General Tips

- The documents in your application speak for you.
- Make sure that you have consistency across all of your documents.
- Answer ALL of the questions.
- PLEASE answer the sub-questions in the order that it is asked.
- Be specific in your answers.
- Over-communication is better than its opposite.
- Make sure that you have made the corrections to your application to your FPGSC's satisfaction BEFORE you submit to REC-H. The completion of the first page and all spaces for signatures indicate that this has been done.

REFERENCE NUMBER	**H22-xxx-xxx-xxx**
TITLE	**xx**
DEGREE	**xx**
RISK OF STUDY *(as per risk assessment sheet)*	**LOW / MEDIUM / HIGH**
PRP	**xx**
PI	**xx**
RECH MEETING DATE	
DATE OF COMMENCEMENT	
DATE OF COMPLETION	
Reviewer name[1]	
RECOMMENDATION[1]	☐ NOT APPROVED ☐ RESUBMISSION ☐ APPROVED WITH MAJOR MODIFICATIONS ☐ APPROVED WITH MINOR MODIFICATIONS ☐ APPROVED WITH NO CORRECTIONS

Your application will always be reviewed by two committee members, after which the recommendations will be compiled into a single document. To aid you in completing the application, this version of the form includes a few comments to help phrase your own answers and to highlight what needs to be included.

Once you (the PI) has completed the application form, it (and all the appendices) needs to be reviewed by your research supervisor (the PRP). Ensure that you keep a record of communication as evidence that your application has already been reviewed by the PRP before submission. Applications will not be accepted without evidence from the PI that the PRP has given the go-ahead for submission.

In the case of Master's and PhD-related studies, your application should include your (SPGSC/FPGSC) approved research proposal as Appendix 1 and the reviewer comments/colloquium feedback as Appendix 9. Your application cannot be submitted without having an approved research proposal.

Before submitting your application, you need to remove the information block at the start of the application form. The information block is highlighted and stretches from the first page to near the end of the third page.

RECH APPLICATION FORM[2] (approval of study is subject to the recommendations below being addressed and implemented)

1	**GENERAL PARTICULARS**
	TITLE OF STUDY
1(a)	**Concise descriptive title of study as approved by FPGSC** "Study" means the research project being conducted. ▪ Please include your proposal research title here. Use the proposal research title approved and recorded by your School and Faculty Postgraduate Studies Committee. ▪ Discuss changes to the title wording with your supervisor. ○ A title change, if it is just about clarifying the study for the reader (e.g., to add an essential component such as the main construct of investigation, or the geographical location, or the target sample, etc.) constitutes a minor amendment. A minor amendment form will need to be completed and tabled at the next meeting of the committee who gave final approval for your study (i.e. your School and Faculty Postgraduate Studies Committee - FPGSC, or the central university REC-H). ○ A slight change in title wording might not be critical for the FPGSC or the REC-H committee, but the Examinations Office will query the title change when you submit your document for the examination, which causes administrative delays.

[1] To be removed when feedback distributed to PRP/PI

[2] This feedback is of an operational/editorial/superficial nature and is for inclusion in the minutes of the meeting but not for discussion at the meeting where the application is tabled. Consideration to be given to the inclusion of appropriate guidance and possible alternatives in the feedback.

	○ A title change reflecting a major shift in the study (e.g. change in research objectives, differing methodology, different target sample – children vs adults, predictive instead of exploratory focus) is seen to be a major amendment. A major amendment form will need to be completed and tabled at the next meeting of the committee who gave final approval for your study (i.e. your School and Faculty Postgraduate Studies Committee - FPGSC, or the central university REC-H). ○ Anything that causes the risk level to change from low risk to high or medium risk, means that your application for ethics approval must be submitted to the REC-H for review. Please redo the ethic risk assessment checklist with your supervisor to determine this. Consult with your faculty REC-H representive when in doubt.
1(b)	**Rationale for this study** ▪ To complete this section, look at your proposal under the "importance of the study" section. Use the critical paragraphs under that heading to complete this section. Remember that this section should not be more than 300 words - you might not be able to simply copy and paste that entire section. ▪ Your ethics reviewers will be reading this section with a view of determining whether your study is worth the time spent on it by the participants. ▪ Make sure not to use outdated references, unless there is a good reason for doing so. ▪ Your ethics reviewers will also be watching out for indications of bias on your side in the language and motivation for the study. Don't assume anything – make sure that you can and do back up every statement that you make from your literature or previous research – this is true for the entire ethics application.
1(c)	**This application focuses specifically on the procedure in which human subjects will be participating (and not on any other procedures of the study nor on the study as a whole).** Describe the contribution of the data collection from human participants to the overall study. You will need to do a bit of reflection when completing this section. Why is it essential to gather data from this specific population for your research?
	PRIMARY RESPONSIBLE PERSON (PRP)
1(d)	**PRP identification and affiliation details**: ▪ "PRP" means primary responsible person. This individual must be a fulltime member of permanent staff or currently active Research Associate. This is usually your supervisor where you are doing the study for degree purposes. ▪ Ensure that all the fields are completed i.e., your main supervisor's: - PRP staff number - Full name, surname, and title e.g. Prof Jane Doe - Email address: Preferably use a university email address. - Faculty - Department/School (This is very important, as ethics numbers are allocated according to your department/school in the faculty) The PRP and the PI can be the same person where the study is not being completed for degree purposes. But, the person would in this instance usually be a university staff member or research associate. Refer to the REC-H website, or make queries with your faculty REC-H representative or with the REC-H chairperson, if your study is being conducted within the scope of a larger (umbrella) study, or where your study was initiated by someone external to the Mandela University and they asked you to assist.
	PRINCIPLE INVESTIGATORS (PI) AND CO-WORKERS
1(e)	**PI (may be same as PRP) identification and affiliation details:** "PI" means Primary Investigator and is the person undertaking the study. This is usually the student in the case of study's conducted for degree purposes (i.e. to obtain a qualification). Ensure that all the fields are completed: - Student number - Full name, surname, e.g. Mr John Doe - Email address: Preferably use a university email address - Faculty - Department/School (This is very important, as ethics numbers are allocated according to your department/school in the faculty)
1(f)	**Name(s) and affiliation(s) of all co-workers** Co-workers could include: - all co-supervisor's / co-promoters, - recruiters, - all co-investigators (e.g. those at other university's also driving the same study where the scope is national or international), - research workers / fieldworkers who will assist you with data collection (e.g. Interns/M-students), - a translator, - a statistician,

	- an independent coder, - etc., If names are not yet known, state the affiliations of the groups from which they will be drawn, and the number of persons involved. Do not re-list the PRP or PI here.
	STUDY DETAILS

1(g)	**Scope of study**:
	
	The delimitations heading in your proposal should assist you in selecting the correct option here:
	
	• Local
	• Regional
	• National
	  ○ NOTE: In the case of a national study, evidence must be included of the ethics approval / plan for such approval at the other universities. This will be described in your full proposal, with evidence attached as appendices to your ethics application – not in this section.
	• International
	  ○ NOTE: In the case of an international study, evidence must be included of the ethics approval / plan for such approval in the other country(ies). You or your colleagues might only be applying for ethics approval at other universities after this application has been processed. This will be described in your full proposal, with evidence attached as appendices to your ethics application – not in this section

