Determining the Difference between Clinical Research and Quality/Performance Improvement at Memorial University Medical Center

A short questionnaire to identify the appropriate process to follow when beginning a scholarly activity

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Let's Get Started…..

This ART is a requirement of all investigators, residents, faculty and others conducting PI/QI activities or research at Memorial University Medical Center. It is intended to: (1) provide a framework for distinguishing QI/PI activities and research projects; (2) provide the process pathway required for each of those; and (3) provide a list of resources available to expedite projects.

The general characteristics of quality/performance improvement and clinical research activities are for use by the Institutional Review Board, administrative reviewers, investigators, and improvers are reviewed here.

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Explanation and Elaboration of Terms

1. **Vulnerable Population**. Any study population that includes students, employees, children, pregnant women, prisoners, active military personnel, individuals who have impaired decision making capacity, or those who are educationally or economically disadvantaged.
2. **Intent**. The state of the investigator's mind that directs the activity.
3. **Quality/Performance Improvement**. The combined and unceasing efforts of everyone – healthcare professionals, patients, and their families, researchers, administrators, payers, planners, educators – to make changes that will lead to better patient outcomes, better system performance, and better professional development.
4. **Clinical Research**. A systematic investigation in a clinical setting designed to develop or contribute to generalizable knowledge (The Common Rule definition of research).

*Ogrinc, G., Nelson, W., Adams, S., O'Hara, A. (2013). An Instrument to Differentiate between Clinical Research and Quality Improvement. *IRB: Ethics & Human Research. 35(5): 1-8.*

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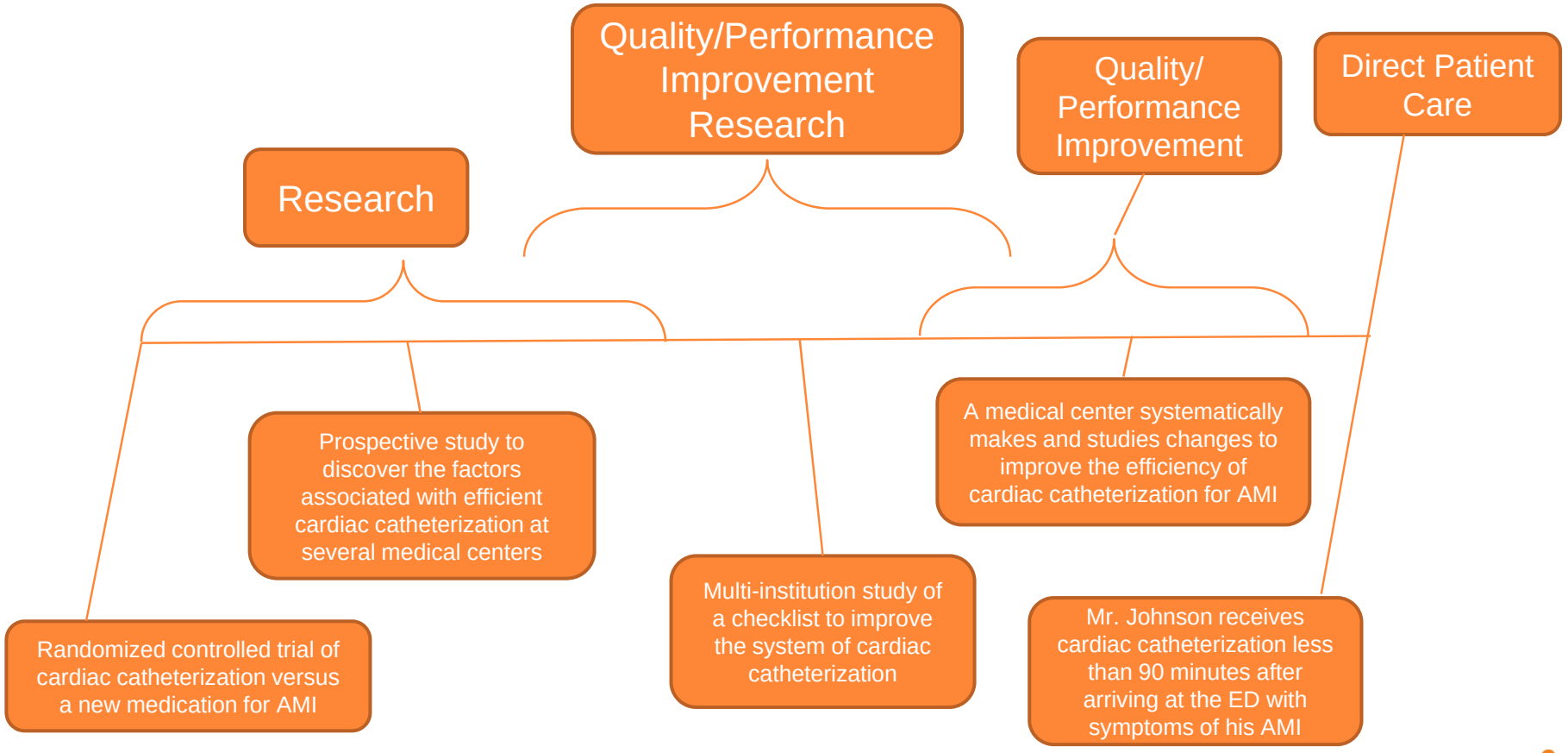
Depiction of the continuum of clinical research, quality/performance improvement, and patient care activities



