**Pandemic Research Risk Assessment Form**

Please complete this Research Risk Assessment Form for research Sponsored either by the University Hospitals of Leicester NHS Trust (UHL), or the University of Leicester (UoL). Not all sections will be relevant – please tick the N/A boxes as appropriate. Please provide as much information and detail as you are able to at this stage. Text is blue is intended to be a guide and can be removed upon completion of that section.

This must be completed by the Chief Investigator or their delegate and sent the Sponsor for processing: submit either by Infonetica (initial) or email to [RGOsponsor@le.ac.uk](mailto:RGOsponsor@le.ac.uk) (updated).

It is expected that queries or actions required are discussed with the Chief Investigator and research teams and plans agreed as part of the risk mitigations required during the pandemic.

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 glossary of definitions can be found at the end of this document.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Sponsor:** | University of Leicester | | | | | | |
| **Sponsor Reference Number:** |  | | | | | | |
| **Full Title:** |  | | | | | | |
| **Short Title:** |  | | | | | | |
| **Chief Investigator:** | Please provide Name and Contact Details | | | **Principal Investigator:** | | Please provide Name and Contact Details | |
| **Main Point of Contact (if different from Chief Investigator or Principal Investigator):** | Please provide Name and Contact Details | | | **Site(s):** | | Please list all participating sites | |
| **Type of Research:** | | | | | | | |
| 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 | |  |
| **Pandemic Research Category**  Based upon the descriptions below, please indicate which category your research falls into. A justification can be added in the box if necessary. | | | | | | | |
| Research directly relates to and informs a response/solution to pandemic | |  | Justification (if required/necessary): | | | | |
| Research where clinical care is heavily woven into the research protocol | |  |
| Research that involves participants who are immunosuppressed (i.e., COPD participants) OR would put participants at risk of immunosuppression (i.e., a drug trial that can cause this) | |  |
| Other (i.e., data studies, questionnaire studies, interventional trials that fall outside of the above) | |  |

**Risk Matrix [Likelihood x Impact]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Likelihood**  **Impact** | **Rare [1]** | **Unlikely [2]** | **Possible [3]** | **Likely [4]** | **Almost Certain [5]** |
| **Catastrophic [5]** | 5 | 10 | 15 | 20 | 25 |
| **Major [4]** | 4 | 8 | 12 | 16 | 20 |
| **Moderate [3]** | 3 | 6 | 9 | 12 | 15 |
| **Minor [2]** | 2 | 4 | 6 | 8 | 10 |
| **Negligible [1]** | 1 | 2 | 3 | 4 | 5 |

