STANDARD APPLICATION FORM

ADAPTED VERSION 26 June 2023

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 OR A POST-MARKETING FOLLOW-UP INVESTIGATION OF A MEDICAL DEVICE

Title of Study: Malignant melanoma in renal transplant recipients: the Irish experience\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Application Version No: V2

Application Date: 2 June 2024

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 or a post-marketing follow-up 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.

Please contact the Health Products Regulatory Authority, the National Research Ethics Committee for Clinical Trials (NREC-CT) or the National Research Ethics Committee for Medical Devices (NREC-MD) if in doubt.

**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:**

Malignant melanoma in renal transplant recipients: the Irish experience

**A2 (a) Is this a multi-site study?** No

If you chose ‘yes’ please delete questions A2 (e) (f) and (g);

If you chose ‘no’ please delete Questions A2 (b) (c) and (d)

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

**Title:** Dr. **Name:** Muireann Roche

**Qualifications:** MB, BCh, BAO

**Position:** Consultant dermatologist

**Dept:** Dermatology

**Organisation:** Beaumont Hospital

**Address:** Beaumont Hospital, Beaumont Road, Dublin 9, Dublin.

**Tel:** 01809xxxx **E-mail:** xxxx@beaumont.ie

**A2 (e) (i) Joint appointment / Dual affiliation applies:**  No

**A2 (e) (ii) If yes, name the organisation the principal investigator will represent for entire duration of this research study:**

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

Beaumont Hospital

**A2 (g) For single-site studies, please provide details of the principal investigator** **at the site.**

**Title:** Dr. **Name:** Muireann Roche

**Qualifications:** MB, BCh, BAO, MD

**Position:** Consultant dermatologist

**Dept:** Dermatology

**Organisation:** Beaumont Hospital

**Address:** Beaumont Hospital, Beaumont Road, Dublin 9, Dublin.

**Tel:** 01809xxxx **E-mail:** xxxx@beaumont.ie

**A2 (g) (i) Joint appointment / Dual affiliation applies:** No

**A2 (g) (ii) If yes, name the organisation the principal investigator will represent for entire duration of this research study:** Answer

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

**Name of site (if applicable):** Beaumont Hospital

**Title:** Dr. **Name:** Nicola Kearney

**Qualifications:** MB, BCh, BAO

**Position:** Registrar

**Dept :** Dermatology

**Organisation:** Beaumont Hospital

**Address:** Beaumont Hospital, Beaumont Road, Dublin 9, Dublin.

**Tel:** 01809xxxx **E-mail:** xxxx@beaumont.ie

**Role in Research e.g. statistical / data / laboratory analysis:** Data collection, analysis and write-up.

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

**Name:** Nicola Kearney

**Position:** Registrar

**Organisation:** Beaumont Hospital

**Address for Correspondence:** Dermatology Department, Beaumont Hospital, Beaumont Road, Dublin 9.

**Tel (work):** 01809xxxx **Tel (mob.):** 087xxxx **E-mail:** xxxx@beaumont.ie

**A5 (a) Is this study being undertaken as part of an academic qualification?** No

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

# **SECTION B STUDY DESCRIPTORS**

SECTION B IS MANDATORY

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

June 2024

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

1 month

**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.**

This retrospective study aims to investigate the incidence of malignant melanoma in Irish renal transplant recipients over a 24 year period from 2000-2024. We plan to perform a retrospective clinical and histological review of melanomas diagnosed in patients who have had a renal transplant in Ireland since the year 2000. The histological review will involve a review of data held on WinPATH, Beaumont Hospital’s histopathological online system. Renal transplant recipients who have had a melanoma diagnosis will be identified using the Irish National Kidney Transplant Service (NKTS) registry, which is based in Beaumont hospital. This registry will also be used to collect information pertaining to the date of their kidney transplant, the date of their melanoma diagnosis, their immunosuppressive regime, any other cancers including skin cancers that they have developed, as well the cause of their graft failure/death. We will also collect person-level data including age and gender. We hope to identify risk factors relating to the development of melanoma in this patient cohort, and to calculate the relative risk of melanoma in Irish renal transplant recipients.

