**Checklist to determine if a QA / QI study requires DSRB review (Version 30 June 2020)**

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| Where the response to all these questions is “No”, the QA/QI study is unlikely to require an IRB review. If you require a formal IRB letter of waiver from review, fill in and submit the DSRB exempt application form for review.  Where the response to any of these questions is “Yes”, the QA / QI study may need an IRB review. Fill in the appropriate application form on ROAM and submit for DSRB review. | | | |
| **S/N** | **Questions** | **Yes** | **No** |
| 1. | Does the proposed quality assurance activity require additional consent from subjects, beyond what is already obtained for clinical practice? |  |  |
| 2. | Does the proposed quality assurance activity pose any risks for subjects beyond those of their routine care? |  |  |
| 3. | Does the proposed quality assurance activity impose a burden on subjects beyond that experienced in their routine care? |  |  |
| 4. | Is the proposed quality assurance activity to be conducted by a person who does not normally have access to the subjects’ records for clinical care? |  |  |
| 5. | Does the proposed quality assurance activity risk breaching the confidentiality of any individuals’ personal information, beyond that experienced in the provision of routine care? |  |  |
| 6. | Does the proposed quality assurance activity involve any clinically significant departure from the routine clinical care provided to the subjects? |  |  |
| 7. | Does the proposed quality assurance activity involve randomization? |  |  |
| 8. | Does the proposed quality assurance activity involve the use of a control group or a placebo? |  |  |
| 9. | Does the proposed quality assurance activity seek to gather information about the participant beyond that collected in routine clinical care? |  |  |
| 10. | Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of health care providers or the institution(s)? |  |  |

For enquiries, please write to ohrpp@nhg.com.sg