**IRB GUIDANCE DOCUMENT  
Research or Quality Improvement**

**Certification that a Project is Not Human Subject Research Requiring IRB Review**

Determining whether a project or study is research or Quality Improvement (QI) is difficult. It is also a very important determination to make because research studies must be submitted to, and approved by, the NEOMED IRB before they can be started. The process in this document must be completed PRIOR to the start of the study or project. Please note that no retroactive or retrospective approval or Certificate will be granted.

The Institutional Review Board (IRB) and the Office of Office of Research and Sponsored Programs at NEOMED have received increasing number of requests to have a formal determination made as to whether their project does not meet the criteria for research and does not require IRB review because it is a QI initiative. One reason this request is made is that the investigators want to ensure that they are proposing a QI initiative and not a research study. Additionally, they would like to have documentation that their project is QI that they can use if they submit their QI results to a national meeting or journal for publication.

This is the definition of research used by the federal government: (d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A series of questions and examples is available from the federal government that can help guide decisions about whether a project qualifies as QI:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

The IRB and Office of Research and Sponsored Programs have designed a series of questions investigators can answer to determine if their project is research or QI. If the response to all questions on the following page is “QI” then the investigators may sign an affirmation that all information is correct and use the Certificate which will then be provided as documentation that their project does not meet the criteria for human subject research and does not require IRB review.

If one or more responses is YES, then the project may be research.

**Please attach a dated description of the QI project, including outcomes that will be collected, with the completed questions and signature page. Should you need assistance when writing your project description, please contact Karen Gil, Ph.D. at** [kmg1@neomed.edu](mailto:kmg1@neomed.edu)**.**

**IRB and the Office of Research and Sponsored Programs**

**Research versus QI Questions for Not Human Subject Certification**

If the answer to all questions is “QI” then the investigators may sign the affirmation on the next page to obtain a Certificate documenting that their project is not research requiring further IRB review. If one or more responses is “Research,” then the project may be research.

**Question 1: Does the analytical or evaluative component of the activity change the way that the clinical care or education activity will be delivered in such a way that risks may be higher for those who participate (e.g., will those who participate be randomized to different interventions to permit statistical comparison of outcomes)?**

Yes – Research

No – QI

**Question 2: Is there funding from an external organization based on support of a “research paradigm” to carry out the proposed activity?**

Yes – Research

No – QI

**Question 3: Is there funding from an external organization with a commercial interest in the results or will the results of the study or project be used for commercial purposes?**

Yes – Research

No – QI

**Question 3: Is the primary intent of the project or study to contribute to generalizable knowledge?**

Yes – Research

No – QI

**Question 4: Has the study been designed so that results will be generalizable (e.g. randomization of subjects, comparison of cases vs controls)?**

Yes – Research

No – QI

**Question 5: Does the project seek to test interventions that are beyond current science and experience, such as new treatments, drugs, biologics, devices or teaching methods?**

Yes – Research

No – QI

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

Yes – Research

No – QI

**Question 7: Is the project undertaken by or for NEOMED AND the goal of the project is immediate audit, evaluation or improvement in patient safety or care?**

Yes – QI

No – Research

**Question 8: What if my project is determined to be QI and I want to publish the results of my QI initiative?**

Intrinsic components of QI are shared learning. It is entirely appropriate to disseminate and replicate QI successes, including through channels that are external to an organization. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QI project does not obligate IRB review as long as the publication does not refer to the activity as human subjects research and makes it clear the publication is the result of a quality improvement initiative as defined above.

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.

Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature Date

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

**The Office of Research and Sponsored Programs is available to help investigators write up the project description.**

NOTE: After the QI database is constructed, the investigators may observe patterns and trends that might contribute to generalizable knowledge. If it is decided at this point to expand the scope of this project by, for example, generating testable hypotheses, then the new project would be research. The investigators could still analyze their QI data as described in the original QI protocol and submit for publication, but any new or additional analyses, with research goals as described in the questions above would be considered research. The investigators would then need to submit an IRB protocol to conduct a research study. If the investigators would like to guidance on this process, please contact the IRB at NEOMED