**Application form performance studies of *in vitro* diagnostic medical devices as defined by the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746**

Version 5.0

* All sections of the application form must 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.
* Completed form must be submitted in machine readable Word or PDF format.

# **Overview of sections of the application**

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# **Performance study overview**

This section relates to key information and timelines of the proposed performance study.

|  |  |  |
| --- | --- | --- |
| A1 | PS-ID (if available) | |
|  | Click or tap here to enter text. | |
| A2 | Performance study title | |
|  | Click or tap here to enter text. | |
| A3 | Lay title | |
|  | Click or tap here to enter text. | |
| A4 | IVDR article | |
|  | Article 57  Article 58 (1)  Article 58 (2)  Article 70 (1)  Article 70 (2) | |
| A5 | Brief lay performance study outline (500 words)  For studies carried out under Article 70 (1), please also outline the additional, invasive or burdensome procedures carried out as a part of the performance study  For studies carried out under Article 70 (2), please also provide a justification. | |
|  | Click or tap here to enter text. | |
| A6 | Therapeutic area | |
|  | Blood  Cancer and neoplasms  Cardiovascular  Congenital disorders  Ear  Eye  Infection  Inflammatory and immune system  Injuries and accidents  Mental health  Metabolic and endocrine | Musculoskeletal  Neurological  Oral and gastrointestinal  Renal and urogenital  Reproductive health and childbirth  Respiratory  Skin  Stroke  Generic health relevance  Disputed aetiology  Other Click or tap here to enter text. |
| A7 | Performance study timelines | |
| a. | Estimated start date (Ireland) | Click or tap here to enter text. |
| b. | Estimated end date (Ireland) | Click or tap here to enter text. |
| c. | Estimated end date (global) | Click or tap here to enter text. |
| A8 | Has this or a similar application been previously submitted for review to this committee? | |
|  | Yes. Please provide previous application ID: Click or tap here to enter text.  No | |
| A9 | Please outline changes to previous application | |
|  | Click or tap here to enter text. | |
| A10 | Is this a combined study (carried out under multiple regulations, eg CTR and MDR and/ or IVDR)? | |
|  | Yes. Please provide information: Click or tap here to enter text.  No | |
| A11 | The study will be conducted lawfully and ethically, including in accordance with ethical principles outlined in the Declaration of Helsinki, ICH-Good Clinical Practice and ISO 20916:2019. | |
|  | Yes  No | |

# **Performance study sponsor**

This section relates to sponsor of the proposed performance study.

Sponsor means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the performance study.

|  |  |  |
| --- | --- | --- |
| B1 | Sponsor type | |
|  | Commercial  Non-commercial | |
| B2 | Sponsor details | |
| a. | Name | Click or tap here to enter text. |
| b. | Country | Click or tap here to enter text. |
| B3 | Sponsor legal representative in EEA details | |
| a. | Name | Click or tap here to enter text. |
| b. | Address | Click or tap here to enter text. |
| c. | Phone number | Click or tap here to enter text. |
| d. | Email address | Click or tap here to enter text. |

# **Performance study application contact person**

This section relates to the main contact person who is to receive correspondence in relation to this proposed performance study.

|  |  |  |
| --- | --- | --- |
| C1 | Performance study application contact person | |
| a. | Name | Click or tap here to enter text. |
| b. | Organisation | Click or tap here to enter text. |
| c. | Address | Click or tap here to enter text. |
| d. | Telephone | Click or tap here to enter text. |
| e. | E-mail | Click or tap here to enter text. |

# **Sites and investigators**

This section relates to sites and investigators involved in the proposed performance study.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| D1 | Countries participating in this performance study (including Ireland) | | | | |
|  | Click or tap here to enter text. | | | | |
| D2 | Sites in the Republic of Ireland and lead site investigators | | | | |
|  | Site name | Site address | Site lead investigator name | Site lead investigator email | Site lead phone number |
|  | 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. |
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|  | 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. |

# **In vitro diagnostic device characteristics**

This section relates to the medical device(s) that is/ are subject of the proposed performance study.

