**City University of Macau**

For official use

Reference No.:

**Faculty of Health Wellness**

**Ethical Review for Behavioral and Social Sciences Research**

**Application Form for Ethical Approval 倫理審批申請表**

|  |  |
| --- | --- |
| Review categories | Exempt review 免除審查  Expedited review 簡易審查 Full review 全面審查 |

|  |  |
| --- | --- |
| **Details for data collection (please check all the situations applicable to your research)資料收集細節（請勾選所有適用於您研究的情況）** |  |
| Part A Summary摘要 （\*Mandatory必填） |  |
| Part B Summary of research protocol 研究方案摘要（\*Mandatory必填） |  |
| Part C Using newly Collected Data 使用新收集數據 |  |
| 1.1 Checklist for expedited/full review 快速/全面審查表單 |  |
| 1.2 Detailed research information for full review (in 1.1 if any YES) 供全面審查的詳細研究資訊 |  |
| Part D Using Existing Documents or Records containing Personal Data 使用包含個人數據的現有文件或記錄 |  |
| Part E Waiver of Written Informed Consent 書面同意書豁免   * 針對現有數據二次分析； * 受試者在生理或心理上無法完成知情同意簽署，同時這種無法簽署知情同意的生理或心理狀態是研究的納入標準之一的情況下才能免除知情同意; * 受試者收到的風險不大於最小風險; * 獲取知情同意將直接導致試驗無法進行; * 倫理審查委員會已進行風險獲益評估，並認為豁免知情同意過程不會增加受試者受害可能性。 |  |
| Part F Benefits利益 （\*Mandatory必填） |  |
| Part G Attachments附件 （\*Mandatory必填） |  |
| Part H Declarations 聲明（\*Mandatory必填） |  |

* 全面審查 （full-board review），其原意為倫理委員會進行全面審查。被判定為風險超過最低限度的研究將接受委員會的全面審查，可對研究方案中的相關研究倫理以及研究參與者保護，考慮得更為周全。根據研究範圍，涉及受保護人群（如兒童、囚犯或殘障人士）的研究將接受委員會的全面審查。
* 簡易審查之原文為（expedited review），其原意為快速審查，亦即研究計畫類型所涉及的研究倫理風險較低，可以更簡易與快速的方式完成其審查程序者，可以採簡易審查方式來進行之。
* 免除審查之原文為（exempt review），其原意為豁免審查，亦即研究方案本要經審查程序，但因研究計畫類型所涉及的研究倫理風險相當低，因此，可加以豁免審查程序，以節省審查資源並有利研究計畫的快速推動。課題主持人雖自行判定研究課題可能符合免除審查，但仍需送審，而由研究倫理審查委員會加以確認，並開立免審證明。

***Please complete Parts A - B and F – H. If you are collecting new data, please also complete Part C. If you are studying existing personal data, document or records, please also complete Part D. If you are collecting new data, and seeking a waiver of informed Consent, please also complete Part E. 請完成 Parts A - B and F – H。此外，如果您正在收集新數據，請填寫C部分。如果您正在研究現有的個人數據、文件或記錄，請填寫D部分。如果您正在收集新數據及尋求豁免知情同意，請同時填寫E部分。***

