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:

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? Yes / No

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: Dr. / Ms. / Mr. / Prof. **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: Dr. / Ms. / Mr. / Prof. **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: Dr. / Ms. / Mr. / Prof. **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: Dr. / Ms. / Mr. / Prof. **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?
Yes / No

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: Dr. / Ms. / Mr. / Prof. **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? Yes / No / Not to my knowledge

C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes / No

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? Yes / No

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

Answer

C2.3 (a) Will there be a time interval between giving information and seeking consent? Yes / No

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? Yes / No

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 <u>at risk</u> 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. <u>It is recognised that not all groups</u>

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 Yes / No

(b) Patients Yes / No

- **Unconscious patients** Yes / No
- **Current psychiatric in-patients** Yes / No
- **Patients in an emergency medical setting** Yes / No

(c) Relatives / Carers of patients Yes / No

(d) Persons in dependent or unequal relationships Yes / No

- **Students** Yes / No
- **Employees / staff members** Yes / No
- **Persons in residential care** Yes / No
- **Persons highly dependent on medical care** Yes / No

(e) Intellectually impaired persons Yes / No

(f) Persons with a life-limiting condition Yes / No
(Please refer to guidance manual for definition)

(g) Persons with an acquired brain injury Yes / No

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)? Yes / No / Non-applicable

D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)? Yes / No / Non-applicable

SECTION E DATA PROTECTION

SECTION E IS MANDATORY

E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes / No

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)? Yes / No

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? Yes / No

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? Yes / No

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? Yes / No

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? Yes / No

F2.4 (b) Will the human biological material be collected specifically for the purposes of this research study? Yes / No

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? Yes / No

F2.5 (b) If yes, will this remaining biological material be retained? Yes / No

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)? Yes / No

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? Yes / No

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? Yes / No

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? Yes / No

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? Yes / No

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'? Yes / No

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

Answer

F5.2 (a) Will consent be obtained? Yes / No

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** Yes / No
ii) **Diagnostic Imaging Facility** Yes / No
iii) **Clinical Laboratory** Yes / No
iv) **Academic Research Centre** Yes / No
v) **Other** Yes / No **Details:** Answer

G1.4 Has each study site/institution in the Republic of Ireland been licensed by the Radiation Protection Society of Ireland? Yes / No

G2 RADIOTHERAPY TRIALS

G2.1 Does the study/trial involve exposure of patients to radiotherapy? Yes / No

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?

Standard Treatment / Experimental

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

Answer

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).

Answer

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

Answer

G2.3 (c) Radiation treatment schedule:

(i) Total dose:

Answer

(ii) Dose per fraction

Answer

(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 <u>each radionuclide</u> to be administered

G3.1 (a) Will any of the study/trial participants be patients? Yes / No

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

G3.1 (b) Will any of the study/trial participants be healthy volunteers? Yes / No

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

<u>G3.2 Dose and Risk Assessment</u>

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? Yes / No

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? Yes / No

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

H2 (a) Does the device have a CE mark? Yes / No	
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?	**H2 (e) If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?**
Within / Outside	Yes / No
H2 (c) If outside, please elaborate:	
Answer	
H2 (d) CE MARK NUMBER:	
Answer	

H3 (a) Is this an application to conduct a clinical investigation of a medical device? Yes / No

H3 (b) If yes, will the Medical Devices section of the Health Products Regulatory Authority (HPRA) be reviewing this study? Yes / No

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? Yes / No

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:

Answer

III. The formulation:

Answer

IV. The authorisation / product number:

Answer

I1.2 (a) Is this an application to conduct a non-interventional trial of a medicinal product? Yes/No

I1.2 (b) Is this trial a post-authorisation safety study? Yes / No

I.2 COSMETICS

I2.1 (a) Does this study involve a cosmetic? Yes / No

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:

Answer

II. The ingredients/composition:

Answer

I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? Yes / No

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

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

Answer

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 Yes / No
A medical device company Yes / No
A university Yes / No
A registered charity Yes / No
Other Yes / No **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?
Yes / No

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.

Source of funding (industry, grant or other):
Answer
Name of Funder:
Answer
Amount of Funding:
Answer
Duration of Funding
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? Yes / No

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.