|  |  |  |
| --- | --- | --- |
| E1 | Product type and generic name of device(s) | |
|  | Click or tap here to enter text. | |
| E2 | Name of device(s) | |
|  | Click or tap here to enter text. | |
| E3 | Model | |
|  | Click or tap here to enter text. | |
| E4 | Proposed class of device according to the IVDR | |
|  | Class A  Class B  Class C  Class D | |
| E5 | CE marked medical device | |
|  | Yes  No. Please describe: Click or tap here to enter text. | |
| E6 | If the device has a CE mark, is it proposed to use the device within its stated intended use for CE marking. | |
|  | Yes  No. Please describe: Click or tap here to enter text. | |
| E7 | 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 | |
| E8 | Is the in vitro diagnostic medical device a companion diagnostic? | |
|  | Yes  No | |
| E9 | General description of the device | |
|  | Click or tap here to enter text. | |
| E10 | Does the device incorporate any of the following: | |
|  | Medicinal substance - please specify Click or tap here to enter text.  Human blood or plasma derivate - please specify Click or tap here to enter text.  Non-viable tissues or cells of human or animal origin or their derivates - please specify Click or tap here to enter text.  No | |
| E11 | Medical device manufacturer | |
| a. | Name | Click or tap here to enter text. |
| b. | Country | Click or tap here to enter text. |
| E12 | Manufacturer legal representative in EEA details | |
| a. | Name | Click or tap here to enter text. |
| b. | Address | Click or tap here to enter text. |
| c. | Phone number | Click or tap here to enter text. |
| d. | Email address | Click or tap here to enter text. |

# **Performance study design and objectives**

This section relates to design and objectives of the proposed performance study.

|  |  |  |  |
| --- | --- | --- | --- |
| F1 | The study is undertaken for the purpose of establishing | | |
|  | Analytical performance of the in vitro diagnostic medical device  Clinical performance of the in vitro diagnostic medical device  Other: Click or tap here to enter text. | | |
| F2 | Does the performance study constitute a controlled design? | | |
|  | Yes  No | | |
| F3 | If yes, please specify design: | | |
|  | Randomised  Open label  Single-blinded  Double-blinded | Parallel-group  Cross-over  Historic data/control  Cohort performance study | Case-Control  Cross-sectional  Other: Click or tap here to enter text. |
| F4 | Primary objective(s) of the performance study | | |
|  | Click or tap here to enter text. | | |
| F5 | Secondary objective(s) of the performance study | | |
|  | Click or tap here to enter text. | | |
| F6 | Primary endpoint(s) | | |
|  | Click or tap here to enter text. | | |
| F7 | Secondary endpoint(s) | | |
|  | Click or tap here to enter text. | | |
| F8 | Please outline how this specific performance study fits into the clinical development plan for the product | | |
|  | Click or tap here to enter text. | | |
| F9 | Will the study be overseen by either of the following: | | |
|  | Data Safety Monitoring Committee  Clinical Events Committee  Other  None – please justify: Click or tap here to enter text. | | |
| F10 | Were any patient organisations or similar engaged in the design of any aspects of the study or participant facing materials? | | |
|  | Yes. Please outline: Click or tap here to enter text.  No | | |

# **Performance study participants**

This section relates to prospective participants of the proposed performance study.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| G1 | Brief overview of the performance study population | | | | |
|  | Click or tap here to enter text. | | | | |
| G2 | Number of participants | | | | |
|  |  | Total | | Intervention group | Control group |
| a. | Participants from Ireland | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. |
| b. | Participants total | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. |
| G3 | Age range | | | | |
|  | In utero  Newborns (0-27 days)  Infants and toddlers (28 days – 35 months)  Children (3-11 years) | | Adolescents (12-15 years)  Adolescents (16-17 years)  Adults (18-64 years)  Elderly (65+ years) | | |
| G4 | Sex | | | | |
|  | Males  Females  Other | | | | |
| G5 | Do participants fall under any of the following groups: | | | | |
|  | Patients  Healthy volunteers  Minors under 16 years of age (Article 61 of EU 746 of 2017)  Participants lacking decision-making capacity (Article 60 of EU 746 of 2017)  Participants in emergency situations (Article 64 of EU 746 of 2017)  Pregnant or breastfeeding participants (Article 62 of EU 746 of 2017)  Participants who might be considered vulnerable or needing additional considerations when consent is being sought | | | | |
| G6 | Participant’s medical condition | | | | |
|  | Click or tap here to enter text. | | | | |
| G7 | Is the medical condition considered to be a rare disease | | | | |
|  | Yes  No | | | | |
| G8 | Main eligibility criteria for performance study participants | | | | |
|  | Click or tap here to enter text. | | | | |
| G9 | Page of the performance study plan/ protocol with more information on study eligibility if applicable | | | | |
|  | Click or tap here to enter text. | | | | |

# **Recruitment and informed consent procedure template**

This section relates to participant recruitment and informed consent procedure of the proposed performance study.