|  |  |
| --- | --- |
| **Risk Level** | **Action and Time-Scale** |
| **1-4 = Minor Risks** | No further preventative action is necessary, but consideration should be given to solutions or improvements. Monitoring is required to ensure controls are maintained. |
| **5-11 = High Incidence Risks** | Efforts should be made to reduce the risk; action plans to be produce and review undertaken. |
| **12-16 = Contingency Risks** | If an extremely harmful situation may arise, even if unlikely, a specific re-evaluation of the task should be undertaken to establish more stringent controls. Work should be monitored closely until the risk has been significantly reduced, in a short period of time. Measures to be included into action plans and improved. |
| **17-25 = Major Risks** | Immediate action or detailed planning to be included with implementation plans. Work should not be started or continued until the risk level has been reduced. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 - 5  Unlikely/Minor = 2 - 10  Possible/Moderate = 3 – 15  Likely/Major = 4 – 20  Almost Certain/Catastrophic = 5 - 25 | **Mitigation Strategies**  Address all concerns identified | **Sponsor Comments (if required)** |
| Recruitment  Will you pause recruitment?  Will you continue recruitment?  How will you obtain informed consent?  Do you need to change to remote consent (i.e., telephone consent)?  How will it be recorded?  How will you ensure capacity? |  |  |  |  |  |
| Follow-up  Will you pause follow-ups?  Will you continue follow-ups?  Will participants be invited to the hospital? Can you do any remotely?  How will you keep participants safe?  How will you keep staff safe? |  |  |  |  |  |
| Data Collection  What assessments can you continue with?  How will you keep track of missed assessments?  Can you collect data remotely?  How will you ensure confidemtiality is maintained?  Will your primary end point be affected?  Will data integrity be a problem? |  |  |  |  |  |
| IMP (CTIMP studies only)  How many participants are actively receiving IMP?  Will they run out?  How will you dispense more to them? Do they have to come to the hospital? Can they send someone else? Will you use a courier (please remember to obtain verbal consent to pass contact and delivery details onto the courier and note this in medical records)? How will you collect evidence of safe receipt of the IMP (i.e., follow-up telephone call)? Consider temperature requirements.  Does Pharmacy have enough stock?  Are your supply chains affected?  Is the expiry date sufficient?  Can the Pharmacy hold more bulk stock?  How will you ensure compliance?  How will you manage dose changes?  How will you ensure tolerability? Record AEs/SAEs? |  |  |  |  |  |
| Safety Reporting  How will activities continue? Who is responsible/delegated these duties? Is there a deputy in place?  How will you record SAEs/AEs/SADEs/SUSARs? |  |  |  |  |  |
| Blinding/Unblinding?  How will the blind be maintained? have you got enough people to unblind? Do you need a deputy? Do unblinded lab results require review? |  |  |  |  |  |
| Medical Devices  Are there any issues identified with the continuation of this research? |  |  |  |  |  |
| Participants  Are they at risk? Will they be at risk by continuing to come to the hospital?  How will you ensure safety follow-ups are completed?  How will you keep data safe? |  |  |  |  |  |
| Research Staff  Do you have enough staff to continue with the research protocol? Will these staff be called away for clinical duties? What if they become poorly/have to self-isolate?  Is there a deputy CI/PI/Lead Research Nurse? |  |  |  |  |  |
| Resource/Space  Will your research space be required for clinical purposes? |  |  |  |  |  |
| Consumables  How will you obtain everything you need to conduct the research? |  |  |  |  |  |
| Labs/Samples/Tissue  Are your labs still operating? What will happen if lab staff are not available? Will your research samples be deprioritised? Can they be stored properly? Can the results be reviewed? Storage and transport issues? |  |  |  |  |  |
| Protocol Compliance  A record of all missed assessments must be maintained on a protocol deviation log as best you can. Who will manage this? |  |  |  |  |  |
| Trial Master File(s)  Please ensure the TMF remains in a safe and secure environment. Please do not take TMFs home because they contain identifiable and confidential data. All documents should be kept in safe place until they can be filed. |  |  |  |  |  |
| Oversight  How will meetings be affected? Do you need to make any changes to the schedule of meetings? Do you need to reschedule Data Safety Monitoring Committees? Trial Steering Committees?? |  |  |  |  |  |
| Other  Please complete this section with any other relevant topics. |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk Assessment Completion or Review Date** | **Completed**  **By** | **Chief/Principal Investigator Comments/Outcome of Risk Assessment** | ***Sponsor Processing Completed By:*** |
|  |  |  |  |

**Glossary and Definitions of Risk Categories and Assessment Criteria**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Likelihood** | **1  Rare** | **2**  **Unlikely** | **3**  **Possible** | **4**  **Likely** | **5**  **Almost certain** | **Impact** | **1**  **Insignificant** [Scratch, bruise] | **2**  **Minor** [First-aid] | **3**  **Moderate**  [Medical treatment] | **4**  **Major**  [Broken bones, serious injury, disease] | **5**  **Severe**  [Death, permanent loss] |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk 1 - 4** | **LOW**  [No changes required] | **Risk 5 - 9** | **Medium**  [Consider changes to study management and processes] | **Risk 10 - 15** | **High**  [Changes to study management and processes to be made and implemented. Consider ceasing research activity] | **Risk 16 - 25** | **Critical**  [Stop / Actions Required – research activity must cease] |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Likelihood categories** | | | | |
| **Rare** | **Unlikely** | **Possible** | **Likely** | **Almost Certain** |
| This will probably never happen/recur. | Do not expect it to happen/recur but it is possible it may do so. | Might happen or recur occasionally. | Will probably happen/recur but is not a persisting issue. | Will undoubtedly happen/recur, possibly frequently. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Impact categories** | | | | |
| **Negligible** | **Minor** | **Moderate** | **Major** | **Catastrophic** |
| No risk to staff, participants, data. | Minor risk of illness to staff/participants. Minor risks to data collection and integrity. Minor risk to IMP. | Moderate risk to staff/participants of illness requiring medical / hospital intervention. Data collection and integrity at moderate risk. Moderate risk to IMP. | Major risk to staff/participants of illness. Major risk to data collection and integrity. Major risk to IMP. | Incident leading to death. Multiple permanent injuries or irreversible health effects to staff/participants. Data at risk. IMP at risk. |