****

**APPLICATION FOR APPROVAL: SUB-STUDY OF UMBRELLA PROJECT**

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

 **PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1 – 3) 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?**

Primary investigators (PI) (in consultation with their supervisor(s), if applicable) for any sub-study of an umbrella project (see full definition under **DEFINITION OF TERMS** below) 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 does not fall under any umbrella project must be submitted on a separate form (RECH-001). Once the scientific merit of the proposal has been reviewed and approved by FPGSC, the FPGSC will refer the umbrella study (including this application) to REC-H for ethical review and approval.

For sub-studies that are substantially similar in recruitment, enrolment and data collection processes, a single combined sub-study application may be completed and submitted.

**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. Read 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.
2. Complete a copy of the Risk Assessment for your sub-study (available from pp 6 – 10 of form RECH-003/U). Make the copy available to the research leader (the person completing form RECH-003/U) for inclusion in the umbrella project submission.
3. Complete Section B (pp 6).
4. Complete Sections 1 to 8 (as from pp 6) in typescript (tab between fields, select from pull-downs, information may be pasted from existing Word® documents), and 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 Sub-study Application Form.doc”).
5. Append the necessary information e.g. Research methodology, Informed consent form, Written information given to participant prior to participation, Oral information given to participant prior to participation, etc. for the sub-study as Appendices correctly labelled and **CORRECTLY ORDERED** as given in the application form and the provided table of Supporting Documentation (pp 5). Complete the Supporting Documentation Included table (pp 5). Incorrect ordering of or missing appendices may result in a delay of the review and approval of the application.
6. **REMOVE THE INSTRUCTION BLOCK AND DEFINITION OF TERMS** (pp 1 – 3).
7. Update the **APPENDIX 8/U-*nn*** (top right hand side of the header of this form) to include the reference numbers of all sub-studies to which this application is relevant.
8. **Electronic copy (signed)**: Print the document, get each page initialled on the lower right hand corner and get Section 9 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 digital signed application to the research leader for inclusion in the umbrella project application.

**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 b) The “**supervisor**“ (if applicable) is the primary responsible person for a sub-study for which a student is a primary investigator (PI). 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 c) “**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.

1 c) “**Duration of data collection**” is the anticipated maximum period (in months) of the PI/research assistants’ direct interaction with human subjects from date of commencement of data collection. This period shall not exceed 12 months. Should the approved data collection procedure require a period exceeding 12 months, the PI (in consultation with the supervisor, if applicable) shall apply for an extension of the data collection procedure after 10 months of the approved period of 12 months has passed and submit such extension application together with an annual report of the data collection activities to date for review and approval.

1 d) “**Data collection procedure/process**” refers to the collection of those methods/techniques used by researchers for the collection of data from human subjects. Data collection methods/techniques shall be aligned with the presented objectives of the data collection procedure.

1 e) “**Recruitment**” refers to the collection of those methods/techniques used by researchers to identify and approach individuals to volunteer to contribute to the data collection for a study (these individuals being referred to as “**volunteers**”). A reasonable period of time should elapse between recruitment of volunteers and enrolment of “**participants**” (those individuals who have indicated a willingness to participate and who have been subsequently selected for participation).

1 f) “**Minimum number of participants**” refers to the minimum number of participants required to make the study viable. It must be noted that it is unethical to require too many participants than is actually necessary (wasting the time of participants) as it is to require too few participants (also wasting participants’ time since the study would then not be viable).

1 h) “**Enrolment**” refers to the collection of those methods/techniques used by researchers to identify, screen and select participants from those who have volunteered to participate in the study. Evidence must be provided of a fair identification, screening and selection process.

1 i) “**Data collection instruments**” refers to samples of methods/techniques used for the collection of data from human subjects (e.g. survey, questionnaire, interview schedule, etc).

1 j) “**Data analysis**” refers to the collection of those methods/techniques used by researchers to analyse the data collected from human subjects.

1 k) “**Data reporting**” refers to the collection of those methods/techniques used by researchers to report on the findings derived from the data collected from human subjects.

2 a) “**Risk**” refers to any possible negative effect of any data collection activity on the welfare of a participant over and above what would be expected from such a participant as a result of routine daily tasks.

2 d) “**Benefit**” refers to any possible positive effect of any data collection activity on the welfare of a participant over and above what would be expected from such a participant as a result of routine daily tasks.

