

IBC Registration (Version 1.1)

1.0 General Information

***Please enter the full title of your study:**

Bacterial multispecies interactions within the human oral microbiome

***Please enter the Short Study Title you would like to use to reference the study:**

oral microbiota IBC

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List the departments associated with this study. Add the Principal Investigator's department as the **PRIMARY DEPARTMENT**. For research conducted at a Norton facility add: Norton Healthcare. For research conducted at a Jewish Hospital/KyOne facility (e.g. Frazier, St Mary's, etc) add: Ky One Health. For research conducted at University Hospital /James Graham Brown Cancer Center add: University Hospital:

Primary Dept?

Department Name

☐

U of L - 41 - Dental-Oral Immun & Infect Dis

3.0 Assign key study personnel (KSP) access to the project

3.1 *Please add a Principal Investigator for the study:

Ramsey, Matthew

3.2 In this section, please add any project personnel that needs to have access to the submission or will need to approve the submission. In the case of the Undergraduate Research Symposium, your mentor and co-authors would be included in this section.

A) Additional Investigators

B) Research Support Staff

Labossiere, Alex
Research Associate

3.3 *Please add a Study Contact. The Study Contact(s) will receive all important system notifications along with the Principal Investigator. If applicable, please add Kentucky One Health, Norton Healthcare or UMC Research as a study Contact. Adding someone here does not add them as study personnel.

Ramsey, Matthew

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. If applicable, please add Kentucky One Health, Norton Healthcare or UMC Research as a study Contact.

3.4 Please select the Designated Approvers:

Lamont, Richard J
Department Chair

Add the name of the individuals authorized to approve and sign off on this protocol.

4.0 RESEARCH TEAM EXPERIENCE AND SNAP SHOT OF EXPERIMENTS

4.1 PI AND RESEARCH TEAM EXPERIENCE

For each member of the research team, provide the following:

Team Member	BSL 1 Experience	BSL 2 Experience	BSL 3 Experience	Training Plan
Ramsey, Matthew	<input type="radio"/> Not Applicable to this Registration <input checked="" type="radio"/> Trained for work at this Biosafety Level <input type="radio"/> Requires training for work at this Biosafety Level	<input type="radio"/> Not Applicable to this Registration <input checked="" type="radio"/> Trained for work at this Biosafety Level <input type="radio"/> Requires training for work at this Biosafety Level	<input checked="" type="radio"/> Not Applicable to this Registration <input type="radio"/> Trained for work at this Biosafety Level <input type="radio"/> Requires training for work at this Biosafety Level	For those selections to the left for which the research team member has no training, please describe your proposed training plan. <hr/>
Labossiere, Alex	<input type="radio"/> Not Applicable to this Registration <input checked="" type="radio"/> Trained for work at this Biosafety Level <input type="radio"/> Requires training for work at this Biosafety Level	<input type="radio"/> Not Applicable to this Registration <input checked="" type="radio"/> Trained for work at this Biosafety Level <input type="radio"/> Requires training for work at this Biosafety Level	<input checked="" type="radio"/> Not Applicable to this Registration <input type="radio"/> Trained for work at this Biosafety Level <input type="radio"/> Requires training for work at this Biosafety Level	For those selections to the left for which the research team member has no training, please describe your proposed training plan. <hr/>

4.2 Summary of Types of Experiments that are covered by this registration

Select ALL that apply

- ☒ Recombinant and/or synthetic nucleic acids (r.sNA)
- ☐ Viral Vectors
- ☒ Infectious agents (virus, bacteria, fungi, parasites, etc)
- ☒ Human materials (blood, tissue, and other potentially infectious materials)
- ☒ Human cell lines
- ☐ Non-Human Primate materials (blood, tissue, and other potentially infectious materials)
- ☐ Non-human primate cell lines

- ☐ Toxin Use/Production
- ☐ Select Agent Use/ Production
- ☐ Animal Studies that involve exposure to rDNA, or recombinant organisms (virus, microbes etc.), and or cell lines,
- ☐ Transgenic Animal Use (rodents, rabbit, pig, fish, arthropod, etc.)
- ☐ Plants, transgenic/recombinant, and/or not native to Kentucky
- ☐ Lentivirus
- ☐ Human Gene Therapy

The use of human cell lines and/or tissues requires that staff:

- Is offered the Hepatitis B vaccine FREE of charge (have each person fill out and sign form and forward to Campus Health Services as instructed on the form). **Link to form**
- Complete Blood Borne Pathogen training (**BBP training**).

5.0 RESEARCH DESCRIPTION, LAY SUMMARY, TECHNICAL SUMMARY

5.1 Type of Proposal

New

5.2 LAY SUMMARY

Please compose a concise (about 200 words or less) summary of your research in everyday language that is easily understandable to a member of the public with a high school education. This entry will be evaluated by the IBC community representative. Avoid acronyms and scientific jargon. Technical terms that cannot be avoided must be explained. Show that you are aware of the degree of risk involved, and broadly comment on how risks will be mitigated.

We study bacteria that grow in the healthy human mouth. We isolate individual species of bacteria and combine them in set groups to understand how their behavior changes alone vs together. These cells are also sometimes exposed to human or other mammal immune cells and blood / serum to quantify how these impact the different bacteria, ie their immune responses. Human isolated microbes are BSL-2 or BSL-1 species that can be contained in appropriate lab settings and are cultured in small volumes (200mL or less). These species can infect humans but typically only represent risk to particularly immunocompromised individuals. All bacterial cultures and mammalian cells / blood / serum are readily inactivated by standard sterilization methods including bleach exposure and autoclaving.

5.3 TECHNICAL SUMMARY

Provide a verbal expansion or step by step "walk-through" of your research methodology. Explain why and how the specific agents are used.

This section should contain sufficient information and detail to ensure that the committee can understand where the risks to the research team exist and the steps to be taken to protect the research team and / or animal resource staff.

Any experiment covered by this IBC should be described (rDNA, virus, infectious agents, BBP, animal work, etc)

Examples Provided:

	Expt Type	Experiment Description
1	AAV	AAV expression vectors will be produced to express several synaptic proteins in retina. A 3 plasmid system will be used. A final volume of <300ul containing 10^{13} gc/ml will be

	production	produced.
2	Blood samples	Blood samples from humans will be obtained and used to isolate DNA/RNA and protein for analyses.
3.	Virus injection into animals	AAV expressing a calcium indicator will be injected into the hippocampus to allow us to measure neuronal activity in vivo
4	Tumor xenograft	human tumor cells will be isolated and injected into nude mice to measure the impact of several test compounds on tumorigenesis.

