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

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| **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? |
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**PI assessment**

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

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