of Principal Investigators CV (2A4 pages max)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Annex 1**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Annex 2***	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Annex 3**** (1 copy per procedure for which risk identified)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\* Please indicate if not yet finalised.

\*\* If the study involves the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence

\*\*\* If the study includes the use of ionizing or non-ionising radiation, radioactive substances or X rays

\*\*\*\* Please complete for each hazardous procedure

## STUDY DESCRIPTORS

Select all descriptors that apply to this study:

Competent volunteer	<input type="checkbox"/>	Cross-over	<input type="checkbox"/>	Biological material	<input type="checkbox"/>
Healthy volunteer	<input type="checkbox"/>	Case-study	<input type="checkbox"/>	Foetal material	<input type="checkbox"/>
Patient volunteer	<input type="checkbox"/>	Longitudinal	<input type="checkbox"/>	Hazardous materials	<input type="checkbox"/>
'Incompetent' patients	<input type="checkbox"/>	Cross-sectional	<input type="checkbox"/>	Invasive procedures	<input type="checkbox"/>
Children (under 16 yrs)	<input type="checkbox"/>	Placebo	<input type="checkbox"/>	Devices (in licence)	<input type="checkbox"/>
Observational	<input type="checkbox"/>	Therapeutic	<input type="checkbox"/>	Medicinal products (in licence)	<input type="checkbox"/>
Interview	<input type="checkbox"/>	Controlled	<input type="checkbox"/>	Devices (outside licence)	<input type="checkbox"/>
Questionnaire	<input type="checkbox"/>	Double-blind	<input type="checkbox"/>	Medicinal products (outside licence)	<input type="checkbox"/>
Record-based	<input type="checkbox"/>	Single-blind	<input type="checkbox"/>		
Randomised	<input type="checkbox"/>	Prospective	<input type="checkbox"/>		
Non-randomised	<input type="checkbox"/>	Retrospective	<input type="checkbox"/>		
X-Ray	<input type="checkbox"/>	Radio Active	<input type="checkbox"/>		

**SECTION 1****Applicant(s) Details****1. Title of project:**

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**2. Principal Investigator:** *(All correspondence will be sent to this address unless indicated otherwise.)*

<b>Family Name:</b>	<b>Forename:</b>	<b>Title:</b>
<b>Contact address</b> <i>(for correspondence regarding application):</i>     		
<b>Tel:</b>	<b>Email:</b>	
<b>Mobile Number / Other Contact Number:</b>		
<b>Present appointment of PI:</b>		
<b>Qualifications of PI:</b>		

**3. Other Investigator(s):**

<b>Family Name:</b>	<b>Forename:</b>	<b>Title:</b>
<b>Department/School:</b>		
<b>Institution:</b>		
<b>Tel:</b>	<b>Email:</b>	
<b>Present appointment:</b>		
<b>Qualifications:</b>		

<b>Family Name:</b>	<b>Forename:</b>	<b>Title:</b>
<b>Department/School:</b>		
<b>Institution:</b>		
<b>Tel:</b>	<b>Email:</b>	
<b>Present appointment:</b>		
<b>Qualifications:</b>		

<b>Family Name:</b>	<b>Forename:</b>	<b>Title:</b>
<b>Department/School:</b>		
<b>Institution:</b>		
<b>Tel:</b>	<b>Email:</b>	
<b>Present appointment:</b>		
<b>Qualifications:</b>		

**Other workers and school/departments/Institutions involved:**

Name	Department/School/Institute	Appointment
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**5. Funding Sources:**

**(i) Has any funding been obtained/sought by the investigator in respect of this study?**

Funding applied for: YES ☐ NO ☐ Not applicable ☐

Funding secured: YES ☐ NO ☐ Not applicable ☐

**(ii) Name of sponsoring organisation from which funding has been obtained/sought?**

**(iii) Does the Investigator(s) have any direct involvement in the sponsoring organisation?**

e.g. financial, share-holding etc: YES ☐ NO ☐ Not applicable ☐

**If YES, give details:**

**NOTE:** Where the research programme has already received funding approval, please attach the letter of offer to this application.

