**VCOM Institutional Review Board: Research Determination Application**

**Prior to completing this application, please read carefully and review the VCOM IRB Quality Assurance/Quality Improvement or Research Assessment Worksheet. This worksheet is available in the Library Manager-Documents for Researchers.**

If you feel you cannot make a determination based upon that worksheet or if you are uncertain how to proceed, please complete and submit this application and the IRB will make the determination. Should the IRB determine this project does constitute human subjects research, you will be directed to submit a full application packet to the IRB.

Please contact the VCOM IRB for any questions on this process: [irb@vcom.vt.edu](mailto:irb@vcom.vt.edu).

**Project Title**

Click here to enter text.

**Project Location**

Click here to enter text.

**Purpose of the Project**

*Describe what you hope to learn from this project (in 3 to 4 sentences). List specific aims or goals to be accomplished. Concisely describe the issue or problem addressed by the project. Describe how the project will be used to assess or improve services, procedures or quality of care at VCOM or a hospital/clinic site. If the project involves clinical or educational practices, describe whether intent is to implement existing knowledge into clinical or educational practice or to generate new knowledge.*

Click here to enter text.

**Literature Review and Synthesis:**

*Summarize the evidence that supports the project. If the project involves translation of existing knowledge into practice, the evidence should be convincing to clearly support practice change if your project is QA/QI. Explain how the translation of evidence will be implemented in clinical or educational practice. State if the project will produce new knowledge or if it will implement evidence into clinical or educational practice.*

Click here to enter text.

**Project Procedures**

*Explain the project design and procedures. Provide assessment measures as appropriate. Describe the population targeted by the project. If the project is aimed at changes in clinical or educational practice, give details of how the project will influence practice change.*

Click here to enter text.

**Data Collection Plan**

*Provide a concise description of how data will be collected and what data will be obtained.*

Click here to enter text.

**Please complete the following sections:**

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| --- | --- | --- |
| **Quality Assessment / Quality Improvement** | **YES** | **NO** |
| Definition: An activity conducted to assess, analyze, critique and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements. | | |
| 1. Do you consider this project to meet the definition of QA/QI? |  |  |
| 1. Will the activity involve randomization into different intervention groups? |  |  |
| 1. Is the activity primarily designed to: |  |  |
| * 1. Improve clinical care or improve some other program? |  |  |
| * 1. Be applied to populations beyond your specific study population? |  |  |

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| **Research** | **YES** | **NO** |
| Definition: A systematic investigation designed to develop or contribute to generalizable knowledge. | | |
| 1. Do you consider this project to meet the definition of research? |  |  |
| 1. Is the activity a systematic investigation including, but not limited to, a hypothesis, research development, testing and evaluation? |  |  |
| 1. Is the activity primarily designed to develop generalizable knowledge? |  |  |
| 1. Is the activity for thesis or dissertation research? |  |  |

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| **Human Subjects Involvement** | **YES** | **NO** |
| Does your project involve? | | |
| 1. Living individuals? |  |  |
| 1. Intervention, including manipulation of a person or a person’s environment? |  |  |
| 1. Interaction through surveys, interviews, tests or observations? (Please attach documentation if “yes.”) |  |  |
| 1. Obtaining identifiable private information about living individuals? |  |  |

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| **Existing Data or Specimens** | **YES** | **NO** |
| 1. List the source of the data or specimens: Click here to enter text. | | |
| 1. Are the data or specimens publically available? |  |  |
| 1. Can the research team identify the individual associated with the data or specimens? |  |  |
| 1. Are the data or specimens de-identified? If “yes,” who did (or who will) de-identify them?  Click here to enter text. |  |  |
| 1. Are the data or specimens coded?  If “yes,” will any member of the research team have access to the key to the code? |  |  |
| 1. Were the data or specimens originally collected as part of clinical care? |  |  |
| 1. Were the data or specimens originally collected for this project? |  |  |
| 1. Were the data or specimens originally collected for research purposes under a VCOM IRB-approved protocol? If “yes,” provide VCOM IRB Number: Click here to enter text. |  |  |

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| **Clinical Considerations** | **YES** | **NO** |
| 1. Does the project include testing the safety and efficacy of a drug or device in a human subject, including analysis or comparison of outcome data about a drug or device? |  |  |
| 1. Does the project involve an investigational new drug or device?  (Please contact the VCOM IRB if you have questions: [irb@vcom.vt.edu](mailto:irb@vcom.vt.edu).) |  |  |
| 1. Will any data resulting from this activity be submitted to the FDA? |  |  |