|  |  |
| --- | --- |
| H1 | How will potential participants be identified?  e.g. publicising the performance study or via existing patient lists |
|  | Click or tap here to enter text. |
| H2 | What resources will be used for recruitment?  (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, through social media or on the radio). |
|  | Click or tap here to enter text. |
| H3 | Will identification of potential participants involve access to identifiable information?  (If yes, describe what measures will be in place to ensure that access to this information will in compliance with national legislation [Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018](https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf) ) |
|  | Click or tap here to enter text. |
| H4 | Who will be approaching potential participants and who will be obtaining informed consent?  Describe the professional role and confirm that training will be provided. Clarify whether there is a prior clinical relationship with potential participants. |
|  | Click or tap here to enter text. |
| H5 | 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. |
| H6 | How much time will potential participants (or their legally designated representative) be given to decide whether to participate? |
|  | Click or tap here to enter text. |
| H7 | 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. E.g. will the PI/ delegate review the PIL with the potential participant in person?) |
|  | Click or tap here to enter text. |
| H8 | What arrangements are in place to obtain informed consent from potential participants (or their legally designated representative) who do not speak the national language or may require additional interpretation support? |
|  | Click or tap here to enter text. |
| H9 | How will it be ensured that participants can withdraw their consent at any point?  (This should include the process, what happens to the data, limitations for withdrawing data how any potential consequences of consent withdrawal will be dealt with) |
|  | Click or tap here to enter text. |
| H10 | Please provide any further information, in relation to the procedure for recruitment and informed consent for the performance study, which has not been provided elsewhere in this document.  (It is recommended that you refer to national guidance to ensure that all required information has been provided) |
|  | Click or tap here to enter text. |

**Performance studies involving adults lacking decision making capacity**

|  |  |  |  |
| --- | --- | --- | --- |
|  | If this performance study does not include adults lacking decision making capacity, please continue to the next [block of questions starting with H17](#_Performance_studies_involving).  (Adults lacking decision making capacity may be recruited into performance studies only where consent has been obtained from a legally designated representative and data of a comparable validity cannot be obtained in performance studies involving participants who are competent to give informed consent. Where potential participants do lack capacity to consent, arrangements should be in place to involve them as much as possible in the decision to participate in the performance study.) | | |
| H11 | Please outline the nature of the condition that has caused diminished decision-making capacity e.g. adults who have dementia, adults who are unconscious, adults who have an intellectual disability etc.) | | |
|  | Click or tap here to enter text. | | |
| H12 | Provide justification for recruiting adults lacking decision making capacity  (This should include the relevance of this condition to the performance study) | | |
|  | Click or tap here to enter text. | | |
| H13 | Who will assess and confirm whether a potential participant has the capacity to consent, and how will this be done? | | |
|  | Click or tap here to enter text. | | |
| H14 | Where capacity to consent will fluctuate or will be borderline, how will potential participants be involved in the decision to participate in the performance study?  (This should include how information will be tailored to ensure participants (potential and existing) are able to understand the information and also how participants who regain capacity will be consented to continue in the performance study) | | |
|  | Click or tap here to enter text. | | |
| H15 | How will a legally designated representative be identified?  (This should include which roles could act as legally designated representative for this performance study) | | |
|  | Click or tap here to enter text. | | |
| H16 | In relation to this study: | | |
| a. | Is this study of such a nature that it can only be carried out on individuals lacking decision-making capacity? | Yes  No | If no, please comment: Click or tap here to enter text. |
| b. | Does this study relate directly to a medical condition which the individuals lacking decision-making capacity have been diagnosed with? | Yes  No | If no, please comment: Click or tap here to enter text. |
| c. | Is the study expected to provide direct benefit to the study participants who lack decision-making capacity? | Yes  No | If no, please comment: Click or tap here to enter text. |
| d. | If there is no prospect of direct benefit to the study participants, are the risks no more than minimal? | Yes  No | If no, please comment: Click or tap here to enter text. |
| e. | A consent declaration will be obtained from the Health Research Consent Declaration Committee (HRCDC) in advance of commencing the research. | Yes  No | If no, please comment: Click or tap here to enter text. |

