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| logo**FOR USE WITH PROJECTS INVOLVING PROGRAM EVALUATION/QUALITY IMPROVEMENT/ASSESSMENT/PROGRAM PLANNING****Non-Research Determination REVIEW PROCESS FORM** |

This document will be reviewed to determine if the proposed project is evaluation, quality improvement, assessment, program planning, strategic planning, or an environmental scan. Please answer all of the sections. If you are filing an amendment, the revision/amendment section is at the end of this document.

**Email this completed form to Trish Wilson: paw@neomed.edu**

FOR OFFICE USE ONLY: Project #

Date Received:

Date Approved:

**Revision Information: 🞏 Amendment Document**

Date Received:

Date Approved:

This proposal is an amendment to an already approved proposal.

[ ]  **Yes** (the project is evaluation or QI only, review by the IRB is not required).

[ ]  **No**

**Section 1: Faculty and Student Information**

**Faculty Information:**

|  |
| --- |
| **Name:**  |
| **University:** [ ]  NEOMED  |
| **Contact Information: Email: Phone:** |

**Student Information:**

|  |
| --- |
| **Name:**  |
| **University:** [ ]  NEOMED [ ]  OTHER If other, please list:  |
| **Contact Information: Email:**  **Phone:** |

**Section 2: Project Information:**

**Project Title:**

|  |
| --- |
|  |

**List the objectives of your project:**

|  |  |
| --- | --- |
|  | **Written Measurable Objectives** |
| **Objective 1** |  |
| **Objective 2** |  |
| **Objective 3** |  |
| **Objective 4** |  |
| **Objective 5** |  |

**List the strategies that will be used for your project (if applicable):**

|  |  |
| --- | --- |
|  | **Strategies** |
| **Strategy 1** |  |
| **Strategy 2** |  |
| **Strategy 3** |  |
| **Strategy 4** |  |
| **Stragegy 5** |  |

**List the outcomes that will be collected:**

|  |  |
| --- | --- |
|  | **Written Measurable Outcomes** |
| **Outcome 1** |  |
| **Outcome 2** |  |
| **Outcome 3** |  |
| **Outcome 4** |  |
| **Outcome 5** |  |

**Section 3: Involved Persons:**

**List those involved with the project (faculty, community preceptors, consultants):**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title** | **Responsibility** | **Contact Information****Email/phone** |
|  |  |  |  |
|  |  |  |  |
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**Section 4: Determination Questions:**

(To check the boxes on this form, double click the box in front of the response you wish to select, then find “Default Value” and select “Checked”. If you wish to spell-check this form, select the Review tab in Word, then click “Spelling and Grammar” on the upper left.)

**Check which columns appropriately describe your project.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Details** | **x** | **Evaluation/QI** | **x** | **Human Subjects Research** |
| **Purpose of project** | [ ]  | To inform decisions and identify improvements to a program or activity. To provide information about the success of programs according to predefined goals and objectives. | [ ]  | To generate new generalizable knowledge (facts, theories, principles, or relationships, etc.) involving accepted scientific methods of observation and inference. |
| **Goals of project** | [ ]  | **To make judgements ABOUT the program**, and to improve or further develop program effectiveness or efficiency.  | [ ]  | To test new innovative practices or understand phenomena (behavioral research, therapeutic interventions, etc.). **To make judgements ABOUT subjects.** |
| **Knowledge created** | [ ]  | Decision-makers; program management who use the findings to improve practices being reviewed to benefit current and future program participants. Knowledge will improve program design and implementation, and identify efficient practice, unintended benefits and risks. | [ ]  | There may not be any benefits to the actual research participants; knowledge is intended for future benefits for others. Findings will contribute to scientific body of knowledge which collectively adds to evidence that will inform practices and policies. |
| **Participants at risk** | [ ]  | There will be no risks beyond the usual intervention; privacy may be a concern., DATA is to be de-identified, anonymized or anonymous. | [ ]  | There may be some risk to participants (minimal or more than minimal risk) including physical, emotion, and privacy risks of harm as a result of change in the usual standard of care/intervention or from being exposed to sensitive questions. |
| **Anonymous/Confidential** | [ ]  | No identifying information collected. Collector will not know participants identities. | [ ]  | DATA utilizes identifiers and collectors will know participants responses and identities. |
| **Data collection** | [ ]  | May use a combination of valid and reliable instruments as well as program specific data. | [ ]  | Valid and reliable instruments that measure concepts of interest. |
| **Data analysis** | [ ]  | Quantitative and/or qualitative analysis, trend analysis, and descriptive statistics. | [ ]  | With inferential statistics to test for significant differences, descriptive statistics, or a qualitative methodology that can compare and contrast qualitative data. |
| **Data dissemination** | [ ]  | Communicate finding within the program and organization primarily by providing specific feedback to those who commissioned the evaluation. Findings may be published with organizational approval (e.g. certificate indicating that project is not human subjects research but program evaluation). | [ ]  | Findings will be applied as widely as possible to increase the body of scientific knowledge by publishing or presenting for others within the discipline. |
| **IRB approval** | [ ]  | **NO**. Complete Evaluation Protocol. | [ ]  | **YES**. Complete IRB Protocol. |

