**Research Committee – Panel on Research Ethics**

**Sub-Panel on Social Science & Humanities Research Ethics (Human Participants)**

Research Ethics Application Form

**Instructions to applicants**

1. Please complete the Application Form, and do not modify its format.
2. The Informed Consent documents in appropriate language, and any written information to research participants must be uniquely identified, and submitted along with the application form.
3. The e-copy of the application form does not require signatures and should be in MS word format.
4. The e-copy of the application documents should be submitted via the Principal Investigator’s UM email account and the Sub-panel will only correspond to UM email address.
5. This form is set up as a series of tables and check boxes[ ] . The table will enlarge to the size you require when you type and the check box will be checked with a click on it. You can also uncheck it with a click.
6. The applicant should ensure the submitted application form is the most current version.
7. For information on research ethics and methodology, please refer to <https://www.um.edu.mo/research/ethic.html>.
8. Please submit your application to rskto.ethics@um.edu.mo.

|  |  |  |
| --- | --- | --- |
| **Application Dossier** | **Requirement** | **Submitted Document(s)** |
| Completed Application Form | Mandatory | [ ] Application Form |
| Written information for participant, such as recruitment advertisement/flyer, information sheet, permission letter from other parties for accessing data/information, etc. | Subject to the research design | [ ] Recruitment Advertisement/Poster[ ] Information Sheet(s)[ ] Permission Letter(s) |
| Participant Informed Consent document(s) | Mandatory for studies collecting new data from human participants | [ ] General Informed Consent Form(s) [ ] Parental Consent Form(s)[ ] Assent Form(s) |
| Questionnaires/Interview Protocols | Subject to the research design | [ ] Data Collection Instrument(s) |

*These documents must be written in plain language appropriate for a non-specialist audience.*

**For Research Ethics Sub-Panel Use Only**

|  |
| --- |
| **Application Log** |
| Ethics Assessment ID:  |  |
| Application received: |  */ / (dd / mm / yyyy)* |
| Sub-panel decision date: |  */ / (dd / mm / yyyy)* |
| Notify applicant of Sub-panel decision: |  */ / (dd / mm / yyyy)* |
| **\*Chair/ delegate:** | [ ] Approved[ ] Exempted, Click or tap here to enter text.[ ] Conditionally Approved, Click or tap here to enter text.[ ] Declined: Click or tap here to enter text. |
| **Print Name:**  |

\* The sub-panel shall not bear any responsibility for any problems, losses, or damage caused by the study.

**PART I: STUDY DETAILS**

1. **Name of Study**

|  |
| --- |
| **Project Title**  |
|  |

1. **Researchers Involved in the Conduct of the Project**

|  |
| --- |
| **Principal Investigator / Primary Supervisor** (*must be a UM full-time staff member*) |
| **Title** |  |
| **Last Name** |  |
| **First Name** |  |
| **Faculty/Department** |  |
| **Email** |  |
| **Phone** |  |

*If you need to add more researchers, please copy and paste the whole table.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Please Choose One**  | [ ] **Co-Investigator** | [ ] **Student Researcher** | [ ] **Other,** *please specify:*Click or tap here to enter text. |
| **Title** |  |
| **Last Name** |  |
| **First Name** |  |
| **Affiliated Institution***(If not affiliated with UM)* |  |
| **Faculty/Department** |  |
| **Email** |  |
| **Phone** |  |

1. **Study Description**

|  |
| --- |
| **In plain language, give a succinct description of the background and the potential significance of the research project** *(250 words max)* |
|  |

|  |
| --- |
| **Clearly state the aims and/or hypotheses of the research project** *(250 words max)* |
|   |

1. **Type of Project**

|  |
| --- |
| [ ] **Staff research** |
| [ ] **Student research** | **If YES**, *check the relevant box*[ ] Undergraduate[ ] Masters[ ] PhD[ ] Other, please specify: Click or tap here to enter text. |
| [ ] **Class project** |
| [ ] **Multi-center research** |
| [ ] **Other** | **If YES**, *please give further details*: Click or tap here to enter text. |

