**APPLICATION FOR APPROVAL**

**LIFE HEALTHCARE HUMAN RESEARCH ETHICS COMMITTEE**

**SECTION A: Information Block**

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| **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 to conduct research at Life Healthcare facilities. Negligible/low risk studies are subject to expedited review by members of the of HREC and the Scientific Research Panel to temporarily serve as members of the Human Research Ethics Committee (HREC). Once the scientific merit of the proposal has been reviewed and approved by the HREC and Scientific Research Committee reviewers, the Scientific Committee will refer medium/high risk studies to HREC for ethical review and approval.**WHEN SHOULD THIS FORM BE HANDED IN?** This form must be completed by applicants applying for ethics approval and/or permission to conduct their research studies at Life Healthcare facilities. The completed form must be submitted together with the research proposal and all other relevant documents (See Table for list of documents to accompany this application on pg 11). **HOW TO COMPLETE THIS FORM:**1. Complete the Risk Assessment form for this study (pp 4 – 10).
2. Complete Section B (pg 11).
3. 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.“B Abrahams **HREC** Application Form.doc”).
4. 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 (pg 5). Complete the Supporting Documentation Included table (pg 11). Incorrect ordering of or missing appendices may result in a delay of the review and approval of the application.
5. **REMOVE THE INSTRUCTION BLOCK AND DEFINITION OF TERMS** (pp 1 – 3).
6. **Electronic copy (signed)**: Print the document, get each page initialled on the lower right-hand corner and add your signature at the end of the form. Electronic signatures could be inserted, and the document saved as a PDF document. OR
7. You could print the document, initial each page, and sign the document, scan in the signed hardcopy.
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**DEFINITION OF TERMS USED IN THE APPLICATION FORM**

1. “**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,

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

3. “**Study**” means the research project being conducted.

4. “**PI**” means primary investigator and is the person undertaking the study

5. “**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 to T HREC.**

6. “**Duration of data collection**” is the anticipated maximum period (in months) of the direct interaction with human participants 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 shall apply for an extension of the data collection procedure and submit such extension application to Research@lifehealthcare.co.za.

7. “**Umbrella research project**” means a broad research project under which several smaller research projects fall. Typically, an umbrella research project is one in which a number of individual researchers collaborate 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 researchers undertaking small research projects. In this case, individual researchers are not required to submit independent ethics applications for as long as the data collection procedures and instruments are significantly similar.

8. “**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.

9. “**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 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).

10. “**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).

11. “**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.

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

13. “**Data analysis**” refers to the collection of those methods/techniques used by researchers to analyse the data collected from human participants.

14. “**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 participants.

15. “**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 because of routine daily tasks.

16. “**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 because of routine daily tasks.

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

18. “**Incidental findings**” refers to any unexpected discovery made during 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.

19. “**Inclusion criteria**” refers to that set of characteristics that all participants must exhibit 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.

20. “**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.

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

22. “**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.

23. “**Institutional environment**” refers to institutions like hospitals, mental institutions, etc.

24. “**Power relationship**” refers to a situation where the PI 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.

25. “**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.

26. “**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.

27. “**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.

28. “**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 because of the current study is not classified as re-use of data.

29. “**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.

30. “**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 participant recruiter and/or gatekeeper and/or sponsor of the study.

31. APPENDIX 10 “**Synopsis**” refers to a 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**

**RISK ASSESSMENT FORM**

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 Department of Health Ethics Guidelines available on the Life Healthcare website and Gateway.

