**SIDRA MEDICINE INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

**REGISTRATION/ APPROVAL APPLICATION**

**Research involving any of the agents listed below must be approved by the Sidra Medicine Institutional Biosafety Committee (IBC) prior to initiation:**

* Pathogens and potential pathogens of humans, animals or plants.
* Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines).
* Recombinant DNA (and RNA) including the creation or use of transgenic plants and animals.
* Any material requiring Health institutes import license or a customs permit.
* Any material that is considered extremely toxic or a hazardous substance that requires work at a Biosafety Level 3.
* Addition of new in vivo work not previously approved by the IBC (previous approval was for in vitro work only).

**Submission guideline:**

* The Principal Investigator (PI) of the research project is responsible for completing all appropriate parts of this registration document and for notifying the IBC when information submitted in this document changes, such as laboratory location, research personnel, procedures, funding, biosafety level (either upgrade or downgrade), etc. If such changes occur, the PI will be required to fill out the Amended application.
* Any submission received after the 10th of each month will be postponed to next month.
* Only typed forms will be accepted, the application must be completed, signed by all appropriate personnel and approved by the department director and submitted to the **IBC coordinator.**
* At the time of submission, you are asked to also submit all grant proposals pertaining to your research and a copy of certification for Safety training and biosafety cabinets Failure to provide all information requested, including requested signatures, will lead to a delay in processing your request. If further instructions are necessary.

**Annual renewal reporting:**

To maintain continuing IBC approval, protocol update reports are submitted annually as follows:

* The Investigators should complete the whole application.
* The Investigators are responsible for updating contact information with the IBC Office, and certification for Safety training and biosafety cabinets.
* Institutional focal point should send courtesy renewal notices via email prior to expiration of the approval for the IBC office and the Investigators.
* Unmodified renewal applications should be reviewed and approved by the Institutional focal point and will be expedited from full committee review.
* In cases where IBC renewal applications are submitted late, resulting in delayed renewal (post expiry date), the approval duration will be reduced accordingly to ensure that triennial renewal dates do not extend beyond three years from the initial approval date.
* Triennial renewal submissions and requests for a change in Principal Investigator (PI) will prompt a laboratory inspection prior to approval.

**Termination:**

Protocols that are not renewed on the day of the expiration are automatically expired at 11:59 pm that same day.

• Expired or Terminated protocols cannot be “re-started” once the expiration is in effect.

• To reactivate an expired protocol, a new application must be completed (refer to the above renewal reporting).

|  |  |  |
| --- | --- | --- |
| **For IBC Office use only** | | **Principal Investigator**  **Wouter Hendrickx** |
| **Date: 18/05/2025** | **Protocol Number:** |

**Instructions:**

* *All Applications MUST be Typed.*
* *For any section that is not applicable, kindly select/write (N/A). The committee will not review application forms that are altered or missing sections.*
* *Often filled application forms are sent back to researchers for additional information. If care is taken to provide sufficient detail in the original Application, then delays in their approval can be avoided.*
* *It is sole responsibility of PI to:*

1. *not involve any member in this project other than those mentioned in this form*
2. *perform all project activities at designated labs*
3. *inform IBC in case of biohazard related incidence(s)*

* *This application form along with all supporting documents shall be “typed” in standard English and submitted to IBC through IRBNet (Umbrella Project Information Form must be submitted along with this application if multiple SDRs are included in single Application).*
* *To add additional rows to the tables, please ‘right click’ inside the last column and add rows below and copy the contents.*

**A. Submission Information**

|  |  |  |
| --- | --- | --- |
| **Project Submission Indicate Yes/No in check boxes** | **Yes** | **No** |
| 1. Is this an existing (approved) IBC application?  * If NO (e.g. this is a new application) skip to the next section |  |  |
| 1. Provide the protocol number for the existing/renewing IBC approved project: | | |
| 1. Have there been any changes in the investigator contact information since the last IBC review interval?  * If YES, section B must be updated to reflect the new Principal Investigator’s information |  |  |
| 1. Have there been any changes in the alternate contact information since the last IBC review interval?  * If YES, Section B must be updated to reflect the new information |  |  |
| 1. Have there been any changes to the funding of this research since the last IBC review interval?  * If YES, Section D question 7 must also be updated to reflect the new information |  |  |
| 1. Have there been any changes in the location of the research facilities since the last IBC review interval? Did the lab relocate to another building or room?  * If YES, Section O must be updated to reflect the new information |  |  |
| 1. Have there been any changes or additions to the recombinant or synthetic nucleic acid molecules or vectors since the last IBC review interval?  * If YES, Section F and K must be updated to reflect the new information included with the previously described materials and procedures * Highlight the updated information in the section |  |  |
| 1. Have there been any changes or modifications to any linked IACUC protocols since the last IBC review interval?  * If YES, Sections D and M must be updated, as applicable |  |  |
| 1. Are there any changes in the title(s) for this continuing IBC protocol?  * If YES, Section D must be updated to reflect the new title information |  |  |
| 1. Have there been any reported injuries/exposures since the last IBC review interval?  * If YES, attach a copy of the report, If NO, skip to question, below |  |  |

**B. Principal Investigator Information**

|  |
| --- |
| Principal Investigator: Wouter Hendrickx |
| Project title: Recapitulation of the human microbiome risk score in mice to elucidate its mechanism of action |
| Department: TBI |
| Phone: 40037409 |
| Email: whendrickx@sidra.org |
| Laboratory safety Representative: Ayesha Jabeen |
| Laboratory safety Representative Phone: 40037357 |
| Laboratory safety Representative Email: ajabeen1@sidra.org |
| Building and Laboratory Room Number: C5-73119 |

|  |
| --- |
| **Co-Investigator**  Alternate Contacts – The named alternate contacts listed below will only receive the IBC approval and final renewal reminder (2 weeks prior to expiration) |
| Alternate contact name: Christophe Raynaud |
| Department: TBI |
| Phone: 40037370 |
| Email: craynaud@sidra.org |
| Building and Laboratory Room Number: C5-73119 |
| Administrative/ Dept. Admin. Name: TBI |
| Email for Departmental Administrator: |