1(h)	**Purpose of study**: Please select the qualification for which you are registered: • Doctoral • Masters • Honours • Undergraduate • Diploma • Other
1(i)	**Funding**: Please select from the source of the financing for the research: • NRF grant • Thuthuka grant • MRC grant • Privately funded • No specific funding • Combination (Specifics follow) • Other (Specifics follow) **Source of funding** If you select "Combination" or "Other" please include the relevant information next to the "Source of funding" text box. Otherwise, select "Not applicable". **Does the sponsor of the study have a vested interest in the study?** This question aims to establish whether the funder has a specific reason for involvement (e.g. financial gain, research support for their product usage, to enhance their own reputation, etc.). Such expectations may potentially influence your study, your presentation of the results, and so on. **Example**: A pharmaceutical company sponsoring a drug trial at a university may have a vested interest in the outcome of the results with a view to increasing their sales or charging more for the product. Discuss these possibilities with your supervisor(s) and note them here. **If YES, describe the extent of the interest and how this risk is to be managed.** Describe how significant the funders' interest is in terms of risk to your study, participants, or communities, and how you and your research team or supervisors' will manage this risk.
1(j)	**Are there any restrictions or conditions attached to publication and/or presentation of the study results?**

	If there are conditions attached to the publication of the results, you need to indicate them here. For example, a company might be happy for you to collect data from their employees but will not allow you to publish their data because of the reputational risk to the company. This does not mean that you should not try. You might get good quality data even in the case of restrictions or conditions and do well in the assessment of your research. However, discuss restrictions or conditions with your supervisor(s), **AND** get ethics approval first, before signing any agreement. **If YES, elaborate (any restrictions or conditions contained in contracts must be made available to the Committee in Appendix 5):** The restrictions could, for example, include a confidentiality agreement. As indicated above, if the research is classified as confidential, the words "Research is subject to a confidentiality agreement" must be inscribed on the cover of the examination copy as per the examination office checklist. Please do NOT sign this, or any other document with any external party, before ethics approval has been obtained – this is to protect both you and the university, as well as your participants.
1(k)	**Date of commencement of data collection** *Definition: "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.* It should be noted that RECH cannot grant retrospective approval, and as such, the start date of data collection can only be after the date of the RECH approval. Data collection can only commence once the researcher is in possession of a letter of approval. Therefore, to be more explicit: no application for approval can be submitted if data has already been collected. You must discard all data collected without ethics approval. As ethics approval is only granted for one year, the researcher is reminded to re-apply for ethics clearance yearly until the data collection phase is complete. Set a reminder for three months before the expiry of the current cycle. **Anticipated duration of data collection in months** *Definition: "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 to conclusion of direct interaction. 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.* Indicate the anticipated duration of data collection. The duration should be stipulated in whole months (e.g. 1 month, 2 months, 3 months, etc.) Do not provide this information in weeks, partial months, or partial years.
1(l)	**Is this application related to any existing and currently active umbrella research project?** *Definition: "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.* The main supervisor or project coordinator of the broad research project will already have (in the context of this question) submitted an application for ethics approval – using the Umbrella Study ethics application form. OR the main supervisor might be submitting the general application at the same time as the students' applications. That is, Masters and Doctoral students must submit independent ethics applications for their parts of the umbrella project. An umbrella research project might also be planned for groups of undergraduate and/or Honours students undertaking small research projects. In this case, individual ethics applications are not required where the research objectives, methodology, data collection procedures, and instruments are the same or significantly similar – however one umbrella sub-study form must be completed for the group by the main supervisor. The main supervisor will also, in addition, have applied for approval of the general project for the group – using the Umbrella Study ethics application form. NOTE: these are two different forms at this stage, but we envision joining the two in the near future. Your response to this item will be 'No' in most cases. **If YES, provide the ethics reference number of the related umbrella project** If no: indicate "Not applicable."
1(m)	State your research objectives here. Use bullet format.

	Make sure that the research objectives here are exactly the same as the ones stated in your research proposal, those described in all letters requesting permission to collect data, and the same as those described to participants verbally or in writing. Consistency is critical. A lack of consistency in the articulation of your research objectives might reflect a lack of focus or confusion on the part of the researcher and lead a reviewer to question the scientific integrity of the study. Research objectives should be directly aligned to the sub-problems or sub-questions for which you will be collecting data. Please note, good research objectives are focused and specific. They include: • An action verb – what you want to do • A type of finding – what you'll know once you've done it
	METHODOLOGY
1(n)	**Recruitment process** *Definition: 'Recruitment' refers to the collection of those methods or techniques used by researchers to (1) identify and (2) approach individuals to participate in the data collection for a study (these individuals being referred to as 'volunteers').* WHEN will each step be undertaken? WHERE will each step be undertaken? BY WHOM? WITH WHOM? HOW? Describe your recruitment process as a procedure. A procedure has sequential steps to follow. So, provide us with detail. Describe in detail HOW you will identify people to approach. - What will you use to help you to identify potential participants? - Will you need the assistance of a specific individual? If so, who? - If you need access to records, which records in particular? - If social media, which ones? Facebook, Instagram? Whatsapp? Telegram? Be specific. You can't just write in general terms. If groups – which groups exactly? Are there people who need to allow you access to the social media data? If so, who are they? Have you shown us in your full proposal that you have made yourself aware of the latest guidelines in the use of social media data for research purposes? - Will you be going through a third party to do any part of this procedure for you? Who? Which part? Your description of the procedure involved here must explain WHO will be identified and approached for inclusion in the study. Describe in detail HOW the identified potential participants will be approached? In other words, HOW do you make them aware of your study? Via what means? By email? In person? WHO will be approaching them? So, for example, if you are going to approach them by email: how will you obtain their email addresses? Who will be sending the emailed information out – you or a third party? Who is the third party? Show us that you are aware of the guidelines around the collection of personal information (i.e., as per the POPI Act). It is not, for example, recommended that you ask anyone for a list of names, contact information (email addresses, cell phone numbers, home addresses, etc). It is better to advertise your research to the target population without the use of their personal information. Please note that details are important. The ethical pitfalls can be easily identified in the details. So please be thorough. It is not sufficient to say that "The participants will be contacted…"; an explanation needs to be provided as to HOW the people will be identified, HOW their contact details will be gathered and HOW will they be provided with the recruitment information (e.g. an email, social media posts, printed documents, etc.). You will need to include details on HOW you will gain access to the population and HOW the population will be contacted. Your recruitment information must include HOW you want them to indicate interest in participation, and/or HOW to contact you. Draft copies of ALL written or verbal communication to the target population must be provided as appendices to your application for ethics approval. In most cases, you will need to gain access to your intended group of participants through a gatekeeper. The gatekeeper is a person at the institution, organisation, or company from whom you need to ask permission to access those who meet the sampling inclusion criteria. Remember, in order to be POPIA compliant, you will need to ask the gatekeeper whether they would be willing to send your recruitment information out on your behalf. However, you also need to be aware of the need to avoid undue influence by, for example, the line manager, or the teacher, and so on – HOW will you avoid this if it is a possibility? **All health research applications for ethics approval should include a copy of the NHREC newsletter in the recruitment information shared with potential participants.**

