**APHA 2010 – Genomics Forum**

**Ethical Challenges to Informed Consent for Genetic Research during Critical Illness**

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**Background**

Clinical investigation conducted in critically ill patients is challenging due to disease severity, treatment complexity, and reliance on surrogate decision makers (SDMs) to provide informed consent. Acquisition of genetic data is increasingly common in critical illness research. The extent to which SDMs understand implications of genetic data collection for purposes of providing permission for research participation is unexplored.

**Methods**

We conducted 23 focus groups and 35 in-depth interviews with African-American, Caucasian and Hispanic SDMs for adult critical care patients in two tertiary care hospitals. Hypothetical scenarios and specific language abstracted from sample informed consent documents were presented to elicit perceptions about genetic technology and learn what information SDMs require to make informed decisions about research participation. Atlas.ti software was used to conduct thematic content analysis.

**Results**

 Participants’ knowledge of genetics was limited and based primarily on media exposure or personal experience (e.g., paternity testing). Misinformation included the belief that genetic material can be ‘used up’ over time. No participant was aware of the potential use of genetics to personalize treatment. While most respondents would permit family members’ participation in genetic research, they required guidance to fully understand details of genetic data collection, such as biobanking for future use, potential for commercialization, etc.

**Conclusion**

Participants expressed willingness to permit genetic research participation, though most lacked a fundamental grasp of this technology. Informed consent processes targeting such knowledge gaps may be essential to ensure that genetic data collection during critical illness is conducted in the most transparent manner possible.

Learning Objectives:

1. Participants will be able to identify logistical aspects of clinical research conducted in the ICU setting that potentially present ethical challenges, and will be able to describe how these challenges are amplified when considering genetic data collection.
2. Participants will be able to identify "milestones" research subjects need to achieve in order to feel confident in their abilities to make an informed decision about providing consent for their family member to participate in genetic research during critical illness.
3. Participants will be able to list key concepts that need to be included during the consent process for studies involving genetic research during critical illness.