**C. Investigator Assurance**

* I attest that the information contained in this registration is accurate and complete.
* I agree to comply with all Sidra- IBC requirements regarding research involving biohazardous and / or recombinant materials.
* I agree not to initiate any research subject to IBC approval unless I have received such approval.
* I agree to notify the IBC immediately of incidents involving biohazardous and / or recombinant nucleic acid agents
* I acknowledge my responsibility for the conduct of this research in accordance with the Sidra - IBC safety guidelines and policies.

a. I have the knowledge and training required to safely handle the materials described.

b. I agree to train all my laboratory personnel according to the BSL of the laboratory.

c. Entry doors to the laboratory will be closed and locked when the laboratory is unattended.

* I agree to provide all personnel working in the laboratory with notification, information and training on the hazards, laboratory security and emergency policies and procedures associated with working in my laboratory. All personnel are further advised that working in a laboratory that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health

**A close-up of a signature

AI-generated content may be incorrect. 19/05/2025 Wouter Hendrickx**

**Signature of Principal Investigator Date Typed/Printed Name**

**A signature on a white background

AI-generated content may be incorrect. 19/05/2025 Christophe Raynaud**

**Signature of Line Manager Date Typed/Printed Name**

**D. Project Information**

|  |
| --- |
| 1. Project title:   Recapitulation of the human microbiome risk score in mice to elucidate its mechanism of action |
| Proposed start date: 01/04/2024 |

**Enter Project Summary on this page below the line.**

1. **Project Description**

Outline the overall goal(s) of the project in the space below. Give enough information to assure that the purpose of the experiments and the techniques used are clear. Please use reasonably laid terms and spell out all acronyms/initials. (PROVIDE SDR Number and Related IRB Number (if applicable))

|  |
| --- |
| SDR -400193  **Objective 1:**  Our first objective revolves around identifying specific dietary interventions that can alter the mouse microbiome to mirror the Low Microbiome Risk profile identified in humans. We will:   1. Feed mice with different diets:    1. AIN93G (Control diet)    2. AIN93G + β-Glucan (31.5 g/kg)    3. AIN93G + Amylose corn starch (100g/kg)    4. AIN93G + Castalagin 0.006g/kg    5. AIN93G AMF butter (SAFE U8978 Version 177) 2. Collect feces from the cage every week until week 14 and sacrifice the mice for intra gut feces, colon, liver, thymus and blood from the heart collection to perform PCR and 16S sequencing and RNA sequencing to identify the diet that recapitulate the best the microbiome of low MBR profile.   This first objective will allow us to identify a “good” (or “low risk”) diet favoring the microbiome of low MBR risk, and a “bad” (or “high risk”) diet, impairing the development of the same microbiome.  **Objective 2:**  Our second objective is to assess the effect of diet induced microbiome on the progression of colon cancer. To do so mice will be provided either the “low risk”, “high risk” or control diet after weaning. In each case syngeneic colon cancer cell line (MCA-38) will be injected in 10 weeks old mice in the wall of the colon to develop colon cancer or under the skin to reflect a tumor distant from the gut. Like in the first objective, feces will be collected every week from the cage and tumor burden will be assessed by whole animal luciferase imaging. At week 14 mice will be sacrificed and tumor, intra gut feces, colon, liver, lung, thymus and blood from the heart will be collected from the mice. PCR and 16S sequencing, Elisa, metabolomics and RNA sequencing will be performed in Sidra Medicine research facility.  The objective is to assess if, like in humans, the presence of the low-risk microbiome profile induced by diet allows a reduction of the tumor burden compared to control or “high risk” diet.  **Objective 3:**  Our third and final objective is to assess if the presence of the low-risk microbiome profile induced by diet improves the efficiency of classic colon cancer treatments. To do so, like in our second objective, the mouse will be provided either the “low-risk”, “high-risk” or control diet after weaning. In each case syngeneic colon cancer cell line will be injected to 10 weeks old mice in the wall of the colon to develop cancer. At week 10, 11 and 12 mice will be injected either with immunotherapy (anti-PD1) or chemotherapy (5-FU). As previously, feces will be collected every week from the cage and tumor burden will be assessed by whole animal NIR imaging. At week 14 mice will be sacrificed and tumor, intra gut feces, thymus, colon, liver, lunch and blood from the heart will be collected from each mouse.  Overall, this project is set to contribute significantly to the scientific community's understanding of the intricate relationships between diet, gut microbiota, and colon cancer. The outcomes could be instrumental in informing dietary recommendations and microbiota-targeted interventions, heralding a new era in colon cancer prevention and treatment. |

1. **Material and Methods**

Outline of the overall experiment(s) that will be performed in the space below. Give enough information to ensure that the procedures of the experiments and the techniques used are clear. Please use reasonably lay terms and spell out all acronyms/initials.

|  |
| --- |
| Experimental Protocols for all objectives:  1. Nucleic acid extraction from feces and tissues:    Following the manufacturers’ instructions from Zymo Kit we will be extracting all the DNA from the samples manually following standard safety procedures.    2. Blood sample processing:  PBMC’s will be collected from all the mice samples and processed using Lymphoprep following all safety procedures.    3. Total RNA sequencing:    All samples for RNA will be extracted using Promega Kit following their instructions. And all the samples will be sent for sequencing.    4. Gene signature profile: Illumina Whole-Genome Gene expression:    Extracted DNA will be sent for Whole genome sequencing.    5. 16S ONT sequencing:    All the samples that were extracted for DNA will be used to do 16S sequencing using the ONT kit following standard procedures.    6. Q-PCR:    Using the extracted RNA for all the samples real time PCR will be performed using the appropriate primers |

1. **Describe procedures involving the use of infectious biological agent(s) or toxin(s) [If animals are being used with infectious agents or toxins, please include (copy/paste) that information from the IACUC research protocol here]:**

|  |
| --- |
| There will be no use of infectious biological agent. We will use cell lines. Only biohazardous material will be used such as vector. Mice will be used in this study - : C57BL/6 mice. As approved by IACUC. |

1. **Laboratory Personnel Information**

5.1. List the PI and other personnel who will be handling biological agents. Include personnel who will have a role in training other lab members.

