**Virtua – Rowan IRB Engagement Review Form**

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| **Guidance**  This form must be submitted prior to completing and submitting an IRB submission to either the Rowan IRB or Virtua IRB. Submit the completed form to the following IRB general emails:  Rowan IRB: [CIRB@rowan.edu](mailto:CIRB@rowan.edu)  Virtua IRB: [irb@virtua.org](file:///\\rowanads.rowan.edu\common\Openarea\Grants\Research%20Office\Research%20Compliance%20Office\Final%20-%20Current%20Records\IRB\Virtua%20IRB\Virtua%20Forms\irb@virtua.org)  Both Rowan IRB and Virtua IRB administration will review the form and determine which IRB should be the IRB of record.  Rowan faculty and staff or Virtua Health employees should complete this form. Students cannot be named as Study Principal Investigator or Lead Site Investigator.  **Note:** You will still be required to submit the research project to the non-Reviewing IRB for local context review. |

**Project Information**

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| **Project Title:** | Click or tap here to enter text. |
| **Funding Source/Sponsor Name:** | Click or tap here to enter text. |
| **Awardee Institution:** | - Not Applicable/No funding source  - Virtua Health System  - Rowan University |
| **Study Principal Investigator (Can be the same as Lead Investigator identified below):** |  |
| **Virtua Health Site Lead Investigator:** | Click or tap here to enter text. |
| **Rowan University Site Lead Investigator:** | Click or tap here to enter text. |

**Project Details**

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| **Research Sites:**  **\*If you selected the Virtua Health System, please complete Attachment A.**  **Note: Check all that apply** | - Virtua Health System\*, please state location: Click or tap here to enter text.  - Rowan University, Stratford Campus  - Rowan University, Camden or Glassboro Campus  - Rowan University, Sewell Campus  - Other:  Click or tap here to enter text. |
| **Populations Targeted:**  **\*If you selected Virtua Patients, please complete Attachment A.**  **Note: Check all that apply** | - Virtua Patients\*  - Virtua Employees  - Rowan University Faculty, Employees or Students  - Pregnant Women, Neonates, & Human Fetuses  - Children  - Prisoners  - Other |
| **Study Types:**    **Note: Check all that apply** | - Drug  - Device  - Observational/Registry  - Retrospective Chart Review  - Biospecimen Collection  - Interventional Non-Drug or Device  - Qualitative/Interview  - Questionnaire/Survey |
| **Will Non-Virtua employees need access to Virtua Patient/Medical Records?**  **\**If you selected Yes, please complete Attachment A.*** | - Yes\*  - No |
| **Will any external researchers be involved in the study?**  **Note: External researchers are individuals who are not employed or do not have an appointment with Virtua Health and/or Rowan University** | - Yes  - No |
| **Is information collected about individuals sensitive and could place subjects at risk for criminal or civil liability, be damaging to their financial standing, insurability, reputation, or be stigmatizing?** | - Yes  - No |

**Brief Summary of Project:**

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| Click or tap here to enter text. |

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| **To Be Completed by Virtua and Rowan IRB Administration** | |
| - Virtua IRB will be the IRB of Record | - Rowan IRB will be the IRB of Record |
| Virtua IRB Signature and Acknowledgement | Rowan IRB Signature and Acknowledgement |
|  |  |
| Name of Virtua Signatory: Click or tap here to enter text. | Name of Rowan Signatory: Click or tap here to enter text. |

**Virtua – Rowan IRB Engagement Review Form - Attachment A**

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| **Please list all involved research personnel and their employing institution:** | |  |  | | --- | --- | | **Name** | **Institution** | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |
| **Please explain if the study will require support from the clinical staff:** |  |
| **Please explain if the study will involve any non-standard of care procedures and how these procedures will be billed:** |  |
| **Please explain if the study will be requesting Epic EMR support in the form of a report, order build, or other:** |  |
| **Please explain where the study data will be stored:** |  |
| **Please explain how the drive is secured, encrypted and access is provided?** |  |
| **Please list those individuals who will have access to the drive?** |  |
| **Will the study involve the transfer of any images outside of the Virtua network?** | - Yes  - No |
| **Will the study involve any data collection platforms, websites, software, patient facing applications, or non-Virtua owned devices (e.g. tablets, laptops, cell phones, etc.)?** | - Yes  - No |
| **If the answer to the above question is “yes” please list all platforms, websites, software, patient facing applications, or non-Virtua owned devices:** | |  | | --- | |  | |  | |  | |  | |  | |  | |  | |  | |
| **Please indicate the expected duration of the study:** |  |

**PI Certification**

I certify that as Principal Investigator, I will supervise and conduct the Study in accordance with all requirements of the Protocol, and budget with adherence to the principles of Good Clinical Practice, if applicable, and any conditions of approval imposed by the IRB of record, and all applicable Virtua policies, statutes and regulations governing the responsibilities of a Principal Investigator, including, but not limited to HIPAA. I have complied with all Rowan University policies and or procedures which Rowan may require as a prerequisite to submission of the Study to Virtua.

Print Name: Signature: Date: