

Ethical Issues Table

Section	Ethics Issues Table	
	Applicant Name	
	Co-Applicant(s)	
	Proposal Title	
	Research Body of Lead Applicant	
Use of Animals in Research		
1	Does your research involve the use of animals?	Yes No
2	Please confirm that Ethical approval will be obtained for the study prior to commencement of any research	Yes No N/A
Human Participants / Material / Data		
3	Does your research involve human participants, human biological material, or identifiable/potentially identifiable data?	Yes No If No, please review entire checklist but do not complete Sections 4-21. If Yes, complete all remaining sections.
4	Please confirm that Ethical approval will be obtained for the study prior to commencement of any research.	Yes No N/A
Human Embryos/Foetuses		
5	Please confirm that your research <u>does not</u> involve Human Embryonic Stem Cells (hESCs)?	Yes No
Humans		
6	Does your research involve human participants?	Yes No N/A
7	Are they vulnerable individuals or groups, patients or persons unable to give informed consent (including children/minors)?	Yes No N/A
8	In the course of your research programme, do you propose to use Clinical Research Facility/Centre (CRF/C) facilities?	Yes No N/A
9	Is a formal sponsor required for the research programme?	Yes No N/A
10	Does your research involve physical interventions on the study participants?	Yes No N/A
11	Does your research involve a clinical trial or investigation?	Yes No N/A

12	Is the clinical trial or investigation covered by the EU Clinical Trials Directive?	Yes No N/A
13	If yes, please confirm that HPRA approval will be obtained prior to study commencement.	Yes No N/A
14	Please confirm that an independent Trial Steering Committee (TSC) will be established.	Yes No N/A
15	Please confirm that the trial or investigation will be registered in a publicly available, free to access, searchable clinical trial or investigation registry	Yes No N/A
16	Please confirm that the requisite insurance cover will be sought for the clinical trial or investigation and evidence of cover submitted to SFI prior to trial initiation.	Yes No N/A
17	Does this clinical trial or investigation involve activities outside of the Republic of Ireland or partnerships with international Collaborators?	Yes No N/A
Human cells/Tissues		
18	Does your research involve human cells or tissues?	Yes No N/A
19	Does your application include an element of biobanking?	Yes No N/A
Personal Data		
20	Does your research involve personal data collection and/or processing?	Yes No N/A
21	If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, please confirm that there has been appropriate informed consent for such use.	Yes No N/A