*\*To add additional personnel, add rows below and copy the contents.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NAME** | **PHONE #** | **EMAIL ADDRESS** | **CREDENTIALS** | **COMPLETED TRAINING** | **ROLE IN PROJECT** |
| Wouter Hendrickx |  | whendrickx@sidra.org | PI | CITI courses, LARC training | Follow up on progress of project |
| Christophe Raynaud |  | craynaud@sidra.org | Staff Scientist | CITI courses, LARC training | Design experiments, perform analyze |
| Ayesha Jabeen |  | Ajabeen1@sidra.org | Research Specialist II | CITI courses, LARC training | Perform experiments, analyze, Train other lab members |
| Ismahane Hayame Belhabib |  | ibelhabib@sidra.org | Post doctoral fellow | CITI courses, LARC training | Design experiments, Perform experiments, analyze |
| Rana Ehab Mohamed Atia Elmalah |  | relmalah@sidra.org | Laboratory Assistant | CITI courses | Perform experiments in lab |

5.2. Briefly describe the training plan for lab members who lack experience in handling biological materials below. Include who will lead the training as well as the practices and techniques that will be taught.

1. **Compliance Protocol Numbers Related to this Protocol** (If none please indicate as N/A)

*Has this project been approved or is being reviewed by Radiation Safety, IACUC or IRB? If approved, attach the respective approval letter(s).*

|  |  |
| --- | --- |
| Radiation Safety Protocol No (s) | N/A |
| IACUC Protocol No(s): | 003/2024 |
| IRB Protocol No(s): | N/A |

1. **Funding Information**

*Please provide a copy of the project narrative submitted as part of your grant proposal. (Do not include other application sections, i.e. budget, etc.)*

|  |  |  |
| --- | --- | --- |
| **Grant/Fund Type** | **Grant No. (ID#) with Grant Title** | **Funding Agency** |
| Internal Grant |  |  |
| External Funding |  |  |
| Partially Funded |  |  |

**E. Biosafety Level**

|  |  |  |
| --- | --- | --- |
| **Biosafety Level Containment and Risk Group Information**  *Note: more than one option may apply to your project; check all boxes that apply to this research application* | | |
| **1. Indicate your assessment of the risk groups (or class) of ALL material(s) used in the research project** | | |
|  | Risk Group 1 | Cell lines, vectors |
|  | Risk Group 2 |  |
|  | Risk Group 3 |  |
|  | Risk Group 4 |  |
| 1. **Indicate ALL biosafety level(s) at which work is performed**   *Note: more than one biosafety level may apply to your project; check all boxes that apply* | | |
|  | BSL-1/ABSL-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/ABSL-2 | **Moderate risk agents (generally risk group 2) of moderate potential hazard to laboratory personnel and the environment**  All the above BSL-1 containment and practices plus the following:  • Access to laboratory is restricted when experimental work is in progress.  • Personnel have specific training in handling of pathogenic agents.  • Extreme precautions taken with use and disposal of contaminated sharps.  • Biological safety cabinets (BSC) or other physical containment devices are used for procedures with a high potential to create aerosols or when high concentrations or large volumes of microorganisms are used.  • Wastes are chemically inactivated or autoclaved before disposal from laboratory.  • Biohazard signs must be posted.  • Personal protective equipment (PPE) and entrance requirements must be met.  • Spills and accidents that result in exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the IBC. |
|  | BSL-3/ABSL-3 | **High risk agents (generally risk group 3) of potential hazard to laboratory personnel and the environment**  All the above BSL-1 & BSL-2 containment and practices plus the following:  • Access to laboratory is restricted to authorized personnel only.  • Personnel have specific training in handling of pathogenic agents.  • Extreme precautions taken with use and disposal of contaminated sharps (decontamination/ autoclaving prior disposal is a must).  • Biological safety cabinets (BSC) CLASS-2B+ or other physical containment devices are used for procedures with a high potential to create aerosols even if small concentrations of microorganisms are used.  • Wastes are chemically inactivated or autoclaved before disposal from laboratory.  • Biohazard signs must be posted.  • Personal protective equipment (PPE) and Double entrance requirements must be met Spills and accidents that result in exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the IBC. |

**F. Protocol Summary**

|  |  |
| --- | --- |
| Indicate all that apply; Check *All* applicable boxes | |
| Using recombinant or Synthetic Nucleic Acid molecules for detection purposes (e.g. GFP, YFP, radioactive nucleotides, etc.) |  |
| Creating or using genomic libraries |  |
| Cloning and vector construction in bacteria or yeasts |  |
| Expression of recombinant or synthetic nucleic acid products in cultured cells |  |
| The use of human cells/cell lines or tissues (e.g. human blood, 293 cell lines, CSF) |  |
| Use of animal cells/cell lines or tissues (e.g. tissue culture research) |  |
| Use of human stem cells or iPS cells (embryonic or adult) If YES provide hSCRO registration/protocol number |  |
| Using or cloning genes from, or into a risk group 2 or 3 agent |  |
| Administration of recombinant or synthetic nucleic acid molecules into animals (e.g. transformed cells, vectors) |  |
| Propagating culture volumes exceeding 10 liters at one time |  |
| The use or manipulation of infectious viruses or replication-defective viruses or viral vector(s) with helper viruses |  |
| Using or cloning of genes from, or into a risk group 4 |  |
| Administration of recombinant or synthetic nucleic acid molecules into humans – (Human Gene Transfer Clinical Trial) |  |
| Using or cloning of toxin molecule genes (e.g. deliberate formation) |  |
| Transfer of a drug resistance trait into a risk group 2 or 3 agent |  |

