The Risk Assessment Form must be completed by the Chief Investigator (Summary and Section 1 &2 only) and Head of Research Operations (UHL) or their delegate when conducting Sponsor reviews on behalf of UHL. It is expected that queries or actions required are discussed with the Chief Investigator and research teams and plans for mitigation agreed as part of the sponsor review process.

Risk can be defined as the likelihood of a potential hazard occurring and resulting in harm to the participant and/or organisation, or to the reliability of the results.

A flowchart of the procedures required is detailed in Appendix 4 of the SOP S-1003 UHL.

**Version 7 onwards, the RAF is completed as part of the Sponsor review and in collaboration with the Chief Investigator. The EDGE Attributes / Workflows are discussed during the meeting with the study team as part of the process. Completion of the RAF document is no longer required.**

|  |  |
| --- | --- |
| **Full Title:** | **Found in EDGE – Study details both Green / Red Levels** |
| **Short Title:** | **Found in EDGE – Study details both Green / Red Levels** |
| **Name of Point of Contact:** | **POC in Contacts – Green Level** | **Name of CI:** | **Study details Green Level** |
| **Email/Phone of POC:** | **POC in Contacts – Green Level** | **If Multi Centre- How Many sites?** |  |
| **Proposed number of patients (include in each arm if applicable):** | **Participants – Green Level****Split by site – each site RED level will indicate site target** | **Study Duration: Green Level dates** | Recruitment Period = **Green Level dates**Total Study Duration including Follow Up = **Green level dates** |
| **Sponsor No:** |  |

|  |
| --- |
| **Study Summary: Green Level Details page** |
| *Include a short summary of relevance and importance of this research and how this research will benefit UHL and/or it’s staff and patients* |

|  |
| --- |
| **Type of Study: - Identified in Mandatory Category 1 Attribute** |
| Clinical trial of an investigational medicinal product | ☐ | Study involving qualitative methods only | ☐ |
| Clinical investigation or other study of a medical device | ☐ | Study limited to working with human tissue samples (or other human biological samples) and data (specific project only) | ☐ |
| Combined trial of an investigational medicinal product and an investigational medical device | ☐ | Study limited to working with data (specific project only) | ☐ |
| Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice | ☐ | Research tissue bank | ☐ |
| Basic science study involving procedures with human participants | ☐ | Research database | ☐ |
| Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology | ☐ | Other study | ☐ |
| **If IMP complete sections below – All identified in Pharmacy Involvement Attribute** |
| **Type of IMP:** | **Type of Research:** | **Risks associated with trial IMP/interventions:** |
| Biological | ☐ | Phase 1 | ☐ | **Type A =** | Comparable to the risk of standard medical care | ☐ |
| Chemical | ☐ | Phase 2 | ☐ | **Type B =** | Somewhat higher than the risk of standard medical care | ☐ |
| Advanced Therapy | ☐ | Phase 3 | ☐ | **Type C =** | Markedly higher than the risk of standard medical care | ☐ |
| Other | ☐ | Phase 4 | ☐ |

**Section 1- Risk Assessment of the Investigational Medical Product or Intervention**

***If this study does not involve an IMP check box*** [ ]  ***and proceed to section 2***

Where risks associated with the IMP/intervention are somewhat or markedly higher than those of standard medical care (i.e. Type B or Type C trials) details regarding specific risks to body systems and proposed methods for clinical monitoring of such risks should be described. The drug risk assessment should be based on available information (e.g. SmPC, Investigator Brochure, British National Formulary other publications)

|  |  |
| --- | --- |
| **Risks associated with IMP / intervention:** | **Justification** *Please give reasons why Type A/B/C was applied for this study* |
| [ ]  Type A: risk *comparable* tothat of standard medical care | **Type of study identified in Pharmacy Involvement Attribute** |
| [ ]  Type B: risk *somewhat higher* than that of standard medical care |
| [ ]  Type C: risk *markedly higher* than that of standard medical care |
| **IMP/Intervention** | **Body System** | **Hazard** | **Likelihood**Rare/Negligible = 1 - 5Unlikely/Minor = 2 - 10Possible/Moderate = 3 – 15Likely/Major = 4 – 20Almost Certain/Catastrophic = 5 - 25 | **Mitigation** | **Comments** |
| *e.g. ABC123* | *Metabolic* | *Hyperglycaemia* | *8* | *Blood glucose monitoring* | *X hourly* |
| **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |

**Section 1- Risk Assessment of the Investigational Medical Product or Intervention (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Risk Factor**Potential source of harm | **Is there a particular**  **risk?**Y/N | **Concerns Identified**Provide details of study-specific considerations/risk concerns | **Likelihood**Rare/Negligible = 1 - 5Unlikely/Minor = 2 - 10Possible/Moderate = 3 – 15Likely/Major = 4 – 20Almost Certain/Catastrophic = 5 - 25 | **Mitigation Strategies**Address all concerns identified | **Additional Monitoring/Audit Methods Required** |
| Manufacture and distribution- IMP sourcing/manufacture/supply- Licence status, QP release - IMP ordering/delivery | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Drug labelling- IMP packaging- IMP labelling- blinding | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Storage- pharmacy/ward- temperature controlled | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Drug accountability | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Application method- dose calculation/strength- duration/regimen of administration- dosing procedure - drug interations- dosing follow up | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Pharmacovigilance- AE/SUSAR reporting- urgent safety measures- out of hours cover- stopping criteria- data monitoring committee | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Unblinding | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |
| Other | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** | **Risk Assessment CTIMP attribute** |