2 e) “**Societal and/or ethical value**” refers to any possible benefit as a result of the study/data collection procedure that would be either temporarily or permanently transferred to the community from which participants are drawn.

2 h) “**Incidental findings**” refers to any unexpected discovery made during the course of data collection/analysis, these findings being outside the scope of the research. Cognisance to be given to relevant mandatory reporting procedures should such be relevant to the context of the study.

3 b) “**Inclusion criteria**” refers to that set of characteristics that all participants must exhibit so as to be included in the data collection procedure. Unless there are good reasons for the deception, inclusion criteria must be made available in writing at the point of recruitment.

3 c) “**Exclusion criteria**” refers to that set of characteristics that excludes volunteers (i.e. those individuals who have been recruited and have indicated a willingness to participate) from contributing to the data collection procedure. Unless there are good reasons for the deception, exclusion criteria must be made available in writing at the point of recruitment.

4 a) “**Consent**” refers to a, preferably written, record of agreement to participate in the data collection process.

4 b) “**Assent**” refers to a, preferably written, record of agreement from a minor to participate in the data collection process. Parents/guardians are required to give consent for researchers to approach minors to participate in any data collection activities and minors are required to give assent. Consent from a parent/guardian does not automatically imply that the affected minor(s) are obligated to assent to participate in the data collection procedure.

4 d) “**Institutional environment**” refers to institutions like hospitals, prisons, mental institutions, etc.

4 e) “**Power relationship**” refers to a situation where the PI and/or PRP and/or participant recruiter (a co-worker/gatekeeper or similar) might be in a position of authority when recruiting participants, thereby creating an effect of undue influence and compromising the voluntariness of the recruitment and enrolment processes.

4 g) “**Gatekeeper**” refers to a person(s) who control(s) access to the participant population. A gatekeeper shall not also fulfil the role of participant recruiter.

6 a) “**Anonymity**” refers to a situation where any data collected does not have any identifying information or direct link to any individual participant or group of participants.

6 b) “**Privacy and confidentiality**” refers to a situation where the researchers have the responsibility to protect data collected and entrusted to them for research purposes from unauthorised access, use, disclosure, modification, loss, theft, etc.

6 d) “**Data re-use**” refers to the use of data collected and entrusted to researchers in the context of the current study for other research purposes. The publication of research manuscripts as a result of the current study is not classified as re-use of data.

7 a) “**Feedback**” refers to the sharing of findings from the data collection procedure with the original source (i.e. participants) and possibly other sources (e.g. sponsors, gatekeepers, community, etc). It is preferred that participants, at least, be the recipients of some form of summarised feedback. Should feedback be given to other sources (e.g. sponsors, gatekeepers, community, etc), this information should be shared at point of recruitment.

9 “**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**

|  |
| --- |
| **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** |
| **Sub-study reference code(s) for which this application is relevant (remove unused rows from/add additional rows to this table if required)** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |
| **H YY - FAC - DEP - nnn /U-xx** |

|  |
| --- |
| **Supporting Documentation Included** |
|  |  |
| **Document**  | **Page reference** |
| Sub-study(ies) Application Form | 3 |
| Appendix 8/U-*nn*.1: Sub-study(ies) Research Proposal (mandatory, 1 for a group of sub-studies that have a research proposal that is essentially the same) |  |
| Appendix 8/U-*nn*.2: Data collection instruments (mandatory, 1 set for a group of sub-studies that have instruments that are essentially the same) |   |
| Appendix 8/U-*nn*.3: Evidence of Researcher Competence for each sub-study in the group (if applicable) |   |
| Appendix 8/U-*nn*.4: Consent form(s) (mandatory, 1 set for a group of sub-studies that have consent forms that are essentially the same) |   |
| Appendix 8/U-*nn*.5: Assent form(s) (if applicable, 1 set for a group of sub-studies that have assent forms that are essentially the same) |   |
| Appendix 8/U-*nn*.6: Budget for reimbursement/remuneration/incentives for each sub-study (if applicable) |   |
| Appendix 8/U-*nn*.7: Gatekeeper/Permission for access/Institutional permission, etc draft letters (mandatory, 1 set for a group of sub-studies that have gatekeeper/ permission for access/institutional permission forms that are essentially the same) |   |
| Appendix 8/U-*nn*.8: Recruitment information (mandatory, 1 set for a group of sub-studies that have recruitment information that is essentially the same) |  |
|  Appendix 8/U-*nn*.8a: Written information at point of recruitment |  |
|  Appendix 8/U-*nn*.8b: Oral information at point of recruitment |  |
| Appendix 8/U-*nn*.9: Enrolment information (mandatory, 1 set for a group of sub-studies that have enrolment information that is essentially the same) |  |
|  Appendix 8/U-*nn*.9a: Written information at point of enrolment |  |
|  Appendix 8/U-*nn*.9b: Oral information at point of enrolment |  |
| Appendix 8/U-*nn*.10: *Other supporting documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |
| Appendix 8/U-*nn*.11: *Other supporting documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |
| Appendix 8/U-*nn*.12: *Other supporting documentation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |   |