**Part A： Summary 摘要**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Principal Investigator 首席研究員** | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | | | | | |
| Name: |  | | Degree Programme/Year: | | |  | | | Student No.: | | | |  | |  |
| Name of Supervisor: | |  | | | | Supervisor email: | | | | | |  | | |  |
|  | | | | | | | | | | | | | | | |
| **Co-Investigator(s)， if any 共同研究者（們），如有** | | | | | | | | | | | | | | | |
| Name: | | | | | | | | Staff/ Student No: | | | | | | | |
| Position職位： | | | | | | | | Department/Unit部門： | | | | | | | |
| Degree Programme/Year (for students only): | | | | | | | | | | | | | | | |
| Name: | | | | | | | | Staff/ Student No: | | | | | | | |
| Position: | | | | | | | | Department/Unit: | | | | | | | |
| Degree Programme/Year (for students only): | | | | | | | | | | | | | | | |
| **Research Proposal/Project 研究方案/項目:** | | | | | | | | | | | | | | | |
| Title: |  | | | | | | | | | | | | | |  |
|  |
| Start date: |  | | | | Expected completion date: | | | | | |  | | | |  |
|  |  | | | |  | | | | | |  | | | |  |
| **Funding Source (please tick as appropriate) 資金來源（如適用，請勾選）：** | | | | | | | | | | | | | | | |
| University internal research grants#  **大學內部研究資助** | | | |  | | | RGC General Research Fund  **研究資助局一般研究基金** | | | | | | |  | |
| Innovation Technology Fund  **創新技術資助** | | | |  | | | Public Policy Research  **公共政策研究** | | | | | | |  | |
| Contract Research#  **合同研究** | | | |  | | | Other external grant#  **其他外部資助** | | | | | | |  | |
| No funding **沒有資金** | | | |  | | |  | | | | | | |  | |
| # Please specify funding source請說明資金來源： | | | | | | | | | | | | | | | |

*\*Delete as appropriate 請刪除不適用的項目*

#### Part B： Summary of Research Proposal 研究方案摘要

**Please summarise on ONE page the objectives of the project and methodology used, and attach a copy of your proposal including any questionnaire and informed consent form to be used. 請用一頁紙概述研究項目目的和研究方法，並附上一份研究方案，包括將使用的調查問卷和知情同意書。**

|  |
| --- |
| **Objectives of the proposal（Within 400 words） 研究目標（400字以內）** |
|  |
| **Research plan and methodology, including research design, participants and sampling, sample size, data collection, measures, and others (Within 500 words) 研究計劃和方法，包括研究設計、參與者與抽樣、樣本量、資料收集、方法及其它（500字以內）** |
|  |

**Part C： Risk Assessment for Newly Collected Data 新收集數據的風險評估**

|  |  |  |
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| **Please answer the following questions, if your proposal involves any newly collected data, to decide if your proposal should be submitted for expedited review. 如果您的研究方案涉及任何新收集的數據，請回答以下問題，以決定您的研究是否應提交簡易審查。** | | |
|  | Yes | No |
| a) Will the study involve action/participatory/treatment research? 研究是否涉及行動/參與/治療干預研究？ |  |  |
| b) Is it possible that the study will involve greater than minimal privacy risks, which could induce stress to research participants, such as political behaviour, illegal conduct, drug or alcohol use and sexual conduct? 該研究是否可能涉及超過最低限度的隱私風險，從而給研究參與者帶來壓力，如政治行為、非法行為、藥物酒精使用及性行為？ |  |  |
| 1. Is it possible that the participants’ burden to complete the procedures will induce greater than minimal stress, in particular, for children, given their age and capacity? 是否有可能參與者完成研究的負擔會超過最小壓力，特別是考慮到兒童的年齡和能力？ |  |  |
| 1. Is it possible that the study will induce greater than minimal physical or psychological stress/pain/discomfort? 研究是否可能造成超過最小程度的生理或心理壓力/疼痛/不適？ |  |  |
| 1. Is it possible that the study will expose participants to greater than minimal physical or medical risk? 研究是否有可能使參與者暴露於超過最低限度的身體或醫療風險？ |  |  |
| 1. Will deception be used during the study?研究是否會使用欺騙手段？ |  |  |
| 1. Will video-recording be used during the study?研究期間是否會使用錄像？ |  |  |
| 1. Will audio-recording be used during the study? 研究期間是否會使用錄音？ |  |  |
| 1. Is there potential conflict of interests? （e.g. financial gain to the investigators， power over participants such as teacher/student relationship）是否存在潛在的利益衝突？ （如調查者的經濟收益，如師生權利關係影響參與者） |  |  |
| 1. Will the study involve vulnerable participants who are unable to give informed consent, e.g., under the age of 18, mentally handicapped individuals? 研究是否會涉及無法做出知情同意的弱勢參與者，如未滿18周歲者、智障者？   - If “Yes”， please specify details of the age group and/or vulnerability 若“是”請詳細說明年齡組和/或脆弱性：  (Parent/Guardian Consent Form should be attached.）（應付上家長/監護人同意書） |  |  |