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Please begin by considering these overarching questions: (Insert Hyperlink Form #1)

1. Will the activities of this project occur within the standard of care? ☐ YES ☐ NO
If NO, then proceed to Research Process algorithm.

2. Is there risk? ☐ YES ☐ NO
If YES, use the charts to determine whether this project requires QI/PI review or the Research Process algorithm.

3. Is this project primarily intended to generate generalizable knowledge? ☐ YES ☐ NO
If YES, proceed to Research Process algorithm.

4. Does this project involve vulnerable populations? ☐ YES ☐ NO
If YES, use the chart to determine whether this project requires QI/PI review or Research Process algorithm.

5. Does this project require informed consent of the patient? ☐ YES ☐ NO
If yes, the proceed to Research Process algorithm.

6. Do you intend to publish the results as peer reviewed? ☐ YES ☐ NO
If yes, this may qualify for either quality/performance improvement and/or research.

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The following completed forms will be required to submit whether your project is determined to be a quality/performance improvement project or research.

Interpretation

Any checkmarks (even one) in the “Clinical Research” column indicates that there are components of clinical research in the proposed activity. The IRB or QI/PI mentors should initiate a discussion with the investigator or improver to clarify the proposal. In an activity such a public health practice, program evaluation, or quality/performance improvement includes a research component, then IRB review should occur under current federal guidelines and the policies of the institution.

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(Insert Hyperlink Form #2)

Attribute	QI/PI Improvement	Clinical Research with Human Subjects
Intent and Background	Describes the natures and severity of a specific local performance gap Focus is to improve a specific aspect of health or health care delivery that is currently NOT consistently and appropriately being implemented at this site	Identifies a specific deficit in scientific knowledge from the literature Proposes to address or identify specific hypotheses
Methods	Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback Plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc.) Statistical methods evaluate system level processes and outcomes over time with statistical process controls or other methods	Specific protocol defines the intervention, interaction, and use of collected data and tissues, plus project may rely on the randomization of individuals to enhance confidence in differences May use qualitative or quantitative methods to make observations, make comparisons between groups, or generate hypotheses Statistical methods primarily compare differences between groups or correlate observed differences with a know health condition
Intended Benefit	Intervention would be considered within the usual clinician-patient therapeutic relationship Direct benefit to participants is indicated (e.g., for the decrease in risk by receiving a vaccination or by creating a safer institutional system) Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost)	Intervention, interaction, or use of identifiable private information occurs outside of the usual clinician-patient therapeutic relationship Direct benefit to each individual participant or for the institution is not typically the intent or is not certain Potential societal benefit in developing or advancing existing generalized knowledge

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(Insert Hyperlink Form #3)