1. **Type of Research** (*Can select more than one*)

|  |  |  |
| --- | --- | --- |
| [ ] Action Research | [ ] Case Study | [x] Mental Health |
| [ ] Oral History/Biographical | [ ] Ethnographic | [ ] Digital/Virtual  |
| [ ] Survey | [ ] Experimental | [ ] Archival |
| [ ] Other, please specify: Click or tap here to enter text. |

1. **Funding Source**

|  |
| --- |
| [ ] Funding will not be sought. |
| [ ] Funding will be sought in the future**If YES**, *please specify the funding agency*: University of Macau |
| [ ] Funding has been sought with the following information: |
| **Name of the funding agency** | **Is funding approved?** |
|  | [ ] Yes, with approval number: Click or tap here to enter text. | [ ] No | [ ] Pending |
|  | [ ] Yes, with approval number: Click or tap here to enter text. | [ ] No | [ ] Pending |
|  | [ ] Yes, with approval number: Click or tap here to enter text. | [ ] No | [ ] Pending |

1. **Has or will this study be submitted to other Human Research Ethics Committees?**

|  |
| --- |
| [ ] No, please go to next section |
| [ ] Yes, with the following information: |
| **Name of the Human Research Ethics Committee** | **Is approval granted?** |
|  | [ ] Yes, with approval number: Click or tap here to enter text. | [ ] No | [ ] Pending |

1. **Does your study involve direct involvement of human participants?**

|  |
| --- |
| [ ] **Yes** |
| [ ] **No, please specify:**[ ] I am using data that has been collected for another purpose[ ] With previous ethics approval with approval number: Click or tap here to enter text.[ ] Data was collected without ethics approval[ ] My study does not involve any data from human participants  (*Please go to part IV*) |

**PART II: PARTICIPANTS DETAILS**

***(To be completed if project involves direct human participation)***

1. **Please identify if you are using potentially vulnerable participants as listed below.**

*(If you are not using potentially vulnerable participants, please skip this question)*

|  |
| --- |
| [ ] Women who are pregnant |
| [ ] Children or young people under the age of 18 |
| [ ] Persons with an intellectual condition or mental condition of any kind |
| [ ] Persons without freedom of movement and/or decision-making authority (e.g., forensic, involuntary patients) |
| [ ] Persons with impaired capacity for communication |
| [ ] Prisoners or people on parole |
| [ ] Persons in dependent or unequal relationships relevant to the research |
| [ ] Deception of participants, concealment, or covert observation |
| [ ] Examining potentially sensitive or contentious issues |
| [ ] Seeking disclosure of information which may be prejudicial to participants |
| [ ] Study of or participation in illegal activities |
| [ ] Other, please specify: Click or tap here to enter text. |

1. **Please describe the participants (in groups) involved in your study (Do NOT blind the identity of the research site)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **How many participants** | **Inclusion criteria** | **Age range** |
| Group 1 |  |  |  |
| Group 2 |  |  |  |

*\** *If you need more rows, please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

*\*\* Please fill in the information in group 1, if the study will only involve one group of participants,*

1. **Do you have any criteria for exclusion from your participant groups?**

|  |
| --- |
| [ ] No, please go to next section. |
| [ ] Yes, with the following criteria: |
|  | Exclusion criteria |
| Group 1 |  |
| Group 2 |  |

*\** *If you need more rows please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

1. **Give details of procedures involving participants**

|  |
| --- |
| *Please provide details about what you are asking participants to do or what is to be done to them. You should provide a clear step-by-step description of what participants will experience if they choose to take part in your project, including interventions, tasks, interviews, etc. (please attach copies of intervention methodologies, instructions, tasks, tests, questionnaires or interview guides to be used and a flow chart if this will clarify the procedures.* |
|  |

1. **Describe how much time you are asking of participants in each group**

|  |  |
| --- | --- |
| Group 1 |  |
| Group 2 |  |

*\** *If you need more rows please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

