**Project Determination Form**

**and IRB Determination Certificate Application**

Determining whether a project or study is human subjects research, program evaluation (PE) or quality improvement (QI) is an important determination to make because human subject research studies must be submitted to, and approved by, the NEOMED IRB before they begin. PE or QI activities, on the other hand, do not require review or oversight from an IRB. Many investigators find it useful to complete the following questionnaire for help in determining the type of project they are conducting.

***Does my project require IRB review and oversight?***

By answering the questions below, you can determine whether your project is research, or non-regulatory PE or QI. Instructions for how to proceed with each type of project may be found after answering the questions and arriving at a determination. To answer the following questions, you should have a fully developed project. If you wish to have a determination certificate issued by the IRB, you are required to answer this questionnaire, and provide a description of the project, including all objectives (if PE) and/or outcomes. Additional guidance on the topic of project determination may be found by reviewing the document [“To IRB or not IRB, Guidance for Health Professions Students, Residents, and Faculty”](https://www.neomed.edu/wp-content/uploads/GUIDANCE.docx)

Question 1: Is the primary intent of the project to contribute to generalizable knowledge so that the outcomes of the project may be applied to a larger population outside of the study sample?

[ ]  Yes – Research

[ ]  No – PE or QI

Question 2: Has the study been designed so that results can be generalized by using such methods as randomization of subjects and comparison of cases vs controls?

[ ]  Yes – Research

[ ]  No – PE or QI

Question 3: Are you aiming to improve internal processes, practices, costs, or productivity for a specific existing intervention/program/activity in a clinical or academic setting? That is, does your project aim to determine how *this* intervention/program/activity affected *this* participant group in *this* setting.

[ ]  Yes – PE or QI

[ ]  No – Research

Question 4: Is the goal of the project to identify improvements that can be made to a program/activity or assess the success of a program/activity according to defined goals and objectives?

[ ]  Yes – PE or QI

[ ]  No – Research

Question 5: Is the intent of the project to test new innovative practices or understand phenomena (behavioral research, therapeutic interventions, etc.) and to make judgements about subjects?

[ ]  Yes- Research

[ ]  No- PE or QI

Question 6: Does the analytical or evaluative component of the project change the way that the academic or clinical care component being studied will be delivered in such a way that risks may be higher for those who participate in the project?

[ ]  Yes – Research

[ ]  No – PE or QI

Question 7: Is there funding for the project from an external organization based on support of a “research paradigm” to carry out the proposed activity?

[ ]  Yes – Research

[ ]  No – PE or QI

Question 8: Is there funding from an external organization with a commercial interest in the results or will the results of the project be used for commercial purposes?

[ ]  Yes – Research

[ ]  No – PE or QI

Question 9: Does the project seek to test interventions that are beyond current science and experience, such as new treatments, drugs, biologics or devices?

[ ]  Yes – Research

[ ]  No – PE or QI

Question 6: Does the project involve care practices, interventions, or treatments that are not standard of care or have not been established in other settings?

[ ]  Yes – Research

[ ]  No – PE or QI

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*Instructions for how to proceed:*

**FOR RESEARCH PROJECTS:**

If any of the above answers are “Research” please complete an IRB application for review. The IRB Application Form may be found at [www.neomed.edu/IRB/Forms](http://www.neomed.edu/IRB/Forms). If you are a student or resident conducting human subjects research at a clinical site, the project must be reviewed by the clinical site’s IRB since the research will occur in a non-NEOMED facility. If the clinical site does not have an IRB, the NEOMED IRB, at the University’s discretion and under very limited circumstances, may agree to review the research project provided the non-NEOMED site has an FWA.

**FOR PROGRAM EVALUATION OR QUALITY IMPROVEMENT PROJECTS:**

If the answers to the above questions are all “QI or PE” no further action is necessary from the NEOMED IRB. Please check with your department chair or residency director/preceptor for any additional internal requirements prior to conducting program evaluation/quality improvement activities.

**FOR A DETERMINATION CERTIFICATE:**

To obtain a certificate of determination, sometimes required by journals and conference organizers prior to accepting QI or PE publications, answer the above questions and provide the following information:

Title of Project:

The project leader/lead investigator may sign on behalf of all investigators associated with this project that all questions have been correctly answered.

I certify that all responses to the above questions are correct.

Project Leader/Supervisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Students and Residents must have a Project Leader or Supervisor sign)

Email address:

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Signature of Project Leader Date

**PLEASE ATTACH A DATED DESCRIPTION OF THE PROJECT, INLCUDING OUTCOMES THAT WILL BE COLLECTED.**

Return this completed form along with an attached project description to Trish Wilson, Regulatory Affairs Coordinator, NEOMED, paw@neomed.edu.

**For additional information on research, program evaluation and quality improvement activities:**

* [**“Research, Quality Improvement and Program Evaluation” What’s the Difference and Who Cares?**](https://neomed.mediasite.com/Mediasite/Play/f0285373984c4ad1917bb3364e5c95241d)**- video presentation by Karen Gil, Ph.D.**
* [**“Contrasting Evaluation and Research”**](https://www.neomed.edu/wp-content/uploads/IRB_EvaluationVsResearchChart.docx)**- the Department of Evaluation and Research Services**
* [**“Research vs. Evaluation**](https://www.neomed.edu/wp-content/uploads/IRB_ResearchOrEvaluation.pptx)**”- slide presentation by Julie Aultman, Ph.D.**