DIVISION OF RESEARCH & INNOVATION
Research Integrity & Compliance

GENERAL RISK ASSESSMENT FORM – IBC Protocol Registration

Details			
Protocol Title:			
Principal Investigator(PI):			
PI Phone Number			
Date(s) of Activity			
Location:			
Approval Date:			
Location Assessed By:		Date Assessed:	
Description			

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.

Name(s):	Signature(s):	Date(s):

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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

Consequence	Description
• **Catastrophic**	Death and extensive injuries
• **Critical**	Life threatening
• **Serious**	Potential illness/impairment
• **Minor**	Material cost, first aid
• **Negligible**	Minor cost, no potential for illness

Probability

	Description
A	Frequent, >50%
B	Probable 11%-50%
C	Occasional, between 1%and 10%
D	Remote chance,<1%
E	Improbable, once in the life of the measuring system, statistically insig.

Risk Guide:

Probability	Neg	Min	Ser	Crit	Cat
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

STEP 1: IDENTIFY POTENTIAL AND EXISTING HAZARDS

Select applicable hazards and assess their individual risk as, high, medium, or low (**H= High M = Medium, L = Low**)by using the risk assessment matrix provided above. Space has been provided to list additional Hazards. (provide details of the hazards and plans for mitigation in the Risk Mitigation Plan)

Select	Hazards	Risk Level
☐	**Formation** - the creation of a genetically altered organism through deliberate or accidental means.	
☐	**Release** the deliberate release or accidental escape of some of these organisms in the workplace and/or into the environment	
☐	**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.	
☐	**Establishment** - the establishment of these organisms within an ecosystem niche, including possible colonization of humans or another biota.	
☐	**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	

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☐	**Effect** - the subsequent occurrence of human or ecological effects due to interaction of the organism with some host or environmental factor.	
☐	**Pathogenicity of all micro-organisms used** (virulence, and strain infectivity / communicability)	
☐	**Mode/Route of transmission** (mode of laboratory transmission may differ from natural transmission)	
☐	**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	
☐	**The risk of the formation of replication competent viruses** when using recombinant viral vectors	
☐	**Form** (stage) of the agent (e.g., presence or absence of cell wall, spore versus vegetation, conidia versus hyphae for mycotic agents)	
☐	**Host range-** Zoonosis: can the pathogen infect both animals and humans?	
☐	**Host factors—**can it cause disease in healthy adult? What populations are at greater 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?	
☐	**Genetic modifications** that alter the risk, such as expression of oncogenes or siRNAs to knockdown tumor suppressors	
☐	**Stability** of biohazard	
☐	**Sharps/Needles Use**	
☐	**Live animal Use**	

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☐	**Animals derived materials Use.**	
☐	**Allergens** (animal, plant, poison ivy, wild parsnips)	
☐	**Zoonotic diseases** (mycobacteria, salmonellosis, parasites, venom, rabies) (provide details in mitigation table)	
☐	**Arthropods** (spider, aphids, ticks etc.)	
☐	**Bites and stings** (ticks, leeches, spiders, bees)	
☐	**Restraint equipment**	
☐	**Large animal handling**	
☐	**Vector-borne diseases** (West Nile virus, Lyme disease)	
☐	**Project activities** (boating, swimming, climbing, all- terrain vehicles)	
☐	**Wildlife** (venomous snakes, scorpions, animal bites, Zoonotic diseases)	
☐	**Boating/swimming/water hazards** (field studies)	
☐	**Hygiene/water or food-borne** (field studies)	
☐	**Transportation accident/failure** (during transportation of biological material or field study)	
☐	**Use of live plants (including transgenic or obnoxious plants)**	
☐	**Use of plant derived materials including transgenic (seeds, flowers, roots)**	
☐	**Use of Human or non-human derived materials**	
☐	**Blood Borne Pathogens (working with human and non-human research materials**	
☐	**Participant injury/illness** (human subject research)	
☐	**Violent persons**	
☐	**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)	
☐	**The equipment** (e.g., uncertified BSCs, cracked centrifuge tubes, improperly maintained autoclaves, overfilled sharps containers, Bunsen burners)	

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☐	**Potential for generating aerosols and droplets** (Manipulating needles, syringes and sharps, manipulating inoculation needles, loops, and pipettes, centrifugation, pouring, decanting, shaking)	
☐	**Extreme weather conditions**	
☐	**Working Alone**	
☐	**Cold environment** (frost bite, Hypothermia, cold water, LN2, dry ice)	
☐	**Electrical hazards**	
☐	**Hazardous equipment** (hammers, drills, etc.)	
☐	**Manual Work** (Lifting, pushing, pulling, digging)	
☐	**Ergonomic Hazards**	
☐	**Fatigue** (e.g., repetitive work)	
☐	**Other -**	

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).

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	Risk	Control Measures Used
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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Hazard	Risk	Control Measures Used

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Step 3: OVERALL RISK ASSESSMENT OF THIS PROJECT

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

*Explain why?

*Required field

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.

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.