

# STANDARD APPLICATION FORM

For the Ethical Review of  
Health-Related Research Studies, which  
are not Clinical Trials of Medicinal  
Products For Human Use  
as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM  
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: \_\_\_\_\_

Application Version No: \_\_\_\_\_

Application Date: \_\_\_\_\_

For Official Use Only – Date Stamp of Receipt by REC:


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This Application Form is divided into Sections.

\*Sections A, B, C, D, E, J and K are **Mandatory**.

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

**IMPORTANT NOTE:** Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

**PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.**

## SECTION A GENERAL INFORMATION

## SECTION A IS MANDATORY

**A1 Title of the Research Study:**

Answer
--------

**A2 (a) Is this a multi-site study?** 

If you chose 'yes' please delete questions A2 (e) and (f), If you chose 'no' please delete Questions A2 (b) (c) and (d)

**A2 (b) If yes, please name the principal investigator with overall responsibility for the conduct of this multi-site study.**

**Title:**

**Name:** Answer

**Qualifications:** Answer

**Position:** Answer

**Dept:** Answer

**Organisation:** Answer

**Address:** Answer

**Tel:** Answer

**E-mail:** Answer

**A2 (c) For multi-site studies, please name each site where this study is proposed to take place, state the lead co-investigator for each of these sites and state if you have got an outcome from the relevant research ethics committee(s).**

Site:	Lead Co-Investigator for each site:	Research Ethics Committee Outcome

**A2 (d) For multi-site studies, please provide details of the Lead Co-Investigators at each site.**

**Title:**

**Name:** Answer

**Qualifications:** Answer

**Position:** Answer

**Dept :** Answer

**Organisation:** Answer

**Address:** Answer

**Tel :** Answer

**E-mail:** Answer

**A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.**

**Title:**

**Name:** Answer

**Qualifications:** Answer

**Position:** Answer

**Dept:** Answer

**Organisation:** Answer  
**Address:** Answer  
**Tel:** Answer      **E-mail:** Answer

**A2 (f) For single-site studies, please name the only site where this study will take place.**

Answer

**A3. Details of Co-investigators:**

**Name of site (if applicable):** Answer  
**Title:**       **Name:** Answer  
**Qualifications:** Answer  
**Position:** Answer  
**Dept :** Answer  
**Organisation:** Answer  
**Address:** Answer  
**Tel:** Answer      **E-mail:** Answer  
**Role in Research e.g. statistical / data / laboratory analysis:** Answer

**A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.**

**Name:** Answer  
**Position:** Answer  
**Organisation:** Answer  
**Address for Correspondence:** Answer  
**Tel (work):** Answer      **Tel (mob.):** Answer      **E-mail:** Answer

**A5 (a) Is this study being undertaken as part of an academic qualification?**

If answer is No, please delete remaining questions in Section A

**A5 (b) If yes, please complete the following:**

**Student Name(s):** Answer  
**Academic Course:** Answer  
**Academic Institution:** Answer

**A5 (c) Academic Supervisor(s):**

**Title:**       **Name:** Answer  
**Qualifications:** Answer  
**Position:** Answer  
**Dept:** Answer  
**Organisation:** Answer  
**Address:** Answer  
**Tel:** Answer      **E-mail:** Answer

**SECTION B STUDY DESCRIPTORS****SECTION B IS MANDATORY**

**B1. What is the anticipated start date of this study?**

Answer

**B2. What is the anticipated duration of this study?**

Answer

**B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.**

Answer

**B4. Provide brief information on the study background.**

Answer

**B5. List the study aims and objectives.**

Answer

**B6. List the study endpoints / measurable outcomes (if applicable).**

Answer

**B7. Provide information on the study design.**

Answer

**B8. Provide information on the study methodology.**

Answer

**B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.**

Answer

**B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).**

Answer

**B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.**

Answer

**B11. How many research participants are to be recruited in total?**

Answer

**B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).**

Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:
Answer	Answer	Answer	Answer	Answer
Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:
Answer	Answer	Answer	Answer	Answer

**B12 (b) Please provide details on the method of randomisation (where applicable).**

Answer

**B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.**

Site:	Number of Research Participants at this site:

## SECTION C STUDY PARTICIPANTS

### SECTION C IS MANDATORY

#### C1 PARTICIPANTS – SELECTION AND RECRUITMENT

**C1.1 How will the participants in the study be selected?**

Answer

**C1.2 How will the participants in the study be recruited?**

Answer

**C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)**

Answer

**C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)**

Answer

**C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project?**

## C2 PARTICIPANTS – INFORMED CONSENT

**C2.1 (a) Will informed consent be obtained?**

**C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.**

Answer

**C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)**

Answer

**C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?**

**C2.2 (b) If no, please justify.**

Answer

**C2.3 (a) Will there be a time interval between giving information and seeking consent?**

**C2.3 (b) If yes, please elaborate.**

Answer

**C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.**

Answer

## C3 ADULT PARTICIPANTS (AGED 18 OR OVER) - CAPACITY

**C3.1 (a) Will all adult research participants have the capacity to give informed consent?**

If answer is Yes, please delete remaining questions in Section C3

**C3.1 (b) If no, please elaborate.**

Answer

**C3.2 Is this research of such a nature that it can only be carried out on adults without capacity? Please elaborate.**

Answer

**C3.3 Is the research expected to provide direct benefit to the research participants (who lack capacity), or if there is no prospect of direct benefit, are the risks no more than minimal? Please elaborate.**

Answer

**C3.4 What arrangements are in place to ascertain the wishes of research participants, who although they lack decision-making capacity, have some ability to understand the significance of the research?**

Answer

**C3.5 What arrangements are in place for research participants who may regain their capacity?**

Answer

**C4 PARTICIPANTS UNDER THE AGE OF 18****C4.1 (a) Will any research participants be under the age of 18 i.e. Children?**

Yes / No

If answer is No, please delete remaining questions in Section C4

**C4.1 (b) If yes, please specify:**

Persons < 16 Yes / No

Persons aged 16 – 18 Yes / No

Children in care Yes / No

**C4.1 (c) If yes to persons < 16, please specify:**

Pre-term neonates Yes / No

Full-term neonates Yes / No

Infants and Toddlers 0 - 4 Yes / No

Children 5 - 8 Yes / No

Children 9 – 12 Yes / No

Adolescents 13 -15 Yes / No

**C4.2 Is this research of such a nature that it can only be carried out on children? Please elaborate.**



Answer

**C4.3 Is the purpose of the research to generate knowledge about the health or social care needs of children?**

Answer

**C4.4 Is the research expected to provide direct benefit to child participants, or if there is no prospect of direct benefit, are the risks no more than minimal? Please elaborate.**

Answer

**C4.5 Will each child receive information about the risks and benefits of the study according to his/her capacity to understand? Please elaborate and provide copies.**

Answer

**C4.6 Will the explicit wish of the child who is capable of forming an opinion and assessing information to refuse to participate or to be withdrawn from the study be considered by the investigators? Please elaborate, outlining the assent process in full. (How will assent be obtained, when and by whom etc.)**

Answer

**C4.7 Please comment on the involvement of parents / legal guardians of the child in the consent process.**

Answer

**C4.8 Please explain your approach to reviewing assent where research subjects reach the age of 18 during the course of the study.**

Answer

**C4.9 Please comment on what will occur if the researcher discovers that a child is at risk during the course of this study?**

Answer

## C5 PARTICIPANTS - CHECKLIST

**C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups**

**in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.**

**Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.**

**(a) Healthy Volunteers**

**(b) Patients**

- **Unconscious patients**
- **Current psychiatric in-patients**
- **Patients in an emergency medical setting**

**(c) Relatives / Carers of patients**

**(d) Persons in dependent or unequal relationships**

- **Students**
- **Employees / staff members**
- **Persons in residential care**
- **Persons highly dependent on medical care**

**(e) Intellectually impaired persons**

**(f) Persons with a life-limiting condition**

*(Please refer to guidance manual for definition)*

**(g) Persons with an acquired brain injury**

**C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).**

Answer

**C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.**

Answer

## SECTION D RESEARCH PROCEDURES

**SECTION D IS MANDATORY**

**D1 (a) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?**

Answer

**D1 (b) What other activities (if any) are taking place for the purposes of this research study e.g. chart review, sample analysis etc?**