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

The literature clearly describes an increased risk of melanoma in renal transplant recipients. However, to the best of our knowledge, this is the only study since 2006 to further investigate this risk in Ireland.

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

Aims:

(1) To evaluate the incidence of malignant melanoma in Irish renal transplant recipients

(2) To identify possible risk factors for the development of malignant melanoma in this patient cohort

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

Measurable outcomes include:

(1) The incidence of melanoma in Irish renal transplant recipients from 2000-2024

(2) Person-level data and clinical characteristics that may be risk factors for their development of a melanoma

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

This is an investigator led retrospective clinical and histopathological review of melanomas diagnosed in Irish renal transplant recipients.

Prospective patients will be identified using the Irish National Kidney Transplant (INKT) registry. Should these patients meet inclusion and exclusion criteria, they will be included in this study.

The histological review will involve a review of data held on WinPATH, Beaumont Hospital’s histopathological online system.

We intend that results will be made available to the public via publication in a medical journal or presentation at a medical conference.

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

Patients will be identified using the Irish National Kidney Transplant Service (NKTS) registry. Should these patients meet inclusion and exclusion criteria, they will be included in this study. Descriptive statics will be used to analyse the data collected, and help will be sought from a renal statistician. The project will be written up in its entirety with the intention of publishing our results in a medical journal.

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

Descriptive statistics will be used in the analysis. I am hoping to obtain statistical advice from the renal statistician, Mr. Patrick Kelly.

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

We anticipate a small sample size based on the available literature and from speaking with the renal transplant data manager, Ms Anne Cooney.

**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?**

Approximately 50 patients.

**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).**

Not 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:** |
| --- | --- |
| BEAUMONT HOSPITAL | APPROXIMATELY 50 PARTICIPANTS. |
|  |  |

# **SECTION C STUDY PARTICIPANTS**

SECTION C IS MANDATORY

# **C1 PARTICIPANTS – SELECTION AND RECRUITMENT**

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

Participants will be selected with the help of the renal transplant data manager, and using the Irish National Kidney Transplant Service (NKTS) registry as information pertaining to skin cancer (melanoma) has been recorded for each patient in this registry.

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

Patients who have been selected will be recruited to this study should they meet inclusion/exclusion criteria, i.e. been diagnosed with a malignant melanoma following the receipt of a renal transplant.

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

All patients who have been registered on the Irish NKTS registry following their renal transplant who were subsequently diagnosed with malignant melanoma.

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

Patients registered on the Irish NKTS registry who did not have a malignant melanoma.

**C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project?** Not to my knowledge

# **C2 PARTICIPANTS – INFORMED CONSENT**

Note: The HSE first released a National Consent Policy for Health and Social Care Research in December 2022. This policy, which will be regularly updated, introduces a definition of consent which combines elements of informed consent to take part and explicit consent for data processing (see Sub-Section E1 for explicit consent for data processing)

**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 or an exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021 applies.**

Retrospective chart review study exemption applies.

**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**

Note: The Assisted Decision-Making Capacity (Amendment) Act 2022 took effect on the 26th April 2023.

Note: Refer to the HSE National Consent Policy for Health and Social Care Research – search “capacity” and / or “emergency”

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

As this is a retrospective chart review, we will not be assessing patients’ capacity and may not be aware whether they have capacity or not based on a review of their electronic health records.

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

# **C4 PARTICIPANTS UNDER THE AGE OF 18**

**C4.1 (a) Will any research participants be under the age of 18 i.e. Children?** No

# **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.**

**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** No

**(b) Patients** Yes

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

**(c) Relatives / Carers of patients** No

**(d) Persons in dependent or unequal relationships** No

* **Students** No
* **Employees / staff members** No

**Persons in residential care** No

* **Persons highly dependent on medical care** No

**(e) Intellectually impaired persons** No

**(f) Persons with a life-limiting condition**  No

(Please refer to guidance manual for definition)

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

Not applicable.

