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**APPLICATION FOR APPROVAL: UMBRELLA PROJECT**

**NELSON MANDELA UNIVERSITY RESEARCH ETHICS COMMITTEE (HUMAN)**

 **PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1 – 2) PRIOR TO COMPLETING THE APPLICATION FORM. THIS INFORMATION BLOCK MUST BE REMOVED PRIOR TO SUBMISSION OF THE APPLICATION FORM.**

**WHO NEEDS TO COMPLETE THIS FORM?**

Research leaders for any umbrella project (see full definition under **DEFINITION OF TERMS** below), including but not restricted to large sponsored research projects, Honours and/or undergraduate group research projects, and in which humans are the subjects of research (hereafter called a *study*) are required to complete this form and submit it together with all relevant supporting documentation for approval first to their Faculty Postgraduate Studies Committee (FPGSC). Applications for any research project that do not fall under any umbrella project must be submitted on a separate form (RECH-001). Once the scientific merit of the umbrella and its sub-study proposals have been reviewed and approved by FPGSC, the FPGSC will refer the study to REC-H for ethical review and approval.

**WHEN SHOULD THIS FORM BE HANDED IN?**

The research proposal must first have been approved by the FPGSC before Ethics approval may be applied for. The ethics application should also have first been screened by the FPGSC before it is referred to the REC-H. Proposals for studies for non-degree purposes from applicants in a Faculty must submit their proposals through a peer review process at Faculty level prior/in parallel to applying for ethical clearance. Proposals for studies for non-degree purposes from applicants not in any Faculty (e.g. HEADS, Library Services, etc) submit their proposals for a peer review process at REC-H in parallel to applying for ethical clearance.

**HOW TO COMPLETE THIS FORM:**

1. The research leader/primary responsible person (PRP) for the umbrella study is ultimately responsible for the completion, compilation and submission of this application form together with one or more application forms for related sub-studies (form RECH-003/S).
2. Each primary investigator (PI) (and his/her supervisor, if applicable) for a sub-study is responsible for providing/contributing to supporting documentation for the relevant sub-study (form RECH-003/S).
3. The research leader (PRP) of the umbrella study and each PI (and his/her supervisor, if applicable) associated with any of the sub-studies of the umbrella study are expected to be familiar with the following documentation available on the REC-H portal: i) Department of Health Research Ethics Guidelines (2015); ii) Protection of Personal Information Act (POPIA) Summary; iii) Research Ethics (Human) Application Process; iv) Nelson Mandela University Code of Conduct for Researchers; and v) Nelson Mandela University Research Ethics Policy.
4. It is recommended that each PI for a sub-study complete a copy of the Risk Assessment for their particular sub-study (pp 6 – 10). This exercise will serve to sensitise all researchers to ethical considerations in the context of their sub-study. The research leader is required to consolidate these contributions into a single risk assessment for submission with this umbrella application for review and approval.
5. The PRP is required to complete Section B (pp 11). Complete Sections 1 and 2 (as from pp 11) in typescript (tab between fields, select from pull-downs, information may be pasted from existing Word® documents).
6. Each sub-study PI is required to contribute to one not necessarily unique submission of form RECH-003/S, these independent forms RECH-003/S to be consolidated and submitted by the PRP together with this umbrella application.
7. The research leader (PRP) is responsible for the collation of all relevant sub-study documentation prior to submission of the application.
8. Save the completed application form. Handwritten forms will not be accepted. Use the “Save as” option to save the application form with a filename containing your name(e.g.“**J Smith** REC-H Umbrella Application Form.doc”).
9. Append the necessary information e.g. completed forms RECH-003/S, Research methodology, Informed consent form, Written information given to participant prior to participation, Oral information given to participant prior to participation, etc. for each sub-study as Appendices correctly labelled and **CORRECTLY ORDERED** as given in the application forms and the provided table of Supporting Documentation (pp 4). Complete the Supporting Documentation Included table (pp 4). Incorrect ordering of or missing appendices may result in a delay of the review and approval of the application.
10. **REMOVE THE INSTRUCTION BLOCK AND DEFINITION OF TERMS** (pp 1 – 2).
11. **Electronic copy (signed)**: Print the document, get each page initialled on the lower right hand corner and get Sections 3 and 4 signed by the relevant parties. Scan in the signed hardcopy and all supporting documentation. Alternatively print the report as a PDF document, correctly appending all supporting documentation to it in a single PDF document, and sign the document digitally. Submit the signed application to the FPGSC representative in the relevant Faculty.

