**<<RESEARCH PROJECT DETAILS >>**

**PROMs Considerations**

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| **Component** | **Comments** |
| What is the aim of the research project? |  |
| Is it appropriate to include a PROM as a primary or secondary outcome? |  |
| If a PROM is to be used as a primary outcome, what information is required to calculate the sample size? |  |
| Is there an existing PROM to measure the specified outcome?  |  |
| If there is an existing PROM has it been appropriately validated according to COSMIN criteria? |  |
| If there is an existing PROM are there any outstanding measurement issues to be resolved? |  |
| What method(s) of data collection are being proposed for the PROMs data collection?* Questionnaire
* Structured interview

Has the PROM been appropriately validated for the proposed method? |  |
| What medium(s) of data collection are being proposed for the PROMs data collection?* Face-to-face
* Postal questionnaire
* Telephone administration
* Computer/web-based administration
* Phone/tablet app

Has the PROM been appropriately validated for the proposed medium? |  |
| Will there be any proxy administration?* Parents
* Relatives
* Professionals

If so has the PROM been appropriately validated for proxy administration?Will proxy administration be undertaken instead of or in addition to self-administration? |  |
| Are there any costs associated with using the PROM? If so how much is this likely to be? |  |
| Are there any other licensing/copyright issues that need to be considered before using the PROM? |  |
| Are there any cultural or language issues that need to be considered (e.g. Welsh language and other non-English languages)? Has the PROM undergone the appropriate cross-cultural validation? |  |
| Will any of the participants be vulnerable groups (e.g. children)? Has the PROM been appropriately validated for this population? |  |
| If any PROMs are included in the study, are they to be used for the economic analysis as well e.g. the EQ-5D is a useful measure of health-related quality of life in itself, but can also be used for the calculation of QALYs  |  |
| Please provide details of the PROM and any proxy to be used with the reference to the original reference or website. |  |