Attribute	QI/PI Improvement	Clinical Research with Human Subjects
Risk	Risk is to privacy or the confidentiality of health information Risk may be described as high for patients by not participating in this activity	Risks may be minimal, but may include physical, psychological, emotional, social, or financial risks, as well as risk to privacy or the confidentiality of health information from participation in the project The informed consent process describes the risks to participants, who individually and voluntarily decide whether to participate or an IRB grants an alteration or waiver of the consent process
Applicability of Results	Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback Extrapolation of results to other settings is possible, but not the main intent of the activity	Results and analysis may be delayed or periodic throughout the duration of the project, expect to protect patient safety. The results will primarily be used to inform further investigations, but may be implemented directly into clinical practice Results are intended to generalize beyond the study population
Sharing & Disseminating	System level outcomes, processes, refinement of the intervention, and the applicability of the intervention in specific settings/contexts may be shard through peer-reviewed publication and presentation outside the institution	It is expected that results will be published or presented to others through a peer-reviewed process

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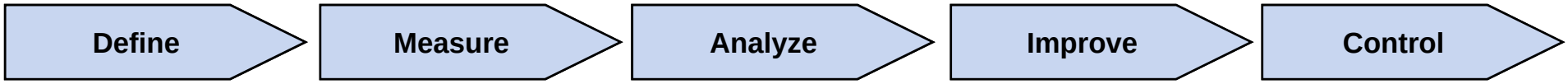
Six Sigma Quality/Performance Improvement Project Roadmap



Define

- ☐ Project Charter
- ☐ Customer CTQ's
- ☐ High Level Process Map
- ☐ Formal Champion Approval

Measure

- ☐ Establish Baseline Performance
- ☐ Identify Project Y(s)
- ☐ Identify Possible Xs
- ☐ Develop & Execute Data Collection Plan
- ☐ Measurement System Analysis

Analyze

- ☐ Identify Vital Few Root Causes of Variation Sources & Improvement Opportunities
- ☐ Define Performance Objective
- ☐ Quantify $ Benefit
- ☐ Formal Champion Approval

Improve

- ☐ Generate Solutions
- ☐ Prioritize Solutions
- ☐ Assess Risks
- ☐ Test Solutions
- ☐ Cost Benefit Analysis
- ☐ Develop & Implement Improvement Plan

Control

- ☐ Implement Sustainable Process Controls – Validate:
  - Control System
  - Monitoring Plan
  - Response Plan
- ☐ Standardize & Translate
- ❑ $ Benefits Validated
- ❑ Formal Champion Approval

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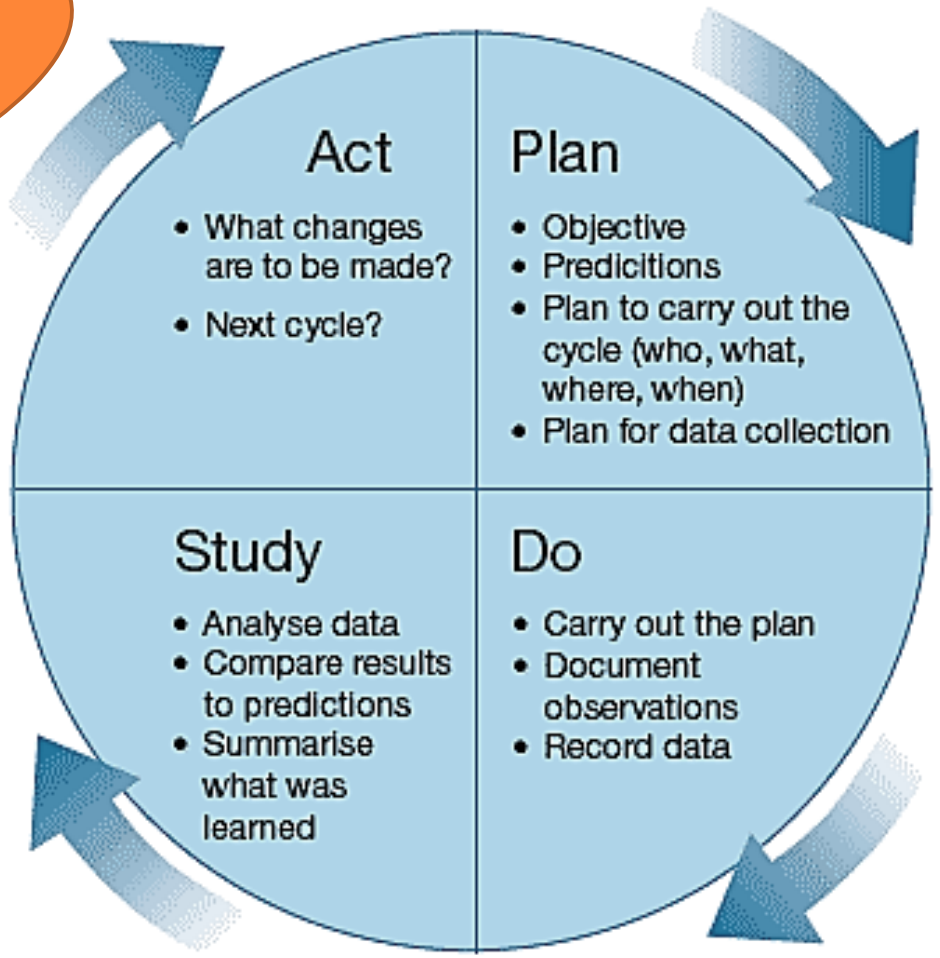
PDSA Quality/Performance Improvement Model



