



**WAYNE STATE UNIVERSITY**

		<b>ISSUED: 9/18/2019</b>
<b>TITLE: Research Compliance Monitor</b>	<b>SALARY TABLE: AP</b>	<b>CLASS CODE: PE377</b>
<b>UNION: P &amp; A</b>	<b>SALARY GRADE: 11</b>	<b>EEO CODE: 30</b>
<b>JOB GROUPING: 30</b>	<b>FLSA: Exempt</b>	<b>EMPLOYEE CLASS: PE</b>

**POSITION PURPOSE**

Conduct post-approval research monitoring visits to observe and document research conduct and regulatory compliance. Submit monitoring reports to the Human Research Protection Program Administration and to the Institutional Review Boards for evaluation and determination of further action. Reports to Associate Vice President, Research.

<b>Essential Job Functions</b>	<b>% Time</b>
Conduct independent post-approval monitoring visits of human participant research protocols, review protocol regulatory documents, informed consent process and data collection. Generate and update research protocol monitoring lists. Coordinate and schedule post approval monitoring visits and, as needed, follow-up visits.	40%
Maintain post approval monitoring report files, communicate findings and deficiencies directly to the Principal Investigator, Human Research Protection Program Administration and Institutional Review Boards when appropriate.	20%
Conduct audit activities to identify adverse events and protocol violations and direct to committee Chair, individual Institutional Review Board, institutional officials and/or regulatory agencies as appropriate. Provide procedural guidance to investigators when adverse events or violations are minor, to ensure policy and regulatory compliance are maintained. Conduct For-Cause Audits as requested by the Institutional Review Board Committee or Human Research Protection Program Administration. Conduct For-Cause Audit of human participant research protocols, review protocol regulatory documents, informed consent process and data collection. Communicate For-Cause Audit findings and deficiencies directly to the Principal Investigator, Human Research Protection Program administration and Institutional Review Boards when appropriate.	15%
Maintain and update post approval monitoring policies and procedures. Develop and provide post approval monitoring education sessions for researchers.	10%
Engage with university and affiliate research departments to ensure compliance with federal regulations and institutional policies. When appropriate, in instances concerning research grants, the Administrator will work with the Sponsored Programs Administration to verify concurrence with the grant proposal.	10%
Perform other related duties as assigned.	5%

THIS DESCRIPTION IS INTENDED TO INDICATE THE KINDS OF TASKS AND LEVELS OF WORK DIFFICULTY THAT WILL BE REQUIRED OF POSITIONS THAT WILL BE GIVEN THIS TITLE AND SHALL NOT BE CONSTRUED AS DECLARING WHAT THE SPECIFIC DUTIES AND RESPONSIBILITIES OF ANY PARTICULAR POSITION SHALL BE. IT IS NOT INTENDED TO LIMIT OR IN ANY WAY MODIFY THE RIGHT OF ANY SUPERVISOR TO ASSIGN, DIRECT AND CONTROL THE WORK OF EMPLOYEES UNDER THEIR SUPERVISION. THE USE OF A PARTICULAR EXPRESSION OR ILLUSTRATION DESCRIBING DUTIES SHALL NOT BE HELD TO EXCLUDE OTHER DUTIES NOT MENTIONED THAT ARE OF SIMILAR KIND OR LEVEL OF DIFFICULTY.

## **MINIMUM QUALIFICATIONS**

**EDUCATION:** Bachelor's degree from an accredited college or university in a discipline related to business, medicine, public health, biomedical, life science or basic science. An equivalent combination of education and experience may be accepted.

**EXPERIENCE:** Requires 2 or more years of experience in a human participant research related job function. Basic monitoring or audit experience, and biomedical or pharmaceutical research experience preferred.

### **KNOWLEDGE, SKILLS AND ABILITIES:**

Ability to manage a comprehensive monitoring program.

Ability to work independently with minimal supervision.

Ability to analyze and articulate complex issues, including scientific and ethical issues.

Ability to communicate effectively with researchers and colleagues, verbally and in writing.

Knowledge of research regulations as they pertain to the conduct of human participant research

Skill in the use of computers and software such as Microsoft Office, Microsoft Outlook and institutional specific software.

Ability to engage researchers and colleagues in a respectful manner.

Ability to maintain privacy and confidentiality as they pertain to research and monitoring activity.

## **WORKING CONDITIONS**

This position is stationed within an office setting but will require local travel within the University and its affiliates to conduct the monitoring and audit visits.

## **ADDITIONAL COMMENTS**

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