**DEFINITION OF TERMS USED IN THE APPLICATION FORM**

“**Negligible risk study**” is a study where the only foreseeable risk is one of inconvenience to the participants. Inconvenience is of a lower level of risk than discomfort.

“**Low risk study**” is a study where the only foreseeable risk is one of discomfort to the participants.

1 a) “**Study**” means the research project being conducted. “**Umbrella research project**” means a broad research project under which a number of smaller research projects fall (like the one(s) for which this application is relevant). Typically an umbrella research project is one in which a number of individual Masters and Doctoral students collaborate, with each individual Masters and Doctoral student conducting research to realise at least one objective of the umbrella research project. It is required that the individual Masters and Doctoral students submit independent ethics applications (form RECH-001) for their parts of the umbrella project. An application for an umbrella research project (form RECH-003/U) is also advised for groups of undergraduate and/or Honours students undertaking small research projects. In this case, individual sub-studies must be submitted for approval on a form RECH-003/S as supporting documentation for form RECH003/U, either individually or as a group submission of sub-studies for as long as the data collection procedures and instruments of such studies are significantly similar.

1 d) “**PRP**” means primary responsible person. This individual must be a fulltime member of permanent staff or currently active research associate, usually the supervisor of the student in the case of the study being for the purposes of acquiring a qualification

1 e) “**PI**” means primary investigator and is the person undertaking the study

1 k) “**Date of commencement of data collection**” is the date upon which data collection for the study will commence. This date must occur after the anticipated date of ethics approval and at least 6 weeks after the date of submission of the application for review.

3 “**Conflict of interest**” refers to a compromised situation as regards ethical conduct of research as a result of conflicting duties, responsibilities or interests (personal, professional or otherwise) on the part of the PI and/or PRP and/or participant recruiter and/or gatekeeper and/or sponsor of the study.

**END OF INFORMATION BLOCK**

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| --- |
| **SECTION A (FOR OFFICIAL USE ONLY)** |
| **Umbrella application reference code:****(*To be completed by a representative from the Faculty Postgraduate Studies Committee (FPGSC)*)** | **H** | **…………** | **…………** | **…………** | **…………/U** |
| **HUMAN** | **YEAR** | **FACULTY** | **DEPARTMENT** | **NUMBER** |
| **Umbrella and sub-study research proposals and methodologies reviewed and approved by Faculty (form RECH-003/U and related forms RECH-003/S)** | * **Yes Date Approved**: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* **No**
 |
| **FPGSC representative signature:** |  |
| **Sub-study reference code (add additional rows to this table if required)** | **Approval Status** | **REC-H Comments** |
| **H YY - FAC - DEP - nnn /U-01** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-02** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-03** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-04** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-05** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-06** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-07** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-08** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-09** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-10** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-11** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-12** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-13** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-14** | 🞏 Approved 🞏 Not approved  |  |
| **H YY - FAC - DEP - nnn /U-15** | 🞏 Approved 🞏 Not approved  |  |