	All other research applications for ethics approval should include a copy of the NHREC newsletter in the recruitment information shared with potential participants BUT should delete irrelevant material.
1(o)	**State the minimum and maximum number of participants involved.** *Definition: "Minimum number of participants" refers to the minimum number of participants required to make the study viable.* NOTE: It is as unethical to require too many participants than is actually necessary (wasting the participants' time) as it is to require too few participants (also wasting participants' time since the study would then not be viable). If you are performing multiple types of data collection, the minimums and maximums should be stated for each group of participants. List the minimum and maximum number of participants to be involved for each data collection phase, method, technique, or participant grouping – if separate numbers are involved.
1(p)	**Sampling Strategy** A: Identify your target population. Why was this population chosen? B: Describe the sampling method or strategy that you will use to get a sample of participants from your target population. Why is this the best method or strategy for this study, or for a phase of the study? You might have more than 1 sampling strategy, but must be able to explain why this is necessary. C: 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. Make sure to use a scientific method to calculate your required number of participants. Remember to ensure that this number must also suit the requirements of your method of data analysis, where relevant. There are various methods of calculating your quantitative data sample size when you know your population size and framework. A link to a popular article is below: • Krejcie and Morgan – Determining sample size for research activities For qualitative data collection, you will normally continue interviewing until you reach saturation. A link to an article is below (you may need institutional access to view it) • Boddy - Sample size for qualitative research There are many more, Google it. • Differing opinions are held with reference to how saturation point is reached. For example, Fugard and Potts (2014) maintain that a sample of thirteen is enough to reach saturation with qualitative data – but what is the latest recommendation(s) in consideration of the scientific scope of your study? Your ethics reviewers will not always be a subject expert but will be checking to make sure that **you** are.
1(q)	**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):** *Definition: "Enrolment" refers to the collection of those methods or 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.* Recruitment and enrolment are two different aspects of your study. The response in 1(n) should detail how you will make initial contact with the participants – how you will 'recruit' interested people. However, not all of those interested might be able to participate, either because they do not meet your sampling procedure or because you have reached the maximum number of participants needed. So, once they have responded to your call for recruitment by indicating interest, the next step is to enrol them in the study. **Example:** Your recruitment information may request that they contact you via email if they are interested in participating. You would then respond by sending them the enrolment information, which may include a link to a survey, a more in-depth overview of what will be required of them in the study, and a consent form (required for any adult human participation) or assent form (required for any non-adult human participation). A copy of the consent and/or assent form(s) must be attached as an appendix to the application. There might be a period of time between volunteer recruitment and the enrolment of 'participants' (those individuals who indicated a willingness to participate and who were subsequently selected for participation). With a survey, you may receive more responses than the maximum indicated in 1(o). What approach will you apply in selecting the applicants you will actually enrol (i.e. what process will you use to exclude volunteers' data from the study)?
1(r)	**Data collection process**

	Definition: 'Data collection procedure or process' refers to those methods or techniques used by researcher(s) for the collection of data from human subjects. Data collection methods or techniques must be aligned with the presented research objectives.' *Definition: 'Data collection instruments" refers to the measures used for the collection of data from human subjects (e.g. survey, questionnaire, interview schedule, etc).'* This section requires you to describe the data collection procedure, and NOT the data collection instruments. You will name the instruments here but will describe it in more detail in your full proposal. Describe in detail the procedure to be followed while collecting data from participants. Copies of all data collection instruments must be included as appendices to the study. You may already have a section related to this in your research proposal, if so copy it here. Otherwise, you will need to describe how your data collection instrument will be administered. For example: - For physical questionnaires: Describe how the participants will complete the consent form and how they will complete the questionnaire. Will you get everyone together in a venue and then hand it out to them? - For an online questionnaire: Describe the tool or platform you will use to develop the questionnaire (or that has already been developed) and how the participants will provide consent. - For interviews: Describe the entire interview process. HOW, WHEN and WHERE will consent be given? HOW it will take place (in-person vs online)? Will the interview be recorded? Have you asked permission to record in the consent form? - For focus groups: Describe the entire process, as for interviews. Consider whether the PI has the experience to lead the focus group or whether the PRP or third-party will need to lead the focus group. The PI might have the necessary experience but can identify that it would be more appropriate to have someone else lead the focus group (e.g. to avoid a power relationship having an undue influence on the data provided, or to ensure greater cultural or linguistic validity, etc.) If a pilot study is to be performed, include this in your discussion and mention this in your response to the question about minimum and maximum numbers in 1(o).
1(s)	**Data analysis** *Definition: 'Data analysis' refers to the collection of those methods or techniques used by researchers to analyse the data collected from human subjects.* You cannot leave the planning of your data analysis until you've obtained ethical clearance to proceed and have data in hand. You need to think it through now to avoid ethical issues and to ensure the scientific integrity of your study. Care must be taken to avoid the stigmatisation of population groups, organisations, or communities. Provide details on the analytic technique(s) to be applied, per research objective, and per phase. Explain why that technique was chosen. In a quantitative study, has the analytic assumptions been met in order to use that specific statistical technique? In a qualitative study, is the choice of method appropriate to the research design? Will the methods used achieve your research objectives? You can use a table here so that it is easy to review. You may have a section heading like this in your proposal, so you can copy your answer from there. Or you could try to summarise that section here. It can however be difficult to try and summarise the main points from this section in your full proposal, so rather err on the side of providing more (rather than less) information here.
1(t)	**Data reporting** *Definition: 'Data reporting' refers to the collection of those methods or techniques used by researchers to report on the findings derived from the data collected from human subjects.* Explain how you will intend to report on your findings. Below are some examples of how you can and will report your findings: • At the very least, you will compile a Treatise, Dissertation or Thesis • Infographic (If you have a confidentiality agreement in place, then you won't be able to do this) • Conference Paper (If you have a confidentiality agreement in place, then you won't be able to do this) • Journal Paper (If you have a confidentiality agreement in place, then you won't be able to do this) • Book (If you have a confidentiality agreement in place, then you won't be able to do this)
2	**RISKS AND BENEFITS OF THE STUDY**
2(a)	*Definition: '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.* Evaluating the acceptability of risks and potential benefits of a research project is central to the work of Research Ethics Committees (at departmental, faculty, and central university ethics committee levels). In practice, this involves conducting a