Experiment Type	Description of Experiment type (be brief, a few sentences)
Bacterial mutagenesi	We utilize an array of plasmid and/or transposon based molecular biology approaches in my lab to delete or replace genes in multiple bacterial species. Kanamycin resistance is our most frequent marker in our constructs and we prioritize using markerless / "clean" deletion strains whenever possible to minimize antibiotic resistance gene utilization. We use plasmids specific to bacteria and do not utilize any mammalian viral, lentiviral or other vectors that could potentially be used to transform human cells.
Blood, serum, saliva	We utilize commercially prepared human or other mammalian serum, saliva and blood samples. These are exposed to bacterial cells typically to measure complement activity of host immune proteins against bacteria. In some cases these fluids are used as a growth medium amendment and we may also utilize them in downstream immunofluorescence work to quantify human protein deposition onto the surface of bacteria of interest. After an IRB protocol is established we will utilize locally collected saliva. All work with these materials are performed in a BSC.
BSL-2 culturing	We routinely culture oral BSL-1 and BSL-2 species including: Streptococcus gordonii, S. mutans, S. mitis, S. cristatus, S. sanguinis, S. oralis, Corynebacterium matruchotii, C. durum, Haemophilus parainfluenzae, Neisseria mucosa, N. elongata, N. subflava, Veillonella parvula, V. atypica, V. dispar, and E. coli (BSL-1 only). We utilize liquid or solid medium cultures and grow them in BSL-2 conditions for the most part at 37C and in volumes <200mL, cell densities can be as high as 5×10^9 cells per mL. Cultures are typically sterilized via 1% bleach (final concentration) exposure for >10m or via autoclave (20m liquid cycle minimum). We utilize both ATCC "type" strains as well as novel isolate species that are within the same risk group.
Bacterial enumerati	Bacteria are frequently counted by serial dilution onto solid media and colonies are counted visually. Cell dilution materials (buffer, pipettes) and solid medium are autoclave sterilized afterwards. Work is performed aseptically in a BSC.

Cell culture	Mammalian cell lines will be grown on commercial medium in plastic cell culture flasks. Cell culturing and manipulation will be performed in a BSC.
Cell infection	Mammalian cell lines will be exposed to bacteria, both cell lines and bacteria will then be lysed and used in bacterial enumeration, or will be fixed in 4% PFA prior to imaging. All infection experiments will be performed in a BSC.
Live microscopy	Cells are occasionally imaged on microscope slide "wet mounts" using no more than 10 microliters of cell sample. Slides are immediately stored in biohazard sharps containers until sterilized via autoclave.

6.0 VIRAL VECTOR SECTION

6.1 Do you use viral vectors to deliver exogenous DNA to cells in culture or animals? If Yes select those that apply.

Select all that apply

- ☒ No, I do not use Viral Vectors
☐ AAV
☐ Lentivirus
☐ Adenovirus
☐ HSV
☐ Retrovirus
☐ Other (Describe below)

7.0 INFECTIOUS AGENTS (OTHER THAN VIRAL VECTOR USE)

7.1 Do you use wildtype or recombinantly modified infectious agents such as viruses, bacteria, protozoa, etc.?

☒ Yes
 ☐ No

7.2 Infectious Agent Data You can find information on most commonly used infectious agents on the "Pathogen Safety Data Sheets and Risk Assessment" website of the Public Health Agency of Canada.

Entry 1

Name	Escheria coli, Exempt strains K12, K-12 If you selected Other above, please provide the full name of the infectious agent below _____
Risk Group of Agent	RG1
Biosafety Level (Recommended and Requested)	Recommended BSL of Agent BSL 1 BSL requested by PI for the use of the this agent in this registration BSL 1

Is this a Select Agent	Is this a Select Agent (see list) <input type="radio"/> Yes <input checked="" type="radio"/> No
Immunization	Is immunization recommended or required to work with agent? <input type="radio"/> Yes <input checked="" type="radio"/> No Describe vaccine <input type="text" value="NA"/>
Medical Surveillance	Is medical surveillance recommended prior to handling? <input type="radio"/> Yes <input checked="" type="radio"/> No If yes, please describe required medical surveillance <input type="text"/>
Infection in humans	<input checked="" type="checkbox"/> Not known to cause disease in immunocompromised and healthy humans <input type="checkbox"/> Can cause disease in immuno-compromised humans but not healthy humans <input type="checkbox"/> Can cause disease in immuno-compromised humans and in healthy humans <input type="checkbox"/> Unknown if it can cause disease in healthy humans
Risk Assessment	Describe pathogenicity, disease incidence and severity <input type="text" value="NA"/> Describe routes of laboratory transmission <input type="text" value="NA"/> Describe Agents Stability (environmental stability, susceptibility to decontamination) <input type="text" value="susceptible to common antimicrobials, autoclaving"/> What is (1) the infectious dose; (2) the concentration per unit volume; (3) volume handled at one time? <input type="text" value="1 - NA, 2 max 10^9 cells per mL, 3 - max volume 1L handled at a time (<10 mL volume typical)"/> What is the origin of the agent (geographic location, host, etc) <input type="text" value="Human"/> Summarize any data available from animal studies (pathogenicity, infectivity and route, or any other information useful to assess risk to personnel). <input type="text" value="NA"/> Describe validated methods to allow lower BSL containment than standard for this organism <input type="text" value="NA"/>

Entry 2

Name

OTHER INFECTIOUS AGENT

If you selected Other above, please provide the full name of the infectious agent below

Corynebacterium matruchotii and C. durum

Risk Group of Agent

RG1

**Biosafety Level
(Recommended and Requested)**

Recommended BSL of Agent

BSL 1

BSL requested by PI for the use of the this agent in this registration

BSL 1

Is this a Select Agent

Is this a Select Agent (**see list**)

☐ Yes ☒ No

Immunization

Is immunization recommended or required to work with agent?

☐ Yes ☒ No

Describe vaccine

NA

Medical Surveillance

Is medical surveillance recommended prior to handling?

☐ Yes ☒ No

If yes, please describe required medical surveillance

Infection in humans

- ☒ Not known to cause disease in immunocompromised and healthy humans
- ☐ Can cause disease in immuno-compromised humans but not healthy humans
- ☐ Can cause disease in immuno-compromised humans and in healthy humans
- ☐ Unknown if it can cause disease in healthy humans

Risk Assessment

Describe pathogenicity, disease incidence and severity

NA

Describe routes of laboratory transmission

NA

Describe Agents Stability (environmental stability, susceptibility to decontamination)

Susceptible to standard bacteriocidal / static procedures

What is (1) the infectious dose; (2) the concentration per unit volume; (3) volume handled at one time?