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| **Supporting Documentation Included** |
|  |  |
| **Document**  | **Page reference** |
| Risk Assessment Form | 3 |
| Application Form | 8 |
| Appendix 1: Umbrella Study Research Proposal (mandatory) |  |
| Appendix 2: International Ethics Approval Process (if applicable) |  |
| Appendix 3: Restrictions/conditions applicable to publication of results of study (if applicable) |  |
| Appendix 4: *Other supporting documentation:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Appendix 5: *Other supporting documentation:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Appendix 6: *Other supporting documentation:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Appendix 7: FPGSC Reviewer comments and communications (mandatory) |  |
| **Sub-study Documentation (full set of form RECH-003/S and supporting documentation, correctly and clearly labelled, required for each sub-study unless the recruitment, enrolment and data collection materials and procedures for each sub-study are substantially the same – in the latter case sub-study applications may be grouped in a single RECH-003/S submission)**For each sub-study/group of sub-studies, provide the sub-study reference(s) (remove unused rows\* from the table below, or add additional rows\*\* to the table if there are more than 15 sub-studies). *\* To remove rows, highlight the rows/cells in rows to be removed, click mouse right button, select DELETE CELLS/ROWS and follow the prompts.* *\*\* To add a row, in the last cell of the table, click mouse right button, select INSERT then INSERT ROWS BELOW. Add the required details.* | **Page reference** |
| Appendix 8**/U-*nn***, where *nn* is the reference number(s) of the sub-study/group of similar sub-studies: Synopsis of sub-study (mandatory for each sub-study/group of similar sub-studies) together with all supporting documentation |  |
| Appendix 8**/U-*nn***, where *nn* is the reference number(s) of the sub-study/group of similar sub-studies: Synopsis of sub-study (mandatory for each sub-study/group of similar sub-studies) together with all supporting documentation |  |
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| Appendix 8**/U-*nn***, where *nn* is the reference number(s) of the sub-study/group of similar sub-studies: Synopsis of sub-study (mandatory for each sub-study/group of similar sub-studies) together with all supporting documentation |  |
| Appendix 8**/U-*nn***, where *nn* is the reference number(s) of the sub-study/group of similar sub-studies: Synopsis of sub-study (mandatory for each sub-study/group of similar sub-studies) together with all supporting documentation |  |
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| Appendix 8**/U-*nn***, where *nn* is the reference number(s) of the sub-study/group of similar sub-studies: Synopsis of sub-study (mandatory for each sub-study/group of similar sub-studies) together with all supporting documentation |  |