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| Criteria | No risk | Negligible to Low risk | Medium risk | High risk |
| ***1. Are the participants of your study*** |  |  | [ ]  Life Healthcare staff/patients?[ ]  in a dependency relationship with the PI?[ ]  to be compensated in any way (e.g. incentive, reimbursement for travel, etc.) for participating in the study? | [ ]  children under the age of 18?[ ]  a sample from an institution (e.g. hospital)?[ ]  handi-capped (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 or too ill)? |
| ***2. Are you administering any process and/or treatment that*** |  | [x]  is expected to result in no foreseeable risk, harm or discomfort to the mental and/or physical well-being of the participants?[ ]  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)? |  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?[ ]  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 research [ ]  collects any articles/documents of property, personal or cultural from participants?[ ]  may result in a traumatic experience for the participants and/or researcher?[ ]  may result in the disclosure of sensitive and/or embarrassing information about the participants and/or researcher?[ ]  involves covert observation of behaviour that is not normally in the public domain?[ ]  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)? | [x]  involves participants undergoing psychological, physiological or medical testing or treatment?[ ]  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?[ ]  could be hazardous to the physical health (e.g. possibly results in illness, injury, pain of 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?[ ]  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?[ ]  could result in the participant learning about a genetic possibility of developing an untreatable disease? |
| 3. ***Are you administering a questionnaire/survey/interview/ focus group/observation practices that*** |  | [ ]  occurs natural environments where the researcher does NOT interact directly with participants?[ ]  occurs in natural environments where the researcher does NOT stage any intervention?[ ]  occurs natural environments where the participants do NOT have a reasonable expectation of privacy?[ ]  occurs in natural environments and dissemination of research findings does NOT identify individual or groups of participants? | [ ]  collects sensitive data from the participants (e.g. personal data that is not normally in the public domain)?[ ]  does not guarantee the anonymity of the participant?[ ]  occurs in natural environments and dissemination of research findings does/ could identify individual or groups of participants?[ ]  occurs in natural environments where the researcher interacts directly with participants?[ ]  occurs in natural environments where the researcher stages an intervention?[ ]  occurs in natural environments where the participants have a reasonable expectation of privacy?[ ]  does not guarantee the confidentiality of data collected from the participants? |  |
| ***4. Are you intending to access participant data from an existing stored repository (e.g. institutional, or data collected from another previously completed or ongoing research study) that*** | [ ]  relies exclusively on publicly available information or accessible through legislation or regulation?[ ]  relies exclusively on secondary use of anonymous information (i.e. no identifiable information is generated or inferred)? | [ ]  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? |  |
| ***5. 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? |  |  |
| ***6. 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? [ ]  a local (e.g. regional, national) study? | [ ]  an international/cross border study?  [ ]  NOT for qualification purposes and also NOT exclusively for quality assurance and/or programme evaluation activities and/or performance reviews?  |  |
| ***7. Has the research methodology (if the study is not for qualification purposes) been reviewed for scientific rigour and approved by an appropriate research body?*** |  | Yes, Specify body:------------------------------- |  |  |
| ***8. Does any sponsor of the study/the researcher have a vested interest in any possible findings of the study?*** | [ ]  No |  | [ ]  Yes |  |
| ***9. Are there any restrictions/******conditions attached to the publication and/or presentation of the study results?*** | [ ]  No |  | [ ]  Yes |  |
| 10. Calculate columns | Number of selections in 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.*** | Number of selections in this column:\_\_\_\_\_\_\_\_***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***  | Number of selections in this column:\_\_\_\_\_\_\_\_\_ | Number of selections in this column:\_\_\_\_\_\_ |
| **No ethics application necessary**  | **Expedited Review: Review by HREC and Scientific Committee accredited and co-opted Scientific Research Committee reviewers (approval for noting at HREC)** | ***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 expedited* reviewers required to ensure proposal/research methodology approval followed by HREC** |

**SECTION B: To be completed by the Principal Investigator (PI)**

**Table 1: List of Documents to accompany the application**

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| **Please submit this form, with the following documentation, in one email to Research @lifehealthcare.co.za** |
| Risk assessment form | Information sheet to participants in the research |
| Abstract | Assent forms (if applicable) |
| Full research proposal | Consent form for participants  |
| Ethical clearance certificate from academic institution  | Data gathering and measuring instruments/tools |
| Letter to institution requesting permission (Gatekeeper permission for access)  | Recruitment information |