1. **Will you be offering reimbursement or any other incentives to participants?**

|  |
| --- |
| [ ] No |
| [ ] Yes, with the following reimbursement / incentives: |
| Group 1 |  |
| Group 2 |  |

*\** *If you need more rows please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

1. **Recruitment**

***If relevant, attach text of the poster / advertisement / email / social media post you plan to use***

|  |
| --- |
| ***15.1 Please explain in full step-by-step detail how you will recruit your participants and invite them to participate***  |
| Group 1 |  |
| Group 2 |  |
|  ***15.2 Please explain how you select participants in each group*** |
| Group 1 |  |
| Group 2 |  |

*\** *If you need more rows please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

1. **Does your project involve other organizations?**

|  |
| --- |
| [ ] No (e.g., the project will be conducted at the University of Macau, online only, or directly from individuals) |
| [ ] Yes, the principal investigator is responsible for ensuring that permission letters are obtained, and stored on file, from each organization before any data collection can occur at the specified organization. |
| **Name of the organization** | **Name of person granting permission**  | **Role in the organization** | **Is permission granted?** |
|  |  |  | [ ] Yes | [ ] Pending |

*\** *If you need more rows please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

1. **Will any dependent or unequal relationship exist between anyone involved in the recruitment and the participants?**

|  |
| --- |
| [ ] No  |
| [ ] Yes, describe the nature of the relationship, and explain what special precautions will preserve the rights of such people to decline to participate or to withdraw from participation once the research has begun. |
|  |

1. **Are any of the researchers a member of, or have any association with, any of the organizations, in which you wish to conduct your research**

|  |
| --- |
| [ ] No |
| [ ] Yes, please explain what your role at that/ those organization(s) is/are and what measures you have implemented to reduce the possibility of coercion. |
|  |

**PART III: RISKS AND PROCEDURES INVOLVE HUMAN PARTICIPANTS**

***(To be completed if project involves direct human participation)***

1. **Are there any physical/psychological/social/economic or legal risks greater than inconvenience or is discomfort, in either the short or long term, from participation in the project?**

|  |
| --- |
| [ ] No |
| [ ] Yes |

1. **Describe the potential risks of participation in the project**

|  |
| --- |
|  |

1. **Are all these risks outlined on the information sheet and, where relevant, on the consent form?**

|  |
| --- |
| [ ] Yes |
| [ ] No, please explain why not: Click or tap here to enter text. |

1. **Outline the arrangements planned to minimise the risks involved in these procedures.**

|  |
| --- |
|  |

1. **Should serious events or emergencies occur during the conduct of the research what will you do? What facilities are available to deal with such incidents? Is an appropriate list of counselling services available with the Information Sheet/Informed Consent Form?** (*illegal activities, participant becomes distressed during data collection or at some time afterwards*)

|  |
| --- |
|  |

1. **Will you use a written Information Sheet to inform each participant about the research project?**

|  |
| --- |
| [ ] Yes |
| [ ] No, please describe how and by whom the explanation will be given to participants. |
|  |

1. **Will all participants, including organizations, be fully informed about the true nature of the research?**

|  |
| --- |
| [ ] Yes |
| [ ] No, please describe the procedure and explain why the real purpose needs to be concealed |
|  |

1. **Please explain how you will obtain informed consent from your participants. If you are not using a signed consent form, explain why one is unnecessary or inappropriate.**

|  |
| --- |
| [ ]  Implied consent – the return of an anonymous survey implies consent |
| [ ]  Signed consent form (please provide the consent form in a separated document). Please explain the process by which the participants will give consent and how the consent form will be returned to the researcher. |
|  |
| [ ]  Other, please specify: Click or tap here to enter text. |

1. **If the participants in your study are unable to consent for themselves, explain how you intend to obtain informed consent. How will adequate information be provided to those who will give consent on their behalf?**

|  |
| --- |
|  |

**PART IV: RISKS AND PROCEDURES INVOLVED IN THE USE OF EXISTING DATA**

***(To be completed if project involves the use of existing data)***

1. **Please describe the form of the data set** (*For example database, spreadsheet)*

