Conducting Research at Virtua

What are Research Review and IRB Approvals?

- Research Review is the formal process at Virtua to ensure investigators are meeting the sufficient requirements of scientific rigor, regulatory compliance, and legal requirements. It helps guide investigators through all of Virtua's policies that may pertain to the individual's research project. Research Review will grant approval for an investigator to submit their project to the Institutional Review Board (IRB).
- The IRB is responsible for protecting the rights and welfare of the human subjects who have volunteered to participate in research. The IRB will review your project for safety and ethical concerns, such as patients being provided with appropriate informed consent to choose to participate in a research study.

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Submitting to Research Review

- If you have a research project, contact researchreview@virtua.org with your study documents, such as your protocol and informed consent document, and you will be provided with a folder of forms and directions for their use.
  - Research Review Form – Required for all projects
  - IT Review Form –Required if you are using software or databases
  - Research Review Letter of Support Template – Required when your study needs operational approval. The research review team can help provide guidance on who may be appropriate.
  - Research Training from the CITI Program Directions –Human Subjects Protections Training is required for all research personnel
  - Research Review Policy

- If you are familiar with the research review process, you can begin to complete all of the forms and training simultaneously. If you have questions, please start by completing the Research Review Form as the team will likely need more information on your project to provide you with further direction and answer your questions.

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What does Research Review evaluate?

- Each project is reviewed for Virtua's requirements to perform a research study such as:
  - Legal documents and/or budget approval
  - Scientific rigor of the research plan (Protocol)
  - IT approval
  - Operational approval/Education of staff
  - Financial Conflict of Interest Forms for Public Health Service Funded Research
  - Special approvals from affiliated institutions
  - Epic integrations
  - Required Trainings

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Final Steps to Full Approval

- When all appropriate Research Review requirements are met, you will receive an email informing you that your study is approved and you may send your submission to the IRB for review.
- When the IRB grants full approval, the project will be assigned an IRB number and you may begin your research trial. They will stamp the final copy of your informed consent document if applicable.

Follow Up

- The Research Review team will contact all investigators on a monthly basis to obtain the status of the study and the number of consented and enrolled patients. This is added to a master research report kept for the organization.
- The IRB requires annual reporting and review of all projects including submissions for special circumstances. Please refer to your IRB's policies for full requirements of submissions.

Consulting Requests

- Virtua employees may be approached to participate in research either as a part of their role within Virtua or as an outside professional engagement. If a third party wishes to engage in research with an employee and does not include Virtua, employees are required to get the following approvals:
  - If you are a VMG clinician, you need prior approval from the Medical Director of your specialty to participate in any outside professional engagements
  - You need to disclose any consulting agreements on your annual conflict of interest forms
  - If any consulting roles are clinical by nature, you have to show proof of your own malpractice coverage

Consulting Considerations

- No Virtua patient, employee, or other confidential and proprietary information should be used or disclosed in any manner.
- Any device or software being used, needs to be reviewed prior to use by Virtua Information Services.
- Any service or product being represented by the provider's consulting role should not be promoted at Virtua.
- If a third party inquires about collaborating in any project ("Research" or otherwise), these requests should be forwarded to the appropriate members from the Corporate Compliance Office to help guide the team.
- Ensure outside professional engagements do not create a conflict of interest and do not ask you to violate the privacy and security of Virtua's patient information. You should never be disclosing information to a third party unless the opportunity was fully vetted and approved by Virtua. If you wish to perform research as part of your role with Virtua, you must submit your research study to the Research Review Committee and they can assist you in meeting Virtua's requirements.

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Questions?

- All questions about performing research at Virtua can be directed to researchreview@virtua.org
- All questions about outside consulting opportunities and compliance can be directed to the Compliance Officer at cofficer@virtua.org or you can reach the Compliance Department by phone at 856-355-0722.

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