**G. Laboratory Policies**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Laboratory Sign on door has the Universal Biohazardous Symbol, Biosafety Level, Principal Investigator’s Name and Phone Number. |  |  |
| Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing of food for human consumption is prohibited in the laboratory. |  |  |
| Procedures describing the appropriate personal protective equipment required for entering and exiting the laboratory are posted near the door. |  |  |
| Laboratory-specific Biosafety manual is prepared, adopted, available and accessible. |  |  |
| Laboratory equipment is routinely decontaminated with the appropriate disinfectant Method(s) of Disinfection: |  |  |
| All procedures are performed to minimize the creation of splashes and/or aerosols. |  |  |
| All procedures involving the manipulations of infectious material that may generate an aerosol will be conducted within a Biosafety Cabinet (vortexing, sonicating). |  |  |
| Principal Investigator will provide information regarding immune competence and conditions that may predispose laboratory personnel to infections. |  |  |
| Incidents resulting in exposure to infectious materials will be immediately reported to the Biosafety Officer. |  |  |
| Only organisms and animals associated with the work being performed will be allowed in the laboratory. |  |  |
| Emergency Chart and Call Down list are posted in the Laboratory. |  |  |
| Policies for safe handling of sharps are posted. |  |  |
| Broken glassware is removed using a dustpan, brush, tongs, forceps or other mechanical means. |  |  |
| Proper gas tubing is being used in with associated instruments |  |  |
| Compressed Gas Cylinders are properly secured. |  |  |
| All Mercury Thermometers have been replaced with non-mercury thermometers (unless otherwise specified in this IBC protocol. |  |  |
| A Chemical Hygiene Plan is prepared, and adopted, available and accessible. |  |  |
| All chemical waste will be removed through scheduled pick up by Boom Company. Only soap and water will be allowed down the sink drains in the laboratory. |  |  |
| Hazardous Waste Containers are properly labeled. |  |  |
| MSDS is available and accessible. |  |  |
| Chemicals are properly stored in chemicals cabinet. |  |  |
| Will you follow all of the safety requirements for the transportation of hazardous materials\* |  |  |

*\* 1. For local transportation (within Sidra research labs):*

* *Whenever transporting chemicals by hand, always use a secondary container such as a bottle carrier, rubber acid carrying bucket, plastic bucket, or a 5-gallon pail*
* *Place all primary biological samples in a sealable, leak-proof secondary container labeled with a biohazard symbol. Suitable secondary containers can include a plastic specimen bag with a zip closure or plastic container with a fitted lid*

*2. For off-campus transportation/shipping:*

* *International legal requirements governing packaging, labeling, and handling must be followed.*

**H. The biosafety cabinets and laboratory benches will be disinfected by:**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Ethanol, 70% with a 15-minute contact time. |  |  |
| Freshly made 1:10 solution of bleach (5% or more of the active ingredient, sodium hypochlorite) with a 3-minute contact time. |  |  |
| Iodine based disinfectant (Wescodyne) |  |  |
| Alkaline based disinfectant (e.g Virkon, Aqua guard) |  |  |
| DNASE and/or RNASE solutions with a 15-minute contact time. Name commercial disinfectant here: |  |  |
| Other method of disinfecting and contact time. Name disinfectant here: |  |  |

**I. Waste Materials will be sterilized by:**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Autoclave: at minimum for 15 minutes at 121° C |  |  |
| Incineration of infectious material and/or animal carcasses: |  |  |
| Others; List other method of Sterilization indicating the name of waste collection & treatment vendor and the current copy of the vendor license to dispose biohazardous & chemical waste.  Animal carcasses are handled by the LARC facility | | |

**J. Laboratory Equipment and Personal Protective Equipment**

|  |  |
| --- | --- |
|  | Will Laboratory Workers require:  Pre-project and post-project serum samples  Immunizations, if selected, complete the ‘Immunization’ table below  Medical Monitoring or Surveillance  N-95 Masks, PAPRs, or other respiratory equipment  **Note:** Surgical Masks are to prevent fecal-oral exposure to infectious agents.  N-95 Masks and PAPRs are to prevent exposure to dust, animal dander, and infectious aerosols. |
| **Building/Rooms(s)** | **Biosafety Level** |
|  | BSL-1 Required: Laboratory Coat  BSL-1 Recommended (optional):  Gloves  Safety Glasses/Side shields/Safety Goggles  Biosafety Cabinet  Fumehood |
| C5 -73119 | BSL-2 Required: Laboratory Coat, Gloves, Safety Glasses/ Side shields/Safety Goggles BSL-2 Recommended (optional):  Fumehood Booties  Surgical Mask  N-95 Mask  PAPR  Biosafety Cabinet  Other: |
|  | BSL-3 Required: Laboratory Coat, 2 Pairs of Gloves, Safety Glasses/Side shields/Safety Goggles, Booties  BSL-3 Respiratory Protection:  N-95 Mask  PAPR  Other: |
|  | BSL-4 Required: Laboratory Coat, 2 Pair of Gloves, Safety Glasses/Side shields/Safety Goggles, Booties Scrubs  BSL-4 Recommended (optional):  N-95 Mask  Tyvek w/ hood and foot covers  PAPR  Other: |
|  | ABSL-1 Required: Laboratory Coat, Gloves ABSL-1  Recommended(optional):  Surgical Mask  N-95 Mask  PAPR  Cage Change Station  Other: |
|  | ABSL-2 Required: Laboratory Coat, Gloves, Safety Glasses/Side shields/Safety Goggles, Booties, Biosafety Cabinet  ABSL-2 Recommended (optional):  Surgical Mask  N-95 Mask  PAPR  Other: |
|  | ABSL-3 Required: Biological Safety Cabinet, Scrubs, Tyvek® Cover Up or equivalent, Gloves with cuffs, PAPR, Booties  Tyvek® Cover Up = Tyvek suit with hood and foot covers (all in one)  SCBA  Other: |

