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| TGHN-256x151px | **[Institution and group name]** |  | **Risk assessment form** |
| Trial number |  | Sponsor |  |

|  |  |  |
| --- | --- | --- |
| **DEFINE RISK CATEGORY FOR THE MEDICINAL PRODUCT(S) BEING TESTED** | | |
|  | **Type A** = Risk comparable to standard medical care | Justification |
|  | **Type B** = Risk somewhat higher than standard medical care |
|  | **Type C** = Risk markedly higher than standard medical care |

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| **DEFINE ADDITIONAL RISKS ASSOCIATED WITH MEDICINAL PRODUCT(S) WHEN COMPARED TO STANDARD CARE** | | | | | |
|  | Adequate systems in place to deal with the risks associated with the medicinal product(s)/device(s) as part of standard care (usually only Type A). | | | | |
| For all other trials, please outline any risks that have been identified and describe the mitigating actions planned (e.g. availability of emergency resuscitation equipment, additional monitoring etc. | | | | | |
| Medicinal product | | Body system | Hazard | Likelihood  (L,M,H) | Mitigation |
|  | |  |  |  |  |
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| **Will a Data Safety Monitoring Board or equivalent be convened?** | | | | | | | | | | | |
| Yes | No | | | | | If no, justify: | | | | | |
| **DEFINE OTHER RISKS ASSOCIATED WITH THE TRIAL DESIGN AND METHODS** | | | | | | | | | | | |
| **Risks to participant safety from clinical procedures specified by the protocol (e.g. additional tests, invasive procedures, increased radiological exposure compared with standard care)** | | | | | | | | | | | |
| Risk | | | | | Specify concerns | | | | Can the risk be minimised? | | Could monitoring methods help to address concerns? |
|  | | | | |  | | | |  | |  |
| **Risks to participant rights from failure to obtain appropriate consent** | | | | | | | | | | | |
| Risk | | | | Specify concerns | | | | | | Can the risk be minimised? | Could monitoring methods help to address concerns? |
|  | | | |  | | | | | |  |  |
| **Risks to participant rights from failure to protect their personal data** | | | | | | | | | | | |
| Risk | | Specify concerns | | | | | Can the risk be minimised?  Specify | | | | Could monitoring methods help to address concerns? Specify |
|  | |  | | | | |  | | | |  |
| **Risks to the reliability of results** | | | | | | | | | | | |
| Risk | | | Specify concerns | | | | | Can the risk be minimised? | | | Could monitoring methods help to address concerns? |
|  | | |  | | | | |  | | |  |

**PI assessment**

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| Can risks be mitigated enough for trial to go ahead? |  |

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| --- | --- | --- | --- |
| Name | **Signature** | Date |  |
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