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|  |

1. **How was the data originally collected?**

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|  |

1. **What was the primary purpose for original collection of data?**

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1. **Please explain what information the participants were given at the time the data was collected from them and how that information was given to them (e.g., Information sheet, verbal explanation).** *If an information sheet was used, please attach a copy (if it is available).*

|  |
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|  |

1. **Will the organization who owns the dataset be fully informed about the true nature of the research?**

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| --- |
| [ ] Yes |
| [ ] No, please describe the procedure and explain why the real purpose needs to be concealed |
|  |

1. **Please explain the method used for obtaining consent from the original participants for the original collection and use of the data.**

|  |
| --- |
| [ ]  Implied consent – the return of an anonymous survey implies consent |
| [ ]  Consent form (please attach the consent form to this application). Please explain the process by which the participants will give consent and how the consent form will be returned to the researcher. |
|  |
| [ ]  Other, please specify: Click or tap here to enter text. |

**PART V MATERIAL AND PROCEDURES**

1. **How will the data be collected?** (*Can select more than one*)

|  |  |  |
| --- | --- | --- |
|  | Please complete as specified | Further information required |
| [ ]  Questionnaire(s) or survey(s) | [ ]  Online [ ]  Printed[ ]  Other, please specify: Click or tap here to enter text. | * Attach questionnaire(s)/ survey(s)
* Please specify how the survey will be returned to you: Click or tap here to enter text.
 |
| [ ]  Fully identifiable (name on it) [ ]  Potentially identifiable (coded)[ ]  Anonymous (never can be identified) |
| [ ]  Interviews | [ ]  Structured[ ]  Semi-structured [ ]  Unstructured | Audio recording [ ] Yes [ ]  NoVideo recording [ ] Yes [ ]  No | * Attach interview questions or lists of topics
 |
| [ ]  Observations | [ ]  With the knowledge of participants[ ]  Without the knowledge of participants | Audio recording [ ] Yes [ ]  NoVideo recording [ ] Yes [ ]  No |  |
| [ ]  Photography or videography | [ ]  With the knowledge of participants[ ]  Without the knowledge of participants | Audio recording [ ] Yes [ ]  NoVideo recording [ ] Yes [ ]  No |  |
| [ ]  Responses to tasks or stimuli or simulations | * Provide copies or description of tasks
 |
| [ ]  Other | Please specify: Click or tap here to enter text. |

1. **Where will the data be collected? If not known, please provide suggested locations.**

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|  |

1. **By whom will the data be collected?**

|  |
| --- |
| [ ] Principal Investigator / Primary Supervisor |
| [ ] Co-Investigator |
| [ ] Student Researcher |
| [ ] Research Assistant |
| [ ] Other, please specify: Click or tap here to enter text. |

1. **Will you require the use of a translator, or will you use documentation translated into a language other than English/Chinese?**

|  |
| --- |
| [ ] No |
| [ ] Yes, please describe how the translator will be utilized. If using translated documents, please provide a copy of the documentation in English/Chinese and a copy in the translation. |
|  |

1. **Does this research involve interactions with children or other vulnerable individuals who are not supervised by a parent/guardian/teacher/care giver?**

|  |
| --- |
| [ ] No |
| [ ] Yes, please explain why supervision is not available and the measures implemented to manage this situation. |
|  |

1. **Is there a dependent or unequal relationship between any person collecting the data and the participant?**

|  |
| --- |
| [ ] No |
| [ ] Yes, please give details and explain the measures implemented to manage this situation. |
|  |

1. **Will you indicate the procedure proposed above to potential participants in your information sheet?**

|  |
| --- |
| [ ] Yes, please give details and explain the measures implemented to manage this situation. |
| [ ] No, please explain why not: Click or tap here to enter text. |

