National Research Ethics Committee for Clinical Trials

Application form for NREC-CT review

**INSTRUCTIONS**

* This application form should be completed and submitted by the Principal Investigator (the person who takes primary responsibility for the conduct of the clinical trial).
* It should be filled out in language comprehensible to a lay person.
* 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
* Digital signatures are accepted and encouraged
* Please provide a copy of this report to your Research Office or equivalent body in your research institution
* All communications to the NRECs should be directed to the National Office via [clinicalrials@nrec.ie](mailto:clinicalrials@nrec.ie)

A. TRIAL IDENTIFICATION

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| A.1 | |
| EudraCT No. | Click or tap here to enter text. |
| Title of Clinical Trial | Click or tap here to enter text. |
| Submission Date | Click or tap here to enter text. |
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| A.2 Trial Duration | | | | |
| Proposed Start Date *(first person first visit)* | Click or tap to enter a date. | | dd/mm/yyyy | |
| Proposed End Date *(last person last visit)* | Click or tap to enter a date. | | dd/mm/yyyy | |
| Expected Duration *(years / months)* | Click or tap here to enter text. | |  | |
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B. APPLICANT IDENTIFICATION

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| B.1 Principal Investigator  (If the point of contact for the review process is not the Principal Investigator, please also include their name, contact details and role in the study in the text box below.)  *[Please submit a 2-page CV for the Principal Investigator]* | |
| Name: | Click or tap here to enter text. |
| Title: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Qualifications: | 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. |
| Additional contact point, if applicable: | Click or tap here to enter text. |
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| B.2 Sponsor | | | |
| Name: | Click or tap here to enter text. | | |
| Status of Sponsor: | Click or tap here to enter text. | | |
| Commercial: |  | Non-Commercial: |  |
| 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. | | |
| Name and contact  details of Sponsor  representative: | Click or tap here to enter text. | | |
| Name and contact  details of Sponsor’s  legal representative  (if sponsor has no  presence in EEA): | Click or tap here to enter text. | | |
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C. DETAILS OF THE CLINICAL TRIAL

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| C.1 | |
| 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 |
| ***If yes, please give details:*** | |
| Click or tap here to enter text. | |

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| C.2 Multi Centre Clinical Trials | | |
| Is this trial a Multi-Centre Trial? | Yes  No | |
| If *Yes*, please submit a list of all proposed sites in Ireland and proposed Investigators including contact number and e-mail. | | |
| Click or tap here to enter text. | | |
| Does this trial involve third countries?  Yes  No | | |
| If *Yes*, please provide further details: | | |
| Click or tap here to enter text. | | |
| Have you received permission from each of the above sites in Ireland to conduct this trial?  *(Please submit a site-specific assessment for each site in Ireland*) | | Yes  No |
| If No, please state why: | | |
| Click or tap here to enter text. | | |

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| C.3 |
| Please name the substance/medical device, which you propose to administer during the clinical trial. (*Please include details of all medicinal products including placebo*.) |
| Click or tap here to enter text. |

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| If the clinical trial does not involve Somatic Cell Therapy, Gene Therapy or Genetically Modified Cells please skip to C. 6. |

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| C.4 Somatic Cell Therapy | | |
| If the clinical trial involves Somatic Cell Therapy (no genetic modification) please specify the origin of cells: | | |
| Autologous | Yes  No | |
| Allogeneic | Yes  No | |
| Xenogeneic | Yes  No | |
| If *xenogeneic*, please specify the species of origin | | Click or tap here to enter text. |

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| C.5 Gene Therapy or Genetically Modified Cells |
| **C.5.1** |
| If the clinical trial involves **Gene Therapy,** please specify the gene(s) of interest. |
| Click or tap here to enter text. |

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| C.5.2 | |
| Please specify the type of gene therapy involved. | |
| ***In vivo***gene therapy | Yes  No |
| ***Ex vivo***gene therapy | Yes  No |