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| 1. **GENERAL INFORMATION**
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| **Particulars of Principle researcher** |
| Choose an item. | **First Name** |  | **Surname** |  |
| **Cell No** |  | **Email** |  |
| **Research study focus** | Choose an item. | **Other:**  |  |
| **Indicate reason for research study**  | Choose an item. |
| **If study is being conducted through a Higher Education Institution (HEI), indicate the qualification type** | Choose an item. |
| **Name of Higher Education Institution through which the research is being conducted** |  |
| **State the Title of the Research Study** |  |
| **Select the study Methodology** | Choose an item. | **Other: (please state)** |
| **Are you a permanent employee/student of Life Healthcare?** | Choose an item. |
| **If yes, in what capacity?** |  |
| **At which Life Healthcare institution are you employed / a student?** |  |
| **List the Life Healthcare Institutions where you wish to conduct your research:** |
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| **Nature of request** | Choose an item. |

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| 1. STUDY INFORMATION
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| **STUDY DETAILS** |
| 1. Scope of study: **Select an item**
 |
| 1. Funding : **Select an item**  Additional information (e.g. source of funds or how combined funding is split) **Type details 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): **Type response here or select “Not applicable”** |
| 1. Date of commencement of data collection: **Click here select a date** Anticipated date of completion of study: **Type duration here**
 |
| 1. Is this application related to any existing and currently active umbrella research project? Yes no NA

If yes, provide the ethics reference number of the related umbrella project. Type response here or not appliacble |
| 1. Objectives of the study (the major objective(s):
 |
| 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**
 |
| **METHODOLOGY** |
| 1. Briefly state the methodology (specifically the procedure in which human subjects will be participating) **1. Recruitment of process** (describe in detail the manner in which individual human participants will be identified and approached for inclusion in the study); **2. sampling strategy** (Provide a detailed motivation as to how the minimum and maximum sample sizes provided are determined); **3. enrolment process** (describe in detail 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); **4. Data collection process** (describe in detail the procedure to be followed while collecting data for participants. All data collection instruments are to be included as addendums); **5. Data analysis** (Provide details on the technique/s to be applied to analyse the collected data**); 6. Data reporting** (Provide details on the technique/s to be applied in order to report on Findings)
 |
| 1. State the minimum and maximum number of participants involved and category of staff **Type number of participants and categories of staff**
 |
| 1. List any ethics training acquired by PI in last three years: Type response here or select not applicable
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| 1. RISKS AND BENEFITS OF THIS STUDY
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| 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.

If NO, please specify what measures will be taken to address the deficiency experience:**Type response here or select “Not applicable”**  |
| 1. Has the person administering the project previous experience with the particular risk factors involved? **Select an item** If YES, please specify: **Type response here or select “Not applicable”**
 |
| 1. Are any benefits expected to accrue to the participant (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. Will you be using equipment of any sort e.g. BP machine? **Select an item** If YES, please specify: **Type response here or select “Not applicable”**
 |
| 1. Will any article of property, personal or cultural e.g. patient records, be collected in the course of the project? **Select an item** If YES, please specify: **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 risk of harm, however slight or temporary, to the researcher while conducting the data collection exercise? Select an item YES NO Not applicable

If YES, state each risk and for each risk state i) whether the risk is reversable, ii) whether there are alternative procedures available and iii) whether there are remedial measures available? Type response here or select Nota applicable |
| 1. Is any insurance available for research related injuries for participants and/or researchers? Select an item YES NO NOT APPLICABLE

If YES, please specify what measures will be taken to address the deficiency in availability of insurance: Typ response here or select NOT APPLICABLE |

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| 1. TARGET PARTICIPANT GROUP
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| a) According to your knowledge has the chosen participant group participated in any previously approved research? Select and item YES NO If YES, briefy describe the study, indicate when it was conducted (YEAR) and include reference to the work/ethics clearance number: Type response her or select NOT APPLICABLE |
| b) Inclusion criteria: describe characteristics that are required to be present in participants in the target group (e.g. age, cultural derivation, background, physical characteristics, disease status etc.) Type response here or select not applicable |
| c) Exclusion criteria: describe particular characteristics (not listed in 4b above) that will automatically exclude volunteers from participation (e.g. particular age, cultural derivation, background, physical characteristic, disease status) please specify:: **Type response here or select “Not applicable”** |
| d) Are participants drawn from Life Healthcare staff? **Select an item** |
| f) If participants are drawn from specific groups of Life Healthcare staff, please specify: **Type response here or select “Not applicable”** |
| g) Are participants drawn from a vulnerable group? **Select an item** If YES, please specify how these participants be managed: **Type response here or select “Not applicable”** |
| h) If participants are drawn from an institutional population (e.g. acute, mental health, rehabilitation, oncology, occupational health), please specify: **Type response here or select “Not applicable”** |
| i) If any records will be consulted for information, please specify the source of records: **Type response here or select “Not applicable”**  |
| j) 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”**  |
| k) Are all participants over 18 years of age? **Select an item** If NO, state justification for inclusion of minors in study: **Type response here or select “Not applicable”** |

