# **The Union University Institutional Review Board**

# **Quality Improvement or Research Checklist for DNP Projects\***

In general, a quality improvement (QI) project does not require IRB review and approval because it is not research that is subject to the federal human subject’s protection regulations. The following questions may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects research. **If all of the questions below can be answered as a Yes, IRB exempt review status will be granted.** If the answer to any of these questions is NO, please consult with the IRB for assistance since IRB review may be required. Consult this link for additional FAQs <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

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| Project Description | YES | NO |
| **Purpose**  Is the activity intended to be expeditiously implemented and improve the process/delivery of care while decreasing inefficiencies within a specific health care setting? |  |  |
| **Scope**  Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge? |  |  |
| **Evidence**  Is there sufficient existing evidence to support implementing this activity to create practice change? |  |  |
| **Clinicians/Staff**  Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place? |  |  |
| **Methods**  Are the methods for the activity flexible (not fixed) and include approaches to evaluate rapid and incremental changes? |  |  |
| **Sample/Population**  Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place? |  |  |
| **Consent**  Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care? |  |  |
| **Benefits**  Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project? |  |  |
| **Risk**  Is the risk to patients/participants no greater than what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment? |  |  |
| **Funding**  Is project generally not externally funded. |  |  |
| **Publication/Presentation**  The intent is to utilize results locally, however, QI practitioners/researchers may opt to share systematic reporting of insights. Note: QI projects should not be referred to as research in publications and presentations. |  |  |

# *\*Adapted with permission from Duke University IRB, May 2021*