224/223

**THE UNIVERSITY OF HONG KONG**

**Human Research Ethics Committee**

Application Form for Ethics Approval

for Taught Postgraduate and Undergraduate Students

Notes:

1. Please read carefully the University’s [Policy on Research Integrity](https://www.rss.hku.hk/integrity/rcr/policy), the [Operational Guidelines and Procedures](https://www.rss.hku.hk/HREC/guidelines.pdf) for the Human Research Ethics Committee, and the summary of the Belmont Report available from the Research Services [website](https://www.rss.hku.hk/integrity/ethics-compliance/hrec-approved-projects) before completing this form.
2. This application form can be used by taught postgraduate and undergraduate students as advised by the respective Faculty/Department.
3. Starting from July 2, 2020, applications from staff and research postgraduate students in the non-clinical Faculties (i.e. Faculties of Architecture, Arts, Business and Economics, Education, Engineering, Law, Science and Social Sciences) should be submitted online via the Human Research Ethics Application System. Applications in hard copy will not be accepted except for staff and research postgraduate students from the Faculties of Dentistry and Medicine referred by the IRB and non-HKU PIs.
4. No data can be collected/analysed before ethics approval is obtained from the relevant committee.

**Part A – Outline of Application**

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| **1. Research Proposal** |

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| Project title: |  |
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| Abbreviated project title# (optional): |  |
|  |
| Data collection period (please tick one of the boxes): |
| 🞏 | From |  | to |  | (dd/mm/yyyy) |
|  | (Ethics approval MUST be obtained prior to any data collection or analysis taking place.) |
| 🞏 | Not applicable as no new data will be collected. |
|  |
| Project start/end dates: | From |  | to |  | (dd/mm/yyyy) |
|  |
| # The project title and name and department of the PI of applications processed by the HREC will be posted on a public webpage maintained by Research Services (<https://www.rss.hku.hk/integrity/ethics-compliance/hrec-approved-projects>) once this application is approved until the expiry of the ethics approval period. If the PI has concerns in revealing the project title on the public webpage, an abbreviated project title can be provided in the application form which will be posted on the public webpage.  |

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| **2. Principal Investigator (PI)** |

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| --- | --- | --- | --- | --- | --- |
| Title: |  | Surname: |  | First name: |  |
|  |
| Department: |  |
|  |
| Position/staff grade: |  | Staff no.: |  |
|  |
| Contact telephone: |  | Email: |  |
|  |
| For student PI only: |
|  |
| Degree and year: |  | Student no.: |  |
|  |
| Name of supervisor: |  | Supervisor email: |  |

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| **3. Co-Investigator(s), if any** |

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| --- | --- | --- | --- | --- | --- |
| Name(surname, first name) | Department (and institution for non-HKU Co-I) | Position (for staff Co-I only) | Programme (for student Co-I only) | HKU staff/ student no., if applicable | Email address |
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| **4. Funding** |

Please check all that apply, and then specify the funding scheme below:

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| HKU internal research grants |  |  |
| Research Grants Council (RGC) |  | GRF / ECS / AOE / TRS / CRF / Others\*: |
| Non-RGC grants |  | ECF / HCPF / HMRF / ITF / PPR / SDF / QEF / Others\*: |
| Contract research |  |  |
| No funding |  |  |

Note: Postgraduate Scholarship (PGS)/Hong Kong PhD Fellowship (HKPF) of RPg students are not considered as research funding.

**Part B – Proposal / Project Details**

Please provide details of your proposal/project in this part in layman terms. Do not enter “see attached”.

