Overall Program Objectives:
- Identify and describe important issues related to pediatric research.
- Define goals of personal and professional education and development.
- Identify revisions to ICH GCP E6 and how they affect clinical research.
- Describe requirements for a Quality Management System and differentiate Quality Control from Quality Assurance.
- Examine the rationale for detailed protocol analysis, differences in qualitative vs quantitative feasibility.

Target Audience:
All Clinical Research Professionals
**Bruce Gordon MD** (Assistant Vice-Chancellor for Regulatory Affairs; Executive Chairman, Institutional Review Boards; Professor, Pediatrics; University of Nebraska Medical Center)

**Title**: Research Involving Children: They’re Not Just Small Adults

**Objectives**: Explain the Belmont Principles, and their ambivalence in the setting of research involving children; Provide justification for inclusion of children in research; Describe the critical ethical issues related to inclusion of children in research; Identify the differences between the concepts of consent, permission and assent, and be able to discuss how federal regulations address these concepts.

**Glenda Guest CCRA, RQAP-GCP, TIACR** (Vice President Norwich Clinical Research Associates)

**Title**: Applying a Quality Systems Approach to the Conduct of Clinical Trials

**Objectives**: Describe 3 broad requirements of a Quality Management System; Differentiate Quality Control from Quality Assurance; Explain the concepts of protocol optimization and data mapping.

**Joy Jurnack RN, CCRC, CIP, FACRP** (Research Nurse Northwell Health, Division of Kidney Research)

**Title**: Professional Development for the CRC: A Shared Responsibility

**Objectives**: Define goals of personal and professional education and development; Examine already existing programs for professional development and discuss benefits of participation; Develop a personalized plan for your professional development over the next few years.
**Christina Talley MS, RAC, CCRP, CCRC** (Program Director, Office of Strategic Research Initiatives, Houston Methodist)

**Title**: Protocol Scoring and Workload Leveling: Elevating Quality at the Clinical Research Site

**Objectives**: Examine the rationale for detailed protocol analysis, differences in qualitative vs quantitative feasibility; Explain how quantitative feasibility measures translate to grading or scoring; Understand how doing this can help overall workload distribution, personnel resource allocation, and financial management; Discuss some of the current feasibility and scoring models used in clinical research; Demonstrate a Protocol Acuity Rating Scale (P.A.R.S.) tool and give examples of how it can be applied to different types of clinical research studies.

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**Tracy Ohrt MS, CCRC, CCRA** (Administrative Director, FDA Regulated Research Oversight Program, UW Institute for Clinical and Translational Research)

**Title**: Implementing ICH GCP E6(R2)

**Objectives**: Review the revisions to the ICH GCP E6; Identify how the revised ICH GCP E6 Guidance affects the conduct of clinical trials; Identify how the revised ICH GCP E6 Guidance affects the oversight of clinical trials.

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**Shari Zeldin BS, CCRC** (Clinical Research Compliance Officer, UW Madison, Department of Medicine)

**Title**: Ensuring Ethics and Patient Safety in the Trenches

**Objectives**: Explain the ethical responsibility of the informed consent process; Interpret the rationale behind specific parameters in a protocol to ensure patient safety; Analyze the difference between clinical care and clinical research.
Network for Lunch Hour 12:15-1:30pm

- MCW CTO & IRB
- Aurora Research Institute
- Aerotek
- UW Carbone Cancer Center
- Investigation Drug Services; Pharmacy Dept Froedtert
- UWM Public Health
- All of Us

Prizes & Giveaways!

**Agenda**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>7:00am-8:00am</td>
<td>Registration &amp; Breakfast</td>
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<tr>
<td>8:00am-9:00am</td>
<td>Christina Talley</td>
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<tr>
<td>9:00am-10:00am</td>
<td>Bruce Gordon</td>
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<tr>
<td>10:00am-10:15am</td>
<td>Break</td>
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<tr>
<td>10:15am-11:15am</td>
<td>Glenda Guest</td>
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<tr>
<td>11:15am-12:15pm</td>
<td>Joy Jurnack</td>
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<tr>
<td>12:15-1:30pm</td>
<td>Networking Lunch</td>
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<tr>
<td>1:30pm-2:30pm</td>
<td>Tracy Ohrt</td>
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<tr>
<td>2:30pm-3:30pm</td>
<td>Shari Zeldin</td>
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</tbody>
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**Cost to Attend**

- $100 any chapter member
- $125 non chapter member, but global member
- $155 non ACRP member

**At the door cost:**

- $200 online
- Money order/cashier check at the door

**Cancellation Fee:**

- $25

**Total Contact Hour Costs per Attendee:**

- $0 - Chapter Members
- $35 - Global Members
- $50 - Non-members

**6 Contact Hours** have been applied for through ACRP. Membership is not required for online registration/application of contact hours.

To receive contact hours:

Purchase the contact hours, sign in at the registration desk and attend the program. Log on to ACRP website after the event. Click on “ACRP Learning Portal” to complete the evaluation within 30 days of the event and obtain the online certificate.

**RSVP HERE!**

Find more information on the ACRP website!

**Chapter Contact Information**

wi.acrp@gmail.com

President: Robyn Furger; rfurger@mcw.edu
*Enter off of Bluemound Rd

*Let the parking attendants know you are here to attend the ACRP Symposium & you will not be charged for parking.

*Use the Zebra or Giraffe Parking Lots.

*Enter in the Main Entrance (yellow circle), go through the building #27 and outside towards the Penguins #26.

*Follow the WOODEN BRIDGE behind the Penguins to get to the Peck Welcome Center #21.

*If you need handicap accommodations:

- or -

*If you have a dietary restriction:

Please contact us at wi.acrp@gmail.com

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**Hotel Accommodations:**

Crowne Plaza Hotel
Milwaukee West
10499 W Innovation Dr
Wauwatosa, WI 53226
P: 414-475-9500

*Please contact us at: wi.acrp@gmail.com if you need a hotel room the night before the Symposium

*The hotel provides a free shuttle to and from the zoo

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*We look forward to seeing you!*