NA, 10⁹/mL, 200mL or less

What is the origin of the agent (geographic location, host, etc)

Human

Summarize any data available from animal studies (pathogenicity, infectivity and route, or any other information useful to assess risk to personnel.

NA

Describe validated methods to allow lower BSL containment than standard for this organism

NA

Entry 3

Name

OTHER INFECTIOUS AGENT

If you selected Other above, please provide the full name of the infectious agent below

oral Veilonella species

Risk Group of Agent

RG1

Biosafety Level (Recommended and Requested)

Recommended BSL of Agent

BSL 1

BSL requested by PI for the use of the this agent in this registration

BSL 1

Is this a Select Agent

Is this a Select Agent (**see list**)

☐ Yes ☒ No

Immunization

Is immunization recommended or required to work with agent?

☐ Yes ☒ No

Describe vaccine

NA

Medical Surveillance

Is medical surveillance recommended prior to handling?

☐ Yes ☒ No

If yes, please describe required medical surveillance

Infection in humans

- ☒ Not known to cause disease in immunocompromised and healthy humans
- ☐ Can cause disease in immuno-compromised humans but not healthy humans
- ☐ Can cause disease in immuno-compromised humans and in healthy humans
- ☐ Unknown if it can cause disease in healthy humans

Risk Assessment

Describe pathogenicity, disease incidence and severity

NA

Describe routes of laboratory transmission

NA

Describe Agents Stability (environmental stability, susceptibility to decontamination)

Susceptible to standard bacteriocidal / static procedures, oxygen exposure.

What is (1) the infectious dose; (2) the concentration per unit volume; (3) volume handled at one time?

NA, 10^9 /mL, 200mL or less

What is the origin of the agent (geographic location, host, etc)

Human

Summarize any data available from animal studies (pathogenicity, infectivity and route, or any other information useful to assess risk to personnel.

NA

Describe validated methods to allow lower BSL containment than standard for this organism

NA

Entry 4

Name

OTHER INFECTIOUS AGENT

If you selected Other above, please provide the full name of the infectious agent below

Commensal oral Neisseria species, NOT meningiditis or diptheriae

Risk Group of Agent

RG2

Biosafety Level
(Recommended and Requested)

Recommended BSL of Agent

BSL 2

BSL requested by PI for the use of the this agent in this registration

BSL 2

Is this a Select Agent

Is this a Select Agent (**see list**)

☐ Yes ☒ No

Immunization

Is immunization recommended or required to work with agent?

☐ Yes ☒ No

Describe vaccine

NA

Medical Surveillance

Is medical surveillance recommended prior to handling?

☐ Yes ☒ No

If yes, please describe required medical surveillance

Infection in humans	<input type="checkbox"/> Not known to cause disease in immunocompromised and healthy humans <input checked="" type="checkbox"/> Can cause disease in immuno-compromised humans but not healthy humans <input type="checkbox"/> Can cause disease in immuno-compromised humans and in healthy humans <input type="checkbox"/> Unknown if it can cause disease in healthy humans
Risk Assessment	Describe pathogenicity, disease incidence and severity <div>Sepsis, endocarditis, upper respiratory infections, uncommon.</div> Describe routes of laboratory transmission <div>Ingestion, inhalation of droplets, mucosal exposure, needle stick</div> Describe Agents Stability (environmental stability, susceptibility to decontamination) <div>Stable at room temperature, easily killed by standard bacteriocidal methods.</div> What is (1) the infectious dose; (2) the concentration per unit volume; (3) volume handled at one time? <div>NA, 10⁹/mL, 200mL or less</div> What is the origin of the agent (geographic location, host, etc) <div>Human oral microbiota</div> Summarize any data available from animal studies (pathogenicity, infectivity and route, or any other information useful to assess risk to personnel. <div>Most species are BSL-1, BSL-2 N. mucosa can cause rare endocarditis.</div> Describe validated methods to allow lower BSL containment than standard for this organism <div>NA</div>

Entry 5

Name	<div>OTHER INFECTIOUS AGENT</div> If you selected Other above, please provide the full name of the infectious agent below <div>Commensal streptococci, S. mitis, oralis, sanguinis, gordonii, mutans</div>
Risk Group of Agent	<div>RG2</div>
Biosafety Level (Recommended and Requested)	Recommended BSL of Agent <div>BSL 2</div> BSL requested by PI for the use of the this agent in this registration <div>BSL 2</div>
Is this a Select Agent	

	<p>Is this a Select Agent (see list)</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p>
Immunization	<p>Is immunization recommended or required to work with agent?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Describe vaccine</p> <p>NA</p>
Medical Surveillance	<p>Is medical surveillance recommended prior to handling?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>If yes, please describe required medical surveillance</p> <p></p>
Infection in humans	<p><input type="checkbox"/> Not known to cause disease in immunocompromised and healthy humans</p> <p><input type="checkbox"/> Can cause disease in immuno-compromised humans but not healthy humans</p> <p><input checked="" type="checkbox"/> Can cause disease in immuno-compromised humans and in healthy humans</p> <p><input type="checkbox"/> Unknown if it can cause disease in healthy humans</p>
Risk Assessment	<p>Describe pathogenicity, disease incidence and severity</p> <p>Can infect damaged heart tissue, upper respiratory infections, rare in healthy individuals</p> <p>Describe routes of laboratory transmission</p> <p>Ingestion, inhalation of droplets, mucosal exposure, needle stick</p> <p>Describe Agents Stability (environmental stability, susceptibility to decontamination)</p> <p>Stable at room temperature, easily killed by standard bacteriocidal methods.</p> <p>What is (1) the infectious dose; (2) the concentration per unit volume; (3) volume handled at one time?</p> <p>NA, 10⁹/mL, 200mL or less</p> <p>What is the origin of the agent (geographic location, host, etc)</p> <p>Human oral microbiota</p> <p>Summarize any data available from animal studies (pathogenicity, infectivity and route, or any other information useful to assess risk to personnel.</p> <p>Some oral streptococci can cause endocarditis (rare). Conjunctivitis can occur if saliva is aspirated into the eye, upper respiratory infections as well. No major antibiotic resistances are dominant within this group.</p> <p>Describe validated methods to allow lower BSL containment than standard for this organism</p> <p>NA</p>

