National Research Ethics Committee – Medical Devices

Application form for the Ethical Review of Clinical Investigations of Medical Devices and Performance Studies of *In Vitro* Diagnostic Medical Devices

Version 4.0

Instructions

* This application form is designed for clinical investigations of medical devices and performance studies of *in vitro* diagnostic medical devices only.
* Unless indicated otherwise, the term ‘medical device’ is used in this form to refer both to medical devices as defined by the Medical Devices Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices as defined by the *In Vitro* Diagnostic Medical Device Regulation (EU) 2017/746.
* All sections of the application form should be completed. If a section does not apply, select ‘No’ or ‘N/A’, or enter ‘N/A’ in the text box, as appropriate.
* Ensure all answers are in plain English comprehensible to a lay person.
* Digital signatures are encouraged. Please ensure that the completed form is submitted in PDF format, not scanned, in order to ensure accessibility.
* Information on this form will remain confidential, however, the NREC-MD may seek an external expert to provide advice on any aspect of the application which lies beyond the expertise of the members.
* Respond to each question carefully. Please contact the National Office for Research Ethics Committees ([devices@nrec.ie](mailto:devices@nrec.ie)) in the event of queries which may arise during the completion of this form.

# Table of Contents

[Table of Contents 2](#_Toc143692773)

[SECTION A – STUDY IDENTIFICATION 3](#_Toc143692774)

[SECTION B – APPLICANT IDENTIFICATION 3](#_Toc143692775)

[SECTION C – DETAILS OF THE STUDY 5](#_Toc143692776)

[SECTION D – MEDICAL DEVICES 6](#_Toc143692777)

[SECTION E – STUDY DESCRIPTIONS 9](#_Toc143692778)

[SECTION F – STUDY PARTICIPANTS 9](#_Toc143692779)

[SECTION G – INFORMED CONSENT 13](#_Toc143692780)

[SECTION H – PARTICIPANTS LACKING DECISION-MAKING CAPACITY 15](#_Toc143692781)

[SECTION I – MINORS 17](#_Toc143692782)

[SECTION J – PARTICIPANTS OF CHILD-BEARING POTENTIAL AND PREGNANT OR BREASTFEEDING PARTICIPANTS 19](#_Toc143692783)

[SECTION K – DATA PROTECTION 19](#_Toc143692784)

[SECTION L – HUMAN BIOLOGICAL MATERIAL 23](#_Toc143692785)

[SECTION M – GENETIC DATA 27](#_Toc143692786)

[SECTION N – COMMERCIAL VALUE 29](#_Toc143692787)

[SECTION O – RADIATION 29](#_Toc143692788)

[SECTION P – MEDICINAL PRODUCTS/COSMETICS/FOOD AND FOODSTUFFS 38](#_Toc143692789)

[SECTION Q – INDEMNITY AND INSURANCE 40](#_Toc143692790)

[SECTION R – COSTS AND RESOURCES, FUNDING AND PAYMENTS 40](#_Toc143692791)

[SECTION S – PAYMENTS TO PARTICIPANTS 41](#_Toc143692792)

[SECTION T – DECLARATION OF NATIONAL PRINCIPAL INVESTIGATOR 42](#_Toc143692793)

SECTION A – STUDY IDENTIFICATION

|  |
| --- |
| A1 This application pertains to: |
| a clinical investigation of a medical device as defined in Medical Devices Regulation (EU) 2017/745  a performance study on an *in vitro* diagnostic medical device as defined in *In Vitro* Diagnostic Medical Device Regulation (EU) 2017/746 |

|  |
| --- |
| A2 Study CIV-ID: |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| A3 Study classification: | |
| **Medical device** | ***In vitro* diagnostic medical device** |
| Article 62 | Article 57 |
| Article 74(1) (please include a PMCF\* NREC application appendix) | Article 58 |
| Article 74(2) | Article 70 (1) (please include a PMPF\* NREC application appendix) |
| Article 75 | Article 70 (2) |
| Article 82 | Article 71 |

\*post-market clinical/performance follow-up

|  |
| --- |
| A4 title of the study: |
| Click or tap here to enter text. |

|  |
| --- |
| A5 Lay title of the study (if different): |
| Click or tap here to enter text. |

SECTION B – APPLICANT IDENTIFICATION

| B1 National/Coordinating Principal Investigator with overall responsibility for the conduct of this study: | |
| --- | --- |
| **Title:** | Click or tap here to enter text. |
| **Name:** | Click or tap here to enter text. |
| **Qualifications:** | Click or tap here to enter text. |
| **Position:** | Click or tap here to enter text. |
| **Organisation/Site:** |  |
| **Address:** | Click or tap here to enter text. |
| **Telephone:** | Click or tap here to enter text. |
| **E-mail:** | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| B2 Study sponsor: | | |
| **Name:** | Click or tap here to enter text. | |
| **Commercial:** | | **Non-Commercial:** |
| **Address:** | Click or tap here to enter text. | |
| **Telephone:** | Click or tap here to enter text. | |
| **E-mail:** | Click or tap here to enter text. | |
| **Name, job title and contact**  **details of sponsor**  **representative:** | Click or tap here to enter text. | |
| **Name, company name and contact**  **details of sponsor’s**  **legal representative**  **(if sponsor has no**  **presence in EEA):** | Click or tap here to enter text. | |

| B3 Device manufacturer: | |
| --- | --- |
| **Manufacturer Name:** | Click or tap here to enter text. |
| **Address:** | Click or tap here to enter text. |
| **Telephone:** | Click or tap here to enter text. |
| **E-mail:** | Click or tap here to enter text. |
| **Name, job title and contact**  **details of manufacturer**  **representative:** | Click or tap here to enter text. |
| **Name, company name and contact**  **details of manufacturer’s**  **authorised representative**  **(if manufacturer has no**  **presence in EEA):** | Click or tap here to enter text. |
| **Name and contact details of the authorised representative for this device (if manufacturer has no presence in EEA):** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| B4 Lead contact person who is to receive correspondence/queries in relation to this application: | |
| **Name:** | Click or tap here to enter text. |
| **Position:** | Click or tap here to enter text. |
| **Department:** | Click or tap here to enter text. |
| **Organisation:** | Click or tap here to enter text. |
| **Address:** | Click or tap here to enter text. |
| **Telephone (Work):** | Click or tap here to enter text. |
| **Telephone (Mobile):** | Click or tap here to enter text. |
| **E-mail:** | Click or tap here to enter text. |

