Form 1

APPLICATION FORM

Application for a Recognised Research Ethics Committee (REC) Opinion on a Clinical Trial on a Medicinal Product for Human Use.

This application form should be completed and submitted by the Chief 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.

A. TRIAL IDENTIFICATION

A.1	
EudraCT No.	
Title of Clinical Trial	
Submission Date	

A.2 Trial Duration					
Proposed Start Date	*(first person first visit)*			dd/mm/yyyy	
Proposed End Date	*(last person last visit)*			dd/mm/yyyy	
Expected Duration	*(years / months)*		Years		Months

B. APPLICANT IDENTIFICATION

B.1 Chief Investigator	
Name:	
Title:	
Position:	
Qualifications:	
Address:	
Tel:	
Fax:	
E-mail:	
(*Please submit a 2 page CV for the Chief Investigator*)	

B.2 Sponsor			
Name:			
Status of Sponsor:			
Commercial:		Non-Commercial	
Address:			
Tel:			
Fax:			
E-mail:			

C. DETAILS OF THE CLINICAL TRIAL

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	

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 no./e-mail.	

Does this trial involve third countries?	☐ *Yes* ☐ *No*

Have you received permission from each of the above sites in Ireland to conduct this trial?	☐ *Yes* ☐ *No*

(Please note that a site specific assessment for each site in Ireland must be submitted before the committee can validate an application for ethical review.)

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*.)

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

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	

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.

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

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*
Viral Vector	☐ *Yes* ☐ *No*
If *Yes*, please specify the type (e.g. adenovirus):	
Others	☐ *Yes* ☐ *No*
If Yes, please specify:	

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	

C.5.5
Please specify the type of genetically modified cells (e.g. hematopietic stem cells).

C.6
Please specify the primary research question/objective.

C.7
Please specify the secondary research questions/objectives.

C.8
What is the scientific justification for the clinical trial?

C.9
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.

C.10	
Will treatment be withheld from research participants as a result of taking part in the clinical trial?	☐ *Yes* ☐ *No*
If Yes, please give details	

C.11
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?

C.12
What are the potential benefits for research participants?

C.13
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?

D. DETAILS OF TRIAL PARTICIPANTS

D.1	
How many research participants and controls are expected to participate at each site in Ireland?	

D.2
How will research participants/controls be identified and recruited?
(If recruitment includes advertisements or written correspondence please provide copies and/or TV/radio scripts and letters.)

D.3
What are the inclusion criteria?

D.4
What are the exclusion criteria?

D.5
What criteria exist for withdrawing research participants prematurely?

D.6			
Will the participants be from any of the following groups? *(tick as appropriate)*			
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.			☐
Please justify their inclusion, outlining how the trial is expected to benefit research participants.			

(NB. 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.)

D.7		
Will research participants be reimbursed for expenses?	☐ *Yes*	☐ *No*
If *Yes*, please clarify		

D.8		
Will they receive any incentives for taking part in the clinical trial?	☐ *Yes*	☐ *No*
If *Yes*, please clarify		

D.9		
Will the participant's general practitioner be notified of his or her participation in the trial?	☐ *Yes*	☐ *No*
If *No*, please clarify		

E. INFORMED CONSENT

E.1		
Will written informed consent be obtained	☐ *Yes*	☐ *No*
If Yes, who will be responsible for obtaining (qualifications and experience)?		
If *No*, please justify.		

E.2
Give details of the manner in which consent will be obtained. ***Please attach copies of both the Information leaflet and Consent form.***

E.3
What arrangements have been made for research participants who might not adequately understand verbal or written information?

F. CONFIDENTIALITY

NB. Investigators should be aware of their responsibilities as provided for in the Data Protection Acts 1998 and 2003.

F.1	
Does the proposed clinical trial involve the retention of biological material (tissue, bodily fluids) or data derived from them?	☐ *Yes* ☐ *No*
If Yes, for what period of time will the biological material and/or data be retained?	

F.2
How will data security be maintained?

F.3
Who will have access to the biological material and/or data?

F.4
If biological material and/or data are to be disposed of please explain how and by whom this will be done?

F.5
How will the results of the clinical trial be reported and disseminated (e.g. peer-reviewed journal, research participants)?

G. FINANCIAL ARRANGEMENTS

G.1
What arrangements have been made for compensation in the event of a claim made by or on behalf of a participant?

G.2	
Is indemnity in place for the conduct of this clinical trial?	☐ *Yes* ☐ *No*
If yes, please submit a copy to the REC.	

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:	
Contact name:	
Address:	
Tel:	
Fax:	
E-mail:	
Amount:	
If *No*, what arrangements have been made to cover the cost of the research?	

G.4	
Does the Chief 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.	

Declaration of the Chief Investigator

This declaration must be signed and sent to the REC 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 letter of approval sent by the Recognised Ethics Committee.
- 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: _____

Date: _____ (dd/mm/yyyy)