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INSTITUTIONAL BIOSAFETY & BIOSECURITY COMMITTEE (IBBC)

Instruction:

Preliminary assessment form is used to identify new proposal(s) or activity involving the use of infectious and potentially infectious agents/materials, biological toxins, living modified organism/genetically modified organism (LMO/GMO) and other biological materials. Submission is to be made by email to: ibc@iium.edu.my

SECTION A: PRINCIPAL INVESTIGATOR'S (PI's) INFORMATION

Name: RAJA NOR ARFANIZAM BINTI RAJA IDRIS

Faculty/Center/Institute: IIUM KUANTAN, DEPARTMENT OF BASIC MEDICAL SCIENCES, KOM

Postal Address: 399-E KAMPUNG GONG PAK MASEH, JALAN PANJI ALAM, 211OO KUALA TERENGGANU

Office Phone No: 09-5572869	**Mobile Phone No: 013-3811911**
Staff No: G2223798	**Email: arfaaaa1911@gmail.com**

Project Title: MOLECULAR CHARACTERISATIONS OF TRIMETHOPRIM-SULFAMETHOXAZOLE RESISTANT *BURKHOLDERIA PSEUDOMALLEI* ISOLATED FROM TERTIARY HOSPITALS.

SECTION B : PROJECT INFORMATION

1. Purpose: [√] Research [ ] Teaching [ ] Clinical Trial [ ] Service [ ] Diagnostic

Others (Please Specify):

2. Project Status [√] New Project [ ] On-Going [ ] Funded

If funded, please provide grant no:

3. Brief summary of the project (including objectives, method and expected outcome):

Melioidosis is a disease that is endemic in Pahang. The estimated yearly incidence of melioidosis was 2.89 per 100,000 people. The pathogen causing this disease is resistant to a broad spectrum of antibiotics, including trimethoprim- sulfamethoxazole - an antibiotic regimen used in the intensive and eradication phases of melioidosis treatment. According to data from Whonet HTAA, from January to December 2023, 19% of melioidosis cases reported were resistant to trimethoprim sulfamethoxazole, compared to 4% and 11% cases in 2021 and 2022 respectively. It is crucial to understand the pathophysiology of antibiotic resistance in SXT, as it could pose a challenge to clinicians in providing appropriate treatment to patients. By determining the molecular characteristics of Trimethoprim-sulfamethoxazole resistance in Burkholderia pseudomallei might help to tackle the issues of SXT resistance thus avoiding relapse and providing appropriate treatment for melioidosis patiens. There are 4 hypotheses in this study;
i)Positive isolates of Burkholderia pseudomallei show significantly different values of susceptibility to SXT antibiotic sensitivity testing.
ii) SXT resistant of Burkholderia pseudomallei shows the presence of BpeEF-OprC gene amplification in PCR compared to SXT sensitive.
iii) SXT resistant of Burkholderia pseudomallei shows an upward trend of the expression level of BpeEF-OprC gene.
iv)SXT resistant of Burkholderia pseudomallei shows significant differences in gene sequences.
The general objective of this study is to evaluate the molecular characteristics of trimethoprim-sulfamethoxazole-resistant Burkholderia pseudomallei from clinical isolates in Hospital Tengku Ampuan Afzan and SASMEC. The specific objectives include;
i)To determine the susceptibility of Burkholderia pseudomallei to trimethoprim- sulfamethoxazole antibiotics by measuring sensitivity levels.
ii)To determine the presence of the BpeEF-OprC gene within sensitive and resistant clinical isolates of Burkholderia pseudomallei by using qualitative PCR.
iii) To measure the level of expression of the resistant genes from clinical isolates of Burkholderia pseudomallei by qRT- PCR.
iv) To elucidate the gene sequence of the resistant genes using the Direct DNA sequencing method.
The study will be conducted at Hospital Tengku Ampuan Afzan in Microbiology and MolecularLaboratory in collaboration with Sultan Haji Ahmad Shah Medical Centre (SASMEC). This is a retrospective study design as data is collected from positive Burkholderia pseudomallei strains between January and early December 2023. There will be 50 samples to be included in this study and the study is estimated to begin from March 2024 until December 2025.

4. Classification and name of biological agent/material to be used in the study:

i.	Infectious or potentially infectious agent, biological toxin, etc. (Proceed to part 5)	√
ii.	Biological toxin (Proceed to part 5)	
iii.	LMO/GMO/CRISPR/Synthetic DNA (Proceed to part 6)	
iv.	Others (Proceed to part 5)	

5. Description of Infectious/potentially infectious agent, biological toxin, and others.

No.	Name of Infectious/potentially infectious agent, biological toxin, and others	Pathogen (Human/animal/plant)	Risk Group	Biosafety level where the work will be performed
1	**Burkholderia pseudomallei**	**Human**	**Group 2**	**BSL 2 (HTAA and CREAM, IIUM)**
2				
3				
4				
5				
6				

6. Description of the LMO(s)

No.	Common and scientific name of donor organism	Common and scientific name of parent/ recipient organism	Vector(s) or method of genetic modification	Identity and function of gene(s) of donor organism responsible for the modified trait	Target organism(s) of the LMO	Target tissues for genetic modification
1						
2						
3						
4						
5						

I hereby declare that all information provided in this application is accurate to the best of my knowledge.

Signature and stamp of PI **Date** 10.02.2024

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Decision by IBBC

☐ Notification or Approval Form submission is required

Form: _____

☐ Exemption from Notification or Approval Form submission

Signature and stamp of IBBC Chairman **Date**