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| **5. Objectives of Study** |
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| **6. Hypothesis, if any** |
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| **7. Elements of Research Methodology that Involve Human Participants (not more than ½ page)** |
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**Part C – Data Collection**

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| **8. Sources of Data** |

Please check all that apply:

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| --- | --- |
|  | New data to be collected from human participants |
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|  |  | Experimental procedures/treatment/intervention |
|  |  | Focus group |
|  |  | Internet survey |
|  |  | Observation |
|  |  | Personal interviews |
|  |  | Self-administered questionnaire |
|  |  | Telephone survey |
|  |  | Others, please specify: |
|  |  |  |
|  | Pre-existing data from human subjects |

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| **9. Study Participants – for New Data to be Collected from Human Participants** |

(a) Recruitment and selection of participants

 (i) How will participants be recruited?

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 (ii) Participant inclusion criteria (e.g. Hong Kong residents aged 18 years and above):

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 (iii) Participant exclusion criteria (e.g. people with metal implants need to be excluded from MRI):

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(b) Who will perform the data collection?

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(c) Where will the data collection take place?

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(d) How long will the data collection take for each participant?

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(e) Possible benefits to participants:

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| **10. Risk Assessment – for New Data to be Collected from Human Participants** |

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| (a) Will the study involve intervention, such as action research/treatment of any type? |  | Yes |  | No |

 If “Yes”, please give details:

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| (b) Will the study involve initial deception of the full context of the study to avoid bias? |  | Yes |  | No |

 If “Yes”, please provide details and attach the debriefing form:

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| (c) Before any attempts are made to minimize privacy risk (e.g. making the forms anonymous), is it possible that the study will involve greater than minimal privacy risks to research participants, either due to collection of sensitive data, such as political behaviour, illegal conduct, drug or alcohol use and sexual conduct, or because there is some risk of re-identification using a unique identifier such as DNA? |  | Yes |  | No |
|  |  |  |  |
| (d) Is it possible that the duration of the procedures will induce greater than minimal stress, in particular, for children, given their age and capacity? |  | Yes |  | No |
|  |  |  |  |
| (e) Is it possible that the study will induce greater than minimal psychological stress/pain/discomfort? |  | Yes |  | No |
|  |  |  |  |
| (f) Is it possible that the study will expose participants to greater than minimal physical or medical risk?Note: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. |  | Yes |  | No |
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If “Yes” to any of Questions 10(c) to (f), please state the precautions taken to minimize such stress/pain/discomfort/risk:

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| (g) Will photography of participants be used during the study? |  | Yes |  | No |
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| (h) Will video-recording of participants be used during the study? |  | Yes |  | No |
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| (i) Will audio-recording be used during the study? |  | Yes |  | No |

If “Yes” to any of Questions 10(g) to (i), please provide details and justifications for the recording, and storage strategies:

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| (j) Will the study involve vulnerable participants who are unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals? |  | Yes |  | No |
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 If “Yes”, please specify details of the age group and/or vulnerability, and attach a Parent/Guardian Consent form:

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| (k) Will the study involve the use of research participants who are/were engaged in activities potentially in breach of the law? |  | Yes |  | No |
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|  If “Yes”, please observe the conditions stated under “Part E – Declaration”, and provide details by explaining (i) the nature of the “illegal/unethical/unsafe conduct” undertaken by the research participants; (ii) whether or not the risk is limited *only* or *primarily* to practitioners and/or consumers; and (iii) how you will protect yourself and the research participants.  [Note: For the online application form in the Human Research Ethics Application System (HREAS), the conditions will be shown as an “alert” pop-up window if “Yes” is ticked and the PI will need to confirm observance to the conditions and complete the follow-up questions before the application form can be submitted. The presentation of this question in the online form can be found under Annex III-a.] |
| (l) Is there any potential conflict of interest? (e.g. financial gain to the investigators, power over participants such as teacher/student relationship) |  | Yes |  | No |
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 If “Yes”, please state details about the conflict of interest and state how that potential conflict will be addressed:

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| (m) Will this study involve matching of personal data from different data sources (e.g. multiple questionnaires)? |  | Yes |  | No |
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 If “Yes”, please explain what identifier will be used for matching:

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| **11. Informed Consent – for New Data to be Collected from Human Participants** |

* When conducting research where seeking written consent is not practical or too sensitive, audio-recorded oral consent or email recorded consent might be less of a privacy risk than written consent and can be considered as an alternative.
* The waiver of recorded informed consent is normally only applicable to newly collected data without personal identifiers. In this case, PIs are required to clearly specify that they are recording data without personal identifiers in their research grant proposals.