	"risk- benefit analysis". Have you assessed risks or harm against the likelihood of benefits? This could be with respect to the individual and/or target community, the incurment of costs by the participant, remuneration, conflicts of interest, and so on. You need to show that you have thought this through carefully as a researcher. Laying all of your cards on the table about the potential risks also shows that you care about your participants, that you are not taking advantage of them, and this improves your credibility. Applications HAVE been rejected where reviewers felt that the risks to participants outweighed the benefits of the study. Put yourself in the shoes of the person that you are communicating with. For example: If you are asking participants questions regarding their workplace, could the company or other employees take offence at their answers? The risk to the participant could be that their honest answers might negatively influence their future at the company. A solution could be to ensure that participants are never identified by name, but only by pseudonym. Using pseudonyms will not always ensure anonymity → answers to demographic questions could still trace responses to individuals where you have a small group of participants, and present a major risk to them.
2(b)	**Does the person administering the project have previous experience with the particular risk factors involved?** NOTE: "the person" referred to here is YOU, but it might be someone else. And you need to declare it here and explain why this needs to be the case. If there are risks mentioned above, you may not have experience dealing with it. You will need to compile a procedure list to follow if something goes wrong. Ensure that it is very detailed and have emergency contact numbers recorded. Your supervisor should probably feature as one of the main emergency contacts. Include this as an appendix to your application.
2(c)	**List any ethics training acquired by the PRP in the past 3 years:** I have completed the TRREE online training programme • Module 1: Introduction of Research Ethics • Module 2.1: Research Ethics Evaluation • Module 3.1: Informed Consent **List any ethics training acquired by the PI (if not also the PRP) in the past 3 years:** I have completed the TRREE online training programme • Module 1: Introduction of Research Ethics • Module 2.1: Research Ethics Evaluation • Module 3.1: Informed Consent It is recommended that all PRPs and PIs complete the TRREE training modules 1, 2.1 and 3.1 (https://elearning.trree.org/). If no training has been completed, then provide an answer of "Not completed". An answer of "Not applicable" is not acceptable as this is always an important factor to consider, especially in the context of high risk studies and vulnerable groups. NOTE: At present, only REC-H members, as well as faculty reviewers of ethics applications, are required to have formal ethics training, and need to present evidence thereof. Other staff and students are ENCOURAGED to make use of opportunities to acquire ethics training. However, a well-considered assessment and acknowledgement of the ethical implications of each part of the study as well as how the researcher has decided to mitigate these (where relevant) must be reflected throughout the documentation.
2(d)	**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.)?** *Definition: 'Benefit' refers to any possible positive effect of any data collection activity on the individual welfare of a participant over and above what would be expected from such a participant as a result of routine daily tasks.* This refers to direct benefits only, not to benefits to the community, or to the professional field involved, and so on. There is often no direct benefit to the participants – and this is acceptable as long as the study is adequately motivated.
2(e)	**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**: *Definition: '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.* What are the benefits of your research to the broader society, the community, the theoretical or practical knowledge base, and so on? There must be some benefit or there would be no point to the exercise. To have social value, a research project should be designed to solve a problem that is relevant to community concerns or that has been identified by the community as a problem that needs to be addressed.

	Many students underestimate or don't even realise the social or ethical value that their study has. Or maybe they were just in a rush and selected 'not applicable' ☺ And remember that you must (and REC-H will) continuously evaluate the risks and benefits of the study.
2(f)	**Will you be using equipment of any sort?** This question appears to be self-explanatory but is more complicated in today's world. If you are using something like MS Teams or Zoom, have you considered all of the security precautions to put in place so that you don't get unwanted strangers in the 'room' and to ensure confidentiality? You must put serious thought into whether you NEED TO use the video recording option – this will have additional requirements to ensure safe parameters for confidentiality. Video recordings will not be permitted unless you cannot do the study without it. If you are using a Dictaphone or Camera to record interviews, you need to state it here. **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?** We take this bit very seriously. Participants must be made aware of your intention to use any kind of equipment or software to record data from them and must provide their permission for you to do so in advance. For example, if you make use of the tools (e.g. audio or video recording) associated with online meeting software such as Teams or Zoom, you will need to explain this in the recruitment information. You must obtain permission (*explicit consent*) from your interviewee to record (sound or video) their data. You need to include this in your consent form as well. Your consent form must be signed by your participant(s) BEFORE data collection can commence. Any data collected without consent must be discarded and you will be considered to be in breach of our code of conduct for researchers. You cannot assume that permission to record is implied by their participation, and verbal agreement is insufficient.
2(g)	**Will any article of property, personal or cultural be collected in the course of the project?** In many research topics, no property, personal or cultural articles are collected from the participant.
2(h)	**Describe the process to be followed in the case of any incidental findings relevant to individual participants:** *Definition: 'Incidental findings' refers to any unexpected discovery made during the course of data collection or analysis, these findings being outside the scope of the research. Cognisance must be given to relevant mandatory reporting procedures should such be relevant to the context of the study.* For example, in a study interviewing prisoners convicted for violent crime: what if a prisoner discloses something about the prison warden or security guards or fellow prisoners regarding illegal misconduct? Are you obligated to inform the prison officials? Have you made yourself aware of relevant mandatory reporting procedures? The basic response to this part of the form should always be, at a minimum, to consult the situation with your supervisor regarding the way forward. If you discover that something has been done unlawfully (fraud, bribery, etc) or detrimental to someone's health, during your data collection and analysis, you need to report it to someone. People can include your Supervisors, the Gatekeeper or even the police. But please explain the process as far as possible in your response to this item.
2(i)	**Is there any risk of harm, however slight or temporary, to the researcher while conducting the data collection exercise?** This question helps us to protect YOU, the researcher. For example, during the lockdown periods associated with the Covid-19 pandemic, researchers were prevented from collecting data in person. Only online data collection was possible. So please acknowledge any risks to yourself or your co-workers, why it is necessary to proceed despite the risks, and indicate what measures you will take to minimise the risk and protect yourselves. Please DON'T muddle your responses. Address each point one by one and use the same formatting.
2(j)	**Is any insurance available for research related injuries for participants and/or researchers?** Nelson Mandela students and staff (i.e. PI/PRP) are covered by the university insurance if they are for e.g. injured while on university duty. It is left to the PI/PRP to apply their minds in their cases if there needs to be liability insurance for participants and/or non-NMU fieldworkers. Claims must be submitted to the Legal Office for investigation, and will only be settled if the university is deemed liable.

