****

**APPLICATION FOR APPROVAL**

**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?**

Researchers for any project 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 umbrella projects (see definition below) must be submitted on a separate form.

 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 for assessment of risk and possible Ethicsclearance before it is referred to the REC-H. Proposals for studies for non-degree purposes from applicants in a faculty as well as those that are not affiliated to a faculty (e.g. Library Services, CriSHET, CANRAD, etc.) must submit their proposals through a peer review process at Faculty level prior to applying for ethical clearance. Those applicants that are affiliated to support service departments or centres (e.g., Library Services, CriSHET, CANRAD, etc.) must identify a relevant Faculty committee to submit the proposal for review.
**ETHICS APPLICATION PROCESS FLOW**

Negligible/low risk studies are subject to expedited review by members co-opted from the FPGSC to temporarily serve as members of the Research Ethics Committee (Human) (REC-H). Once the proposal’s scientific merit has been reviewed and approved by FPGSC, the FPGSC will refer medium/high risk studies to REC-H for ethical review and approval.

**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 the Risk Assessment of the study (pp 6 – 10).
3. Complete Section B (pp 11).
4. Complete Sections 1 to 8 (as from pp 11) 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 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. 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. **Electronic copy (signed)**: Print the document, get each page initialled on the lower right-hand corner and get Sections 9 and 10 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.

1 d) “**PRP**” means primary responsible person. This individual is most often a full-time member of permanent staff, usually the supervisor of the student in the case of the study being for the purposes of acquiring a qualification. However, the PRP may also be a research or professional associate.

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.

1 k) “**Duration of data collection**” is the anticipated maximum period (in months) of the PI/PRP/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/PRP 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 l) “**Umbrella research project**” means a broad research project under which a number of smaller research projects fall. 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 for their parts of the umbrella project. An umbrella research project is advised for groups of undergraduate and/or Honours students undertaking small research projects. In this case, individual students are not required to submit independent ethics applications for as long as the data collection procedures and instruments are significantly similar.

1 m) “**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 n) “**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 o) “**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 q) “**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 r) “**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 s) “**Data analysis**” refers to the collection of those methods/techniques used by researchers to analyse the data collected from human subjects.

1 t) “**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.

APPENDIX 10 “**Synopsis**” refers to a brief summary of the application form content. It should be written in simple, non-technical and jargon-free language which is readily understood by REC-H members who include non-scientists, non-experts in the PI’s field and who represent the community. Acronyms must be spelt out when used for the first time.

**END OF INFORMATION BLOCK**

|  |
| --- |
| **SECTION A (FOR OFFICIAL USE ONLY)****(To be completed by a representative from the Faculty Postgraduate Studies Committee (FPGSC))** |
| **Application reference code:** | **H** | **…………** | **…………** | **…………** | **…………** |
| **HUMAN** | **YEAR** | **FACULTY** | **DEPARTMENT** | **NUMBER** |
| **Resolution of FPGSC Committee:\*****\*** *As per completed form RECH-RISK (attached to this application – pp 3 – 7)* | * **Negligible/Low risk study**

**Expedited ethics approval given by (for noting by the REC-H) \*\***  **Date**: **\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­\_\_\_\_\_****Reviewer name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Reviewer name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** **Medium/High risk study**

**Referred to REC-H for consideration** (if referred to REC-H, electronic copy of application documents to be emailed to Imtiaz.Khan@mandela.ac.za) **\*\*** *Reviewer comments and all communication relevant to the approval process attached as Appendix 9.* |
| **Research proposal and methodology reviewed and approved by Faculty** | * **Yes Date Approved**: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* **No**
 |
| **FPGSC representative signature:** |  |

|  |
| --- |
| **Supporting Documentation Included** |
|  |  |
| **Document (for review by two to three primary committee members)** | **Page reference** |
| Risk Assessment Form | 3 |
| Application Form | 8 |
| Appendix 1: Research Proposal (mandatory) |  |
| Appendix 2: Gatekeeper/Permission for access/Institutional permission, etc draft letters (mandatory) |  |
| Appendix 3: Evidence of Researcher Competence (if applicable) |  |
| Appendix 4: International Ethics Approval Process (if applicable) |  |
| Appendix 5: Restrictions/conditions applicable to publication of results of study (if applicable) |  |
| Appendix 6: *Other supporting documentation:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Appendix 7: *Other supporting documentation:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Appendix 8: *Other supporting documentation:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| Appendix 9: FPGSC Reviewer comments and communications (mandatory) |  |
| **Document (for review by all committee members)** | **Page reference** |
| Appendix 10: Data collection instruments (mandatory) |  |
| Appendix 11: Recruitment information (mandatory) |  |
|  Appendix 11a: Written information at point of recruitment |  |
|  Appendix 11b: Oral information at point of recruitment |  |
| Appendix 12: Enrolment information (mandatory) |  |
|  Appendix 12a: Written information at point of enrolment |  |
|  Appendix 12b: Oral information at point of enrolment |  |
| Appendix 13: Consent form(s) (mandatory) |  |
| Appendix 14: Assent form(s) (if applicable) |  |
| Appendix 15: Budget for reimbursement/remuneration/incentives (if applicable) |  |