**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.**

This information will not be known at the time of recruitment. This person-level data will not be gathered.

# **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?**

Nil.

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

Review of Irish NKTS registry and of WinPATH (histopathology system).

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

Nil.

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

A greater understanding of the incidence and risk factors for the development of melanoma in renal transplant recipients in Ireland.

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

No

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

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

Not applicable.

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

Not applicable.

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

Not applicable.

**D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?** 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?**

Not applicable.

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

Note: refer to the HSE National Consent Policy for Health and Social Care Research – search “findings”

Not applicable.

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

We hope that aggregated results will be made available via publication of a research paper in a medical journal. They may also be discussed at national/international dermatology conferences.

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

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

# **SECTION E DATA PROTECTION**

SECTION E IS MANDATORY

# **E1 DATA PROCESSING - CONSENT**

Note: The HSE first released a National Consent Policy for Health and Social Care Research in December 2022. This policy, which will be regularly updated, introduces a definition of consent which combines elements of informed consent to take part and explicit consent for data processing (see Sub-Section C2 for informed consent to take part)

**E1.1 (a) Will explicit consent be sought for the processing of data?** 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’ or an exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021 applies.**

Retrospective chart review study exemption applies.

**E1.1 (c) If yes, please confirm that a copy of the ‘explicit consent’ will be provided to the data subject prior to the commencement of the health research. This is mandatory requirement under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021.**

Answer

# **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?**

1. The data being collected is minimised to what is necessary.
2. The data will be collected from patients’ electronic heath records (NKTS registry and WinPATH) and kept secure on an encrypted excel file which will only be accessed from Beaumont Hospital computers in a locked office.
3. No identifiable data will be shared outside Beaumont hospital.

**E2.2 Please specify the data controller**\*[[1]](#footnote-0)**; joint data controllers (if applicable) and any data processors**\*[[2]](#footnote-1) **involved in the research.**

| **Name of Organisation which is the sole Data Controller for this research study** | **Name of Organisations which are the Joint Data Controllers for this research study (where applicable)** | **Name of Organisations which are data processors acting on behalf of / and under the instruction of the sole data controller or joint data controllers (if any)** |
| --- | --- | --- |
| Answer | Beaumont Hospital, Beaumont Road, Dublin 9. | Answer |
|  | **Please note contracts will apply** |

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

Nil funding.

**E2.4 Please specify any person other than employees of 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.**

All data will only be shared with employees of the data controller.

**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.**

All researchers have undertaken GDPR 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?**

Yes

**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?)**

Only pertinent patient information will be collected. The data will only be retained until the study has been completed.

**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.**

Any data processed from this study will be stored on an encrypted excel file which will only work from a Beaumont computer, in the dermatology office.

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

The data on the excel spreadsheet will be encrypted.

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

Any data processed from this study will be stored on an encrypted excel file which will only work from a Beaumont computer, in the dermatology office. Only dermatology staff have access to this office which is locked when it is not in use.

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

Electronic data which is no longer required will be permanently deleted from the Beaumont server as well as all previous versions of the document.

**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.**

Not applicable.

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

The results of the study derived from the data will be available in peer reviewed journals.

# **E3 DATA PROCESSING - GENERAL**

**E3.1 What media of data will be collected?**

Data from electronic health records (Irish NKTS registry/WinPATH).

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

Pseudonymised.

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

Dr. Nicola Kearney

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

In an encrypted excel file on a password protected hospital computer in the dermatology office, on site in Beaumont Hospital. Only dermatology staff have access to this office.

**E3.4 (a) Will data collected be at any stage leaving the site (s) or organisation (s) of origin?** **Please note contracts may apply**

No

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

Not applicable

**E3.5 Where will data analysis take place and who will perform data analysis (if known)? Please note contracts may apply**

Beaumont Hospital. The investigators involved in this project will perform data analysis.

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

Yes

**E3.6 (b) If yes, for how long, for what purpose, and where will it be retained? [Note – if retention for future research purposes applies, please specify]**

Note: refer to the HSE National Consent Policy for Health and Social Care Research – search “broad” and “secondary”

It will be retained until the write up of the project is complete.

