

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

INSTRUCTIONS:

Who completes this form: *This form is for all Team Members (physicians, residents, medical students, and all others) who have completed the NetLearning CBL module “Determining the Difference between Clinical Research and Quality/Performance Improvement at Memorial University Medical Center” and are conducting Research and/or Quality/Performance Improvement at Memorial University Medical Center. A confirmation of completion of the above NetLearning module must accompany this form.*

Where can I find the form: *The form can be located in one of the following locations:*

- www.memorialhealth.com, Medical Education, Medical Research
- Link embedded within the NetLearning CBL module “Determining the Difference between Clinical Research and Quality/Performance Improvement at Memorial University Medical Center”
- Memorial Health Intranet, <http://mhwebmoss2/feelbetter/default.aspx>, Forms and Requests, Research Ethics – IRB
- Memorial Health Intranet, <http://mhwebmoss2/feelbetter/default.aspx>, Forms and Requests, Print and View Moore Wallace Forms

Who validates the form: *Once completed, the form and supporting Research Proposal or Quality/Performance Improvement Charter must be initially reviewed with the Program Director, physician sponsor, or the project mentor for accuracy. The form must then be submitted to Patricia Sharpe, Manager of Clinical Trials (Research Only), Jean Wiggins, Medical Education Administration (Medical Students/Residency Programs QI/PI Only), or Maribeth Schaefer, Senior Process Excellence Consultant (Nursing and other Clinical Departments QI/PI Only) for final review to identify and confirm the appropriate pathway (Research or Quality/Performance Improvement) for the principle investigator. To be valid, the form must be signed by both the principle investigator and reviewers (initial and final). A form with no signatures will be considered incomplete and not accepted.*

Who keeps the form: *This form is required and must be included with the project submission documents. The signed form will signify that completion of due diligence occurred to determine whether the project is Research or Quality/Performance Improvement. The principle investigator is responsible for following the appropriate ethical guidelines, project requirements, and documentation deadlines as identified by Research, Medical Education Administration, or Process Excellence.*

Please begin by considering these overarching questions:

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, then 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.

Continue by checking the boxes in the next two charts that most closely describes your project:

Attribute	QI/PI Improvement	Clinical Research with Human Subjects
Intent and Background	<input type="checkbox"/> Describes the natures and severity of a specific local performance gap <input type="checkbox"/> 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	<input type="checkbox"/> Identifies a specific deficit in scientific knowledge from the literature <input type="checkbox"/> Proposes to address or identify specific hypotheses
Methods	<input type="checkbox"/> Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback <input type="checkbox"/> Plan for intervention and analysis includes an assessment of the system (i.e., process flow diagram, fishbone, etc.) <input type="checkbox"/> Statistical methods evaluate system level processes and outcomes over time with statistical process controls or other methods	<input type="checkbox"/> 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 <input type="checkbox"/> May use qualitative or quantitative methods to make observations, make comparisons between groups, or generate hypotheses <input type="checkbox"/> Statistical methods primarily compare differences between groups or correlate observed differences with a known health condition

Intended Benefit	<ul style="list-style-type: none"><input type="checkbox"/> Intervention would be considered within the usual clinician–patient therapeutic relationship<input type="checkbox"/> Direct benefit to participants is indicated (e.g., for the decrease in risk by receiving a vaccination or by creating a safer institutional system)<input type="checkbox"/> Potential local institutional benefit is specified (e.g., increased efficiency or decreased cost)	<ul style="list-style-type: none"><input type="checkbox"/> Intervention, interaction, or use of identifiable private information occurs outside of the usual clinician–patient therapeutic relationship<input type="checkbox"/> Direct benefit to each individual participant or for the institution is not typically the intent or is not certain<input type="checkbox"/> Potential societal benefit in developing or advancing existing generalized knowledge
-------------------------	---	---

Attribute	QI/PI Improvement	Clinical Research with Human Subjects
Risk	<input type="checkbox"/> Risk is to privacy or the confidentiality of health information <input type="checkbox"/> Risk may be described as high for patients by not participating in this activity	<input type="checkbox"/> 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 <input type="checkbox"/> 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	<input type="checkbox"/> Mechanisms of the intervention are expected to change over time (i.e., an iterative activity) in response to ongoing feedback <input type="checkbox"/> Extrapolation of results to other settings is possible, but not the main intent of the activity	<input type="checkbox"/> 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 <input type="checkbox"/> Results are intended to generalize beyond the study population
Sharing & Disseminating	<input type="checkbox"/> System level outcomes, processes, refinement of the intervention, and the applicability of the intervention in specific settings/contexts may be shared through peer-reviewed publication and presentation outside the institution	<input type="checkbox"/> It is expected that results will be published or presented to others through a peer-reviewed process

REQUIRED SIGNATURES:

- The above choices are accurate and the proposed project is Research QI/PI
- The above choices need further review and clarification. The proposal must be resubmitted with additional documentation to support Research QI/PI

Principle Investigator

Date

Initial Reviewer: (please circle – Program Director, Physician Sponsor, Mentor)

Date

Final Reviewer: (please circle – Research, Medical Education, Process Excellence)

Date

NetLearning printed confirmation of completing the CBL module “Determining the Difference between Clinical Research and Quality/Performance Improvement at Memorial University Medical Center” is attached.