Instructions for use:

1. Define the risk(s) explicitly in terms of effect of the risk on the participants, study, and Trust (see Appendix 2 for examples of risks and descriptors)

2. Use the descriptors in Appendix 2 to determine the severity score (s) for the potential outcome of the risk occurring.

3. Use the descriptors in Appendix 1 to determine the likelihood score(s) for the risk occurring.

4. Use the risk score matrix below to calculate the overall risk score by multiplying the severity score by the likelihood score = risk score. Assessing Likelihood of Event (see below).

Risk Scoring Matrix



**Identifying Risks *(see Appendix 2 for some examples)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Risk** | **Risk(s) Identified**  | **Severity (see Appendix 2)** | **Likelihood (see Appendix 1)** | **Mitigation(s) in place** | **Risk Rating Number (Risk vs Likelihood) see table below for score.** |
| **Risks to Participant** |  |  |  |  |  |
| **Risks to Staff** **(exceptional risks only)** |  |  |  |  |  |
| **Risks to Study** |  |  |  |  |  |
| **Risks to Trust** |  |  |  |  |  |
| **Highest risk rating** |  |  |  |  |

Appendix 1 – Likelihood score and descriptor

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1****Extremely unlikely**  | **2****Low** | **3****Moderate** | **4****High** | **5****Very High** |
| Unlikely to happen except in very rare circumstances. Less than 1 chance in 1,000 (< 0.1% probability). No gaps in control. Well managed. | Unlikely to happen except in specific circumstances. Between 1 chance in 1,000 & 1 in 100 (0.1 - 1% probability). Some gaps in control; no substantial threats identified | Likely to happen in a relatively small number of circumstances. Between 1 chance in 100 & 1 in 10 (1- 10% probability). Evidence of potential threats with some gaps in control. | Likely to happen in many but not the majority of circumstances. Between 1 chance in 10 & 1 in 2 (10 - 50% probability). Evidence of substantial threats with some gaps in control. | More likely to happen than not. Greater than 1 chance in 2 (>50% probability). Evidence of substantial threats with significant gaps in control. |