|  |
| --- |
| **SECTION B: (To be completed by the group of researchers who are the primary investigators (PIs) of the group of sub-studies to which this application refers, in consultation with supervisors, if applicable)**  |
| We (the PIs and supervisor(s)) declare that we have familiarised ourselves 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  |

|  |
| --- |
| 1. GENERAL PARTICULARS
 |
| **TITLE(S) OF SUB-STUDY(IES)** |
| 1. For each sub-study that is substantially similar in recruitment, enrolment and data collection procedures, provide the reference and a concise descriptive title of the sub-study as approved by FPGSC (if applicable). References must correspond with those appearing in the associated form RECH-003/U (Section 1 e). Remove unused rows\* from row 2 onwards from the table below, or add additional rows\*\* to the table if there are more than 8 sub-studies for which this application is relevant).

*\* 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-8 in it, click mouse right button, select INSERT then INSERT ROWS BELOW. Add the required details.* |
| **Reference** | **Sub-study Title** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **…/U-**Choose an item. | **Type title of sub-study here** |
| **SUPERVISOR(S):*****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.*** |
| 1. For each of the above sub-studies, provide the supervisor identification and affiliation details in the appropriate places (if applicable). References must correspond with those appearing in the associated form RECH-003/U (Section 1 e). Remove unused rows\* from row 2 onwards from the table below, or add additional rows\*\* to the table if there are more than 8 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 cell with …/U-15 in it, click mouse right button, select INSERT then INSERT ROWS BELOW. Add the required details.* |
| **Reference** | **Supervisor staff number** | **Name** | **Email address** | **Faculty** | **Department** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **…/U-**Choose an item. | **Type supervisor staff number here** | **Type supervisor name here** | **Type supervisor Email address here** | **Select Faculty** **Specify here, if “other”** | **Type department name here** |
| **STUDY DETAILS** |
| 1. Date of commencement of data collection: **Click here select a date** Anticipated duration of data collection in months: **Type duration here**
 |
| 1. Objectives of ONLY the ***data collection procedure*** of the study for which this application is relevant (i.e. the major objective(s) of the evaluation/experiment/survey, etc for which ethics clearance is required): **Type objectives here**
 |
| **METHODOLOGY (Full approved research proposal for sub-study/group of sub-studies to be included as *Appendix 8/U-nn.1*)** |
| 1. **Recruitment process** (describe in detail the manner in which individual human subjects will be identified and approached for inclusion in the study): **Type summarised method here**
 |
| 1. State the minimum and maximum number of participants involved. In the cases of a mixed methodology being used, for each data collection phase/method/technique/participant grouping/sub-study, list the phase/method/technique/ participant grouping/sub-study and indicate the required number of participants for the relevant phase/method/technique/participant grouping/sub-study in the appropriate places below. Min: **Type minimum number here** Max: **Type maximum number here**
 |
| 1. **Sampling Strategy** (provide a detailed motivation as to how the minimum and maximum sample sizes given in 1 f) above are determined. Reference may be made to key scientific sources.)