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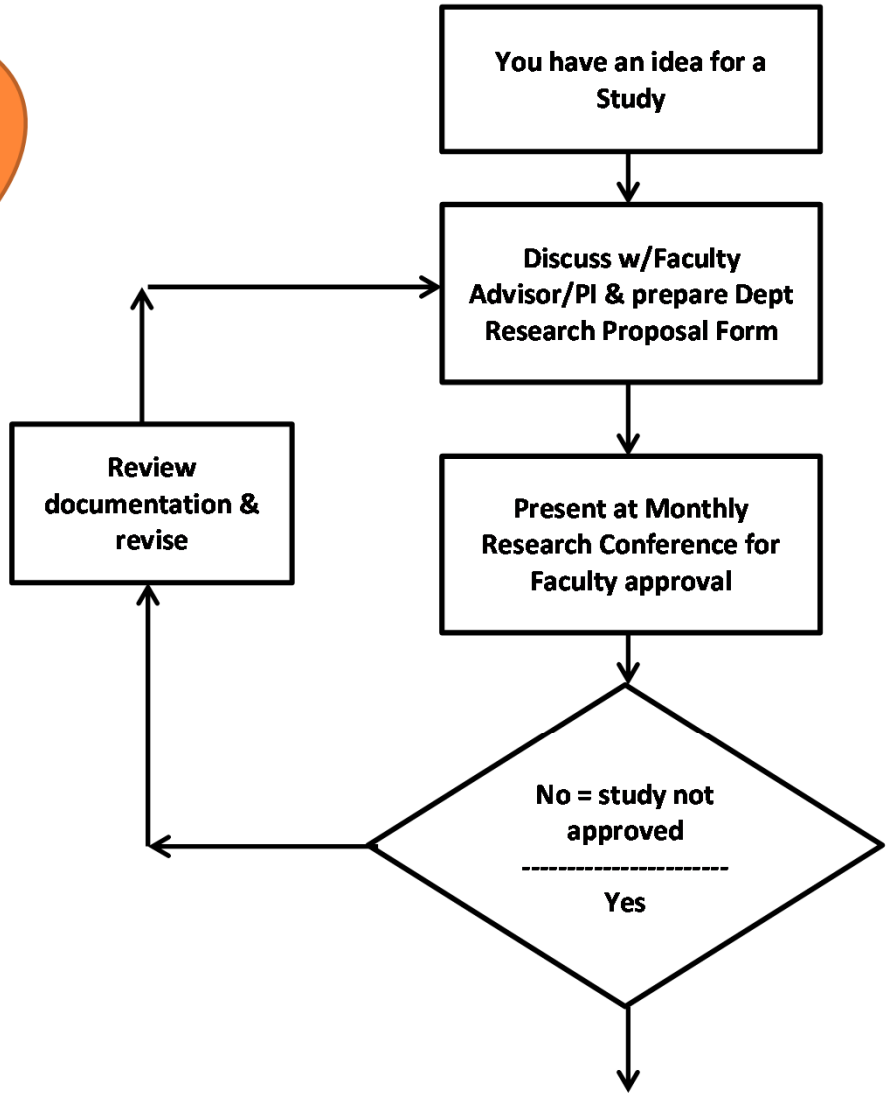
Research Process Algorithm Part I