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| For Expedited Review: ***- If you have answered “No” to all of the questions (a) – (j) above, your application may qualify for an expedited review, meaning that your research involves minimal risk[[1]](#footnote-1). However, informed consent is still required unless reasons why this is infeasible are adequately justified. 如果您對上述（a）-（j）的所有問題回答均為“否”，則您的申請可能符合簡易審查的條件，即您的研究涉及的風險極低。 但是，除非有充分理由證明不可行，否則仍需獲得知情同意。*** |

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| For Full Review： 全面 ***- If you have answered “Yes” to any of the above questions (a) – (j), please give more details on your study design and methodology in the questions (k) to (t). 如果您對上述問題（a） – （j）的任一問題回答“是”，請在 （k） -（t）中詳細說明您的研究設計和方法*** |
| 1. The selection and recruitment of participants （Attach any initial letter of contact and Consent Form） 參與者的選擇和招募（附上最初的聯繫函和同意書）      1. Rationale for sample size calculation 計算樣本量的理由 2. How will participants be recruited/identified？ 如何招募/識別參與者？ 3. What are the inclusion and exclusion criteria？納入和排除標準是什麼？ 4. Description of any specific data collection, such as interviews, questionnaire (including telephone) survey or experimental procedures like deception (please attach Deception Form) and any treatment or intervention任何特定資料收集的描述，如訪談、問卷（包括電話）調查或實驗程序（如欺騙手段，請附上欺騙表格），以及任何治療或干預方法。 5. Please state who will perform the data collection， how long it will take and where the data collection will take place. 請說明由誰進行資料收集，需要多長時間以及在哪裡進行資料收集。 6. Can the participants be allowed to withdraw at any time without prejudice?參與者是否可以隨時退出，而不會受到不公平對待？ 7. Will there be any stress/discomfort to participants？參與者會有任何壓力/不適嗎？ 8. Please provide details of any audio and/or video recording including the justifications for the recording. 請提供任何音頻和/或視頻錄製的詳細資料，包括錄製的理由。 9. Please identify any potential conflict of interest and how that potential conflict will be addressed. 請指出任何潛在的利益衝突，以及如何處理這些潛在的衝突。 |

**Part D: Using Existing Documents or Records Containing Personal Data**

**使用包含個人資料的現有文檔或記錄**

**Please complete this section if you are using existing documents or records that contain any personal data. 如果使用包含任何個人資料的現有文檔或記錄，請填寫本部分。**

|  |
| --- |
| Will existing documents or records containing any personal data be used? 是否會使用包含任何個人資料的現有文檔或記錄？ Yes  No  - If “Yes”, please give more details of the personal data being obtained by answering questions (a) – (h) in the following. 若“是”，請回答下列問題（a） – （h） ，並詳細說明所獲取的個人資料  - If “No”， please skip this Part D. 若“否”，請跳過D部分。 |
| 1. What is the source of the data? 數據來源是什麼？   b) Were the data originally collected for research purposes? 最初收集數據是否用於研究目的 Yes  No   |  |  | | --- | --- | | - | If “Yes” is checked, please attach a copy of the Consent Form for the original collection of data. 如果勾選“是”，請附上原始資料收集同意書的副本 | | - | If “No” is checked， please provide the Personal Information Collection Statement. 如果勾選“否”，請提供個人信息收集聲明。 | | - | For all situations, please explain how this research is consistent with the purpose and use specified when the data were originally collected. 在所有情況下，請解釋本研究如何與最初資料數據時指定的目的和用途保持一致。 | |
| c) Please list the types of personal data being used, if not already listed in the Consent Form for the original collection of data or Personal Information Collection Statement. 如原始資料收集同意書或個人信息收集聲明中未列出，請列出正在使用的個人數據類型 |

