MANUAL TITLE			POLICY NAME	
Research Administration			RESEARCH REVIEW	
MANUAL OWNER	**DATE OF ISSUE**	**DATE OF LAST REVIEW**	**DATE OF REVISION**	**EFFECTIVE DATE**
Research Administration	04/02/2019	06/14/2021	06/14/2021	06/14/2021
REVIEW INTERVAL	**REVIEWED / APPROVED BY: (Committees)**			
36 Months	Virtua Research Council			

THIS POLICY IS APPLICABLE TO:
Virtua Health, Inc.
Virtua - Memorial Hospital Burlington County, Inc.
Virtua - West Jersey Health System, Inc.
Virtua Memorial Burlington - Psych
Virtua Health and Rehabilitation at Mt. Holly
Virtua Health and Rehabilitation Center at Berlin
Virtua Home Care – Community Nursing Services
Virtua Home Care at West Jersey
Virtua Health Foundation, Inc.
Virtua Medical Group (VMG)
Virtua Our Lady of Lourdes Hospital, Inc.
Virtua Willingboro Hospital, Inc.

POLICY:

Research studies to be conducted at Virtua must undergo research review in order to ensure sufficiency of rigor, regulatory and legal compliance, feasibility, and alignment with Virtua's Mission, Vision, and Strategic Imperatives. All research studies, including Principal Investigator (PI) initiated research, will be reviewed by the Office of Research Administration (ORA).

Research review is not a substitute for Institutional Review Board (IRB) review. All research proposals must be reviewed by the IRB. Proposals must be submitted for research review in advance of IRB approval. IRB review will not commence until the IRB is notified of research review approval.

Research review is intended as a final review of well-developed proposals with established organizational support for teams qualified to conduct research. Researchers are encouraged to contact the ORA early in the proposal development for support with research methods, regulatory and legal requirements, or to secure organizational support.

PROCEDURE:

1) The PI should contact the ORA early in their project for guidance. They will be asked to fill out a Research Review Form and submit the following documents including but not limited to as applicable:
   a) Research Review Form
   b) Strategic Alignment and Operational Feasibility Letter of Support for Research Study
   c) Research protocol
   d) Informed Consent
   e) Contract template
   f) Project Budget

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g) Financial Conflict of Interest Form for federally funded studies
h) Financial Conflict of Interest Training forms for federally funded studies
i) Human Subject Protection Training Certificate
j) Good Clinical Practice Training Certificate

2) The ORA will review the study for the following requirements as applicable to the individual project:
   a) Strategic Alignment and Operational Feasibility: Investigators will provide evidence of strategic and operational approval and support through the signature of appropriate leaders on the Strategic Alignment and Operational Feasibility Letter of Support for Research Study. Investigators may discuss appropriate leaders with the committee and the committee may require additional approvals or verification of operational procedures and compliance with additional Virtua policies.
      i) Review of compliance with additional Virtua policies as applicable:
         (1) Information Services: All software or digital portals or electronic devices should be reviewed and approved via Virtua's Information Technology Security Services.
         (2) Purchasing: Any proposals involving Virtua purchasing a service or device should be reviewed and approved by the Purchasing department.
         (3) Support Services: All FDA approved devices which Virtua is purchasing or placing in stock should be reviewed and approved by the Product Value Analysis Committee.
            (a) Exceptions apply to:
               (i) Devices that are not FDA approved and are considered investigational
               (ii) Devices that are being supplied free of charge to Virtua strictly for Research where there is no intention to hold as an in stock device.

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(4) Pharmacy: Any proposals involving storing drug in the pharmacy will be reviewed for appropriate storage and documentation procedures.
(5) Lab: Appropriate procedures and documentation should be in place to track any lab samples.
(6) Virtua Public Health Service (PHS) Research Financial Conflict of Interest Policy

b) Scientific Review: The protocol will be reviewed for scientific soundness. Researchers can contact the ORA for support in identifying appropriate guidance for their study.
   i) Protocols should include the following as applicable:
      (a) Introduction
      (b) Methods
      (c) Protection of Human Subjects
         (i) Consent
            1. Describe process
            2. Attach as appendix
            3. If waiving documentation of consent, or waiving consent altogether, provide rationale
         (ii) Data management
            1. Describe process to de-identify protected health information
            2. Describe how data security will be maintained
            3. Describe how and when data will be destroyed
      (d) Risk/Benefit
         (i) Describe any potential risk to subjects including risk to privacy and confidentiality.
   ii) Nursing studies will be reviewed and approved by the Nursing Research Council.

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c) Legal Review: Studies will be reviewed for any legal requirements such as needing a full contract, data use agreement, investigator agreement, or other such document.
d) Budget: Research review will ensure that any research is appropriately financially supported or have been approved to operate without funding. The Research Committee may request a standard of care analysis to be submitted.
e) Inclusion in the Electronic Medical Record (EMR): All investigators of prospective studies enrolling Virtua patients will be required to attend or delegate attendance to Epic research training. They will be required to build the study in Epic and link enrolled patients to the study and maintain review of the research billing report.
    i) If there will be documentation in the patient medical record that is for research purposes only, this will be reflected in the informed consent.
    ii) Any requests for Epic use that are not currently in place may have to be reviewed and approved by the Health IT Privacy and Security Committee.
    iii) Any research-specific Epic builds will be reviewed and approved.
f) Required Training: All researchers will need to complete a Human Subjects Protection course. Researchers who will be administering an informed consent to patients will also be required to complete Good Clinical Practice Training.

3) Reviewers will make one of the following decisions:
    i) Approved
    ii) Rejected
        (1) In the event that the committee recommends the study be rejected, a Research Review Committee will be convened. All members will have an opportunity to review the study prior to the meeting. The investigator may appeal the rejection by making a presentation to the Research Review Committee.
4) After research review has approved the study, the investigator may submit to the IRB for their approval.

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5) The IRB may at times accept studies before research review has been completed at their own discretion. Research review will also be expected to weigh in on the appropriateness to accept a study early.