**Read the following questions and answer them by checking the boxes to the right.**

|  |  |  |
| --- | --- | --- |
| **Question** | **Yes** | **No** |
| 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)?
 | [ ]  | [ ]  |
| 1. Is there funding from an external organization based on support of a “research paradigm” to carry out the proposed activity?
 | [ ]  | [ ]  |
| 1. Is there funding form an external organization with a commercial interest in the results or will the results of the study or project be used for commercial purposes?
 | [ ]  | [ ]  |
| 1. Is the primary intent of the project or study to contribute to generalizable knowledge?
 | [ ]  | [ ]  |
| 1. Has the study been designed so that results will be generalizable (e.g. randomization of subjects, comparison of cases vs. controls)?
 | [ ]  | [ ]  |
| 1. Does the project seek to test interventions that are beyond current science and experience, such as new treatments, drugs, biologics, devices, or teaching methods?
 | [ ]  | [ ]  |
| 1. Does the project involve care, teaching practices, interventions, or treatments that are not standard of care or have not been established in other settings?
 | [ ]  | [ ]  |
| 1. 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?
 | [ ]  | [ ]  |

**Does your proposed project meet the criteria above in order to be considered evaluation/QI/Assessment/Program Planning?**

[ ]  **Yes** (the project is evaluation or QI only, review by the IRB is not required).

[ ]  **No** (the project is subject to IRB review and all appropriate documents and procedures must be followed).

**Do you plan to publish your results or present at a conference in any way?**

[ ]  **Yes** (Publications or presentations of projects determined to be non-research should be identified, written about, and referred to as quality improvement, program evaluation projects. )

[ ]  **No** (You will be able to proceed without IRB approval).

I certify that all responses to the above questions are correct. (Person submitting the proposal)

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature Date

**Section 5: Required Attachments: (these are required)**

Add the following as attachments to this document:

1. Project description (an executive summary of the project)
2. Project timeline (a Gantt Chart)
3. Survey or questionnaire being used (if applicable)
4. Program plan outline or strategic plan outline if conducting program or strategic planning
5. Assessment, QI, or evaluation plan if conducting an assessment, QI, or evaluation project

*NOTE: After the assessment, QI, or PE 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 assessment, QI, or PE 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.*

**Section 6: Approval:**

This project has been approved as a non-research, non-human subjects project:

**Type of project approved:**

[ ]  Community Assessment

[ ]  Program/Course Evaluation

[ ]  Quality Improvement

[ ]  Program Planning

[ ]  Strategic Planning

[ ]  Environmental Scan

**The following documents were present in the application:**

[ ]  Project description

[ ]  Project timeline

[ ]  Survey or questionnaire being used (if applicable)

[ ]  Program plan outline or strategic plan outline if conducting program or strategic planning

[ ]  Assessment plan if conducting an assessment

[ ]  QI plan if conducting a QI project

[ ]  Evaluation Plan if conducting an evaluation

**Determination:**

[ ]  **Approval**

[ ]  **Non-approval**

 **Areas of Concern for non-approval:**

**Determination for publishing or presentation:**

[ ]  **Approval**

[ ]  **Non-approval**

 **Areas of Concern for non-approval:**

**Reviewer Signatures:**

**Reviewer 1:**

Name Date

**Section 7: Amendments:**

Please use this section to request an amendment/addendum to a currently approved non-research project. This includes changes in project design, data collection, or participants. Please complete, sign, scan, and e-mail this form to Trish Wilson at paw@neomed.edu. Please attach all requested documents.

Write amendment below:

**1) Please provide a short summary of the amendment/addendum you are requesting.**

**If this amendment is to change any surveys or other data collection forms, please attach the revised documents.**

**2) Please provide a justification for this amendment/addendum request. How will this change or improve the project?**

I certify that all responses to the above questions are correct. (Person submitting the proposal)

Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**Additional Attachments:** (please list)

1.

2.

3.

**Section 8: Amendment Approval**

**Does this change the determination of the project?**

[ ]  **Yes: (If yes, the student will have to apply to IRB for the project.)**

[ ]  **No**

**Is there further documentation needed?**

[ ]  **Yes: (If yes, please list what is needed)**

*
*

[ ]  **No**

**Determination:**

[ ]  **Approval**

[ ]  **Non-approval**

 **Areas of Concern for non-approval:**

**Reviewer Signatures:**

Name Date