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Research Process Algorithm Part II

Prepare IRB Forms:

- Original Research Protocol Submission
- Research Application Checklist
- Conflict of Interest (all investigators)

Prepare other documentation:

- NIH Training Certificate (all investigators)
- Current CV (all investigators)
- Full protocol – See examples under "Research"
- Synopsis
- Data Collection Form
- Consent form (if applicable) – Title page, Body, HIPAA Authorization, ICF COI Language
- Budget (if you're requesting funding)
- Grant Award notice (if applicable)
- Drug/Device information (if applicable)

Submit completed packet to Research Director for review:
Program Research Director-Surgery
Royek-OB-GYN
Whittle-Pediatrics
Carpenter-Internal Medicine
Pallay-Family Practice
Britt-Radiology

Determine reason for rejection & revise (consult Faculty Advisor)

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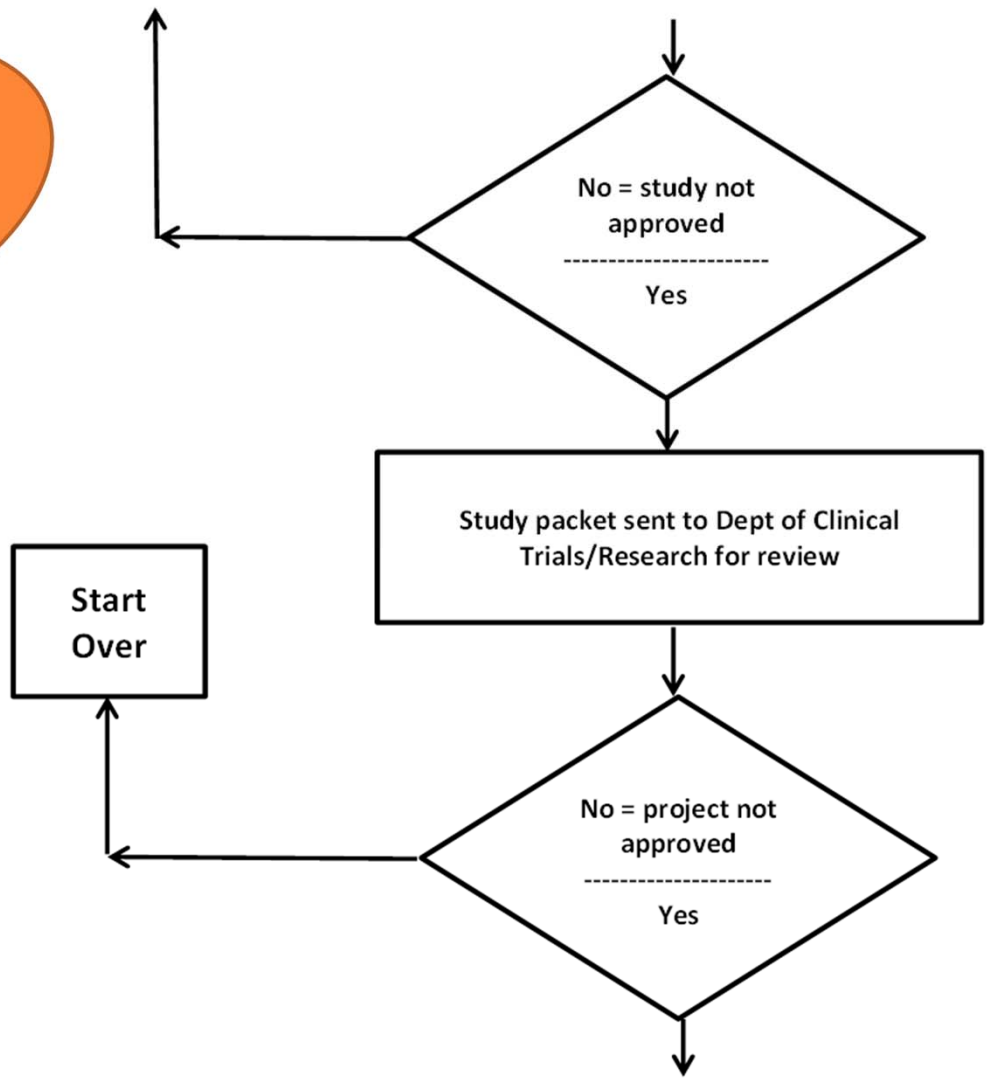
Research Process Algorithm Part III



