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| QI/QA Project Participant Contact Information |
| Name and Credentials:  Relationship with FNU:  Address:  Phone number:  FNU Email address:  FNU Faculty member(s) involved in project design and approval:  *Please attach a PDF copy of your NIH or CITI Human Subjects Training* |
| Project Site Information |
| Organization/Site Name:  Address:  Phone number:  Site Contact Person and Title  Site Contact person’s email address: |
| QI/QA Project Description  (Please provide a brief description of your project. Address the overall purpose, site/setting, population, and your role in the project QI/QA activities. ) |
| Project title:  Purpose/Aim:  Site/Setting:  Population:    Applicants role in the project activities: |
| **\*\*\*\*Before continuing with this document go to this link to access information about QI projects:** [**Quality Improvement Frequently Asked Questions**](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/) **then continue with this document.**  **\*Review this resource for additional Information (Quality Improvement or Research) \***  Children’s Hospital of Philadelphia (2015). Quality improvement vs. research. Retrieved  from <https://irb.research.chop.edu/quality-improvement-vs-research>.  **Determination of Research Activity**  The definition of “Research” as defined by the Department of Health and Human Services (DHHS) regulations: **“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”** 45 CFR 46.102 (d)  **To be considered a “systematic investigation”,** the concept of a research project must meet ALL of the following: *\*\*\*A systematic investigation may be described as an activity planned in advance and many non-research activities include systematic investigation)\*\*\**   * Attempt to answer research questions (in some research, this would be a hypothesis). * Is methodologically driven, that is, it collects data or information in an organized and consistent way. * The data or information is analyzed in some way, be it quantitative or qualitative data. * Conclusions are drawn from the results.   **“Generalizable Knowledge”** would include one or more of the following concepts:   * The knowledge contributes to a theoretical framework of an established body of knowledge. * The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study. * Publication, presentation or other distribution of the results is intended to inform the field of study. * The results are expected to be generalized to a larger population beyond the site of data collection. * The results are intended to be replicated in other settings. * Web based publication for professional purposes.   + *Publication and presentation are typical methods used to disseminate research findings, thereby contributing to “generalizable knowledge”. However, not all information that is published or presented represents generalizable knowledge.*   A **"human subject"** means a living individual about whom an investigator (whether professional or student) conducting **research** obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. |
| Is the activity a **systematic investigation** designed to develop or contribute to **generalizable knowledge**? Yes No  Does the **Research** involve Human Subjects? Yes No  A “**Yes”** to either of these questions indicates that you may need to complete the **FNU IRB application.** Complete the remainder of this questionnaire to assist in determining if your project includes **Research Activities.** |
| 1. Funding: Is the project supported by Federal funds? Yes No   **If yes, contact the FNU IRB for additional guidance.** |
| 1. Is your project designed to develop new knowledge or validate new treatments?   Yes No |
| 1. Do activities directly benefit a process, system or program; This activity might or might not benefit patients? (i.e., may include improving quality of care, patient satisfaction, cost of care, or clinical processes) Yes No |
| 1. If an intervention is used will there be random assignment to participants OR will the participants be randomly assigned to different interventions for comparison?   Yes No |
| 1. Are the risks from an intervention to participants greater than minimal?   Yes No |
| 1. Does the project involve a new, innovative intervention that has not been tested in other settings or that has a lack of published evidence demonstrating its benefit?   Yes No |
| 1. Does the practice site have plans to discontinue the QI/QA project after your involvement ends despite demonstration of benefit? Yes No |
| 1. Are the project activities fixed with a rigid goal, methodology, and unchangeable despite feedback regarding the impact on quality of care, patient satisfaction, cost of care, or clinical processes?   Yes No |
| 1. Are project activities being implemented as part of the routine clinical care or standard practices provided to the patient population, or routine care and standard practices related to a process, system or program at the project site?   Yes No |
| 1. Do you certify that all of the information provided in this application accurately describes the QI/QA project you would like to complete? Yes No |

**Resources**

Baily, M.A., Bottrell, M., Lynn, J., & Jennings. (2006). The ethics of using QI methods to improve health care quality and safety (Special Report). The Hastings Center. Retrieved from http://www.thehastingscenter.org/Research/Archive.aspx?id=1220

Children’s Hospital of Philadelphia (2015). Quality improvement vs. research. Retrieved from <https://irb.research.chop.edu/quality-improvement-vs-research>

Szanton, S.L., Taylot, H.A., Terhaar, M. (2013). Development of an institutional review board preapproval process for Doctor of Nursing Practice students: Process and outcome. *Journal of Nursing Education, 52*(1), 51-55.

U.S. Department of Health & Human Services (HHS) (2016). Quality Improvement FAQ’s. *Office from Human Research Protections (OHRP)*. Retrieved from <http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html>

U.S. Department of Health & Human Services (HHS) (2016, February). Human Subject Regulations Decision Charts. Retrieved from <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>