SECTION C – DETAILS OF THE STUDY

|  |
| --- |
| C1 (a) Has this or a similar application been previously submitted for review to this or any other Ethics Committee in the Republic of Ireland? |
| Yes  No |
| **C1 (b) If yes*,* please give details:** |
| Click or tap here to enter text. |

|  |
| --- |
| C2 Please describe all changes from the previous application, together with a rationale for those changes. |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| **C3 (a) Is this study to be carried out in multiple sites in the Republic of Ireland?** | Yes  No |
| **C3 (b) Please list all proposed sites in the Republic of Ireland and proposed investigators, including contact number and email:**  (Please submit a CV for each site principal investigator). | |
| Click or tap here to enter text. | |
| **C3 (c) Has permission been received from each site in the Republic of Ireland to conduct this study?**  (Site permission is required. Please submit a site-suitability form for each site in the Republic of Ireland) | Yes  No |
| **C3 (d) If no,please state why:** | Click or tap here to enter text. |

|  |
| --- |
| C4 (a) Will this study be conducted in countries other than the Republic of Ireland? |
| Yes  No |
| **C4 (b) If yes, please provide a list of countries where this study will take place:** |
| Click or tap here to enter text. |

|  |
| --- |
| C5 Anticipated study start date (DD MMM YYYY): |
| Click or tap to enter a date. |

|  |
| --- |
| C6 Anticipated study duration (months/years): |
| Click or tap here to enter text. |

SECTION D – MEDICAL DEVICES

|  |
| --- |
| D1 Name of the medical device(s) or *in vitro* diagnostic medical device(s) to be investigated: |
| Click or tap here to enter text. |

|  |
| --- |
| D2 Device generic name or nomenclature: |
| Click or tap here to enter text. |

|  |
| --- |
| D3 Device identifier (UDI-DI): |
| Click or tap here to enter text. |

| D4 General description of the medical device: |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| D5 Proposed device classification: | |
| **Medical device** | ***In vitro* diagnostic medical device** |
| Class I | Class A |
| Class I | Class B |
| Class IIa | Class C |
| Class IIb | Class D |
| Class III |  |

|  |
| --- |
| D6 Device development stage: |
| Click or tap here to enter text. |

|  |
| --- |
| D7 (a) Does the medical device have a CE mark? |
| Yes  No |
| **D7 (b) If yes*,* state the body/bodies who affixed the CE mark and provide the CE mark number (NANDO code).** |
| Click or tap here to enter text. |
| **D7 (c) If the device has a CE mark, is it proposed to use the device within its stated intended use for CE marking?** |
| Yes  No  N/A |
| **D7 (d) If no to D7(c), please describe:** |
| Click or tap here to enter text. |
| **D7 (e) If the device does not have a CE mark, or if being used outside its intended use, is this study being undertaken for the purposes of obtaining a CE mark?** |
| Yes  No  N/A |

|  |
| --- |
| D8 (a) Does this device incorporate a medicinal substance, including a human blood or plasma derivative? |
| Yes  No |
| **D8 (b) If yes, please provide details:** |
| Click or tap here to enter text. |

|  |
| --- |
| D9 (a) Is this device a companion diagnostic? |
| Yes  No |
| **D9 (b) If yes, please provide details:** |
| Click or tap here to enter text. |

|  |
| --- |
| D10 (a) Is this application submitted in association with an application for a clinical trial in accordance with regulation (EU) No 536/2014?  (Please consult the [EMA guidance](https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices) on medicinal products used in combination with a medical device) |
| Yes  No |
| **D10 (b) If yes, please enter the applicable EudraCT No:** |
| Click or tap here to enter text. |

|  |
| --- |
| D11 (a) Is this device manufactured using non-viable tissues or cells of human or animal origin, or their derivatives? |
| Yes  No |
| **D11 (b) If yes, please describe:** |
| Click or tap here to enter text. |

|  |
| --- |
| D12 (a) Will a comparator device be used during this clinical investigation? |
| Yes  No |
| **D12 (b) If yes, please provide details of the comparator device, including its classification and any information necessary for the identification of the comparator device.** |
| Click or tap here to enter text. |

SECTION E – STUDY DESCRIPTIONS

|  |
| --- |
| E1 Provide a brief lay (plain English) description of the study.  Please ensure the language used is at a level suitable for use in a study participant information leaflet. |
| Click or tap here to enter text. |

|  |
| --- |
| E2 What is the scientific justification for this study? |
| Click or tap here to enter text. |

|  |
| --- |
| E3 List the aims and objectives of this study. |
| Click or tap here to enter text. |

|  |
| --- |
| E4 Provide a brief description of the design and methods of the proposed study e.g. randomised, controlled. |
| Click or tap here to enter text. |

|  |
| --- |
| E5 Provide information on the statistical approach to be used in the analysis of your results (if appropriate). |
| Click or tap here to enter text. |

|  |
| --- |
| E6 How will the results of the study be reported and disseminated? (e.g. online, peer-reviewed journal, research participants, public engagement) |
| Click or tap here to enter text. |

SECTION F – STUDY PARTICIPANTS

|  |  |
| --- | --- |
| F1 How many study participants and controls are to be recruited in total in the Republic of Ireland? | |
| Participants | Click or tap here to enter text. |
| Controls | Click or tap here to enter text. |

|  |
| --- |
| F2 How many participants are to be recruited overall? |
| Click or tap here to enter text. |

|  |
| --- |
| F3 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference). |
| Click or tap here to enter text. |
| **F3 (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), please explain why the sample size to be used has been chosen. It is important to obtain the advice of a statistician in relation to all research studies.** |
| Click or tap here to enter text. |

|  |
| --- |
| F4 Please provide details on the method of randomisation (where applicable). |
| Click or tap here to enter text. |

|  |
| --- |
| F5 Please describe how participants will be:   * identified * recruited * selected |
| Click or tap here to enter text. |

|  |
| --- |
| F6 What resources will be used for recruitment?  (List and describe the format of the resources, e.g. paper or electronic and how these will be presented to potential participants e.g. via the post, in the clinic/hospital, through social media, radio etc. If recruitment includes advertisements or written correspondence, please provide copies and/or TV/radio scripts and letters) |
| Click or tap here to enter text. |

|  |
| --- |
| F7 (a) Will identification of potential participants involve access to identifiable information? |
| Yes  No |
| **F7 (b) If yes, describe what measures will be in place to confirm that access to this information will be lawful.** |
| Click or tap here to enter text. |

|  |
| --- |
| F8 Please outline and justify the inclusion criteria for study participants. |
| Click or tap here to enter text. |

|  |
| --- |
| F9 Please outline and justify the exclusion criteria for study participants. |
| Click or tap here to enter text. |