Entry 6

Name	<div>OTHER INFECTIOUS AGENT</div> <div>If you selected Other above, please provide the full name of the infectious agent below</div> <div>Haemophilus parainfluenzae</div>
Risk Group of Agent	<div>RG2</div>
Biosafety Level (Recommended and Requested)	<div>Recommended BSL of Agent</div> <div>BSL 2</div> <div>BSL requested by PI for the use of the this agent in this registration</div> <div>BSL 2</div>
Is this a Select Agent	<div>Is this a Select Agent (see list)</div> <div><input type="radio"/> Yes <input checked="" type="radio"/> No</div>
Immunization	<div>Is immunization recommended or required to work with agent?</div> <div><input type="radio"/> Yes <input checked="" type="radio"/> No</div> <div>Describe vaccine</div> <div>NA</div>
Medical Surveillance	<div>Is medical surveillance recommended prior to handling?</div> <div><input type="radio"/> Yes <input checked="" type="radio"/> No</div> <div>If yes, please describe required medical surveillance</div> <div></div>
Infection in humans	<div><input type="checkbox"/> Not known to cause disease in immunocompromised and healthy humans</div> <div><input type="checkbox"/> Can cause disease in immuno-compromised humans but not healthy humans</div> <div><input checked="" type="checkbox"/> Can cause disease in immuno-compromised humans and in healthy humans</div> <div><input type="checkbox"/> Unknown if it can cause disease in healthy humans</div>
Risk Assessment	<div>Describe pathogenicity, disease incidence and severity</div> <div>Can present in rare endocardial infections, upper respiratory infections and STI's. Incidence is uncommon and severity is low if treated early.</div> <div>Describe routes of laboratory transmission</div> <div>Ingestion, inhalation of droplets, mucosal exposure, needle stick</div> <div>Describe Agents Stability (environmental stability, susceptibility to decontamination)</div> <div>Stable at room temperature, easily killed by standard bacteriocidal methods.</div> <div>What is (1) the infectious dose; (2) the concentration per unit volume; (3) volume handled at one time?</div> <div>NA, 10⁹/mL, 200mL or less</div>

What is the origin of the agent (geographic location, host, etc)

Human oral microbiota

Summarize any data available from animal studies (pathogenicity, infectivity and route, or any other information useful to assess risk to personnel.

Some strains can cause STI's, upper respiratory infections or endocarditis. All are infrequent and no major antibiotic resistant strains are prominent or used in our work.

Describe validated methods to allow lower BSL containment than standard for this organism

NA

7.3 Describe Transactive or Infectious Proteins (e.g. Prion Proteins)

Protein Name / Agent	Cellular Target	Hazards of Exposure
No records have been added		

8.0 HUMAN AND /OR PRIMATE DERIVED MATERIAL

8.1 Human and /or Primate materials

Indicate ALL that apply

- ☒ Human blood, body fluids, tissues, etc.
- ☒ Human Cell Lines (primary or immortal)
- ☐ Human ES cells
- ☐ Primate blood, body fluids tissues etc
- ☐ Primate cell lines
- ☐ None of the above

8.2 COLLECTION / ANALYSIS OF HUMAN SOURCE MATERIAL - OTHER

Please list below any primary human source (clinical specimens) or primate material used in the research study.

We use commercially available human serum and blood from scientific vendors. We also utilize human cell lines available from commercial vendors such as ATCC. Donated human saliva and tooth biofilm "plaque" are also primary sources of microbes for isolation.

8.3 ORGAN, TISSUE OR CELL CULTURES (OTCC)

This table is intended for listing organ, tissue or cell cultures (OTCC) with bloodborne pathogen potential (i.e. those from a human or primate source).

Origin / Name (Co7, HeK293, etc.)	Cell Type	Recipient of rDNA / microbe or Virus	Comment (any other data useful to IBC regarding safety issues)
Select Primate type		Recipient of microbe /Virus?	
<input checked="" type="radio"/> Human			

<input type="radio"/> Primate Name of Cell Line <input type="text" value="A549"/>	<input type="radio"/> Primary <input checked="" type="radio"/> Immortal	<input checked="" type="radio"/> Yes <input type="radio"/> No Recipient of rDNA <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="text" value="A549 airway epithelial cells."/>
Select Primate type <input checked="" type="radio"/> Human <input type="radio"/> Primate Name of Cell Line <input type="text" value="HL-60"/>	<input type="radio"/> Primary <input checked="" type="radio"/> Immortal	Recipient of microbe /Virus? <input checked="" type="radio"/> Yes <input type="radio"/> No Recipient of rDNA <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="text" value="HL-60 myeloid precursor cell line, differentiates into neutrophils."/>

9.0 ANIMALS

9.1 ANIMALS

Indicate if your research involves the use of animals (this includes **wild-type** exposed to biological agents (human cells, viruses, micro-organisms etc.) or **transgenic animals** of any species.

- ☒ No Animals used (mammals, fish, arthropods, insects, etc)
- ☐ Transgenic rodents: purchased (company or collaborator) and/or bred at ABSL1 and NOT exposed to any biohazard (r/sNA, virus, microbe, human or non-human-primate cell line)
- ☐ Transgenic: All other animals (vertebrate and non-vertebrate)
- ☐ Transgenic Animal Production (mammals, fish, arthropods, insects, etc)
- ☐ Animals are exposed to r/sNA or biohazards (virus, microbe, etc.) (vertebrate and non-vertebrate)
- ☐ Non-Mammalian Animals (fish, arthropods, insects, worms etc)

10.0 TOXINS OF BIOLOGICAL ORIGIN

10.1 TOXINS USE?

Does your research involve the use of biologically-derived toxins? Indicate if you **purchase** and or **produce** toxin

- ☒ No Toxin use
- ☐ Purchase of Toxin
- ☐ Production of Toxin
- ☐ Toxin expressed transiently in animal or cell line

11.0 PLANT USE

11.1 Do you use whole plants?

☐ Yes ☒ No

12.0 HUMAN GENE TRANSFER

12.1 Human Gene Transfer Trial

- If an IB and full protocol were not provided by the sponsor, or if your study is independent, the attachments should be written to include:
- A scientific abstract.
- The proposed clinical protocol, including tables, figures, and any relevant publications.
- Summary of preclinical studies conducted in support of the proposed clinical trial or reference to the specific section of the protocol providing this information.
- Product description, for instance:
 - Derivation of the delivery vector system including the source (e.g., viral, bacterial, plasmid), associated modifications (i.e., deletions to attenuate or self-inactivate, encapsulation in any synthetic complex, changes to tropisms), and previous clinical experience with the system
 - Genetic content of the transgene or nucleic acid delivered, including the species source of the sequence, and whether any modifications have been made (e.g., mutations, deletions, truncations)
 - Any other material to be used in preparation of the agent (vector and transgene) to be administered to research subjects (e.g., helper virus, packaging cell line, carrier particles)
 - Methods for replication-competent virus testing
 - Intended ex vivo or in vivo target cells and transduction efficiency
 - Gene transfer agent delivery method

Will human subjects be used in Human Gene Transfer trials?