**6. Proposed start date and duration of study:**

Proposed Start date:

Duration (months):

**7. Signature of relevant personnel:****Principal Investigator declaration**

*The information in this application form is accurate to the best of my knowledge and belief and I take full responsibility for it.*

*I understand that it is my responsibility to obtain institutional approval where appropriate before the project takes place.*

*I agree to supply interim and final reports to the Research Ethics Committee from which approval was granted for this project.*

*I agree to advise the Research Ethics Committee from which approval was granted for this project and any local researchers taking part in the proposal of any material changes to the proposal or any adverse or unexpected events that may occur during this project.*

*I agree to advise the Research Ethics Committee in the event of premature termination, suspension or deferral of this project and to provide a report outlining the circumstances for such termination, suspension or deferral.*

**Signature of Principal:** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Co-Signed by Supervisor where the P.I. is a Student:** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Office of Research/Institution/Supervisor**

*I am fully aware of the details of this project and agree for it to continue as outlined here. I can confirm that the necessary facilities and resources are available to the researcher.*

**Name:** \_\_\_\_\_ **Department:** \_\_\_\_\_

## SECTION 2

## Study Details

*This section must be completed. A copy of the protocol should be enclosed with the application form but it is **not** sufficient to complete questions by referring to the protocol.*

**8. Aims and objectives of study** (i.e. what is the intention of the study, key research questions?)

**9. Scientific/theoretical background<sup>1</sup> to study** (Approx. 250 words)

**10. Brief plan of investigation<sup>2</sup>** (i.e. what do you intend to do?) (Approx. 250 words)

**11. List procedures or investigations involving risks to participants' well-being or safety** (what, when, how often and risks associated with all procedures)

<sup>1</sup> A succinct background to be provided and to include reference to published work

<sup>2</sup> Please append detailed study protocol to this application; this brief description summarizes protocol only.

**12. Study design** (tick as appropriate)

Survey/Questionnaire	<input type="checkbox"/>
Case Study	<input type="checkbox"/>
Observational	<input type="checkbox"/>
Action research	<input type="checkbox"/>
Record based	<input type="checkbox"/>
Cohort	<input type="checkbox"/>
Case control	<input type="checkbox"/>
Other	<input type="checkbox"/>
(please specify)	

Interviews	<input type="checkbox"/>
• individual	<input type="checkbox"/>
• group	<input type="checkbox"/>
• person-to-person	<input type="checkbox"/>
• telephone	<input type="checkbox"/>
• electronic	<input type="checkbox"/>
Forms of Recording	<input type="checkbox"/>
• Video	<input type="checkbox"/>
• Audio	<input type="checkbox"/>
• Photography	<input type="checkbox"/>
• Notes	<input type="checkbox"/>
• Electronic recording	<input type="checkbox"/>

**13. Size of the study (including controls):**

(i) How was the size of the study determined?

(ii) Was there formal statistical input into the overall study design?

YES: ☐NO: ☐

(iii) What method of analysis will be used?

**14. Where<sup>3</sup> will the study take place and in what setting?****15. Does the study involve:****(i) distribution of a questionnaire?**YES: ☐NO: ☐

If YES, please append a copy of the questionnaire to this application. Please indicate whether the appended questionnaire is:

Non-validated: ☐Validated: ☐**(ii) the use of a existing medicinal product or medical device?**YES: ☐NO: ☐

If YES, is this medical product or device being used within the terms of its current product licence?

YES: ☐NO: ☐If NO, please complete **Annex 1** of this application.**(iii) the use of a new medicinal product or medical device?**YES: ☐NO: ☐If YES, please complete **Annex 1** of this application.**(iii) the use of ionising or non-ionising radiation, radioactive substances or X rays?**YES: ☐NO: ☐If YES, please complete **Annex 2** of this application.<sup>3</sup> Geographical location; laboratory, hospital, general practice, home visits etc.