(a) How will you record informed consent? (Please check all boxes that apply)

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|  | Written consent |  | Audio-recorded consent |  | Online/Email recorded consent |

If you will not record informed consent, please complete the following Questions (i) to (iii) below and submit an information sheet.

 (i) Please explain why the proposed study presents no more than minimal risk to the participants?

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 (ii) Why does a waiver of recorded informed consent not adversely affect the rights and welfare of the participants?

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 (iii) Do you know the identity of respondents?

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|  | Yes |  | No |

 (Note: Knowing the identity of respondents is distinct from whether their identity is recorded.)

 If “Yes”, please explain why the study is not practicable with recorded informed consent:

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| **12. Data Retention – for New Data to be Collected from Human Participants**  |

(a) How long will the data containing personal identifiers be kept after publication of the first paper arising from the research project?

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(b) How long will the anonymized data be kept after publication of the first paper arising from the research project?

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Note: According to the Operational Guidelines and Procedures of the Committee (http://www.rss.hku.hk/integrity/ethics-compliance/hrec), the minimum retention period for research data and records is 3 years after publication or public release of the research to ensure that there are no problems with consent, fabrication and falsification. PIs are strongly advised to remove all personal identifiers for long term retention of their research data, in order to minimize privacy risks. Data with personal identifiers must not be kept beyond 5 years after publication unless there is explicit written consent from the participants to retaining the data with personal identifiers preserved, such as in oral histories. Anonymised data and records should be retained for as long as they are of continuing value to the researcher and the wider research community.

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| **13. Pre-existing Data from Human Subjects**  |

(a) What is the source of the original dataset?

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| (b) Are the original dataset in existing documents/records publicly available? Note: “publicly available” means that the data can be accessed without an approval process. If "Yes", please indicate where the dataset is available (e.g. web address):  If “No”, please specify the approving authority for access: |  | Yes |  | No |
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| (c) Were the original dataset originally collected for academic research purpose? If “Yes”, please attach a copy of the Consent Form for the original collection of data.If “No” please attach a copy of the Personal Information Collection Statement.  |  | Yes |  | No |
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For **ALL** situations, please explain how this research is consistent with the purpose and use specified when the data were originally collected:

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| (d) Are the original dataset sensitive? (e.g. sexual preference, health status, criminal activity)  |  | Yes |  | No |

Please provide **full details** on types of personal data to be used:

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| (e) Do the original dataset contain any personal identifiers?  |  | Yes |  | No |

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|  If “No”, it means neither the researcher nor the source providing the data can identify a subject based upon the information provided with the data. |
|  If “Yes”: |
| (i) Is the personal identifier direct or indirect? |  | Direct |  | Indirect |
|  Direct identifier – e.g. name, address, ID card no., medical record no., etc.  Indirect identifier – e.g. assigned code that can make a subject reasonably identifiable. |  |  |  |  |
| (ii) Will you abstract/record any subject identifiers in the data extraction process? |  | Yes |  | No |  | N/A |

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| (f) Will any **new** data be collected from subjects, other than the data obtained from the original dataset? (If “Yes”, please complete Questions 9 to 12.) |  | Yes |  | No |
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**Part D – Attachments**

Please check the boxes as appropriate to indicate which of the following documents are enclosed to this application.

