LauraLynn
IRELAND'S CHILDREN'S HOSPICE

STANDARD APPLICATION FORM

ADAPTED VERSION (AUGUST 2018)
EDITED (31 August 2018)
Includes Administrative Changes
8 March 2021, 16 April 2021, 31 May 2021

LauraLynn Research Ethics Committee

For the Ethical Review of Health-Related Research Studies, which are not subject to National Research Ethics Committee Review

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT
OR A CLINICAL INVESTIGATION OF A MEDICAL DEVICE
REQUIRING HPRA AUTHORISATION

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 **Sections H and I** within the form before any attempt to complete the Standard Application Form. **Section H** is designed to assist applicants in ascertaining if their research study is in fact a clinical investigation of a medical device. **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:

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:

Qualifications:

Position:

Dept:

Organisation:

Address:

Tel no:

Email:

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:

Qualifications:

Position:

Dept :

Organisation:

Address:

Tel :

E-mail:

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:

Qualifications:

Position:

Dept:

Organisation:

Address:

Tel:

E-mail:

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

Name of site (if applicable):

Title Dr. / Ms. / Mr. / Prof:

Name:

Qualifications:

Position:

Dept :

Organisation:

Address:

Tel:

E-mail:

Role in Research e.g. statistical / data / laboratory analysis:

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

Name:

Position:

Organisation:

Address for Correspondence:

Tel (work):

Tel (mob):

Email:

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):

Academic Course:

Academic Institution:

A5 (c) Academic Supervisor(s)

Title Dr. / Ms. / Mr. / Prof:

Name:

Position:

Dept:

Tel no:

Email:

Address:

Organisation:

Qualification:

Tel:

E-mail:

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

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

B2. What is the anticipated duration of this study?

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.

B4. Provide brief information on the study background.

B5. List the study aims and objectives.

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

B7. Provide information on the study design.

B8. Provide information on the study methodology.

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

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

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.

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

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:
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:

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

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?

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

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

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

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 to take part in the research 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. Please note explicit consent to process personal data for research purposes is mandatory under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations unless the data is anonymous or a 'consent declaration' has been obtained.

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

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.

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

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

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.

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.

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

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.

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?

C3.5 Where conducting research with adults who lack capacity, for data processing purposes please state whether:

a) a consent declaration has been obtained in advance of commencing the research;
b) the individual's "legal representative" consented; or
c) the data has been anonymised.

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.

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

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.

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.

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.)

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

C4.8 Please explain your approach to consenting research subjects if they reach the age of 18 during the course of the study.

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?

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 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.</u>

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 ☐
- **Patients in an emergency medical setting** Yes ☐ No ☐
- **Current psychiatric in-patients** 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).

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.

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?

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

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

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

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.

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

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

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?

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

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

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 explicit consent be sought for the processing of data? Yes ☐ No ☐

E1.1 (b) If no, please elaborate. Please note explicit consent is mandatory under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations 2018 unless the data is anonymous or a 'consent declaration has been obtained'

E2 DATA PROCESSING – GOVERNANCE AND PROCEDURE

YOU MUST ANSWER ALL QUESTIONS IN THIS SECTION AS THEIR FULFILLMENT IS A MANDATORY REQUIREMENT UNDER THE DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018

E2.1 Please specify which arrangements are in place to ensure that personal data will be processed as is necessary; a) to achieve the objective of the health research and; b) to ensure that shall not be processed in such a way that damage or distress to the data subject?

E2.2 Please specify the data controller; joint data controllers (if applicable) and any data processors involved in the research.

E2.3 Please specify any person or organisation who provides funding for, or otherwise supports, the project.

E2.4 Please specify any person other than the named data controller, joint controllers or processors with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.

E2.5 The provision of training in data protection law and practice to anyone involved in carrying out the health research is a mandatory legal requirement. Please specify the provision of training.

E2.6 Has a "risk assessment" and/or "data protection impact assessment" been carried out, taking in to account local policy and/or legal requirements?

E2.7 Please specify the measures in place that demonstrate compliance with the data minimisation principle (Is it adequate, relevant and limited to what is necessary?)

E2.8 Please specify the controls in place to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.

E2.9 Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased.

E2.10 Please specify measures to protect the security of the personal data concerned.

E2.11 Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed.

E2.12 Please specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.

E2.13 Please specify which arrangements are in place to ensure that personal data is processed in a transparent manner.

E3 DATA PROCESSING - GENERAL

E3.1 What media of data will be collected?

E3.2 (a) Would you class the data collected in this study as anonymous, pseudonymised or identifiable data?

E3.2 (b) If 'PSEUDONYMISED', please confirm who will retain the 'key' to re-identify the data?

E3.3 Where will data which is collected be stored?

E3.4 (a) Will data collected be at any stage leaving the site(s) of origin?

Yes ☐ No ☐

E3.4 (b) If yes, please elaborate.

E3.5 Where will data analysis take place and who will perform data analysis (if known)?

E3.6 (a) After data analysis has taken place, will data be retained?

Yes ☐ No ☐

E3.6 (b) If yes, for how long, for what purpose, and where will it be retained?

E3.7 Please comment on the confidentiality of collected data.

E3.8 Will any of the interview data collected consist of audio recordings / video recordings?

Yes ☐ No ☐

E3.9 (a) Will any of the study data collected consist of photographs/ video recordings?

Yes ☐ No ☐

E3.9 (b) If yes, please elaborate.

E4 ACCESS TO HEALTHCARE RECORDS

E4.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? Yes ☐ No ☐

If answer is No, please delete remaining questions in Section E4

E4.1 (b) If yes, please elaborate.

E4.1 (c) Who will access these healthcare records?

E4.1 (d) Will consent be sought from patients for research team members to access their healthcare records? Yes ☐ No ☐

Consent is required from the patient to access healthcare records for research purposes unless a 'consent declaration' has been granted or the records are anonymous

If answer is Yes, please delete remaining questions in Section E4

E4.2 (a) Who or what legal entity is the data controller in respect of the healthcare records?

E4.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent? A 'consent declaration' or anonymised records are the only options here.

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.

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

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.

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?

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

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

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.

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.

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

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.

F3.3 Who will access the material?

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

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.

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 'consent declaration' from the declaration committee is warranted.

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?

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

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

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

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.

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.

F5.2 (a) Will consent be obtained?

Yes ☐ No ☐ Consent is mandatory ☐

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.

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.

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

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.

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.

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:

G1.2 (a) Does this study / trial involve <u>ADDITIONAL</u> radiation exposure other than normally received as part of standard care?

Yes ☐ No ☐

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

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:

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

Yes ☐ No ☐

Note: A National Research Ethics Committee to review research studies
which involve exposure to medical ionising radiation is under negotiation

SECTION H MEDICAL DEVICES

Note: A National Research Ethics Committee to review
clinical investigations of medical devices was set up in May 2021

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)?

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

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:	
H2 (d) CE MARK NUMBER:	

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

Note: A National Research Ethics Committee to review clinical trials of medicines was set up May 2021

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:

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? 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:

II. The ingredients/composition:

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:

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.

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

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

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:

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?

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.)

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.

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):
Name of Funder:
Amount of funding:

Duration of Funding:

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

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.

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).

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).

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.

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