## **Performance studies involving minors (under 16yrs of age)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | If this performance study does not include minors, please continue to the next [block of questions starting with H22](#_Performance_studies_where).  (It may be presumed that minors can consent to participate in the study from age 16 unless there is evidence to suggest otherwise. Minors younger than 16 may be recruited into performance studies only where consent has been obtained from a guardian(s) with parental responsibility or designated legally designated representative and where the performance study is such that it can only be carried out on minors. The minor should take part in the informed consent procedure as much as would be appropriate based on age and mental maturity. Where it would be appropriate, please specify any different arrangements for different age ranges.)  Please review the NO [Guidance on age of consent for regulated research in Ireland](https://www.nrecoffice.ie/guidance-on-age-of-consent-for-regulated-research-in-ireland/) | | |
| H17 | Provide justification for recruiting minors | | |
|  | Click or tap here to enter text. | | |
| H18 | How will potential participants be involved in the decision to participate in the performance study?  (Describe arrangements for obtaining and recording assent, including who will be obtaining consent and details of their training and experience with children) | | |
|  | Click or tap here to enter text. | | |
| H19 | How will a legally designated representative be identified?  (This should include which roles could act as legally designated representative for this performance study) | | |
|  | Click or tap here to enter text. | | |
| H20 | How will participants be consented to continue in the performance study when they reach the age of legal competence? | | |
|  | Click or tap here to enter text. | | |
| H21 | In relation to this study: | | |
| a. | Is this study of such a nature that it can only be carried out on minors? | Yes  No | If no, please comment: Click or tap here to enter text. |
| b. | Does this study relate directly to a medical condition which the minors have been diagnosed with? | Yes  No | If no, please comment: Click or tap here to enter text. |
| c. | Is the purpose of the study to generate knowledge about the health care needs of minors? | Yes  No | If no, please comment: Click or tap here to enter text. |
| d. | Is the study expected to provide direct benefit to the participants? | Yes  No | If no, please comment: Click or tap here to enter text. |
| e. | Are the risks more than minimal? | Yes  No | If no, please comment: Click or tap here to enter text. |
| f. | Will each minor receive information about the risks and benefits of the study according to their capacity to understand? | Yes  No | If no, please comment: Click or tap here to enter text. |
| 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 | If no, please comment: Click or tap here to enter text. |

## **Performance studies where consent witnessed by an impartial witness will likely be used**

|  |  |
| --- | --- |
|  | If this performance study does not propose for the consent to be witnessed by an impartial witness, please continue to the next [block of questions starting with H25](#_Performance_studies_in).  (Where a participant is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. The witness is required to sign and date the informed consent document.) |
| H22 | Why is an impartial witness required? |
|  | Click or tap here to enter text. |
| H23 | How will an impartial witness be identified? |
|  | Click or tap here to enter text. |
| H24 | How will it be known that the potential participant gives their informed consent? |
|  | Click or tap here to enter text. |

## **Performance studies in an emergency situation**

|  |  |  |  |
| --- | --- | --- | --- |
|  | If this performance study is not carried out in emergency situations, please continue to [section I](#_Study_procedures).  (Information on the performance study may be given and informed consent may be obtained after the decision to include the participant in the performance study. This is where the decision is taken at the time of the first intervention in accordance with the protocol and, due to the urgency of the situation, the person is unable to give consent, nor can a legally designated representative be identified.) | | |
| H25 | Describe why it would not be possible to obtain consent from potential participants or a legally designated representative prior to recruiting into the performance study. | | |
|  | Click or tap here to enter text. | | |
| H26 | What arrangements will be in place to obtain informed consent from the participant or from a legally designated representative, whichever can be obtained soonest?  (Where a legally designated representative is expected to be required due to the participant not having capacity to consent, please also complete section 2 of this document) | | |
|  | Click or tap here to enter text. | | |
| H27 | How will it be ensured that a potential participant has not expressed any previous objection to participate in the performance study? | | |
|  | Click or tap here to enter text. | | |
| H28 | In relation to this study: | | |
| a. | Is the participant unable to provide prior informed consent and to receive prior information on the clinical investigation due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition? | Yes  No | If no, please comment: Click or tap here to enter text. |
| b. | Are there scientific grounds to expect that participation in the clinical investigation will have the potential to produce a direct clinically relevant benefit for the participant resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the participant, or in the diagnosis of its condition? | Yes  No | If no, please comment: Click or tap here to enter text. |
| c. | Is it not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative? | Yes  No | If no, please comment: Click or tap here to enter text. |
| d. | Will the investigator certify that he or she is not aware of any objections to participate in the clinical investigation previously expressed by the participant? | Yes  No | If no, please comment: Click or tap here to enter text. |
| e. | Does the clinical investigation relate directly to the participant’s medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent? | Yes  No | If no, please comment: Click or tap here to enter text. |
| f. | Is the clinical investigation of such a nature that it may be conducted exclusively in emergency situations? | Yes  No | If no, please comment: Click or tap here to enter text. |
| g. | Does the clinical investigation pose a minimal risk and burden to the participant in comparison with the standard treatment? | Yes  No | If no, please comment: Click or tap here to enter text. |
| h. | A consent declaration will be obtained from the Health Research Consent Declaration Committee (HRCDC) in advance of commencing the research | Yes  No | If no, please comment: Click or tap here to enter text. |