**16. Peer Review/Critique<sup>4</sup>****Has the protocol been subject to peer review?**YES: ☐ NO: ☐

If the review formed part of the process of obtaining funding, please give the name and address of the funding organisation:

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If the review took place as part of an internal process, please give brief details:

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If no review has taken place, please explain why and offer justification for this:

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**17. Does the study fall into any of the following categories?**

Pilot:	YES: <input type="checkbox"/>	NO: <input type="checkbox"/>	Not applicable: <input type="checkbox"/>
Multi-centre study	YES: <input type="checkbox"/>	NO: <input type="checkbox"/>	Not applicable: <input type="checkbox"/>

***If this is a multi-centre study, please complete the following details, otherwise go to question 17.***

**(i) Which centres are involved?**

<u>Contact Name</u>	<u>Department/Centre</u>

**(ii) Which ethics committees have been approached, and what is the outcome to date?**

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**(iv) Who has control of the data generated?**

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<sup>4</sup> If you are in possession of any referee or other scientific critique reports relevant to your proposed research, please forward copies with your application form.

**SECTION 3****Recruitment of participants****18. Who is being studied?**

If non-competent persons are being studied, please give details of reasons for non-competence

**19. How will be the participants in the study be:**

(i) Selected?

(ii) Recruited? (Please append advertisement materials to application)

**20. What criteria will be used for inclusion and exclusion of participants?**

(i) Inclusion criteria:

(ii) Exclusion criteria:

**21. How many participants will be recruited and of what age groups?****22. If applicable, how will the control group in the study be:**

(i) Selected?

(ii) Recruited? (please append advertisement materials to application)

**23. What criteria will be used for inclusion and exclusion of the control group?**

(i) Inclusion criteria:

(ii) Exclusion criteria:

**24. If applicable, how many controls will be recruited and of what age group?**

**25. Are the participants/controls included in this study involved in any other research investigation at the present time?**

YES: ☐

NO: ☐

If YES, please give details

**26. Will participants receive any payment or other incentive to participate?**

YES: ☐

NO: ☐

(i) If YES, give details of incentive per participant?

If YES, what is the source of the incentive?

**SECTION 4****Consent**

**27. Is written consent for participation in the study to be obtained?**

YES: ☐NO: ☐

If YES, please attach a copy of the consent form to be used (*Guidance on consent is given in the Guidance Notes*)

If NO written consent is to be obtained, please explain why

**28. How long will the subject have to decide whether to take part in the study?**

(If less than 24 hours, please justify)

**29. Does the study include participants for whom English is not a first language?**

YES: ☐NO: ☐

If YES, give details of special arrangements made to assist these participants

**30. Please attach a copy of the written participant information sheet**

If NO information sheet is to be given to participants, please justify

**31. If you are recruiting from a vulnerable groups (Children under 16 years of age; People with learning difficulties; Unconscious or severely ill participants; Other vulnerable groups e.g. dementia, psychological disorders, etc.), please specify and justify**

(ii) What special arrangements have been made to deal with the issues of consent and assent for vulnerable participants e.g. is parental or guardian agreement to be obtained, and if so in what form?

(iii) In what way, if any, can the proposed study be expected to benefit the individual who participates?

**32. Are women of childbearing potential included in this study?**

YES: ☐

NO: ☐

If YES, does the protocol/participant information sheet address the following:

- ☐ scientific justification
- ☐ negative teratogenic studies
- ☐ warning participants that foetus may be damaged
- ☐ requirement for initial negative pregnancy test
- ☐ forms of contraception defined
- ☐ duration of use to exceed drug metabolism
- ☐ exclude those unlikely to follow contraceptive advice
- ☐ notify investigator if pregnancy suspected.