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| d) Are any of the data listed above sensitive? 上述資料中有任何敏感資料嗎？ Yes  No   * + If “Yes”， please provide full details. 如果“是”，請提供完整詳情。 |
| e) Is the source of data publicly available[[2]](#footnote-2)? 數據來源是否公開？ Yes  No  f) How are data identified when they are made available to your research team? (Please indicate by marking the appropriate box below.) 當數據提供給您的研究團隊時，如何識別這些數據？（請在下面適當的方框內標記。） |
| i)  Direct Identifier (i.e. name, address, ID card number, medical record number, etc.) 直接標識碼（即姓名、地址、身份證號碼、醫療記錄編號等）  ii) Indirect Identifier (i.e. an assigned code which could be used by the investigator or the source providing data to identify a subject, such as tracking code used by the source.) 間接標識碼（即研究員或提供數據的來源用以識別對象的指定代碼，例如來源使用的追蹤碼。） |
| iii)  No Identifier (i.e. neither the researcher nor the source providing the data can identify a subject based upon information provided with the data.) 無標識碼（即研究者和提供數據的來源均無法根據提供的數據識別對象。） |
| g) If i) or ii) is checked above and you are requesting permission to study archived data, will you abstract and record any subject identifiers as a part of the data collection process? 如果上面勾選了 i) 或 ii)，且您正在請求許可研究存檔數據，您是否會在數據收集過程中摘錄並記錄任何受試者標識碼？ |
| Yes  No  Does Not Apply |
| h) Will any data be collected from subjects after the submission of this application? 在提交此申請後，是否會從受試者那裡收集任何數據？ |
| Yes  No |
| *-* If “Yes”， please complete Part C 若是,請填寫C部分 |

**Part E： Assessment for a Waiver of Written Informed Consent 豁免書面知情同意的評估**

**The waiver of written informed consent is only applicable to data without personal identifiers, e.g., where data are tabulated or where oral consent is audio-recorded, PIs are required to clearly specify that they are using data without personal identifiers in their research grant proposals. 豁免書面知情同意僅適用於沒有個人標識的數據，例如數據被製成表格或口頭同意被音頻錄製的情況。主要研究人員（PIs）需在其研究資助提案中明確指出他們使用的是沒有個人標識的數據。**

|  |
| --- |
| **Please answer the following questions if you are collecting new data, and wish to apply for a waiver of informed consent. 如果您正在收集新數據，並希望申請豁免知情同意，請回答以下問題。** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | When conducting research where seeking written consent is not practical or too sensitive, oral consent might be less of a privacy risk than written consent and can be considered as an alternative. Please submit a full justification below and attach an information sheet to this application. 進行研究時，如果徵求書面同意是不切實際或過於敏感，口頭同意可能比書面同意的隱私風險更小，可以考慮將口頭同意作為一種替代方式。請在下面提交完整的理由，並在本申請中附上一份資訊表。   |  |  |  |  | | --- | --- | --- | --- | | a) | Will there be oral consent? 將會有口頭同意嗎？ | Yes | No | |  | If “Yes”, will the oral consent be audio recorded? | Yes | No | |  | 如果是「是」，口頭同意將會被音頻錄製嗎？ |  |  | | b) | Is participation anonymous? 參與是匿名的嗎？ | Yes | No | |  | If “No”, i.e. participation is not anonymous, your proposed research is not normally qualified for a waiver of informed consent. Measures should be taken to code the data collected and delete all personal identifiers on the spot. 如果「否」，即參與不是匿名的，則您提供的研究通常不符合豁免知情同意的條件，應採取措施對所收集的數據進行編碼，並立即刪除所有個人標識。 | | |  1. If participation is not anonymous, please explain why the study is not practicable without a waiver. 如果參與不是匿名的，請解釋為什麼在沒有豁免的情況下研究不可行。 |
|  | d） Please explain why the proposed study presents no more than minimal risk to the participants. 請解釋為什麼所提出的研究對參與者的風險不超過最低限度。 |
|  | e) Please explain why a waiver of informed consent will not adversely affect the rights and welfare of the participants. 請解釋為什麼豁免知情同意不會對參與者的權利和福利產生不利影響。 |