☐ Yes ☒ No

13.0 PI RISK ASSESSMENT SUMMARY

13.1 PI Risk Assessment Summary

Summarize the types of experiments and **your assessment of there risk to personnel and the environment**. Be sure to include risk assessment for each of the experiment types in the Technical Summary above. Be sure to include any information on **select agent** use. Detailed experimental protocols should not be included, but be sure to describe any special risks of the agents of which the IBC should be aware.

This proposal describes our labs use of RG-2 and RG-1 organisms. All species used here are common residents of the human oral microbiome or laboratory E. coli strains. All personnel in the lab will receive both applicable basic biosafety and lab safety training as well as bloodborne pathogen exposure training. Further, the PI, Dr. Ramsey will instruct each lab member on proper handling procedures for RG-2 organisms including inoculation, aseptic transfers, waste disposal and culture sterilization procedures. Lab members will be notified that the RG-2 organisms we use present a risk to immunocompromised individuals and/or those with congenital or recent heart defects. All RG-2 organisms used here are easily treated with standard antibiotic therapy. We have placed administrative controls on risk by limiting the volume of culture to 200mL or less and physical controls by minimizing the use of sharps and mandatory BSC utilization for culture work whenever possible. The RG-2 organisms we use here represent no / very minimal risk to most healthy individuals and the culture methods we use do not allow for an elevated risk of aerosolization or sharps exposure. For tissue culture based work we utilize BSL-2 / RG2 procedures throughout and work under the presumption that the cell lines / medium may contain infectious agents. We utilize standard commonly available lab cell lines that have not been typically shown to carry infectious material apart from RG-2 organisms described above that we may infect these cell lines with. All handling and sterilization will be carried out according to BSL2/RG-2 guidelines. Included in this package are lab SOP's for spill response, biohazard exposure and a bloodborne pathogen control plan. There are no special risks of these organisms to healthy individuals. We do not use select agents in this laboratory.

13.2 Do you use molecular cloning (standard DNA cloning) or synthesize large (>100bp) DNA or RNA fragments for use in your studies.

☒ Yes ☐ No

13.3 Are there any increased risks with the recombinant or synthetic DNA molecules you will clone/use? Examples:

- expression of oncogenes
- Toxin expression
- Cloning fragments from RG 2,3 or 4 agents

☒ Yes ☐ No

Please explain the nature of the plasmid/vector/insert combination and the nature of the increased risk.
Example: The mutant form of the p53 oncogene will be expressed using a eukaryotic promotor and injected into mice so care is needed not to inject into investigator.

We may clone and complement genes into bacteria to restore functions to gene deletion strains that could inadvertently enhance their ability to survive in a human host. Care will be taken with these strains to limit their total amounts, restrict their use to only when necessary, and to limit exposure to the personnel culturing them by strict adherence to our BSL2/RG-2 guidelines. We do not feasibly expect any significant concern for enhanced virulence in these species after any genetic manipulation. No toxins or other known cytotoxic elements are planned for cloning and expression in these strains at this time. We will endeavor to utilize inducible or native promoters to express our complementation strains to limit the production of any host material that may alter their properties.

14.0 RISK GROUP AND BIOSAFETY LEVEL

14.1 RISK GROUPS

Assess the appropriate pathogenicity of the organism, mode of transmission and host range for all agents utilized in the work described in this IBC application. Select all applicable Risk Group(s) from the list.

Examples:

RG1: E.coli K12, Lab strains of *S. cerevisiae*,

RG2: Human cell lines.

RG3: Lentiviral vectors, Influenza virus, agents that require BSL3 containment.

RG4: Ebola (these agents cannot be handled at U of Louisville)

Go Here for comprehensive data on most biohazards (right click and open new window) [Pathogen Safety Data Sheets and Risk Assessment](#) (Canada)

- ☒ Risk Group 1: Agents are NOT associated with disease in healthy adult humans (lab strains of *E.coli*, yeast, probiotics)
- ☒ Risk Group 2: Agents ARE associated with human disease that is rarely serious for which preventive or therapeutic interventions ARE OFTEN available (hepatitis B, seasonal influenza))
- ☐ Risk Group 3 : Agents ARE associated with serious or lethal human disease for which preventive or therapeutic interventions MAY be available (Lentivirus vectors; Japanese Encephalitis Virus)
- ☐ Risk Group 4: Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are NOT USUALLY available. NOT ALLOWED AT U OF L
- ☐ No organisms used

14.2 BIOSAFETY LEVELS and CONTAINMENT PRACTICES

Assess the appropriate physical and biological containment. Mark the appropriate biological safety level(s) for handling the infectious agents and/or recombinant/synthetic materials. Select all applicable biosafety level(s).

- ☒ BSL-1: Low risk agents (generally risk group 1) of minimal potential hazard to laboratory personnel and the environment • Work is done on open bench tops; physical containment devices are usually not required • Standard microbiological practices are observed (washing hands and disinfecting exposed surfaces upon completion of work; all liquid and solid wastes potentially contaminated with recombinant or synthetic nucleic acids are decontaminated before disposal) • Biohazard signs should be posted
- ☒ BSL-2: Moderate risk agents (generally risk group 2; Lentiviral vectors) of moderate potential hazard

to laboratory personnel and the environment (NOTE: Human cell lines must be handled at BSL2 containment).