If NO, please explain

*Note 1: A signed consent form is needed from each participant confirming their understanding of any potential side effects of the research in general and with any specific consequences to woman or men*

**SECTION 5****Details of interventions**

**33. Does the study involve the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence?**

YES: ☐NO: ☐

If YES, please complete Question 33 and Annex 1 of the Application Form.

**34. Does the study involve investigations and/or interventions on either participants or controls?**

(Please tick YES/NO as appropriate. If YES, details should be available in the protocol)

**Investigation/Intervention**

Self completion questionnaires

Interviews/interview administered questionnaires

Video/audio tape recording

Physical examination

Internal physical examination

Venepuncture\*

Arterial puncture\*

Biopsy material\*

Other tissue/body sample\*

Imaging investigation (not radiation)

Other investigations not part of normal care

Additional out patient attendance

Longer inpatient stays

Local anaesthesia

General anaesthesia

<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO
<input type="checkbox"/>	YES	<input type="checkbox"/>	NO

Other – please detail

Please indicate and justify where treatment is withheld as a result of taking part in the project.

**35. Will any ionising or non-ionising radiation, or radioactive substances or X-Rays be administered to a participant?**

YES: ☐NO: ☐

If YES, please complete Annex 2 of the Application Form.

**36. Where research conducted in a general practice setting, will all GPs whose patients will be involved, be required to sign to indicate that they are aware of and in agreement with the planned project?**

YES: ☐NO: ☐Not applicable: ☐

If NO, please explain why not

\* Please see Guidance Notes

\*\* All interventions before being applied should be detailed and clearly explained on an information sheet

**SECTION 6****Risks and ethical problems****37. Are there any potential risks to participants?**YES: ☐NO: ☐If YES, please complete **Annex 3** for each procedure for which a potential risk occurs.**38. Is this study likely to cause any discomfort or distress, either physical or mental?**YES: ☐NO: ☐

If YES, estimate the degree and likelihood of discomfort or distress entailed and the precautions to be taken to minimise them.

Please include other potential embarrassments to the subject that should be explained prior to obtaining consent (e.g. state of undress etc)

**39. What particular ethical problems or issues do you consider to be important or difficult with the proposed study?**

(i) Will treatments provided during the study be available if needed at the end of the study?

YES: ☐NO: ☐Not applicable: ☐

(ii) If NO, is this made clear in the participant information sheet?

YES: ☐NO: ☐

If NO, please give reasons

**40. I have checked with the appropriate offices in AIT and can clarify that my project does not have any Health & Safety risks?**YES: ☐NO: ☐

**SECTION 7****Indemnity**

*Product liability and consumer protection legislation make the supplier and producer (manufacturer) or any person changing the nature of a substance, e.g. by dilution, strictly liable for any harm resulting from a consumer's use of a product.*

**41. Arrangements for indemnification<sup>5</sup>/compensation**

(i) What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for negligent harm? Not applicable: ☐

(ii) What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for non-negligent harm? Not applicable: ☐

(ii) Will an undergraduate student be involved directly in conducting the project?

YES: ☐NO: ☐

**42. In cases of equipment or medical devices, have appropriate arrangements been made with the manufacturer to provide indemnity?**

YES: ☐NO: ☐Not applicable: ☐

If YES, please give details and enclose a copy of the relevant correspondence with this application

**43. In cases of medicinal products, have appropriate arrangements been made with the manufacturer to provide indemnity?**

YES: ☐NO: ☐Not applicable: ☐

If YES, please give details and enclose a copy of the relevant correspondence with this application

**44. I have checked with the Office of the Secretary / Financial Controller that my research application is covered under the Institute Indemnity Policy?**

YES: ☐NO: ☐

<sup>5</sup> Where there is more than one institution /organisation involved in the study, each institution /organization is responsible for its own indemnity cover, and confirmation of such cover must be appended to the application.