|  |
| --- |
| F10 What criteria exist for withdrawing research participants prematurely (if relevant)? |
| Click or tap here to enter text. |

| F11 (a) Will the participants be from any of the following groups? | | | |
| --- | --- | --- | --- |
| Children under 16 years of age |  | Adults with learning disabilities |  |
| Children under 18 years of age |  | Adults who have a terminal illness |  |
| Adults who are unconscious |  | Adults with mental illness |  |
| Adults in emergency situations |  | Prisoners |  |
| Pregnant participants / participants of child-bearing age |  | Healthy volunteers |  |
| Adults with dementia |  | Those who could be considered to need additional support or to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students. |  |
| **F11 (b) Please justify their inclusion, outlining how the trial is expected to benefit the participant cohort(s) selected.** | | | |
| Click or tap here to enter text. | | | |

|  |
| --- |
| F12 (a) Will any participants recruited to this study be simultaneously involved in any other research project? |
| Yes  No  Not to my knowledge |
| **F12 (b) If yes, please comment.** |
| Click or tap here to enter text. |

|  |
| --- |
| F13 What activities, procedures or interventions (if any) are study participants asked to undergo or engage in for the purposes of this study? |
| Click or tap here to enter text. |

|  |
| --- |
| F14 What other activities (if any) are taking place for the purposes of this study e.g. chart review, sample analysis etc? |
| Click or tap here to enter text. |

|  |
| --- |
| F15 (a) Will treatment be withheld from research participants as a result of taking part in this study? |
| Yes  No  N/A |
| **F15 (b) If yes, please provide details** |
| Click or tap here to enter text. |

|  |
| --- |
| F16 What are the potential adverse effects, risks, or hazards for research participants either from giving or withholding medications, devices, ionising radiation, or from other interventions, which may cause inconvenience or changes to lifestyle? |
| Click or tap here to enter text. |

|  |
| --- |
| F17 What are the potential benefits for research participants? |
| Click or tap here to enter text. |

|  |
| --- |
| F18 What procedures are in place to monitor the health of the research participants during the study and/or when they are no longer involved in the trial? |
| Click or tap here to enter text. |

|  |
| --- |
| F19 (a) Will the interventions, including the device, provided during the study be available to participants after the termination of the study? |
| Yes  No  N/A |
| **F19 (b) Please clarify.** |
| Click or tap here to enter text. |

|  |
| --- |
| F20 Please comment on how individual participant results will be collected. Please provide details of any data collection tools and include an example of a case report form as part of the documentation to be submitted. |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| F21 will the participant's general practitioner (GP) and/or hospital consultant be informed of their participation in the study?  (A copy of the GP letter should be submitted with the application). | |
| General Practitioner | Yes  No  N/A |
| Hospital Consultant | Yes  No  N/A |

SECTION G – INFORMED CONSENT

Note: Explicit consent (informed consent that is recorded) to process personal data for research purposes is specified as one of the necessary safeguards under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations. If explicit consent cannot be obtained, a consent declaration from the Health Research Consent Declaration Committee (HRCDC) may be required. For more information, visit – [www.hrcdc.ie](http://www.hrcdc.ie)

|  |
| --- |
| G1 (a) Will informed consent be obtained prior to participation in the study? |
| Yes  No |
| **G1 (b) If no*,* please justify:** |
| Click or tap here to enter text. |
| **G1 (c) If no, will consent from the participant(s) be sought at any stage during the study? (i.e. deferred consent)** |
| Click or tap here to enter text. |

|  |
| --- |
| G2 (a) Will informed consent be obtained from participants for data processing associated with the study? |
| Yes  No |
| **G2 (b) If no*,* please justify:** |
| Click or tap here to enter text. |

|  |
| --- |
| G3 Give details of the manner in which consent will be obtained.  (Please comment on the extent to which consent is sought and recorded for different elements of the study). |
| Click or tap here to enter text. |

|  |
| --- |
| G4 Who will approach/make contact with potential participants and who will obtain informed consent?  (Describe the professional role and whether there is a prior clinical relationship with potential participants) |
| Click or tap here to enter text. |

|  |
| --- |
| G5 When will informed consent be obtained?  (Describe when and where informed consent will be obtained and how privacy will be ensured) |
| Click or tap here to enter text. |

|  |
| --- |
| G6 How long will potential participants (or their legally designated representative) be given to decide whether to participate?  (Please note that a minimum of 24 hours is advised) |
| Click or tap here to enter text. |

|  |
| --- |
| G7 How will it be assured that potential participants (or their legally designated representative) have understood the information and that consent is informed?  (This should include how the informational needs of individuals will be identified and addressed) |
| Click or tap here to enter text. |

|  |
| --- |
| G8 What arrangements are in place to seek informed consent from potential participants (or their legally designated representative) who do not speak English?  (Please note that translations must be completed by certified translators, and the translation certificates submitted to NREC before translated documents may be used). |
| Click or tap here to enter text. |

|  |
| --- |
| G9 How will it be ensured that participants can withdraw their consent at any point?  (This should include how any potential consequences of consent withdrawal will be dealt with) |
| Click or tap here to enter text. |

|  |
| --- |
| G10 Please provide any further information, in relation to the procedure for recruitment and informed consent for the study, which has not been provided elsewhere in this document. |
| Click or tap here to enter text. |

SECTION H – PARTICIPANTS LACKING DECISION-MAKING CAPACITY

|  |
| --- |
| H1 Will all participants have the decision-making capacity to give informed consent? |
| Yes  No |

If answer is Yes, please skip remaining questions in Section H.

|  |
| --- |
| H2(a) What accommodations will be made for participants who might not adequately understand verbal or written information? |
| Click or tap here to enter text. |
| **H2(b)** **Please also state clearly how the consent and assent process will be managed for those research participants who are lacking decision-making capacity.** |
| Click or tap here to enter text. |

|  |
| --- |
| H3 Who will assess and confirm whether a potential participant has the capacity to consent? |
| Click or tap here to enter text. |

|  |
| --- |
| H4 Where capacity to consent will fluctuate or will be borderline, how will potential participants be involved in the decision to participate in the trial? (This should include how information will be tailored to ensure participants (potential and existing) are able to understand the information and how participants who regain capacity will be consented to continue in the trial) |
| Click or tap here to enter text. |