|  |  |
| --- | --- |
|  | Select the box next to any statement that is relevant to any one of the sub-studies, or the umbrella study as a whole. This will sensitise researchers to the content to be addressed in the umbrella application. It is assumed that all researchers are familiar with the DoH Ethics Guidelines available on the REC-H portal.  |
|  |  |  |  |  |
|  | No risk | Negligible to Low risk | Medium risk | High risk |
| ***Are the subjects/participants of your study*** |   |   | [ ]  University staff/students? | [ ]  children under the age of 18? |
|   |   | [ ]  in a dependency relationship with the PI and/or PRP? | [ ]  a sample from an institution (e.g. hospital)? |
|   |   | [ ]  to be compensated in any way (e.g. incentive, reimbursement for travel, etc.) for participating in the study? | [ ]  handicapped (e.g. mentally or physically) persons? |
|   |   |   | [ ]  socially and/or economically disadvantaged persons? |
|   |   |   | [ ]  persons of diminished physical and/or mental and/or educational capacity (e.g. traumatised)? |
|   |   |   | [ ]  elderly? |
|   |   |   | [ ]  persons who are not competent to give participation consent (e.g. due to language challenges)? |
| ***Are you administering any process and/or treatment that*** |   | [ ]  is expected to result in no foreseeable risk, harm or discomfort to the mental and/or physical well-being of the participants? |  could be hazardous to the social well-being (e.g. possibly results in damage to social networks/relationships with others, discrimination, social stigmatisation, discovery of previously unknown paternity status) and/or result in discomfort associated with the social well-being of the participants and/or researcher? | [ ]  involves participants undergoing psychological, physiological or medical testing or treatment? |
|   | [ ]  is expected to result in the only foreseeable discomfort being that of inconvenience (e.g. time and effort required by participants to complete questionnaire/form, participate in a street survey)? | [ ]  could be hazardous to the economic well-being (e.g. possibly results in the imposition of direct and/or indirect financial commitments on participants) and/or result in discomfort associated with the economic well-being of the participants and/or researcher? | [ ]  involves the collection and use of human biological samples (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath? |
|   |   | [ ]  collects any articles/documents of property, personal or cultural from participants? | [ ]  could be hazardous to the physical health (e.g. possibly results in illness, injury, pain) of the participants and/or researcher? |
|   |   | [ ]  may result in a traumatic experience for the participants and/or researcher? | [ ]  could be hazardous to the psychological well-being (e.g. possibly results in feelings of worthlessness, guilt, anger, fear) of the participants and/or researcher? |
|   |   | [ ]  may result in the disclosure of sensitive and/or embarrassing information about the participants and/or researcher? | [ ]  could be hazardous to the legal well-being (e.g. possibly results in the discovery and prosecution of criminal activity) of the participants and/or researcher? |
|   |   | [ ]  involves covert observation of behaviour that is not normally in the public domain? | [ ]  could result in the participant learning about a genetic possibility of developing an untreatable disease? |
| ***Are you administering any process and/or treatment that*** |   |   | [ ]  could result in the participants feeling humiliated, manipulated and/or in other ways treated disrespectfully and/or unjustly? |   |
|   |   | [ ]  uses specialised equipment on the participants? |   |
|   |   | [ ]  could result in discomfort associated to the physical health (e.g. the act of measuring blood pressure, minor side effects of taking medication) of the participants and/or researcher? |   |
|   |   | [ ]  could result in discomfort associated with the psychological well-being (e.g. feelings of anxiety due to being interviewed) of the participants and/or researcher? |   |
|   |   | [ ]  could result in discomfort associated with the legal well-being of the participants and/or researcher? |   |
|   |   | [ ]  could result in the identification and/or re-identification of a participant from a resulting report? |   |
|   |   | [ ]  could result in risks to non-participants (e.g. distress to relatives upon discovering that a participant suffers from a serious genetic disorder, infectious disease risks to a community, social/economic discrimination of subgroup populations)? |   |
| ***Are you administering a questionnaire/survey/interview/ focus group/observation practices that*** |   | [ ]  occurs in public spaces and natural environments where the researcher does NOT interact directly with participants? | [ ]  collects sensitive data from the participants (e.g. personal data that is not normally in the public domain)? |   |
|   | [ ]  occurs in public spaces and natural environments where the researcher does NOT stage any intervention? | [ ]  does not guarantee the anonymity of the participant? |   |
|   | [ ]  occurs in public spaces and natural environments where the participants do NOT have a reasonable expectation of privacy? | [ ]  occurs in public spaces and natural environments and dissemination of research findings does could identify individual or groups of participants? |   |
|  | [ ]  occurs in public spaces and natural environments and dissemination of research findings does NOT identify individual or groups of participants? | [ ]  occurs in public spaces and natural environments where the researcher interacts directly with participants? |   |
|  |  | [ ]  occurs in public spaces and natural environments where the researcher stages an intervention? |   |
|  |  | [ ]  occurs in public spaces and natural environments where the participants have a reasonable expectation of privacy? |   |
|   |  | [ ]  does not guarantee the confidentiality of data collected from the participants? |   |
| ***Are you intending to access participant data from an existing stored repository (e.g. school, institutional, university records or data collected from another previously completed or ongoing research study) that*** | [ ]  relies exclusively on publicly available information or accessible through legislation or regulation? | [ ]  requires access to participant information (in non-identifiable form, e.g. summarised form) as part of an existing published or unpublished source or database? | [ ]  requires access to participant information (in individually identifiable or re-identifiable form) as part of an existing published or unpublished source or database? |   |
| [ ]  relies exclusively on secondary use of anonymous information (i.e. no identifiable information is generated or inferred)? |  |  |   |
| ***Do you intend publishing the findings of your study in a publication that*** | [ ]  requires no evidence of human ethics approval/acknowledgement? | [ ]  requires evidence of human ethics approval/acknowledgement? |   |   |
| ***Is this study*** | [ ]  exclusively for quality assurance and/or quality improvement studies (audits) and/or programme evaluation activities and/or performance reviews? | [ ]  for qualification purposes at Nelson Mandela University?  | [ ]  an international/cross border study?  |   |
|  | [ ]  a local (e.g. regional, national) study? | [ ]  NOT for qualification purposes at NMU and also NOT exclusively for quality assurance and/or programme evaluation activities and/or performance reviews? |   |
| ***Has the research methodology (if the study is not for qualification purposes) been reviewed for scientific rigour and approved by an appropriate research body at Nelson Mandela University?*** |  | [ ]  Yes. Specify body:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  No |   |
| ***Does any sponsor of the study/the researcher have a vested interest in any possible findings of the study?*** | [ ]  No |  | [ ]  Yes |   |
| ***Are there any restrictions/conditions attached to the publication and/or presentation of the study results?*** | [ ]  No |  | [ ]  Yes |   |
|  | Number of selections in this column: \_\_\_\_\_\_ | Number of selectionsin this column: \_\_\_\_\_\_ | Number of selectionsin this column: \_\_\_\_\_\_ | Number of selectionsin this column: \_\_\_\_\_\_ |
|   | ***If number of selections in in this column is more than 0 and there are no selections in any of the other columns, then no review for ethics is required.*** | ***If number of selections in in this column is more than 0 and there are no selections in any of Medium and High risk columns, then the application would qualify for an expedited review*** | ***If the sum of the number of selections in Medium and High risk columns is more than 0, irrespective of whether selections appear in other columns, then the application would require full review after the proposal has been approved by the Faculty*** |
|  | **No ethics application necessary** | **Expedited Review: Faculty level review by accredited and co-opted Faculty reviewers (approval for noting at REC-H)** | **Faculty review required to ensure proposal/research methodology approval followed by Central REC-H review** |