|  |  |  |
| --- | --- | --- |
| **Immunization:**  Indicate immunization status and monitoring of laboratory personnel (It is the PI’s responsibility to ensure that all his/her staff are vaccinated with appropriate vaccines) | | |
| **Name of researcher** | **Immunization status and Monitoring** | **Date of immunization** |
| Wouter Hendrickx | Hepatitis -B (titer level - 73)  Tdap | 05/12/2023  06/02/2024 |
| Christophe Raynaud | Hepatitis -B (titer level ->1000)  Tdap | 10/02/2024  08/02/2024 |
| Aayesha Jabeen | Hepatitis -B (titer level -365)  Tdap | 20/02/2023  05/09/2021 |
| Ismahane | Hepatitis -B  Tdap | Hep B -2 shots – 24/12/2024; Tdap – 18/12/2024 |
| Rana | Hepatitis -B  Tdap | Hep B shots -First -15/09/2024; second – 15/10/2024; third – 17/05/2025  Tdap – 01/06/2015 |

|  |  |  |
| --- | --- | --- |
| **Investigator Experience and Training Requirements** | | |
| **Indicate Yes/No in check boxes:** | **Yes** | **No** |
| 1. Does the investigator have prior experience with organisms (viruses, bacteria, fungal agents, etc.), vectors, or recombinant materials described in this application?  * If YES, provide the number of years of laboratory and safety experience working with these materials * If NO, describe training and/or experience with relevance to biosafety in microbiological and biomedical laboratories |  |  |
| 10 – 15 years | |
| 1. Please list all current training, including on-line modules, live sessions, etc., relevant to the proposed work that will support IBC approval of research with the recombinant materials described. Specifically identify the training such as: Chemical Hygiene, General laboratory safety, required IACUC training, etc. | | |

**K. Vectors, Hosts, and Recombinant or Synthetic Nucleic Acid Molecules Used**

|  |  |  |  |
| --- | --- | --- | --- |
| **Do not leave blanks,** If the question is not applicable to your research, indicate: **NONE or N/A** (not applicable) | | | |
| If desired, insert vector map(s) at the end of this form (Additional Materials). | | | |
| 1. List the organisms (bacteria, viruses or fungi, etc.) used in the research.  * Provide the specific strains of organisms to be used * Describe how these organisms will be used in the research * If no such organisms are used, state NONE | Lentivirus vector | | |
| 1. List any known oncogenes or toxins that will be expressed and identify the expression system(s) used for expression. | Luciferase and Puromycin expression | | |
| **Indicate Yes/No in check boxes:** | | **Yes** | **No** |
| 1. Does the research include any oligonucleotides used to manipulate gene function (e.g. siRNA, shRNA, etc.). | |  |  |
| 1. What genes will be expressed or targeted for altered expressions (knockdown)? | N/A | | |
| 1. What type of vector is used with the oligonucleotides? | No | | |
| 1. Is there any potential for increased virulence by manipulation of any of the nucleic acid molecules or genes listed above with respect to the vector or organism? | |  |  |
| 1. List all cell lines or eukaryotic cells including commercially available human cell lines (e.g. CHO, COS, or HEK 293 cells) to be used in the research  * State the species of origin of each of the cell lines used * If no cells are used, state NONE in the first column | MC-38 | | |
| **Specify the Recombinant or Synthetic Nucleic Acid Molecules, including as much information as possible about:** | | | |
| * nature of the insert; |  | | |
| * protein that may be expressed |  | | |
| * percentage of any viral genome in the construct; |  | | |
| * cloning/expression/transfection vectors used; | CMV- Luciferase Lentivirus ( Infection) | | |
| * recipient host cell lines (human, animal, plant, etc.) or bacterial strains; | MC- 38 colon cancer cell line | | |
| * packaging cell lines and assay system used to measure helper virus titre or titre of replication competent virus (background) generated; | Puromycin antibiotic selection | | |
| * host range of packaged viral vector; and | CMV Luciferase lentivirus | | |
| * Expected phenotype of the animal if applicable, including any expected behavioral traits, disease predispositions, or health problems. | To develop colon cancer in the mice to study its affects | | |

**L. Biological Materials Information**

|  |  |  |
| --- | --- | --- |
| **1. Biological materials** | | |
| **Indicate Yes/No in check boxes:** | **Yes** | **No** |
| 1.1 Are you working with biological material that may be infectious or a toxin? If yes, then you must complete question 2 If no, then the next section |  |  |
| 1.2 Will the Biological Agent(s) / Microorganism(s) / Toxin(s) be:  Cultured from Human Tissue, Fluids, or Blood.  Cultured from Animal Tissue, Fluids, or Blood.  Cultured by a Principal Investigator from Sidra Medicine or collaborative organizations?  If yes, what is the name of the PI  Cultured in a laboratory outside of Sidra medicine Facilities?  If yes, what is the name of the PI and the Laboratory.  Does Not Apply |  |  |
| **2. Name the Biological Agents(s)/Microorganism(s), Biosafety Level, and “X” the source.**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | | | **Source or Origin** | | | | | | | | | | | | | | | | **Biological Agent(s) / Microorganis m(s) / Toxin(s) and Strains** | **Biosafety Level**  **(1,2,3, or 4)** | **Blood borne Pathogens or other potentially infectious** | **Addgene** | **ATCC** | **Agilent/Startgene** | **BioRad** | **EMD** | **Fermentas** | **Fisher Scientific** | **NEB** | **Qiagen** | **Roche** | **Geogia State Univ.** | **Georgia Tech** | **Univ. Of GA** | **VWR** | **Other** | | MC - 38 | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | Sigma | | Lenti-CMV-Luciferase-puro | 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | Thomas Scientific | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   Other: | | |
| If Human Source or Non-Human Primate Material is being used, has the material been treated prior to use in the laboratory (such as formalin fixing or heat treatment)? |  |  |
| Will you be using any of the following Human and/or Non-Human Primate Biological Material:  Blood  Serum  Cells  Cell Culture  Tissue  Feces  Urine  Bones  Saliva  Other: Please list here: | | |