|  |
| --- |
| H5 How will a legally designated representative be identified?  (This should include which roles could act as legal representative for this study) |
| Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| H6 In relation to this study: | | |
|  |  | **Please comment:** |
| H6 (a) Is this study of such a nature that it can only be carried out on individuals lacking decision-making capacity? | Yes  No | Click or tap here to enter text. |
| H6 (b) Does this study relate directly to a medical condition which the individuals lacking decision-making capacity have been diagnosed with? | Yes  No | Click or tap here to enter text. |
| H6 (c) Is the study expected to provide direct benefit to the study participants (who lack decision-making capacity)? | Yes  No | Click or tap here to enter text. |
| H6 (d) If there is no prospect of direct benefit to the study participants, are the risks no more than minimal? | Yes  No  N/A | Click or tap here to enter text. |

| H7 Where conducting a study with individuals who lack decision-making capacity, for data processing purposes please state whether: | | |
| --- | --- | --- |
|  |  | If no, please provide justification | |
| H7 (a) A consent declaration will be obtained from the Health Research Consent Declaration Committee (HRCDC) in advance of commencing the research | Yes  No | Click or tap here to enter text. | |
| H7 (b) The individual’s ‘legally designated representative’ has consented for participation and provided assent for data processing | Yes  No | Click or tap here to enter text. | |
| H7 (c) Conditions set out in article 64 of Regulation 2017/745 and article 60 of Regulation 2017/746 have been met where appropriate. | Yes  No | Click or tap here to enter text. | |
| H7 (d) The data has been anonymised. | Yes  No | Click or tap here to enter text. | |
| H7 (e) An exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021 applies is applicable. | Yes  No | Click or tap here to enter text. | |

SECTION I – MINORS

Please consult article 65 of Regulation 2017/745 and article 61 of Regulation 2017/746

|  |
| --- |
| I1 Will any participants be minors? |
| Yes  No |

If answer is No, please skip remaining questions in Section I

|  |
| --- |
| I2 How will potential participants who are minors be involved in the decision to participate in the study?  (Describe arrangements for obtaining and recording assent, including who will be obtaining assent and details of their training and experience with children) Please submit copies of both the Information Leaflet(s) and Assent form. |
| Click or tap here to enter text. |

|  |
| --- |
| I3 (a) Give details of the manner in which consent will be obtained from Parents/Legal Guardians.  Please submit copies of both the Information Leaflet(s) and Consent form. |
| Click or tap here to enter text. |
| **I3 (b)** **How will a legal guardian of a minor be identified?**  (This should include which roles could act as legal guardian for this study) |
|  |

|  |
| --- |
| I4 How will participants be consented to continue in the study when they reach the age of legal competence?  (A participant cannot provide consent in their own right for the processing of their personal data until they reach the age of 18 years). |
| Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| I5 In relation to minors (in accordance with Regulation 2017/745 and 2017/746): | | |
|  |  | **Please comment:** |
| I5 (a) Is this study of such a nature that it can only be carried out on minors? | Yes  No | Click or tap here to enter text. |
| I5 (b) Does this study relate directly to a medical condition which the minors have been diagnosed with? | Yes  No | Click or tap here to enter text. |
| I5 (c) Is the purpose of the study to generate knowledge about the health care needs of minors? | Yes  No | Click or tap here to enter text. |
| I5 (d) Is the study expected to provide direct benefit to the participants? | Yes  No | Click or tap here to enter text. |
| I5 (e) Are the risks more than minimal? | Yes  No | Click or tap here to enter text. |
| I5 (f) Will each minor receive information about the risks and benefits of the study according to their capacity to understand? | Yes  No | Click or tap here to enter text. |
| I5 (g) Please confirm that the explicit wish of the minor who is capable of forming an opinion and assessing information to refuse to participate or to be withdrawn from the study will be respected by the investigators. | Yes  No | Click or tap here to enter text. |
| I5 (h) For data processing purposes please state whether conditions set out in article 65 of Regulation 2017/745 and article 61 of Regulation 2017/746 have been met where appropriate. | Yes  No | If no, please provide justification.  Click or tap here to enter text. |

SECTION J – PARTICIPANTS OF CHILD-BEARING POTENTIAL AND PREGNANT OR BREASTFEEDING PARTICIPANTS

Please consult article 66 of Regulation 2017/745 and article 62 of Regulation 2017/746

|  |  |
| --- | --- |
| J1 Does this study include participants of child-bearing potential or pregnant or breastfeeding participants? | |
| Child-bearing potential | Yes  No |
| Pregnant | Yes  No |
| Breastfeeding | Yes  No |

If answer is No in each case, please skip remaining questions in Section J

|  |
| --- |
| J2 If included, is the study expected to provide direct benefit to participants of child-bearing potential or pregnant or breastfeeding participants or their embryo, foetus or child after birth, outweighing the risks and burdens involved? |
| Click or tap here to enter text. |

|  |
| --- |
| J3 When a study involves pregnant or breastfeeding participants, is particular care being taken to avoid any adverse impact on the health of the embryo, foetus, or the child? Please describe. |
| Click or tap here to enter text. |

SECTION K – DATA PROTECTION

**Data processing – Governance and Procedure**

Note: Explicit consent (informed consent that is recorded) to process personal data for research purposes is specified as one of the necessary safeguards under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations. If explicit consent cannot be obtained, a consent declaration from the Health Research Consent Declaration Committee (HRCDC) may be required. For more information, visit – www.hrcdc.ie

|  |
| --- |
| K1 Which arrangements are in place to ensure that personal data processed as a part of this study will be processed as is necessary; a) to ensure the data being processed is safeguarded under terms and conditions; b) to achieve the objective of the study and; c) to ensure that it shall not be processed in such a way that causes damage or distress to the data subject? |
| Click or tap here to enter text. |

|  |
| --- |
| K2 Please specify all data controllers/joint data controllers (if applicable) and any data processors involved in the study. |
| Click or tap here to enter text. |

|  |
| --- |
| K3 Please specify any person/third party 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. |
| Click or tap here to enter text. |

|  |
| --- |
| K4 (a) Will any data from the study be transferred outside of the EU? |
| Yes  No |
| **K4 (b) If yes, specify which arrangements are in place to ensure that personal data will be processed as is necessary; a) to ensure the data being processed is safeguarded under terms and conditions; b) to achieve the objective of the study and; c) to ensure that it shall not be processed in such a way that causes damage or distress to the data subject?** |
| Click or tap here to enter text. |

|  |
| --- |
| K5 Please specify the controls in place to limit access to the data undergoing processing in order to prevent unauthorised consultation, access, dissemination, alteration, disclosure, erasure, or loss of information and/or personal data. |
| Click or tap here to enter text. |

|  |
| --- |
| K6 Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased. |
| Click or tap here to enter text. |

