Appendix 1

**Checklist for Determining Research vs. Other Activities**

**Title of Project:**

**Project Lead:       Department/Unit:       Manager/Executive Sponsor:**

**Manager/Sponsor e-mail:**

**This table is intended to compare and contrast the general characteristics of quality improvement (QI) / evidence-based practice (EBP) and research activities\***

**For each item, choose the** description of each attribute as it most likely relates to your project. **Please forward the completed, signed checklist of your project to** MCRI@mchs.com

|  |  |  |
| --- | --- | --- |
| **Attribute** | **Quality Improvement or Evidence-Based Practice** | **Clinical Research with Human Subjects**  |
|  |
| **Goal/Purpose** | [ ]  Improve healthcare or other processes/care in local settings with limited application beyond local context | [ ]  Generate new knowledge applicable to other populations |
|  | [ ]  Change processes or interventions based on an established body of applicable scientific evidence, professional guidelines or standards, or internal performance data (for operational changes) | [ ]  Test new interventions or ideas which are based on scientific theories or hypotheses but not yet supported in the scientific literature. Addresses a specific deficit in knowledge identified from the peer-reviewed literature. |
| **Describe the goal / purpose of the project or activity. Your description should give direct support to the box(es) you checked.**  |
| **Methods** | [ ]  Established QI models and methodologies including Continuous Quality Improvement, Plan-Do-Study-Act, Six Sigma, Lean, etc.  | [ ]  Theoretical model guides research design and analysis |
|  | [ ]  Established EPB model(s) are utilized, such as the Iowa Model, Stetler Model, ARCC, Ace Star Model, Johns Hopkins EBP Model | [ ]  Uses qualitative and quantitative methods to make observations and comparisons between groups to answer the study hypothesis or question |
|  | [ ]  Mechanisms of the intervention may change over time in response to ongoing feedback; adjustments may be made to refine the process as project progresses | [ ]  Prior to the start of the project, a written protocol specifies the intervention and/or interaction with participants, and/or **use of existing data and/or tissues**. The project may rely on randomization to enhance confidence in results. Changes are limited. |
|  | [ ]  The performance of healthcare, department or educational processes over time is evaluated with statistical process control or other methods | [ ]  Statistical methods primarily focus on individuals (e.g., patients, colleagues, students) as the unit of analysis. There may be adjustment of results based on relevant individual characteristics (e.g., age, co-morbidities). |
| **Describe the steps taken to carry out the project or activity. Your description should give direct support to the box(es) you checked.** |
| **Included Participants** | [ ]  All individuals in a specific setting; power analysis not applicable  | [ ]  Specific subjects meeting inclusion/exclusion criteria; generally requires a power analysis to establish the number of subjects needed; may use control groups |
| **Describe who is participating in the project, or, whose data is being used for the project.** |
| **Risks or Unintended Consequences** | [ ]  No added risks to participants; goal is quality, safety, operational improvement and/or risk reduction based on established best practices | [ ]  Participants may be exposed to risks or experience consequences beyond those encountered in everyday life, with their consent |
| **If your project involves interactions with people (e.g., patients, students, colleagues), will those participants be doing anything different from what they would normally be doing if the project did not take place? If yes, describe.** |
| **Intended Impact**  | [ ]  Improvements are immediately applicable to local setting; benefits to participants are expected as part of the process | [ ]  Direct benefit to individual participants or to the institution is not typically the intent or is not certain |
| [ ]  Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost) | [ ]  There may be a potential societal benefit in developing new generalizable knowledge |
| **Applicability of Results** | [ ]  Dissemination is primarily local; may be reported outside organization if data protections are in place and with appropriate organizational approval | [ ]  Primary goal is to disseminate the findings at research conferences and in peer-reviewed journals |
| [ ]  Implementation is immediate with review of results occurring throughout the process and potentially used for next QI or EBP activity | [ ]  Results are intended to generalize beyond the institution  |
| **How will the results or information obtained from your project be used? Where or to whom will the results of your project be reported?** |

***Note:*** *I****f a publication is anticipated, consider the journal requirements regarding IRB reviews/determinations. IRB reviews cannot occur after data collection. Any IRB review must be prospective, that is, BEFORE any data collection work commences.***

**Explanation and Elaboration of Terms**

1. **Quality Improvement**: The combined and unceasing efforts of everyone – health care professionals, patients and their families, researchers, administrators, payers, planners, educators – to make changes that will lead to better outcomes, system performance, and professional development.
2. **Evidence-Based Practice**: A process by which the best scientific evidence is combined with patient preferences/values and clinician expertise to achieve optimal health outcomes. EBP is often used to drive redesigns or changes in patient care processes. EBP projects are often QI projects where improvements in care quality are the primary goal.
3. **Research**: A systematic investigation designed to develop or contribute to generalizable knowledge (the Federal Policy for the Protection of Human Subjects or "Common Rule" definition of research). If an activity such as public health practice, program evaluation, or quality improvement includes a research component, then IRB review must occur under current federal guidance and MCHS IRB policies.

Decisions on whether a project constitutes research is based on the description provided at the time of review.  **If updates are planned** that alter the intent, objectives, or interactions with participants, or if any other proposed modification significantly affects the nature or conduct of the project, the project lead must **submit a revised project description, using this checklist form, for re-review by the Mount Carmel Research Institute prior to implementation.**

**Person Completing Checklist:
 *Print Name Signature Date***

***Completed Checklist Reviewed by: Mount Carmel Research Institute Representative***

***Please forward the completed signed, checklist*** MCRI@mchs.com.

\*Adapted from a publication entitled: An Instrument to Differentiate between Clinical Research and Quality Improvement; Ogrinc, Greg, William A. Nelson, Susan M. Adams and Ann E. O'Hara; IRB Ethics & Human Research; September – October 2013; Vol 35, Number 5. / *Version 082814: Issued and adapted by SJMHS Ann Arbor IRB Office (734-712-5470) D. Wahlberg* Revised 09/30/14: Issued and adapted by MCHS IRB Office 9/22/16; revised 1/8/19; revised 11/2020