**SECTION 8****Confidentiality**

**45. Will the study include the use of any of the following?**

Audio/Video recordings      YES: ☐      NO: ☐

Observation of participants: YES: ☐      NO: ☐

**If YES to either:**

(i) How are confidentiality and anonymity to be ensured?

(ii) What arrangements have been made to obtain consent for these procedures?

(iii) What will happen to the tapes at the end of the study?

**46. Will the study data be held on computer?**

YES: ☐      NO: ☐

If YES, will the data be held so that participants cannot be identified from computer files (i.e. no name, address, medical chart number or other potential identifier such as GMS or RSI number)?

YES: ☐      NO: ☐

If NO, please give reasons

**47. Will records (preferably paper records) linking study participant ID with identifying features be stored confidentially?**

YES: ☐      NO: ☐

Please give details of arrangements for confidential storage

For how long will records be retained prior to destruction?

**48. Will the participants' medical records be examined by investigators in the study?**YES: ☐ NO: ☐If YES, will information relevant **only** to this study be extracted: YES: ☐ NO: ☐ Not applicable: ☐

(i) If extra information is extracted, please justify

(ii) What, if any, additional steps have been taken to safeguard the confidentiality of personal medical records?

**49. Will research workers outside the employment of AIT examine medical or other personal records?**YES: ☐ NO: ☐

If YES, it is the responsibility of the Principal Investigator to ensure that research workers understand that: Information obtained about and from research participants is confidential to the study and must not be divulged except in legitimate methods of study data presentation or exceptional circumstances as discussed and agreed with the principal investigator.

Please ensure that you complete the **Submission Checklist** on the front cover of this application form and **include all relevant enclosures**.

**THANK YOU.**

## ANNEX 1

*This form is to be used if the study involves the use of a new medical product or medical device, or the use of an existing product outside the terms of its product licence.*

**(i) Does this project have Irish Medicines Board approval or has an application been made?**

YES: ☐ NO: ☐ Not applicable: ☐ Application is at present with IMB: ☐

If approval applied for, state date of application:

**(ii) Is a pharmaceutical or commercial company arranging this trial?**

YES: ☐ NO: ☐

If YES, attach indemnification.

If NO, has the licensing authority been notified? YES: ☐ NO: ☐

**(iii) Does the drug(s) or medical device have a product license(s) for the purpose for which it is to be used?**

YES: ☐ NO: ☐

If YES, please give details

**(iv) Is any drug or medical device being supplied by a company with a Clinical Trial Exemption Certificate or in response to an investigator with a Clinical Trial Exemption, or Doctors' Exemption?**

YES: ☐ NO: ☐

If YES, give details of:

Clinical Trial Certificate Number:

Clinical Trial Exemption Number:

Doctors' Exemption Number:

**(v) Details of drug use or medical device (please complete the table below)**

Approved name:

Generic name:

Trade name:

STRENGTH	DOSAGE	FREQUENCY	ROUTE	DURATION OF COURSE
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**(vii) Who will administer the drug or fit the medical device?**

**(viii) If a medical device, has the device been through acceptance and safety testing?**

YES: ☐

NO: ☐

Please give details

**(ix) Who is supplying the drug(s)/medical device? (If imported, name country)**

**(x) Who will dispense the drug(s)/medical device?**

What is their qualification to dispense the drug(s)/medical device?

**(xi) Does the organisation and performance of this trial conform to European Directives on Good Clinical Practice?**

YES: ☐

NO: ☐

If no, please detail and explain

## ANNEX 2

*This form is to be used if the study involves the use of ionizing or non-ionising radiation, radioactive substances or X-Rays. A competent Radiation Protection Advisor must be involved in implementing this section.*