**PART VI USE AND DISCLOSURE OF INFORMATION**

1. **Are you collecting, using or disclosing PERSONAL INFORMATION, HEALTH INFORMATION or SENSITIVE INFORMATION?**

|  |
| --- |
| [ ]  No, [ ]  I am obtaining participants names from a public domain source, and I am using an anonymous survey and I am not using a consent form or collecting their names in any other way.[ ]  I am not obtaining participants names at any point during the research.[ ]  I am using fully de-identified data from a database. I will never be able to reasonably ascertain the identity of any individual.[ ]  I am not using any data related to human participants, please skip part VI[ ]  No, please specify: Click or tap here to enter text. |
| [ ] Yes,[ ]  Personal information (e.g., name, student number)[ ]  Sensitive information (e.g., sexual behavior, illegal activities)[ ]  Health information (e.g., medical history, diagnosis) |

1. **How will information be handled to safeguard confidentiality?**

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|  |

1. **Describe the procedures you will use to protect participants from any distress, embarrassment or other harm that might be caused when the data is reported.**

|  |
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1. **Does the Participant Information Consent Form explain the following?**

|  |  |  |
| --- | --- | --- |
| [ ] Yes | [ ]  No | The identity of the organization/principal investigator collecting the information and how to contact it/him/her? |
| [ ] Yes | [ ]  No | The purposes for which the information is being collected? |
| [ ] Yes | [ ]  No | The period for which the records relating to the participant will be kept? |
| [ ] Yes | [ ]  No | The steps taken to ensure confidentiality and secure storage of data? |
| [ ] Yes | [ ]  No | The types of individuals or organizations to which your organization usually discloses information of this kind? |
| [ ] Yes | [ ]  No | How privacy will be protected in any publication of the information? |
| [ ] Yes | [ ]  No | The consequences (if any) for the individual if all or part of the information is not provided. |

1. **Does the project involve the collection, use or disclosure of identified or potentially identifiable information from sources other than the individual whose information it is?**

|  |
| --- |
| [ ] No, please go to Q51 |
| [ ] Yes. |

1. **Does the project involve the collection, use or disclosure of information without the consent of the individual whose information it is (or their legal guardian)?**

|  |
| --- |
| [ ] No, please go to Q51 |
| [ ] Yes. |

1. **Please provide the sources of information will be collected from and list the information or records to be collected.**

*Only answer this question if the project involves the collection of identified (or potentially identifiable) information from a source other than the individual (or their legal guardian) without the consent of the individual or their legal guardian.*

|  |  |  |
| --- | --- | --- |
| **Source** | **Permission** | **Information or records to be collected***(e.g. contact information; complete medical history)* |
| **Quantity** | **Type** |
|  | [ ] Yes[ ] Pending[ ] No, please explain why permission is not available: Click or tap here to enter text. |  |  |
|  |  |
|  |  |
|  | [ ] Yes[ ] Pending[ ] No, please explain why permission is not available: Click or tap here to enter text. |  |  |
|  |  |
|  |  |

*\** *If you need more rows please click on a row, go to TABLE on the menu bar and then to INSERT on the drop-down menu. Click on ROWS BELOW.*

1. **Please explain why information will not be collected or used in a de-identified form.**

|  |
| --- |
|  |

1. **Please explain why you will not obtain consent from the individual(s) whose information will be collected or used?**

|  |
| --- |
|  |

1. **What are the specific purposes for which the information will be collected or used?**

|  |
| --- |
|  |

1. **Will the data be shared with third parties during or after the completion of the study?**

|  |
| --- |
| [ ]  No, the data can only be accessed by the UM research team of this study. |
| [ ] Yes,[ ]  Open data repositories[ ]  Journal publisher(s)[ ]  Research collaborator(s), please specify: Click or tap here to enter text. [ ]  Government department(s), please specify: Click or tap here to enter text.[ ]  Other, please specify: Click or tap here to enter text. |

1. **Describe the security arrangements for storage of the information. Where will the information be stored? Who will have access to the information?**

|  |
| --- |
|  |

1. **For what period of time will the information be retained? How will the information be disposed of at the end of this period?**

|  |
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1. **How will the privacy of individuals be respected in any publication arising from this project?**