**Type motivation here** |
| 1. **Enrolment process** (describe in detail the manner in which volunteers will be selected and enrolled for participation. Include in the description any strategies to be used should the minimum number of participants not be reached): **Type summarised method here**
 |
| 1. **Data collection process** (describe in detail the procedure to be followed while collecting data from participants. Copies of all data collection instruments to be included as *Appendix 8/U-nn.2*): **Type summarised method here**
 |
| 1. **Data analysis** (provide details on the technique(s) to be applied in order to analyse the collected data): **Type summarised method here**
 |
| 1. **Data reporting** (provide details on the technique(s) to be applied in order to report on findings): **Type summarised method here**
 |

|  |
| --- |
| 1. RISKS AND BENEFITS OF THIS STUDY
 |
| 1. Is there any risk of harm, embarrassment or offence, however slight or temporary, to the participant, third parties or to the community at large? **Select an item**If YES, state each risk, and for each risk state i) whether the risk is reversible, ii) whether there are alternative procedures available and iii) whether there are remedial measures available.**Type response here or select “Not applicable”**
 |
| 1. Does the person administering the project (PI and/or supervisor) have previous experience with the particular risk factors involved? **Select an item** If YES, please specify: **Type response here or select “Not applicable”**

If NO, please specify what measures will be taken to address the deficiency in experience: **Type response here or select “Not applicable”** Include in *Appendix 8/U-nn.3* evidence/motivation of researcher(s) expertise to manage the identified risks in particular and the data collection procedures in general.  |
| 1. List any ethics training acquired by the supervisor in the past 3 years: **Type response here or select “Not applicable”**

List any ethics training acquired by the PI in the past 3 years: **Type response here or select “Not applicable”** |
| 1. Are any benefits (temporary, permanent or otherwise) expected to be transferred to the **participant as a result of the data collection procedure** (e.g. improved health, mental state, financial etc.)? **Select an item** If YES, please specify the benefits: **Type response here or select “Not applicable”**
 |
| 1. Describe the level to which the study endeavours to promote social and/or ethical value, in particular to the benefit of the community from which participants are drawn: **Type response here or select “Not applicable”**
 |
| 1. Will you be using equipment of any sort? **Select an item** If YES, please specify: **Type response here or select “Not applicable”**

If mechanical methods of observation be are to be used (e.g. one-way mirrors, recordings, videos etc.), will participant’s consent to such methods be obtained? **Select an item**  If NO, justify: **Type response here or select “Not applicable”**   |
| 1. Will any article of property, personal or cultural be collected in the course of the project? **Select an item** If YES, please specify:  **Type response here or select “Not applicable”**

Describe what will be done with the article of property upon conclusion of the data collection process: **Type response here or select “Not applicable”** |
| 1. Describe the process to be followed in the case of any incidental findings relevant to individual participants: **Type response here or select “Not applicable”**
 |
| 1. Is there any risk of harm, however slight or temporary, to the researcher while conducting the data collection exercise? **Select an item**

If YES, state each risk and for each risk state i) whether the risk is reversible, ii) whether there are alternative procedures available and iii) whether there are remedial measures available. **Type response here or select “Not applicable”** |
| 1. Is any insurance available for research related injuries for participants and/or researchers? **Select an item**

If YES, please specify: **Type response here or select “Not applicable”** If NO, please specify what measures will be taken to address the deficiency in availability of insurance: **Type response here or select “Not applicable”**  |

|  |
| --- |
| 1. TARGET PARTICIPANT GROUP
 |
| * 1. According to your knowledge, has the chosen participant group participated in any previously approved research? **Select an item**

If YES, briefly describe the study, indicate when it was conducted (year is sufficient) and include reference to the work/ethics clearance number (if known): **Type response here or select “Not applicable”** |
| * 1. **Inclusion criteria**: describe particular characteristics that are required to be present in participants in the target group (e.g. particular age, cultural derivation, background, physical characteristics, disease status etc.): **Type response here or select “Not applicable”**
 |
| * 1. **Exclusion criteria**: describe particular characteristics (not listed in 3 b) above) that will automatically exclude volunteers from participation (e.g. particular age, cultural derivation, background, physical characteristics, disease status etc.) please specify: **Type response here or select “Not applicable”**
 |
| * 1. Are participants drawn from Nelson Mandela University students? **Select an item**