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

Strictly confidential to investigators involved in this research project.

**E3.8 Will any of the interview data collected consist of audio recordings / video recordings?** No

**E3.9 (a) Will any of the study data collected consist of photographs/ video recordings?** No

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

Answer

# **E4 ACCESS TO HEALTHCARE RECORDS**

**E4.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?** Yes

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

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

We will be accessing patients’ electronic health records in order to obtain information about both their melanoma and their renal transplant (Irish NKTS registry/WinPATH)

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

Co-investigator, Dr. Nicola Kearney, or a delegated member of the study team will access these healthcare records.

**E4.1 (d) Will consent be sought from patients for research team members to access their healthcare records? 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 or an exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021 applies.**  No

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?**

Beaumont Hospital.

**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 or an exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021 are the only options here.**

Retrospective chart review study exemption applies.

# **SECTION F HUMAN BIOLOGICAL MATERIAL**

# **F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL**

**F1 1 (a) Does this study involve human biological material?** No

If the answer is No, please delete Section F

# **SECTION G RADIATION**

# **G1 RADIATION – GENERAL**

Note: A National Research Ethics Committee to review research studies

which involve exposure to medical ionising radiation is under negotiation.

Pending set up of a National REC, studies which involve exposure to medical ionising radiation may only be reviewed by a research ethics committee which has been recognised to give a single national opinion under S.I. No. 29/2023

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

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

# **SECTION H MEDICAL DEVICES**

Note: A National Research Ethics Committee to review clinical investigations of medical devices, and post-marketing follow up 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?**  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?** No

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

# **I.2 COSMETICS**

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

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

# **I.3 FOOD AND FOOD SUPPLEMENTS**

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

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

# **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.**

Yes. Clinical indemnity scheme.

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

Clinical indemnity scheme applies. I also have private indemnity cover with MPS.

**J3.1 Please give the name and address of the sponsor for this clinical trial (or the legally responsible entity or entities for research other than clinical trials)** [[3]](#footnote-2)

| **CLINICAL TRIAL** | **RESEARCH OTHER THAN CLINICAL TRIALS** |
| --- | --- |
| **Name and Address of Sponsor:** | **Name and Address of Legally Responsible Entity/Entities:** | **Area of Responsibility:** |
|  | Beaumont Road, Dublin 9, Ireland. | Responsible for study design and conduct. |
| Answer | Answer |
| Answer | Answer |

**J3.2 Please specify if the sponsor or legally responsible entity / entities is/are pharmaceutical companies, medical device companies, academic institutions, registered charities or other.**

Beaumont Hospital is an academic teaching hospital.

**J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place by the above-named sponsor, legally responsible entity or entities in respect of this research study.**

None

# **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.)**

Staff time pertaining to identifying all renal transplant recipients who have been diagnosed with a melanoma since the year 2000.

# **K2 FUNDING**

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

No

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

Funding not required

**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.**

N/A

**K2.1(e) Is the study funded by a ‘for profit’ organisation?** No

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

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

N/A

# **K3 PAYMENTS TO INVESTIGATORS**

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

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

N/A

# **K4 PAYMENTS TO PARTICIPANTS**

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

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

N/A

# **SECTION L ADDITIONAL ETHICAL ISSUES**

**L1 (a) Does this project raise any additional ethical issues?** No

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

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

1. ‘The data controller for a research study is the organisation that determines the purpose and the manner by which personal data are processed for the research study (i.e. ‘Whom’, ‘Why’, ‘How’).’ **– HSE RGMS Framework, Sept ‘21** [↑](#footnote-ref-0)
2. ‘A data processor is defined as the organisation that processes personal data on behalf of, and under the instruction of, the data controller (i.e. two distinct organisations).’ **– HSE RGMS Framework, Sept ‘21** [↑](#footnote-ref-1)
3. Refer to HSE RGMS Framework, Sept ’21 for more information - https://hseresearch.ie/governance-framework/ [↑](#footnote-ref-2)