# **Study procedures**

This section relates to study procedures carried out in the proposed performance study.

|  |  |  |
| --- | --- | --- |
| I1 | What procedures or interventions are participants asked to undergo or engage in for the purposes of this study? | |
|  | Click or tap here to enter text. | |
| I2 | What other activities are taking place for the purposes of this study e.g. chart review, sample analysis etc? | |
|  | Click or tap here to enter text. | |
| I3 | Will treatment be withheld from participants as a result of taking part in this study? | |
|  | Yes. Please provide details: Click or tap here to enter text.  No  N/A | |
| I4 | What are the potential adverse effects, risks, or hazards for participants? | |
|  | Click or tap here to enter text. | |
| I5 | What are the potential benefits for participants? | |
|  | Click or tap here to enter text. | |
| I6 | What procedures are in place to monitor the health of the participants during and after the performance study | |
|  | Click or tap here to enter text. | |
| I7 | Will the interventions, including the device and any associated equipment or software, provided during the study be available to participants after the termination of the study? | |
|  | Yes  No  N/A  Please clarify: Click or tap here to enter text. | |
| I8 | Please provide a timeline of the study activities and procedures, either as a description or as a chart | |
|  | Click or tap here to enter text. | |
| I9 | Page of the performance study plan/ protocol with more information on study procedures |
|  | Click or tap here to enter text. |

# **Data protection compliance**

This section relates to data processed as a part of the proposed performance study.

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)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| J1 | Entities involved processing of personal data | | | | |
|  | Name | Location | | Role in the investigation, eg controller, processor | Data format |
|  | 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. |
| J2 | In what format will the data collected in this clinical investigation be processed as? | | | | |
|  | Irrevocably anonymised  Pseudonymised  Fully identifiable | | | | |
| J3 | If data will be pseudonymised, please confirm who will retain the ‘key’/master list which may be used to re-identify the data and what security measures are in place? | | | | |
|  | Click or tap here to enter text. | | | | |
| J4 | Will any data from the clinical investigation be transferred outside of the EU? | | | | |
|  | Yes  No | | | | |
| J5 | If yes, specify which arrangements are in place to ensure that personal data will be processed is processed in line with GDPR? | | | | |
|  | Click or tap here to enter text. | | | | |
| J6 | Other than for the objectives outlined in the MDR, please specify below for how long you will retain personal data after the clinical investigation. | | | | |
| a. | Irrevocably anonymised | | Click or tap here to enter text. | | |
| b. | Pseudonymised | | Click or tap here to enter text. | | |
| c. | Fully identifiable | | Click or tap here to enter text. | | |
| J7 | After the clinical investigation is completed, will the personal data be: | | | | |
|  | Irrevocably anonymised. Please outline how and by whom: Click or tap here to enter text.  Archived or otherwise retained. Please outline how and by whom: Click or tap here to enter text.  Erased. Please outline how and by whom: Click or tap here to enter text. | | | | |
| J8 | Outline any ethical considerations pertaining to the proposed data processing and management and what measures are in place to minimise distress or damage to the participants. | | | | |
|  | Click or tap here to enter text. | | | | |
| J9 | All study activities will be in compliance with the General Data Protection Regulations (EU) 2016/679 and the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018, and as amended under SI 18 of 2021 | | | | |
|  | Yes  No | | | | |

**Future use of data**

|  |  |
| --- | --- |
| J10 | Will data collected during this study be stored for future use?  *For other use than described in the protocol. Note that some purposes (secondary use of samples) may require additional approval, in Most Member States by an ethics committee* |
|  | Yes, please complete J11-J17  No, data will be destroyed, please continue to [section K](#_Collection,_storage_and) |
| J11 | What is the purpose of the future use? |
|  | Click or tap here to enter text. |
| J12 | Where will the samples be stored? |
|  | Click or tap here to enter text. |
| J13 | Who will have access to the samples? |
|  | Click or tap here to enter text. |
| J14 | Who will have access to the data code list (if applicable)? |
|  | Click or tap here to enter text. |
| J15 | Will the participants be recontacted to give new consent to the use of the data in future research? If not, explain |
|  | Click or tap here to enter text. |
| J16 | Who will use the data? |
|  | Click or tap here to enter text. |
| J17 | How will incidental findings be handled? |
|  | Click or tap here to enter text. |