If participants are drawn from specific groups of students, please specify: **Type response here or select “Not applicable”** Are participants drawn from Nelson Mandela University staff? **Select an item** If participants are drawn from specific groups of staff, please specify: **Type response here or select “Not applicable”**  |
| * 1. Are participants drawn from a primary/secondary school population? **Select an item** If YES, please specify (include the name and geographical region of the school): **Type response here or select “Not applicable”**
 |
| * 1. If participants are drawn from an institutional population (e.g. hospital, prison, mental institution), please specify: **Type response here or select “Not applicable”**
 |
| * 1. If participants are drawn from any particular/unique cultural community (e.g. particular nation, social group, etc), please specify how consideration has been given to the inclusion of a relevant cultural advisor in the data collection procedure: **Type response here or select “Not applicable”**
 |
| * 1. If any records will be consulted for information to complement the data collected, please specify the source of records: **Type response here or select “Not applicable”**
 |
| * 1. Will each individual participant know his/her records are being consulted? **Select an item** If YES, state how these records will be obtained: **Type response here or select “Not applicable”**

 If NO, give reasons: **Type response here or select “Not applicable”** |
| * 1. Are all participants at least 18 years of age? **Select an item**

If NO, state justification for inclusion of minors in study: **Type response here or select “Not applicable”** |

|  |
| --- |
| 1. CONSENT and ASSENT (in the case of minors) OF PARTICIPANTS
 |
| 1. **Consent**: Is consent to be given in writing? **Select an item** If YES, include the consent form with this application (*Appendix 8/U-nn.4*). *Refer to the consent form checklist for guidance on the expected contents of such a consent form*.If NO, state reasons why written consent is not appropriate in this study. **Type response here**
 |
| 1. **Assent (if any participant is younger than 18 years of age)**: Is assent to be given in writing? **Select an item**

If YES, include the assent form with this application (*Appendix 8/U-nn.5*). *Refer to the assent form checklist for guidance on the minimum contents of such an assent form*.If NO, state reasons why written assent is not appropriate in this study. **Type response here or select “Not applicable”**   |
| 1. Are any participant(s) subject to legal restrictions preventing them from giving effective informed consent? **Select an item** If YES, please justify: **Type response here or select “Not applicable”**
 |
| 1. Do any participant(s) operate in an institutional environment, which may cast doubt on the voluntary aspect of consent? **Select an item** If YES, state what special precautions will be taken to obtain a legally effective informed consent: **Type response here or select “Not applicable”**
 |
| 1. Do any participant(s) exist in a power relationship with the PI/PRP/supervisor, which may cast doubt on the voluntary aspect of consent? **Select an item** If YES, state what special precautions will be taken to obtain an effective informed consent: **Type response here or select “Not applicable”**
 |
| 1. Will participants receive reimbursement/remuneration/incentives for their participation? **Select an item**

If YES, justify and state on what basis the reimbursement/remuneration/incentives is/are calculated, and how the accuracy of the information can be guaranteed. If applicable, include a budget of such reimbursement/ remuneration/incentives (*Appendix 8/U-nn.6*) to enable the assessment of whether such reimbursement/ remuneration/incentives are reasonable and/or required. **Type response here or select “Not applicable”**How will the exclusion of the reimbursement/remuneration/incentive(s) from the study possibly affect the study’s outcome? **Type response here or select “Not applicable”** |
| 1. Which gatekeeper(s)\* will be approached for initial permission to gain access to the target group? (e.g. principal, nursing manager, chairperson of school governing body, etc. Copies of gatekeeper **DRAFT**\*\* letters to be included in *Appendix 8/U-nn.7*) **Type response here or select “Not applicable”**

\* *Standard practice for Nelson Mandela University student/staff participants is a selection of one of the following: i)* ***DVC:Research, Innovation and Internationalisation*** *for staff and/or student participants across more than a single Faculty (**dvc.re@mandela.ac.za**); ii)* ***Executive Dean*** *for student participants from multiple Departments in the same Faculty; OR iii)* ***Head of Department*** *for student participants from a single Department*.*The gatekeeper for access to Nelson Mandela University student database data for the purposes of research is either Student Records or Legal Services.* \*\* *Gatekeepers shall not be approached for permission to access potential participants until Ethics approval has been acquired. Upon Ethics approval being granted and thereafter gatekeeper permission being received, copies of such completed permission letters must immediately be submitted to the REC-H secretariat prior to the commencement of data collection activities.* |
| 1. Do you require consent of an institutional authority for this study? (e.g. Department of Education, Department of Health, etc. Copies of institutional permission **DRAFT**\* letters to be included in *Appendix 8/U-nn.7*) **Select an item**  If YES, specify: **Type response here or select “Not applicable”**