### A. RADIOACTIVE SUBSTANCES

**(i) Details of substances to be administered** *(please complete the table below)*

INVESTIGATION	RADIONUCLEIDE	CHEMICAL FORM	QUANTITY OF RADIOACTIVITY TO BE ADMINISTERED (MBq)	ROUTE	FREQUENCY

**(ii) Estimated Effective Dose (Effective Dose Equivalent) (mSv)**

*(Please supply source of reference or attach calculation)*

**(iii) Absorbed dose to organ or tissues concentrating radioactivity (mGy) (Specify dose and organ)**

*(Please supply source of reference or attach calculation)*

**(iv) Administration of Radioactive Substances Advisory Committee certificate holder to oversee/administer substance**

Name of Person:

Position:

Certificate No.:

*I have assisted in and approve the protocol and arrangements that have been made in this project for the administration of the radioactive substance(s).*

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

### B. X-RAYS

**(i) Details of radiographic procedures** *(please complete the table below)*

INVESTIGATION	ORGANS	FREQUENCY

**(ii) Estimated Effective Dose (Effective Dose Equivalent) (mSv)**

(Please supply source of reference or attach calculation)

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**C. NON IONISING RADIATION****(i) Details of procedures** *(please complete the table below)*

INVESTIGATION	ORGANS	FREQUENCY

**(iv) Who has given safety advice?**

Name of Person:

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Position:

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Qualification to advise:

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*I have assisted in and approve the safety of the protocol and arrangements that have been made in this project*

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**ANNEX 3****Risk Assessment Form – Procedures Involving Human Subjects**

Procedure no.:

Title of Procedure:

Name of Assessor(s):

Assessment Date:

Does this procedure already have ethical approval? YES:

☐

NO:

☐

If YES, enter Approval No. and Expiry Date:

Approval No:

Expiry Date:

**1. Please provide a brief description of the procedure;****2. Location in which the Procedure will take place**

(e.g. Research Laboratory – Room No. , Teaching Laboratory – Room No., Hospital clinic – specify, etc)

**3. Subject(s) to be used (tick as appropriate)**

Undergraduate student(s)

☐

Postgraduate student(s)

☐

University staff or campus personnel

☐

Members of the general public

☐**4. What is the level of any potential risks for participants?****[To be explained BEFORE obtaining consent]**

None

☐

Minimal only

☐

Moderate

☐

Significant

☐

(ii) If the risk is other than minimal, please give details and likelihood of risk occurrence

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(ii) If the risk is other than minimal, please give details of precautions taken to minimise the risk

--

**5. Actions to be taken in the event of adverse response or medical emergency**

Please provide details of arrangements to deal with adverse events, including reporting to the relevant authorities and follow-up

--

**6. Appropriate level of supervision required for procedure** (please tick as appropriate)

Post-graduate researcher	<input type="checkbox"/>
Research/ lecturing Staff	<input type="checkbox"/>
Paramedical personnel	<input type="checkbox"/>
Medical personnel – Nurse	<input type="checkbox"/>
Medical personnel – Doctor	<input type="checkbox"/>
Medical personnel – Other	<input type="checkbox"/>

If other personnel, please specify title and/or required qualification

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**7. Other documentation required for this assessment**

Pre-test subject questionnaire	<input type="checkbox"/>
Detailed protocol	<input type="checkbox"/>
Other	<input type="checkbox"/>

If other documentation is required, please describe

--

**8. Signature**

Signed: \_\_\_\_\_  
Signature of Principal Investigator

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_



**FOR COMPLETION BY HEAD OF SCHOOL / INSTITUTE / DEPARTMENT****Risk Assessment Form – procedures involving human subjects**

In the School /Department/ Institute of:

Procedure no.:

Title of Procedure:

Name of  
Assessor(s):

Assessment Date:

**9. Approval of Procedure**☐

Granted

☐

Subject to conditions (see below)

☐

Refer to Hospital Ethics Committee

Other, please specify

**10. Comments and/or conditions****11. Signature**Signed: \_\_\_\_\_  
Signature of Head of School /Department/Institute

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

*(Please copy this Annex as necessary)*