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**EVALUATION FORM TO EVALUATE WHETHER THE STUDY QUALIFIES AS A LARGER STUDY**

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| # | **Criteria for evaluation** | **Yes** | **No** | **If no, please comment** |
| 1 | Is there an approved and detailed original proposal available? |  |  |  |
| 1.1 | Is there a clear and well-defined problem statement indicating the gap that this research is filling and motivating the larger study? |  |  |  |
| 1.2 | Are there clear aims/objectives for the study? |  |  |  |
| 1.3 | Is the methodology well-defined? |  |  |  |
| 1.4 | Is there a clearly stated research design? |  |  |  |
| 1.5 | Has sampling been clearly described (type and process)? |  |  |  |
| 1.6 | Are there clear inclusion and exclusion criteria? |  |  |  |
| 1.7 | Has the recruitment process been described? |  |  |  |
| 1.8 | Has the informed consent process been clearly described? |  |  |  |
| 1.9 | Does the informed consent form comply with the latest requirements? (See checklist for informed consent) |  |  |  |
| 1.10 | Is it clear how the research team and fieldworkers were trained? |  |  |  |
| 1.11 | Has the method/s and process of data gathering clearly been described? |  |  |  |
| 1.12 | Is data analysis clearly described and appropriate (statistical consultation if applicable)? |  |  |  |
| 1.13 | Are the ethical aspects of the project described in the proposal? * When and from whom ethical approval was obtained
* Anticipated risks and precautions
* Benefits
* Privacy and confidentiality throughout the research process
* Anonymity and respect
* Justice (fair recruitment and burden evenly distributed)
* Management of vulnerability
 |  |  |  |
| 2 | Is there a clearly identified project leader/principle investigator? |  |  |  |
| 3 | Has the research team been well described? |  |  |  |
| 4 | Are you still within the ethics approval time frame?  |  |  |  |
| 5 | Has the title been registered? |  |  |  |
| 6 | Is there valid informed consent documentation available at the appropriate language level? If necessary is there translated informed consent forms available? |  |  |  |
| 7 | Is the required supplementary information such as questions, interview schedules and/or questionnaires available? |  |  |  |
| 8 | If applicable is the advertisement available? |  |  |  |
| 9 | Are the necessary contracts available (e.g. collaborators, sponsors)? |  |  |  |
| 10 | Are confidentiality agreements available (e.g. fieldworkers, transcribers)? |  |  |  |
| 11 | Is proof of authority/power of attorney of signatories to agreements available? (If applicable) |  |  |  |
| 12 | Is the process of data storage fully described? |  |  |  |
| 13 | Is the process of research monitoring clearly described? |  |  |  |
| 14 | Is it clearly stated how results will be made known? |  |  |  |
| 15 | Is there a budget available? |  |  |  |
| 16 | **Is there a clear outline of how many possible Masters and Doctoral sub-studies can be accommodated within the project and specifically what each student will be doing?** |  |  |  |
| 17 | Are there any other current sub-studies running under the larger project? |  |  | How many?Indicate the names of the running sub-studies and the students involved. |
| 18 | Were there any amendments made to the project? |  |  | If yes:How many?When?**Please attach the approval by the HREC** |
| 19 | Were there any extensions granted for the project? |  |  | If yes:Until when?**Please attach the approval by the HREC** |
| **Final comments by the project leader:** |
| **Recommendation by the reviewers** | **Yes** | **No** | **If yes, please comment** |
| Qualifies as a larger study and can continue |  |  |  |
| Continuation as a larger study with revision |  |  |  |
| Discontinue |  |  |  |
| Name of reviewer 1 | Signature of reviewer 1 | Date |
|  |  |  |
| Name of reviewer 2 | Signature of reviewer 2 | Date |
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