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**The North Texas Chapter of ACRP presents:**

**“Complimentary” Fall Symposium**

**Saturday, October 10, 2020**

**“Root Cause Analysis and Corrective and Preventive Actions (CAPAs)”**

**Janet Holwell, CCRC, CCRA, TIACR, FACRP / Clinical Research Consultant, Forest Hills, NY**

**This is a virtual presentation through** [**www.zoom.com**](http://www.zoom.com)

**Zoom.com is free to download and participate in the comfort of your home**

**Register at NorthTexas@acrpnet.org**  **by 12:30 pm** Friday October 9, 2020

\*\* Online attendance will be limited to first 100 participants

**Program Description:** Managing compliance in clinical research is vital to successful clinical trials. Regulatory authorities expect that all stakeholders identify noncompliance, perform root cause analysis, put corrective and prevention action in place and then evaluate the effectiveness of the intervention. Without root cause analysis, interventions cannot be effectively identified and designed. This presentation will delineate the scientific concepts of root cause analysis and apply them specifically in the clinical trial setting. There will be a hands-on activity using tools provided.

**Learning Objectives:**

* Understand how to use RCA tools to support quality system execution
* Identify a possible cause, evaluate it against facts and differentiate facts from assumptions
* Implement Gilbert’s Behavioral Engineering Model for a diagnostic root cause analysis process
* Assess proposed Corrective and Preventive Action Plans (CAPA) for adequacy once the root cause is identified

**The level of this presentations is Core.**

**Agenda:** 8:30 – 9:00 am Log on and ensure connectivity

9:00 am – 12:00 pm Presentation, Breakout Sessions, Questions & Answers

**Online Registration:** *Membership is not required for online registration at*

[**https://www.avectraacrp.com/eweb/DynamicPage.aspx?Reg\_evt\_key=1bf90944-6bbe-46af-9e8b-45f668b522ce&WebCode=EvtRedirectorTL**](https://www.avectraacrp.com/eweb/DynamicPage.aspx?Reg_evt_key=1bf90944-6bbe-46af-9e8b-45f668b522ce&WebCode=EvtRedirectorTL)

**Once you have registered, your name will show up in your “Online Community Room” on the ACRP website. The log-in and call-in information for the Zoom meeting will be posted by 2:00 pm on Friday October 9, 2020.**

**Cost to attend: $0 – the North Texas Chapter is pleased to provide our Fall Symposium at no charge this year.**

**Target Audience:** Anyone working in or pursuing a career in clinical research

**ACRP Contact Hours:** 3.0 contact hours have been applied for through The Association of Clinical Research Professionals (ACRP). These credits can be used to meet the certification maintenance requirement.

**To receive contact hours**: Purchase the contact hours and attend the program. Cost of contact hours:

* ACRP Global and North Texas Chapter member: $0
* ACRP Global Member only: $15 per contact hour
* Non-member: $30 per contact hour

Your sign-in will be in zoom.com online and will be used as our sign-in sheet.

Approximately 3 days after the program,

* Click on the “My Account” dropdown after you log into the website
* Click on the “My Courses” link under “My Account”
* Scroll to the bottom of the page and click on the “Access My Course” button for Chapter Events; this will take you to the learning portal
* From there, the course should be in your learning portal under Chapter Events tab, complete the evaluation and have the contact hours added to your account from there.

**Contact** [**NorthTexas@acrpnet.org**](mailto:NorthTexas@acrpnet.org)**,** [**lynetteww@icloud.com**](mailto:lynetteww@icloud.com) **or azach78766@aol.com with questions or concerns.**