**M. Animal use Research Work**

|  |  |  |
| --- | --- | --- |
| **Animal Use Information, Part I**  NOTE: If you are obtaining cells or tissues from live vertebrate animals under an IACUC protocol specific to this research, or you plan on administering recombinant or synthetic nucleic acid molecules/materials to animals, (including cells from other genetically modified animals, or transformed cells) you must complete this section | | |
| **Indicate Yes/No in check boxes:** | **Yes** | **No** |
| 1. Does the work involve live (living) vertebrate animals?  * If NO skip to Section N |  |  |
| 1. Is there an Institutional Animal Care and Use Committee (IACUC) application submitted or approved for this research involving recombinant or synthetic nucleic acid molecules?  * If YES provide the IACUC protocol number(s) to be linked to this IBC project * NOTE: If you are not the named Principal on the linked animal protocol application, provide the name of the investigator on the IACUC protocol in addition to the IACUC protocol number   ATTENTION: Research described in an IACUC protocol involving materials under IBC oversight must correspond to an approved IBC protocol |  |  |
| 1. Will tissues, cells, or organs from animals be used in in vitro experiments? For example, do you plan to harvest tissues for culture or biometric analysis?  * If YES, please review (Project Summary) to ensure the details are provided |  |  |
| 4. Will transgenic, knockouts, gene-targeted, or other genetically engineered animals be used? |  |  |
| 5. Does the project involve rodents (parental or offspring) that contain more than 50% of the genome of an exogenous eukaryotic virus from a single virus family? |  |  |
| 6. Does the project involve rodents where a transgene is under the control of a gamma-retroviral long-terminal repeat (LTR) and where the LTR is functional? |  |  |
| 7. Will recombinant or synthetic nucleic acids be administered to live or intact animals? Injection of viral vectors, transfected cells, plasmids, or the transplantation of genetically modified cells, tissues or organs into animal research subjects that fall under IACUC oversight. |  |  |
| 1. Will you follow all the safety requirements for the shipment of biological material |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Animal Subjects Involvement; Part II**  Complete this section for administration of recombinant or synthetic nucleic acid molecules into live animal subjects | | | |
| 1. What are the target cells/tissues/organs for the recombinant/ synthetic genetic material? | colon | | |
| 1. List ALL recombinant/synthetic nucleic acid molecules or materials to be administered to animals:  * include both transformed or infected cells and any vectors (viral or non-viral). * For cells, identify the vector(s) used to modify the cells prior to administration. | Modified MC -38 colon cancer cell line . CMV\_ luciferase lentivirus will be used to modify the MC-38 cell line. | | |
| **Indicate Yes/No in check boxes:** | | **Yes** | **No** |
| 1. **Do you anticipate that work with the live animal subjects will be conducted at a different BSL than the in vitro or wet bench portions of the study?**  * **If NO go to question 5** | |  |  |
| 1. Explain the requirement for different containment requirements for the work with the animals. If this requirement is related to a downgrade request, please ensure that appropriate support of the position is detailed within the application. | All animal work will be done in LARC Qatar University and it is the responsibility of the facility for carcass and decontamination. | | |
| 1. Provide the animal species (and strain if applicable) receiving the experimental agents; be sure to list each species to be used. | C57BL/6 mice | | |
| 1. Describe the route of administration for each experimental agent used in vivo and per species as applicable | Perianal injection of modified MC-38 colon cancer cell lines | | |
| 1. Provide the concentration and volume for each recombinant or synthetic nucleic acid molecule to be administered and per species. | 1x104 MCA-38 cells suspended in sterile PBS | | |
| **NOTE TO ANIMAL USERS:** For animal research involving the administration of experimental agents/materials at BSL-2 or higher, the (Laboratory Animal Resources) must be notified | | | |

**N. Human Subjects Involvement**

|  |  |  |  |
| --- | --- | --- | --- |
| **The term “primary cells” indicates that the cell cultures are directly derived from human tissues, cells or samples** | | | |
| **Indicate Yes/No in check boxes:** | | **Yes** | **No** |
| 1. Does work involve human subjects, unfixed human tissues or blood, or \*primary human cell cultures that are obtained directly from human participants?  * Cell lines available commercially (e.g. from a cell bank such as ATCC) do not qualify as \*primary cells, as they are generally immortalized. * If NO skip to the next Section. | |  |  |
| 1. Has an Institutional Review Board (IRB) application been submitted?  * IRB Exemption information. * If NO skip to question 4. | |  |  |
| 1. Provide the IRB protocol (preferred) or the IRB submission date: |  | | |
| 1. Will human tissues or primary cells\* be used in vitro?  * If NO skip to question 6. | |  |  |
| 1. Describe the use of the tissues or cells in your research if not described in the Project Summary, Section F. | | | |
| 1. Is this a gene transfer proposal\*\* (deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules into human subjects)? See the information box below.  * If YES, supporting documents must be submitted for review of a new human gene transfer proposal. * Please contact the IBC Office for additional information regarding clinical trial review of human gene transfer proposals. | |  |  |