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| **SECTION B: (To be completed by the leading researcher)**  |
| I declare that I have familiarised myself with the content of the following documentation and applied this knowledge in the completion of this application form: [ ]  REC-H Standard Operating Procedures, with emphasis on the section on the responsibilities of the PRP and PI [ ]  Department of Health Research Ethics Guidelines (2015) [ ]  Protection of Personal Information Act (POPIA) summary [ ]  Code of conduct for Researchers [ ]  Research Ethics Policy  |

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| --- |
| 1. GENERAL PARTICULARS
 |
| **TITLE OF STUDY** |
| 1. Concise descriptive title of umbrella study as approved by FPGSC (if applicable):

**Type title of study here** |
| 1. Rationale for this study: briefly (300 words or less) describe the background to this study i.e. why are you doing this particular piece of work. A few (no more than 5) key scientific references may be included: **Type rationale here**
 |
| 1. **This application focusses specifically on the procedure in which human subjects will be participating** (and not on any other procedures of the study nor necessarily on the study as a whole). Describe the placement of ***this application for ONLY the data collection from human participants*** in the context of the above-mentioned study (see 1 a) above), i.e. describe the contribution of the data collection from human participants to the overall study.

**Give description here** |
| **RESEARCHERS:*****Please note -*** ***The Protection of Personal Information Act, 2013 (POPI Act) has been promulgated and implemented on 1 July 2020. All personal identifiable information provided by you shall be treated in accordance with this statute and only used for research ethics application and/or reporting processes, as indicated in the University’s Privacy Policy. By providing your information, you are giving your consent for the use of all of your personal identifiable information, provided to the University, for the aforesaid purposes.*** |
| **PRIMARY RESPONSIBLE PERSON (PRP)** |
| 1. PRP identification and affiliation details:

**Type PRP staff number here Type PRP name here Type PRP Email address here**Faculty **Select Faculty** **Specify here, if “other”**Department (or equivalent): **Type department name here**  |
| **PRINCIPLE INVESTIGATORS AND CO-WORKERS** |
| 1. For each sub-study, provide the PI identification and affiliation details in the appropriate places (remove unused rows\* from row 2 onwards from the table below, or add additional rows\*\* to the table if there are more than 15 sub-studies). For added rows, provide sequential reference numbers for additional sub-studies. The references must be correct and accurate across this application as well as the related form RECH-003/S.

*\* To remove rows, highlight the rows/cells in rows to be removed, click mouse right button, select DELETE CELLS/ROWS and follow the prompts* *\* To add a row, in the cell with …/U-15 in it, click mouse right button, select INSERT then INSERT ROWS BELOW. Add the required details.*  |
| **Reference** | **Staff/student number** | **Name** | **Email address** | **Faculty** | **Department** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type PI staff/student number here** | **Type PI name here** | **Type PI Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| 1. Name(s) and affiliation(s) of all other co-workers (e.g. co-investigator/assistant researchers/supervisor/co-supervisor/promoter/co-promoter/participant recruiter, etc). If names are not yet known, state the affiliations of the groups from which they will be drawn, e.g. Interns/M-students, etc. and the number of persons involved: **Type names and affiliations of all co-workers here. If relevant, for each distinct supervisor of sub-studies, give the reference(s) of the sub-study(ies) from the list above**
 |
| **STUDY DETAILS** |
| 1. Scope of study: **Select an item**

In the case of an International study, include evidence of the ethics approval / plan for such approval in the other country(ies) in *Appendix* *4* | 1. Purpose of study: **Other**