3	**TARGET PARTICIPANT GROUP**
3(a)	**According to your knowledge, has the chosen participant group participated in any previously approved research?** This is because we don't want to oversample any group or introduce unanticipated confounding variables into the study. Respond in the affirmative if you know that your target population has been requested to participate in research studies before.
3(b)	**Inclusion criteria**: *Definition: 'Inclusion criteria' refers to that set of characteristics that all participants must exhibit so as to be included in the data collection procedure.* 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.). Unless there are good reasons for the deception, inclusion criteria must be made available in writing at the point of recruitment. Use the information from your proposal on delineation and/or the study population to describe the characteristics you are looking for in participants. There will almost always be some form of inclusion criteria, i.e. some criteria that makes specific persons suitable candidates for participation in the study. Consider whether: i. the criteria are clearly stated and reasonable, ii. any individuals are being inappropriately included as participants, iii. any are being individuals inappropriately excluded as participants, iv. the study includes vulnerable groups such as children, prisoners, psychiatric patients, individuals with impaired decision-making capacity → If yes, are adequate safeguards included to protect their rights and welfare? v. the inclusion of vulnerable populations is justified, vi. the study can be done without involving vulnerable populations, vii. the study will target or exclude a particular ethnic or language group, viii. who, in the research team, will decide if an individual participant is eligible, and ix. the selection of participants is appropriate for the question(s) being asked.
3(c)	**Exclusion criteria**: *Definition: '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. Specify the 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.). Use the information from your proposal on delineation of the study population to describe the characteristics you are **not** looking for in participants. For example: one interested person matches the inclusion criteria above but he/she is retired and you are only looking for employed people → the exclusion characteristic in this case would be 'retired'.
3(d)	**Are participants drawn from Nelson Mandela University students?** **If participants are drawn from specific groups of students, please specify:** **Are participants drawn from Nelson Mandela University staff?** **If participants are drawn from specific groups of staff, please specify:** This section is self-explanatory. If your answer is "Yes" for any of these questions, then your application will have to serve at institutional level. Refer to 1(k) to see the implications in terms of time. Did you know that university students are seen as a vulnerable group? There are risks of: - oversampling due to the convenience factor, - undue influence on participation and responding because of power relationships (even between students), - stigmatisation, - etc. This is ONE of the reasons why RECH reviews the recruitment, selection, enrolment, data collection, and reporting so carefully. The same is true for staff.

	A positive response to this items alerts us immediately that we need to make sure that protective mechanisms are put into place to protect participants.
3(e)	**Are participants drawn from a primary/secondary school population?** Primary and secondary school learners also constitute a vulnerable group. And, as with students and staff, we immediately know that there are specific permission and reporting processes to follow.
3(f)	**If participants are drawn from an institutional population (e.g. hospital, prison, mental institution), please specify:** The question refers to a sample group drawn from an institutionalised population (e.g. hospital, prison, mental institution). Schools, for example, are not institutionalised populations in this sense. These are highly vulnerable groups where: - participants might have limited capacity to consent, - power relationships could negatively affect participation or responses, - participants could be easily used for research purposes for the sake of the greater community with their rights over-ruled or even not considered. The risk of stigmatisation and potential risks to participations following data collection should also be considered and acknowledged here, together with how these potential risks will be managed.
3(g)	**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**: This is for studies that collect data physically in the community. The researcher needs to take note of the cultural norms and standards of that community. For example: Collecting data from people in a small village regarding the farming methods employed. Permission to talk to the people in the village might need to be received from the Chief. Thus, a relevant cultural advisor (community leader or ward counsellor) might be needed to ensure that you do not offend anyone. Engage key stakeholders such as community representatives and policy makers in designing the protocol, conducting the research and distributing the findings. Community participation could help you to craft a suitable informed consent process, appropriate risk reduction interventions, and other decisions.
3(h)	**If any records will be consulted for information to complement the data collected, please specify the source of records:** This does not refer to any data collected using the data collection tools (survey, interviews or focus groups) outlined in this application. It refers to pre-existing data such as health or employment records. Make sure not to assume that you can use the data if you easily have access to the records through your or your supervisor's employee status in relation to the records. POPIA would be VERY important in this type of situation.
3(i)	**Will each individual participant know his/her records are being consulted?** For example, if you are analysing tender documentation submitted as part of a Case Study. Do the tenderers know that you are inspecting their documents? The tenderers are unlikely to permit you to look at their documentation if you ask them individually. However, the QS company might allow you to inspect the documents after being anonymised. The anonymisation is crucial. If YES, state how these records will be obtained. The example above: asked each tenderer individually. If NO, give reasons. The example above: The documents were anonymised. And with POPIA an additional question is: Has each individual participant given prior permission for their identifying information as recorded to be used for this purpose in advance? There is some debate regarding the use of aggregated and anonymised data. Demonstrate your knowledge of the current practice and opinion in your field / profession and motivate for the use of data where participants did not expressly consent to the use of their anonymised data in advance.
3(j)	Are all participants at least 18 years of age?

	When dealing with professionals in the working world, the participants are generally over 18. Remember, that if you plan to have participants who are younger than 18, you will need to request assent and your study would need to be approved at an institutional level.
4	**CONSENT / ASSENT (in the case of minors) OF PARTICIPANTS**
Note 4(a)	• ***Recruitment information to participants and informed consent forms should always inform them that complaints or concerns can be expressed to the researcher, RECH-H, then to NHREC, and then to SAHPRA.*** • ***The REC-H ethics approval number should be included in the consent form.*** • ***The contact details of the researcher(s), the REC-H (rd@mandela.ac.za), and the relevant regulatory authority should be included in the consent form.***
4(a)	**Consent: Is consent to be given in writing?** *Definition: "Consent" refers to a, preferably written, record of agreement to participate in the data collection process.* If YES, include the consent form with this application (Appendix 14). Refer to the consent form checklist for guidance on the expected contents of such a consent form. Please tailor the draft consent or assent form to be suitable to the intended reader. That is, make it easy to understand, in a pleasing format, and without the use of academic jargon. Make sure that If NO, state reasons why written consent is not appropriate in this study. - Take note that there is seldom, if ever, a reason for participants not to provide consent. It is a legal requirement to record informed consent. You will need a very good reason to indicate why consent is not needed. - The effect of POPIA on the code of conduct of researchers must be born in mind here. As does the 2015 guidelines from the DoE. We've historically required written consent, but now, other forms of consent can be accepted. Example, yes/no buttons on emails, and so on. However, consent must still be informed, explicit, and voluntary. Explicit – means that consent MUST involve an action on the part of the participant. Implicit consent is NOT acceptable e.g. your implicit consent is assumed by your completion of this survey. Consent must still be recorded. Oral consent can be recorded and stored, however then you will have to store individual recordings separately for each participant. AND the oral consent CANNOT be part of the data collection recording for obvious reasons. Oral consent is also difficult to work with for auditing purposes so I would not recommend its use. For more information on the consent form, refer to A13 Informed Consent, near the end of this template.
4(b)	**Assent (if any participant is younger than 18 years of age): Is assent to be given in writing?** *Definition: "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.* When dealing with professionals, the participants are generally over 18. If you are, however, targeting a population which consists of minors, you will need to provide an assent form. RECH will be looking for ethical issues such as: power relationships, individual right to autonomy i.e. to decide for yourself (no matter how young / no matter what the issue is), issues in beneficence, and so on. Paramount is that the best interests of the child be considered and upheld. Some additional considerations include: - whether consent should be re-obtained when the child reaches 18 years, reflecting the child's evolving maturity and capacity to give consent. - in addition, there are certain matters where, for reasons of sensitivity, it may be desirable and ethically justifiable for minors to consent independently of a competent person. This is particularly important for research where children may not be willing to participate if their parents must know about the nature of the research in order for permission to be obtained. If YES, include the assent form with this application (Appendix 14). If NO, state reasons why written assent is not appropriate in this study.
4(c)	**Are any participant(s) subject to legal restrictions preventing them from giving effective informed consent?** When dealing with professional, the participants are generally not subject to legal restrictions preventing them from giving effective informed consent. If YES, please justify:

	Example: Individuals who might be mentally disabled or senile. Maybe the study wishes to observe (covertly or otherwise) such individuals performing certain tasks. Consent would then be required to be obtained from their legal caregivers and/or family members who care for them, or similar. **Example:** Cross-country research when POPIA meets the European Data Protection Board (GDPR) (European) - lawyers need to get involved in the negotiated procedure before you can proceed. For instance: POPIA does not consider a human biological sample collected during the research process by itself as inherently identifiable and does not fall under POPIA's definition of personal information. In contrast, the GDPR has recently prescribed that genetic data be treated as personal data.
4(d)	**Do any participant(s) operate in an institutional environment, which may cast doubt on the voluntary aspect of consent?** *Definition: "Institutional environment" refers to institutions like hospitals, prisons, mental institutions, etc.* If YES, state what special precautions will be taken to obtain a legally effective informed consent. For instance, a participant may be a patient at a hospital and feel that they need to consent to participation, otherwise their level of care may be compromised. The emphasis here is on the consent/assent procedure. That is, how will consent / assent be obtained. Have you thought about and already prepared special precautions that might need to be taken?
4(e)	**Do any participant(s) exist in a power relationship with the PI/PRP, which may cast doubt on the voluntary aspect of consent?** *Definition: "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.* Example: Suppose you are conducting a Case Study in which the Managing Director of a firm is conducting a study and distributes questionnaires to their staff members. In that case, it may cast doubt on the voluntary aspect of consent as participants may feel they have to participate as it is a request from their superior at work. You will have to find another way to distribute the questionnaires, excluding the Managing Director as a recruiter. In such cases, if the Managing Director is not the gatekeeper, the gatekeeper may be used to distribute the questionnaires.
4(f)	**Will participants receive reimbursement/remuneration/incentives for their participation?** 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. Try to avoid monetary incentives unless absolutely required. It should not be assumed that people must be compensated to participate in research studies. However, compensation can improve participation rates, making the sample of respondents more representative of the population under study. In some cases, participants may feel that some compensation is appropriate, given their contribution of valuable information and time (Information from the University of Alberta). Example: If you are conducting interviews using Zoom or MS Teams, you might want to reimburse them for the use of their data. Below is some more information on "The Use of Incentives In Research" • The Use of Incentives In Research However, please note that your application will automatically be considered a medium risk if you provide an incentive (which means it needs to serve at institutional level for consideration) The guideline is that **f**inancial or other forms of compensation are not considered to be a benefit but rather **recompense for research-related inconvenience.** You also need to consider the following questions: - Is the compensation to participants reasonable? - What happens If the participant does not complete the study? - Are there adequate plans to avoid out-of-pocket expenses and costs incurred by participants (e.g., travel expenses, parking costs, and lost wages)? - If children or adolescents are involved, who receives the compensation? - Does compensation cover extra costs when parents or caretakers are expected to accompany participants on research visits? How will the exclusion of the reimbursement/remuneration/incentive(s) from the study possibly affect the study's outcome?

	In most cases reimbursement is not considered, so it has no effect, but it may be considered that the lack of incentive could lower the response rate.
4(g)	**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)** *Definition: "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 (Refer to 4e, which defines a power relationship).* The gatekeeper should not actively recruit participants. The gatekeeper may send out the recruitment information on behalf of the PRP/PI (as they may not be allowed to share participant contact details as a result of POPIA). However, the gatekeeper should not accept responses from the participants, instead, the recruitment information should request that the participants contact the researchers directly, should they wish to be enrolled in the study. It is very seldom that a study does not require a gatekeeper. In many cases you are recruiting participants because of their involvement in a specific population group at a company, organisation or cultural group. The gatekeeper is the contact person or person who serves as the contact point for gaining initial access to the participants in the group. Examples of gatekeepers are: - someone in a managerial position at a company, - the head of an organisation - a representative from a cultural group * *Standard practice for Nelson Mandela University student/staff participants is a selection of one of the following:* *i)* ***DVC: Research, Innovation and Internationalisation*** *for any staff and also if student participants are recruited 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.***
4(h)	**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)** Examples of the above mentioned are: • City of Cape Town: When wanting to survey City of Cape Town employees • Department of Education: When wishing to interview Department of Education senior management
5	**INFORMATION TO PARTICIPANTS**
5(a)	**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))** This is a mandatory appendix. This is normally the letter you will send to participants to recruit them to the study. Here you need to explain the full procedure in detail. We want to know what information you are going to share, WHERE, by WHOM, HOW, and WHEN in order to attract interest from the target group to participate in your study. Paint a picture for us with your words. We will only ask for more information if you don't ☺ We are also interested in how you put this to the target group and will be examining your draft written or oral recruitment information very carefully. More details on this appendix is provided in section A11, below.
5(b)	**Who will provide this information to the participant?** It depends on your recruitment strategy, but this normally the PI, PRP, research assistant or gatekeeper.
5(c)	**Will the information provided be complete and accurate?** There are studies which exclude information from participants, such as whether they will be in a group taking an actual drug or a placebo. For most studies conducted in the faculty of EBET, information exclusion or deception should not be necessary.
5(d)	**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))** This should include the following:

	• A cover letter explaining the enrolment process. More details on this appendix is provided in section A12, below. • The consent form. More details on this appendix is provided in section A13 below. • In cases where the data collection instrument is a questionnaire, the participants may also be provided with a copy of the data collection instrument or a web link to it, in the case of an on-line questionnaire. As with recruitment, please explain the full procedure in detail. The enrolment procedure begins when they've read your recruitment letter or email or Facebook group post, and they think "*yes this sounds interesting!*". How will they know how to contact you? Tell us about the WHO, WHEN, HOW, WHERE for every step from the start of enrolment right until the point where the signed consent forms are securely stored in the PRP's office or network drive. How do they know to contact you confidentially? How do you get consent in hand?
5(e)	**Who will provide this information to the participant? (Give name and role)** Generally, the student (PI), supervisor (PRP) or a research assistant.
6	**PRIVACY, ANONYMITY AND CONFIDENTIALITY OF DATA**
6(a)	**Will the participant be identified by name in your research?** *Definition: "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.* Make sure that you are aware of POPI regulations in the collection of personal information. You have to be able to confidently explain the need for the personal and identifying information collected. It is important to not make any participant identifiable. Never identify participants by name. Wherever dealing with case studies focusing on a specific company, school, university, organisation, etc. (hereafter referring to all as organisation) avoid using the specific name of the organisation as it may result in a reputational risk to the researcher, university and/or the organisation if inaccurate results are reported or if the results shed an unflattering light on the organisation. This could, in extreme cases, result in legal action. In addition, anonymity would be breached if, for example, you use the name of the employer if there is possibly only a single participant per company. **If NO, specify the provisions made to protect the participant's rights to anonymity.** Normally, participants are given codes or pseudonyms. Be SPECIFIC about provisions made.
6(b)	**Are provisions made to protect participant's rights to privacy and to preserve confidentiality with respect to data?** Yes *Definition: "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.* **If YES, specify:** Example: Password protect the data if stored digitally. Remember that confidentiality is NOT the same as anonymity. Which parts of your recruitment/enrolment/data collection/storage requires confidentiality and how do you ensure that? To ensure compliance with POPIA in relation to consent, responsible parties should assess the balance between the risk of harm resulting from a loss of privacy to the data subject, the strength of the governance framework that regulates the re-use of data, the potential utility of data for future use, and the model of consent adopted. Where the risk to privacy is higher, greater safeguards should be put in place to mitigate against potential harms. Where a research project is determined 'high risk', a full privacy impact assessment should be conducted to determine where further safeguards may be necessary to protect personal information and mitigate against any potential harm to the data subject.
6(c)	**Will data collected be stored in any way?** Please answer the sub-questions in the order that it is asked. Answer ALL of the questions. Be specific in your answers. Yes, data collected would have to be stored for data analysis and verification. The answers should be given according to the Roman numerals. The following is a list of acceptable answers provided by REC-H.
(i)	Data must be stored by the PRP.
(ii)	Indicate how many copies would be stored.
(iii)	Data must be stored for five (5) years for validation and audit purposes.