# **Collection, storage and future use of human biological samples**

This section relates to collection, storage and future use of human biological samples as a part of the proposed performance study. Please consult the [National Office Guidance on use of biological samples and associated data.](https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/)

Description of the biological samples involved in the performance study

|  |  |
| --- | --- |
| K1 | Does this performance study involve the collection or processing of biological samples? |
|  | Yes  No. Please continue to [section L](#_Radiation).  Note: The sponsor needs to fill in at least one of the sections |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| K2 | Entities involved in processing of biological samples | | | |
|  | Name | Location | Lead name | Role in the investigation |
|  | 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. |

**Newly collected samples**

|  |  |
| --- | --- |
|  | If this performance study does not involve the collection of new samples, please continue to next [block of questions starting with K7](#_Archival_samples). |
| K3 | What type(s) of samples will be collected from the participant?  State the original material that is collected from the patient e.g. blood, tissue (state type of tissue), urine, saliva etc. Do not include information on the preparation of the sample. |
|  | Click or tap here to enter text. |
| K4 | Total number of samples, fragments (e.g. aliquots, tissue blocks, sections) and the total volume (if applicable) per individual participant: |
|  | Click or tap here to enter text. |
| K5 | The maximum number of samples and maximum volume (if applicable) on one single occasion: |
|  | Click or tap here to enter text. |
| K6 | Will the samples be collected as part of routine health care? |
|  | Click or tap here to enter text. |

## **Archival samples**

|  |  |
| --- | --- |
| K7 | Does this performance study involve the collection of existing samples (e.g. archived diagnostic or other biobank samples)? |
|  | Yes, please complete questions K8-K10  No, not applicable. Please continue to next [block of questions starting with K11](#_Use,_storage,_and). |
| K8 | What type(s) of archived samples will be used? |
|  | Click or tap here to enter text. |
| K9 | Provide the total number of samples, fragments (e.g. aliquots, tissue blocks, sections) and total volume (if applicable) that the Sponsor needs to access from each individual participant.  Example: 20 sections per biopsy from each individual participant is needed |
|  | Click or tap here to enter text. |
| K10 | Will new consent be obtained for the use of the archive samples in the performance study (if in line with national legislation)? If not, explain.  (If applicable, add the text of the original consent) |
|  | Click or tap here to enter text. |

## **Use, storage, and transfer of biological samples for a purpose within the objective of this performance study**

Note: This section must be filled in for both newly collected and existing archive samples

|  |  |
| --- | --- |
| K11 | Where will the samples be analysed?  i.e. within the clinical laboratory, within/outside the Sponsor’s organization, within/outside the Member State where collected or within/outside EU/EEA. |
|  | Click or tap here to enter text. |
| K12 | If the samples will be sent to another organisation for analyses (as part of the performance study), how will they be managed after the analyses have been carried out?  i.e. destroyed, returned to responsible entity for the samples (legally), stored at the site where analysed, anonymised etc.  Note: An agreement (Material Transfer Agreement or equivalent) that regulates how the sample are to be handled shall be established with the recipient |
|  | Click or tap here to enter text. |
| K13 | Where will the samples be stored?  i.e. within/outside the Sponsor’s organisation, within/outside the Member State where collected or within/outside EU/EEA |
|  | Click or tap here to enter text. |
| K14 | How long will the samples be stored? |
|  | Click or tap here to enter text. |
| K15 | What is the connection between samples and individual participant? |
|  | Direct connection (samples marked with e.g. initials, date of birth)  Pseudonymised connection (samples marked with code)  No connection, samples are anonymised (i.e. samples can neither directly nor indirectly, with reasonably means according to recital 26 of the General Data Protection Regulation (EU) 2016/679, be linked to the sample donor) |
| K16 | Who will have access to the samples? |
|  | Click or tap here to enter text. |
| K17 | Who will have access to the sample code list (if applicable)? |
|  | Click or tap here to enter text. |

## **Genetic data**

|  |  |
| --- | --- |
| K18 | Does this study involve the generation of ‘genetic data’?  As per GDPR, 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. Please specify the nature of, and purpose for, the generation of genetic data: Click or tap here to enter text.  No. Please continue to next [block of questions starting with K21](#_Future_use_of). |
| K19 | Will a search for secondary genetic findings unrelated to the primary research question be carried out? |
|  | Yes. Please outline: Click or tap here to enter text.  No |
| K20 | 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.  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. |
|  | Yes  No. Please justify: Click or tap here to enter text. |