|  |  |
| --- | --- |
|  | Select the box next to any statement that is relevant to your study. This will assist you in determining the path for review as well as sensitise you to the content to be addressed in your application. It is assumed that you 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? |  |   |
| ***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** |

|  |
| --- |
| **SECTION B: (To be completed by the applicant)**  |
| We (the PI and PRP) 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 OF STUDY** |
| 1. Concise descriptive title of 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):  |
| **PRINCIPLE INVESTIGATORS AND CO-WORKERS** |
| 1. PI (may be same as PRP) identification and affiliation details:

**Type PI staff number/student number here Type PI name here Type PI Email address here**Faculty **Select Faculty** **Specify here, if “other”**Department (or equivalent): **Type department name here** |
| 1. Name(s) and affiliation(s) of all 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**
 |
| **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”** |
| 1. Date of commencement of data collection: **Click here select a date** Anticipated duration of data collection in months: **Type duration here**
 |
| 1. Is this application related to any existing and currently active umbrella research project? **Select an item**

If YES, provide the ethics reference number of the related umbrella project: **Type response here or select “Not applicable”** |
| 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 to be included as *Appendix 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, list the phase/method/technique/ participant grouping and indicate the required number of participants for the relevant phase/method/technique/ participant grouping 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 o) 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 10*): **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 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 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 PRP in the past 3 years: **Type response here or select “Not applicable”**

List any ethics training acquired by the PI (if not also the PRP) 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 13*). *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 14*). *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, 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 15*) 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 2*) **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 2*) **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 11a*) and any oral information given as (*Appendix 11b*)
 |
| 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 12a*) and any oral information given as (*Appendix 12b*)) **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. PRIVACY, ANONYMITY AND CONFIDENTIALITY OF DATA
 |
| 1. Will the participant be identified by name in your 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 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 2*)? **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 PRP/PI 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 PRP and PI 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”**
 |
| I would like the REC-H to take note of the following additional information: **Type response here or select “None”** |

|  |
| --- |
| 1. DECLARATION
 |
| I am aware that data collection will only commence once final approval for the study has been granted and I am 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”**  |
|  **19 June 2023**SIGNATURE: **Type name here** (Primary Responsible Person) Date |
|  **19 June 2023**SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |

|  |
| --- |
| 1. SCRUTINY BY FACULTY AND INTRA-FACULTY ACADEMIC UNIT
 |
| This study has been discussed, and is 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 |

|  |
| --- |
| 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 1: Research proposal (approved by FPGSC, mandatory)** |
| Attach the full protocol and methodology to this application, as "Appendix 1”  |
| **APPENDIX 2: Draft letters for institutional permissions, gatekeepers, access to private property, etc. (mandatory)** |
| 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. |
| **APPENDIX 3: Evidence of Researcher Expertise to conduct study (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 3". |
| **APPENDIX 4: International ethics approval (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 4". |
| **APPENDIX 5: Restrictions/conditions applicable to publication of results (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 5". |
| **APPENDICES 6 – 8: Any additional and relevant supporting documentation (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 9: FPGSC Reviewer comments and communications (mandatory)** |
| Attach the required information to your application, as "Appendix 9". |
| **APPENDIX 10: Data collection instruments (mandatory)** |
| Attach as "Appendix 10". |
| **APPENDIX 11: Written and/or Oral information given to human subject on recruitment (mandatory)** |
| Attach as "Appendix 11". 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 12: Written and/or Oral information given to volunteers prior to participation, at the point of enrolment (mandatory)** |
| Attach the required information to your application, as "Appendix 12". |
| **APPENDIX 13: Informed consent form(s) (mandatory)** |
| If no written consent is required, motivate at 4a). The intention is that you make sure you have covered all the aspects of informed consent as applicable to your work. |
| **APPENDIX 14: Informed assent form(s) (if applicable)** |
| Only required in the case of participants being minors. |
| **APPENDIX 15: Budget for reimbursement/remuneration/incentives (if applicable)** |
| If applicable, attach the required information to your application, as "Appendix 15” in support of the response to 4 f). |