- ☐ BSL-3: Indigenous or Exotic agents which may cause serious or potentially lethal disease, via respiratory exposure (inhalation); High risk agents (generally risk group 3), BSL-3 containment facilities, and practices

14.3 Biosafety Level 1 Practices

- ☒ Follow practices as described below
☐ Deviate from practices described below, please explain:

Standard Biosafety Level 1 practices:

1. **Handwashing:** Hands must be washed immediately or as soon as feasible after removing gloves or other personal protective clothing.
2. **Personal Protective Equipment (PPE):** PPE such as gloves, safety glasses and a laboratory coat should be worn whenever biological work is conducted in the laboratory. No sandals are allowed in the laboratory.
3. **Use of Sharps:** Minimize the use of and exposure to sharps in the workplace. Never recap, bend or shear needles. As often as possible, replace glassware with less breakable materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
4. **Food and Beverage:** Eating, drinking, storing food and drink for human consumption, smoking, applying cosmetics or lip balm and handling contact lenses in the laboratory or other work areas is prohibited.
5. **Aerosol Generation:** Any procedures that could potentially generate aerosols or other inhalation hazards must be performed in a manner that will minimize airborne pathogen transmission.
6. **Proper Labeling:** Place a color-coded label incorporating the universal biohazard symbol on any potentially contaminated equipment or work surface to warn others of biohazard contamination that may not be easily visible. This includes freezers, refrigerators and incubators.
7. **Autoclave Safety:** Always wear heat-resistant gloves, goggles or safety glasses, and a laboratory coat when opening an autoclave. Be sure to allow the superheated steam to exit before attempting to remove the contents.
8. **Spills:** Always clean spills from the periphery of the spill towards the center, after placing paper towels over the spill. Make sure that the cleaning materials are disposed of in an appropriate manner. Report all spills to the Biological Safety Office.
9. **Mouth Pipetting:** Mouth pipetting may lead to accidental ingestion of biological specimens and is strictly prohibited.
10. **Decontamination Procedures:** A fresh 0.5 – 1 percent sodium hypochlorite (a 1 to 10-20 dilution of household bleach) will be used to decontaminate equipment, work surfaces, and liquid waste. In locations where bleach would cause corrosion, another appropriate disinfectant should be used to decontaminate. All solid waste shall be autoclaved prior to disposal.
11. **Local Transport of Infectious Materials:** All infectious materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities.
12. **Storage:** All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space (e.g., freezers and refrigerators).
13. **No open-toed shoes, shorts, or short skirts are allowed in the laboratory for all biosafety levels.**

14.4 Biosafety Level 2 Practices

- ☒ Standard Biosafety Level 2 practices:
☐ Deviate from Standard BSL2 practices described, please explain:

Standard Biosafety Level 2 practices: (Those in blue extend standard BSL1 practices)

1. **Local Transport of Infectious Materials:** All infectious materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities. Packaging and labeling must comply with the IATA dangerous goods or DOT hazardous materials regulations.
2. **Bloodborne Pathogens:** All PIs using human blood or blood products, unfixed tissue, body fluids or organ or cell cultures of human origin will follow the procedures outlined in the Bloodborne Pathogen Exposure Control Plan.
3. **No plants shall be allowed in the laboratory.**
4. **Attention to sharps;** use of safety needles when possible.
5. **Transport of Select Agents/Toxins:** EH&S must be notified of all transfers or shipments off campus.
6. **SOPs:** The PI is responsible for developing laboratory SOPs and training laboratory staff in specific procedures.
7. **Biological Safety Cabinets:** Procedures with a potential for creating aerosols or splashes must be conducted inside a biological safety cabinet or with other appropriate personal protective equipment as determined by the Biosafety Office (BSO).

Above **PLUS** Biosafety Level 1 Practices (below)

1. **Handwashing:** Hands must be washed immediately or as soon as feasible after removing gloves or other personal protective clothing.
2. **Personal Protective Equipment (PPE):** PPE such as gloves, safety glasses and a laboratory coat should be worn whenever biological work is conducted in the laboratory. No sandals are allowed in the laboratory.
3. **Use of Sharps:** Minimize the use of and exposure to sharps in the workplace. Never recap, bend or shear needles. As often as possible, replace glassware with less breakable materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
4. **Food and Beverage:** Eating, drinking, storing food and drink for human consumption, smoking, applying cosmetics or lip balm and handling contact lenses in the laboratory or other work areas is prohibited.
5. **Aerosol Generation:** Any procedures that could potentially generate aerosols or other inhalation hazards must be performed in a manner that will minimize airborne pathogen transmission.
6. **Proper Labeling:** Place a color-coded label incorporating the universal biohazard symbol on any potentially contaminated equipment or work surface to warn others of biohazard contamination that may not be easily visible. This includes freezers, refrigerators and incubators.
7. **Autoclave Safety:** Always wear heat-resistant gloves, goggles or safety glasses, and a laboratory coat when opening an autoclave. Be sure to allow the superheated steam to exit before attempting to remove the contents.
8. **Spills:** Always clean spills from the periphery of the spill towards the center, after placing paper towels over the spill. Make sure that the cleaning materials are disposed of in an appropriate manner. Report all spills to the Biological Safety Office.
9. **Mouth Pipetting:** Mouth pipetting may lead to accidental ingestion of biological specimens and is strictly prohibited.
10. **Decontamination Procedures:** A fresh 0.5 – 1 percent sodium hypochlorite (a 1 to 10-20 dilution of household bleach) will be used to decontaminate equipment, work surfaces, and liquid waste. In locations where bleach would cause corrosion, another appropriate disinfectant should be used to decontaminate. All solid waste shall be autoclaved prior to disposal.
11. **Local Transport of Infectious Materials:** All infectious materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities.
12. **Storage:** All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space (e.g., freezers and refrigerators).
13. **No open-toed shoes, shorts, or short skirts are allowed in the laboratory for all biosafety levels.**

14.5 Biosafety Level 2+ practices

15.0 PERSONAL PROTECTIVE EQUIPMENT (PPE) & LABORATORY PRACTICES

15.1 PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal Protective Equipment (PPE) provides a barrier against skin, mucous membrane or respiratory exposure to biohazardous agents and prevents the spread of contamination.

Select all items of PPE that are utilized in this research study.

- ☒ Gloves
- ☒ Lab Coats, Front-fastened coats suitable for BSL-1 and 2.
- ☐ Lab Coats/Gowns: Back-closure or wrap-around coats with snug-fitting cuffs; suitable for BSL-2 or 3.
- ☐ Scrubs
- ☐ Tyvec coverall or jumpsuit
- ☒ Protective eyewear: safety glasses with side protectors or eye goggles.
- ☐ Face shield.
- ☐ N-95 respiratory protection
- ☐ Powered Air Purifying Respirator (PAPR)
- ☒ Shoes: closed-toe shoes
- ☐ Shoe covers

15.2 LABORATORY PRACTICES

- ☒ Needles and syringes are not recapped or reused
- ☒ Sharp containers are only 2/3 full before disposal
- ☐ Chemical restraint (animals)
- ☐ Physical restraint (animals)
- ☒ Biological material transported outside of the laboratory in rigid container with lid and biohazard symbol
- ☐ Biological material transported outside of the laboratory in other container.
- ☒ Vortexing/mixing/centrifugation performed in tightly capped tubes
- ☐ Centrifugation performed in aerosol containment capsules for BSL3 containment
- ☒ Pipetting in Biosafety Cabinet
- ☐ Practices disrupt normal airflow of Biosafety Cabinet (Describe below)
- ☐ Other non-standard for microbial lab techniques performed on bench top (Describe below)

15.3 ENGINEERING CONTROLS

Engineering controls include the use of safety equipment as well as the laboratory facility design.