Answer

**D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.**

Answer

**D3. What is the potential benefit that may occur as a result of this study?**

Answer

**D4 (a) Will the study involve the withholding of treatment?**

Yes / No / Non-applicable

**D4 (b) Will there be any harms that could result from withholding treatment?** Yes / No

**D4 (c) If yes, please elaborate.**

Answer

**D5 (a) How will the health of participants be monitored during the study, and who will be responsible for this?**

Answer

**D5 (b) How will the health of participants be monitored after the study, and who will be responsible for this?**

Answer

**D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?** Yes / No / Non-applicable

**D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?**

Answer

**D7. Please comment on how individual results will be managed.**

Answer

**D8. Please comment on how aggregated study results will be made available.**

Answer

**D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)?**

**D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)?**

## SECTION E DATA PROTECTION

SECTION E IS MANDATORY

### E1 DATA PROCESSING - CONSENT

**E1.1 (a) Will consent be sought for the processing of data?**

**E1.1 (b) If no, please elaborate.**

Answer

### E2 DATA PROCESSING - GENERAL

**E2.1 Who will have access to the data which is collected?**

Answer

**E2.2 What media of data will be collected?**

Answer

**E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?**

Answer

**E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?**

Answer

**E2.4 Where will data which is collected be stored?**

Answer

**E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.**

Answer

**E2.6 (a) Will data collected be at any stage leaving the site(s) of origin?**

Yes / No

**E2.6 (b) If yes, please elaborate.**

Answer

**E2.7 Where will data analysis take place and who will perform data analysis (if known)?**

Answer

**E2.8 (a) After data analysis has taken place, will data be destroyed or retained?**

Answer

**E2.8 (b) Please elaborate.**

Answer

**E2.8 (c) If destroyed, how, when and by whom will it be destroyed?**

Answer

**E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?**

Answer

**E2.9 Please comment on the confidentiality of collected data.**

Answer

**E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? Yes / No**

**E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?**

Answer

**E2.11 (a) Will any of the study data collected consist of photographs/ video recordings? Yes / No**

**E2.11 (b) If yes, please elaborate.**

Answer

**E3 ACCESS TO HEALTHCARE RECORDS**

**E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?**

If answer is No, please delete remaining questions in Section E3

**E3.1 (b) If yes, please elaborate.**

Answer

**E3.1 (c) Who will access these healthcare records?**

Answer

**E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records?**

If answer is Yes, please delete remaining questions in Section E3

**E3.2 (a) Who or what legal entity is the data controller in respect of the healthcare records?**

Answer

**E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?**

Answer

**SECTION F HUMAN BIOLOGICAL MATERIAL****F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL**

**F1 1 (a) Does this study involve human biological material?**

If the answer is No, please delete Section F

**F2 BODILY TISSUE / BODILY FLUID SAMPLES PROSPECTIVELY COLLECTED**

**F2.1 Does this study involve the prospective collection of human biological material?**

**F2.2 Please state the type of human biological material which is being prospectively collected.**

Answer

**F2.3 Who or what institution will be the custodian of the prospectively collected human biological material?**

Answer

**F2.4 (a) Will the human biological material be collected as part of routine clinical care?**

**F2.4 (b) Will the human biological material be collected specifically for the purposes of this research study?**

**F2.4 (c) With reference to your responses to question F2.4 (a), F2.4 (b), please provide more detail, in particular, in relation to whether participants will be consented to the taking of a sample or to the use of a sample (or part of a sample) which will be taken anyway for clinical reasons.**

Answer

**F2.5 (a) With respect to human biological material which it is proposed to prospectively collect for the purposes of this research study, after the laboratory analysis which this research study involves, will any human biological material remain?**

**F2.5 (b) If yes, will this remaining biological material be retained?**

**F2.5 (c) If yes, for how long and where will samples be retained?**

Answer

**F2.5 (d) If yes, for what purpose will samples be retained?**

Answer

**F2.5 (e) If yes, please comment on consent for retention of biological material.**

Answer

**F2.5 (f) If yes, will this human biological material and/or any data derived from it be used for any other purpose (including future research projects)?**