\* *Institutions shall not be approached for permission to access potential participants until Ethics approval has been acquired. Upon Ethics approval being granted and thereafter institutional permission being received, copies of such completed permission letters must immediately be submitted to the REC-H secretariat prior to the commencement of data collection activities.* |

|  |
| --- |
| 1. INFORMATION TO PARTICIPANTS
 |
| 1. What information will be offered to the participant at point of **recruitment** (i.e. before he/she consents to participate)? (Attach written information given as (*Appendix 8/U-nn.8a*) and any oral information given as (*Appendix 8/U-nn.8b*))
 |
| 1. Who will provide this information to the participant? (Give name and role)

 **Type name of information provider here** **Type role of information provider here** |
| 1. Will the information provided be complete and accurate? **Select an item** If NO, describe the nature and extent of the deception involved and explain the rationale for the necessity of this deception: **Type response here or select “Not applicable”**
 |
| 1. What information will be offered to the participant at point of **enrolment** (i.e. when he/she consents to participate)? (Attach written information given as (*Appendix 8/U-nn.9a*) and any oral information given as (*Appendix 8/U-nn.9b*)) **Type response here or select “Not applicable”**
 |
| 1. Who will provide this information to the participant? (Give name and role)

 **Type name of information provider here** **Type role of information provider here** |
| 1. Will the information provided be complete and accurate? **Select an item** If NO, describe the nature and extent of the deception involved and explain the rationale for the necessity of this deception: **Type response here or select “Not applicable”**
 |

|  |
| --- |
| 1. PRIVACY, ANONYMITY AND CONFIDENTIALITY OF DATA
 |
| 1. Will the participant be identified by name in any component of the research? **Select an item**  If YES, justify. If NO, specify the provisions made to protect the participant’s rights to anonymity: **Type response here or select “Not applicable”**
 |
| 1. Are provisions made to protect participant’s rights to privacy and to preserve confidentiality with respect to data? **Select an item** If NO, justify. If YES, specify: **Type response here or select “Not applicable”**
 |
| 1. Will data collected be stored in any way? **Select an item**  If YES, please specify\*: (i) By whom? (ii) How many copies? (iii) For how long? (iv) For what reasons? (v) How will the data be secured from unauthorised access? (vi) How are the consent/assent forms stored in relation to all other data collected? (vii) What will become of the data upon conclusion of the study (how will the data be disposed of)? **Type response here**

\* *Standard practice is that data should be stored by the PRP and supervisor for the purposes of verification and validation of such data. Deviation from standard practice requires motivation*. |
| 1. Will stored data be made available for re-use in any subsequent research? **Select an item**

If YES, how will participant’s consent be obtained for such re-usage and how exactly will the data be re-used? **Type response here or select “Not applicable”**  |
| 1. Will any part of the data collection be conducted on private property (including shopping centres. Copies of permission to access private property **DRAFT**\* letters to be included in *Appendix 8/U-nn.7*)? **Select an item**

If YES, specify and state how consent\* of property owner is to be obtained: **Type response here or select “Not applicable”**  \* *Owners (or similar) of private properties shall not be approached for permission to conduct data collection activities on such properties until Ethics approval has been acquired. Upon Ethics approval being granted and thereafter owners (or similar) of private properties permission being received, copies of such completed permission letters must immediately be submitted to the REC-H secretariat prior to the commencement of data collection activities.* |
| 1. Are there any contractual secrecy or confidentiality constraints on the data collected? **Select an item**  If YES, specify: **Type response here or select “Not applicable”**
 |

|  |
| --- |
| 1. FEEDBACK
 |
| 1. Will feedback be given to participants? **Select an item** If YES, specify whether feedback will be written, oral or by other means and describe how this is to be given (e.g. to each individual immediately after participation, to each participant after the entire project is completed, to all participants in a group setting, etc.): **Type response here or select “Not applicable”**

If NO, motivate reasons why it is not possible to provide participants with feedback. **Type response here or select “Not applicable”** |
| 1. If you are working in a primary/secondary school or other institutional setting, will you be providing teachers, school/institutional authorities or equivalent a report summarising your results\*? **Select an item** If YES, specify, if NO, motivate: **Type response here**

