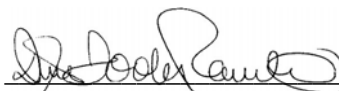


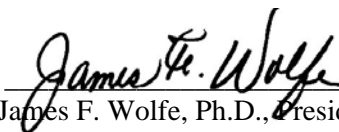
Edward Via Virginia College of Osteopathic Medicine

Policy Order No. F019v2A1

Effective Date: April 1, 2007



Dixie Tooke-Rawlins, Dean
And Chief Administrative Officer



James F. Wolfe, Ph.D., President

ADDENDUM TO VCOM IRB POLICY NO. F019v2

VCOM Policy on Institutional Review Board Self Assessment

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1. PURPOSE

The purpose of this policy is to assist VCOM’s Institutional Review Board (IRB) in assessing its human subjects protection program. The tool is primarily designed to assess compliance with the federal regulations for the protection of human subjects in research. Additional information is requested to gain an understanding of the VCOM IRB’s program including: 1) elements of the program that may go beyond the requirements of the federal regulations, 2) volume of work conducted by the VCOM IRB, and 3) available resources for the human subjects protection program.

2. INSTRUCTIONS

This self-assessment tool shall be completed by one or more individuals knowledgeable about the VCOM IRB’s human subjects protection program, such as the IRB Chair, IRB Coordinator or Dean.

Once this tool is completed, the VCOM IRB should be able to assess its human subjects protection program, including its strengths and weaknesses. The tool may identify areas where clarification of regulatory requirements is needed or where to focus necessary education; these areas should be corrected and/or addressed as soon as possible.

3. SCHEDULE

The VCOM IRB shall perform this self-assessment and complete the tool on an annual basis. A copy of the completed tool, all findings and notes on actions taken based upon these findings shall be filed with the IRB files and available for inspection by the Dean's office and Office of Human Research Protections (OHRP) if required.

4. RESOURCES

The Office of Human Resource Protections (OHRP) is available to assist in this process and provide consultation toward increasing the performance, efficiency, and quality of the human subjects protection program. The OHRP web site on quality assurance and quality improvement is:
<http://www.hhs.gov/ohrp/qi/>.

The Federal Register Notice on Quality Assurance Self-Assessment Tool for IRBs can be found at:
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-11428-filed.

PDF text of Objectives and Overview of the OHRP Quality Improvement Program:
<http://www.hhs.gov/ohrp/humansubjects/qip/qipdesc.pdf>.