|  |
| --- |
| K7 Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed. |
| Click or tap here to enter text. |

|  |
| --- |
| K8 Please specify other technical and organisational measures designed to ensure that data processing is carried out in accordance with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, together with processes for testing and evaluating the effectiveness of such measures. |
| Click or tap here to enter text. |

|  |
| --- |
| K9 Please specify which arrangements are in place to ensure that personal data is processed in a transparent manner. |
| Click or tap here to enter text. |

|  |
| --- |
| K10 Please describe the measures that will be implemented in the case of a data security breach in order to mitigate the possible adverse effects. |
| Click or tap here to enter text. |

|  |
| --- |
| K11 Please specify the provision of training in data protection law and practice to anyone involved in carrying out the health research.  (The completion of training in data protection law and practice by anyone involved in carrying out the health research is a mandatory legal requirement) |
| Click or tap here to enter text. |

|  |
| --- |
| K12 Please specify the measures in place that demonstrate compliance with the data minimisation principle.  (Is the data adequate, relevant and limited to what is necessary?) |
| Click or tap here to enter text. |

|  |
| --- |
| K13 Please specify measures to protect the security of the personal data concerned. |
| Click or tap here to enter text. |

**Data processing – General**

|  |  |
| --- | --- |
| K14 What forms of data will be collected? | |
| Paper-based | Yes |
| Electronic/Digital  (may include images) | Yes |
| Audio | Yes |
| Video | Yes |
| Photography | Yes |
| Other | Yes |
| If ‘Other’ please comment: | Click or tap here to enter text. |

|  |  |
| --- | --- |
| K15 Will the data collected in this study be processed as anonymous, pseudonymous, or identifiable data? | |
| Anonymous | Yes |
| Pseudonymous | Yes |
| Identifiable | Yes |

|  |
| --- |
| K16 If data will be pseudonymised, please confirm who will retain the ‘key’/master list which may be used to re-identify the data? |
| Click or tap here to enter text. |

|  |
| --- |
| K17 Where will data which is collected be stored and who will have access to this data? |
| Click or tap here to enter text. |

|  |
| --- |
| K18 Where will data analysis take place and who will perform data analysis? |
| Click or tap here to enter text. |

|  |
| --- |
| K19 After data analysis has taken place, will data be retained? If yes, who will have access, for how long, for what purpose, and where will it be retained? |
| Click or tap here to enter text. |

|  |
| --- |
| K20 How will confidentiality of the study data be maintained? |
| Click or tap here to enter text. |

**Access to healthcare records**

|  |
| --- |
| K21 Will personally identifiable data of potential participants be accessed by the Sponsor through healthcare records? |
| Yes  No |

If answer is No, please proceed to Question K24

|  |
| --- |
| K22 If yes, please describe what measures will be in place to confirm that access to this data will be lawful as per Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018. Please outline who will access the data and any other measures taken to ensure lawful access. |
| Click or tap here to enter text. |

|  |
| --- |
| K23 Who or what legal entity is the data controller in respect of the healthcare records? |
| Click or tap here to enter text. |

|  |
| --- |
| K24 (a) Has the Irish site Data Protection Officer(s) (DPO) contributed to/given feedback on the risk assessment/DPIA? |
| Yes  No |
| **K24 (b) Please provide evidence of the feedback.** |
| Click or tap here to enter text. |

SECTION L – HUMAN BIOLOGICAL MATERIAL

|  |
| --- |
| L1 Does this study involve human biological material? |
| Yes  No |

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

**Bodily Tissue/Bodily Fluid samples prospectively collected**

|  |
| --- |
| L2 Does this study involve the prospective collection of human biological material? |
| Yes  No |

If answer is no, please proceed to Question L10.

|  |
| --- |
| L3 Please confirm what type of human biological material is being collected. |
| Click or tap here to enter text. |

|  |
| --- |
| L4 Who or what institution will be the custodian of the prospectively collected human biological material? |
| Click or tap here to enter text. |

|  |
| --- |
| L5 Will the human biological material be collected as part of routine clinical care? |
| Yes  No |

|  |
| --- |
| L6 Will the human biological material be collected specifically for the purposes of this study? |
| Yes  No |

|  |
| --- |
| L7 With reference to your responses to questions L5 and L6, please provide more detail as to whether participants will be consented separately to the taking of a sample or to the use of a sample (or part of a sample) which will be collected for clinical reasons. |
| Click or tap here to enter text. |

|  |
| --- |
| L8 (a) With respect to human biological material to be prospectively collected and analysed for the purposes of this study, will any human biological material remain? |
| Yes  No |
| **L8 (b) If yes, will this remaining biological material be retained?** |
| Yes  No |
| **L8 (c) If yes, for how long and where will biological material be retained? Who will have access to the samples?** |
| Click or tap here to enter text. |
| **L8 (d) If yes, for what purpose will biological material be retained?** |
| Click or tap here to enter text. |
| **L8 (e) If yes, please comment on consent for retention of biological material.** |
| Click or tap here to enter text. |
| **L8 (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  N/A |
| **L8 (g) If yes, please comment on consent for future use of human biological material.**  (Note: blanket consent is not lawful under Irish legislation, broad informed consent is lawful). |
| Click or tap here to enter text. |

|  |
| --- |
| L9 (a) Will the human biological material be collected specifically for the purposes of depositing in a biobank? |
| Yes  No |
| **L9 (b) If yes, please provide specific information in relation to the proposed biobank.** |
| Click or tap here to enter text. |
| **L9 (c) If yes, please confirm that the study participants will be informed in all information leaflets that their biological material will be deposited in a biobank, and that consent will be requested as a separate, optional item in the informed consent form.** |
| Click or tap here to enter text. |

**Bodily Tissue/Bodily Fluid samples retrospectively collected**

|  |
| --- |
| L10 Does this study involve accessing retrospectively collected human biological material? |
| Yes  No |

If answer is no, please skip remaining questions in Section L.

|  |
| --- |
| L11 Please state the type of human biological material which is being accessed. |
| Click or tap here to enter text. |

|  |
| --- |
| L12 Who will access the material? |
| Click or tap here to enter text. |

|  |
| --- |
| L13 Who (or which institution) is the current custodian of the material? |
| Click or tap here to enter text. |

|  |
| --- |
| L14 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. |
| Click or tap here to enter text. |

|  |
| --- |
| L15 (a) Do you intend to contact patients to seek their consent to use stored human biological material? |
| Yes  No |
| **L15 (b) If no, please justify why existing consent is considered sufficient.** |
| Click or tap here to enter text. |