Select all safety equipment or facility features that are applicable to this research study.

- ☒ Biological Safety Cabinet (BSC)
- ☒ Centrifuge equipped with safety-seal rotor and/or buckets.
- ☒ Sharps Waste Container: puncture-resistant, biohazard-labeled, leak-proof sides and bottom.
- ☒ Biohazard waste container: biohazard-labeled, fiber board box, lined with red, biohazard bag.
- ☒ Contaminated serological pipet/pipet tip waste collection: leak-proof, puncture-resistant tray with disinfectant solution.
- ☒ Broken glass waste container: plain, fiber board box lined with plastic bag; for non-biohazardous broken glass, pipets, pipet tips.
- ☒ Transport container: break-resistant, leak-resistant, locking-lid/secure-closure secondary container to transport agents between facility locations.

15.4 Health Surveillance/Immunization

- ☒ Hepatitis B Vaccine offered to all lab personnel
- ☐ Serum sample banking: Consult with Environmental Health and Safety - Biological Safety Office
- ☐ Custom health surveillance/immunization program
- ☐ Orthopoxviruses (vaccinia and others)

☐ Other Vaccine

15.5 Describe other techniques performed in Biosafety Cabinet and on top of Lab Bench

Inoculation and aseptic transfer of cell and bacterial cultures as well as spreading cultures onto solid agar medium will be performed in BSC cabinets in Room 341-343 in the School of Dentistry. Lab bench utilization of cells will only be performed with cells in sealed vials or with cells post exposure to cell lysis reagents, effectively sterilizing them. One exception will be to utilize 2mL optical cuvettes which will be filled with no more than 1mL of bacterial culture for optical density measurements. Cuvettes will be filled in the BSC and transported in a covered container to the spectrophotometer. Cuvettes are disposable and will be placed into BSL2 waste containers after measurements are made. Lab personnel will wear all BSL-2 PPE when handling cultures in the BSC and at the bench.

16.0 LOCATION & EQUIPMENT

16.1 Research Location(s) Please list the building, room numbers, research activities performed in that space, and the highest biosafety level for that space and research activity. Include Facilities and rooms where animals will be exposed to or housed after exposure to biohazardous agents.

Building Name/Rm #	Description of Activities	Maximum Biosafety Level
Building Name <input type="text" value="School of Dentistry"/> Room # <input type="text" value="341"/>	All protocol activities described will take place here with the exception of microscopy (rm 343). Our primary BSC is in this room and all BSC related work will take place here.	<input type="text" value="BSL2/ABSL2"/> Agent Used Here? <input checked="" type="radio"/> Yes <input type="radio"/> No Agent Stored here? <input checked="" type="radio"/> Yes <input type="radio"/> No
Building Name <input type="text" value="School of Dentistry"/> Room # <input type="text" value="343"/>	Non-BSC and microscopy work will take place here.	<input type="text" value="BSL2/ABSL2"/> Agent Used Here? <input checked="" type="radio"/> Yes <input type="radio"/> No Agent Stored here? <input checked="" type="radio"/> Yes <input type="radio"/> No
Building Name <input type="text" value="School of Dentistry"/> Room # <input type="text" value="342"/>	BSC related work will take place here in the 2nd BSC in our space. Centrifugation of live culture material will also take place here.	<input type="text" value="BSL2/ABSL2"/> Agent Used Here? <input checked="" type="radio"/> Yes <input type="radio"/> No Agent Stored here? <input checked="" type="radio"/> Yes <input type="radio"/> No

16.2 PHYSICAL CONTAINMENT EQUIPMENT

Indicate the location and type of any biosafety cabinet(s) used.

Building	Room Number	Class and Type	Exhausted to Outside
<input type="text" value="School of Dentistry"/>	<input type="text" value="341"/>	NSF49/ MFTR Spec model Forma 1128 BSC	<input type="radio"/> Yes <input checked="" type="radio"/> No

School of Dentistry

342

NSF49/ MFTR Spec
model Nuaire 201-
430

☐ Yes ☒ No

17.0 DECONTAMINATION AND WASTE DISPOSAL

17.1 Decontamination and Waste Disposal

Lab or Surface Disinfectant

- ☒ Freshly prepared 10% commercial bleach (0.5% sodium hypochlorite) with 10 minutes contact time
- ☒ Other Disinfectant (Provide details below)

17.2 Provide Name, Concentration and Contact Time for each "other" agent used.

Name	Contact Time (minutes)	Concentration
Ethanol (follow up / secondary)	5 minutes, followed by soap and water. ONLY used when corrosion is a concern.	70% Ethanol 30% water
MicroChem Plus disinfectant	10 minutes	2%

17.3 Solid Waste and Sharps

- ☒ Materials will be autoclaved for a minimum of 15 minutes, at 121°C, under 15 psi (pounds per square inch)
- ☐ Animal carcasses are placed in red biohazard bags and returned to animal the animal facility for disposal
- ☐ Animal carcass disposal, Other (describe below)
- ☒ Infectious Sharps: Puncture resistant container with a biohazard symbol: autoclaved prior to disposal by autoclaving or placing in red biohazard bag and box
- ☐ Human Tissue (Describe below)
- ☐ Other (Describe below)

17.4 Liquid Waste

- ☒ Freshly prepared 10% commercial bleach (0.5% sodium hypochlorite) with 30 minutes contact time
- ☒ Other (describe below)

Describe other methods of liquid Waste Disposal

Autoclaving of small volumes of liquid culture (<5mL) may occur to prevent frequent manipulation of many small samples. This is done to minimize risk of handling samples to the researcher. Autoclaving will be used at appropriate minimums or greater (15 mins, 121C, 15 psi).

17.5 Equipment decontamination procedure

Please detail how you will decontaminate equipment

Wipedown with 2% MicroChem, 10 minute contact time pause and then wipedown with 70% ethanol.