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| --- |
| **\*\*What is Human Gene Transfer**  Human Gene Transfer is defined as the deliberate transfer into human research participants of either:  1) Recombinant nucleic acid molecules or DNA or RNA derived from recombinant nucleic acid molecules  2) Synthetic nucleic acid molecules or DNA or RNA derived from synthetic nucleic acid molecules that meet any ONE of the following criteria:  A. Contain more than 100 nucleotides.  B. Possess biological properties that enable integration into the genome (for example, cis elements involved in integration)  C. Have the potential to replicate in a cell.  D. Can be translated or transcribed. |

**O. Research Facilities Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Facilities: Locations where the recombinant or synthetic nucleic acid molecule research will be conducted** | | | | |
| **Indicate Yes/No in check boxes:** | | | **Yes** | **No** |
| 1. Is this “research” for a “Core Facility” with the goal or mission of production and distribution of materials to other research laboratories? | | |  |  |
| 1. Are recombinant or synthetic nucleic acid molecules or materials manufactured by or obtained from an outside/external source (e.g. commercial vendor)?  * If NO skip to question 4 | | |  |  |
| 1. Identify the materials obtained, and the sources responsible for providing the materials | |  | | |
| 1. Are recombinant or synthetic nucleic acid molecules or materials produced by or obtained from another institutional laboratory (e.g. collaborating researcher or “Core” facility)?  * If NO skip to question 6 | | |  |  |
| 1. Identify the materials obtained from other laboratory facilities and provide the IBC registration number for each laboratory | |  | | |
| 1. Provide information about facilities for all locations, including the facility used for working with animals or tissue culture, as applicable to your described project.  * Provide the procedures performed in each location, for example, cell transfections, propagation of plasmids, administration of viral vector into animals, animal housing, etc. | | | | |
| Location #1 | Room number and building | LARC, Qatar University, H10 building | | |
| Describe procedures for this location | All animal procedure from housing to sacrifice will be done in LARC facility | | |
| Provide biosafety level | BSL2 | | |
| Location #2 | Room number and building | Sidra Medicine, C5-73119 | | |
| Describe procedures for this location | All invitro work will be done here | | |
| Provide biosafety level | BSL2 | | |
| Location #3 | Room number and building |  | | |
| Describe procedures for this location |  | | |
| Provide biosafety level |  | | |
| Location #4 | Room number and building |  | | |
| Describe procedures for this location |  | | |
| Provide biosafety level |  | | |