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| --- | --- |
| (1) Full research proposal including any questionnaire and/or interview script(i) |  |
| (2) Parent/Guardian Consent Form ([sample documents](https://www.rss.hku.hk/integrity/ethics-compliance/hrec-forms)) |  |
| (3) Informed Consent Form/Information Sheet ([standard templates of Informed Consent Form and sample language](https://www.rss.hku.hk/integrity/ethics-compliance/hrec-forms))(ii) |  |
| (4) Consent script, for oral consent or email reply for consent ([sample documents](https://www.rss.hku.hk/integrity/ethics-compliance/hrec-forms))(ii) |  |
| (5) Deception: post debriefing consent form ([sample documents](https://www.rss.hku.hk/integrity/ethics-compliance/hrec-forms)) |  |

Notes: (i) Mandatory; (ii) Mandatory unless waiver has been applied for or no data collection is being undertaken.

**Part E – Declaration**

In making this application, I certify that I have read and understand the University’s Policy on Research Integrity, the Operational Guidelines and Procedures of the Human Research Ethics Committee (HREC), and the summary of the Belmont Report, and I will comply with the ethical principles of these documents. I will report to the HREC/Faculty/Department if there is any amendment, new information on the project and any research-related incidents, such as physical or emotional harm to the participants during the research process or breaches of confidentiality. I undertake not to proceed with data collection/analysis before ethics approval is obtained from the relevant committee, and understand that failure to do so will lead to disciplinary action.

*For applications that may involve research participants who are/where engaged in activities in breach of (or potentially in breach of) the applicable laws (including those of Hong Kong and/or those of other relevant jurisdictions)*

In case sensitive data, namely, information related to possible illegal/unlawful conduct of research participants needs to be collected, I will take extra precautions to minimize risk to my research participants and myself and avoid any unethical action that may be illegal, especially when it is in breach of the Personal Data (Privacy) Ordinance or other relevant laws of Hong Kong and/or those of other relevant jurisdictions.

As sensitive data could place research participants at significant risk if a criminal investigation were to take place, I understand that I would be required by a court order to hand over data, and that destruction of such materials after a court order to produce it has been issued could result in criminal prosecution.

In order to safeguard research participants and myself, I will store data including answers to questionnaires, interview transcripts, etc. (held electronically or in hard copy) in a manner so that it cannot be directly matched with the identity of individual research participants (such as names of participants, date of interview, location of interview etc.).

In the event that an ethics application involves research participant(s) under investigation by a competent authority or participant(s) subject to legal proceedings in court of otherwise (criminal, civil or disciplinary), I understand that the University will normally suspend the processing of the ethics application until the completion of the relevant investigation or legal proceedings.

I will oblige by the following principles:

1. serious and due consideration must be given to whether or not such involvement is well justified, taking into account such factors as academic merit, alternative research methods and sources, potential risks, mitigation measures and interests of stakeholders;
2. there must not be any act, conduct or activity that may bring the University into disrepute;
3. there must not be aiding, abetting, counselling or incitement in respect of any offence or potential offence;
4. legal duties to report or disclose as required under the applicable laws must be discharged (e.g. legal provisions in respect of offences of drug trafficking, money laundering, terrorism, national security, etc.);
5. there must not be obstruction to criminal or other investigations by the competent authorities or the commission of acts tending to pervert the course of justice;
6. requests for the disclosure of information/documents (including confidential information/documents) as required under the compulsion of applicable laws must be complied with; and
7. in the informed consent form, in addition to being provided with the general information, prospective research participants must be informed of the risks and circumstances in which confidentiality may not be maintained (e.g. compulsion by relevant legal authorities to hand over research materials or answer questions) and what additional safeguards the PI will therefore undertake to protect the integrity of the research and the identity of research participants, subject to compliance with the applicable laws.

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| Name of Principal Investigator |  | Signature |  | Date |

I/We hereby endorse this application with my approval and confirm that the investigator(s) is/are appropriately qualified in the research area involved to conduct the proposed research project, and is/are capable of undertaking this research study in a safe and ethical manner.

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| Name of Supervisor (if appropriate) |  | Signature |  | Date |
|  |  |  |  |  |
| Name, Head of Dept/Dean of Faculty/Faculty Reviewer\* |  | Signature |  | Date |

\* Please delete as appropriate.

February 2023