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| C.5.3 | |
| Please specify the gene transfer product that will be used. | |
| **Nucleic acid (e.g. plasmid)** | Yes  No |
| If *Yes*, please specify: | Naked  Complexed |
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| **Viral Vector** | Yes  No |
| If *Yes*, please specify the type (e.g. adenovirus): | Click or tap here to enter text. |
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| **Others** | Yes  No |
| If Yes, please specify: | Click or tap here to enter text. |

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| C.5.4 | | |
| If the clinical trial involves Genetically Modified Cells, please specify their origin. | | |
| Autologous | Yes  No | |
| Allogeneic | Yes  No | |
| Xenogeneic | Yes  No | |
| If *xenogeneic*, please specify the species of origin | | Click or tap here to enter text. |

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| C.5.5 |
| Please specify the type of genetically modified cells (e.g. hematopietic stem cells). |
| Click or tap here to enter text. |

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| C.6 |
| Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet. |
| Click or tap here to enter text. |

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| C.7 |
| Please specify the primary research question/objective. (Please ensure that the Clinical Trial Protocol has been provided for the review of the NREC-CT.) |
| Click or tap here to enter text. |

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| C.8 |
| Please specify the secondary research questions/objectives. |
| Click or tap here to enter text. |

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| C.9 |
| What is the scientific justification for the clinical trial? |
| Click or tap here to enter text. |

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| C.10 |
| Give a brief description of the methods and design of the proposed clinical trial e.g. randomised, controlled. (This should also include details of the duration of research participant involvement and exactly what procedures they will undergo.) |
| Click or tap here to enter text. |

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| C.11 | |
| Will treatment be withheld from research participants as a result of taking part in the clinical trial? | Yes  No |
| *If Yes, please give details* | |
| Click or tap here to enter text. | |

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| C.12 |
| 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?  (All research on human beings carries the possibility of harm. Whether the risk of harm is acceptable or not depends on the importance of the question being addressed and the likelihood of a meaningful result from the study as well as the extent and severity of the possible harm. Harms can be physical, psychological, psychosocial, or other and can include pain, discomfort, inconvenience or change to lifestyle. Even seemingly innocuous questionnaires can upset patients and / or change the way they view or manage their illness. It is also wise to classify the harms listed. Harms can be classified as serious, non-serious, transient etc. It is also useful to committees if you state the risk (probability) of the harms occurring, where this is possible: the risk of harms occurring can in some studies be stated with accuracy.  It is recognised however that for many studies, the risk (probability) of harm occurring will not be quantifiable. Where relevant, please also state in your answer what measures will be put in place, if any, to ensure the risk of these harms occurring is minimised.  Include any information about engaging with the study population to assess the likelihood and potential severity of harm as well as acceptability.  Please ensure any relevant harms listed in response to this question are clearly outlined in any Information Leaflets related to this study.) |
| Click or tap here to enter text. |

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| C.13 |
| What are the potential benefits for research participants? (There may be a direct benefit for research participants. There may be a benefit for the healthcare in general or for an organisation / site or service.) |
| Click or tap here to enter text. |

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| C.14 |
| What procedures are in place to monitor the health of the research participants during the trial or when they are no longer involved in the trial? (It is recognised that in many research studies, monitoring of the health of participants is neither appropriate nor necessary. Please provide details however if the health of participants is being monitored. Participants should also be informed of this monitoring in all relevant Information Leaflets) |
| Click or tap here to enter text. |

D. DETAILS OF TRIAL PARTICIPANTS

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| D.1 | |
| How many research participants and controls are expected to participate at each site in Ireland? | Click or tap here to enter text. |
| How many research participants are to be recruited overall? | Click or tap here to enter text. |

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| D.2 |
| Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference where appropriate). (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. |

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| D.3 |
| How will research participants/controls be identified and recruited? |
| Click or tap here to enter text. |

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| D.4 |
| 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. |
| If recruitment includes advertisements or written correspondence, please provide copies and/or TV/radio scripts and letters. |

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| D.5 | |
| Will identification of potential participants involve access to identifiable information? | Yes  No |
| 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. | |