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

## **Future use of samples**

|  |  |
| --- | --- |
| K21 | Will newly collected samples or existing archive samples be stored for future use?  *For other use than described in the protocol. Note that some purposes (secondary use of samples) may require additional approval, in Most Member States by an ethics committee* |
|  | Yes, please complete K22-K31  No, samples will be destroyed, please continue to [section L](#_Radiation). |
| K22 | What is the purpose of the future use? |
|  | Click or tap here to enter text. |
| K23 | How long will the samples be stored? |
|  | Click or tap here to enter text. |
| K24 | Where will the samples be stored? |
|  | Click or tap here to enter text. |
| K25 | What is the connection is between samples and individual participant? |
|  | Direct connection (samples marked with e.g. initials, date of birth)  Pseudonymised connection (samples marked with code)  No connection, samples are anonymised (i.e. samples can neither directly nor indirectly, with reasonably means according to recital 26 of the General Data Protection Regulation (EU) 2016/679, be linked to the sample donor) |
| K26 | Who will have access to the samples? |
|  | Click or tap here to enter text. |
| K27 | Who will have access to the sample code list (if applicable)? |
|  | Click or tap here to enter text. |
| K28 | Will the donor be recontacted to give new consent to the use of the samples in future research? If not, explain |
|  | Click or tap here to enter text. |
| K29 | Who will use these samples? |
|  | Click or tap here to enter text. |
| K30 | How will incidental findings be handled? |
|  | Click or tap here to enter text. |

# **Radiation**

This section relates to medical exposure to ionising radiation undertaken as a part of the proposed performance study.

|  |  |
| --- | --- |
| L1 | Does this performance study involve medical exposure to ionising radiation: |
|  | Yes  No. Please continue to [section M](#_Financial_arrangements_-). |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| L2 | Type of ionising radiation | | | | | | | | | | |
| a. | Exposure to radioactive materials | | | | Yes  No | | | | | | |
| b. | Therapeutic ionising radiation | | | | Yes  No | | | | | | |
| c. | Diagnostic ionising radiation | | | | Yes  No | | | | | | |
| d. | Other | | | | Yes  No | | | | | | |
| e. | If other, please provide details: | | | | Click or tap here to enter text. | | | | | | |
| L3 | Does this performance study involve additional radiation exposure other than received as part of standard care? | | | | | | | | | | |
|  | Yes. Please outline: Click or tap here to enter text.  No | | | | | | | | | | |
| L4 | Please specify the type of facility where the radiation is due to take place at: | | | | | | | | | | |
|  | Type of facility | | | | Yes/No | | Name of site | | | | |
| a. | Radiation oncology unit: | | | | Yes  No | | Click or tap here to enter text. | | | | |
| b. | Diagnostic imaging facility: | | | | Yes  No | | Click or tap here to enter text. | | | | |
| c. | Clinical laboratory: | | | | Yes  No | | Click or tap here to enter text. | | | | |
| d. | Academic research centre: | | | | Yes  No | | Click or tap here to enter text. | | | | |
| e. | Other: Click or tap here to enter text. | | | | Yes  No | | Click or tap here to enter text. | | | | |
| L5 | Have all relevant sites in the Republic of Ireland been licensed by the Environmental Protection Agency (EPA) of the Republic of Ireland? | | | | | | | | | | |
|  | Yes  No. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L6 | Have all relevant sites in the Republic of Ireland been registered with the Health Information and Quality Authority (HIQA)? | | | | | | | | | | |
|  | Yes  No. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L7 | Details of the radiological investigation/ procedure undertaken as a part of this performance study | | | | | | | | | | |
|  | Radiological procedure name | Maximum number of scans per participant | Effective dose per scan | Frequency  e.g. 1 every 3 months | | Standard 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. | mSv | Click or tap here to enter text. | | Click or tap here to enter text. | | mSv | mSv | | mSv |
|  | Click or tap here to enter text. | Click or tap here to enter text. | mSv | Click or tap here to enter text. | | Click or tap here to enter text. | | mSv | mSv | | mSv |
|  | Click or tap here to enter text. | Click or tap here to enter text. | mSv | Click or tap here to enter text. | | Click or tap here to enter text. | | mSv | mSv | | mSv |
| L8 | Please confirm that the procedures are justified. | | | | | | | | | | |
|  | Yes  No. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L9 | Please provide details of the examinations. | | | | | | | | | | |
|  | Click or tap here to enter text. | | | | | | | | | | |
| L10 | Dose Information: | | | | | | | | | | |
| a. | Estimated total effective dose equivalent for the performance study (mSv): | | | | | | | | | mSv | |
| b. | Time interval over which dose is calculated: | | | | | | | | | Click or tap here to enter text. | |
| c. | Estimated additional dose above standard level of care (mSv): | | | | | | | | | mSv | |
| d. | Risk Category | | | | | | | | | Click or tap here to enter text. | |
| e. | Dose constraint for performance study: | | | | | | | | | Click or tap here to enter text. | |
| L11 | Are the proposed procedures compliant 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. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L12 | Please confirm that the information on the ionising radiation procedures and any associated risks are accurately described in the participant information leaflet | | | | | | | | | | |
|  | Yes  No. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L13 | Please confirm that the site medical physics expert reviewed the performance study protocol and information included in section L of this application form and is satisfied that the information herein provides a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks.  This question must be completed for all performance studies involving medical exposure to ionising radiation. | | | | | | | | | | |
|  | Yes  No. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L14 | Medical physics expert registration number | | | | | | | | | | |
|  | Click or tap here to enter text. | | | | | | | | | | |
| L15 | Please insert medical physics expert signature & date of signature | | | | | | | | | | |
|  |  | | | | | | | | | | |
| L16 | Please confirm that radiation oncologist/radiologist reviewed the information pertaining to exposure to ionising radiation included in section L of this application form and is satisfied that the exposure to ionising radiation planned in this research performance study is reasonable and compliant with SI 256/2018.  This question must be completed for all performance studies involving therapeutic ionising radiation. | | | | | | | | | | |
|  | Yes  No. Please comment: Click or tap here to enter text. | | | | | | | | | | |
| L17 | Please insert radiation oncologist/radiologist signature & date of signature | | | | | | | | | | |
|  |  | | | | | | | | | | |