**Bodily Tissue/Bodily Fluid samples – Sample movement**

|  |  |
| --- | --- |
| L16 (a) Will human biological material at any stage leave the institution(s) of origin? | |
| Yes  No | |
| **L16 (b) If yes, for what purpose?** | |
| Click or tap here to enter text. | |
| **L16 (c) If yes, please state where samples will be sent.** | |
| Click or tap here to enter text. | |
| **L16 (d) If yes, please state if the samples leaving the institution(s) of origin will be anonymised, pseudonymised, identifiable, etc.** | |
| Click or tap here to enter text. | |
| **L16 (e) If samples will be pseudonymised please confirm who will retain the ‘key’/master list which will be used to re-identify the samples.** | |
| Click or tap here to enter text. | |
| **L16 (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 describe.** | |
| Click or tap here to enter text. | |
| **L16 (g) Will human biological material at any stage leave the Republic of Ireland or the EU?** | |
| Leave the Rep. of Ireland | Yes  No  N/A |
| Leave the EU | Yes  No  N/A |
| **L16 (h) If yes, specify which arrangements are in place to ensure that personal data associated with the biological material will be processed as is necessary; a) to ensure the data being processed is safeguarded under terms and conditions; b) to achieve the objective of the health research and; c) to ensure that it shall not be processed in such a way that causes damage or distress to the data subject?** | |
| Click or tap here to enter text. | |

SECTION M – GENETIC DATA

|  |
| --- |
| M1 (a) Does this study involve the generation of ‘genetic data’?  As per GDPR[[1]](#footnote-2), genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained. |
| Yes  No |

If answer is No, please skip remaining questions in Section M.

|  |
| --- |
| M1 (b) If yes, please specify the nature of, and purpose for, the generation of genetic data. |
| Click or tap here to enter text. |

|  |
| --- |
| M2 (a) Will consent be obtained?  When the generation of genetic data for research purposes gives rise to the processing of personal data, explicit consent is mandatory safeguard under the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018. consent for generating genetic data is required under the Disability Act 2005 Part IV. |
| Yes  No  N/A |

|  |
| --- |
| M2 (b) If no or N/A, please fully explain why it is not intended to obtain consent for generating genetic data.  Please indicate whether it is intended to seek a consent declaration from the Health Research Consent Declaration Committee (HRCDC). |
| Click or tap here to enter text. |

|  |
| --- |
| M3 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. |
| Click or tap here to enter text. |

|  |
| --- |
| M4 (a)  (i) Will participants be informed of clinically relevant important incidental findings (unexpected clinically or socially relevant data) which arise from the study? |
| Yes  No |
| **(ii) Will a search for secondary genetic findings unrelated to the primary research question be carried out?** |
| Yes  No |
| **M4 (b) If no to (a), please outline how this will be communicated to participants, and comment on the responsibilities of researchers regarding non-disclosure of important incidental findings to participants.** |
| Click or tap here to enter text. |
| **M4 (c) If yes to (a),**  **(i) Set out the steps that will be taken and the information that will be provided to participants, prior to the generation and processing of genetic data in relation to any potential implications for the health of participants, which may become known as a result of study activities. Please confirm that participant consent for the communication of findings has been captured in the information leaflet(s) and the consent/assent form as an optional item.** |
| Click or tap here to enter text. |
| **(ii) Set out the arrangements that will be in place to address and inform the participant of any potentially significant results or information arising from the processing of genetic data. Please include reference to diagnostic laboratory confirmation of results, and the involvement of a clinical geneticist, as applicable.** |
| Click or tap here to enter text. |
| **(iii) In the event that generating genetic data leads to information regarding a genetic predisposition for medical conditions and/or diseases, including but not limited to those which are generally considered to be untreatable, set out the arrangements in place to ensure that the individual concerned will have access to appropriate counselling.** |
| Click or tap here to enter text. |

|  |
| --- |
| M5 Consent is required from the participant for disclosure of genetic information to third parties, including family members. Please ensure that that consent to share genetic information with family members is captured in the information leaflet and consent/assent form as an optional item, and give details below. |
|  |

SECTION N – COMMERCIAL VALUE

|  |
| --- |
| N1 (a) Will the human biological material in this 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  N/A |
| **N1 (b) If yes, please describe.** |
| Click or tap here to enter text. |

SECTION O – RADIATION

**Radiation General**

|  |  |
| --- | --- |
| **O1 Does this study involve exposure to radiation:** | Yes  No |

If answer is No, please skip remaining questions in Section O.

|  |  |
| --- | --- |
| O2 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 |
| **If other, please provide details:** | Click or tap here to enter text. |

|  |
| --- |
| O3 (a) Does this study involve additional radiation exposure other than normally received as part of standard care? |
| Yes  No |
| **O3 (b) If yes, please describe:** |
| Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| O4 Please specify if this study is due to take place at a: | | |
| **Type of facility** | **Yes/No** | **Name of site** |
| **i) Radiation oncology unit:** | Yes  No | Click or tap here to enter text. |
| **ii) Diagnostic imaging facility:** | Yes  No | Click or tap here to enter text. |
| **iii) Clinical laboratory:** | Yes  No | Click or tap here to enter text. |
| **iv) Academic research centre:** | Yes  No | Click or tap here to enter text. |
| **v) Other:** | Yes  No | Click or tap here to enter text. |
| **If other, please provide details:** | Click or tap here to enter text. | Click or tap here to enter text. |

|  |
| --- |
| O5 (a) Has each study site/institution in the Republic of Ireland been licensed by the Environmental Protection Agency (EPA) of the Republic of Ireland? |
| Yes  No |
| **O5 (b) Has each study site/institution in the Republic of Ireland been registered with the Health Information and Quality Authority (HIQA)?** |
| Yes  No |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| O6 (a) Please outline the details of the radiological investigation/ procedure carried out as a part of this study | | | | | | | | | | |
| Radiological investigation/ procedure name | Maximum Number of scans per study participant | Effective dose per scan | Frequency  e.g. 1 every 3 months | Standard level of care frequency if relevant | Total dose mSv | | | Standard level of care dose mSv | | Dose in excess of Standard level of care  mSv |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | | Click or tap here to enter text. | | Click or tap here to enter text. |
| **O6 (b) Please confirm that the examinations are justified:** | | | | | | | | | Yes | |
| **O6 (c) Please provide details of the examinations.** | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | |
| **O6 (d) Dose Information:** | | | | | | | | | | |
| **Estimated total effective dose equivalent for the study (mSv):** | | | | | | | Click or tap here to enter text. | | | |
| **Time interval over which dose is calculated:** | | | | | | | Click or tap here to enter text. | | | |
| **Estimated additional dose above standard level of care (mSv):** | | | | | | | Click or tap here to enter text. | | | |
| **Risk Category:** | | | | | | | Click or tap here to enter text. | | | |
| **Dose constraint for study:** | | | | | | | Click or tap here to enter text. | | | |
| **O6 (e) Compliance with HIQA Guidance on Dose Constraints for Carers and Comforters and Individuals Participating in Medical and Biomedical Research Involving Medical Exposures to Ionising Radiation, February 2020:** | | | | | | | Yes  No | | | |
| **O6 (f) Risk Information:** | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | |
| **O6 (g) Comments/Recommendations:** | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | |
| **O6 (h) Is the risk information in the participant information leaflet appropriate?** | | | | | | Yes  No | | | | |
| **O6 (i) Phrase to be placed in the consent form and participant information leaflet (if required):** | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | |

