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| **Details** | | | |
| **Protocol Title:** | Enter Protocol Title here. | | |
| **Principal Investigator(PI):** | Enter full name here. | | |
| **PI Phone Number** | Enter #. | | |
| **Date(s) of Activity** | From: Click or tap to enter a date. To: Click or tap to enter a date. | | |
| **Location:** | Enter Location here. | | |
| **Location Assessed By:** | Enter name here. | **Date Assessed:** | Click to enter a date. |
| **Description:** Click or tap here to enter text. | | | |

**Acknowledgement of Participating Personnel** (add additional pages if necessary)**:**

I, the undersigned, have been trained on this risk assessment and understand the known or potential risks involved with participating in the protocol activities.

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| **Name(s):** | **Signature(s):** | **Date(s):** |
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| **RMS Staff fill out this Box** |  |
| Person reviewing form: | Click or tap here to enter text. |
| Dates of approval: | From: Click or tap to enter a date. |
|  | To: Click or tap to enter a date. |

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| What are the consequences of this incident occurring? Consider what could reasonably happen. Look at the descriptions and choose the most suitable consequence. | | What is the likelihood of the consequence identified in step 1 happening? Consider this *without* new or interim controls in place. Look at the descriptions and choose the most suitable probability. | | 1. Take severity rating and select the correct column 2. Take probability rating and select the correct line 3. The risk score is where the two rating cross on the matrix below. Add risk to chart.   **H= High M = Medium, L = Low** |
| **Severity** | | **Probability** | | **Risk Guide:** |
| **Consequence** | **Description** |  | **Description** | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | | **Severity** | | | | | | **Neg** | **Min** | **Ser** | **Crit** | **Cat** | | **Probability** | **A** | **L** | **M** | **H** | **H** | **H** | | **B** | **L** | **M** | **H** | **H** | **H** | | **C** | **L** | **M** | **M** | **H** | **H** | | **D** | **L** | **L** | **M** | **M** | **H** | | **E** | **L** | **L** | **L** | **M** | **M** | |
| * **Catastrophic** | Death and extensive injuries | **A** | Frequent, >50% |
| * **Critical** | Life threatening | **B** | Probable 11%-50% |
| * **Serious** | Potential illness/impairment | **C** | Occasional, between 1%and 10% |
| * **Minor** | Material cost, first aid | **D** | Remote chance,<1% |
| * **Negligible** | Minor cost, no potential for illness | **E** | Improbable, once in the life of the measuring system, statistically insig. |  |

**STEP 1: IDENTIFY POTENTIAL AND EXISTING HAZARDS**

Select applicable hazards and assess their individual risk as, high, medium, or low by using the risk assessment matrix provided above. Space has been provided to list additional Hazards.

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| **r/sDNA Hazards** | | **Risk** | **Agent Hazards** | | **Risk** | **Other Hazards** | | **Risk** |
|  | **Formation** - the creation of a genetically-altered organism through deliberate or accidental means. | Choose Risk |  | **Pathogenicity**, virulence, and strain infectivity / communicability | Choose Risk |  | **Host range-** Zoonosis: can the pathogen infect both animals and humans? | Choose Risk |
|  | **Release** the deliberate release or accidental escape of some of these organisms in the workplace and/or into the environment | Choose Risk |  | **Mode/Route of transmission** (mode of laboratory transmission may differ from natural transmission) | Choose Risk |  | **Host factors—**can biohazard cause disease in healthy adult? What populations are at greater risk | Choose Risk |
|  | **Proliferation** - the subsequent multiplication, genetic reconstruction, growth, transport, modification and die-off of these organisms in the environment, including possible transfer of genetic material to other organisms. | Choose Risk |  | **Infectious dose** (the number of microorganisms required to initiate infection can vary greatly with the specific organism, patient, and route of exposure) or LD50 for toxic materials | Choose Risk |  | **Epidemiology—**is the biohazard endemic or foreign to the geographical research area? Is there a risk to the biohazard escaping the research facility and entering the environment? | Choose Risk Level. |
|  | **Establishment** - the establishment of these organisms within an ecosystem niche, including possible colonization of humans or other biota. | Choose Risk |  | **The risk of the formation of replication competent viruses** when using recombinant viral vectors | Choose Risk |  | **The facility** (e.g., BSL-2, open floor plan [more risk] versus separate areas or rooms for specific activities [less risk], sufficient space versus crowded space, workflow, equipment present) | Choose Risk Level. |
|  | **Effect** - the subsequent occurrence of human or ecological effects due to interaction of the organism with some host or environmental factor. | Choose Risk |  | **Form** (stage) of the agent (e.g., presence or absence of cell wall, spore versus vegetation, conidia versus hyphae for mycotic agents) | Choose Risk |  | **The equipment** (e.g., uncertified BSCs, cracked centrifuge tubes, improperly maintained autoclaves, overfilled sharps containers, Bunsen burners) | Choose Risk |
|  | **Gene Drive—**genetic engineering technology that propagates a particular suite of genes throughout a population by altering the probability that a specific allele will be transmitted to offspring from the natural 50% probability | Choose Risk |  | **Invasiveness** of agent (ability to produce certain enzymes) | Choose Risk |  | **Potential for generating aerosols and droplets** (Manipulating needles, syringes and sharps, Manipulating inoculation needles, loops, and pipettes, centrifugation, pouring, decanting, shaking) | Choose Risk |
|  | **Genetic modifications** that alter the risk, such as expression of oncogenes or siRNAs to knockdown tumor suppressors | Choose Risk . |  | **Stability** of biohazard | Choose Risk |  | **Use of animals** | Choose Risk |
|  | **OTHER:\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | Choose Risk |  | **OTHER:\_\_\_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | Choose Risk |  | **OTHER: \_\_\_\_\_\_\_\_\_\_**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | Choose Risk |