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| D.7 |
| What criteria exist for withdrawing research participants prematurely (if relevant)? |
| Click or tap here to enter text. |

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| D.8 | | | |
| Will the participants be from any of the following groups? *(tick as appropriate)* | | | |
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| Children under 16 |  | Adults with learning disabilities |  |
| Adults who are unconscious |  | Adults who have a terminal illness |  |
| Adults in emergency situations |  | Adults with mental illness |  |
| Pregnant women / women of child-bearing age |  | Prisoners |  |
| Adults suffering from dementia |  | Healthy volunteers |  |
| Those who could be considered to be vulnerable or have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students. | | |  |
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| *Please justify their inclusion, outlining how the trial is expected to benefit research participants.* | | | |
| Click or tap here to enter text. | | | |

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| *Note:* Parts 4 and 5 of Schedule 1 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 clearly outline the conditions and principles which apply in relation to the treatment of Minors or Incapacitated Adults who are participants in medical research. |

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| D.9 | | |
| Will research participants be reimbursed for expenses?  (Research participants may be reimbursed for lost earnings, travel costs and other 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 e.g. time away from work. Any reimbursements or compensation that might be offered to prospective participants should first be approved by a REC in order 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 |
| If *Yes*, please clarify | Click or tap here to enter text. | |

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| D.10 | | |
| Will they receive any incentives for taking part in the clinical trial? (There may be instances where research participants will be paid for any inconvenience and time given to the study. Payments may be financial or non-financial, e.g. entry into prize draws, gifts vouchers, book tokens. Payment that is disproportionate to the time involved or is likely to encourage participants to take risks, is ethically unacceptable. The timing of payments must be such that they do not constitute undue inducement.) | | Yes  No |
| If *Yes*, please clarify | Click or tap here to enter text. | |

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| D.11 | | |
| Will the participant’s general practitioner be notified of his or her participation in the trial? (If *Yes*, please ensure permission is sought from the research participant for the researcher to make contact with the research participant’s general practitioner. If the general practitioner is being informed, please provide a copy of the letter to the GP for review by the committee. Patient safety should be the key factor in deciding whether it will be necessary to inform the participant’s General Practitioner.) | | Yes  No |
| If *No*, please clarify | Click or tap here to enter text. | |

E. INFORMED CONSENT

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| *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 you cannot obtain explicit consent as part of your study, you may require a Consent Declaration. For more information, please visit – www.hrcdc.ie |

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| E.1 | | | |
| Will written informed consent be obtained for participation in the study? | | Yes  No | |
| If *No*, please justify. | Click or tap here to enter text. | | |
| If *No*, will consent from the research participant(s) be sought at any stage during the research study? | Click or tap here to enter text. | | |
| Will written informed consent be obtained for data processing associated with the study? | | | Yes  No |
| If *No*, please justify. | | | Click or tap here to enter text. |
| If *No*, will consent from the research participant(s) be sought at any stage during the research study? | | | Click or tap here to enter text. |

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| E.2 |
| Give details of the manner in which consent will be obtained. (Please comment on the extent to which consent is sought and captured for different elements of the clinical trial. Please provide details if consent should be obtained from those with parental responsibility where minors are involved in the study.) |
| Click or tap here to enter text. |
| Please attach copies of both the Information leaflet and Consent and / or Assent form. |

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| E.3 |
| Who will be approaching potential participants and who will be obtaining informed consent? (Describe the professional role and whether there is a prior clinical relationship with potential participants) |
| Click or tap here to enter text. |

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| E.4 |
| When will free and 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. |

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| E.5 |
| How long will potential participants (or their legal representative) be given to decide whether to participate? |
| Click or tap here to enter text. |

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| E.6 |
| How will it be assured that potential participants (or their legal 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. |

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| E.7 |
| What arrangements are in place to obtain informed consent from potential participants (or their legal representative) who do not speak the national language? |
| Click or tap here to enter text. |

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| E.8 |
| 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. |