**Radiotherapy trials**

|  |  |
| --- | --- |
| **O7 Does the study involve exposure of participants to radiotherapy?** | Yes  No |

If answer is No, please skip the remaining questions in subsection on radiotherapy trials and continue at section on radionuclides.

|  |
| --- |
| O8 (a) Is the planned radiotherapy part of standard treatment or is it experimental in terms of dose/technique/rationale? |
| Standard Treatment  Experimental |
| **O8 (b) If experimental, please elaborate** |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| O9 In relation to the radiotherapy please provide details of the following: | |
| **(a) dose delivery technique to be used e.g. 3-dcrt (3-dimensional conformal radiation therapy), intensity modulated radiation therapy (IMRT) and volumetric arc therapy (VMRT).** | Click or tap here to enter text. |
| **(b) Imaging/verification technique to be used e.g. image guided radiation therapy (IGRT) etc.** | Click or tap here to enter text. |
| **(c) Radiation treatment schedule (include total dose, dose per fraction and number of fractions per day)** | Click or tap here to enter text. |
| **(d) Expected spectrum of acute and long-term radiation-induced side effects** | Click or tap here to enter text. |

| O10 Radiotherapy Planning | |
| --- | --- |
| **(a) Planning volumes of interest (tumour related volume and organs at risk)** | Click or tap here to enter text. |
| **(b) Planning dose volume constraints (DVCs) for organs at risk (OARs).** | Click or tap here to enter text. |
| **(c) Details of patient positioning/set-up/immobilization, inclusive of pre-treatment preparation e.g. bladder filling protocol, IV contrast etc.** | Click or tap here to enter text. |
| **(d) Details of radiotherapy plan evaluation parameters (i.e. planning target volume [PTV] coverage)** | Click or tap here to enter text. |
| **(e) What toxicity scoring criteria are to be used?** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| O11 For experimental radiotherapy, please provide the following information: | |
| **(a) Standard alternatives. Please ensure to detail and contrast the experimental protocol with ‘standard’ therapy.** | Click or tap here to enter text. |
| **(b) Potential additional risks/toxicities associated with the experimental protocol.** | Click or tap here to enter text. |

|  |
| --- |
| O12 (a) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. physics quality assurance (beam and dose). |
| Click or tap here to enter text. |
| **O12 (b) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. clinical quality assurance.** |
| Click or tap here to enter text. |

|  |
| --- |
| O13 Clinical monitoring/assessment during radiotherapy and supportive care: please provide a detailed summary of the clinical monitoring of patients included in the study/trial. |
| Click or tap here to enter text. |

|  |
| --- |
| O14 Describe the criteria for radiotherapy adverse event reporting |
| Click or tap here to enter text. |

**Radionuclides**

|  |  |
| --- | --- |
| **O15 Does the study involve exposure of participants using radionuclides?** | Yes  No |

If answer is No, please skip to section O28 - Declarations.

|  |
| --- |
| O16 Is the use of radionuclides for imaging or therapy purposes? |
| Imaging  Therapy |

If the answer is ‘imaging’, please skip to Section O28 - Declarations.

|  |
| --- |
| O17 (a) Is the planned therapy part of standard treatment or is it experimental in terms of dose/technique/rationale? |
| Standard Treatment  Experimental |
| **O17 (b) If experimental, please elaborate.**  Please attach a detailed risk assessment |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| O18 in relation to the planning of the therapy please provide details of the following: | |
| **(a) State the target organ:** | Click or tap here to enter text. |
| **(b) State the radionuclide being used:** | Click or tap here to enter text. |
| **(c) State the name of radiopharmaceutical/medical device being used:** | Click or tap here to enter text. |

|  |
| --- |
| O19 (a) Is the radiopharmaceutical/medical device licensed for this action by the Health Products and Regulatory Authority (HPRA)? |
| Yes  No |
| **O19 (b) State the route of administration:** |
| Click or tap here to enter text. |

|  |
| --- |
| O20 State the imaging/verification technique to be used (if any): |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| O21 Radiation treatment schedule: | |
| **(a) Total number of administrations.** | Click or tap here to enter text. |
| **(b) State if there are any special requirements for the administration of the radiopharmaceutical to the participant.** | Click or tap here to enter text. |
| **(c) Time interval between administrations.** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| O22 Dosimetric Considerations: | |
| **(a) Total administered activity per treatment (specify activity per unit volume/weight if it is based on organ/body volume.** | Click or tap here to enter text. |
| **(b) Estimated dose to the target organ [Gy] per administration.** | Click or tap here to enter text. |
| **(c) State the dose constraint to the target organ (if any).** | Click or tap here to enter text. |
| **(d) Estimated whole body dose (effective dose equivalent) [mSv] per administration.** | Click or tap here to enter text. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **O23 (a) Will any of the study participants be patients?** | | | Yes  No | | |
| **O23 (b) Details of patients to be studied:** | | | | | |
| **Number (whole study)** | **Age range** | **Sex** | | **Clinical condition** | **Total effective of target tissue dose per individual** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **O24 (a) Will any of the study participants be healthy volunteers?** | | | Yes  No | |
| **O24 (b) Details of healthy volunteers to be studied:** | | | | |
| **Number (whole study)** | **Age range** | **Sex** | | **Total effective of target tissue dose per individual** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. |

|  |
| --- |
| O25 (a) What is the total research protocol dose from the exposure (if any)? |
| Click or tap here to enter text. |
| **O25 (b) What component of this is the additional dose over and above standard practice?** |
| Click or tap here to enter text. |
| **O25 (c) What are the risks associated with this dose?** |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| **O26 Will the exposure exceed the exposure that might be received as part of normal care?** | Yes  No |