# **Financial arrangements - Compensation for performance study participants and performance study funding**

This section provides information on the financial transactions and compensation provided for participants and those supporting participants in the performance study as well as the funding of the performance study.

Please note that for performance studies, which involve incapacitated adults, minors or breast-feeding participants, no incentive or financial inducement may be given to the participants or their legally designated representatives except for compensation of expenses or loss of earnings directly related to the participation in the investigation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| M1 | Will compensation be offered? (select one box) | | | | | |
|  | Yes. Please complete questions M2-M7  No Please explain why not: Click or tap here to enter text. | | | | | |
| M2 | Who will be offered compensation and in what form? (Select all boxes that apply) | | | | | |
|  |  | Participants | Parent / Carer | Legal representative | | Other individuals |
| a. | Travel expenses |  |  |  | |  |
| b. | Accommodation expenses |  |  |  | |  |
| c. | Meal expenses |  |  |  | |  |
| d. | Loss of earnings |  |  |  | |  |
| e. | Monetary payment |  |  |  | |  |
| f. | Non-monetary payment |  |  |  | |  |
| g. | Other: Click or tap here to enter text. |  |  |  | |  |
| M3 | If you enter “other individuals”, please specify who will be the recipient of the compensation or the type of compensation: | | | | Click or tap here to enter text. | |
| M4 | If loss of earnings is compensated, please explain how the amount is calculated with justification: | | | | Click or tap here to enter text. | |
| M5 | If monetary payment is offered, please specify the amount with justification: | | | | Click or tap here to enter text. | |
| M6 | If non-monetary payment is offered, please specify the type and value of the benefit with justification: | | | | Click or tap here to enter text. | |
| M7 | Are there any conditions attached to the payment of compensation?  (for example, where the full performance study or stages of the performance study must be completed) | | | | | |
|  | Yes, please describe: Click or tap here to enter text.  No | | | | | |

**Performance study funding**

|  |  |  |
| --- | --- | --- |
| M8 | Funder | Click or tap here to enter text. |
| M9 | Relationship to sponsor (if different) | Click or tap here to enter text. |
| M10 | Amount | Click or tap here to enter text. |
| M11 | Duration | Click or tap here to enter text. |
| M12 | Has the funding been secured | |
|  | Yes  No. Please comment: Click or tap here to enter text. | |
| M13 | Please confirm that the funding covers all performance study procedures and participant reimbursement & compensation | |
|  | Yes  No. Please comment: Click or tap here to enter text. | |