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| --- |
| **Biological Safety Cabinet** |
| Indicate the type of Biological Safety Cabinet(s) (BSC) you intend to use. Please check the applicable boxes and enter the location IDs:  Class II A (recirculating) Location ID.  Class II B1 (70% exhausted – ducted outside) Location ID.  Class II B2 (100% exhausted – ducted outside) Location ID.  Other (Specify):  None |
| Is the biological safety cabinet(s) certified annually?  No  Yes. Provide date(s) and a copy of most recent certification : |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Personnel and Training Information**  ***This information is ONLY required for applications with a designated containment of BSL-2+ or higher at this time***   * List only the personnel working with the materials described in this application in the laboratory * Please list each individual on a separate line, be sure to include all pertinent information * Listed personnel must be current on all applicable Health and Safety training prior to IBC granting approval * To expedite IBC approval of your research, please verify current training certificates. | | | | |
| **Name** | **E-mail address** | **Health and Safety Training \*** | | |
| **Training Course & Date** | **Completed (Y/N)** | **Required (Y/N)** |
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**P. Environmental, Health & Safety, and Risk Evaluation**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **The following table provides an overview of the types of Health and Safety related assessments that occurred in the facility to confirm HSE assessment activities conducted and to be verified by IBO audit** | | | | | | | | |
| 1. Will the research involve contact with and/or exposure to the following | | | | | | | Yes | No |
| Pesticides include herbicides, fungicides, growth enhancers, and other regulated substances. (Specify use): | | | | | | |  |  |
| Work with specifically regulated chemicals (see-attached list). | | | | | | |  |  |
| Chemical warfare materials/agents. | | | | | | |  |  |
| Compressed gases. | | | | | | |  |  |
| Corrosives (Please specify name and strength (e.g., percent by volume) of acids and / or bases, if known). | | | | | | |  |  |
| Cryogens. | | | | | | |  |  |
| Endothermic reactions (requiring high temperature to initiate and maintain reaction). | | | | | | |  |  |
| Exothermic reactions (combustion reactions). | | | | | | |  |  |
| Explosives, ordnance, firearms, tranquilizer guns, shock-sensitive materials. | | | | | | |  |  |
| Flammable or combustible liquids or solids. | | | | | | |  |  |
| Peroxide-forming chemicals. | | | | | | |  |  |
| Pressurized systems (hydraulic, pneumatic, etc.) contain gases and/or liquids. | | | | | | |  |  |
| Pyrophoric or dangerous when wet chemicals or spontaneously combustible materials. | | | | | | |  |  |
| Potential for formation of dangerous reaction side-products or intermediaries. | | | | | | |  |  |
| 1. Chemical storage & waste management (tick if yes only)  * Chemical stored by compatibility * Flammables stored properly * Chemical and waste properly labelled | | | | | |  | If yes, By Whom  Lab staff  HSE Team | |
| 1. Environmental Assessment Activities (monthly, quarterly, biannually)  * Chemical Inventories conducted, Frequency   Monthly  Quarterly  Biannually other, specify     * Satellite accumulation area inspection; frequency   Monthly  Quarterly  Biannually other, specify     * Hazardous waste accumulation area inspection; frequency   Monthly  Quarterly  Biannually other, specify     * Review of MOE regulations and other legal requirements to be reviewed annually or when regulations changed | | | | | |  | If yes, By Whom  Lab staff  HSE Team | |
| 1. Risk Evaluation   This Hazard Analysis Form should include, if applicable: a description of any required skills, training, or experience for staff members performing the specified operation; and any calculations used in the development of the Hazard Analysis Form. This document was prepared in accordance with and is controlled by the hazard analysis custodian   * 1. **Types or sources of hazards include (mark those that apply):**  |  |  | | --- | --- | | Eye intrusion | Glassware | | Mechanical | Instruments | | Lacerations | Chemical Compatibility | | Electric | Syringes | | Slips/Trips/Falls | Exotherms | | Noise | Consequences of failed engineering or administrative controls | | Muscle/Back Strain | Disposal procedures including environmental impact | | Heat | Ergonomics | |  |  |   Other | | | | | | | | |
| * 1. **Risk Assessment Table Use the below Scheme to identify risk / mitigation** | | | | | | | | |
| Hazard to safety or health | Potential consequences of hazard (Risk) | Initial Risk rated | | Controls in place | Final risk rated | | Risk Rating | Additional Recommended Controls |
| impact | likelihood | impact | likelihood |
| For example release of hazardous substances into air | Inhalation of hazardous substances lead to irritation of lungs (health) | 4 | 4 | Work only under strict conditions engineering controls:(in fume hood, administrative control: signage dedicated area etc) | 4 | 2 | 8 |  |
| MCA-38 colon cancer cells | biohazard from handling and manipulation | 2 | 2 | Use BSL-2 practices, PPE (gloves, lab coat), biosafety cabinet, proper disposal protocols | 2 | 2 | 2 |  |
| Animal handling (mice) | Bite, scratch, allergic reactions; stress to animals | 1 | 1 | Training required; PPE; handling under supervision; minimize stress and restraint duration | 1 | 1 | 1 |  |
| Isoflurane | Inhalation can cause dizziness or respiratory depression in humans | 2 | 2 | Use in fume hood or dedicated anesthetic machine with scavenging system; training; PPE | 2 | 2 | 2 |  |
| Injection procedures | Risk of needle stick, infection, improper dosing, animal injury | 3 | 3 | Sharps protocol, PPE, restraint training, use of anesthetics for invasive procedures | 3 | 3 | 3 |  |
| * 1. **Regulated Chemicals**   Indicate which (if any) chemicals from the following list will be used in the course of this project. These chemicals have the own chemical specific standards to be considered in a project.   |  |  |  |  | | --- | --- | --- | --- | | **Y or N** | **Chemicals** | **Y or N** | **Chemicals** | | N | Acetylaminofluorene | N | Hydrogen cyanide | | N | Acetylene | N | Dibromo chloropropane | | N | Acrylonitrile | N | Dibromo-3-chloropropane | | N | Alpha-Naphthylamine | N | Dichlorobenzidine and salts | | N | Aminodiphenyl | N | Dimethylaminoazobenzene | | N | Anhydrous ammonia | N | Ethylene oxide | | N | Asbestos | N | Ethyleneimine | | N | Benzene | N | Formaldehyde | | N | Benzidine | N | Hydrogen | | N | Beta-Naphthylamine | N | Inorganic arsenic | | N | Beta-propiolactone | N | Lead | | N | Bis-Chloromethyl ether | N | Liquefied petroleum gas (LP-Gas) | | N | Butadiene | N | Methyl chloromethyl ether | | N | Cadmium | N | Methylene Chloride | | N | Carcinogens | N | Methylenedianiline | | N | Chromium (VI) | N | Nitrosodimethylamine | | N | Coal tar pitch volatiles | N | Nitrous Oxide | | N | Coke oven emissions | N | Oxygen | | N | Cotton dust | N | Vinyl chloride | | N | Cyanogen chloride |  |  |  * 1. **Chemicals of Special Concern (List of MOI Chemicals (Schedule 3 Chemical Weapon Convention)** – refer to MOI list   Not Applicable  Applicable; List in the table below   |  |  |  |  | | --- | --- | --- | --- | | **#** | **Chemical Name** | **CAS No** | **HS Code** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | | | | |

**IBC Group Protocol Checklist**

**IBC Number: IBC**

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria** | | **YES** | **NO** |
| 1 | A separate document (Template for info on Umbrella Protocol) describing the research background, methodology and objectives of each listed individual protocol was submitted. |  |  |
| 2 | Please indicate the number of subprotocols under the group/master protocol: Do all the subprotocols fall within the same category? Protocols are defined by their agents, techniques, experiment and facility. |  |  |
| 3 | A comprehensive list of materials including (but not limited to) biotoxins, select agents, biological samples, cells, and cell lines of both human & animal origin was submitted for each protocol unless the same materials are used in all subprotocols. |  |  |
| 4 | The same set of samples (e.g., blood samples, etc.), and cells/cell lines are used throughout the IBC group protocol, in other words, the same samples are used to study different diseases or disease outcomes. |  |  |
| 5 | The same research procedures/experiments are applied to the group of subprotocols (e.g., use of zebrafish as a model to study different disease outcomes). |  |  |
| 6 | The staff listed under the group protocol are involved in several subprotocols. |  |  |
| 7 | Have you submitted the following documents? External/international samples: a collaboration agreement Human/animal samples: approval letter (if available) or inclusion of the IRB/IACUC number to show evidence that an application has been made. |  |  |
| 8 | All questions in the IBC application form were answered and where required valid support documents, such as (but not limited to) calibration certificates, training certificates, and vaccination certificates were submitted. |  |  |
| 9 | No subprotocols were added to the existing approved group protocol in the annual renewal application/amendment application. |  |  |

**Investigator Assurance**

I certify that the information provided within this application is accurate to the best of my knowledge.

Please note that failure to disclose and provide comprehensive information (incomplete applications) might result in review/approval process delay or rejection**.**

|  |  |  |
| --- | --- | --- |
| **Wouter Hendrickx** | **A close-up of a signature  AI-generated content may be incorrect.** | **19/05/2025** |
| **Name of the Principal Investigator** | **Signature of the Principal investigator** | **Date** |