**F2.5 (g) If yes, please comment on consent for future use of human biological material.**

Answer

**F2.6 (a) Will the human biological material be collected specifically for the purposes of depositing this human biological material in a biobank?**

**F2.6 (b) If yes, please provide specific information in relation to this proposed biobank.**

Answer

**F2.6 (c) If yes, will research participants be informed in all information leaflets and consent forms that this is a biobank?**

Answer

### F3 BODILY TISSUE / BODILY FLUID SAMPLES RETROSPECTIVELY COLLECTED

**F3.1 Does this study involve accessing retrospectively collected human biological material?**

**F3.2 Please state the type of human biological material which is being accessed.**

Answer

**F3.3 Who will access the material?**

Answer

**F3.4 Who (or which institution) is the current custodian of the material?**

Answer

**F3.5 Please state for what purpose the human biological material was originally collected and please comment on the nature of consent for the collection of this material.**

Answer

**F3.6 (a) Do you intend to contact patients to seek their consent to use stored human biological material?**

**F3.6 (b) If no, please justify why existing consent is considered sufficient, or why a waiver of consent from the research ethics committee is warranted.**

Answer

### F4 BODILY TISSUE / BODILY FLUID SAMPLES – SAMPLE MOVEMENT



**F4.1 (a) Will human biological material at any stage leave the institution(s) of origin?**

**F4.1 (b) If yes, for what purpose?**

Answer

**F4.1 (c) If yes, please state where samples will be sent?**

Answer

**F4.1 (d) If yes, please state if the samples leaving the institution(s) of origin will be anonymous, irreversibly anonymised, pseudonymised, coded, identifiable etc?**

Answer

**F4.1 (e) If 'coded' please confirm who will retain the 'key' to re-identify the samples?**

Answer

**F4.1 (f) Does a memorandum of understanding (or agreement / contract) exist between the institution(s) of origin and the institution(s) to which the samples will be sent? Please elaborate.**

Answer

## F5 GENETIC TESTING

**F5.1 (a) Does this research study involve 'genetic testing'?**

**F5.1 (b) If yes, please specify the nature and purpose of the genetic testing.**

Answer

**F5.2 (a) Will consent be obtained?**

**F5.2 (b) If yes, please set out the steps that will be taken and the information that will be provided to study participants prior to genetic testing and processing of genetic data in relation to any potential implications for the health of the study participant which may become known as a result of the genetic testing and the processing of genetic data.**

Answer

**F5.3 (a) Please set out the strategy and arrangements that will be in place to address any significant results or information arising from the genetic testing or processing of genetic data with the study participant.**

Answer

**F5.3 (b) What strategy / arrangements will be in place regarding third party disclosure, in particular, to family members or others?**

Answer

**F5.4 Please set out what arrangements will be in place to ensure the privacy and confidentiality of study participants' genetic data throughout the life cycle of the research.**

Answer

## F6 COMMERCIAL VALUE

**F6.1 (a) Will the human biological material in this research study or the data derived from the analysis of the human biological material be commercially valuable or is there the possibility that it will become commercially valuable?  Yes / No**

**F6.1 (b) If yes, please elaborate.**

Answer

## SECTION G RADIATION

### G1 RADIATION – GENERAL

**G1.1 (a) Does this study/trial involve exposure to radiation?  Yes / No**

If answer is No, please delete remaining questions in Section G

**G1.1 (b) If yes, please specify:**

- i) Exposure to radioactive materials  Yes / No
- ii) Therapeutic ionising radiation  Yes / No
- iii) Diagnostic ionising radiation  Yes / No
- iv) Other  Yes / No      Details:  Answer

**G1.2 (a) Does this study / trial involve ADDITIONAL radiation exposure other than normally received as part of standard care?  Yes / No**

**G1.2 (b) If yes, please elaborate.**

Answer

**G1.3 Please specify if this study is due to take place at a: -**

- i) Radiation Oncology Unit
- ii) Diagnostic Imaging Facility
- iii) Clinical Laboratory
- iv) Academic Research Centre
- v) Other  Details:

**G1.4 Has each study site/institution in the Republic of Ireland been licensed by the Radiation Protection Society of Ireland?**

## G2 RADIOTHERAPY TRIALS

**G2.1 Does the study/trial involve exposure of patients to radiotherapy?**

If answer is No, please delete remaining questions in Subsection G2

**G2.2 (a) Is the planned radiotherapy part of standard treatment or is it experimental in terms of dose / technique / rationale?**

**G2.2 (b) If experimental, please elaborate.**

**G2.3 IN RELATION TO THE RADIOTHERAPY PLEASE PROVIDE DETAILS OF THE FOLLOWING:**

**G2.3 (a) Dose Delivery Technique to be used e.g. 3-DCRT (3-dimensional conformal radiation therapy), IMRT (intensity modulated radiation therapy).**

**G2.3 (b) Imaging/Verification Technique to be used e.g. IGRT (image guided radiation therapy) etc.**

**G2.3 (c) Radiation treatment schedule:**

**(i) Total dose:**

**(ii) Dose per fraction**

**(iii) Number of fractions per day**

Answer

**G2.3 (d) Expected spectrum of acute and long-term radiation-induced side effects**

Answer

**G2.4 RADIOTHERAPY PLANNING**

**G2.4 (a) Planning Volumes of interest (tumour related volume and organs at risk)**

Answer

**G2.4 (b) Planning Dose volume constraints (DVCs) for organs at risk (OARs).**

Answer

**G2.4 (c) Details of patient positioning/set-up/immobilization, inclusive of pre-treatment preparation e.g. bladder filling protocol, IV contrast etc.**

Answer

**G2.4 (d) Details of radiotherapy plan evaluation parameters (i.e. planning target volume [PTV] coverage)**

Answer

**G2.4 (e) What toxicity scoring criteria are to be used?**

Answer

**G2.5 For experimental radiotherapy, please provide the following information:**

**(a) Standard alternatives. Please ensure to detail and contrast the experimental protocol with 'standard' therapy.**

Answer

**(b) Potential additional risks/toxicities associated with the experimental protocol.**

Answer

**G2.6 (a) Radiotherapy quality assurance at delivery:**

**Please describe the quality assurance programme i.e. PHYSICS quality assurance (beam and dose).**

Answer

**G2.6 (b) Radiotherapy quality assurance at delivery:**

**Please describe the quality assurance programme i.e. CLINICAL quality assurance.**

Answer

**G2.7 Clinical Monitoring/Assessment during radiotherapy and supportive care: please provide a detailed summary of the clinical monitoring of patients included in the study / trial.**

Answer

**G2.8 Criteria for Radiotherapy Adverse Event Reporting**

Answer

**G3 RADIONUCLIDES**

**Please complete the tables below for each radionuclide to be administered**

**G3.1 (a) Will any of the study/trial participants be patients?**

<b>Details of patients to be studied</b>				
<b>Number (whole study)</b>	<b>Age range</b>	<b>Sex</b>	<b>Clinical condition</b>	<b>Total effective or target tissue dose per individual</b>
[TA]	[TA]	[TA]	[TYPE ANSWER=TA]	[TA]

**G3.1 (b) Will any of the study/trial participants be healthy volunteers?**

<b>Details of healthy volunteers to be studied</b>			
<b>Number (whole study)</b>	<b>Age range</b>	<b>Sex</b>	<b>Total effective dose per individual</b>
[TA]	[TA]	[TA]	[TYPE ANSWER=TA]

**G3.2 Dose and Risk Assessment**

**G3.2 (a) What is the total research protocol dose from the exposure (if any)?**

Answer

**G3.2 (b) What component of this is the additional dose over and above standard practice? What are the risks associated with this dose?**

Answer

**G3.2 (c) DECLARATION BY MEDICAL PHYSICIST (for Section G3 Radionuclides)**

I am satisfied that the information in sub-section G3.1 and the assessment in sub-section G3.2 provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Please Print Name:** \_\_\_\_\_