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1. **Are procedures in place to manage, monitor and report adverse and/or unforeseen events relating to the collection, use or disclosure of information?**

|  |
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|  |

**PART VII FEEDBACK AND DEBRIEFING**

1. **In what form will you publish this research? (***Can select more than one***)**

|  |
| --- |
| [ ]  Thesis |
| [ ]  Journal article / book / chapter |
| [ ]  Conference presentation |
| [ ]  Report to organization |
| [ ]  Online web based |
| [ ]  Oral presentation |
| [ ]  Other, please specify: Industry practitioner-oriented report, industry workshops |

1. **In what form will information about results of the project be communicated to participants and / or parents and guardians?**

|  |
| --- |
| [ ]  Summary |
| [ ]  Copy of journal article / book / chapter |
| [ ]  Conference presentation |
| [ ]  Report to organization |
| [ ]  Online web based |
| [ ]  Oral presentation |
| [ ]  Results will not be communicated to participants and / or public, please go to Q58 |
| [ ]  Other, please specify: Click or tap here to enter text. |

1. **How will participants be provided with the results?**

|  |
| --- |
| [ ]  Participants will be provided with the researchers’ contact details in the Information Sheet/Recruitment Document(s)/Informed Consent Form to request the results |
| [ ]  Participants will be advised of the website on which the results will be available |
| [ ]  Other, please specify: Click or tap here to enter text. |

1. **Will any other persons or organization be provided with the results?**

|  |
| --- |
| [ ]  Yes, please specify: Click or tap here to enter text. |
| [ ]  No |

1. **How will others be provided with the results?**

|  |
| --- |
| [ ]  In totally de-identified summary form in which no individual can be identified |
| [ ]  In de-identified summary form, but in a manner which may allow individuals to be identified |
| [ ]  In identified form, or in a manner which may allow participants to be identified |
| [ ]  Other, please specify: Click or tap here to enter text. |

1. **Is a form of debriefing required because deception has been employed or because the research has aroused emotional feelings? How will this be arranged?**

|  |
| --- |
|  |

1. **How will information about results of any tests be communicated to participants and / or parents and guardians? What arrangements will be in place to deal with participants’ distress in the case of adverse test results?**

|  |
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|  |

**PART VIII OTHER ETHICAL ISSUES**

1. **Are there any other ethical issues raised by the proposed project? What is your response to them?**

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|  |

**PART IV: DECLARATION AND SIGNATURE**

We, the undersigned, declare the following

1. I/We declare that the information supplied in this application is to the best of our knowledge and accurate.
2. I/We agree to uphold the protection of research participants’ rights and safety through adherence to local laws and institutional policies.
3. I/We understand that approval by the Sub-panel is subject to regular renewal according to policy.
4. I/We agree to report to the Sub-panel for
	1. Any planned change(s) to the study, and further agree not to implement any change(s) without receiving prior approval, except to eliminate immediate hazard to research subjects or when the change(s) involve only logistical or administrative issues.
	2. Any unanticipated problems involving risks to subjects such as severe adverse event within 24 hours of its identification
5. I/We agree to keep all study documents for a period of **at least three years** after study closure.
6. I/We agree to maintain adequate records and to make them available for audit/inspection.
7. I/We agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
8. I/We undertake to assure that any documents translated into a language other than English are accurate and accept full responsibility for any events arising as a result of inaccuracies is such translations.
9. I/We acknowledge the sub-panel shall not bear any responsibility for any problems, losses, or damage caused by the study.
10. I/We understand that it is my/our responsibility to obtain any additional ethical, legal or other approvals for this application.

|  |  |  |  |
| --- | --- | --- | --- |
| *For academic’s research project:* | **Name** | **Signature** | **Date (dd/mm/yyyy)** |
| **Principal investigator (PI)** |  |  |  |
| *For student’s research project:* | **Name** | **Signature** | **Date (dd/mm/yyyy)** |
| **Academic Supervisor** |  |  |  |
| **Student** |  |  |  |