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**R7e**

**RESEARCH ETHICS APPLICATION FORM FOR MICROBIOLOGY AND BIOCHEMISTRY PROTOCOLS**

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| --- |
| **INSTRUCTIONS**   * The application must be typed. * This form must be submitted with a R7a. |

1. **PROJECT DETAILS**

|  |  |
| --- | --- |
| **Start date:** | **End date:** |

|  |  |
| --- | --- |
| **I confirm that I plan to inform the prospective participants about the research project by using an Information Sheet/Covering Letter:** | |
| **YES** | **NO** |
| (If yes, it must be enclosed) |  |

|  |  |
| --- | --- |
| **I confirm that I plan to invite prospective participants to sign a consent form:** | |
| **YES** | **NO** |
| (If yes, it must be enclosed) |  |

1. **PLEASE ANSWER THE FOLLOWING QUESTIONS**
2. **Mark “X” in the appropriate boxes if your research:**

|  |  |
| --- | --- |
|  | Involves children or young people aged under 18 years |
|  | Involves adults older than 18 years |
|  | Involves collecting environmental samples (e.g. soil, river water, ….) |
|  | Involves using samples of human biological material collected before or archived |
|  | Involved in testing a medicinal product |
|  | Involves taking new samples of human biological material (e.g. blood, stool, tissue) |
|  | Involves isolation of microorganisms |

1. **Briefly summarize the project’s aim, objectives, and methodologies:**

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|  |

1. **What is the potential distress to participants?**

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| --- |
|  |

1. **How will the potential participants in the project be?**

|  |  |
| --- | --- |
| **Identified** |  |
| **Approached** |  |
| **Recruited** |  |

1. **Will informed consent be obtained from participants?**

YES NO

1. **What measures will be put in place to assure the confidentiality of personal data, when applicable?**

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|  |

1. **USE OF BIOHAZARDS AND RADIATION – RISK ASSESSMENT**

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| --- |
| **Please answer the following questions** |
| 1. **What will the concentration and quantity of the organism concerned be?** |
|  |
| 1. **Is there a potential for transmission? (by contact or aerosol)?** |
|  |
| 1. **Will the nature of the work be using a liquid culture or aerosol?** |
| YES/NO |
| 1. **Will a GMO be used in the study, and if so, what specific risk is associated with the GMO?** |
| YES/NO |
| 1. **Is there a risk of by-products such as spores, toxins or virulence factors?** |
| YES/NO/NA |
| 1. **Is there a risk of unknown contaminants such as cells or cell lines with latent oncogenic viruses?** |
| YES/NO/NA |
| 1. **Does the study include working with prokaryotes? If yes, name them.** |
| YES/NO/NA |
| 1. **Does the study involve working with eukaryotes such as parasites? If yes, (a) name them, and (b) indicate whether the project involves in vivo or in vitro organisms.** |
| YES/NO/NA |

1. **INDICATE BIOSAFETY LEVEL REQUIRED FOR THE RESEARCH**

|  |  |
| --- | --- |
|  | **Biosafety level 1**  Standard laboratory practices. This includes use of defined and characterized strains of viable infectious agents that do not cause disease. |
|  | **Biosafety level 2**  Either by ingestion, inoculation or mucous membrane contamination exposure is a risk. |
|  | **Biosafety level 3**  There is a high risk of aerosol-borne disease, a life-threatening disease which may occur at a low dosage. |
|  | **Biosafety level 4**  Agents are very transmissible resulting in very serious and often fatal disease for which treatment is limited or unavailable. |

1. **SIGNATURES**

I have considered the design of this project, and in my opinion, this is the most effective and feasible protocol that has the lowest impact on the animals and the environment. This work is being conducted according to the ethical standards accepted in this field of research.

1. **SIGNATURES**

**Project Leader**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Surname Signature Date

**Other researchers involved in this project:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Surname Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Surname Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Surname Signature Date

**Project supervisor** *(Applicable for Student Projects)*

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Name and Surname Signature Date

**Research Ethics Committee resolution:**

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| --- | --- |
| **Approved** |  |
| **Not Approved** |  |

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Name and Surname Signature Date

Chairperson, REC