Ethical Issues Table

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**Science Foundation Ireland requires evidence that relevant ethical and regulatory approval has been granted for studies involving human or animal subjects as well as human cells/tissues prior to research commencing.**

**Submission of an application to Science Foundation Ireland represents an agreement by the applicant to obtain the relevant approval for any research which requires ethical and/or regulatory approval prior to the commencement of the research.**

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| **Section** | **Ethics Issues Table** | | |
| **Applicant Name** | | |  |
| **Proposal Title** | | |  |
| **Research Body of Applicant** | | |  |
| **Use of Animals in Research** | | | |
| 1 | Does your research involve the use of animals? | Yes  No | |
| **Human Participants / Material / Data** | | | |
| 2 | 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 3-19. If Yes, complete all remaining sections. | |
| **Human Embryos/Foetuses** | | | |
| 3 | Does your research involve Human Embryonic Stem Cells (hESCs)? *Research using human embryonic stem cells or tissues will not be supported by SFI.* | Yes  No  N/A | |
| **Humans** | | | |
| 4 | Does your research involve human participants? | Yes  No  N/A | |
| 5 | Are they vulnerable individuals or groups, patients or persons unable to give informed consent (including children/minors)? | Yes  No  N/A | |
| 6 | In the course of your research programme, do you propose to use Clinical Research Facility/Centre (CRF/C) facilities? | Yes  No  N/A | |
| 7 | Is a formal sponsor required for the research programme? | Yes  No  N/A | |
| 8 | Does your research involve physical interventions on the study participants? | Yes  No  N/A | |
| 9 | Does your research involve a clinical trial or investigation? | Yes  No  N/A | |
| 10 | Is the clinical trial or investigation covered by the EU Clinical Trials Directive? | Yes  No  N/A | |
| 11 | If yes, please confirm that HPRA approval will be obtained prior to study commencement. | Yes  No  N/A | |
| 12 | Will an independent Trial Steering Committee (TSC) be established? | Yes  No  N/A | |
| 13 | Will the trial or investigation be registered in a publicly available, free to access, searchable clinical trial or investigation registry? | Yes  No  N/A | |
| 14 | Will the requisite insurance cover be sought for the clinical trial or investigation and evidence of cover submitted to SFI prior to trial initiation? | Yes  No  N/A | |
| 15 | 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** | | | |
| 16 | Does your research involve human cells or tissues? | Yes  No  N/A | |
| 17 | Does your application include an element of biobanking? | Yes  No  N/A | |
|  | **Personal Data** | | |
| 18 | Does your research involve personal data collection and/or processing? | Yes  No  N/A | |
| 19 | If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, will appropriate informed consent for such use be sought? | Yes  No  N/A | |