 If **Other**, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Funding : **Select an item**  Source of funding:**Type details here or select “Not applicable”**

Does the sponsor of the study have a vested interest in the study: **Select an item** If YES, describe the extent of the interest and how this risk is to be managed. **Type response here or select “Not applicable”**  |
| 1. Are there any restrictions or conditions attached to publication and/or presentation of the study results? **Select an item**

If YES, elaborate (any restrictions or conditions contained in contracts must be made available to the Committee in *Appendix* *5*): **Type response here or select “Not applicable”** |
| **METHODOLOGY**  |
| *Full approved overarching research proposal for the umbrella study to be included as Appendix 1. This proposal should clearly indicate the contribution of each sub-study to the umbrella study. Relevant sub-study protocols to be described in Appendices supported by form RECH-003/S (together with relevant supporting documentation), one submission per sub-study.* |

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| 1. ETHICAL AND LEGAL ASPECTS
 |
| * 1. The DoH Research Ethics Guidelines (2015) pp 12 lists a number of documents relevant to ethical and legal aspects of research studies. It is advised that the PRP peruse these documents and list below those that are deemed relevant to this umbrella study.

The following documents are relevant and will be included in the references of any publication emanating from this study. **Type response here or select “Not applicable”*** 1. The PRP declares that (s)he is familiar with at least the contents of the Belmont Report and that it will be included in the references: **Select an item**  If NO, motivate: **Type response here or select “Not applicable”**
 |
| I would like the REC-H to take note of the following additional information: **Type response here or select “None”** |

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| 1. DECLARATION
 |
| I am aware that data collection for any sub-study will only commence once final approval for the umbrella study has been granted and that the PI is in receipt of an approval letter for the relevant sub-study. Retrospective approval is not permitted.I declare that I am familiar with and support the protocols of all sub-studies appended to this submission. **I SELECT AN ITEM aware of potential conflict(s) of interest which should be considered by the Committee**. If affirmative, specify: **Type response here or select “Not applicable”**  |
|   **05 August 2022**SIGNATURE: **Type name here** (Primary Responsible Person) Date |

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| 1. SCRUTINY BY FACULTY AND INTRA-FACULTY ACADEMIC UNIT
 |
| This umbrella study and associated sub-studies have been discussed, and are supported, at Faculty and Departmental (or equivalent) level. This is attested to by the signature below of a Faculty (e.g. FRTI, FPGSC, or similar) and Departmental (e.g. HoD) representative, neither of whom may be a previous signator. |
|   NAME and CAPACITY (e.g. HoD) SIGNATURE Date |
| NAME and CAPACITY (e.g. Chair:FacRTI/FPGSC) SIGNATURE Date |

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| 1. APPENDICES
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| In order to expedite the processing of this application, please ensure that all the required information, as specified below, is attached to your application. You are required to please clearly label each Appendix in the top right hand corner of all supporting documentation and retain the numbering order, transferring page numbers to the Supporting Documentation table on pp 2 of this application. Any deviation from this requirement may result in a delay in the review and approval of the application. |
| **APPENDIX 1: Umbrella study research proposal (approved by FPGSC, mandatory)** |
| Attach the full protocol and methodology to this application, as "Appendix 1”. The proposal should clarify the contribution of each sub-study to the overall umbrella study. |
| **APPENDIX 2: International ethics approval (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 2". |
| **APPENDIX 3: Restrictions/conditions applicable to publication of results (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 3". |
| **APPENDICES 4 – 6: Any additional and relevant supporting documentation for the umbrella study(if applicable)** |
| If applicable, attach the required information to your application, as a clearly labelled Appendix and refer to such from within the application form. |
| **APPENDIX 7: FPGSC Reviewer comments and communications (mandatory)** |
| Attach the required information to your application, as "Appendix 7". |
| **APPENDIX 8/U-*nn*: Sub-study Application (mandatory for each distinct type of sub-study, i.e. multiple sub-studies that are substantially similar in recruitment, enrolment and data collection procedures may submit a shared study application) together with relevant supporting documentation (refer to form RECH-003/S)** |
| Attach the required information to your application, as "Appendix 8/U-*nn*", where *nn* is the reference of the sub-study(ies). With reference to form RECH-003/S, all Appendices related to a distinct type of sub-study must appear together. |