|  |
| --- |
| O27 (a) Please explain how the planned exposure compares with standard of care 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. |
| Click or tap here to enter text. |
| **O27 (b) If pregnant or breastfeeding participants are to be included in the study, give reasons and details of special radiation protection measures to be taken.** |
| Click or tap here to enter text. |

|  |
| --- |
| O28 Declarations |

|  |  |  |
| --- | --- | --- |
| O28 (a) Declaration by medical physics expert (for all studies involving ionising radiation). Digital signatures are encouraged. | | |
| I am satisfied that the information in Section O and the assessment in Section O provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks | | Yes |
| **Signature:** | Click or tap here to enter text. | |
| **Print Name:** | Click or tap here to enter text. | |
| **Date (DD/MMM/YYYY):** | Click or tap here to enter text. | |

|  |  |  |
| --- | --- | --- |
| O28 (b) Declaration by radiation oncologist/radiologist (for studies involving therapeutic ionising radiation). Digital signatures will be encouraged | | |
| I am satisfied that the exposure to ionising radiation planned in this research study (as defined in Section O) is reasonable and that the risks are adequately described in the participant information sheet for the study. | | Yes |
| **Signature:** | Click or tap here to enter text. | |
| **Print Name:** | Click or tap here to enter text. | |
| **Date (DD/MMM/YYYY):** | Click or tap here to enter text. | |

SECTION P – MEDICINAL PRODUCTS/COSMETICS/FOOD AND FOODSTUFFS

**Non-interventional trials of medicinal products**

|  |  |
| --- | --- |
| P1 Does this study involve a medicinal product? | |
| Yes  No | If no, continue at P3. |

|  |
| --- |
| P2 If yes, please state: |
| **(i) The trade name of the medicinal product:** |
| Click or tap here to enter text. |
| **(ii) The name of the active substance:** |
| Click or tap here to enter text. |
| **(iii) The formulation:** |
| Click or tap here to enter text. |
| **(iv) The authorisation/product number:** |
| Click or tap here to enter text. |

**Cosmetics**

|  |
| --- |
| P3 Does this study involve a cosmetic? |
| Yes  No |

If no, continue at P5.

|  |
| --- |
| P4 If yes, please state: |
| **(i) The trade name of the cosmetic:** |
| Click or tap here to enter text. |
| **(ii) The ingredients/composition:** |
| Click or tap here to enter text. |

**Food and food supplements**

|  |
| --- |
| P5 Does this study involve food or food supplements? |
| Yes  No |

If no, continue at Section Q.

|  |
| --- |
| P6 If yes, please elaborate: |
| Click or tap here to enter text. |

SECTION Q – INDEMNITY AND INSURANCE

|  |
| --- |
| Q1 What arrangements have been made for compensation in the event of a claim made by or on behalf of a participant? |
| Click or tap here to enter text. |

|  |
| --- |
| Q2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this study at each site.  (Please submit a copy of relevant insurance to the NREC-MD) |
| Click or tap here to enter text. |

SECTION R – COSTS AND RESOURCES, FUNDING AND PAYMENTS

|  |  |
| --- | --- |
| R1 (a) Has funding for the study been secured? | |
| Yes  No  N/A | |
| **R1 (b) If yes, give details of funding organisation(s) and amount secured and duration:** | |
| **Organisation:** | Click or tap here to enter text. |
| **Contact name:** | Click or tap here to enter text. |
| **Address:** | Click or tap here to enter text. |
| **Tel:** | Click or tap here to enter text. |
| **Fax:** | Click or tap here to enter text. |
| **E-mail:** | Click or tap here to enter text. |
| **Amount:** | Click or tap here to enter text. |
| **Duration:** | Click or tap here to enter text. |
| **R1 (c) If no or N/A, what arrangements have been made to cover the cost of the research?** | |
| Click or tap here to enter text. | |

|  |
| --- |
| R2 (a) Does the National Principal Investigator or any of the investigators have any direct/indirect involvement in the outcome of the study that could in any way be regarded as a possible conflict of interest, including financial interest(s), membership of advisory board(s) etc.? |
| Yes  No |
| **R2 (b) If yes, please explain.** |
| Click or tap here to enter text. |

|  |
| --- |
| R3 (a) Do any conflicts of interest exist, including in relation to funding or potential funding? |
| Yes  No |
| **r3 (b) If yes, please describe.** |
| Click or tap here to enter text. |

SECTION S – PAYMENTS TO PARTICIPANTS

|  |
| --- |
| S1 (a) Will research participants be reimbursed for expenses?  (Research participants may be reimbursed for lost earnings, travel costs and other reasonable expenses incurred. Another acceptable form of reimbursement might be the provision of free medicines or services. Compensation for the time and inconvenience involved in research participation (e.g. payment at minimum wage level) might also be permissible as research participants should not be expected to bear the costs that relate to taking part in a study. However, it is important to note that compensation is understood to mean a recompense for losses sustained. Any reimbursements that might be offered to prospective participants should first be approved by a REC to ensure that they are measurable and do not reflect any undue inducement by encouraging people to act against their better judgment or take unnecessary risks.) |
| Yes  No  N/A |
| **S1 (b) If yes, please clarify** |
| Click or tap here to enter text. |

|  |
| --- |
| S2 (a) Will research participants receive any incentives for taking part in the study? |
| Yes  No |
| **S2 (b) If yes, please clarify** |
| Click or tap here to enter text. |

SECTION T – DECLARATION OF NATIONAL PRINCIPAL INVESTIGATOR

|  |  |  |
| --- | --- | --- |
| Declaration of the National Principal Investigator  (This declaration must be signed and sent to the NREC-MD together with a proof of payment of the requisite fee before the application will be considered as valid. Digital signatures are encouraged). | | |
| I certify that the information in this form is accurate to the best of my knowledge, and I take full responsibility for it. | | Yes |
| I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in the relevant Good Clinical Practice Guidelines, (International Conference on Harmonisation’s Good Clinical Practice Guidelines (ICH GCP), International Organisation for Standardisation 14155 (ISO 14155)), and the relevant European Regulations, Medical Devices Regulation (EU) 2017/745*, In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746). | | Yes |
| If the study is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the letter of approval sent by the NREC-MD. | | Yes |
| I am aware of my responsibility to be up-to-date and comply with the requirements of the law relating to security and confidentiality of participant or other personal data. | | Yes |
| **Signature:** | Click or tap here to enter text. | |
| **Print Name:** | Click or tap here to enter text. | |
| **Date (DD/MMM/YYYY):** | Click or tap here to enter text. | |

1. https://gdpr-info.eu/ [↑](#footnote-ref-2)