Appendix 2 – examples of risks with severity score

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **1****Very low**  | **2****Low** | **3****Moderate** | **4****High** | **5****Very High** |
| **Risk to Participant** |  |  |  |  |  |
| Participant Population | No research involvement of human participantsParticipants are NHS staff rather than participants | Participant group not considered vulnerable – able to give informed consent, may benefit from taking part  | Participants with potential limited capacity to consent e.g. early stages of cognitive impairment limited English.Specialist clinical areas with limited treatment options.Healthy volunteers in studies with moderate risk attached to the interventionParticipants with poorly controlled / complex illnesses  | Participants with severely compromised capacity to consent – unconscious, young children, cognitively impaired.Participants with poor prognosis / terminal disease & participants not likely to gain any benefit from taking partHealthy volunteers in studies with high risk attached to the intervention | Any study where side effects of the intervention have a realistic chance of being fatal or causing serious harm (more than 30%) |
| Intervention  | Non invasive procedures Questionnaire / interview or survey research. Minor intervention e.g. taking blood or skin samples  |  Involves a clinical intervention which represents only a slight deviation from normal treatment and / or basic safety and efficacy testing has been carried out e.g. Phase 3 or 4 trials | Involves a clinical intervention which represents a significant change from standard care | Involves a clinical intervention which represents a significant change from standard care withholding of all / elements of standard careBasic safety and efficacy data not yet available for the investigational product e.g. Phase 1 and 2 trials  | Significant risk derived from single highly invasive clinical intervention or combination of interventions – e.g. surgical techniques, radiotherapy, cytotoxic drugs or combinations of the above  |
| Consent | Consent not necessary / REC and necessary national approvals to go ahead without it  | Clearly defined process for informed consent with named designation of responsibility.Clear defined recruitment process.Clear and concise consent form and participant information sheet. | Complex consent process / Unclear process for recording consent Complex participant information sheet.Participants given limited time to consider taking part, in balance with the requirements of the study. | Unclear provision for informed consent.Consent does not cover all aspects of research.Inexperience/inappropriate staff taking informed consent.No explanation of recruitment process.No identification of potential risks or hazards. | No approved consenting procedure.   |
| **Risk to Study** |  |  |  |  |  |
| Investigator*Complexity of study must be taken into consideration in assessment of risk.*  | No local investigatoror minimal involvement e.g. recruitment only.Experienced Principal / Chief Investigator supported by well trained and experienced team Study team have up to date training in GCP / governance  |  Experienced Principal / Chief Investigator, with small research team / limited support from collaborators, sponsors  | PI/ CI has limited experience of leading a studyInexperienced / stretched teamSome awareness of governance issues  | No prior experience of leading a complex studyNo evidence of governance / GCP awareness Discrepancy between ethics application, participant information, consent and/or protocol/trial information. | Previously investigated for fraud/misconduct or there is evidence to suggest the team is dysfunctional. |
| Protocol*Complexity of study must be taken into consideration in assessment of risk.* | Minor or insignificant participant involvement with clear rationale and scientific justification Clear complete rationale and scientific justification.Clearly defined proposal.Clear guidance for protocol violationIndependent expert and peer review with written summary. | Clear developmental background for investigational drug or device. | Poor guidance for potential protocol deviations or errors.Limited scientific background for study intervention.No documentation of review process in line with Trust policy.Complex protocol or invasive procedure. | Potential for deviation from protocol.No protocol violation contingency defined.New/experimental treatment without clear scientific background. | Previous instances of inappropriate / unauthorised deviation from protocol. Potential for FraudPotential for violation of inclusion and exclusion criteriaMajor potential for deviation from protocol, which may result in harm to study participant. |
| **Risk to Trust** |  |  |  |  |  |
| Personal Data/ Information Governance  | No Personal Data being used (i.e., fully anonymised) | Data pseudonymised such that recipient will not be able to identify Study ParticipantsPseudonymised data to be sent outside the EEAAppropriate provision for archivingData stored in secure site | Poorly defined processes of data recording and storage.Archiving considered but no provision made.Participant Identifiable Data (PID) going off-site | PID to be sent to sites outside EEA Potential for fabrication, falsification, distortion/omission or corruption of research data.No limits on data access.Archiving not considered. Data to be stored in open environment.Study team not trained in IG | Previous breaches of data protection / confidentiality  |
| Finance | No cost ramifications Fully funded research.  | Partially funded research with directorate picking up the excess (with approval from directorate).   | Under-costed Partially funded – unclear who is picking up the remainder  | Unfunded and/or unsupported by CLRN. No defined contract with or between research organisations. | Previously identified issues of poor costing or use of funds.Previous instances of PI signing off contract without R&D |
| Contracts | Use of appropriate contract template as per IRAS recommendations with no changes to standard wording made | Appropriate contract template used but insignificant modifications made to standard wording | Appropriate contract template used with minor modifications made to standard wordingIncorrect contract template used  | Appropriate contract template used with significant & multiple modifications made to standard wording | No defined contract with or between research organisations.Incorrect contract template used with significant changes made impacting the trusts safety, operational and financial basis’ |
| Reputational (risk of reputational impact, both positive or negative, either through the taking part as a sponsor, site or PIC or through the completion of a study and its conclusions) | Positive impact on trust’s reputation as a result of running / conclusion of the trial/study Significant positive impact on trust’s reputation as a result of running / conclusion of the trial/study Positive media attention received  | minor / insignificant negative impact upon the Trust’s reputation as a result of running / conclusion of the trial/studyIndifferent media attention received  | Moderate negative impact upon the Trust’s reputation as a result of running / conclusion of the trial/studyMildly negative media attention received  | Major negative impact upon the Trust’s reputation as a result of running / conclusion of the trial/study. Some reputational damageNegative /pessimistic media attention received  | The negative impact upon the Trust’s reputation as a result of running / conclusion of the trial/study would be catastrophic and high riskSignificant negative media attention received and reputational damage |