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| E.9 |
| Please provide any further information, in relation to the procedure for recruitment and informed consent for the clinical trial, which has not been provided elsewhere in this document. |
| Click or tap here to enter text. |

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| If this clinical trial does not involve participants lacking decision-making capacity, please skip to E.14 |

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| E.10 |
| What arrangements have been made for research participants who might not adequately understand verbal or written information? (Please also state clearly how the issue of consent and assent will be managed for those research participants who are lacking decision-making capacity) |
| Click or tap here to enter text. |

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| E.11 |
| Who will assess and confirm whether a potential participant has the capacity to consent? |
| Click or tap here to enter text. |

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| E.12 |
| 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 also how participants who regain capacity will be consented to continue in the trial) |
| Click or tap here to enter text. |

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| E.13 |
| How will a legal representative be identified? (This should include which roles could act as legal representative for this trial) |
| Click or tap here to enter text. |

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| If this clinical trial does not involve participation of a minor, please skip to Section F |

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| E.14 |
| How will potential participants who are minors be involved in the decision to participate in the trial? (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. |

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| E.15 |
| How will a legal representative of a minor be identified? (This should include which roles could act as legal representative for this trial) |
| Click or tap here to enter text. |

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| E.16 |
| How will participants be consented to continue in the trial when they reach the age of legal competence? |
| Click or tap here to enter text. |

F. CONFIDENTIALITY

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| Note: Investigators should be aware of their responsibilities as provided for in the Data Protection Act 2018 and the Health Research Regulations 2018. |

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| F.1 | | |
| Does the proposed clinical trial involve the retention of biological material (tissue, bodily fluids)? | Yes  No | |
| If *Yes*, please state the type of human biological material. | | Click or tap here to enter text. |
| If *Yes*, for what period of time will the biological material be retained? | | Click or tap here to enter text. |

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| F.3 |
| Who will have access to the biological material? (Describe the professional role and qualifications) |
| Click or tap here to enter text. |

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| F.4 |
| If the biological material is to be disposed of please explain how and by whom this will be done? |
| Click or tap here to enter text. |

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| F.1 | | |
| Does the proposed clinical trial involve the retention of data derived from the biological material? | Yes  No | |
| If *Yes*, for what period of time will the data be retained? | | Click or tap here to enter text. |

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| F.2 |
| How will data security be maintained? |
| Click or tap here to enter text. |

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| F.3 |
| Who will have access to the data? (Describe the professional role and qualifications) |
| Click or tap here to enter text. |

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| F.4 |
| If data are to be deleted, pseudonymised of anonymised of please explain how and by whom this will be done? |
| Click or tap here to enter text. |

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| F.5 |
| How will the results of the clinical trial be reported and disseminated? (e.g. peer-reviewed journal, research participants, public engagement) |
| Click or tap here to enter text. |

G. FINANCIAL ARRANGEMENTS

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| G.1 |
| 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. |

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| G.2 |
| Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site. |
| Click or tap here to enter text. |
| (Please submit a copy of relevant insurance to the NREC-CT) |

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| G.3 | | |
| Has funding for the clinical trial been secured? | | Yes  No |
| 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. | |
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| If *No*, what arrangements have been made to cover the cost of the research? | | |
| Click or tap here to enter text. | | |

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| G.4 | | |
| Does the Principal Investigator or any of the investigators have any direct/indirect involvement in the outcome of the clinical trial that could in anyway be regarded as a possible conflict of interest? | | Yes  No |
| If *Yes*, please explain. | Click or tap here to enter text. | |

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| Declaration of the Principal Investigator |
| This declaration must be signed and sent to the NREC-CT together with the requisite fee before the application will be considered as valid.   * I certify that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. * I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in the International Conference on Harmonisation’s Good Clinical Practice Guidelines (ICH GCP) and the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (S.I. No 190 of 2004). * If the clinical trial is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the decision letter sent by the NREC-CT. * 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 patient or other personal data. |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name: Click or tap here to enter text.  Date: Click or tap here to enter text. (dd/mm/yyyy) |