Quality Improvement or Research Worksheet

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SEQ	Issue and Guidance	Rating
1	Are patients randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? *Randomization done to achieve equitable allocation of a scarce resource need not be considered and would not result in a "yes" here.*	☐ Yes ☐ No
2	Does the project seek to test issues that are beyond current science and experience, such as new treatments (*i.e.*, is there much controversy about whether the intervention will be beneficial to actual patients – or is it designed simply to move existing evidence into practice?). *If the project is performed to implement existing knowledge to improve care – rather than to develop new knowledge – answer "no". If the project includes a manipulation of the subject or subject's environment for research purposes, then answer "yes".*	☐ Yes ☐ No
3	Are researchers who have no ongoing commitment to improvement of the local care situation (and who may well have conflicts of interest with the patients involved) involved in key project roles? *Generally answer "yes" even if others on the team do have professional commitments. However, where the project leaders with no clinical commitment are unaffiliated with the project site, it may be that the project site is not engaged – and does not require IRB approval/oversight – even if the project leaders' roles do require IRB oversight at their institutions.*	☐ Yes ☐ No
4	Is the protocol fixed with a fixed goal, methodology, population, and time period? *If frequent adjustments are made in the intervention, the measurement, and even the goal over time as experience accumulates, the answer is more likely "no."*	☐ Yes ☐ No
5	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? *Answer "yes" especially if feedback is delayed or altered in order to avoid biasing the interpretation of data.*	☐ Yes ☐ No
6	Is the project funded by an outside organization with a commercial interest in the use of the results? Is the sponsor a manufacturer with an interest in the outcome of the project relevant to its products? Is it a non-profit foundation that typically funds research, or internal research accounts? *If the project is funded by third-party payors through clinical reimbursement incentives, or through internal clinical/operations funds vs. research funds, the answer to this question is more likely to be "no."*	☐ Yes ☐ No

Adapted from Baily MA, et al., The Ethics of Using QI Methods to Improve Health Care Quality and Safety (2006). See also OHRP Quality Improvement Frequently Asked Questions: http://www.hhs.gov/ohrp/qualityfaq.html (last accessed June 22, 2009).

If the weight of the answers tends toward "yes" overall, the project should be considered "research" and approved by an IRB prior to implementation. If the weight of the answers tends toward "no," the project probably is not "research" and is not subject to IRB oversight unless local institutional policies differ. Answering "yes" to sequence #1 or #2 – even if all other answers are "no" – typically will result in a finding that the project constitutes research.

Note: It is important to consult with your local IRB if you are unsure how they would handle a particular case, as the analysis of the above issues cannot always be entirely objective and IRB policies and approaches vary significantly.