ACTIVITY TITLE: ***Protecting Human Research Participants (PHRP)***

Jointly sponsored by University Health Services Professional Education Programs (UHS–PEP) of Virginia Commonwealth University Health System (Virginia Commonwealth University Continuing Medical Education) and the Office of Extramural Programs, Office of Extramural Research, NIH.

MEDIA: ***Internet Enduring Material***

Estimated time to complete activity: 3.0 hours | Release date: March 1, 2014 | Expiration date: February 28, 2016

INTRODUCTION

This course is designed to prepare investigators involved in the design and/or conduct of research involving human subjects to understand their obligations to protect the rights and welfare of subjects in research. The course material presents basic concepts, principles, and issues related to the protection of research participants.

As a part of NIH's commitment to the protection of human subjects and its response to Federal mandates for increased emphasis on protection for human subjects in research, the NIH Office of Extramural Research released a policy on Required Education in the Protection of Human Research Participants in June 2000. This course is specifically designed for extramural investigators and is one (of many) possibilities for meeting the policy requirement.

EDITORS

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TARGET AUDIENCE

The target audience for this activity is physicians and other healthcare professionals involved in the design and/or conduct of human subjects research.

EDUCATIONAL OBJECTIVES

Upon completion of this course, learners should be better able to:

- Describe the history and importance of human subjects protections
- Identify research activities that involve human subjects
- Discover the risks a research project might pose to participants
- Identify how to minimize the risks posed by a research project
- Describe additional protections needed for vulnerable populations
- Assess additional issues that should be considered for international research
- Describe appropriate procedures for recruiting research participants and obtaining ***informed consent***
- Identify the different committees that monitor human subjects protections
- Explain the importance of study design in the protection of research participants

PHYSICIAN CONTINUING EDUCATION

ACCREDITATION STATEMENT

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of University Health Services Professional Education Programs (UHS-PEP) of Virginia Commonwealth University Health System and the **National Institutes of Health, Officer of Extramural Research, Office of Extramural Programs**. UHS-PEP is accredited by the ACCME to provide continuing medical education for physicians.

AMA CREDIT DESIGNATION STATEMENT

UHS-PEP designates this Internet enduring material for a maximum of 3.0 ***AMA PRA Category 1 Credits™***. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

METHOD OF PARTICIPATION

There are no fees for participating in the Protecting Human Research Participants (PHRP) content. If after successful completion of this activity, you wish to receive ***AMA PRA Category 1 Credit™*** for this activity, you must

1. read the educational objectives and faculty disclosures;
2. review the educational activity;
3. complete the post-activity assessment, and
4. click on the Link to take you to the UHS Professional Education (UHS-PEP) website to request CME credits.There is a $25 charge to certify your participation, print your Certificate and have your CME credits recorded by UHS-PEP.

It is estimated that it will take approximately 3 hours to complete all four modules and the post-activity assessment.

CME/CE CREDITS

Physicians who complete the post-activity assessment with a score of 75% or better may view and print a Certificate of Completion immediately. Those physicians who wish to receive CME credit may access that opportunity at the conclusion of the activity.

PLANNERS AND AUTHOR(S) DISCLOSURE STATEMENT

Staff Disclosure

These Editors, and Planners and managers at UHS-PEP and NIH have no relevant financial relationships to disclose:

- Ann M. Hardy, DrPH, Editor
- Maria Stagnitto, RN, MSN, Editor
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DISCLOSURE OF OFF-LABEL USE

This educational activity does not contain discussion of published and/or investigational uses of agents that are not indicated by the FDA.

DISCLAIMER

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development.

ACKNOWLEDGEMENT OF COMMERCIAL SUPPORT

This activity has no commercial support.

CME/CE INQUIRIES

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