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| 1. CONSENT OF PARTICIPANTS
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| 1. Is consent to be given in writing? **Select an item** If YES, include the consent form with this application [Appendix 2]. If NO, state reasons why written consent is not appropriate in this study. **Type response here or select “Not applicable”**
 |
| 1. Assent (if any participant is younger that 18 years of age): is assent to be given in writing? Select an item **YES NOT NOT APPLICABLE**

If Yes, include the assent form with this application. 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. Are any participants subject to legal restrictions preventing them from giving effective informed consent? **Select an item YES NO NOT APPLICABLE**

If YES, please justify: **Type a 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 and item YES NO NOT APPLICABLE**

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, which may cast doubt on the voluntary aspect of consent? **Select an item YES NO NOT APPLICABLE**

If YES, state what special precautions will be taken to obtain effective informed consent: **Type response here or select NOT APPLICABLE**  |
| 1. Will participants receive remuneration for their participation? **Select an item** If YES, justify and state on what basis the remuneration is calculated, and how the veracity of the information can be guaranteed. **Type response here or select “Not applicable”**
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| 1. Which gatekeeper will be approached for initial permission to gain access to the target group? (e.g. principal, nursing manager, hospital manager) **Type response here or select “Not applicable”**
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| 1. Do you require consent of an institutional authority for this study? (e.g. Department of Education, Department of Health) **Select an item**  If YES, specify: **Type response here or select “Not applicable”**
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| 1. INFORMATION TO PARTICIPANTS
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| 1. What information will be offered to the participant before he/she consents to participate? (Attach written information)
 |
| 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 wne he/she consents to participate)? (Attach written information given and any oral information given as addendums) **Type response here or select not applicable**
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| 1. PRIVACY, ANONYMITY AND CONFIDENTIALITY OF DATA
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| 1. Will the participant be identified by name in your research? **Select an item**  If YES, justify: **Type response here or select “Not applicable”**
 |
| 1. Are provisions made to protect participant’s rights to privacy and anonymity 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. If mechanical methods of observation 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 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 participant’s anonymity be protected? **Type response here or select “Not applicable”**

**\*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? **Select an item**

If YES, how will participant’s consent be obtained for such re-usage? **Type response here or select “Not applicable”**  |
| 1. Are there any contractual secrecy or confidentiality constraints on this data? **Select an item**  If YES, specify: **Type response here or select “Not applicable”**
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| 1. FEEDBACK
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| 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’ feedback: **Type your response here or select NOT APPLICABLE** |
| 1. If you are working in a school or other institutional setting, will you be providing the relevant authorities a copy of your results? **Select an item** If YES, specify, if NO, motivate: **Type response here or select “Not applicable”**
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| 1. ETHICAL AND LEGAL ASPECTS
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| a) I will ensure Life Healthcare is protected ethically and legally by ensuring the following considerations when conducting the study at its facilities: **Type response here** |
| 1. I would like the REC to take note of the following additional information: **Type response here or select “None”**
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| 1. DECLARATION
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| If any changes are made to the above arrangements or procedures, I will bring these to the attention of the Research and Ethics Committee. I have read, understood and will comply with the *Ethics in Health Research: Principles, Processes and Structures* and have taken cognisance of the availability of the publication (on-line) [www.nhrec.org.za](http://www.nhrec.org.za)I have read and understood the **Life Healthcare** **Standard Operating Guideline** *for application to conduct research*.All participants are aware of any potential health hazards or risks associated with this study.[ ]  **I have read and agree with the condition as stated above**.  |
|  **Type name here** (Primary Investigator) Date |