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**ASSESSMENT OF RISK FOR A STUDY**

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|  | Select the box next to any statement that is relevant to your study. This will assist you in determining the path for review as well as sensitise you to the content to be addressed in your application. It is assumed that you are familiar with the DoH Ethics Guidelines available on the REC-H portal. If there is any ⌧ in any of 3 rightmost columns, application for Ethics Review is a requirement. The Application Form (RECH-001) requires a similar Risk Assessment measure. This Risk Assessment Form is for your personal use and is not required to be submitted for review. | | | |
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|  | No risk | Negligible to Low risk | Medium risk | High risk |
| ***Are the subjects/participants of your study*** |  |  | staff/students from Nelson Mandela University and/or other institutions? | children under the age of 18? |
|  |  | in a dependency relationship with the PI and/or PRP? | a sample from an institution (e.g. hospital)? |
|  |  | to be compensated in any way (e.g. incentive, reimbursement for travel, etc.) for participating in the study? | handicapped (e.g. mentally or physically) persons? |
|  |  |  | socially and/or economically disadvantaged persons? |
|  |  |  | persons of diminished physical and/or mental and/or educational capacity (e.g. traumatised)? |
|  |  |  | elderly? |
|  |  |  | persons who are not competent to give participation consent (e.g. due to language challenges)? |
| ***Are you administering any process and/or treatment that*** |  | is expected to result in no foreseeable risk, harm or discomfort to the mental and/or physical well-being of the participants? |  could be hazardous to the social well-being (e.g. possibly results in damage to social networks/relationships with others, discrimination, social stigmatisation, discovery of previously unknown paternity status) and/or result in discomfort associated with the social well-being of the participants and/or researcher? | involves participants undergoing psychological, physiological or medical testing or treatment? |
|  | is expected to result in the only foreseeable discomfort being that of inconvenience (e.g. time and effort required by participants to complete questionnaire/form, participate in a street survey)? | could be hazardous to the economic well-being (e.g. possibly results in the imposition of direct and/or indirect financial commitments on participants) and/or result in discomfort associated with the economic well-being of the participants and/or researcher? | involves the collection and use of human biological samples (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath? |
|  |  | collects any articles/documents of property, personal or cultural from participants? | could be hazardous to the physical health (e.g. possibly results in illness, injury, pain) of the participants and/or researcher? |
|  |  | may result in a traumatic experience for the participants and/or researcher? | could be hazardous to the psychological well-being (e.g. possibly results in feelings of worthlessness, guilt, anger, fear) of the participants and/or researcher? |
|  |  | may result in the disclosure of sensitive and/or embarrassing information about the participants and/or researcher? | could be hazardous to the legal well-being (e.g. possibly results in the discovery and prosecution of criminal activity) of the participants and/or researcher? |
|  |  | involves covert observation of behaviour that is not normally in the public domain? | could result in the participant learning about a genetic possibility of developing an untreatable disease? |
| ***Are you administering any process and/or treatment that***  ***Are you administering any process and/or treatment that*** |  |  | could result in the participants feeling humiliated, manipulated and/or in other ways treated disrespectfully and/or unjustly? |  |
|  |  | uses specialised equipment on the participants? |  |
|  |  | could result in discomfort associated to the physical health (e.g. the act of measuring blood pressure, minor side effects of taking medication) of the participants and/or researcher? |  |
|  |  | could result in discomfort associated with the psychological well-being (e.g. feelings of anxiety due to being interviewed) of the participants and/or researcher? |  |
|  |  | could result in discomfort associated with the legal well-being of the participants and/or researcher? |  |
|  |  | could result in the identification and/or re-identification of a participant from a resulting report? |  |
|  |  | could result in risks to non-participants (e.g. distress to relatives upon discovering that a participant suffers from a serious genetic disorder, infectious disease risks to a community, social/economic discrimination of subgroup populations)? |  |
| ***Are you administering a questionnaire/survey/interview/ focus group/observation practices that*** |  | occurs in public spaces and natural environments where the researcher does NOT interact directly with participants? | collects sensitive data from the participants (e.g. personal data that is not normally in the public domain)? |  |
|  | occurs in public spaces and natural environments where the researcher does NOT stage any intervention? | does not guarantee the anonymity of the participant? |  |
|  | occurs in public spaces and natural environments where the participants do NOT have a reasonable expectation of privacy? |  occurs in public spaces and natural environments and dissemination of research findings does could identify individual or groups of participants? |  |
|  | occurs in public spaces and natural environments and dissemination of research findings does NOT identify individual or groups of participants? | occurs in public spaces and natural environments where the researcher interacts directly with participants? |  |
|  |  | occurs in public spaces and natural environments where the researcher stages an intervention? |  |
|  |  | occurs in public spaces and natural environments where the participants have a reasonable expectation of privacy? |  |
|  |  | does not guarantee the confidentiality of data collected from the participants? |  |

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| ***Are you intending to access participant data from an existing stored repository (e.g. school, institutional, university records or data collected from another previously completed or ongoing research study) that*** | relies exclusively on publicly available information or accessible through legislation or regulation? | requires access to participant information (in non-identifiable form, e.g. summarised form) as part of an existing published or unpublished source or database? | requires access to participant information (in individually identifiable or re-identifiable form) as part of an existing published or unpublished source or database? |  |
| relies exclusively on secondary use of anonymous information (i.e. no identifiable information is generated or inferred)? |  |  |  |
| ***Do you intend publishing the findings of your study in a publication that*** | requires no evidence of human ethics approval/acknowledgement? | requires evidence of human ethics approval/acknowledgement? |  |  |
| ***Is this study*** | exclusively for quality assurance and/or quality improvement studies (audits) and/or programme evaluation activities and/or performance reviews? |  for qualification purposes at Nelson Mandela University?  | an international/cross border study? |  |
|  | a local (e.g. regional, national) study? |  |  |
| ***Has the research methodology (if the study is not for qualification purposes) been reviewed for scientific rigour and approved by an appropriate research body at Nelson Mandela University?*** |  | Yes. Specify body:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | No |  |
| ***Does any sponsor of the study/the researcher have a vested interest in any possible findings of the study?*** | No |  | Yes |  |
| ***Are there any restrictions/conditions attached to the publication and/or presentation of the study results?*** | No |  | Yes |  |

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|  | Number of selections  in this column: \_\_\_\_\_\_ | Number of selections  in this column: \_\_\_\_\_\_ | Number of selections  in this column: \_\_\_\_\_\_ | 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.*** | ***If number of selections in in this column is more than 0 and there are no selections in any of Medium and High risk columns, then the application would qualify for an expedited review*** | ***If the sum of the number of selections in Medium and High risk columns is more than 0, irrespective of whether selections appear in other columns, then the application would require full review after the proposal has been approved by the Faculty*** | |
|  | **No ethics application necessary** | **Expedited Review: Faculty level review by accredited and co-opted Faculty reviewers (approval for noting at REC-H)** | **Faculty review required to ensure proposal/research methodology approval followed by Central REC-H review** | |