**Project Determination Form**

**Certificate of Non Human Subject Research Activity**

Determining whether a project or study is human subjects research, program evaluation (PE), quality improvement (QI), or other non-research activity 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 prior to completing any additional applications that may be required.

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

By answering the questions below, you can determine whether your project is research or another non-regulatory type activity. 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, 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 or other non-research activity

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 or other non-research activity

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 or other non-research activity

[ ]  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 or other non-research activity

[ ]  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 or other non-research activity

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 or other non-research activity

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 or other non-research activity

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 or other non-research activity

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 or other non-research activity

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 or other non-research activity

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*Instructions for how to proceed:*

1. **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.

1. **FOR PROGRAM EVALUATION , QUALITY IMPROVEMENT, or OTHER NON-HUMAN SUBJECTS RESEARCH ACTIVITIES:**

If the answers to the previous 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 these types of activities.

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***FOR A CERTIFICATE OF DETERMINATION***

To obtain a certificate of determination for activities which are not human subject research activities, (certificate is not required by NEOMED but sometimes required by journals and conference organizers prior to accepting projects for publications or posters), answer the questions on the previous page, provide the following additional information below, and attach a DETAILED abstract of the project. (See instructions for writing an abstract below.)

Title of Project:

Project Leader/Faculty Advisor:

(Students and Residents must have the Project Leader or Faculty Advisor sign this form below)

Email address of project leader/advisor:

**Assurance Statement:**

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

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Signature of Project Leader/Faculty Advisor Date

Abstract Instructions:

If you are requesting a certificate for a quality improvement or program evaluation project, you must attach a very detailed description of the process or program you have (or will) examine. An explanation of how your activities served to evaluated or improve the process/program should be the focus of your written abstract. A good way to demonstrate this is to bullet point the stated objectives of the current program/process being studied and to follow each objective with an explanation of how the project you conducted helped improve or evaluate the stated program/process objectives.

Please use the brief outline below when writing your project’s abstract:

1. Start with a written description of the current state/status of the existing program/process that your project seeks/sought to evaluate or improve at NEOMED.
2. State the objectives of the current program/process followed by how that data you have collected will/has addressed these objectives.
3. Next explain how the data you have/will collect has helped improve or evaluate each of the program/process objectives.
4. Close with how the data you have/will collected will provide for future improvement for the program/process being studied and explain if data from this project could lead to future projects/studies.

For additional information on research, program evaluation and quality improvement activities, please review the following resources:

* [“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.

**Please send this form along with a detailed abstract of the project to : Trish Wilson, Regulatory Affairs Coordinator,** **paw@neomed.edu****.**