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| **Physical hazards** | | **Risk** | **Animal Hazards** | | **Risk** | **Other Hazards** | | **Risk** |
|  | **Hot environment** (High UV, heat stress, dehydration | Choose Risk |  | **Project animals** (bites, kicks, biological fluids, zoonotic diseases) | Choose Risk |  | **Infectious agents:**  Click or tap here to enter text. | Choose Risk |
|  | **Cold environment** (frost bite, Hypothermia, cold water) | Choose Risk |  | **Bites and stings** (ticks, leeches, spiders, bees) | Choose Risk |  | **Allergens** (pollen, poison ivy, wild parsnips) | Choose Risk |
|  | **Electrical hazards**  Click or tap here to enter text. | Choose Risk |  | **Restraint equipment** Click or tap here to enter text. | Choose Risk |  | **Participant injury/illness** | Choose Risk Level. |
|  | **Hazardous equipment** (hammers, drills, etc.)Click or tap here to enter text. | Choose Risk |  | **Large animal handling**Click or tap here to enter text. | Choose Risk |  | **Working Alone** | Choose Risk Level. |
|  | **Manual Work** (Lifting, pushing, pulling, digging) | Choose Risk |  | **Vector-borne diseases** (West Nile virus, Lyme disease)Click or tap here to enter text. | Choose Risk |  | **Transportation accident/failure** | Choose Risk |
|  | **Ergonomic Hazards**  (repetitive motion) | Choose Risk |  | **Project activities** (boating, swimming, climbing, all- terrain vehicles) | Choose Risk |  | **Violent persons** | Choose Risk |
|  | **Fatigue** (driving long hours) | Choose Risk . |  | **Wildlife** (venomous snakes, scorpions, animal bites, Zoonotic diseases) | Choose Risk |  | **Use or Storage of Hazardous Chemicals** (disinfectants, anaesthetics, medications) \*\*submit list to RMS | Choose Risk |
|  | **OTHER:**Click or tap here to enter text. | Choose Risk |  | **OTHER:**Click or tap here to enter text. | Choose Risk |  | **OTHER:**Click or tap here to enter text. | Choose Risk |

**STEP 2: RISK MITIGATION PLAN**

For hazards identified in Step 1, please list appropriate controls to eliminate or lessen the risk to project personnel. For hazards ranked H and M, mitigation must be in place and approved by RMS. Please be sure to include as many of the mitigation controls that you will be using as possible. This plan will be returned to you if it is incomplete or inadequate (i.e., if no PPE is included in your plan).

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| **Priority** | **Control** | **Example** |
| 1. | Eliminate | Removing the hazard. |
| 2. | Substitute | Replacing a hazardous process with a less hazardous one. |
| 3. | Isolation | Isolating the hazard from the person at risk. |
| 4. | Engineering | Redesign a process or piece of equipment to make it less hazardous. |
| 5. | Administrative | Adopting safe work practices and providing appropriate training and instruction. |
| 6. | PPE | Utilizing Personal Protective Equipment (PPE) to protect personnel |

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| Hazard | Problem | Controls |
| EXAMPLE: Working in/near Water | Drowning | Provide appropriate safety equipment, work in pairs, report back to PI/Supervisor when task is completed |
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**Step 3: OVERALL RISK ASSESSMENT**

Taking into account the hazards identified in Step 1 and the likelihood and consequences of the hazards, assess the overall risk of the activity.

Low Risk

Medium Risk

High/Extreme Risk

Provide copies of risk assessment to all research staff. All participants must have the minimal level of skill, experience, training, and physical fitness to safely perform the activities. **All training including lab specific training must be documented.**

List Training here.

*This Risk Assessment is completed based on information provided on the referenced protocol. The Assessment does not identify each and every risk associated with this protocol.  The Principal Investigator (PI) has primary responsibility for overall health and safety for this protocol. If any changes effecting safety and health are made to this protocol, the PI is to contact the IBC and UNT Risk Management Services.*