(iv)	Indicate for what reasons the data would be stored.
(v)	Indicate how the data would be secured from unauthorised access
(vi)	Indicate how the consent/assent forms would be stored.
(vii)	Indicate what would happen to the data upon conclusion of the study.
6(d)	**Will stored data be made available for re-use in any subsequent research?** *Definition: "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.* Generally, no. The publication of research manuscripts as a result of the current study is not classified as re-use of data. Consent is unnecessary where the information is already in the public domain. **If YES, how will participant's consent be obtained for such re-usage and how exactly will the data be re-used?** You will need to explain how the participant's consent be obtained for such re-usage and how exactly will the data be re-used. Participants must be fully informed about how their data will be re-used when giving consent. Thus, vaguely stating "future research" is not good enough. Researchers need to ensure that: - further data processing is only for research purposes, - there is no other secondary purpose beyond research, - and that appropriate safeguards are in place, such as an ethics review, prior to further processing of the data. - The data subject must have already consented to such further processing. NOTE: A new ethics application form will need to be completed for the study re-using the data.
6(e)	**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)?** In cases where the data is collected in-person at a company's premises, permission will be required, but this forms part of the gatekeeper letter. Even if the PI is an employee at the company, permission will still be required, as access for employment purposes does not automatically provide permission for research purposes. **If YES, specify and state how consent* of property owner is to be obtained:** *** 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.**
6(f)	**Are there any contractual secrecy or confidentiality constraints on the data collected?** **If YES, specify:** There are cases where this comes into play. For example, a company might require you to sign a confidentiality agreement first if you are using them as a case study. Also see 1(j). We will make sure through our Law Faculty representative, or the Legal Office that all is in order. But please, try NOT to sign anything like that until your application has been approved through us. We are on YOUR side.
7	**FEEDBACK**
7(a)	**Will feedback be given to participants?** *Definition: "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.* It is good practice to give feedback to participants. **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.):** Feedback is normally given as a summarised report of the findings, a link to a conference paper or even a YouTube link to an "explainer" video.

7(b)	**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*?** The Department of Education expects a researcher who wants to make use of school learners and facilities for research purposes to request permission to do so from them first, and then to provide them with a copy of the research study.
8	**ETHICAL AND LEGAL ASPECTS**
8(a)	**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.** Pick the relevant documents: • The Belmont Report: www.edu/irb/pdfs/BelmontReport.pdf – Include at least this one, as you will need to answer Yes to the next question. • Declaration of Helsinki 2013: www.wma.net/e/policy/pdf/17c.pdf • Medical Research Council: Guidelines on Ethics for Medical Research: HIV Preventive Vaccine Research: www.sahealthinfo.org/ethics/ethicsbooks5.pdf • The Singapore Statement on Research Integrity www.singaporestatement.org • Human Heredity and Health in Africa (H3Africa) Initiative http://h3africa.org/ **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:** Yes
8(b)	**I would like the REC-H to take note of the following additional information** If you have any additional information please indicate it here.
9	**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"** *Definition: "Conflict of interest" refers to a compromised situation involving 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.* Please complete appropriately and indicate awareness or not of potential conflicts of interest.
10	**SIGNATURES BY FACULTY**
	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.
11	**APPENDICES** Ensure that your appendices are numbered according to the numbering indicated in this section. There are several mandatory appendices. Your application cannot be processed if these appendices are not included. Do not paste the contents of the various appendices in the boxes on the form. Create the appendices as separate documents. It is easier for the reviewers if the documents are all separate - otherwise they need to scroll to-and-fro to see if things in the application form correspond to what is mentioned in a specific appendix. It is easier if the two documents can simply be opened side-by-side. If you have the tools to do so, you may combine all of your documents into a single document once the application has been approved. OR you could submit a pdf with bookmarks. The university does provide a few template documents (such as an informed consent form) to use when compiling your application. These documents may be found here: https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H)/Human-Ethics-Reference-Documentation
A1	**RESEARCH PROPOSAL (approved by FPGSC, mandatory)**

	This appendix is **mandatory**. For studies which are for Master's or PhD purposes, this needs to be the SPGSC/FPGSC approved research proposal. For undergraduate studies or studies which are not for qualification purposes, a full research methodology should be provided.
A2	**DRAFT LETTERS FOR INSTITUTIONAL PERMISSIONS, GATEKEEPERS, ACCESS TO PRIVATE PROPERTY ETC (mandatory)**
	This appendix is **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. The letters are considered draft as they are not allowed to be sent to the gatekeeper before ethics approval has been granted and must include the study's ethical clearance number (which will only be available after approval). The following are elements to be considered when compiling your gatekeeper letter: - Create the gatekeeper letter on the official university letterhead. - Since it's a letter, you need to include address information of the recipient as well as your own contact details. - Inform the gatekeeper what the study is about, who your intended participants are, what you need the participants to do and how much of their time you will require as part of the data collection process. - Inform the gatekeeper what their role is/request that they help you, e.g. to forward an email to participants in a specific department. - If you are going to be conducting any data collection in person on premises under control of the gatekeeper, you need to ask permission to access the premises for this purpose (even if you are an employee). - Include the REC-H number of the study, once allocated.
A3	**EVIDENCE OF RESEARCHER EXPERTISE TO CONDUCT STUDY (if applicable)**
	If applicable, attach the required information to your application.
A4	**INTERNATIONAL ETHICS APPROVAL (if applicable)**
	If applicable, attach the required information to your application.
A5	**RESTRICTIONS/ CONDITIONS APPLICABLE TO PUBLICATION OF RESULTS (if applicable)**
	If applicable, attach the required information to your application.
A6	**ANY ADDITIONAL AND RELEVANT SUPPORTING DOCUMENTATION (if applicable)**
	If applicable, attach the required information to your application.
A7	**DRAFT LETTERS FOR INSTITUTIONAL PERSMISSIONS, GATEKEEPERS, ETC.**
A8	**DATA COLLECTION INSTRUMENTS (if applicable)**
	The content of all data collection instruments or methods must align with your research objectives.
A9	**FPGSC REVIEWER COMMENTS AND COMMUNICATIONS (mandatory)**
	This is a **mandatory** appendix. On first submitting your application for review, this appendix will only contain any information if you are a registered Master's or PhD student with an approved research proposal. This appendix will consist of the feedback you received from the reviewers regarding your research proposal, as well as evidence that the application was approved. Once your application has been reviewed you will receive the reviewer comments in a document similar to this one. You will be required to address the comments by revising your application and appendices and by adding your own response comments to the received review form. When you re-submit your application to the committee, after you have made amendments, the review form (with your comments) needs to be included as an extension of this appendix.
A10	**DATA COLLECTION INSTRUMENTS (mandatory)**
	This is a **mandatory** appendix. This appendix needs to contain the final (not draft) versions of your data collection instruments. Your ethical clearance is tied to the data collection instrument and an application cannot be lodged without including your data collection instrument (i.e., the questionnaire or list of interview questions). Data collection instruments include, but are not limited to: - The questionnaire - Interview questions (referred to as the interview schedule) - Focus group interview schedule / questions. NOTE: choose your measure carefully. - Have you made yourself conversant with the measure's history in terms of its development, reliability and validity – motivate for its appropriateness for use with this target group and for this purpose in your full research proposal. - Why did you choose this measure instead of others available measuring the same construct (where relevant)? - Do you need to ask the developer for permission to use the measure for research purposes? - If the measure was developed in another country, have any adaptations been made to suit the South African context? Remember, if you need to make a change to your data collection instruments, (e.g. change a question), after your application has been approved, you will need to submit a request for an amendment. This also applies to any other change in your study, related to participants, data collection and/or related information. More information on amendments may be found here: https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H)/Amendment-to-a-Study