18.0 RECOMBINANT AND/OR SYNTHETIC NUCLEIC ACID USE (r.sNA)**18.1 Does your Research Involve the Use of Recombinant and/or Synthetic Nucleic Acid Molecules (r.sNA) or Transgenic Animals?** NIH Guidelines NIH FAQ Sheet☒ Yes ☐ No**18.2 Does your research involve the introduction of a clinically used antibiotic resistance gene into a pathogenic microorganism or virus (this includes into the genome of the organism or on a plasmid)? NOTE: this does not include E.coli K12 strains used commonly in standard cloning experiments.**☐ Yes ☒ No**18.3 Select ALL the NIH Guideline categories that are appropriate for this proposal**

Check if Appropriate	Review Requirements	Description / Examples
<input type="checkbox"/> III-A	Experiments requiring IBC, RAC review, and/or NIH Director or are major actions.	Transfer of a drug resistance trait to pathogenic micro-organisms that are not known to acquire the the trait naturally, if such acquisition could compromise the ability to control disease agents in Humans, veterinary medicine, or agriculture, will be reviewed by the RAC. Typically th is invovles adding a clini9ncally used antibiotic into an infectious organism.
<input type="checkbox"/> III-B	Experiments requiring IBC, RAC review, and/or NIH Director and/or NIH/OBA Review and approval before initiation.	Experiments involving the cloning of toxin molecules with LD50 of less than 100 nanograms per kilogram body weight (see link above). Experiments that have been approved as Major Actions under Sec. III-A-1-a of the NIH Guidelines.
<input type="checkbox"/> III-C	Experiments requiring IBC, RAC review, and/or NIH Director and/or NIH/OBA Review and approval before initiation.	Human Gene Therapy Trials (USE IBC-Human Studies form)
		<ul style="list-style-type: none">• Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.• Experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals.

☑ III-D

Experiments requiring IBC approval **before** use

- Production of transgenic animals
- Use whole plants
- LESS COMMON EXAMPLES:
- Introduction of recombinant DNA into risk group 2, 3 or 4 agents (mostly BSL2, BSL3, and BSL4 organisms) (BSL4 not allowed at U of L)
- Experiments in which DNA from risk group 2, 3 or 4 agents (mostly BSL2, BSL3, and BSL4 organisms) is transferred into nonpathogenic prokaryotes or lower eukaryotes
- **Experiments involving more than 10 liters of culture**

☑ III-E

Experiments that require IBC notice **simultaneous** with initiation

- Experiments involving the formation of recombinant or synthetic molecules containing **no more than 2/3** of the genome of any eukaryotic virus
- Experiments involving the creation of recombinant DNA molecules in tissue culture
- Experiments that don't fall into any other category, such as experiments involving the introduction of risk group 1
- DNA/RNA into risk group 1 organisms such as E. coli BL21 (not K12 strain!)

- Oligos, siRNA, shRNA, (that do not produce a toxin or are designed to integrate or replicate.
- Most standard cloning and expression vector manipulations in E.coli K12 (NOT involving oncogene, tumor
- suppressor or toxins)
- Purchase of transgenic animals.
- Breeding two transgenic rodents

<input checked="" type="checkbox"/> III-F	Experiments Exempt From NIH Guidelines but that Require Notification of the IBC	in which the offspring remain at ABSL1 containment. <ul style="list-style-type: none"> • Escherichia coli K-12 Host-Vector Systems. • Saccharomyces Host-Vector Systems. • Kluyveromyces Host-Vector Systems. • Bacillus subtilis OR Bacillus licheniformis Host-Vector Systems. • Extrachromosomal Elements of Gram Positive Organisms 	
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19.0 DUAL USE RESEARCH OF CONCERN

19.1 Dual Use Questions - Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. ([link to NIH](#))

- ☐ Enhances the harmful consequences of the agent or toxin
- ☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
- ☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- ☐ Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- ☐ Alters the host range or tropism of the agent or toxin
- ☐ Enhances the susceptibility of a host population to the agent or toxin
- ☐ Generates or reconstitutes an eradicated or extinct agent or
- ☒ No Dual Use Concerns

20.0 FIRST AID IF EXPOSURE OCCURS

20.1 FIRST AID / PROPHYLAXIS

Are there special situations regarding prophylactic treatment if exposure to any agent in this protocol were to occur?

☐ Yes ☒ No

21.0 SHIPPING

21.1 Do You Ship Select or Infectious agents to another Institution?

☒ Yes ☐ No

Describe shipping method. **Select agents MUST be shipped by DEHS authorized personnel**

Shipment of BSL2 species used here may be necessary to send strains to collaborators within the 48 contiguous states in the USA. Shipment of these strains will be done according to procedures for "Category B" samples and will defer to instructions at <https://louisville.edu/dehs/biological-safety/biological-safety-files/flowchart-for-shipping-biological-materials> where applicable. Whenever possible strains will be shipped on solid medium sealed shut with parafilm and in triply redundant plastic sealant

bags which contain absorbent material in a greater amount than any solid or liquid medium present. Samples are marked with DOT required biohazardous information and labelling. Sealed cryovials of strains may be required for overnight shipment on dry ice and will be stored within triply redundant plastic sealed containers containing absorbent material and marked with relevant DOT labeling for Dry Ice and Biohazardous materials. We prefer to ship through DEHS personnel if possible even though these are not select agents.

22.0 ADDITIONAL ITEMS

22.1 Are there any issues related to your work that needs to be shared with the IBC and has not already been included in registration?

☐ Yes ☒ No

DEPARTMENT OF University of Louisville
ENVIRONMENTAL HEALTH 1800 Arthur St
AND SAFETY Louisville KY 40208-2729

January 24, 2025

RE: IBC 24-409: *Bacterial multispecies interactions within the human oral microbiome*
Effective 01/24/2025; Expires 01/24/2030

Dr. Ramsey,

The Institutional Biosafety Committee has reviewed and approved your IBC registration IBC 24-409 for a period of five (5) years. During the approval period, it is your responsibility to notify the IBC of any changes to your IBC registration via a Modification Request in iRIS. Furthermore, you must submit a renewal of your IBC registration before the end of the approval period to avoid lapses in your research activities.

As a reminder, it is also your responsibility to ensure that all individuals performing activities under this registration maintain required training for the duration of the approval period. Specifically, if you and your personnel are working with human or primate source materials, annual Bloodborne Pathogen training is required. The Department of Environmental Health and Safety offers online training courses through SciShield at <https://louisville.scishield.com>. Finally, you as the Principal Investigator must ensure that your personnel receive and document the completion of agent specific and laboratory specific training.

If you have any questions, please contact the Biosafety Office at 852-6670 or biosafe@louisville.edu.

Sincerely,

Tim Mulliger

Lab Safety and IBC Coordinator
Department of Environmental Health and Safety