**G4 CLINICAL ASSESSMENT**

**G4.1 Will the exposure exceed the exposure that might be received as part of normal care?**

**G4.2 Assessment of additional exposure**

**G4.2 (a) Please explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. Consideration should be given to the specific objectives of the exposure, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation.**

Answer

**G4.2 (b) If pregnant or breastfeeding mothers are to be studied give reasons and details of special radiation protection measures to be taken.**

Answer

**G4.3 DECLARATION BY RADIATION ONCOLOGIST**

I am satisfied that the exposure to ionising radiation planned in this research study (as defined in sub-section G2 and/or G3) is reasonable and that the risks are adequately described in the participant information sheet for the study.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Please Print Name:** \_\_\_\_\_

## SECTION H MEDICAL DEVICES

**H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device?**

If answer is No, please delete remaining questions in Section H.

**H1 (b) If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?**

Answer

**H1 (c) If yes, please provide a general description of the medical device.**

Answer

<b>H2 (a) Does the device have a CE mark?</b>	
Yes / No	
<b>H2 (b) If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark?</b>	<b>H2 (e) If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?</b>
Within / Outside	Yes / No
<b>H2 (c) If outside, please elaborate:</b>	
Answer	
<b>H2 (d) CE MARK NUMBER:</b>	
Answer	

**H3 (a) Is this an application to conduct a clinical investigation of a medical device?**

**H3 (b) If yes, will the Medical Devices section of the Health Products Regulatory Authority (HPRA) be reviewing this study?**

## SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

### I.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

**I1.1 (a) Does this study involve a medicinal product?**

If the answer is No, please delete remaining questions in subsection I1

**I1.1 (b) If yes, please state:**

**I. The trade name of the medicinal product:**

Answer

**II. The name of the active substance:****III. The formulation:****IV. The authorisation / product number:**

**I1.2 (a) Is this an application to conduct a non-interventional trial of a medicinal product?**

**I1.2 (b) Is this trial a post-authorisation safety study?**

**I.2 COSMETICS**

**I2.1 (a) Does this study involve a cosmetic?**

If the answer is No, please delete remaining questions in subsection I2

**I2.1 (b) If yes, please state:**

**I. The trade name of the cosmetic:**

**II. The ingredients/composition:**

**I.3 FOOD AND FOOD SUPPLEMENTS**

**I3.1 (a) Does this study involve food or food supplements?**

If the answer is No, please delete remaining questions in subsection I3

**I3.2 (b) If yes, please elaborate:**

**SECTION J INDEMNITY AND INSURANCE**

**SECTION J IS MANDATORY**



**J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.**

Answer

**J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.**

Answer

**J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?**

Answer

**J3.2 Where an organisation is legally responsible, please specify if this organisation is:**

A pharmaceutical company

A medical device company

A university

A registered charity

Other  If yes, please specify: Answer

**J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?**

Answer

## SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

### K1 COST AND RESOURCE IMPLICATIONS

**K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)**

Answer

### K2 FUNDING

**K2.1 (a) Is funding in place to conduct this study?**

**K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.**

Answer

**K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.**

<b>Source of funding (industry, grant or other):</b>
Answer
<b>Name of Funder:</b>
Answer
<b>Amount of Funding:</b>
Answer
<b>Duration of Funding</b>
Answer

**K2.1(d) Please provide additional details in relation to management of funds.**

Answer

**K2.1(e) Is the study funded by a 'for profit' organisation?  Yes / No**

**K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding?  Yes / No**

**K2.2 (b) If yes, please elaborate.**

Answer

### K3 PAYMENTS TO INVESTIGATORS

**K3.1 (a) Will any payments (monetary or otherwise) be made to investigators?  Yes / No**

**K3.1 (b) If yes, please provide details of payments (including amount).**

Answer

### K4 PAYMENTS TO PARTICIPANTS

**K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants?  Yes / No**

**K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).**

Answer

## SECTION L ADDITIONAL ETHICAL ISSUES

**L1 (a) Does this project raise any additional ethical issues?**

If answer is No, please delete remaining questions in Section L.

**L1 (b) If yes, please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.**

Answer

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.