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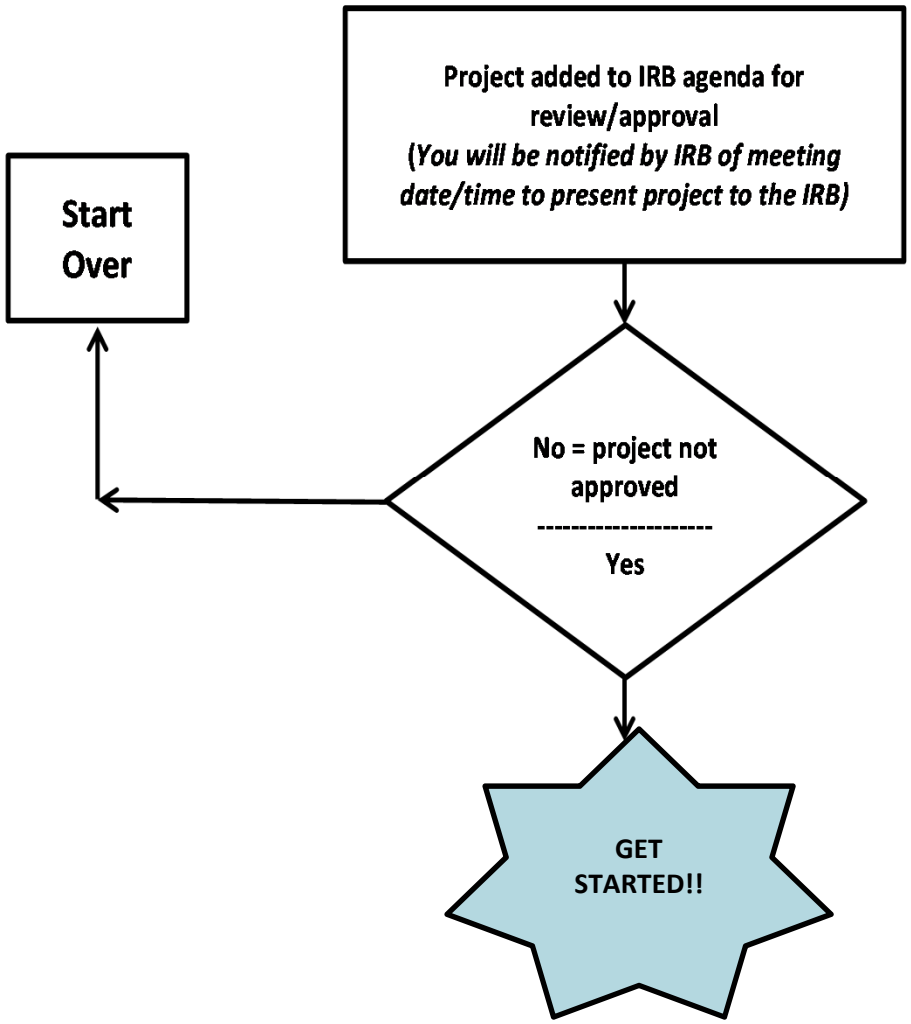
Research Process Algorithm Part IV



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Who is available to help me navigate this process?

Quality/Performance Improvement

Contact	E-mail	Phone Number
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Research

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Reminders:

- **Form must be completed and included in the Research Proposal or QI/PI Charter**
- **Form must include all appropriate signatures**
- **Contact Patricia Sharpe (Research), Jean Wiggins (Medical Education Administration), or Maribeth Schaefer (Process Excellence) with questions or concerns about the process**

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