A11	**WRITTEN AND/OR ORAL INFORMATION GIVEN TO HUMAN SUBJECT ON RECRUITMENT (mandatory)**
	This is a **mandatory** appendix. It should consist of the information you plan to send to the participants to recruit them into the study. When performing in-person recruitment, this information should consist of a letter and/or an oral overview. When performing on-line recruitment, the information is normally a combination of an email, a letter and/or a social media post. When creating your recruitment information, consider the following: - Your process: How do you plan on performing the recruitment? For instance, will you send an email to participants in which the recruitment information is included as the body of the email or will the information be included as an attachment? If you are performing recruitment on social media; will you be using a brief initial statement to inform participants of the study and then have them click on an link with further information or will you be posting an entire letter's worth of information directly as a post (probably not the best approach)? - Use the official university letterhead and ensure that you check your grammar, possibly via a third-party or a software-based tool. What information should you include (at the very least): - WHAT the name of the study is and WHAT it's about. - WHY they are being considered for participation. - The ethics number of the study. - The PI and/or the PRP's contact details or, in some cases, the contact details of a research assistant. - WHO gave permission for them to be approached. - WHAT will be expected of them (e.g. to complete a questionnaire or be interviewed), WHERE it will take place, WHO will be involved, how much TIME will it take, and so on. - Foreseeable risks and benefits. - Any costs or remuneration involved for them. - What steps they should take to opt in to the study (e.g. should they click on a link or contact you via email) and what will happen next. - WHERE their data will go / be stored, WHO will see it / have access to it, WHAT it will be used for. - How long their data will be stored for. - That they can withdraw from the study at any stage. - The steps they need to take to withdraw from the study, and that their information/data will be destroyed as a result. - Recruitment information to participants and informed consent forms should always inform them that complaints or concerns can be expressed to the researcher, REC-H, then to NHREC, and then to SAHPRA. Make sure that all written or verbal communication with potential participants/participants should be at an appropriate reading level and easy to understand. Avoid academic jargon. Translate where appropriate. A lack of understanding will compromise the 'informed' part of the consenting process. You can create your own format.
A12	**WRITTEN AND/OR ORAL INFORMATION GIVEN TO VOLUNTEERS PRIOR TO PARTICIPATION, AT THE POINT OF ENROLMENT (mandatory)**
	This is a **mandatory** appendix. Once participants have indicated that they are willing to participate, the information in this appendix should be given to enrol them into the study. This information may take the form of a letter, an email, an online message, printed information or oral information. It could usually just be a copy of the recruitment letter. In some online studies, the recruitment and enrolment information is the same, i.e., a single initial email. Make sure to clearly label appendices accordingly.
A13	**INFORMED CONSENT FORM(S) (mandatory)**
	This is a **mandatory** appendix. Asking a gatekeeper for access to the participants is not enough. Each participant must also consent. The consent form might have been merged with the preamble to an online questionnaire / survey. Make this clear to the reviewers if this is the case in your study, otherwise they will look for the **mandatory** consent form, which wasn't included. You will need to consider WHEN to provide the consent form to participants (it should be clearly defined as part of your process) and HOW you will retrieve the consent forms from them (taking in printed copies or having them email it back). If email will be used will the consent form be included as the body of the email or will the information be included as an attachment? They need to be told that you need to make sure they understand that they have the right to agree (consent) or refuse to participate in the study. HOW and WHEN will this be handled? Remember that you cannot and must not 'require' them to do anything. Their participation is to help you, not them. Use the official university letterhead and ensure that your check your grammar, possibly via a third-party or a software-based tool.

	When writing the consent form content, remember: - To ask for permission to record interviews or focus group(s). - When performing interviews, assure the participants that you will preserve their anonymity by using pseudonyms. - When performing focus group interviews, notify the participants that you will attempt to preserve their anonymity by using pseudonyms, but that you cannot guarantee it as there will be other participants joining them in the focus group. - The PI and/or the PRP's contact details (or, in some cases, the contact details of a research assistant), the contact details of the REC-H (rd@mandela.ac.za), and the relevant regulatory authority should be included in the consent form. - IF applicable: ask for their permission to re-use data in a future study (as per 6(d)). - Provide areas for the participant and researcher to sign. The following is a university-provided template of a consent form: https://rd.mandela.ac.za/rcd/media/Store/documents/RecH/Information-and-Informed-Consent-Template.doc Note that this truly only a template in terms of the content generally required in a consent form. You need to adapt the template in terms of content and formatting. The template cannot simply be submitted as is. Before submission, remove the orange/brown block at the top of the template. You are not required to use this template, it is provided only to help researchers who do not already have their own preferred version of an informed consent form.
A14	**INFORMED ASSENT FORM(S) (if applicable)**
	Only required in the case of participants being minors. The following is a university-provided template of an assent form: https://rd.mandela.ac.za/rcd/media/Store/documents/RecH/Assent-Form-for-Child-Participants-Template.doc Note that this truly only a template, you will need to enter all of the information related to your study. The template cannot simply be submitted as is. You are not required to use this template, it is provided only to help researchers who do not already have their own preferred version of an assent form.
A15	**BUDGET FOR REIMBURSEMENT/ REMUNERATION/ INCENTIVES (if applicable)**
	If applicable, attach the required information to your application. Refer comments regarding remuneration above.