\* *A qualification manuscript, or a copy of treatise/dissertation/thesis is excluded from this response.* |

|  |
| --- |
| 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 PI and supervisor (if applicable) peruse these documents and list below those that are deemed relevant to this 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 supervisor(s) and PI(s) declare that they are 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”**
 |
| The supervisor(s) and PI(s) would like the REC-H to take note of the following additional information: **Type response here or select “None”** |

|  |
| --- |
| 1. DECLARATION
 |
| The supervisor(s) and PI(s) are aware that data collection for any sub-study will only commence once final approval for the umbrella study has been granted and the supervisor(s) and PI(s) are in receipt of an approval letter to this effect. Retrospective approval is not permitted.**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** (Supervisor) Date |
|   **05 August 2022**SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |

|  |
| --- |
| 1. APPENDICES
 |
| 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 8/U-*nn*.1: Sub-study(ies) research proposal (approved by FPGSC, mandatory)** |
| Attach the full protocol and methodology to this application, as "Appendix 8/U-*nn*.1”, where *nn* is the series of sub-study references for which this application is applicable.  |
| **APPENDIX 8/U-*nn*.2: Data collection instruments (mandatory, 1 set for a group of sub-studies that have instruments that are essentially the same)** |
| Attach as "Appendix 8/U-*nn*.2", where *nn* is the series of sub-study references for which this application is applicable. Highlight in the instruments any minor differences between similar sub-studies. |
| **APPENDIX 8/U-*nn*.3: Evidence of Researcher Expertise to conduct study for each sub-study in the group (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 8/U-*nn*.3", where *nn* is the series of sub-study references for which this application is applicable. |
| **APPENDIX 8/U-*nn*.4: Informed consent form(s) (mandatory, 1 set for a group of sub-studies that have consent forms that are essentially the same)** |
| If no written consent is required, motivation is required. The intention is that you make sure you have covered all the aspects of informed consent as applicable to your work. Attach required information to your application, as “Appendix 8/U-*nn*.4”, where *nn* is the series of sub-study references for which this application is applicable. |
| **APPENDIX 8/U-*nn*.5: Informed assent form(s) (if applicable, 1 set for a group of sub-studies that have consent forms that are essentially the same)** |
| Only required in the case of participants being minors. Attach required information to your application, as “Appendix 8/U-*nn*.5”, where *nn* is the series of sub-study references for which this application is applicable. |
| **APPENDIX 8/U-*nn*.6: Budget for reimbursement/remuneration/incentives (if applicable)** |
| If applicable, attach required information to your application, as “Appendix 8/U-*nn*.6”, where *nn* is the series of sub-study references for which this application is applicable. |
| **APPENDIX 8/U-*nn*.7: Draft letters for institutional permissions, gatekeepers, access to private property, etc (mandatory, 1 set for a group of sub-studies that have institutional permissions, gatekeepers, access to private property, etc that are essentially the same)** |
| Attach any draft letters required to carry out the research e.g. application for Department of Education permission for research carried out in schools, etc. Attach required information to your application, as “Appendix 8/U-*nn*.7”, where *nn* is the series of sub-study references for which this application is applicable. |
| **APPENDIX 8/U-*nn*.8: Written and/or Oral information given to human subject on recruitment (mandatory, 1 set for a group of sub-studies that have recruitment information that is essentially the same)** |
| Attach required information to your application, as “Appendix 8/U-*nn*.8”, where *nn* is the series of sub-study references for which this application is applicable. The intention is that you make sure you have covered all the aspects of written and/or oral information to be supplied to human subjects, as applicable to your work. This information must be made available at the point of recruitment and be transparent as to aspects such as inclusion/exclusion, risks/benefits, dissemination of findings, etc. |
| **APPENDIX 8/U-*nn*.9: Written and/or Oral information given to volunteers prior to participation, at the point of enrolment (mandatory, 1 set for a group of sub-studies that have enrolment information that is essentially the same)** |
| Attach required information to your application, as “Appendix 8/U-*nn*.9”, where *nn* is the series of sub-study references for which this application is applicable. |
| **APPENDICES 8/U-*nn*.10, 8/U-*nn*.11 and 8/U-*nn*.12: Any additional and relevant supporting documentation for the sub-study(ies) (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. |