**Section 2 - Risk Assessment of the Medical Device**

***If this study does not involve a medical device check box*** [ ]  ***and proceed to section 3***

Where risks associated with device are higher than normal (i.e. device used outside of CE marking, or device without CE marking) details regarding specific risks to body systems and proposed methods for clinical monitoring of such risks should be described. The device risk assessment should be based on available information (e.g. Investigator Brochure, Device Technical Specification)

|  |  |
| --- | --- |
| **Use of the medical device:** | **Justification** |
| [ ]  CE marked device used within its intended purpose(s) | **Type of study identified in Medical Devices / Equipment Attribute** |
| [ ]  CE marked device which has been modified or will be used outside its intended purpose(s) |
| [ ]  Non-CE marked device |
| **Device** | **Body System** | **Hazard** | **Likelihood**Rare/Negligible = 1 - 5Unlikely/Minor = 2 - 10Possible/Moderate = 3 – 15Likely/Major = 4 – 20Almost Certain/Catastrophic = 5 - 25 | **Mitigation** | **Comments** |
| **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |

**Section 3 – Research Risk Assessment**

***Mark risk as “N/A” if not relevant for this study. List any other risks identified for this study in “Other”***

1. **Participants’ Rights and Safety**

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| --- | --- | --- | --- | --- | --- |
| **Risk Factor**Potential source of harm | **Is there a particular**  **risk?**Y/N | **Concerns Identified**Provide details of study-specific considerations/risk concerns | **Likelihood**L = LowM = MediumH = High | **Mitigation Strategies**Address all concerns identified | **Additional Monitoring/Audit Methods Required** |
| Participant population- healthy volunteer/patient- age/vulnerable group - rare disease/illness- non-adherence to study intervention | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |
| Enrollment- eligibility criteria (restrictive inclusion/exclusion)- withdrawal | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |
| Consent- verbal/written- emergency situation- proxy/legal representative-consent for data/tissue | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |
| Participant privacy (data protection)- data access- collect personal identifiable data- collect sensitive information- data sharing/transfer outside UK/EU or NHS organisation-appropriate permissins in place to access patient data | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |
| Study assessment methods- samples/tests/biopsies/procedures- visit schedule vs. standard care | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |
| Other | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** | **Risk Assessment Devices attribute** |

1. **Facilities, Equipment and Resources**

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| **Risk Factor**Potential source of harm | **Is there a particular**  **risk?**Y/N | **Concerns Identified**Provide details of study-specific considerations/risk concerns | **Likelihood**L = LowM = MediumH = High | **Mitigation Strategies**Address all concerns identified | **Additional Monitoring/Audit Methods Required** |
| Study staff experience- appropriate qualifications- research experience- ICH-GCP, ISO14155 trained- protocol training- sponsor SOP awareness- time allocation | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Partner organisations- additional sites, external service provider/third party - geography- language- international regulations | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Study management-adequate lead site staff-experience of trial manager- responsibilites of CTU | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Resource availability-patient population/recruitment rate- departments/clinics/wards- (special) equipment- equipment servicing/maintenance | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Other | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |

1. **Study Design and Reliability of Results**

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| **Risk Factor**Potential source of harm | **Is there a particular**  **risk?**Y/N | **Concerns Identified**Provide details of study-specific considerations/risk concerns | **Likelihood**L = LowM = MediumH = High | **Mitigation Strategies**Address all concerns identified | **Additional Monitoring/Audit Methods Required** |
| Data collection/management- source data- (e)CRF design and completion- database design and entry- quality control/verification checks | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Sample collection/management-storage and sample tracking-temperature monitoring-shipment to external labs | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Study recruitment power- number feasible- participant withdrawal- loss to follow up | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Blinding and/or randomisation- blinded allocation- single/double blind- unblinding procedures | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Primary and secondary outcomes- objective vs. subjective- (un)blinded assessors- external verification | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Complexity of study design- intervention- treatment arms/groups- visit schedule and follow up- crossover, dose escalation/adjustment, MTD | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Other | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |

1. **Documentation, Governance and Compliance**

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| --- | --- | --- | --- | --- | --- |
| **Risk Factor**Potential source of harm | **Is there a particular**  **risk?**Y/N | **Concerns Identified**Provide details of study-specific considerations/risk concerns | **Likelihood**L = LowM = MediumH = High | **Mitigation Strategies**Address all concerns identified | **Additional Monitoring/Audit Methods Required** |
| Trial master file maintenance | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Protocol, regulatory and SOP compliance | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Funding-costed appropriately-funds for duration of study-all NHS costs included at all sites | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Oversight- monitoring/auditing- management groups- steering committee- meetings | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| IP Issues | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |
| Other | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** | **Risk Assessment 12a/12b Attribute** |

**Risk Assessment Form (RAF) Completion, Review and Revision Record**

This Risk Assessment should be reviewed and amended if necessary whenever substantial amendments are made. An annual review of the RAF should be made whether or not there have been any amendments. It is recommended that this occurs at the same time as the submission of annual reports to REC or submission of the annual DSUR.

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| **Risk Assessment Completion or Review Date** | **Completed****By** | **State Initial Completion or** **Reason for Review** | **Version of RAF Reviewed** | **Protocol Version & Date** | **Outcome of Review** *(Revision Required/ no revision required)* | **Summary of Revisions** |
| Covered by Sponsor workflows | Covered by Sponsor workflows | Covered by Sponsor workflows | Covered by Sponsor workflows | Covered by Sponsor workflows | Covered by Sponsor workflows | Covered by Sponsor workflows |
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