

## Symposium C5: Methodological Challenges in Intervention Research

### *Informed Consent: Considerations for Vulnerable Populations during Intervention Research*

Michelle A. McMahon, MSN, RN, University of Massachusetts Dartmouth, Dartmouth, MA

**Purpose:** To present selected strategies to mitigate methodological challenges and enhance the informed consent process when conducting intervention research with vulnerable populations.

**Background:** Nurse researchers are challenged to ensure adequate informed consent accompanies all research endeavors. Due to the intricate procedures and technical language surrounding intervention research, there is an increased likelihood that certain participants may not be able to make a fully informed decision during the consent process. Specifically at risk are vulnerable populations, including those with age or developmental risk, groups which may feel coerced, individuals with cognitive impairment or people with highly vulnerable health statuses. These groups require special protection efforts during the informed consent process. When conducting intervention research with vulnerable populations, researchers must balance meeting the assumptions of the federal guidelines for the Protection of Human Subjects (CFR §46.116), while also recognizing caveats inherent to fulfilling these required components of informed consent. Approach: Literature review/synthesis

**Major Points and Rationale:** Based on the Belmont Report, a triad for effective informed consent with vulnerable populations is offered to frame the symposium discussion.

**Conclusion:** During intervention research informed consent should include considerations regarding individual tailoring of the intervention information, assessment of the participant's comprehension and assurance of the voluntariness of study participants. If any of these components are not proactively considered during design or implementation phases, the research process may be compromised.