**Part F： Benefits 利益**

**Please state any possible benefit to participants. 請說明對參與者可能帶來的利益。**

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**Part G： Attachments 附件**

**Please tick as appropriate to indicate which of the following documents are enclosed to this application. 請在適當的方框內打勾，說明本申請附有以下哪些文檔。**

|  |  |
| --- | --- |
| （1） Full research protocol （note i）完整的研究方案（i必填寫，備註附件1） |  |
| （2） Measures， including questionnaires， interviewing guides， observation notes， and others （note ii）措施，包括調查問卷、訪談提綱、觀察記錄等（ii可選，備註附件2） |  |
| （3） Informed Consent Form （note ii）知情同意書（ii可選，備註附件2） |  |
| （4） Deception： post-debriefing consent form 欺騙：事後解釋同意書（ii可選，備註附件2） |  |
| （5） Participant recruitment materials （note ii）參與者招募材料（ii可選，備註附件3） |  |

Notes:

(i) Mandatory必填;

(ii) Mandatory unless waiver has been applied for or no data collection is being undertaken.除非已申請豁免或未進行數據收集

**Part H： Declaration 聲明**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| In making this application, I certify that I have read and understand the University’s *Policy for Ethical Practice*, and I will comply with the ethical principles of these documents. I will submit, as appropriate, a *Report for Research Progress or Amendment of an Approved Project* if there are significant changes to my research, or an adverse incident, or when the report for annual progress due.在提交此申請時，我證明我已閱讀並理解大學的倫理實踐政策，我將遵守這些文件的倫理原則。如有我的研究發生重大變更、不良事件，或年度進展報告到期時，我將適時提交研究進展報告或已批准項目的修改報告。 | | | | |
|  | | | | |
| Date: |  | Signature: |  |  |
| （Signature of Applicant）申請人簽名 | | | | |
|  | | | | |
| Date: |  | Signature: |  |  |
| （Signature of supervisor）督導簽名 | | | | |
| (for RPG/TPG students only 僅限研究型研究生和授課研究生) | | | | |

**Part I： Committee Approval 委員會批准**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| After discussion, this research plan is approved. 經過討論，本研究計劃獲得批准。 | | | | |
|  | | | | |
| Date: |  | Signature: |  |  |
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| I hereby endorse this application with my approval and confirm that the investigator(s) are appropriately qualified in the research area involved to conduct the proposed research project, and am capable of undertaking this research study in a safe and ethical manner. 我在此以我的批准簽署此申請，並確認研究者在涉及的研究領域具有適當的資格來進行所提出的研究項目，且能夠以安全和倫理的方式進行此研究。 | | | | |
|  | | | | |
| Date: |  | Signature: |  |  |
| Dean of Faculty 學院院長 | | | | |
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1. 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. 最小風險是指研究中預期的傷害或不適的概率及程度，不高於日常生活中或進行常規身體或心理檢查或測試時通常會遇到的傷害或不適。 [↑](#footnote-ref-1)
2. Please note that the term “publicly available” means that the general public can obtain the data. Sources are not considered “publicly available” if access to the data is limited to researchers. 請注意，“公開可用”一詞意味著一般公眾可以獲得數據。如果數據的訪問僅限於研究人員，則這些來源不被視為“公開可用”。 [↑](#footnote-ref-2)